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Case reports

Pectoral fascia preservation during modified radical mastectomy: why and when

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Context
The surgical treatment of breast cancer has changed significantly over time, but modified radical mastectomy (MRM) is still performed in about 20–30% of patients undergoing surgeries. Many articles that have studied the breast lymphatic system claim that the deep fascia is very poor in lymphatic vessels.
Aim
The aim of our study was to detect the benefits and oncological safety of pectoral fascia preservation in patients undergoing MRM.
Materials and methods
Totally, 73 patients with early breast cancer underwent MRM. The patients were randomized between removal (n=37) and preservation (n=36) of pectoral fascia.
Results
The amount of blood loss, operative time and drain output was significantly reduced in a case of pectoral fascia preservation (P>0.00001); in addition, seroma was significantly reduced (P=0.025). No chest wall recurrence had occurred in both groups.
Conclusion
Pectoral fascia preservation is safe and has many advantages as regards operative time, blood loss, seroma formation and cosmetic appearance of the flaps. It is oncologically safe compared with pectoral fascia resection, provided that good selection of the patient was done.

Keywords:
breast cancer, pectoral fascia, pectoral fascia preservation

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Introduction

Breast cancer is the most prevalent malignancy among women [1]. The surgical treatment of breast cancer has evolved from the radical mastectomy of Halsted to more limited surgery, which was introduced by Patey. In both techniques, pectoral fascia was resected to ensure radicality. Although breast conservation is considered the standard surgical approach for the treatment of early breast cancer patients, modified radical mastectomy (MRM) is still performed in about 30% of breast cancer patients [2–4].

Many articles that study the breast lymphatic system claim that the deep fascia is very poor in lymphatic vessels [5,6].

Dalberg *et al.* [7] published the only study that compared pectoral fascia preservation and excision and concluded that there was no significant increase in local recurrence in the preservation group.

Da Silva *et al.* [8] studied the specimens from 30 cases of MRM in order to determine clinical and pathological factors that were associated with invasion of pectoral fascia and demonstrate that tumor–pectoral fascia distance was the only significant independent variable to predict pectoral fascia invasion.

The aim of our study was to detect the benefits and oncological safety of pectoral fascia preservation in patients undergoing MRM.

Materials and methods

This prospective randomized control clinical trial was conducted at General Surgery Department, Zagazig University, between February 2013 and March 2014. Approved by local ethical committee of our faculty.

Totally, 96 patients were diagnosed with early breast cancer by complete history taking, clinical evaluation and full investigations and the diagnosis was proved histopathologically.

Informed consent was obtained from all patients.

Inclusion criteria

Female patients with early breast cancer and candidates for MRM were included in this study.

Exclusion criteria

The exclusion criteria were as follows:

(1) Stages III and IV breast cancer.
(2) Inflammatory breast cancer.
(3) Tumor very close to, or invading, the pectoral fascia.

Totally, 23 patients were excluded from the study, 14 refused participation, and nine had a deeply seated tumor. Seventy-three patients were included in the study and randomized into two groups: group I comprised patients (n=37) in whom the pectoral fascia was resected and group II comprised patients (n=36) in whom the pectoral fascia was preserved.

All patients underwent MRM with level II axillary dissection and closed with suction drain, which was removed when the amount of drain was between 20 and 30 ml/day.

Our patient received adjuvant chemotherapy protocols according to estrogen receptors (ER), progesterone receptors (PR), human epidermal growth factor receptor (HER2) and proliferation index (KI67).

All patients were followed up early postoperatively for drain output, seroma formation and cosmetic appearance of the flaps and late for recurrence.

All patients were followed up until January 2017 (34–48 months), with a mean follow-up period of 41 months.

Results

Totally, 73 patients were included in this study; the mean age of the patients was 55.9 years in group I and 57.4 years in group II. Tumor and patient features of our study are given in Table 1.

Intraoperative

The mean of intraoperative blood loss in group I was 300 ml, whereas it decreased significantly in group II to 198 ml (P=0.00001). As regards the operative time, it was about 80 min (mean) in group I and decreased significantly in group II to 59 min (P=0.00001), as shown in Table 2.

Early postoperative

The volume of initial 7-day drain output was decreased significantly in group II, 501 ml, whereas in group I it was 791 ml (P=0.00001). As regards the duration of drains, in group I it was 15.3 days, whereas it decreased significantly in group II to 8.7 days (P=0.00001). Seroma occurred in nine patients in group I, whereas it occurred in only two patients in group II (P=0.025), as shown in Table 2.

Pathological examination of excised pectoral fascia

Histopathological examination of pectoral fascia in group I (excised group) revealed negative deep

Table 1 Demographic, clinical, and pathological features of patients in the study

	Group I: excised pectoral fascia (n=37)	Group II: preserved pectoral fascia (n=36)	Tests	P-value
Age (mean) year	55.9	57.4	t=0.737	0.231
Tumor stage				
T1	7	9	χ^2=0.643	0.724
T2	28	26		
T3	2	1		
Stage				
I	5	7	χ^2=0.467	0.494
II	32	29		
Number of excised LN	18	19		
ER				
Positive	22	19	χ^2=0.331	0.565
Negative	15	17		
PR				
Positive	22	20	χ^2=0.113	0.735
Negative	15	16		
HER2				
Positive	19	15	χ^2=0.687	0.406
Negative	18	21		

HER2, human epidermal growth factor receptor; ER, estrogen receptor; LN, lymph node; PR, progesterone receptors.

Table 2 Intra-operative and post-operative characteristics of patients in the study

	Group I: excised pectoral fascia (n=37)	Group II: preserved pectoral fascia (n=36)	Tests	P-value
Intraoperative blood loss (mean) (ml)	300	198	t=10.571	>0.00001
Operative time (mean) (min)	80	59	t=11.405	>0.00001
Volume of initial 7-day drain output	791	501	t=44.404	>0.00001
Duration of drain (mean) (days)	15.3	8.7	t=25.233	>0.00001
No of patients with seroma	9	2	χ^2=5.022	0.025
Recurrence	No	No		1

pectoralis margin in all cases and tumor–pectoral fascia distance varied from 48 mm to 5 mm.

Long-term follow-up

The follow-up period of our patients was 34–48 months, with a mean follow-up period of 41 months. Our patients were followed up for chest wall recurrence by clinical examination and CA15-3. Breast ultrasonography, chest radiography and chest computed tomography were performed if there is suspected induration. No local recurrence occurred in both groups during this period, as shown in Table 2.

Discussion

Fisher stated that breast cancer is a systemic disease from the start and any change in local surgical management will have no effect on overall survival, and breast conservation is considered standard treatment for malignant breast diseases [9,10].

Dalberg *et al.* [7] has published the only comparative study between preservation and resection of pectoral fascia. Therefore, we tried to focus on the benefit of pectoral fascia preservation and oncological safety.

In our study, many benefits for pectoral fascia preservation were observed as regards operative time, blood loss, drain output, seroma formation and cosmetic appearance of the flaps.

Subfascial plane also can be used for immediate reconstruction by breast implant and pectoral fascia provides more soft-tissue coverage [11].

All those benefits encourage preservation of pectoral fascia, but oncological safety is the most important point. Dalberg *et al.* [7] concluded that chest wall recurrence and overall survival are not significantly affected by preservation of pectoral fascia with long-term follow-up, but there is an increased risk for local recurrence of 1.8 among patients with fascia preservation.The most important risk factors for chest wall recurrence after MRM are deeply located tumor and excessive nodal spread [12–14]. Postoperative irradiation plays an important and significant role in controlling and decreasing the incidence of chest wall recurrence [15]. In our study, we excluded all patients with deeply seated tumor near the pectoral fascia, and this is may be the cause of absence of recurrence through the period of follow-up.

Pectoral fascia preservation is not mandatory in all cases, and choice of the patient is the most important factor; a tumor that is away from the pectoral fascia is less liable for local recurrence.

Conclusion

Pectoral fascia preservation is safe and has many advantages as regards operative time, blood loss, seroma formation and cosmetic appearance of the skin flaps. It is oncologically safe as compared with pectoral fascia resection, provided that good selection of the patient was done.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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A comparative study on the effect of laparoscopic simulation on skill training in laparoscopic surgery

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Context
This study examined the effect of using laparoscopic simulation on the enhancement of psychomotor capabilities linked to performing laparoscopic appendectomy.
Participants and methods
Thirty surgical trainees carried out a laparoscopic appendectomy in the operating room (OR). The participants were then randomized to have a training course of six sessions (1 h each) on our simple simulator (MED-SIMU) or no training. Subsequently, all participants performed a further laparoscopic appendectomy in the OR. Both operations of each participant were recorded on video tapes, and assessed by two blinded laparoscopic senior surgeons using the predefined objective criteria such as time to complete the operation and the error counting.
Results
No differences in baseline variables were found between the two groups. Surgeons who received simulator training carried out laparoscopic appendectomy significantly faster than those in the control group (P=0.0006) and showed a greater improvement in error (P=0.0001).
Conclusion
Surgeons who had simulator training showed a greater enhancement in performance in the OR than those in the control group. Our simple surgical simulator is, therefore, a suitable tool for the training of laparoscopic motor skills and could be included in surgical training programs.

Keywords:
laparoscopy, simulator, training

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Introduction

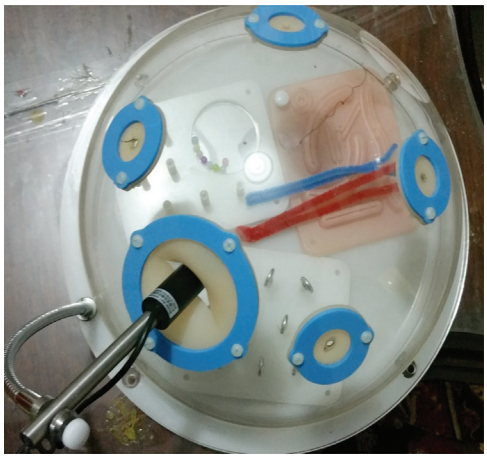
Laparoscopy has grown to be the standard progress for many conditions in almost all surgical specialties [1–3]. It is obvious, however, that during the learning curve of the surgeons, laparoscopy is accompanied with a longer operation time and a superior rate of surgical complications. [4–8]. The possibility of beating these problems throughout the learning curve by appropriate training and ensuring that surgeons carry out enough number of cases are also been known [9]. The first obstacles in learning laparoscopy are psychomotor and perceptual. Focusing on patients' safety and rights and concern over costs of operating theater time are factors that confront the conventional surgical approach and give an increasing need for new methods in the training of laparoscopic surgeons [10]. Although simulation comes with important advantages in the spot of training for novel capabilities and procedures, proof of the shift of skills from the fake environment to the operating room is still inadequate [11,12].

Participants and methods

This study was carried out in the Emergency Department in Zagazig University Hospitals during February 2017. Participants were employed between March 2014 and March 2016. Thirty surgeons with limited practice in laparoscopic surgery (two to five laparoscopic appendectomies) participated in the study. All participants did a laparoscopic appendectomy, supervised by an experienced laparoscopic surgeon. The participants were then randomized to either a group that received training on our simple simulator (MED-SIMU, lyd917, China) (Fig. 1) or a control group that did not receive training. Randomization was done using closed envelopes. Training included six sessions (1 h each) in 3 weeks. Six tasks were of increasing difficulty and were designed to imitate the techniques used during the laparoscopic appendectomy. Task 1, the participant was asked to hold a sphere and place it in a small box. In task 2, the sphere was held, transferred between instruments, and then put in the box. Task 3 consisted of holding alternately the parts of a pipe. Task 4

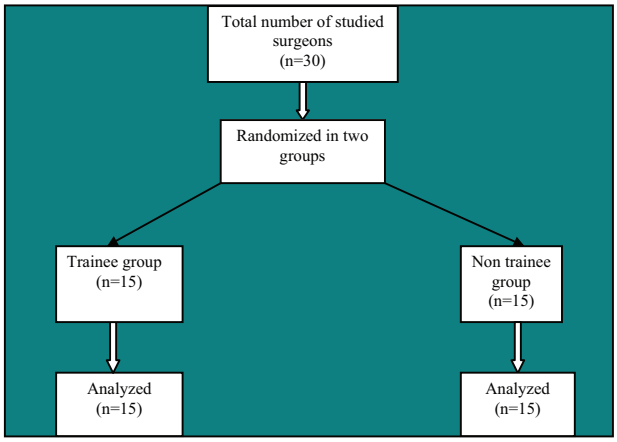
required the participant to hold the sphere, touch it with the tip of the other instrument, remove and re-enter this instrument, and once more touch the sphere. Task 5 involved putting a thread through a sequence of holes. Task 6 involved making an intracorporeal knot. Within 3 weeks after the initial operation, all participants carried out another laparoscopic appendectomy, supervised by an expert laparoscopic surgeon who was blinded to the training status. The operations carried out by the participants were documented on video tapes and assessed by two senior surgeons highly skilled in laparoscopic surgery. We compared the time required to carry out the two operations for each surgeon and calculated the number of errors mentioned by the reviewers in the two operations for each surgeon. Errors were related to the psychomotor skills only and not related to the technical knowledge and anatomy. Cases presented with complications or discovered as complicated during surgery were excluded and the participant submitted to operate another case. The only assessed component of the operation was starting from the point at which dissection the mesoappendix took place and control of the base and removing the specimen outside the abdominal cavity. All cases were operated via three ports (supraumbilical, left iliac fossa, and suprapubic). The video tapes reviewers were blinded to the training category of the participants and performed the evaluation independently. The statistical analysis was done using data from the 30 surgeons.

Figure 1



The used simulator (MED-SIMU).

Figure 2



Flow of the participants through the study.

Results

We statistically analyzed 30 participants (15 in each group) whose operative procedures were documented on video tapes; their flow is demonstrated in Fig. 2. The demographic data of the participants are shown in Table 1. There was a fair agreement in the assessment scores provided by the two reviewers related to changes in the time taken to complete the operation, and error counted between the first and the second laparoscopic appendectomies, as shown in Table 2. Participants who received simulator training performed laparoscopic appendectomy significantly faster than did individuals in the control group (P=0.0006, t-test). Furthermore, the simulator-trained group showed considerably greater progress in their error (P=0.0001, t-test).

Discussion

Enormous types of simulators exist for laparoscopic training in general surgery with different degrees of validity and dependability. They differ widely in their platforms (physical or virtual reality) [13]. Physical simulators contain a box trainer and real instruments (as used in the laparoscopic theater). The equipment used in those simulators can offer texture and behavior like real tissues. The measurement method can be scored by a trained viewer [14–17]. Mammal's models have also been used to advance laparoscopic skills [18–21]. The conversion from the 'dry lab' to the 'wet lab' should be a necessary part of the exercise procedure of a laparoscopic surgeon. Animal training models offer an extensive variety of training applications, but

Table 1 Demographic data of the participants

	Trained group	Nontrained group
Sex ratio (male : female)	13 : 2	14 : 1
Age (years)	31.92 (28–32)	32 (29–33)
Time since graduation (years)	5.14 (5–7)	6.12 (5–7)
Number of laparoscopic appendectomy performed	3.2 (2–5)	2.95 (2–5)

Table 2 Time of the procedure and errors difference between the two groups

	First operation		Second operation	
	Trained group	Nontrained group	Trained group	Nontrained group
Duration of the procedure (min) [range (mean)]	45–75 (60)	55–70 (65.3)	40–60 (49.9)	45–75 (60.2)
P value	0.015		0.0006	
Number of calculated errors	5–7 (6)	5–9 (7.2)	2–5 (3.47)	4–8 (6)
P value	0.007		0.0001	

although this is important, it is also costly and we do not have an animal lab in our hospital.

Most training devices such as pelvic trainers or VR simulators provide training abilities with a spotlight on eye-hand harmonization, targeting the skill of suturing and knotting techniques. The low cost of pelvic trainers has paved the way for their widespread use [22]. We have adopted the use of a simple simulator (MED-SIMU) consisting of a box with four lateral ports for a needle holder and forceps, while a camera and PC monitor are used to simulate a two-dimensional laparoscopic field. Similar equipment for laparoscopic training had been described by Beatty [22].

In our study, training schedule was for 6 h for each trainee (2 h weekly) and this was double the training hours in a similar study conducted by Ahlberg *et al.* [23], who denoted no improvement in skills after training with a VR simulator. However, the participants in that study were trained for 3 h, and may not have reached the area of stability in their learning curves. A previous study established that the learning curve for junior surgeons reached an area of stability after eight repetitions of the whole six tasks, a course that may need more than 3 h of training [23]. This study discovered that there was a significant reduction in the time of the second operation in the trained group, more than that in the nontrained group; this was in agreement with Grantcharov *et al.* [24] in a similar study.Our study revealed that there was a significant reduction in the number of psychomotor errors in the trained group, more than that in the nontrained group; this was in agreement with Grantcharov *et al.* [24]. In our study, we used a MED-SIMU simulator that costs around 500 US dollars including the shipping, which is much cheaper than the virtual simulator fees, and provided a thorough training of our junior staff.

Conclusion

Laparoscopic surgery has a significant component in the field of surgical therapy and includes procedures with variant levels of complexity. Therefore, laparoscopy should be an important component of the training for junior surgical staff. In this study, surgeons who had simulator training showed a considerably greater advance in performance in the operating room than did those in the control group. MED-SIMU laparoscopy trainer represents a promising economic tool for training in laparoscopic surgery.

Financial support and sponsorship
Nil.

Conflicts of interest
There are no conflicts of interest.

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Improved detection of lymph nodes in cases of rectal cancer using combined methylene blue injection and fat clearance compared with fat clearance alone

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Introduction
Evaluation of lymph nodes (LNs) in rectal cancer is a fundamental component of all staging systems. Fat clearance and ex-vivo injection of methylene blue into the inferior mesenteric artery are known methods that can improve LN yield in patients with rectal cancer especially after neoadjuvant chemoradiation. Both techniques were widely compared with routine manual palpation of LNs. The question is that 'Do adding ex-vivo injection of methylene to fat clearance as a single combined technique give further superiority on fat clearance alone regarding detection of nodal harvest and status?'.

Patients and methods
This study was carried out through comparing clinicopathological data of 40 patients whose specimens were subjected to combined ex-vivo injection of inferior mesenteric artery and xylene fat clearance (group I) with that of 30 patients whose specimens underwent only xylene fat clearance. All patients presented with resectable rectal cancer and have received neoadjuvant chemoradiotherapy.

Results
There was a statistically significant difference regarding total nodal harvest in group I compared with group II (17.52±6.32 vs. 14.56±5.64; $P<0.05$). Similarly, detection of at least 12 LNs was statistically different (87.5 vs. 63.3%; $P<0.05$). However, it was not the case regarding detection of nodal metastases (55 vs. 56.7%), which was not significantly different ($P=0.085$).

Conclusion
Using ex-vivo methylene blue injection into the inferior mesenteric artery and xylene fat clearance as a single combined technique shows a significant difference when compared with xylene fat clearance alone regarding total LN harvest and detection of the optimal number of LNs in cases of rectal cancer. However, it did not show such significance regarding detection of nodal metastases.

Keywords:
fat clearance, lymph node, methylene blue, rectal cancer

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Introduction

Lymph nodes (LNs) number and status in colorectal cancer present one of the most important pathologic predictors of patient outcome that can also determines the degree of benefit from adjuvant chemotherapy [1–3]. Approximately 68% of patients with negative nodal involvement will survive 5 years, compared with only 40% of those with metastases [4]. For accurate staging, the evaluation of at least 12 LNs in colorectal resection specimens is widely reported in clinical guidelines [1,5–10]. Neoadjuvant chemoradiotherapy can affect getting the maximal LN harvest with subsequent inaccurate staging and prediction of the patient's prognosis. Efforts to maximize nodal harvest seem to be a good clinical practice to overcome the inefficient routine manual palpation [8,11,12]. Fat clearance techniques are widely used to improve LN harvest particularly in patients receiving neoadjuvant therapy [13]. However, Cohen *et al.* [14] and Jass *et al.* [15] reported that fat clearance alone does not improve significantly LN harvest, so there is still a need for further methods to achieve this job. Sanchez *et al.* [16] modified the fat clearing method by injecting methylene blue into the inferior mesenteric artery of rectal cancer resection specimens, *ex vivo*, to stain LNs blue followed by fat clearance. These advanced methods showed significant differences regarding LN harvest when compared with routine manual palpation but with little data regarding comparing these methods with each other.

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Patients and methods

This study was carried out through a review of medical records of two groups of patients who underwent elective surgery for resectable rectal cancer with intent to cure after receiving neoadjuvant chemoradiotherapy. All patients were operated at either Department of surgery, Faculty of medicine, or Department of Surgery, Medical Research Institute, University of Alexandria. Group I, as a retrospective study group, included data collected from 40 patients operated between June 2013 and June 2015 as a part of previous research [17]. Specimens of these patients were subjected to ex-vivo injection of inferior mesenteric artery followed by xylene.

Group II, as a prospective study group, included 30 patients who were operated between January 2014 and January 2017 as a part of ongoing study. Specimens of this group were subjected only to xylene fat clearance. Surgical procedures for both groups were done by two expert surgical teams, and pathological studies were done by two expert pathologist one for each group.

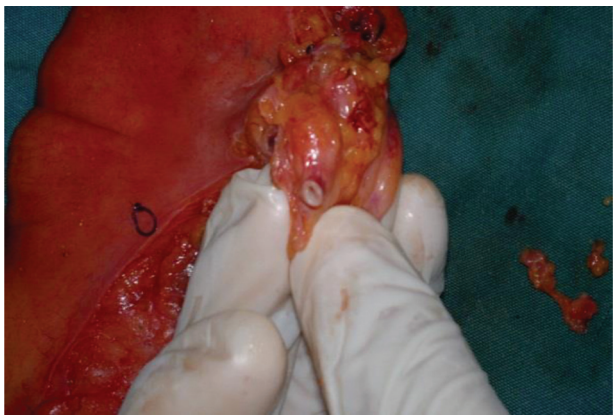
Review of medical records involved data regarding history taking, clinical examination, and laboratory and radiological findings. Surgery was performed at least 6 weeks after completing neoadjuvant therapy. Using total mesorectal excision technique, surgical procedures were either abdominoperineal resection or low anterior resection.

Ex-vivo injection of methylene blue was done by the surgeon. After identification of the inferior mesenteric artery stoma in the fresh specimen, cannulation of the artery was done using the plastic tube portion of a standard 16–20 G intravenous catheter, followed by injection of 15–20 ml of methylene blue solution (50 mg diluted with 0.9% saline in the ratio 1 : 3). Subsequently, the specimens were fixed in formalin for 24 h. Serial sectioning of the mass was done together with mouting of radial, proximal, and distal margins. The regional fat was dissected and cut into less than 0.5-cm sections and processed in ascending concentration of alcohol, then placed overnight in xylene. After clearing, meticulous picking of visible LNs was preformed followed by cutting, staining, and examination by microscopy (Figs 1–6). In group II, specimens were subjected to the previous steps without injection of methylene blue.

Statistical analysis

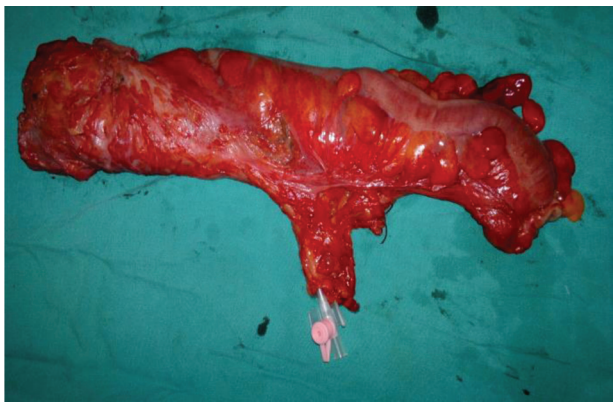
It was performed using IBM SPSS statistics for Windows (version 20.0; IBM Corp., Armonk, New York, USA). Qualitative data were described using number and percent. It was compared using χ^2-test. Numeric data were expressed in mean±SD and compared using student *t*-test or the Mann–Whitney rank-sum test, depending on the

Figure 1



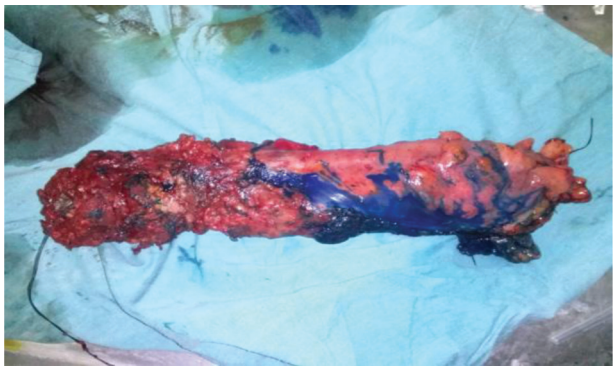
Identification of inferior mesenteric artery.

Figure 2



Cannulation of inferior mesenteric artery.

Figure 3



Blue staining of mesorectal surface.

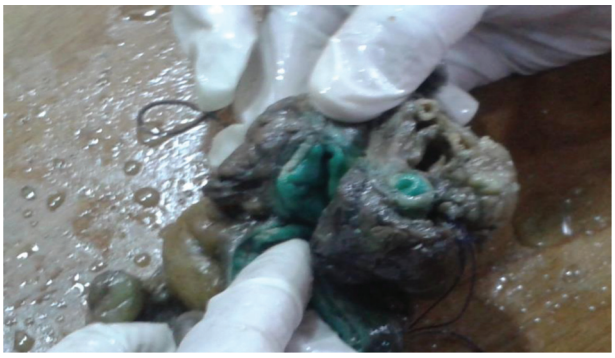
results of the distribution test. Statistical significance was considered at P 0.05 or less.

Results

Both groups were matched according to demographic, anatomical, surgical, and tumor histopathological data without statistical significance (Table 1). A total number of 701 (17.52±6.72) LNs were identified in group I compared with 437 (14.3.7±5.63) LNs in group II, which was a statistically significant difference (P=0.019).

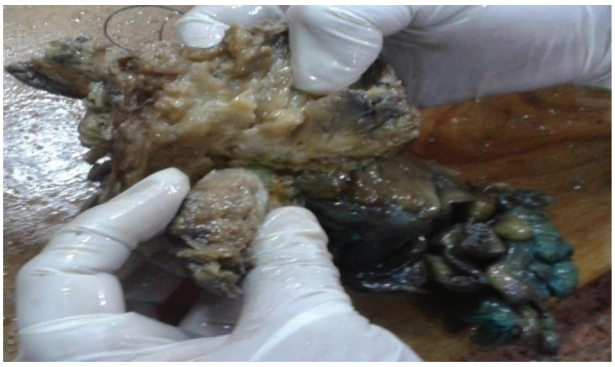
At least 12 LNs were identified in 35 (87.5%) patients of group I compared with 19 (63.3%) patients in group II, which was also statistically significant (P<0.001). Metastases were detected in 22 (55%) patients in group I and 17 (56.7%) patients in group II with (P=0.988) (Table 2). Retrieved LNs were measured and categorized according to their size. The difference in nodal harvest between the two groups was most pronounced and statistically significant in LNs measuring up to 2 mm and more than 2 to up to 4 mm categories. However, for the

Figure 4



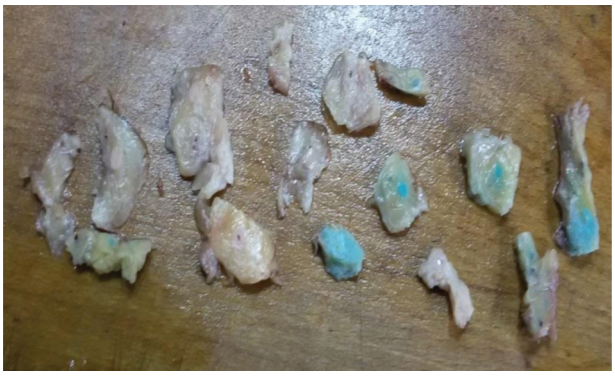
After fixation in formalin for 24 h.

Figure 5



Regional fat dissection.

Figure 6



After xylene fat clearance.

Table 1 Comparison between the two studied groups according to demographic data, tumor location, surgical procedures, and histological criteria.

	Group I (n=40)	Group II (n=30)	Test of significance	P
Sex [n (%)]				
Male	26 (65.0)	18 (60.0)	χ^2=0.213	0.644
Female	14 (35.0)	12 (40.0)		
Age (years) [n (%)]				
Minimum–Maximum	23.0–77.0	26.0–72.0	t=0.568	0.572
Mean±SD	52.35±14.84	50.60±12.62		
BMI (mean±SD)	26.80±2.19	26.90±1.74	t=0.013	0.981
Tumor location [n (%)]				
Lower rectum	16 (40.0)	11 (36.7)	χ^2=0.053	0.818
Middle rectum	24 (60.0)	11 (63.3)		
Surgical procedure [n (%)]				
Abdominoperineal resection	11 (27.5)	9 (30)	χ^2=1.458	0.483
Low anterior resection	29 (72.5)	21 (70)		
Histological type [n (%)]				
Adenocarcinoma	32 (80.0)	25 (83.3)	χ^2=0.366	0.416
Mucinous carcinoma	8 (20)	5 (16.7)		

χ^2: χ^2-test. t: Student t-test.

LNs in the more than 4 mm categories, the difference was statistically insignificant (Table 3).

Discussion

For decades, fat clearance techniques were adopted by many centers to improve nodal harvest in cases of colorectal cancer [18–21]. Methylene blue injection into the superior rectal or the inferior mesenteric artery has been introduced as a simple effective alternative technique [22–24]. Each of these methods was widely compared with the routine manual palpation showing significant differences regarding nodal harvest especially after neoadjuvant chemoradiation. Fat clearing techniques have been claimed to be a time consuming method, so addition of methylene blue injection technique to fat clearance may help in identification of LNs by intense blue staining of them, decreasing the time consumed in LNs identification [16]. Sanchez *et al.* [16] reported evident significant difference regarding LN harvest comparing combined ex-vivo methylene blue

Table 2 Comparison between the two studied groups according to lymph node harvest

	Group I (n=40)	Group II (n=30)	Test of significance	P
Optimal harvest [n (%)]				
≤11	5 (12.5)	11 (36.7)	χ^2=33.826*	<0.001*
≥12	35 (87.5)	29 (63.3)		
Total harvest				
n	701	437		
Minimum–Maximum	8.0–23.0	7.0–24.0		
Mean±SD	17.52±6.2	14.57±2.34	Z=2.348	0.019*
Median	17.0	14.0		
Metastatic LN				
Number (% of total)	216 (30.81)	147 (30.20)		
Minimum–Maximum	2.0–11.0	1.0–12.0		
Mean±SD	9.82±6.74	8.65±5.40	Z=0.037	0.08
Median	5.0	5.0		
Metastatic cases [n (%)]	22 (55)	17 (56.7)	χ^2=0.015	0.988

χ^2 for χ^2-test. Z for Mann–Whitney test. LN, lymph node. *Statistically significant at P≤0.05.

Table 3 Comparison between the two studied groups according to size of lymph nodes

	Group I	Group II	Z	P
L.Ns ≤2 mm				
Number (% of total)	74 (10.56)	29 (6.73)		
Min.–Max.	0.0–8.0	0.0–4.0		
Mean±SD.	1.85±1.17	0.97±1.12	3.399*	<0.001*
Median	3.0	1.0		
Positive LNs (% of +ve)	5 (2.32)	4 (3.03)		
L.Ns >2 to ≤4 mm				
Number (% of total)	89 (12.7)	40 (9.28)		
Min.–Max.	0.0–9.0	0.0–4.0		
Mean±SD.	2.25±1.51	1.33±0.91	3.828*	<0.001*
Median	5.0	2.0		
Positive LNs (% of +ve)	12 (5.56)	9 (6.82)		
L.Ns >4 to ≤6				
Number (% of total)	196 (27.96)	137 (30.86)		
Minimum–Maximum	2.0–11.0	2.0–12.0		
Mean±SD	4.9±1.86	4.57±1.44	0.029	0.88
Median	7.0	7.0		
Positive LNs (% of +ve)	79 (36.56)	54 (40.90)		
LNs >6				
Number (% of total)	342 (48.79)	225 (52.2)		
Minimum–Maximum	4.0–15.0	4.0–13.0		
Mean±SD	8.55±2.34	7.5±2.15	0.015	0.988
Median	8.0	9.0		
Positive LNs (% of +ve)	120 (55.56)	65 (49.25)		

+ve: for total number of positive lymph nodes. Z: Mann–Whitney test. LN, lymph node. *Statistically significant at P≤0.05.

injection and fat clearance with manual palpation of surgical specimens of rectal adenocarcinoma in patients receiving neoadjuvant chemoradiotherapy. In the present study, we tried to demonstrate the possible superiority of using combined methylene blue injection and fat clearance in comparison with the popular technique of using only fat clearance taking into consideration the superiority of both techniques on routine manual palpation regarding total nodal harvest especially after neoadjuvant therapy. Both groups were matched regarding demographic, anatomical, surgical, and tumor histopathological criteria.

In the present study, the total nodal harvest was statistically superior in group I (17.52±6.72 vs. 14.3.7±5.63; P=0.031). This can be explained by the visualization and detection of a significant higher number of smaller LNs in group I. This is an evident finding regarding LNs measuring up to 2 mm and more than 2 to up to 4 mm categories, which was not the case regarding larger LNs categories. This increase in individual nodal harvest reflects a significant detection of an optimal number of at least 12 LNs in group I compared with group II (87.5 vs. 63.3%; P<0.05).

Although there was a presence of a significant difference in total nodal harvest and detection of the optimal number of LNs, the difference between the two groups regarding the rate of patients with nodal metastasis was not statistically significant (55.00 vs. 56.70%; P=0.98), with also no significant difference regarding the mean of affected nodes (9.82±6.74 vs. 8.65±5.40; P=0.08). Taking into consideration that fat clearance technique by itself has improved detection of total and metastatic nodes, so it may be accepted to say that no further significant detection of metastatic nodes could be achieved using other methods, and subsequently, nonsignificant difference in this study can be easily explained. However, there are several studies that revealed absence of a significant difference regarding detection of nodal metastases even when these studies compared advanced techniques with routine manual palpation of LNs [22,25,26]. Parson *et al.* [25] in their SEER database reported evident increase in LN harvest over time which was associated with the outcome but with no increase in LN positivity.

Markle and colleagues studied a group of 669 cases of colorectal cancer using special methods to improve nodal harvest (methylene blue injection alone in 559 cases, fat clearance alone in 55 cases, and a combined methylene blue injection followed by fat clearance in another 55 cases). Although they compared this group with a cohort of 663 historical cases using only conventional manual dissection, they reported no significant difference regarding nodal positivity rates, which were even absolutely identical at 37% (P=0.98), with only trends toward higher rates of nodal metastases in subgroups of high-grade cancers and rectal cancers without neoadjuvant therapy [22]. They compared their results with Ricciardi *et al.* [26], who conducted a detailed analysis of more than 120 000 cases, and concluded that the poor nodal harvest did not significantly cause detection of lower rate of metastases. Märkl *et al.* [22], depending on their sequential LN preparation and examination, detected the first metastatic node among the first nine detected node in close proximity with the tumor in 86% of cases.

In another publication, Märkl and colleagues found that in only two of 81 cases the largest metastatic node was less than 4 mm whereas the largest LN in all other cases was large enough to be missed during routine examination. They concluded that the pathologists may show a poor performance regarding detecting high number of LNs, but they are much more effective regarding crucial nodes [27]. Herrera *et al.* [28] noticed that though metastases in LNs from rectal adenocarcinoma occur frequently in small LNs (≤5 mm), but mostly of perirectal distribution rendering them easily expected by the pathologists. Kim and colleagues even reported that fat clearance did not increase metastatic LNs yield in both neoadjuvant and nonneoadjuvant groups. This might reflect the fact that one certified pathologist who is specialized in colorectal disease can perform precise pathologic assessment by manual dissection, and this may explain their relatively small additional benefit of fat clearing in detecting more metastatic LNs [29]. Back to our study, the significance of small LNs was the key to explain absence of significant difference regarding detection of nodal metastases though significant difference regarding total nodal harvest. Analysis of detected metastatic LNs in group I revealed that categories of LNs size less than 2 and 2–4 mm contained only 2.32 and 5.56 % of total metastatic nodes, respectively, though these two size categories were responsible for the significant difference regarding total nodal harvest and detection of optimal number of LNs.

Conclusion

Though adding methylene blue injection technique to widely used fat clearance method gave superiority

over using fat clearance alone regarding total nodal harvest and detection of optimal number, it did not show similar statistical significance regarding detection of nodal metastases. Nevertheless, we recommend this combined technique as it can achieve a sufficient nodal harvest in patients with rectal cancer treated with neoadjuvant chemoradiation, as this total harvest is strongly associated with outcome of the patients.

Limitations of this study include the small number of cases and absence of randomization between the two groups. Moreover, although being experts, presence of two pathologists is another limitation.

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Conflicts of interest

There are no conflicts of interest.

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Comparison between full and partial revascularization during endovascular management of multilevel lower limb arterial disease in diabetic patients: assessment of functional outcomes and midterm results

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Introduction
The multilevel arterial arteriosclerosis leads to a major loss of blood perfusion to the target tissues with resultant critical limb ischemia.
Aim
The aim of this article is to compare the results between total revascularization of all level arterial lesions versus revascularization of the proximal lesions regarding limb salvage rates, midterm primary patency rates, and secondary patency rates.
Patients and methods
A prospective study conducted on diabetic patients with symptomatic peripheral arterial disease affecting more than one level of lower limb arterial tree, from January 2013 till the end of December 2013, with critical limb ischemia and no previous attempts of revascularization. Follow-up was 1 year.
Results
A total of 101 diabetic patients were included. Their mean age was 64.4±14 years, and 62.4% were males. They were divided into two groups: group F had full revascularization for all diseased arterial levels and group P had revascularization for the proximal lesion only. Lesions were crossed intraluminal in 54 (53.5%) and subintimal in 47 (46.5%). Stents were used in 44 (43.6%). Primary patency rate was higher in group F than in group P (72.3 vs. 33.3%, P=0.002). The secondary patency rates were higher in group F compared with group P at 6 months (84 vs. 44%) and at 12 months (78 vs. 38%) (P=0.001). Total limb salvage rate was 80.2% and a major amputation rate was 19.8% over a 1-year follow-up period; limb salvage in group F was 88% and in group P was 44% (P=0.001).
Conclusion
In diabetic patients with multilevel arterial lesions affecting more than one arterial territory, total correction of all arterial lesions should be done with direct pulsatile flow to the foot as it is associated with better primary and secondary patency rates and higher limb salvage rates than correction of the proximal lesions.

Keywords:
angioplasty, critical limb ischemia, diabetics, multilevel arterial lesions, stenting

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Introduction

The most common reason of mortality and morbidity in patients with diabetes mellitus is diabetic vasculopathy, where macrovascular disease is responsible for high incidence of vascular diseases such as stroke, myocardial infarction, and peripheral arterial diseases (PAD) [1]. The multilevel arterial arteriosclerosis leads to a major loss of blood perfusion to the target tissues with frequent microthrombi that would obliterate distal vascular beds with resultant critical limb ischemia (CLI) [2]. Advances in endovascular techniques and tools have allowed the successful treatment of more complex occlusive diseases. This has led to a paradigm shift in the treatment of CLI where multiple series have reported successful treatment of CLI at the aortoiliac, femoral, popliteal, and tibial levels [3]. Many studies of patients with multilevel disease showed a significantly improved primary and secondary patency as well as limb salvage rates whenever multiple-level intervention is attempted as compared with single-level intervention for the same patient cohort [4]. Traditionally, endovascular management of multilevel arterial occlusive disease was perceived as a difficult procedure. Whenever such difficulties preclude treatment of all lesions, management usually reside to significant proximal lesions, thus improving the

head pressure for collateral circulation to more distal territories.

Aim

This is a prospective study to assess the clinical effectiveness and related midterm patency rates of endovascular management for atherosclerotic lesions affecting more than one level in lower limb arterial tree in diabetic patients comparing the results between total revascularization of all level arterial lesions versus revascularization of only significant proximal lesions. The following endpoints will be compared: the limb salvage rates, the midterm primary and secondary patency rates.

Patients and methods

This is a prospective study conducted during a 12-months period (January–December 2013) on diabetic patients with symptomatic PAD due to atherosclerotic arterial lesions, affecting more than one level of lower limb arterial tree, admitted to the Vascular Surgery Division, Kasr Al Ainy Hospital, Cairo University, and the Vascular Surgery Department, National Institute of Diabetes and Endocrinology, experiencing critical lower limb ischemia with no history of previous attempts of lower limb revascularization. The research was approved by the committee of the department of general surgery for evaluation of masters and doctorate theses in 2014. Nondiabetic patients, patients with mild or moderate claudication only, patients with single level of lower limb arterial lesions, those with previous history of lower limb revascularization, and those with severe renal impairment were excluded from the study. All patients had an arterial duplex performed for diagnosis and characterization of all the arterial lesions. Preoperative computed tomography angiography was standard practice in our study, performed for all patients before the intervention; all patients had a full vascular clinical assessment, including history, physical examination, risk factor profile, serum creatinine level test, ankle/brachial index (ABI), and peak systolic velocity measurements. Based on this assessment, appropriate medical management was commenced to all patients, along with risk factor modification.

Procedure details

Patients were admitted at the day of the procedure where a loading dose of clopidogrel (300 mg) was to be given the night of the procedure. Under local anesthetic (lidocaine 2%: 3–5 mg/kg), three sites of arterial access were used depending on the anatomy of the lesions and the operator's preference; ipsilateral antegrade femoral arterial access was performed in patients with middle one-third superficial femoral artery (SFA) lesion or more distal lesions, where contralateral femoral access with a cross-over sheath was performed in patients with either nonflush occlusion of common iliac artery (CIA), external iliac artery (EIA), common femoral artery, and proximal one-third SFA lesions. Brachial artery access technique was used in aortoiliac lesions. All patients received 5000 IU intra-arterial heparin immediately following sheath insertion, and a second dose of 5000 IU intra-arterial heparin was given if procedure time exceeds 2 h. Initial digital subtraction angiogram was performed to gather information regarding diseased segment's location(s), length and degree of stenosis or occlusion, and the extent of distal run-off.

Revascularization strategy

In aortoiliac lesions regardless of being either stenosis or occlusion, we adopt the primary stenting concept with balloon expandable stents for CIA and self-expanding stents for EIA. For SFA stenotic lesions, our policy involves liberal use of noncompliant plain balloons of appropriate lengths and diameters with slow increments (2 atm/30 s) till the nominal pressure is reached to minimize the incidence of subsequent dissection or rapid recoil; however, in total occlusion, the subsequent strategies differ according to the lesion crossing whether intraluminal or subintimal. Intraluminal passage would follow the prestated dilatation policy with secondary bail-out stenting in case of residual stenosis (? 30%) or flow-limiting dissection covering the whole lesion, whereas subintimal passage would call for selective stenting of either entry or exit points, if needed. For popliteal and infrapopliteal vessels, we change our platform to 0.018 or 0.014 with the use of their dedicated over-the-wire balloon catheters or rapid exchange ones. We encouraged the use of support catheters.

For ethical reasons, we attempted at total revascularization of all documented arterial lesions affecting the target limb; however, in certain conditions subjected to the operator's judgment, we were only able to treat the proximal lesions only leaving the more distal lesions without intervention. These conditions include extended time of procedure, use of large amount of contrast, patients with renal impairment, deterioration of the general condition of the patient during the procedure, or failure to cross-distal lesions.

Following percutaneous transluminal angioplasty (PTA), with or without stenting, final angiogram

was obtained, and procedure outcome was recorded. In case of arterial spasm, 0.1-mg nitroglycerine was given as an intra-arterial bolus. The arterial access sheath was removed when appropriate, and hemostasis achieved by manual compression. Most patients were discharged on the second day following the procedure after receiving instructions on risk factors to control and treatment including the following: enoxaparin subcutaneously every 12 h for 2 days, aspirin 81 mg/day for life, clopidogrel 75 mg/day for at least 3 months, and atorvastatin given routinely (40 mg for 2 weeks and then 20 mg for 6 months). Clinical outcome, including improvement in rest pain and ulcer healing/resolution, was documented before discharge and at subsequent outpatient visits, with repeat ABI and/or ankle peak systolic velocity, and arterial duplex was performed within 6 weeks.

Follow-up

Clinical improvement was documented before discharge and at subsequent outpatient visits. Wound closure and limb salvage are our primary endpoint. Clinical improvement was judged by palpable peripheral pulse, increase of claudication distance, disappearance of rest pain, wound healing, and limb salvage. Technical failure was defined as an inability to cross the proximal lesions at the time of the primary procedure or by the presence of greater than or equal to 50% restenosis within the first 30 days after the initial procedure. Clinical follow-up data were collected at each clinic visit. Surviving patients remained on this surveillance protocol at 3, 6, and 12 months, with follow-up duplex performed after 6 weeks and after 6 months. The clinical status of the patients and ABI index were evaluated at the same intervals, except in patients with huge ulceration in the leg or heavily calcified pedal arteries. The ultrasound examination measured the patency of the treated artery and any evidence of residual or new occlusions. Clinical outcomes, primary patency, secondary patency, and complications were reported according to the 'Recommended standards for reports' by Rutherford and Becker [5]. An increase in ABI of at least 0.10 was accepted as evidence of hemodynamic improvement, whereas a decrease of less than 0.10 or more was deemed to be a hemodynamic failure. Early mortality (<30 days) was reported. Limb salvage was defined as no amputation proximal to the metatarsus. Any above-the-ankle amputation was considered a failure of the revascularization procedure. All periprocedural and postprocedural complications were evaluated and documented. All statistical calculations were done using computer programs statistical package for the social science (SPSS, version 15; SPSS Inc., Chicago, Illinois, USA) for Microsoft Window.

Results

During the 12-month period of the study, 101 eligible diabetic patients were enrolled with mean age of 64.4±14 years; of which, 62.4% were male. Patient's presentations ranged from lifestyle-limiting claudication to major tissue loss (Rutherford clinical categories 3–6). As in inclusion criteria, all had multilevel atherosclerotic occlusive disease, and they were classified according to the most proximal significant lesions into four subgroups (Table 1):

(1) Group A: CIA.
(2) Group B: EIA or common femoral.
(3) Group C: SFA.
(4) Group D: popliteal artery.

The more distal the proximal lesion is, the worst the category of presentation.

Otherassociated comorbidities and risk factors (e.g. hypertension and ischemic heart disease, smoking, renal impairment, hyperlipidemia, stroke, or chest disease) were recorded for each group, together with the numbers of risk factors and comorbidities in each individual patient as shown in Table 2.

As our purpose of the study is to assess the effect of either total revascularization or partial revascularization on limb salvage, following completion of the intended procedures, our population was classified into two major groups: one group had full revascularization for all/most of significant lesions ending in at least one direct vessel uninterrupted continuous flow to the foot (group F), whereas the other had those unfortunate

Table 1 Presentations in different subgroups

Presentation	A [*n* (%)]	B [*n* (%)]	C [*n* (%)]	D [*n* (%)]	Total presentation [*n* (%)]
Intermittent claudication	0	0	3 (4)	0	3 (3.0)
Rest pain	3 (50.0)	1 (20.0)	14 (6.7)	1 (16.7)	19 (18.8)
Minor tissue loss	3 (50.0)	4 (80.0)	55 (65.0)	5 (83.3)	67 (66.3)
Major tissue loss	0	0	12 (14.3)	0	12(11.9)
Total subgroup	6	5	84	6	101

P=0.482.

Table 2 The numbers of risk factors and comorbidities among the subgroups

Subgroup	Number of comorbidities					Total
	1	2	3	4	5	
A	0	1	3	2	0	6
B	0	0	4	1	0	5
C	3	16	38	21	6	84
D	0	3	1	2	0	6
Total	3	20	46	26	6	101

P=0.6.

Table 3 Patients' distribution among groups

Subgroup	F [*n* (%)]	P [*n* (%)]	Total
A	3 (3.6)	3 (16.7)	6 (5.9)
B	3 (3.6)	2 (11.1)	5 (5.0)
C	71 (85.5)	13 (72.2)	84 (83.2)
D	6 (7.2)	0 (0.0)	6 (5.9)
Total	83 (100)	18 (100)	101 (100)

P=0.065.

Table 4 Initial technical success according to presentation

Presentation	Intermittent claudication (%)	Rest pain (%)	Minor tissue loss (%)	Major tissue loss (%)	Total (%)
Initial technical success	94.7	94.7	97.0	75.0	94.1

P=0.029.

Table 5 The primary patency rates for groups F and P

Primary patency	F (%)	P (%)	Total (%)	*P*-value
At 3 month	91.6	50.0	84.2	0.001
At 6 month	77.1	38.9	70.3	0.002
At 12 month	72.3	33.3	65.3	0.002

Table 6 Secondary patency rates for groups P and F

Groups	F (%)	P (%)	Total (%)	*P*-value
At 6 month	84.3	44.4	77.2	0.001
At 12 month	78.3	38.9	71.3	0.001

Table 7 Major amputation and limb salvage rates in both patient groups

	F [*n* (%)]	P [*n* (%)]	Total [*n* (%)]
Above-knee amputation	4 (4.8)	3 (16.7)	7 (6.9)
Below-knee amputation	6 (7.2)	7 (38.9)	13 (12.9)
Total amputations	10 (12)	10 (55.6)	20 (19.8)
Total limb salvage	73 (88)	8 (44.4)	81 (80.2)

patients in whom our strategy was not fulfilled with absent direct continuous uninterrupted flow to the foot (group P). The distribution of group F and group P among different subgroups (A, B, C, and D) is shown in Table 3.

Antegrade approach was used in 73 (72.2%) patients, divided into ipsilateral femoral access in 69 patients and brachial access in four patients (using long sheath), whereas contralateral access with cross-over sheath was used in 28 (27.7%) patients. The lesions were crossed intraluminal in 54 (53.5%) patients and subintimal in 47 (46.5%) patients. Stents were used in 44 (44/101, 43.6%) patients. The initial technical success was significantly better in patients presented with minor tissue loss (97.0%) (Table 4).

Vessel perforation occurred in three patients, one in anterior tibial artery (ATA) and two in posterior tibial artery (PTA), and all were managed by prolonged balloon inflation.

Primary patency rate at 12 months was significantly higher in group F than in group P (72.3 vs. 33.3%; *P* =0.002), as shown in Table 5.

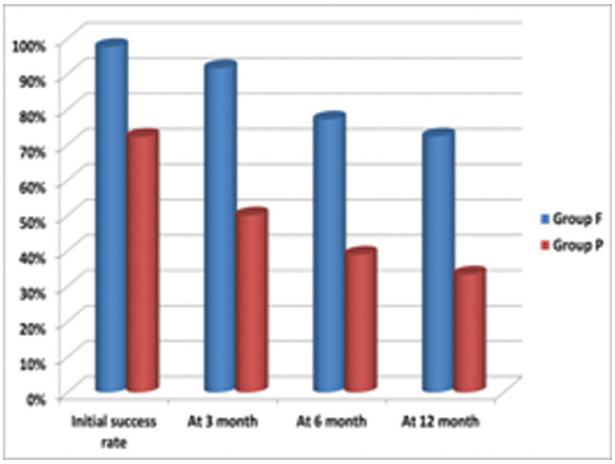
Reintervention was needed in eight patients owing to restenosis or total occlusion of the treated lesions presenting with either lost pulses, rest pain, or deterioration of the wound healing. The secondary patency rates were significantly higher in group F compared with group P at 6 months and at 12 months, as shown in Table 6.

We achieved a limb salvage rate of 80.2% (81 patients) and a major amputation rate of 19.8% (20 patients) over 1-year follow-up period. Above-knee amputation was done for seven (6.9%) patients and below-knee amputation for 13 (12.9%) patients in our study. Group F showed significantly higher limb salvage rate and significant lower amputation rate than group P (*P*=0.001). Furthermore, we had three not-procedure-related mortalities during the follow-up period (Table 7 and Figs 1 and 2).

Discussion

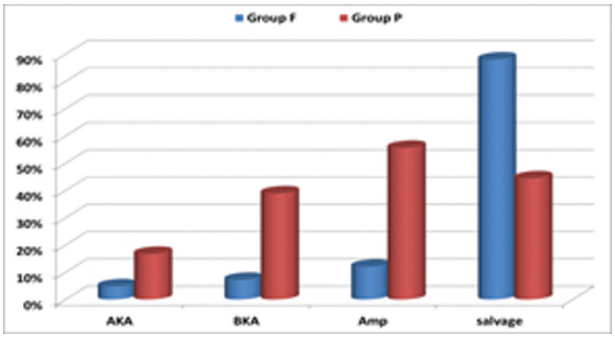
Diabetic vasculopathy (macrovascular disease) is the most common reason of mortality and morbidity in diabetes and is responsible for high incidence of vascular diseases such as stroke, myocardial infarction, and peripheral vascular diseases (PAD) [1]. Diabetics are up to 15 times more likely than nondiabetics to experience a major amputation. Diabetes is also associated with decreased primary patency following endovascular interventions [6]. Endovascular interventions for CLI continue to have variable reported results, adequate rates of limb salvage can be achieved in patients undergoing multilevel interventions for CLI, and improved patency is seen with multilevel compared with isolated tibial interventions [3]. In our study, 101 diabetic patients of different age and sex were scheduled for angioplasty

Figure 1



The primary patency rates for groups P and F.

Figure 2



Major amputation and limb salvage rates in both patient groups. AKA, above-knee amputation; Amp, amputations; BKA, before-knee amputation.

with multilevel arterial disease in lower limbs. All patients enrolled in our study were diabetics, and most of them had also other associated comorbidities and risk factors (e.g. hypertension, ischemic heart disease, smoking, renal impairment, stroke, or chest disease), which were presented in the study as numbers of comorbidities and risk factors for each patient. Among our 101 diabetic patients with critical lower limb ischemia, the technical success rate was 91.1%, and after 12 months of follow-up, primary patency rate, secondary patency rate, and limb salvage were 65.3, 71.3, and 80.2%, respectively. Our initial technical success was significantly better in patients with minor tissue loss (97.0%), patients with rest pain, and patients with intermittent claudication (94.7%) than in patients with major tissue loss (75%) (P=0.029).

Although there were no significant differences in primary patency rates between the different study subgroups (A, B, C, and D) at 12-month follow-up, primary patency was significantly higher in group F with full revascularization for all diseased arterial level than in group P, where the significant proximal lesions only were treated when we failed to deal with the distal level of occlusions. Such distal level of occlusion was the femoropopliteal segment in aortoiliac lesions or the tibial arteries in SFA lesion. Our secondary patency rate was 71.3%, and we noticed significantly higher secondary patency rates in group F compared with group P at 6 months (P=0.001) and at 12 months (P=0.001), but we did not notice significant differences of secondary patency rates between the different subgroups (A, B, C, and D). We also found that increasing numbers of risk factors and comorbidities had drawback on the primary patency rate at 3 month and 12 month and on limb salvage rates with increase in the amputation rate. Abularrage *et al.* [6] reviewed that diabetes mellitus is an independent predictor of decreased long-term primary patency after PTA/stent in 920 patients who underwent 1075 PTA/stent procedures, and long-term limb salvage remains inferior in diabetic patients compared with nondiabetic patients owing to a more severe clinical presentation and poor run-off. Miura *et al.* [7] in his study considered superficial femoral plus iliac lesions in addition to age, dialysis, left ventricular dysfunction, diabetes, hematoma prolonging hospitalization, and coronary artery disease as positive predictors of all-cause mortality.

Similar to our results, two studies of patients with multilevel lower limb arterial disease showed significantly improved secondary patency rates of multilevel intervention compared with single-level intervention. Sadek *et al.* [4] in a study for endovascular therapy of multilevel lower limb arterial lesions on 85 patients mentioned a limb salvage rate of 81%, similar to our limb salvage rate of 80.2%. Their group F patients showed significantly higher limb salvage rate and significant lower amputation rate than group P, but there were no significant differences in limb salvage rate or major amputations rate between the different subgroups (A, B, C, and D) [4]. Fernandez *et al.* [3] showed a limb salvage rate of 81% for isolated tibial disease and 95% for multilevel arterial lesions (P=0.05). Wound healing was achieved in 69% in isolated tibial lesions and in 87% in multilevel disease (P=0.05) [3].

Guo *et al.* [2] in a study including 53 patients with TASC II D femoropopliteal occlusive disease showed a technical success rate of 95% with mean follow-up period of 12.2±6.1 months (5–38 months). Primary

patency rate at 1 year was 63%, assisted primary patency rate at 1 year was 77%, and secondary patency rate at 1 year was 96%. These results were significantly better than our results because they included lesions in femoropopliteal segment only which was treated mainly by primary stenting whereas other levels of arterial lesion were not included [2].

We also noticed that patients who presented with minor tissue loss or rest pain showed significantly higher limb salvage rates whereas patients who presented with major tissue loss showed higher amputation rates. These findings were reported before in a study by Ghoneim *et al.* [8] for lower limb multilevel arterial diseases which showed that the presence of major tissue loss was associated with a significantly worse limb salvage rate with total limb salvage rate of 90.7% at 2-year follow-up.

In most of diabetic patients with multilevel arterial lesions, the tibial arteries most often are heavily calcified and plagued by long occlusive lesions, which add to the complexity of the procedure if the decision was taken to treat those below-the-knee tibial lesions after correction of the proximal aortoiliac or femoropopliteal disease with more radiation exposure and more contrast dye used. Graziani *et al.* [9] in their study reported that 66% of all below-the-knee lesions were occlusions in 417 diabetic patients with critical lower limb ischemic and foot ulcer, and 50% were occlusions >10 cm. Moreover, the vascular involvement is extremely diffuse and particularly severe in tibial arteries, with high prevalence of long occlusions [9]. If the original presentation was not in any form of tissue loss (i.e. incapacitating claudication or rest pain), it may be prudent to correct the proximal disease only if full correction of all lesions is technically challenging with close observation of clinical improvement. If no improvement was achieved in the early postintervention period, patients may be scheduled for secondary intervention to treat the distal disease at a second stage. So, based on our findings, we can outline that in diabetic patients with multiple levels of arterial diseases, all efforts should be exerted to achieve total correction of all lesions to secure good in-line pulsatile flow to the foot. Correction of the proximal lesions only cannot be considered satisfactory especially in patients presenting with tissue loss as it is usually associated with inferior patency rates and low overall limb salvage rates.

There are some limitations of the present study: first, this is a single-arm study without a control group. Therefore, the rates of technical success, patency rates, and limb salvage rates were not assessed for comparison with a single-level lesion or nondiabetic patients, and hybrid procedure was not included in the management as minimally invasive procedures in medically high-risk patients with complex anatomy. Second, study design was prospective which added a limitation affecting the number of patients and their distributions in the groups. Finally, we have relatively large number of patients who were lost to follow-up for more than 1 year. This may be attributed to socioeconomic factors and lack of proper insurance system. So, we consider these results as midterm results.

Conclusion

In diabetic patients with multiple level of arterial atherosclerotic lesions affecting more than one arterial territory, all efforts should be exerted to achieve total correction of all arterial lesions with direct pulsatile flow to the foot as it is associated with better primary and secondary patency rates and significantly higher limb salvage rates than correction of the proximal arterial lesions only.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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Portal and mesenteric vein resection during pancreaticoduodenectomy and total pancreatectomy

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Background
Portal vein invasion by a malignant pancreatic mass is currently not a contraindication to pancreatic resection with acceptable oncologic outcomes.
Aim
The aim of this paper was to identify the perioperative morbidity and long-term outcomes of venous resection (VR) during pancreaticoduodenectomy (PD) and total pancreatectomy (TP) operations.
Materials and methods
We carried out a retrospective study of patients undergoing PD or TP between March 1995 and December 2014 at Mayo Clinic in Jacksonville, Florida, using data collected from an institutional review board-approved prospective database. Preoperative, operative, and postoperative clinicopathological data were collected and analyzed.
Results
Out of 601 patients who underwent PD and TP in this study, 104 (17.3%) underwent VR. The types of VR and reconstruction were as follows: type I (lateral venorrhaphy) in 49 (47.1%) patients, type II (patch graft) in 10 (9.6%) patients, type III (primary anastomosis) in 27 (26%) patients, and type IV (interposition venous graft) in 16 (15.4%) patients. Two (1.9%) patients underwent no portomesenteric reconstruction. The 90-day major postoperative complications and mortality in patients with VR were 44.2 and 7.7%, respectively, versus 29.2 and 4.4%, respectively, in patients with standard resection. The 1-year, 3-year, 5-year, and 7-year survival rates in VR with periampullary adenocarcinoma (PAAC) were 55.1, 27, 21.9, and 15.4%, respectively, whereas in patients with PAAC without VR, the survival rates were 78.4, 45.6, 34.6, and 30.9%, respectively ($P<0.01$).
Conclusion
VR and reconstruction with PD can be performed safely with acceptable perioperative morbidity and long-term survival rates to achieve complete removal of the tumor.

Keywords:
pancreaticoduodenectomy, portal vein, reconstruction, venous resection

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Introduction

Despite the current practice of a multidisciplinary team approach including advances in neoadjuvant chemotherapy and radiotherapy, 5-year survival after pancreatic resection for adenocarcinoma is still limited to 15–25% [1,2]. Involvement of major peripancreatic vessels is encountered in about half of the patients with pancreatic cancer [3,4] and the overall surgical resection rate is only 15–20% [5,6].

Complete resection of the tumor remains the only chance for cure. Invasion of the portal vein (PV) or the superior mesenteric vein (SMV) is currently not a contraindication to surgery, and vein resection and reconstruction can be performed with acceptable oncologic outcomes, almost comparable to patients who received standard resection. Given the improvements in morbidity and mortality rates, surgical resection is preferred over a bypass procedure whenever a complete tumor excision is deemed likely by preoperative and operative assessments [2,7].

The aim of the present study was to analyze the postoperative outcome and survival of patients with pancreaticoduodenectomy (PD) or total pancreatectomy (TP) and portomesenteric venous resection (VR) at our institution.

Materials and methods

A retrospective study of patients who underwent PD and TP between March 1995 to December 2014 at

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the Mayo Clinic in Jacksonville, Florida, was carried out using data collected from an institutional review board-approved prospective database.

Patients were divided into two groups: patients who underwent associated venous (portal–mesenteric) resection and those who underwent standard resection. The two groups were compared in terms of demographic features, surgical procedures, tumor pathologic findings, and perioperative outcome.

The exclusion of metastatic disease and the assessment of vascular involvement and the need for VR were determined by the preoperative imaging studies, such as enhanced computed tomography (CT) with pancreatic protocol, or MRI, and CT angiography.

The International Study Group of Pancreatic Surgery (ISGPS) guidelines and the National Comprehensive Cancer Network guidelines [8] for patients with borderline resectability were used. The tumors with borderline venous resectability include the following: (a) venous distortion of the SMV/portal venous axis in the CT scan, which may include short-segment venous occlusion with sufficient vessel length allowing reconstruction; (b) encasement of the gastroduodenal artery or even hepatic artery without extension to the celiac axis; and (c) tumor abutment of the superior mesenteric artery with less than 180° of the vessel wall circumference.

Operative strategy

PD or TP was performed either open or laparoscopically. The abdomen was explored for occult metastatic disease and the tumor was assessed for resectability. When separation of the tumor from the surrounding mesenteric vasculature was not feasible during surgery, vascular resection and reconstruction were performed to remove the tumor completely.

The ISGPS classification of VR was used as follows [8]:

(1) Type I: partial venous excision with direct closure (venorrhaphy) by suture closure.
(2) Type II: partial venous excision using a patch.
(3) Type III: segmental resection with primary veno–venous anastomosis.
(4) Type IV: segmental resection with an interposition venous conduit and at least two anastomosis.

Histopathological data on pancreatic tumor staging were collected according to the tumor, node, and metastases staging system. R1 and R2 resections were assessed at the surgical margin.

Patients with venous reconstruction received postoperative anticoagulant therapy in the form of low-molecular weight heparin and transitioned to oral Warfarin once oral intake was tolerated. After discharge, they were maintained on anticoagulant therapy for 3 months postoperatively.

All patients with VR were evaluated postoperatively for venous patency by duplex ultrasound on the same day of surgery and by CT or MRI portography within 3 weeks after the procedure. Long-term follow-up of PV patency was assessed by CT or MRI portography.

Postoperative complications within 90 days of surgery were graded [9] from 0 to 5 on the basis of the most severe postoperative complication for each patient. Grade I and II complications were considered minor and grade III, IV, and V complications were considered major. International consensus guidelines were used to evaluate complications when applicable [10,11].

The follow-up period was from the date of surgery to September 2015, with a median follow-up period 79 months. Any death during the hospital stay or within the first 90 days after surgery related to surgery was defined as perioperative mortality. Readmissions to any facility were recorded for 90 days after surgery.

Statistical analysis

Data were collected and entered into the computer using SPSS version 21.0 (SPSS Inc., Chicago, Illinois, USA) for statistical analysis. A χ^2-test or Fisher's exact test was used for qualitative variables. The Student's *t*-test and the Mann–Whitney *U*-test were used for quantitative data. Multivariable Cox regression analysis was used to determine independent predictors of mortality. A Kaplan–Meier curve was plotted for the analysis of total survival and disease-free survival and a log-rank test was used to compare the survival for both groups. The *P* value was considered statistically significant when it was less than 0.05.

Results

From March 1995 to December 2014, 601 patients underwent PD and TP for benign and malignant pancreatic diseases. Among these patients, 104 (17.3%) were treated with PD or TP combined with VR with reconstruction if appropriate. Three hundred

and fifty-five (59.1%) patients underwent PD or TP for PAAC; 87 of these patients underwent VR and reconstruction with the pancreatic resection. The demographic data and clinicopathologic findings of all patients and patients with PAAC are listed in Tables 1 and 2.

The laparoscopic approach was introduced in October 2008. A total of 305 patients (50.7%) in this series had PD and TP after this date; 152 (49.8%) of these patients underwent open surgery and 153 (50.2%) underwent laparoscopic surgery. The conversion to open surgery occurred in 28 (18.3%) patients. PV involvement of the tumor was the reason for conversion in 14 patients.

Of the 125 patients who underwent complete laparoscopic surgery, 103 (82.4%) underwent laparoscopic PD and 22 (17.6%) patients underwent laparoscopic TP.

Portomesenteric VR was performed in the 104 patients: 73 patients underwent PV resection and 31 underwent SMV resection. The resections were performed according to the ISGPS classification of vein resection, which included type I (lateral venorrhaphy) in 49 (47.1%) patients, type II (patch graft) in 10 (9.6%) patients (six from bovine pericardium graft and four from gonadal vein), type III (primary anastomosis) in 27 (26%) patients, type IV (interposition venous graft) in 16 (15.4%) patients (13 by poly tetra fluoro ethylene synthetic graft, two from gonadal vein, and one from splenic vein), and for two (1.9%) patients no portomesenteric reconstruction could be performed because of mesenteric vein thrombosis.

Eleven (10.6%) patients underwent laparoscopic VR (10 lateral venorrhaphy, one bovine pericardial batch graft).

Table 3 shows the postoperative outcome. Major postoperative complications were found in 46 (44.2%) patients with VR compared with 145 (29.2%) patients without VR ($P<0.01$).

Twenty (19.2%) patients had portal vein thrombosis (PVT) or superior mesenteric vein thrombosis (SMVT) after VR (mean: 1.8±3.1 months; range: 0.05–18 months). Eighteen (90%) patients had early PV/SMVT in the

Table 1 Patient characteristics, preoperative, and operative data for all 601 patients with pancreaticoduodenectomy and total pancreatectomy

	VR positive (*n*=104) [*n* (%)]	VR negative (*n*=497) [*n* (%)]	*P* value
Age [mean±SD (range)] (years)	66.8±11.4 (21.4–84.5)	65.5±12.1 (18.2–86.9)	0.28
Sex			
Male	53 (51)	244 (49.1)	0.73
Female	51 (49)	253 (50.9)	
Preoperative main symptoms			
Jaundice	58 (55.8)	196 (39.4)	0.01
Weight loss	64 (61.5)	245 (49.3)	0.06
Nausea/vomiting	63 (60.6)	258 (51.9)	0.4
Abdominal pain	59 (56.7)	257 (51.7)	0.35
Asymptomatic	6 (5.8)	76 (15.3)	0.01
Comorbidities			
HTN	59 (56.7)	304 (61.2)	0.81
DM	29 (27.8)	130 (26.2)	
Cardiac disease	28 (26.9)	145 (29.2)	
ASA			
I	1 (1)	1 (0.2)	0.23
II	24 (23.1)	116 (23.4)	
III	69 (66.3)	354 (71.2)	
IV	10 (9.6)	26 (5.2)	
Types of surgery			
PD	86 (82.7)	418 (84.1)	0.72
TP	18 (17.3)	79 (15.9)	
Laparoscopic	11 (10.6)	114 (22.9)	0.01
Open	93 (89.4)	383 (77.1)	
Operative time [mean±SD (range)] (min)	484±123 (219–930)	395±115 (126–824)	<0.01
Estimated blood loss [mean±SD (range)] (ml)	1592.7±2218.7 (75–18 000)	638.6±849.3 (15–7000)	<0.01
Perioperative blood transfusion [mean±SD (range)] (unit)[a]	7±11 (0–60)	2±5 (0–50)	<0.01

ASA, American Society of Anesthesiologists; CA 19-9, carbohydrate antigen 19-9; DM, diabetes mellitus; HTN, hypertension; PD, pancreaticoduodenectomy. [a]Included units during the resection and all subsequent postoperative blood transfusions.

Table 2 Patient characteristics, preoperative, and operative data in 355 patients with periampullary adenocarcinoma

	VR positive (*n*=87) [*n* (%)]	VR negative (*n*=268) [*n* (%)]	*P* value
Age [mean±SD (range)] (years)	68.1±9.2 (44.7–83.3)	68.4±10.1 (33.3–86.9)	0.82
Sex			
Male	45 (51.7)	144 (53.7)	0.74
Female	42 (48.3)	124 (46.3)	
Biliary stent	45 (51.7)	139 (51.9)	0.98
CA 19-9 [mean±SD (range)]	1619.1±6824.7 (1–45 107)	320±947 (0.9–7393)	**0.01**
Types of surgery			0.21
PD	74 (85.1)	241 (89.9)	
TP	13 (14.9)	27 (10.1)	
Laparoscopic	9 (10.3)	62 (23.1)	**0.01**
Open	78 (89.7)	206 (76.9)	
Operative time(min) Mean±SD (Range)	476±110 (219–809)	387±113 (136–819)	<**0.01**
Estimated blood loss [mean±SD (range)] (ml)	1396.1±1529.7 (75–8500)	593.9±679.2 (30–6000)	<**0.01**
Perioperative blood transfusion[a] [mean±SD (range)] (unit)	6±9 (0–55)	2±4 (0–24)	<**0.01**
Type of PAAC			
Pancreatic	82 (94.3)	170 (63.4)	<**0.01**
Bile duct	2 (2.3)	24 (9)	
Ampullary	3 (3.4)	74 (27.6)	
Duodenal	0	0	
Tumor size [mean±SD (range)] (cm)	3.5±1.8 (0.5–14)	2.9±1.7 (0.3–10)	**0.01**
Tumor stage			
T1	4 (4.6)	21 (7.8)	**0.02**
T2	7 (8)	52 (19.4)	
T3	72 (82.9)	167 (62.4)	
T4	3 (3.4)	17 (6.3)	
Unavailable	2 (1.1)	11 (4.1)	
	(*n*=82)	(*n*=170)	
Stages			0.53
IA	3 (3.7)	8 (4.7)	
IB	2 (2.4)	10 (5.9)	
IIA	16 (19.5)	38 (22.3)	
IIB	57 (69.6)	106 (62.3)	
III	1 (1.2)	3 (1.8)	
IV	1 (1.2)	2 (1.2)	
Unavailable	2 (2.4)	3 (1.8)	
Tumor grade			
Well differentiated	9 (10.3)	35 (13.1)	0.90
Moderately differentiated	45 (51.8)	133 (49.5)	
Poorly differentiated	31 (35.6)	94 (35.1)	
Unavailable	2 (2.3)	6 (2.3)	
Resection margin			
R0	66 (75.9)	236 (88.1)	**0.01**
R1/R2	21 (24.1)	32 (11.9)	
Lymph node			
N0	25 (28.7)	113 (42.2)	**0.03**
N1	62 (71.3)	155 (57.8)	
LNR [mean±SD (range)]	0.15±0.16 (0–58)	0.14±0.19 (0–1)	0.7
Lymph vessels invasion			
Yes	50 (57.5)	105 (39.2)	<**0.01**
No	37 (42.5)	163 (60.8)	
Perineural invasion			
Yes	68 (78.2)	146 (54.5)	<**0.01**
No	19 (21.8)	122 (45.5)	
Recurrence	48 (55.2)	92 (34.3)	**0.01**

ASA, American Society of Anesthesiologists; CA 19-9, carbohydrate antigen 19-9; DM, diabetes mellitus; HTN, hypertension; LNR, lymph node ratio; PD, pancreaticoduodenectomy; PDAC, pancreatic ductal adenocarcinoma; TP, total pancreatectomy; VR, venous resection.
[a]Included units during the resection and all subsequent postoperative blood transfusions. Bold values are statistically significant.

first 3 postoperative months, one patient had SMVT at 5 months, and one patient had late thrombosis at 1.5 years postoperatively, which was associated with the tumor recurrence. The estimated patency of PV after reconstruction for type I, II, III, and IV reconstruction was 91.7, 80,75, and 68.8%, respectively.

The management of PVT was conservative by anticoagulant therapy in 18 (90%) patients, surgical thrombectomy for SMVT in one patient, and tissue plasminogen activator and placement of a PV stent by interventional radiology in one patient.

Forty-eight (55.2%) of 87 patients with VR in PAAC had tumor recurrence, which was significantly higher than those undergoing resection for PAAC without VR ($P<0.01$). In the univariate analysis, there was a significant relationship between tumor recurrence and VR in PAAC ($P<0.01$).

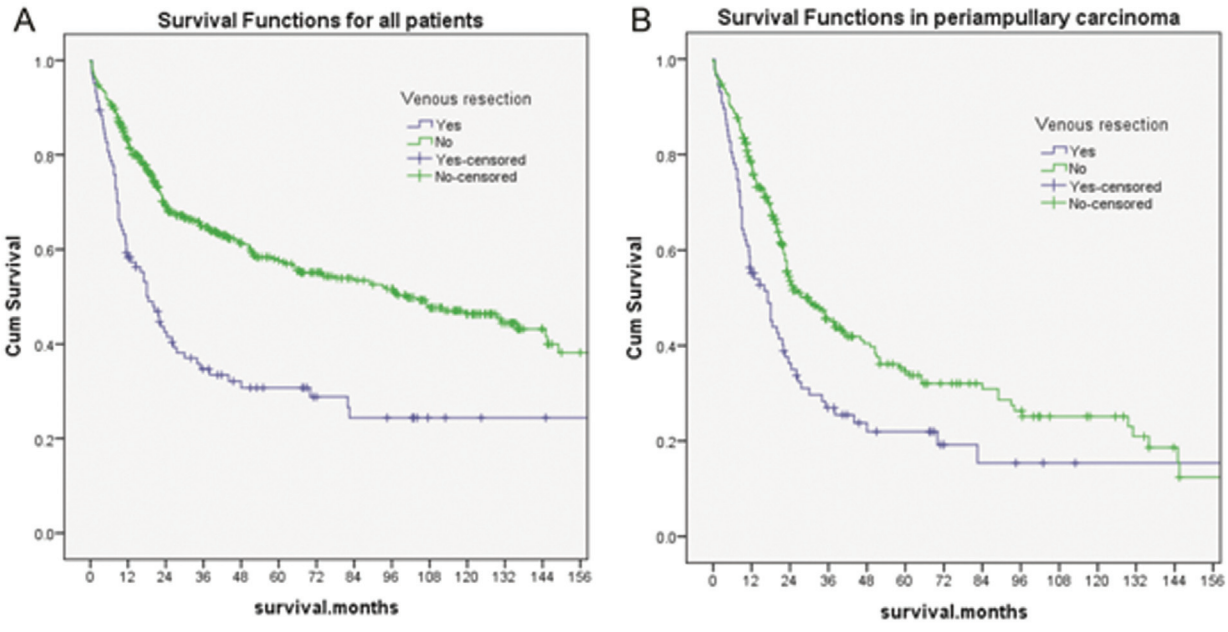
The 1-year, 3-year, 5-year, and 7-year overall total survival rates for all 601 patients were 78.6, 56.6, 52.9, and 48.4%, respectively. The 1-year, 3-year, 5-year, and 7-year total survival rates for all 104 patients with VR were 58.6, 35.3, 31.3, and 24.8%, respectively, and the 90-day perioperative mortality was eight (7.7%) patients. The 1-year, 3-year, 5-year, and 7-year survival rates for all patients without VR (497 patients) were 82.9, 65.1, 57.8, and 53.6%, respectively ($P<0.01$) (Fig. 1a).

Table 3 Postoperative data and complications

Variables	VR positive (*n*=104) [*n* (%)]	VR negative (*n*=497) [*n* (%)]	*P* value
Hospital stay [mean±SD (range)] (days)	12±13 (4–98)	11±11 (4–148)	0.28
ICU stay [mean±SD (range)] (days)	4±11 (0–59)	2±8 (0–144)	0.04
Clavien grades of complication			0.55
0	22 (21.2)	184 (37)	
I	9 (8.7)	47 (9.4)	
II	27 (26)	121 (24.3)	
IIIa	24 (23.1)	83 (16.7)	
IIIb	3 (2.9)	11 (2.2)	
IVa	2 (1.9)	9 (1.8)	
IVb	9 (8.7)	20 (4)	
V	8 (7.7)	22 (4.4)	
Rehospitalization in the first 3 months	34 (32.7)	103 (20.7)	**0.01**
Recurrence	48/78 (55.2)	92/268 (34.3)	**0.01**

VR, venous resection. Bold values are statistically significant.

Figure 1



Kaplan–Meier curve for survival. (a) Survival in all patients in our study with venous and standard resection; (b) survival in patients with periampullary adenocarcinoma with venous and standard resection

The 90-day perioperative mortality for 87 patients who underwent VR in PAAC was five (5.7%) patients. The 1-year, 3-year, 5-year, and 7-year survival rates (including the perioperative mortality) were 55.1, 27, 21.9, and 15.4%, respectively. However, in patients with PAAC without VR (268 patients), the 90-day perioperative mortality was 12 (4.5%) patients and the survival rates were 78.5, 45.9, 34.9, and 31.2%, respectively ($P<0.01$) (Fig. 1b).

In the univariate analysis, VR was a risk factor for survival ($P<0.01$), but in multivariate analysis, it was not an independent predictor of poor survival in patients with PAAC. Other independent risk factors for survival in patient with PAAC identified by multivariate analysis are listed (Table 4).

Discussion

Complete resection is the only chance for cure in patients with pancreatic cancer. Limited oncological alternatives have driven surgeons across the world to extend the operative procedures to remove PAAC with PV resection, arterial resection, other multivisceral resections, or even the resection of liver metastases in selected patients [7,12,13].

Table 4 Cox regression multivariate analysis of factors affecting long-term survival in patients with periampullary adenocarcinoma

Variables	*P*	Hazard ratio (95% confidence interval)
ECOG status	**0.001**	0.323 (0.169–0.616)
Venous resection	0.308	0.850 (0.622–1.161)
Perioperative blood transfusion	**0.001**	0.678 (0.552–0.834)
Pathological type of PAAC		
Pancreatic	0.323	0.895 (0.718–1.115)
Bile duct	0.547	1.081 (0.838–1.394)
Ampullary	0.083	1.251 (0.971–1.612)
Tumor grade		
Well differentiated	0.288	1.313 (0.794–2.171)
Moderately differentiated	0.534	0.867 (0.554–1.358)
Poorly differentiated	0.165	0.727 (0.463–1.140)
Positive margin	**0.001**	0.567 (0.400–0.804)
Positive LNs	**0.001**	0.559 (0.407–0.769)
Lymph node ratio		
0	0.855	0.063 (0–4.968)
>0 to 0.2	0.836	0.044 (0–3.468)
>0.2 to 0.4	0.830	0.038 (0–3.041)
>0.4	0.824	0.034 (0–2.715)
Lymph vessel invasion	**0.016**	0.834 (0.720–0.967)
Recurrence	**0.001**	0.407 (0.302–0.549)

ECOG, Eastern Cooperative Oncology Group; LN, lymph node; PAAC, periampullary adenocarcinoma. Bold values are statistically significant.

The morbidity, mortality, and long-term survival rates reported by many centers after VR are similar to those related to the standard surgical technique [5,14]. In our experience, major postoperative complications and mortality rates were significantly higher in the group of VR than the other group with standard surgical resection. This finding is similar to meta-analyses of a Nationwide Inpatient Sample database that included 10 206 patients who underwent pancreatectomy with VR. The study identified an increase in intraoperative and postoperative morbidity, but without an increase in mortality [15]. Ouaissi *et al.* [16] and Muller *et al.* [17] indicated that the procedure is safe, but not associated with favorable long-term survival.

In contrast to previous studies, a meta-analysis by Yu *et al.* [18] evaluating 22 retrospective studies including 2890 patients confirmed that there was no difference in perioperative morbidity and mortality rates between the two groups of patients, and these results compare favorably with that of other surgical series from high-volume single-center reviews and consensus statements published by experts around the world [5,7,14,19,20].

Beltrame *et al.* [4] reported that these differences between centers could be explained by the rate of obtaining an R0 resection [21]. In their series, the R0 resection rate was 86% in pancreatic cancer, with a median survival of 17 months versus 10 months for R1 patients. In our experience, the R0 resections rate was 75.9% in VR with PAAC, with a median survival of 28.7 versus 14.3 months for R1 and R2 patients.

In one of the previous studies [4], surgical complications occurred in 21 (33%) patients, with seven patients with pancreatic fistula, and two patients experienced PVT 11 and 13 months after the operation. The mortality rate in the group without VR was 3 versus 4% in the VR group. Overall survival was 42% at 1 year, 10% at 2 years, and 2% at 3, 4, and 5 years. In patients without evidence of vascular invasion, the overall survival was 69% at 1 year, 31% at 2 years, and 6% at 3 and 5 years versus 30% at 1 year and 0% at 2 years in patients with confirmed vascular infiltration. This survival rate is lower than that in the present series.

In another study Kulemann *et al.* [2], the overall 3-year and 5-year survival rate was 26 and 16%, respectively. In their univariate survival analysis, nodal disease, resection margin, intraoperative blood transfusions, tumor grading, and the extent of resection influenced survival. Survival after PD with PV

resection was not significantly inferior to that after standard resection.

In a previous study Al-Haddad *et al.* [22] from our institution in 2007 looking at 22 patients undergoing VR for pancreatic tumors, the 1-year and 3-year survival rates in patients with VR were 41.9 and 20% versus 1-year, 3-year, and 5-year survival rates of 64.7, 33.5, and 25% in the group that underwent pancreatic resection without VR, respectively. There was a slight survival benefit in patients who did not require VR, although this did not reach statistical significance (P=0.18).The present study has a larger number of patients and longer periods of follow-up, with nearly the same results, but with statistically a significant difference in survival (P<0.01).

In this series, six patients underwent venous reconstruction by bovine pericardium as a graft patch with good postoperative outcome and only one patient had postoperative PVT. Also, synthetic grafts such as poly tetra fluoro ethylene can be used for venous reconstruction [23,24].

Kendrick and Sclabas [25] reported that major VR with PD can be safely performed laparoscopically in selected patients. Venous reconstruction was performed in 11 patients and included primary suture venorrhaphy in four patients, patch venorrhaphy in four patients, tangential stapling in two patients, and interposition grafting using the left renal vein in one patient.

In terms of histopathological confirmation of vascular infiltration, Beltrame *et al.* [4] reported vascular invasion in 69% of cases; 86% had a negative margin (R0) and 14% had microscopic neoplastic residue (R1). The median survival was 9.5 versus 16.5 months in patients with and without histopathological reports of vascular invasion, respectively (P=0.02). The depth of tumor invasion has been shown to be a negative prognostic factor of survival. In other series, the pathology confirmed vascular invasion in 64 and 61% of cases [22,26]. Further studies are needed to evaluate the depth of vein involvement and its significance to resection.

Beltrame *et al.* [4] reported that there was a trend of better survival in the last period, as also found in our study, even though the rate of recurrence after resection was not significantly modified. This was explained by the introduction of more effective chemotherapeutic regimens (FOLFIRINOX) [27] for the treatment of relapsing tumors. There were limited data in this study on neoadjuvant and adjuvant chemoradiation therapy, and further studies are needed to examine whether multimodal treatment with a new chemotherapeutic regimen and radiotherapy [27,28] may improve the outcome after surgery in locally advanced pancreatic cancer.

Although PD or TP combined with VR and reconstruction presented a higher incidence of postoperative complications compared with standard resection, this approach can be performed safely with acceptable perioperative morbidity and mortality rates to achieve a complete removal of the tumor. The oncologic benefits of VR are still controversial, but long-term survival rates following VR for patients with PAAC are acceptable and VR can assist to accomplish a margin negative resection. A careful multispecialty evaluation and selection of patients with locally advanced tumors is recommended, and these patients should be considered for VR when feasible and when treatment can be performed at a high-volume center with experienced surgeons.

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Conflicts of interest
There are no conflicts of interest.

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Comparative study between the complications of laparoscopic sleeve gastrectomy and laparoscopic mini-gastric bypass

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Background
Obesity is considered a preventable worldwide epidemic. It can cause high rates of morbidity and mortality. Laparoscopic sleeve gastrectomy (LSG) and laparoscopic mini-gastric bypass (LMGB) are both safe and effective procedures for the surgical management of morbid obesity. Bleeding and leakage are the most fearful life-threatening complications.
Patient and methods
This prospective study comprised 150 morbidly obese patients. The study was conducted between July 2015 and March 2016, after which there was a follow-up for 12 months among all the patients. The patients were divided equally into two groups: group A comprised LSG patients, whereas group B comprised LMGB patients.
Results
Among the Group A patients, four (5.3%) exhibited complications: hemorrhage (1.3%), gastric leakage (1.3%), and gall-bladder stones (2.6%). In group B, five (6.6%) patients had complications: biliary reflux (1.3%), deep venous thrombosis (1.3%), and gall-bladder stones (3.9%). No mortality occurred in the study.
Conclusion
Both LSG and LMGB are safe and effective procedures. The study found no statistically significant difference between either procedure, in the incidence of complications.

Keywords:
bariatric surgery, leakage, mini-gastric bypass, morbid obesity, sleeve gastrectomy

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Introduction

Obesity is a leading, although preventable, cause of death worldwide, with increasing rates of occurrence in both adults and children. It is one of the most serious public health problems of the 21st century [1]. In 1997, the WHO formally recognized obesity as a global epidemic [2]. In 2013, the American Medical Association classified obesity as a disease [3]. The most important health consequences of obesity include type II diabetes mellitus, osteoarthritis, obstructive sleep apnea, social stigmatization, cancer, cardiovascular disease, nonalcoholic fatty liver disease, and metabolic syndrome [4]. Bariatric surgery is a demonstrably effective and safe technique for the treatment of morbid obesity and obesity-associated comorbidities [5]. Laparoscopic sleeve gastrectomy (LSG), a restrictive form of bariatric surgery, is one of the most popular and effective bariatric operations worldwide [6]. Its complications include hemorrhage, staple-line leak, stricture, obstruction, nutritional deficiencies, gastroesophageal reflux disease (GERD), cholelithiasis, deep venous thrombosis (DVT), and failure of weight loss [7]. Laparoscopic mini-gastric bypass (LMGB) is a mixed restrictive and malabsorptive bariatric surgery. Complications are similar to those of LSG, in addition to anastomosis leakage, marginal ulcers, and chronic alkaline reflux [8]. The aim of the this study is to compare the complications among the LSG group with those among the LMGB group.

Patients and methods

This prospective comparative study was carried out at the Kasr Alainy and Beni Suef University hospitals between July 2015 and March 2016 and ethically approved. The follow-up procedures, among all the patients for 12 months thereafter, ended by March 2017. The cohort included 150 patients, who were divided into two equal groups. Group A included 75 patients who had undergone LSG, and group B included 75 patients who had undergone LMGB. Both groups had the same inclusion criteria: patients with BMI exceeding 40 kg/m^2 or BMI exceeding 35 kg/m^2, with associated comorbidities, such as hypertension, diabetes mellitus,

hyperlipidemia, arthritis, and cardiac disease. Heavy sweet-eaters were included in group B only. The exclusion criteria for both the groups were patients with previous bariatric surgery and previous upper-gastrointestinal surgery – open or laparoscopic. Other criteria included patients with a history of these conditions: laparoscopic cholecystectomy, hiatus hernias, heavy sweet-eating in group A only, drug or alcohol abuse, and psychiatric disorders. Only the patients whose ages were between 18 and 60 years were included in the study. All the patients' medical histories were recorded. Thorough physical examinations were conducted on all of them, to detect any associated comorbidities. The preoperative evaluation of all the patients included the routine laboratory investigations, as well as thyroid profiles. Abdominal ultrasound was done to assess the presence of gall-bladder stones. Chest radiography and pulmonary-function tests were used to detect chest comorbidities. ECG and echocardiography were performed on all the patients. Patients were informed about the possible complications, after which they signed an informed consent.

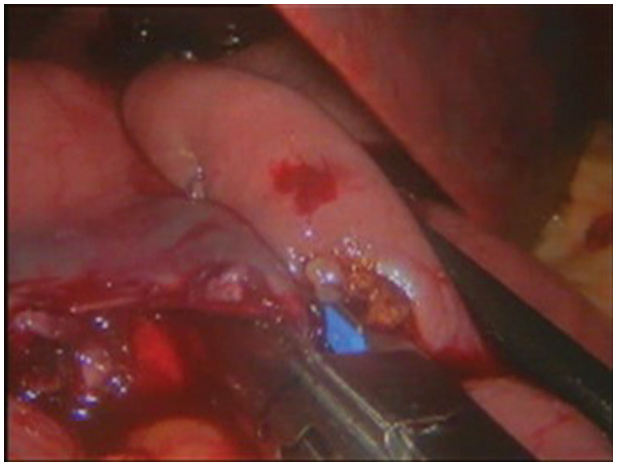
Operative steps of laparoscopic sleeve gastrectomy

The patients were placed in a supine position, with their arms and lower limbs spread apart. They were made to wear above-knee elastic stockings. A dose of 20 mg low-molecular-weight heparin (clexane) was administered subcutaneously as a prophylactic measure against DVT. Gastric decompression was achieved by the insertion of a nasogastric tube. Pneumoperitoneum was achieved using a closed technique that involved placing a Veress needle in the left-subcostal area of the abdomen. In total, five ports were applied as follows: one 10 mm port just below the xiphoid process, for liver retraction; one 10 mm port placed 15–20 cm below the xiphoid process, for a 30° scope; two 12 mm working ports placed in the left and the right mid-clavicular line, in line with the camera port; and one 5 mm port at the left anterior axillary line, a few centimeters below the left costal margin, for assistance. Mobilization of the greater curvature of the stomach was possible, using sealing devices, such as LigaSure (Valleylab a division of Tyco Healthcare Group LP Boulder, Colorado 80301-3299 USA) vessel sealing, 5 mm blunt tip (Covidien; Valleylab a division of Tyco Healthcare Group LP Boulder, Colorado 80301-3299 USA), proximally to the gastroesophageal junction, and, distally, 3 cm proximal to the pylorus. The anesthetist removed the nasogastric tube and inserted an orogastric 40 Fr bougie, extending it till the first part of the duodenum. To divide the stomach, a 60 mm endoscopic gastrointestinal stapler – Endo GIA Universal 12 mm Stapler, Covidien Auto Suture (Covidien) was used. This helped create a gastric tube, extending along the line with the bougie. The staple line was not oversewn. Endoclips were used to control the bleeding points along the staple line. The bougie was drawn proximally up to the gastroesophageal junction, and the pylorus was closed with a grasper. Methylene blue was injected through the bougie, to detect intraoperative leakage. Nelaton drain was applied close to the staple line. The excised part of the stomach was removed through the 12 mm port.

Operative steps of laparoscopic mini-gastric bypass

The position of the patient, prophylaxis against DVT, pneumoperitoneum, and the port sites are similar in both LMGB and LSG. The lesser omentum at incisura is divided at its attachment with the stomach. The stomach is divided transversely, using the Endo GIA 45 mm stapler that has the blue cartilage. The anesthetist passes down the 40 Fr bougie. The Endo GIA 60 mm stapler is used to create, proximally, an upward division of the stomach alongside the bougie. This division of the stomach extends till the gastroesophageal junction, creating a long, narrow, longitudinal gastric pouch. Endoclips are used to control the bleeding points along the staple line. The greater omentum is retracted from left to right, to enable the exact identification of the duodenojejunal junction. The small bowel is run to 200 cm distal to the duodenojejunal junction. The small bowel is then sutured, with the gastric pouch side to side, by vicryl 3/0 sutures, as a prophylactic step to prevent biliary reflux. The bougie is then removed. In the small bowel and in the distal part of the gastric pouch, two adjacent stomas are created. The pouch and the small bowel are anastomosed, using the 45 mm endogastrointestinal stapler (Fig. 1). The bougie is further pushed

Figure 1



The gastrojejunal anastomosis done using end GIA 45 mm stapler

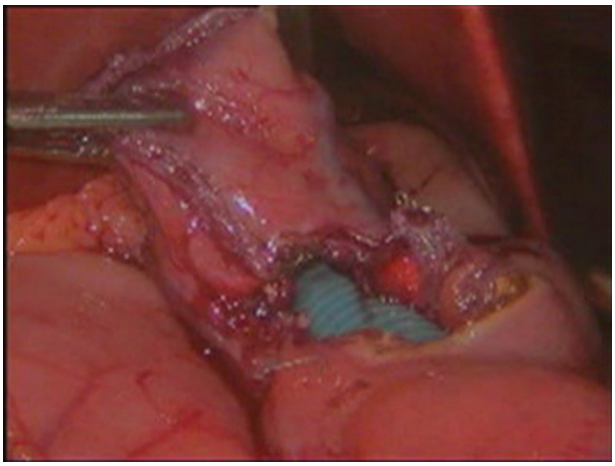
through the gastric pouch to the efferent jejunal limb (Fig. 2). The closure of the anastomotic opening is performed, using vicryl absorbable suture 3/0 in two layers. The bougie is drawn proximally up to the gastroesophageal junction. The afferent and efferent bowel loops are closed with atraumatic graspers. Methylene blue is injected through the bougie to detect intraoperative leakage. Nelaton drain is applied below the anastomosis, near the staple line.

Postoperative care in both groups

Postoperative care included the close monitoring of the vital signs, the urine output, and drains. Intravenous antibiotics, analgesics, proton-pump inhibitors (PPI), and intravenous fluid were administered. Subcutaneous low-molecular-weight heparin was continued. The patient was encouraged to be ambulant a few hours after surgery. Gastrografin meal was done on the next postoperative day, to detect leakage. If the test was negative, the patient was allowed to start oral sugar-free fluids. Uncomplicated cases were discharged after 48 h. Oral PPIs, as well as vitamin supplementations, were prescribed. The patients were instructed to receive the appropriate diet. Physical exercises were started in the second postoperative week. Patients were advised to participate in three sessions of exercise a week, the duration of each session being about 45–60 min.

Follow-up procedures were carried out every 2 weeks in the outpatient clinic, to monitor the weight loss and to highlight complications. All the patients were tested for complete blood count, serum iron, vitamin B_{12}, and serum calcium. They also underwent an abdominal ultrasound, at 6 and 12 months after surgery, to detect gall-bladder stones.

Figure 2



The bougie passing through the anastomosis

Results

This prospective comparative study included 150 morbidly obese patients, divided equally into two groups: group A, being LSG patients, and group B, being LMGB patients. Tables 1 and 2 summarize the demographic and clinical data of the patients in group A and group B, respectively.

Group A: laparoscopic sleeve gastrectomy group

The complications encountered in four patients who underwent LSG, numbered four (5.3%). Of these, two occurred early: one (1.3%) patient developed intraoperative hemorrhage on the first postoperative day, and one (1.3%) patient developed gastric leakage. A year after surgery, two (2.6%) patients developed gall-bladder stones. Table 3 summarizes the different types of complications that occurred in the LSG group.

Hemorrhage occurred in a 28-year-old woman, who had a BMI of 45 kg/m^2, with no associated comorbidity. Bleeding occurred intraoperatively, during the division of the short gastric vessels using a harmonic scalpel. Intraoperative control was difficult, and the patient began to develop tachycardia and

Table 1 Demographic and clinical data of the patients in group A

Number of LSG cases	Women	Men	Age range (years)	Age (mean)	BMI range (kg/m^2)	Comorbidities
75	57	18	18–55	38	35–55	10 (5 with diabetes, 3 with hypertension, and 2 with hyperlipidemia)

LSG, laparoscopic sleeve gastrectomy.

Table 2 Demographic and clinical data of the patients in group B

Number of LGMB patients	Women	Men	Age range (years)	Age (mean/ year)	BMI range (kg/m^2)	Comorbidities
75	39	36	18–53	34.7	35–57	14 (5 with diabetes, 4 with hypertension, 3 with osteoarthritis, and 2 with hyperlipidemia)

LMGB, laparoscopic mini-gastric bypass.

hypotension. Immediate midline laparotomy was done. Splenectomy, together with the under-running of the short gastric vessels, was done. Sleeve gastrectomy was completed, using linear staplers. The patient had a smooth postoperative course, and was discharged 4 days after surgery.

Gastric leakage occurred in a 32-year-old man with a BMI of 48 kg/m^2, with no associated comorbidities. The leakage was discovered on the first postoperative day by routine gastrografin meal, although the intraoperative methylene-blue test had been negative. Exploration was done through a left-subcostal incision, revealing a minor leak at the gastric fundus close to the gastroesophageal junction. Repair and drainage were done. The patient had a smooth postoperative course; the follow-up gastrografin meal revealed no leakage; and the patient was discharged 7 days after surgery.

Gall-bladder stones developed in two (2.6%) patients, 12 months after surgery. Both were women, with BMIs of 45 and 50 kg/m^2, respectively. The diagnosis was made by abdominal ultrasound, during the follow-up period. Both patients had abdominal pain. Laparoscopic cholecystectomy was done.

The laboratory results done during the follow-up period, to detect the nutritional deficiencies, did not reveal any abnormality. No complications, regarding GERD or gastric obstruction, occurred. All the patients achieved their expected weight loss at the expected times, with no incidence of weight-loss failure. No mortality occurred in this group.

Group B: laparoscopic gastric mini-bypass group

Complications were encountered in five (6.6%) patients. Biliary reflux presented in one (1.3%) patient postoperatively, after 1 month. Another patient (1.3%) developed DVT 6 months postoperatively. Of the patients, three (3.9%) developed gall-bladder stones, two of them, 6 months postoperatively, and the third patient, a year after the surgery.

The patient who developed biliary reflux was a woman with BMI 51 kg/m^2. The patient had epigastric pain, nausea, and bilious vomiting. Upper-gastrointestinal endoscopy was diagnostic. Resolution of the condition occurred, with conservative management (bile salt binders and PPI), over 3 months.

Only one (1.3%) patient developed DVT. Her BMI was 50 kg/m^2. The patient complained of pain and swelling in the calf muscles, and the examination revealed tender, swollen calf muscles. The diagnosis was confirmed by venous duplex. The patient started a therapeutic dose of anticoagulant.

Gall-bladder stones occurred in three (3.9%) women, with BMIs of 44, 49, and 51 kg/m^2, respectively. Whereas two of them were asymptomatic, the third presented with right hypochondrial pain. The diagnosis was made by abdominal ultrasound during the follow-up period. Laparoscopic cholecystectomy was done. Table 4 summarizes the different types of complications that occurred in the LMGB group.

The laboratory results, for the tests done during the follow-up period to detect the nutritional deficiencies, did not reveal any abnormality. No complications regarding leakage, bleeding, marginal ulcer, stenosis, or obstruction occurred at the gastrojejunal anastomosis. No weight-loss failure and no mortality occurred in this group. Table 5 and Chart 1 summarize the incidence of complications in both groups.

Table 3 Complications in the laparoscopic sleeve gastrectomy group (*n*=75)

Complications	*N* (%)
Total	4 (5.3)
Hemorrhage	1 (1.3)
Staple-line leakage	1 (1.3)
Gall-bladder stones	2 (2.6)

LSG, laparoscopic sleeve gastrectomy.

Table 4 Complications in the laparoscopic mini-gastric bypass group (*n*=75)

Complications	*N* (%)
Complications	
Total	5 (6.6)
DVT	1 (1.3)
Gall-bladder stones	3 (3.9)
Biliary reflux	1 (1.3)

DVT, deep venous thrombosis; LMGB, laparoscopic mini-gastric bypass.

Table 5 The incidence of complications in both the groups

Complications	LSG Group [*N* (%)]	LGMB Group [*N* (%)]	*P* value*
Total	4 (5.3)	5 (6.6)	1
Hemorrhage	1 (1.3)	0	1
Leakage	1 (1.3)	0	1
Gall-bladder stones	2 (2.6)	3 (3.9)	1
DVT	0	1 (1.3)	1
Biliary reflux	0	1 (1.3)	1

DVT, deep venous thrombosis; LSG, laparoscopic sleeve gastrectomy. *Statistically significant if $P<0.05$.

Discussion

The pandemic of our generation is, undoubtedly, the rise and prevalence of obesity. It is defined as a BMI greater than 30 kg/m^2 [9]. From a global perspective, an estimated 1.48 billion adults are thought to be overweight, of whom 502 million individuals are classified as obese [10]. The LSG was adopted as a primary procedure. Over time, it has become the most popular bariatric operation worldwide. It is effective for weight loss, and results in the improvement, even the resolution, of comorbidities like type-2 diabetes, and has low morbidity and mortality [7]. LMGB surgery is another safe and simple surgical intervention for treating morbid obesity and diabetes mellitus, and is now being performed more frequently [11].

Complications in both procedures include hemorrhage, staple-line leak, stricture, obstruction, nutritional deficiencies, GERD, cholelithiasis, and weight-loss failure. LMGB has additional complications, in the form of marginal ulcer, anastomotic leakage, and chronic alkaline reflux [8]. Compared with LMGB, LSG seems to have a smaller risk of complications, but the potential complications can be as severe as those associated with other techniques. The most feared complications after LSG and LMGB are leakage and hemorrhage [12].

The American Society for Metabolic and Bariatric Surgery Clinical Issues Committee statement quotes an overall complication rate for LSG of 0–24% and a mortality rate of 0.39% [13], whereas the highest overall complication rate in LMGB was 9% [14]. Tables 6 and 7 summarize the incidence of complications after LSG and LMGB, respectively, among different studies as well as this one.

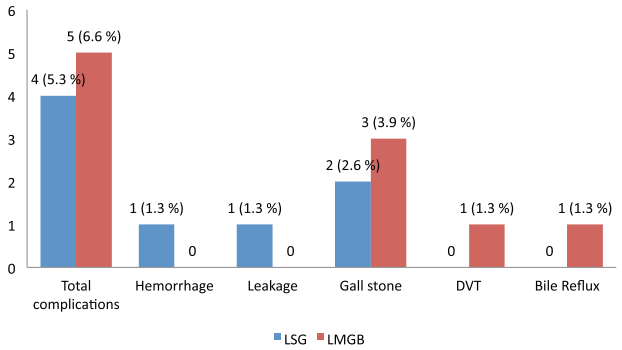
Leakage

Staple-line and anastomotic leakage continues to be the most serious, life-threatening complication, and the most frequent cause of death after bariatric surgery. It ranges from 1 to 3% [25].

Leaks after LSG commonly occur at the gastroesophageal junction [26]. The patho-physiology of staple-line leaks after LSG is unclear. Compromise of blood supply, especially at the angle of His near the crura, stapler-device failure, poor technique, and postoperative gastroparesis – with an intact pylorus causing increasing intragastric pressure – have all been implicated [27]. Patients may present with abdominal pain, tachycardia, nausea and vomiting, abdominal distention, and fever [28]. Reinforcement of the staple line does not reduce the incidence of leakage [26]. The treatment of leakage is challenging: early leaks are usually managed by surgical repair, and delayed leaks, conservatively, by intravenous antibiotics, drainage, and stenting [29].

In this study, one (1.3%) patient suffered from an early gastric leak (first postoperative day) at the gastroesophageal junction, confirmed by the routine gastrografin meal, and it was successfully managed by surgical repair and drainage. Oversewing the staple line is not followed routinely in this practice. Table 8 summarizes the percentage of leakages among the LSG group, in different studies compared with the current one.

Chart 1



The incidence of complications in the laparoscopic sleeve gastrectomy and laparoscopic mini-gastric bypass groups

Table 6 The incidence of complications among laparoscopic sleeve gastrectomy patients in different studies, including the current one

References	Number of patients (complication rate) [*N* (%)]
Cottam *et al.* [15]	126 (14)
Hamoui *et al.* [16]	118 (15)
Frezza [17]	53 (9.4)
Triantafyllidis *et al.* [18]	85 (12.9)
Mittermair *et al.* [19]	153 (8)
Kular *et al.* [20]	118 (46)
Lee *et al.* [21]	519 (1.6)
This study	75 (5.3)

Table 7 The incidence of complications among the laparoscopic mini-gastric bypass group in different studies, including the current one

References	Number of patients (complication rate) [*N* (%)]
Chevallier *et al.* [22]	451 (11)
Noun *et al.* [23]	923 (6.8)
Musella *et al.* [24]	974 (15.5)
Kular *et al.* [20]	1054 (5.9)
Lee *et al.* [21]	519 (9.5)
This study	75 (6.6)

Table 8 Leakage among the laparoscopic sleeve gastrectomy group in different studies, including the current one

References	Number of patients	Leakage [*N* (%)]
Frezza [17]	53	2 (3.7)
Lalor *et al.* [30]	148	1 (0.7)
Mittermair *et al.* [19]	153	3 (1.9)
Kular *et al.* [20]	284	0 (0)
Lee *et al.* [21]	519	6 (1.2)
This study	75	1(1.3)

Leak after LMGB may occur at the excluded stomach, gastric tube, or the gastrojejunal anastomosis, with an incidence of around 1% [24]. No leakage developed among the LMGB patients in this study. Table 9 summarizes the percentage of leakage among the LMGB group in different studies, including the current one.

Hemorrhage

Hemorrhage is one of the most serious and life-threatening complications. The risk of postoperative bleeding has been reported to be between 1 and 6% after LSG. The source of bleeding can be either intraluminal or extraluminal [17].

Bleeding can result from staple-line injuries, trocar-site injuries, splenic injuries, or liver lacerations caused by retractor injuries [16]. Patients present with tachycardia, hypotension, and a drop in serum hemoglobin. Intraluminal bleeding from the staple line usually presents with upper-gastrointestinal bleeding (hematemesis and melena). Intraluminal bleeding is managed by following resuscitative measures, and upper-gastrointestinal endoscopy may be required. Extraluminal bleeding may be managed conservatively; however, surgical re-exploration may be mandated [31].

In the LSG group in this study, one (1.3%) patient developed intraoperative bleeding during the division of the short gastric vessels. The bleeding was managed as described above. In the LMGB group, however, bleeding did not occur. Table 10 demonstrates the incidence of bleeding in LSG in different studies, including the current one.

Cholelithiasis

Rapid weight loss is associated with the formation of cholesterol gallstones, within 6–12 months of the operation [32]. The incidence was around 8.42% in the LSG group, and 12.7% in the LMGB group. The diagnosis is usually made by abdominal ultrasound during the follow-up period [33]. In this study, two patients developed gall-bladder stones after LSG, and three patients after LMGB. Diagnosis was achieved by abdominal ultrasound during the follow-up period. Laparoscopic cholecystectomy was done for all the patients, even the asymptomatic ones in the LMGB group, to prevent any occurrence of calcular obstructive jaundice in the absence of endoscopic access. Table 11 demonstrates cholilithiasis after LSG, compared with LMGB, in different studies, including the current one.

Table 9 Leakage among the laparoscopic mini-gastric bypass group in different studies, including the current one

References	Number of patients	Leakage [*N* (%)]
Noun *et al.* [23]	1000	5 (0.5)
Kular *et al.* [20]	1054	2 (0.2)
Musella *et al.* [24]	974	7 (0.7)
This study	75	0 (0)

Table 10 The incidence of bleeding in laparoscopic sleeve gastrectomy in different studies, including the current one

References	Number of patients	Bleeding [*N* (%)]
Frezza [17]	53	1 (1.8)
Lalor *et al.* [30]	148	1 (0.7)
Mittermair *et al.* [19]	153	5 (3.3)
Kular *et al.* [20]	118	4 (3.3)
Lee *et al.* [21]	519	1 (0.2)
This study	75	1 (1.3)

Table 11 Cholelithiasis after laparoscopic sleeve gastrectomy compared with laparoscopic mini-gastric bypass

	Percentage of gall-stone formation after LSG	Percentage of gall-stone formation after LMGB
Kular *et al.* [20]	10.5	8.3
Mishra *et al.* [33]	8.42	12.7
This study	2.6	3.9

LMGB, laparoscopic mini-gastric bypass; LSG, laparoscopic sleeve gastrectomy.

Biliary reflux

Bile reflux was defined as bilious vomiting and/or documented bile in the esophagus on upper-gastrointestinal endoscopy with the presence of GERD-like symptoms. The incidence of bile reflux has been 1.8% [34]. Kular *et al.* [20] reported 18 (2.0%) cases of bile reflux after LMGB. Conversely, according to authors performing LMGB, biliary reflux has rarely been found, and, if present, it has been symptomatic only in a small number of patients [24]. Patients with mild symptoms are successfully managed conservatively; however, those with severe symptoms are cured by stapling the afferent loop and by a laterolateral jejunojejunostomy [23].

In this study, one (1.3%) patient presented with mild symptoms that were successfully managed, using conservative methods.

Table 12 Deep venous thrombosis in different studies, including the current one

References	Number of patients	Complication rate [*N* (%)]
Kular *et al.* [20]	1054	0 (0)
Musella *et al.* [24]	974	0 (0)
Noun *et al.* [23]	923	1 (0.1)
This study	75	1(1.3)

Deep venous thrombosis

DVT and pulmonary embolism are frightening complications after any major surgery. After bariatric surgery, which is one of the operations for patients with high-risk factors, the risks of these two complications exist. Prophylaxis against DVT is recommended for every patient [35].

In the current study, one (1.3%) patient developed DVT, 6 months after surgery. Her BMI was 44 kg/m^2. The patient complained of pain and swelling in the calf-muscle area, and the examination revealed tender and swollen calf muscles. The diagnosis was confirmed by venous duplex. The patient started a therapeutic dose of anticoagulant. Table 12 summarizes the percentage of DVT among LMGB group in different studies as well as this one.

Nutritional deficiency, weight-loss failure, obstruction, marginal ulcer, GERD, and dumping syndrome were not encountered in the patients in this study.

Mortality

The incidence of mortality after LMGB ranged from 0 to 0.18%; however, it was reported to be about 1.5% after LSG [26,36]. No mortality occurred in this cohort.

Conclusion

LSG and LMGB are both safe and effective procedures for the surgical management of morbid obesity. Bleeding and leakage are the most common and most serious complications in both procedures. The incidence of complications between both procedures is not significantly different.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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Value of pharmacologic thromboprophylaxis for prevention of thromboembolic complications in bariatric surgery

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Objective
The objective of this study was to assess safety and efficacy of pharmacologic thromboprophylaxis in morbidly obese patients undergoing bariatric surgery for prevention of silent deep vein thrombosis (DVT).
Patients and methods
This prospective study included 50 morbidly obese patients scheduled for primary one-stage laparoscopic bariatric surgery randomly allocated into one of two treatment groups according to the method of thromboprophylaxis. Group M (n=25) was subjected to mechanical prophylaxis with bilateral graduated compression stockings. Group MC (n=25) was subjected to mechanical plus pharmacologic prophylaxis using 40 mg of the low-molecular-weight heparin enoxaparin subcutaneously, 12 h before surgery, and postoperatively daily for 2 weeks. Bilateral lower limb venous duplex was done to detect silent DVT (the primary outcome measure), before discharge and after 2 weeks.
Results
Three patients developed silent DVT (6%); all of them were among group M (P=0.235, relative risk: 0.47, 95% confidence interval: 0.35–0.64). There was no significant difference between patients with DVT and those without DVT regarding age, BMI, operative time, comorbidities, or type of surgery. No bleeding complications were recorded in the two studied groups.
Conclusion
Perioperative low-molecular-weight heparin extending for 2 weeks postoperatively combined with graduated compression stockings is safe and effective for the prevention of silent DVT following laparoscopic bariatric surgery.

Keywords:
bariatric surgery, deep vein thrombosis, pulmonary embolism thromboembolic, thromboprophylaxis

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Introduction

The prevalence of obesity has been markedly accelerated during the past three decades, with marked geographical disparities. Egypt was classified among countries with high prevalence of obesity, especially in women, despite being one of the developing countries. It has been estimated that the prevalence of obesity is 26.4% in men and 48.4% in women [1].

Currently, bariatric surgery is widely adopted as the most effective therapeutic option for morbid obesity. It was estimated that 5875 procedures were performed in Egypt in 2014 including 4570 laparoscopic procedures [2]. However, it is a major surgical procedure with a risk of significant early and late morbidity and of perioperative mortality [3].

Patients undergoing bariatric surgery are at an increased risk for venous thromboembolism (VTE) [4,5]. Obesity *per se* is a moderate risk factor for VTE [6], but it interacts with other risk factors increasing the risk of VTE development and recurrence [7]. Moreover, venous hemodynamics are affected by obesity; dilatation and reduced venous flow were reported in lower limbs using color-coded duplex ultrasound [8]. Surgery adds more risk of VTE, which is higher with open procedures compared with laparoscopic procedures [9].

The optimal prophylactic method for VTE following bariatric surgery has yet to be elucidated. The main recognized options include mechanical compression devices, chemoprophylaxis, and use of inferior vena cava filters. Many studies investigated the safety and efficacy of pharmacologic prophylaxis of VTE in bariatric surgery, but no consensus on a recommendation of the ideal drug, regimen, dosing, or duration of use has been reached [10].

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This study was conducted to examine the safety and efficacy of pharmacologic thromboprophylaxis in morbidly obese patients undergoing bariatric surgery for the prevention of silent deep vein thrombosis (DVT).

Patients and methods

This prospective study included 50 morbidly obese patients scheduled for primary one-stage laparoscopic bariatric surgery in the Department of Surgery, Kasr El-Aini Hospital, Cairo University, between March 2015 and September 2015. Patients were enrolled in the study if their age was 18 years or more with a preoperative BMI greater than or equal to 40 kg/m^2 or BMI greater than or equal to 35 kg/m^2 with associated comorbidities (hypertension, dyslipidemia, type 2 diabetes mellitus, sleep apnea, and so on). All patients have a history of failure of conservative treatment of weight loss. The study was approved by the Institutional Review Board of the Faculty of Medicine, Cairo University. All of the participants provided an informed consent to participate in the study.

Exclusion criteria included documented congenital or acquired coagulation disorders, concomitant anti-coagulant or antiplatelet aggregation therapy for other risk factors, hypersensitivity to heparins, previous heparin-induced thrombocytopenia, history of recent or old thromboembolism, postoperative complications, and symptomatic postoperative thromboembolism.

Routine preoperative laboratory investigations were performed for all patients in addition to abdominal and pelvic ultrasound scan and pulmonary function test. Mini-gastric bypass or laparoscopic sleeve gastrectomy was performed according to the patient's selection after consultation with the staff of the bariatric surgery team. Participants were randomly allocated into one of two treatment groups according to the method of thromboprophylaxis. Group M included 25 patients who were subjected to mechanical prophylaxis only in the form of below-knee graduated compression stockings on both lower limbs. Group MC had – in addition to mechanical prophylaxis – pharmacologic prophylaxis using 40 mg of subcutaneous enoxaparin injections (Clexane 40 mg; Sanofi-Aventis, Karachi, Pakistan) 12 h before surgery, and postoperatively every 24 h for 2 weeks. Early postoperative ambulation was initiated in all patients as soon as they recover the effects of anesthesia to reduce venous stasis.

Bilateral lower limb venous duplex was performed before patient discharge for detection of silent DVT. The test was repeated during the follow-up visit after 2 weeks if no evidence of DVT was found on discharge. Examination was performed with a 3–7.5 MHz transducer using a Voluson E8 Machine (General Electric, Boston, MA, USA) by an experienced operator. The iliac, femoral, great saphenous, popliteal, peroneal, post-tibial, and soleal veins were evaluated on transverse and long-axis views. Examination was done in the supine position for iliac and femoral veins, and then the other veins were assessed in an upright position.

The primary outcome measure of the study was detection of silent DVT using duplex ultra-sonography. The secondary outcome measures were adverse effects of pharmacologic therapy – that is bleeding complications.

Statistical analysis

Statistical analysis was done using IBM SPSS statistics (version 22; IBM Corp., Armonk, New York, USA). Numerical data were expressed as mean, SD, and range. Qualitative data were expressed as frequency and percentage. χ^2-Test (Fisher's exact test) was used to examine the relation between qualitative variables. For quantitative data, comparison between the two groups was done using independent sample *t*-test or Mann–Whitney test as appropriate. All tests were two-tailed. A *P*-value less than 0.05 was considered significant.

Results

There were 45 female and five male participants with a mean age of 40.5 years and a mean BMI of 45.7 kg/m^2. Laparoscopic sleeve gastrectomy was done in 39 (78%) patients and mini-gastric bypass was done in 11 (22%) patients. All procedures were completed laparoscopically with no conversion to open surgery (Table 1).

Three (6%) patients developed silent DVT; all of them were among the 25 patients who received mechanical thromboprophylaxis only (*P*=0.235). Relative risk (RR) of combined methods was 0.47 [95% confidence interval (CI): 0.35–0.64]. There was no significant difference between patients with DVT and those without DVT regarding age, BMI, operative time, comorbidities, or type of surgery (Table 2).

The three patients who developed silent DVT were treated initially with a low-molecular-weight heparin (LMWH) (Clexane) and warfarin until international normalized ratio reaches 2–3, and then warfarin was

Table 1 Demographic and clinical characteristics of the two studied groups

	Group M (*n*=25)	Group MC (*n*=25)	*P*-value
Age (years)			
Mean±SD	38.3±9.3	41.5±10.6	0.262
Range	20–55	18–57	
Sex			
Male/female	1/24	4/21	0.349
BMI (kg/m^2)			
Mean±SD	44.6±5.3	46.9±7.8	0.229
Range	37.5–50.5	38–69.5	
Comorbidity			
Diabetes mellitus	3 (12)	4 (16)	1.000
Hypertension	7 (28)	5 (20)	0.508
Type of surgery			
Laparoscopic sleeve gastrectomy	21 (84)	18 (72)	0.306
Mini-gastric bypass	4 (16)	7 (28)	
Operative time (min)	154±36	166±45	0.303

Data are presented as mean±SD or *n* (%).

Table 2 Comparison between patients who developed silent deep vein thrombosis and those who did not

	Silent DVT		*P*-value
	Positive (*n*=3)	Negative (*n*=47)	
Age (years)	42.3±6.0	35.8±10.1	0.244
BMI (kg/m^2)	45.3±3.8	44.2±5.4	0.465
Operative time (min)	162±48	158±36	0.636
Hypertension	1 (33.3)	11 (23.4)	1.000
Diabetes mellitus	0 (0.0)	7 (14.9)	1.000
Type of surgery			
LSG	3 (100.0)	36 (76.6)	1.000
MGB	0 (0.0)	11 (23.4)	

Data are presented as mean±SD or *n* (%); DVT, deep vein thrombosis; LSG, laparoscopic sleeve gastrectomy; MGB, mini-gastric bypass.

continued alone for 6 months to keep the international normalized ratio at 2–3. There were no complications recorded in the two studied groups in the form of bleeding, hematoma, wound leak, wound infection, or cardiopulmonary complications.

Discussion

This study demonstrated that combined mechanical and chemothromboprophylaxis is suggested to be superior to mechanical methods only for prevention of silent DVT in patients undergoing laparoscopic bariatric surgery. The difference between mechanical only and combined groups was not statistically significant (*P*=0.235); however, the RR of combined therapy was 0.47 (95% CI: 0.35–0.64).

Prevention of VTE is a priority to improve patient safety in hospitals especially after surgical procedures that carry a significant risk of developing thrombotic complications, such as bariatric surgery. On the basis of the results of previous studies, we extended the thromboprophylaxis for 2 weeks as it was reported that DVT can occur after discharge from the hospital and within 1 month [11,12].

In the current study, asymptomatic DVT occurred in 6% of patients. Most of the studies in the literature reported the incidence of clinical VTE while rates of potential asymptomatic patients were not included. The Bariatric Outcomes Longitudinal Database [13] reported an incidence of VTE of 0.42% in a data set of 74 000 patients; the risk was 1.5% after open surgery and 0.34% after laparoscopic procedures. A comparable figure (0.4%) was reported by the Longitudinal Assessment of Bariatric Surgery (LABS) study [14], whereas the Michigan Surgery Collaborative (MBSC) [15] reported a DVT rate of 0.21%.

The main restraints in thromboprophylaxis in bariatric surgery focus on the risk of significant postoperative bleeding that may require blood transfusions and reoperation with subsequent increased hospital stay and costs. This is of course linked to pharmacologic anticoagulants. Nevertheless, many studies have reported effective thromboprophylaxis with LMWH and unfractionated heparin with variable incidence of significant bleeding.

LMWH in general or abdominal surgery was reported to reduce the risk of clinical Pulmonary Embolism (PE) and clinical VTE by about 70% with an approximate doubling of the risks of major bleeding and wound hematoma (RR: 1.88; 95% CI: 1.54–2.28) [16]. Similar results were reported in studies of gastrointestinal, gynecologic, urological, and thoracic surgery [17].

In fact, the optimal dose of prophylactic heparin in bariatric surgery patients is not clear. LMWH dose is calculated according to body weight. Thus, many studies used an adjusted dose higher than the standard prophylactic dose. Scholten *et al.* [18] concluded that high dose of enoxaparin (40 mg/12 h) can reduce the incidence of DVT without an increase in bleeding complications following bariatric surgery. However, a prospective nonrandomized study that compared unfractionated heparin with 40 mg of subcutaneous enoxaparin twice daily reported that enoxaparin was associated with more frequent postoperative blood transfusion and reoperation for bleeding [19]. These high doses of enoxaparin carry the risk of significant bleeding complications.

In a multicenter pilot study, Imberti *et al.* [20] compared two prophylactic doses of LMWH in bariatric surgery: a standard dose and a 150% of the standard dose. The rates of VTE in the adjusted-dose group was lower (0.8 vs. 1.5%), but not significantly different. The rates of bleeding were 5% for the adjusted-dose group compared with 6.1% for the standard-dose group. Another study reported no VTE events with a standard dose and 167% of the standard dose. Major bleeding rate was 3% in the higher-dose group compared with none in the standard-dose group. Scholten *et al.* [18] compared enoxaparin 30 mg twice daily with 40 mg twice daily. The higher-dose group had a significantly lower incidence of VTE events (0.6 vs. 5.4%), with no significant difference in bleeding. Other studies used different doses with different regimens.In the current study, we used 40 mg of enoxaparin 12 h preoperatively and once a day for 2 weeks. This extended chemoprophylaxis regimen combined with bilateral above-knee graduated compression stockings effectively prevented symptomatic and asymptomatic DVT. The practice of postdischarge prophylaxis was based on the possibility of VTE after discharge. Froehling *et al.* [11] reported increased incidence of VTE from 0.3 to 1.9% between 7 and 30 days postoperatively after bariatric surgery. Postdischarge prophylaxis is used in abdominal or pelvic cancer surgery and in major orthopedic surgery [21,22].

An important finding in the current study is that the three patients who developed silent DVT do not have special characteristics to be considered a significant risk factor for the development of thromboembolism. This emphasizes our point of view of the necessity of combined prophylaxis regardless of the presence or absence of known risk factors.

We can conclude that the perioperative use of the LMWH enoxaparin in a dose of 40 mg daily for 2 weeks postoperatively combined with graduated compression stockings is safe and effective for the prevention of DVT following laparoscopic bariatric surgery.

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Conflicts of interest
There are no conflicts of interest.

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Repair of uncomplicated umbilical hernia in cirrhotic patients: experience of an institute

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Objective
The objective of this study was to present experience of a single institute in the management of uncomplicated umbilical hernia (UH) in cirrhotic patients.
Patients and methods
The study included 232 patients with UH: 103 patients class A, 83 Child–Pugh class B, and 46 Child–Pugh class C. Ascites was mild in 46 patients, moderate in 80 patients, and severe in seven patients, whereas 99 patients had no ascites. All patients underwent classic repair with proline mesh insertion if required.
Results
A total of 71 patients had direct defect closure and 161 patients had mesh repair. Operative time was significantly longer in class C patients than other classes and in patients of class B than class A. Peritoneal drainage was required in 109 patients with significantly higher frequency in class C. ICU admission was required in 33 patients with significantly higher frequency and longer duration in patients of class C. Duration of subcutaneous wound drainage was significantly longer, frequency of patients who developed short-term postoperative complications was significantly higher and hospital length of stay was significantly longer for patients of class C. During the follow-up for 23.2±7.9 months, 23 patients developed recurrent UH with significantly higher frequency in class C than other classes. Recurrence rate was significantly lower with mesh repair than direct closure (6.8 vs. 16.9%). During follow-up, 14 (6%) patients died secondary to causes not related to surgery with significantly higher in class C.
Conclusion
Elective UH repair in cirrhotic patients is feasible and is associated with acceptable rate of postoperative complications and no surgery-related mortalities. Mesh repair significantly reduced the recurrence rate. The pronounced outcome of patients of class A points to the necessity of early repair of UH to get the benefit of hepatic reserve and minimal volume of ascetic fluid.

Keywords:
cirrhotic patients, mesh repair, morbidities, mortalities, recurrence, uncomplicated umbilical hernia

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Introduction

The underlying etiologies for umbilical hernia (UH) development in cirrhotic patients include weakness of muscles of the anterior abdominal wall secondary to poor nutrition [1] and recanalized umbilical vein induces restoration of supraumbilical fascial defect [2]. In such patients' population, UH was exaggerated when longstanding ascites is present leading to increased intra-abdominal pressure. The high intra-abdominal pressures when applied to areas of parietal weakness causes hernia formation and/or enlargement [3].

Surgical repair of UH in ascetic patients is a challenge [4] with high anesthetic and surgical risk [5]. However, permanent mesh can be used in hernias in cirrhotic patients with minimal wound-related morbidity and a significantly lower recurrence rate (RR) [6,7]. Thus, the current study aimed to present the experience of a single institute in the management of uncomplicated UH in cirrhotic patients.

Patients and methods

The current prospective comparative study was conducted at the General Surgery Department, National Hepatology and Tropical Medicine Research Institute, Cairo, Egypt, since June 2012 till June 2016. The study protocol was approved by the Local Ethical Committee. Inclusion criteria included patients with varying degrees of liver dysfunction and presented with uncomplicated UH. Patients with complicated UH, compromised respiratory functions,

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or hernia at other abdominal wall orifices were excluded from the study. Patients fulfilling inclusion criteria or their near relatives signed fully informed written consent for study participation and undergoing the assigned surgical procedure.

All patients underwent clinical examination to assure diagnosis and inclusion criteria. Ascites was graded according to definitions of the International Ascites Club [8] as three grades (grades 1–3) according to the extent of ascites and the method for detection using ultrasound or clinical examination (Table 1).

Patients underwent preoperative estimation of serum albumin and total bilirubin levels and international normalized ratio, and then they were classified according to the Child–Turcotte–Pugh scoring system [9] into three classes: class A: 5–6 points, class B: 7–9 points, and class C: 10–15 points. The risk for developing 3-month mortality was calculated using the model for end-stage liver disease (MELD) score which is based on the etiology of cirrhosis and laboratory variables [10].

No special preoperative preparation was needed for class A cases. For patients of classes B and C, hepatic function support, control of ascites, and reduction of portal vein pressure reduction so as to allow class C patients to near class B level for safer elective surgery; on the other side, associated comorbidities were also controlled.

General anesthesia using sevoflurane was applied if general condition and results of liver function tests permit; otherwise, local infiltration anesthesia in conjunction with intravenous anesthetic infusion was used. All patients received prophylactic broad-spectrum antibiotic prior to skin incision. All patients were assigned for classic repair with proline mesh insertion according to requirement with wound drainage. Peritoneal drainage was provided if indicated to relieve abdominal pressure to allow wound healing.

Immediate postoperative (PO) care was conducted at postanesthetic care unit unless there is an indication for admission to ICU as delayed recovery, development of respiratory embarrassment, or if patient was preoperatively at risk of cardiac or cerebrovascular accident.

Collected operative data included operative time, amount of operative bleeding, the frequency of patients had mesh insertion, and if it was onlay or sublay, the frequency of peritoneal drainage. Immediate PO data included the frequency of ICU admission and length of stay (LOS). Short-term PO data included duration of wound drainage, frequency of patients developed wound infection, seroma and duration of peritoneal drainage. During follow-up for at least 6 months, the frequency of patients developed recurrence or other surgery-related morbidities and/or mortality were recorded.

Statistical analysis

The obtained data were presented as mean±SD, ranges, numbers, and ratios. Results were analyzed by one-way analysis of variance and χ^2-test using the SPSS (version 15, 2006; SPSS Inc., Chicago, Illinois, USA) for Windows statistical package. P value less than 0.05 was considered statistically significant.

Results

The study included 232 cirrhotic patients with UH; 103 (44.4%) patients were Child–Pugh (CP) class A, 83 (35.8%) patients were CP class B, and 46 (19.8%) patients were of CP class C. There was nonsignificant ($P>0.05$) difference between the studied patients as regards age, sex, and frequency of additional morbidities. Patients of class C had a significantly higher BMI compared with patients of class A ($P_1=0.001$) and class B ($P_2=0.004$) with significantly ($P_1=0.027$) higher BMI of patients of class B than class A. Patients of class A had a significantly ($P_1=0.001$) lower MELD score than patients of other classes with significantly ($P_2=0.001$) lower score of patients of class B than class C. A total of 91 (42.7%) patients had no ascites and all were of Child class A; 46 (19.8%) patients had mild ascites; 80 (34.5%) patients had moderate ascites; and only seven (3%) patients had

Table 1 Criteria and score points for calculation of Child–Pugh score [9]

Criteria	Scores (points)		
	1	2	3
Serum total bilirubin	<2 mg/dl	2–3 mg/dl	>3 mg/dl
Serum albumin	>3.5 g/dl	2.8–3.5 g/dl	<2.8 g/dl
International normalized ratio	<1.7	1.71–2.20	>2.2
Ascites	No	Controlled	Poorly controlled
Encephalopathy	No	Controlled	Poorly controlled

severe ascites. The frequency of patients had ascites grade 3 among patients of class C which was significantly (P_1 and P_2<0.001) higher compared with patients of class A (P_1<0.001) and class B (P_2<0.001) with significantly (P_1<0.001) higher frequency among patients of class B than class A. Details of enrollment data of studied patients are shown in Table 2.

A total of 118 (50.9%) patients received local anesthesia; 72 patients of class B and 46 patients of class C, whereas the other 114 (49.1%) patients received general anesthesia. Mean diameter of the umbilical defect, in its greatest dimension, was 3.5&#x00B1 range: 1–6 cm with significantly wider defect in patients of class C than patients of class A (P_1=0.002) and class B (P_2=0.047) and nonsignificantly (P>0.05) wider defect in patients of class B than patients of class A. Totally, 71 (30.6%) patients had anterior abdominal wall muscles of appropriate strength and small umbilical defects that allowed direct defect closure without the need for mesh application. The frequency of patients who required mesh repair was significantly higher among patients of class C compared with patients of classes A (P_1<0.001) and B (P_2<0.001) with significantly (P_1<0.001) higher frequency among patients of class B compared with class A. A total of 14 patients, nine of class B and five of class C, received sublay mesh insertion followed by muscle approximation, so as to minimize ascetic fluid loss; the frequency of patients required sublay mesh was significantly higher in patients of classes B and C than those of class A. A total of 147 patients received onlay mesh with a significantly higher frequency among patients of classes B and C compared with patients of class A (Fig. 1).

No patient of class A required peritoneal drainage, whereas 109 patients, 63 (75.9%) patients of class B and 46 (100%) patients of class C, required peritoneal drainage to lessen the intra-abdominal pressure so as to allow wound healing with significantly higher

Table 2 Patients' enrollment data

Data	CP classes			
	Class A (*n*=103)	Class B (*n*=83)	Class C (*n*=46)	Total (*n*=232)
Age (years)	46.5±10.9	50±11.5	46.8±11.3	48±11.3
Sex [*n* (%)]				
Males	68 (66)	56 (67.5)	31 (67.4)	155 (66.8)
Females	35 (34)	27 (32.5)	15 (32.6)	77 (33.2)
BMI data				
Weight (kg)	87±8.6	91.6±16.4	98.6±7.2	90.9±12.5
P value		P_1=0.027	P_1=0.001	
			P_2=0.004	
Height (cm)	169.7±3.5	170.2±3.3	169.9±3.1	169.9±3.3
BMI (kg/m^2)	30.2±2.6	31.7±5.9	34.2±2.4	31.5±4.2
P value		P_1=0.037	P_1=0.001	
			P_2=0.002	
MELD score				
Mean score	15.2±1.1	22.1±1.3	28.3±1.6	21.9±6.4
P value		P_1=0.001	P_1=0.001	
			P_2=0.001	
Ascites grade [*n* (%)]				
No	99 (96.2)	0	0	99 (42.7)
Mild (grade 1)	4 (3.8)	20 (24.1)	22 (47.8)	46 (19.8)
Moderate (grade 2)	0	63 (75.9)	17 (37)	80 (34.5)
Severe (grade 3)	0	0	7 (15.2)	7 (3)
P value		P_1<0.001	P_1<0.001	
			P_2<0.001	
Additional morbidity [*n* (%)]				
No morbidities	41 (39.8)	22 (26.6)	5 (10.9)	68 (29.3)
Diabetes mellitus	29 (28.2)	29 (34.9)	16 (34.8)	74 (31.9)
HR dysfunction	12 (11.7)	13 (15.7)	11 (23.9)	36 (15.5)
Cardiac disease	13 (12.6)	10 (12)	8 (17.4)	31 (13.4)
Malignancy	0	1 (1.2)	1 (13)	23 (2.2)

Data are presented as mean±SD; CP class, Child–Pugh class; HR dysfunction, hepatorenal dysfunction; MELD, model for end-stage liver disease; P_1, significant difference between patients of class A; P_2, significant difference between patients of class B; P>0.05, nonsignificant difference; P<0.05, significant difference.

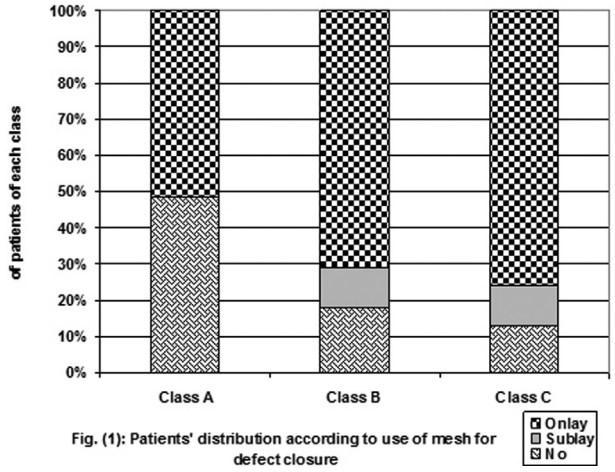
frequency of peritoneal drainage among patients of class C than patients of class B (P_2=0.0003).

The mean amount of operative blood loss was 177±42; range: 105–350 ml with nonsignificantly (P>0.05) higher amounts of blood loss in patients of class C than patients of the other classes. Mean operative time was 65.7±10; range: 45–90 min operative time was significantly (P_1 and P_2=0.001) longer for patients of class C compared with patients of the other classes and significantly (P_1=0.001) longer operative time in patients of class B than class A (Table 3 and Fig. 2).

Thirty-three (14.2%) patients required ICU admission for a mean duration of 2.3±0.7; range: 1–4 days. The frequency of ICU admission among patients of class C was significantly (P_2=0.0005) higher than patients of class B with nonsignificantly (P>0.05) longer duration of ICU stay (Table 4).

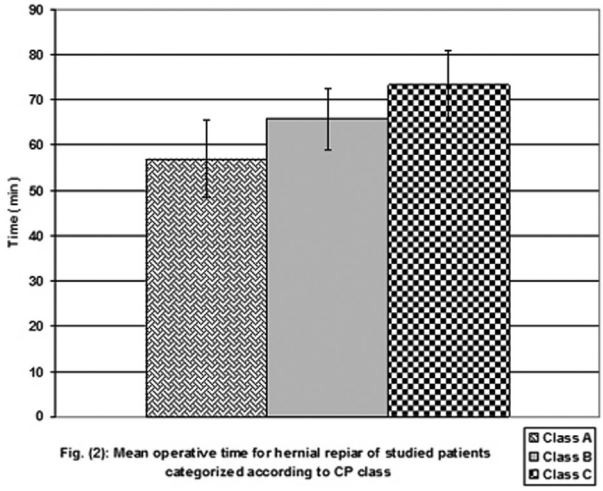
Mean duration of subcutaneous wound drainage was significantly longer in patients of class C compared with that of patients of class A, whereas in patients of class B, duration of wound drainage showed a

Figure 1



Patients' distribution according to the use of mesh for defect closure.

Figure 2



Mean operative time for hernial repair of studied patients categorized according to Child–Pugh class.

Table 3 Operative data of studied patients categorized according to Child–Pugh class

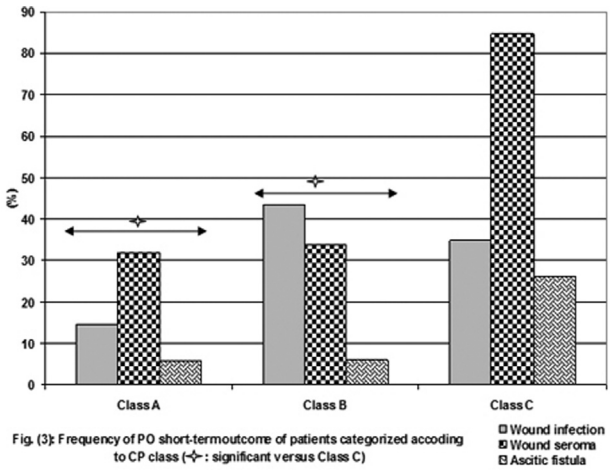
Data	Classes			
	Class A (n=103)	Class B (n=83)	Class C (n=46)	Total (n=232)
Mode of anesthesia				
General	103 (100)	11 (13.3)	0	114 (49.1)
Local	0	72 (86.7)	46 (100)	118 (50.9)
Diameter of umbilical defect (cm)	3.4±1.02	3.5±0.87	4±0.92	3.5±1
		P_1>0.05	P_1=0.002	
			P_2=0.047	
Mesh insertion				
No	50 (48.5)	15 (18.1)	6 (13)	71 (30.6)
Sublay	0	9 (10.8)	5 (10.9)	14 (6)
Onlay	53 (41.5)	59 (71.1)	35 (76.1)	147 (63.4)
			P_1=0.011	P_1=0.001
				P_2=0.003
Peritoneal drainage				
No	103 (100)	20 (24.1)	0	123 (53)
Yes	0	63 (75.9)	46 (100)	109 (47)
				P_2=0.0003
Amount of operative blood loss (ml)	170±39	184±47	192±43	177±42
Operative time (min)	57±8.7	65.9±6.8	73.2±7.8	65.7±10
		P_1=0.001	P_1=0.001	
			P_2=0.001	

Data are presented as mean±SD or n (%); P>0.05, nonsignificant difference; P<0.05, significant difference.

nonsignificant ($P>0.05$) difference compared with patients of other classes. A total of 129 (55.6%) patients developed short-term PO complications for a frequency of 1.4 complications per affected patient. The frequency of PO complications was significantly higher in patients of class C compared with patients of classes A ($P_1=0.001$) and B ($P_2=0.013$). Moreover, the frequency of PO complications was significantly ($P_1=0.001$) higher among patients of class C (1.46/patient) than patients of other classes (0.5/patient in class A and 0.68/patient in class B). On the contrary, the frequency of PO complications was nonsignificantly ($P>0.05$) higher among patients of class B than class A (Fig. 3). Mean hospital LOS was significantly longer for patients of class C compared with those of classes A and B (P_1 and $P_2=0.001$) with significantly longer duration for patients of class B ($P_1=0.001$) than patients of class A (Table 5).

Mean duration of follow-up was 23.2±7.9; range: 6–42 months with nonsignificant ($P>0.05$) difference between patients of the three classes. A total of 23 patients developed recurrent UH throughout follow-up period for a total RR of 9.9%. However, the frequency of recurrence was nonsignificantly higher

Figure 3



Frequency of postoperative short-term outcome of patients categorized according to Child–Pugh class (☆: significant vs. class C).

Table 4 ICU data of studied patients categorized according to Child–Pugh class

Data	CP classes			
	Class A (n=103)	Class B (n=83)	Class C (n=46)	Total (n=232)
Frequency of admission	0	13 (15.7)	20 (43.5)	33 (14.2)
P value			$P_2=0.0005$	
Duration of stay (days)	0	2.3±1	2.8±0.9	2.3±0.7
P value			$P_2>0.05$	

Data are presented as mean±SD or *n* (%); CP class, Child–Pugh class; P_1, significant difference between patients of classes A and B; P_2, significant difference between patients of classes A and C; P_3, significant difference between patients of classes B and C; $P>0.05$, nonsignificant difference; $P<0.05$, significant difference.

Table 5 Short-term postoperative data of studied patients categorized according to Child–Pugh class

Data	CP classes			
	Class A (n=103)	Class B (n=83)	Class C (n=46)	Total (n=232)
Frequency of peritoneal drainage	0	63 (55.6)	46 (100)	109 (47)
			$P_2=0.0003$	
Duration of wound drainage (days)	1.6±0.8	1.8±0.9	2.2±0.7	1.7±0.8
		$P_1>0.05$	$P_1=0.001$	
			$P_2>0.05$	
Wound infection	15 (14.6)	25 (43.4)	16 (34.8)	56 (24.1)
Wound seroma	33 (32)	28 (33.7)	29 (84.8)	100 (43.1)
Ascitic fistula	6 (5.8)	5 (6)	9 (26.1)	23 (9.9)
P value		$P_1>0.05$	$P_1=0.001$	
			$P_2=0.013$	
Frequency (complication/patient)	0.5	0.68	1.46	1.4
		$P_1>0.05$	$P_1=0.001$	
			$P_2=0.001$	
Total length of hospital stay (days)	2.4±0.6	2.9±0.7	6.2±0.8	3.3±1.6
		$P_1=0.001$	$P_1=0.001$	
			$P_2=0.001$	

Data are presented as mean±SD or *n* (%); CP class, Child–Pugh class; P_1, significant difference between patients of classes A and B; P_2, significant difference between patients of classes A and C; P_3, significant difference between patients of classes B and C; $P>0.05$, nonsignificant difference; $P<0.05$, significant difference.

among patients of class C compared with patients of classes A and B (P_1 and P_2 >0.05), with nonsignificantly (P_1>0.05) higher frequency of recurrence among patients of class B than patients of class A. Moreover, the RR was significantly (P=0.006) lower among patients who had mesh repair (6.8%) than those who had direct closure (16.9%) as shown in Fig. 4. Unfortunately, 14 patients died throughout the follow-up period for a frequency of 6%; but no patient died secondary to surgical complication. Mortality rate was significantly higher among patients of class C compared with patients of class A (P_1=0.002), but was nonsignificantly (P_2>0.05) higher compared with class B and nonsignificantly (P_1>0.05) higher mortality rate among patients of class B than class A (Table 6).

Discussion

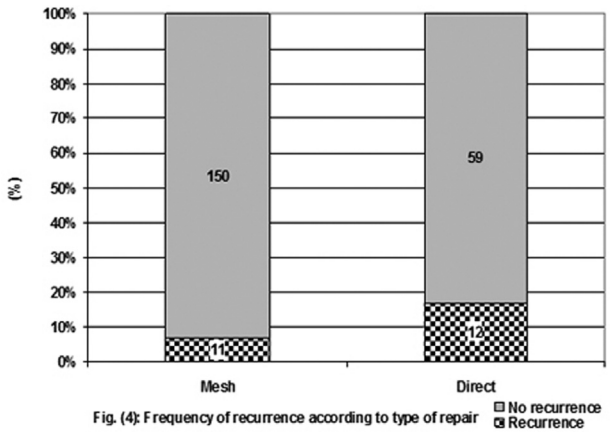
The current study included 232 cirrhotic patients presented with uncomplicated UH; to illustrate the outcome of surgical repair, patients were categorized according to Child–Turcotte–Pugh grading and the outcome for each class was illustrated and compared. In line with this, de Goede *et al*. [11] and Kotb *et al*. [12] documented that preoperative MELD and CP scores appeared to be predictive of PO risks in patients with liver cirrhosis who undergo nonhepatic surgery.

The frequency of patients had ascites grade 3 was significantly higher among patients of class C than patients of other classes and this was reflected clinically as significantly higher BMI and wider umbilical defect and could define a relation between ascetic fluid volume and severity of heniation; similarly Wang *et al*. [13] reported that the volume of ascites and CP scores had positive correlations with UH.

A total of 23 (9.9%) patients developed recurrent UH with significantly higher RR among class C patients than patients of other classes and among patients who had direct closure (16.9%) versus patients who had mesh repair (6.8%). In support of these data, Youssef and El Ghannam [14] reported an RR of 10% with mesh repair and 35% with direct repair of UH in ascetic patients. Besides, Eker *et al.* [15] reported an RR of 7% after UH repair. Recently, Winsnes *et al.* [16] reported cumulative RR of 8.4% and Coelho *et al.* [17] found hernia repair with mesh is associated with lower RR than direct repair of UH in a cirrhotic patient.

The mean operative time (65.7±10 min) was significantly longer for patients of class C compared with patients of the other classes with significantly longer operative time in patients of class B than class A. In line with this finding, Hassan *et al.* [18] studied 70 cirrhotic patients who underwent elective sublay UH mesh repair and reported a mean operative time of 67.45 min. Besides, Kotb *et al*. [12] reported significant difference in operative time among patients of the three CP classes and was longest in group C when compared with the other two groups.

Figure 4



Frequency of recurrence according to the type of repair.

Table 6 Follow-up postoperative data of studied patients categorized according to Child–Pugh class

Data	CP class			
	Class A (n=103)	Class B (n=83)	Class C (n=46)	Total (n=232)
Duration (months)	23.8±8.1	22.4±7.2	22±8	23.2±7.9
Recurrence				
Frequency	8 (7.8)	7 (8.4)	8 (17.4)	23 (9.9)
P value		P_1>0.05	P_1>0.05 P_2>0.05	
Mortality				
Frequency	2 (1.9)	5 (6)	7 (15.2)	14 (6)
P value		P_1>0.05	P_1=0.002 P_2>0.05	

Data are presented as mean±SD or n (%); CP class, Child–Pugh class; P_1, significant difference between patients of classes A and B; P_2, significant difference between patients of classes A and C; P_3, significant difference between patients of classes B and C; P>0.05, nonsignificant difference; P<0.05, significant difference.

Short-term PO complications were reported in 129 patients for a frequency of 1.4/patient with significantly higher frequency of PO complications and significantly higher frequency per patient in class C than in classes A and B. Similarly, Youssef and El Ghannam [14] reported early PO ascitic fluid leakage in 15%, and mild superficial wound infection in 25% of patients had mesh repair, whereas in patients who had direct repair ascitic leakage occurred in 30% and wound infection in 15%. Besides, Choi *et al*. [19] and Lasheen *et al*. [20] reported an overall complication rate of 42 and 30%, respectively, after elective repair of UH in ascetic patients.

On contrary to these results, Hassan *et al*. [18] reported wound infection in 2.8%, seroma in 4.2%, ascitic fistula in 1.4%, and recurrence in 1.4% of patients and Kotb *et al*. [12] reported no recurrence, no morbidities after a 6-month follow-up; however, such discrepancy could be attributed to their small sample size (n=70 and 40 patients, respectively) and short duration of follow-up (6 months).

The mean hospital LOS was significantly longer for patients of class C compared with those of classes A and B with significantly longer duration for patients of class B than class A. Similarly, Kotb *et al*. [12] reported significant difference in hospital stay among patients categorized according to CP classes.

During follow-up, 14 (6%) patients died secondary to causes unrelated to surgery with significantly higher mortalities among patients of class C. In line with the reported figure, Eker *et al*. [15] and Choi *et al*. [19] reported a mortality rate of 7 and 6.2%, respectively, after elective UH repair in patients with liver cirrhosis. Similar to the obtained results, Kotb *et al*. [12] and Eker *et al*. [15] reported no surgery-related mortality in their series of ascetic patients underwent UH repair.

One point of discrepancy in the literature is to operate or not on UH in cirrhotic patients especially if ascetic; the current study illustrates the beneficial outcome of hernial repair of uncomplicated UH, irrespective of the severity of hepatic derangement as judged by preoperative investigations and clinical evaluation and expressed as CP class and allow rejecting the traditional concepts regarding operative decision in cirrhotic patients especially if ascetic. In support of such opinion, multiples previous studies [18,19,21–24] have documented that early repair of UH in cirrhotic patients is safer than it was in the past and can be considered for selected patients to safeguard against the increased morbidity and mortality associated with urgent repair later on.

Conclusion

The obtained results and review of literature allowed to conclude that elective UH repair in cirrhotic patients is feasible and is associated with acceptable rate of PO complications and no surgery-related mortalities. Mesh repair improves outcome as significant reduction of RR. The pronounced outcome of patients of class A points to the necessity of early repair of UH to get the benefit of hepatic reserve and minimal volume of ascetic fluid. However, there was no definite contraindication for repair of UH in patients of classes B and C and PO peritoneal drainage helps healing of the repair site.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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Prediction of nipple and areola complex invasion in breast cancer patients: clinical and pathological study of surgical specimens

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Background
Nipple–areola sparing (NAS) mastectomy is nowadays considered the most common conservative procedure used for both risk reduction (prophylaxis) and cancer treatment. We regard the oncological safety as a first concern in the management of breast cancer (BC) patients.
Aim
The aim of this study was to assess the predictive value of clinical and pathological criteria that might affect decision making for NAS mastectomy in BC patients.
Patients and methods
This study included 60 cases of operable BC that underwent MRM. All specimens were subjected to histopathological examination of the subareolar tissue to prove or disprove malignant infiltration of the nipple–areola complex (NAC), and their data were plotted against the preoperative predictive factors.
Results
The incidence of occult NAC malignancy was 15%. Predictive factors influencing NAC invasion were tumour–nipple distance less than 4 cm, grade III tumour, lymph node metastasis, lymphovascular invasion, human epidermal growth factor receptor-2 positivity, oestrogen receptor/progesterone receptor negativity, retroareolar/centrally located tumour and multicentric tumours.
Conclusion
NAS mastectomy for the management of BC would be appropriate in carefully selected patients who have peripherally located tumours, grade I or II, not multicentric or multifocal, with tumour-to-nipple distance greater than 4 cm, and human epidermal growth factor receptor-2 negative with no lymphovascular invasion of the subareolar plexus or axillary lymph nodes metastasis.

Keywords:
breast cancer, nipple–areola complex, nipple–areola sparing mastectomy

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Introduction

Breast cancer (BC) remains the most frequently diagnosed cancer among women. Surgical techniques have evolved from radical mastectomy to less invasive and cosmetically acceptable surgical approach in recent years [1].

Mastectomy is a common surgical option in case of BC treatment or prophylaxis. It is considered as an operation that is associated with several problems for the patient, affecting the overall postoperative quality of life: altered body image, diminished self-worth and loss of a sense of feminity along with anxiety and depression [2].

Oncoplastic breast surgery is becoming popular, aiming to provide adequate oncological clearance of a tumour with attention to breast aesthetics [3].

Nipple–areola sparing (NAS) mastectomy is nowadays considered the most conservative procedure that improves the overall quality of life for women, allowing excellent cosmetic results because it provides a natural-appearing breast [4].

The NAS mastectomy reconstruction is related to autologous and alloplastic techniques and sometimes includes contralateral breast surgery [5].

In addition to the aesthetic benefits of NAS mastectomy, recent studies reported low rates of local recurrence and no significant difference

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between long-term follow-up between NAS mastectomy and mastectomy [6].

Many factors affect nipple involvement (NI) and areola involvement, such as patient's age, tumour size, tumour location (central vs. peripheral), tumour-to-nipple distance, lymphovascular invasion (LVI), lymph node metastasis, histological type and grade of the tumour and multifocal/multicentric tumour [7].

We designed this study to evaluate factors that affect nipple–areola complex (NAC) invasion to put the selection criteria for NAS mastectomy.

Patients and methods

This study was carried out in the Department of General Surgery and Department of Pathology, Faculty of Medicine, Zagazig University Hospitals, during the period from January 2014 to July 2016. The study was complied with the local guidelines of the research IRB/ ethics committee of Zagazig University Hospitals and all patients included gave informed consents. The study included 60 Egyptian female patients with BC; all of them were subjected to modified radical mastectomy (MRM) operation.

Inclusion criteria were as follows:

(1) Female patient more than 18 years.
(2) BC patients with healthy looking noninvaded skin of the nipple and areola.

Exclusion criteria were as follows:

(1) Age less than 18 years.
(2) Refusal to participate.
(3) Being unfit for surgery.
(4) Previously subjected to chemotherapy or radiotherapy for BC.
(5) Inflammatory BC cases.
(6) Presence of skin changes involving NAC.

In this study, we evaluated the oncological safety for NAS mastectomy procedure by searching for the factors that predict the presence of NAC invasion. This procedure is performed by history taking and clinical examination. Thereafter, we searched for the presence of the occult malignant cells in the subareolar tissue in the breast specimens of the standard MRM.

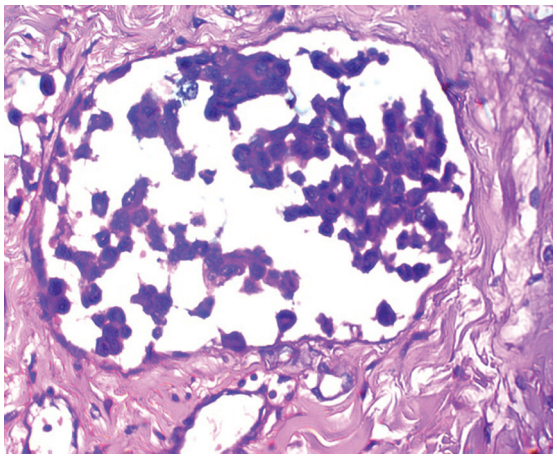
Standard MRM was performed for all patients, removing all breast tissue, the NAC, necessary skin and total axillary lymph nodes.

Breast specimen was examined by a single expert pathologist using standard hematoxylin and eosin stains under light microscopy. Tissue just underlying the NAC was examined for evidence of malignancy (Fig. 1).

All specimens were examined by a single expert pathologist to search for malignancy in the subareolar tissue.

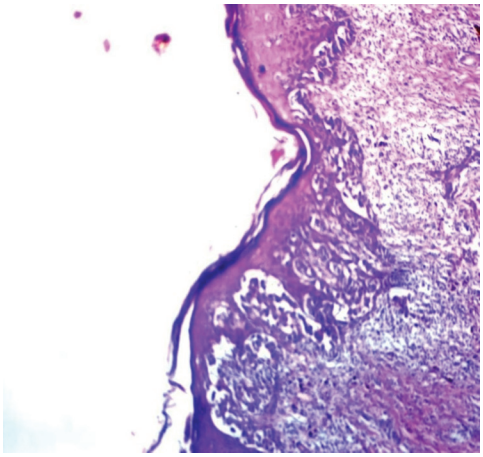
Immunohistochemistry was performed on paraffin sections by using anti-ER antibody (Clone D07, 1 : 50 dilution; Dako, Denmark), anti-PR antibody (PR 636, 1 : 50 dilution; Dako, Denmark) and polyclonal human epidermal growth factor receptor-2 (HER2) antibody in the Herceptin kit (Hercep test; Dako, Denmark), according to the manufacturer's instructions by using EnVision System (Dako, Denmark) for detection. For oestrogen receptor

Figure 1



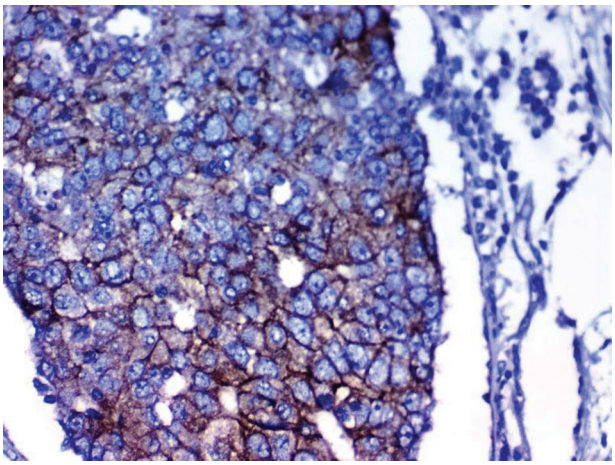
Infiltrating duct carcinoma (IDC) grade III showing malignant ductal epithelial cells inside the vessel lumen (tumor emboli) (H&E ×400).

Figure 2



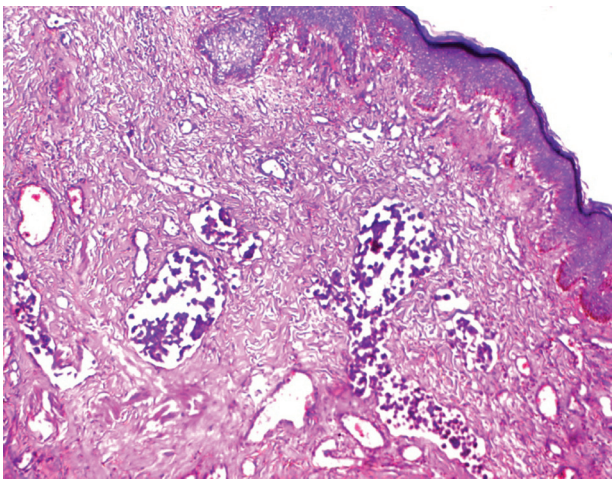
Infiltrating duct carcinoma (IDC) grade III, showing infiltration of the overlying epidermis by groups of malignant ductal epithelial cells (H&E ×100).

Figure 3



Infiltrating duct carcinoma (IDC) grade III, showing positive HER2 /neu membranous immunoreactivity (Score 3) (IHC ×400).

Figure 4



Infiltrating duct carcinoma (IDC) grade III, showing lymphovascular invasion in the subareolar plexuses (tumor emboli) (H&E ×100).

(ER) and progesterone receptor (PR) expression, moderate-to-strong nuclear staining in 1% or more of tumour cells was considered positive. HER2/neu was considered positive if at least 10% of tumour cells exhibited 3+ membranous staining (Fig. 2–8).

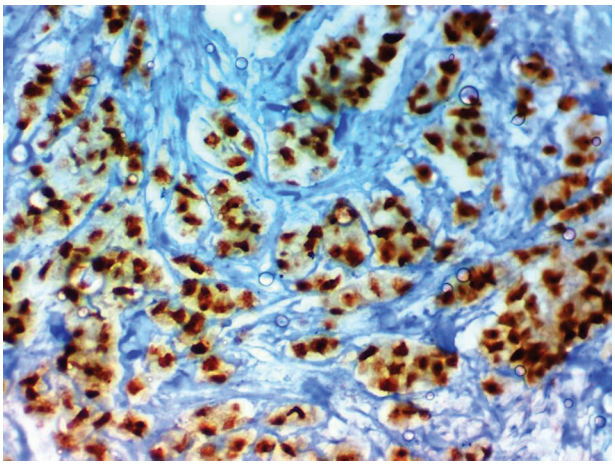
Statistical analysis

Statistical analysis was performed using SPSS software (SPSS Inc., Chicago, Illinois, USA). Data were expressed as mean±SD for quantitative variables. For categorical variables Fisher's exact test or χ^2-test was used. A *P* value less than 0.05 was considered significant.

Results

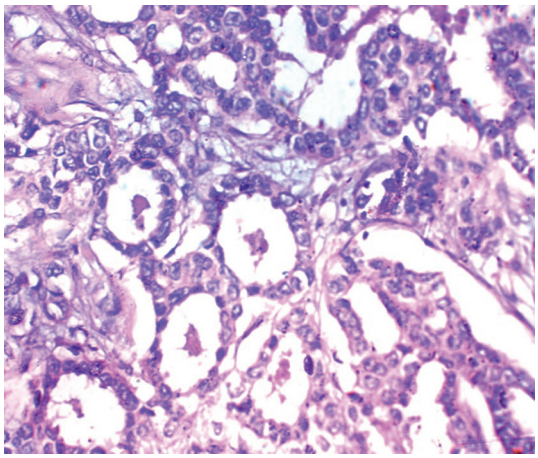
A total of 60 patients were included in this study. Their ages ranged from 28 to 78 years with a mean age of 51.1 years (Table 1).

Figure 5



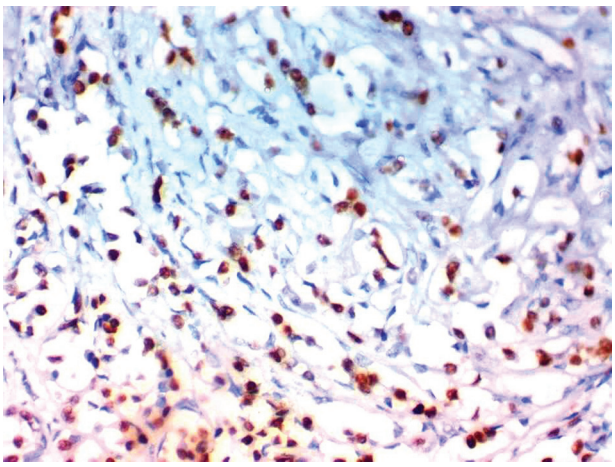
Infiltrating duct carcinoma (IDC) grade III, showing strong PR nuclear immunoreactivity (IHC ×400).

Figure 6



Infiltrating duct carcinoma (IDC) grade II, showing tubular formation (H&E ×400).

Figure 7



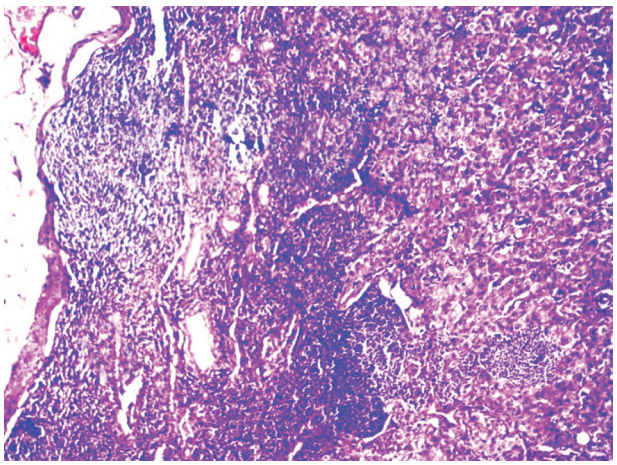
Infiltrating duct carcinoma (IDC) grade III, showing strong ER nuclear immunoreactivity (IHC ×400).

We included 60 patients: one of them had bilateral BC and nine of them had multifocal BCs; each one had two masses. Therefore, we had 60 patients, 61 breasts and 70 masses.

There was no statistically significant association between the age and menstrual state of the patient and NAC invasion (P=0.121 and 0.558, respectively). Moreover, there was no statistically significant association between positive family history of BC and NAC invasion (P=1.000) (Table 1).

However, there was a statistically significant association between nipple retraction as a patient's complaint and NAC invasion, in which 2% of patients were without NAC invasion complaint of nipple retraction versus 36.7% of patients with NAC invasion (P=0.001) (Table 2).

Figure 8



Lymph node positive for IDC, showing loss of normal nodal architecture that's replaced by malignant ductal epithelial cells (H&E ×100).

There was no statistically significant association between breast size and NAC invasion (P=0.186) (Table 2). However, there was a highly statistically significant association between centrally located tumours and NAC invasion (P<0.001) (Table 2).

Multifocal tumours were associated with statistically significantly higher incidence of NAC invasion (P<0.001) (Table 3). However, there was no statistically significant association between tumour size neither clinically assisted or ultrasound-assisted and NAC invasion (P=0.401 and 0.838, respectively) (Table 4).

There was a highly statistically significant association between the mass-to-nipple distance and NAC invasion (P<0.001) (Table 5).

There was a statistically significant association between the histological grade of the tumour and NAC invasion (P=0.002) (Table 6).

Number of positive lymph nodes in patients with NAC invasion was significantly higher than the number of patients without NAC invasion (P=0.011) (Table 6).

There were statistically significant associations between ER negativity, PR negativity, and HER2 positivity and NAC invasion (P<0.001, 0.004, 0.001, respectively) (Table 7).

Discussion

Oncoplastic surgery has become a key aspect of BC treatment, as it considers both oncological and cosmetic outcomes. The idea of sparing the skin of the breast is to facilitate the immediate breast reconstruction [8].

Table 1 Demographic data of the studied groups

Demographic data	NAC invasion [*n* (%)]		Tests	*P* value (significance)
	Absent (*N*=50)	Present (*N*=11)		
Age (years)				
Mean±SD	51.26±12.56	49.90±10.26	0.332[a]	0.741 (NS)
Median (range)	52 (28–76)	49 (33–62)		
<40	13 (26)	2 (18.2)	4.224[b]	0.121 (NS)
40–60	20 (40)	8 (72.7)		
>60	17 (34)	1 (9.1)		
Menstrual state				
Premenopausal	18 (36)	5 (45.5)	0.343[b]	0.558 (NS)
Postmenopausal	32 (64)	6 (54.5)		
Family history				
Negative	37 (74)	8 (72.7)	0.008[b]	1.000 (NS)
Positive	13 (26)	3 (27.3)		

NAC, nipple–areola complex. [a]Independent samples Student's *t*-test. [b]χ^2-test. P<0.05, significant.

Table 2 Clinical data of the studied groups

Clinical data	NAC invasion [*n* (%)]		Tests	*P* value (significance)
	Absent (*N*=50)	Present (*N*=11)		
Patient's complaint				
Painless lump				
Absent	18 (36)	7 (63.6)	2.847[a]	0.174 (NS)
Present	32 (64)	4 (36.4)		
Painful lump				
Absent	36 (72)	9 (81.8)	0.449[a]	0.711 (NS)
Present	14 (28)	2 (18.2)		
Axillary lump				
Absent	48 (96)	11 (100)	0.455[a]	0.500 (NS)
Present	2 (4)	0 (0)		
Nipple discharge				
Absent	49 (98)	11 (100)	0.224[a]	1.000 (NS)
Present	1 (2)	0 (0)		
Bleeding per nipple				
Absent	50 (100)	10 (90.9)	4.621[a]	0.180 (NS)
Present	0 (0)	1 (9.1)		
Nipple retraction				
Absent	49 (98)	7 (63.6)	14.149	0.003 (S)
Present	1 (2)	4 (36.7)		
Breast size (bra size)				
Mean±SD	42.48±2.47	43.63±2.65	−1.321[b]	0.186 (NS)
Median (range)	42 (38–46)	44 (40–46)		
Bilaterality				
No	50 (100)	9 (90)	5.085[a]	0.167 (NS)
Yes	0 (0)	1 (10)		
Focality				
Unifocal	50 (100)	2 (18.2)	47.990[a]	<0.001 (HS)
Multifocal	0 (0)	9 (81.8)		

HS, highly significant; NAC, nipple–areola complex; S, significant. [a]χ^2-test. [b]Mann–Whitney *U*-test. $P<0.05$, significant.

Table 3 Site of the tumour of the studied groups

Tumour site	NAC invasion [*n* (%)]		Tests	*P* value (significance)
	Absent (*N*=50)	Present (*N*=20)		
Nonpalpable				
No	50 (100)	18 (90)	5.147[a]	0.079 (NS)
Yes	0 (0)	2 (10)		
Upper outer 1/4				
No	16 (32)	12 (60)	4.667[a]	0.081 (NS)
Yes	34 (68)	8 (40)		
Upper inner 1/4				
No	44 (88)	19 (95)	0.778[a]	0.664 (NS)
Yes	6 (12)	1 (5)		
Lower outer 1/4				
No	44 (88)	20 (100)	2.625	0.173 (NS)
Yes	6 (12)	0 (0)		
Lower inner 1/4				
No	47 (94)	18 (90)	0.345	0.619 (NS)
Yes	3 (6)	2 (10)		
Central				
No	50 (100)	14 (70)	16.406	<0.001 (HS)
Yes	0 (0)	6 (30)		
Axillary tail				
No	49 (98)	19 (95)	0.463	0.493 (NS)
Yes	1 (2)	1 (5)		

HS, highly significant; NAC, nipple–areola complex. [a]χ^2-test. $P<0.05$, significant.

Table 4 Size of the tumour (cm) of the studied groups

Size of the tumour (cm)	NAC invasion		Test	*P* value (significance)
	Absent (*N*=50)	Present (*N*=20)		
Clinical				
Mean±SD	3.30±1.13	2.85±1.30	–0.839•	0.401 (NS)
Median (range)	3 (1.50–6)	3 (0–4.50)		
Ultrasound				
Mean±SD	2.60±1.01	2.57±0.81	–0.205•	0.838 (NS)
Median (range)	2.50 (1–6)	3 (1–4)		

NAC, nipple–areola complex. •Mann–Whitney *U*-test. ‡Chi-square (χ^2) test. $P<0.05$, significant.

Table 5 Distance from mass to nipple in the studied groups

Variable	NAC invasion		Test	*P* value (significance)
	Absent (*N*=50)	Present (*N*=20)		
Distance from mass to nipple				
Mean±SD	7.24±2.73	3.15±2.80	–5.320•	<0.001 (HS)
Median (range)	6 (4.50–16)	2.75 (0–12)		

NAC, nipple–areola complex. •Mann–Whitney *U*-test. ‡Chi-square (χ^2) test. $P<0.05$, significant.

Table 6 Histopathological examination of the studied groups

Histopathological examinations	NAC invasion [*n* (%)]		Test	*P* value (significance)
	Absent (*N*=50)	Present (*N*=11)		
Histopathology of MRM				
IDC	42 (84)	10 (90.9)	0.944‡	0.624 (NS)
ILC	4 (8)	0 (0)		
IDC+ILC	4 (8)	1 (9.1)		
Histopathological grade				
Grade I	0 (0)	0 (0)	9.350‡	0.002 (S)
Grade II	30 (60)	1 (9.1)		
Grade III	20 (40)	11 (90.9)		
Lymph node				
Node negative	20 (40)	0 (0)	6.546‡	0.011 (S)
Node positive	30 (60)	11 (100)		

IDC, invasive duct carcinoma; ILC, invasive lobular carcinoma; MRM, modified radical mastectomy; NAC, nipple–areola complex; S, significant. ‡χ^2-test. $P<0.05$, significant.

Table 7 Biological markers of the studied groups

Biological markers	NAC invasion [*n* (%)]		Test	*P* value (significance)
	Absent (*N*=50)	Present (*N*=11)		
ER				
Negative	9 (18)	10 (90.9)	22.349[a]	<0.001 (HS)
Positive	41 (82)	1 (9.1)		
PR				
Negative	12 (24)	8 (72.7)	9.715[a]	0.004 (S)
Positive	38 (76)	3 (27.3)		
HER2/neu overexpression				
Negative	46 (92)	1 (9.1)	35.049[a]	<0.001 (HS)
Positive	4 (8)	10 (90.9)		

ER, oestrogen receptor; HER2, human epidermal growth factor receptor-2; NAC, nipple–areola complex; PR, progesterone receptor; S, significant. [a]χ^2-test. $P<0.05$, significant.

The main benefits of NSM are oncological safety, preservation of inframammary fold and breast contour, absence of skin colour differences as in flaps, better cosmetic result, sensation of integrity and positive psychological effects related to the nipple preservation [9]. In this study, NAC involvement was noted in nine of 60 mastectomy specimens. Therefore, the incidence of occult NAC involvement was 15%. This rate indicates that even patients who had clinically normal-appearing NAC should be carefully selected for NAS

mastectomy. This falls in the same range reported by Gomez *et al*. [10], who reported that the incidence of NI ranges from 0 to 58%.

In this study, there was no statistically significant association between age groups and NAC invasion (P=0.121) and this matches with Zhang *et al.* [7].

In this study, there was no statistically significant association between menstrual state and NAC invasion (P=0.558). This coincides with Abou Nagah and El-Sabaa [11].

In this study, there was no statistically significant association between family history and NAC invasion (P=1.000).

In this study, the most common patient complaint was painless lump (58.3%), painful lump (26.7%) and nipple retraction (8.3%). There was a statistically significant association between nipple retraction and NAC invasion (P=0.003) .Other patient's complaints had no statistically significant association with NAC invasion, such as painless lump (P=0.174), painful lump (P=0.711), axillary lump (P=0.500) and bleeding per nipple (P=0.180).

In this study, there was no statistically significant association between breast size (measured using the bra size) and NAC invasion (P=0.186) and this matches with Abou Nagah and El-Sabaa [11].

In this study, there was a statistically highly significant association between focality and NAC invasion (P<0.001). This is in agreement with Zhang *et al.* [7], Wang *et al.* [12] and Weidong *et al.* [13], who suggested that patients with multifocal or multicentric tumours are at a higher risk to have NI, and this is in disagreement with Brachtel *et al*. [14], who found no significant association between multifocal tumours and NAC invasion.

There was a highly significant association between centrally located tumours and NAC invasion, as tumours located in the central areas are more likely to have nipple invasion (NI) compared with peripheral areas (P<0.001). This is in agreement with Wang *et al.* [12], Weidong *et al.* [13], Khan *et al.* [15], Gulben *et al.* [16] and Simmons *et al.* [17].

In this study, there was no statistically significant association between tumour size neither clinically assisted or ultrasound-assisted and NAC invasion (P=0.401 and 0.838). This is in agreement with Loewen *et al.* [18], Schecter *et al.* [19] and Vlajcic *et al*. [20], whose results failed to show any statistically significant association between tumour size and occult NI. This differs from the findings of Zhang *et al*. [7], who reported that the risk for NAC invasion increased significantly in patients with larger tumours.

In this study, there was a statistically highly significant association between the tumour–nipple distance and NAC invasion (P<0.001). This was reported by Weidong *et al*. [13], Brachtel *et al*. [14] and Vlajcic *et al*. [20].

In our study, the optimum cutoff of distance from mass to nipple as a predictor for NAC invasion in breast carcinoma was less than or equal to 4 cm. Therefore, all tumours with distance more than 4 cm from the nipple are expected less likely to have NAC invasion. Therefore, we can conclude that a distance more than 4 cm is needed for NAS mastectomy. This coincides with the finding of Vlajcic *et al*. [20], who found that the NAC could be safely preserved with tumour-to-nipple distance more than 4 cm. This differs from Zhang *et al*. [7], who suggested that a distance of 2.5 cm from the tumour to the nipple is required to reduce the risk for NI.

In our study, there was no statistically significant association between histological type of the tumour and NAC invasion (P=0.624). This is in agreement with Zhang *et al*. [7] and in disagreement with Brachtel *et al*. [14], who found a significantly higher incidence of NI in invasive ductal carcinoma tumours with an extensive intraductal component.

In this study, there was a statistically significant association between histological grade of the tumour and NAC invasion (P=0.002). This is in agreement with Eisenberg *et al*. [21] and Pirozzi *et al*. [22]; however, it differs from Gulben *et al*. [16] and Simmons *et al*. [17], who found no significant association in rates of NAC invasion and tumour grades.

In this study, there was a statistically significant association between positive lymph node invasion and nipple invasion (P=0.001). This coincides with the finding of Mallon *et al*. [23], but in disagreement with the findings of Simmons *et al*. [17], who did not show a higher incidence of NAC invasion in the lymph node positive group.

In this study, there was no statistically significant association between tumour stage and NAC invasion (P=0.342). This is in disagreement with Zhang *et al.* [7], who suggested that patients with stage III and IV diseases were found to be at significantly higher risk for NAC invasion than those with stage I and II diseases.

In our study, there was a statistically highly significant association between ER negativity and NAC invasion, in which 18% of patients without NAC invasion had negative ER versus 90.9% of patients with NAC invasion (P<0.001).

In our study, there was a statistically highly significant association between HER2 positivity and NAC invasion (P<0.001), and this is in agreement with Zhang *et al.* [7], who suggested that patients with positive (HER2) have a higher rate of NAC invasion.

In our study, the incidence of occult nipple malignancy increased with tumour-to-nipple distance less than 4 cm, lymph node metastasis, LVI, HER2 amplification, multicentricity and retroareolar location, and this matches with Mallon *et al.* [23]. However, it is in disagreement with Wang *et al.* [12], who found that NAC involvement is strongly associated with tumour size and the expression levels of ER and PR were not associated with NAC involvement.

According to our study, the ideal patients for NAS mastectomy should have the following criteria: clinically normal NAC, tumour–nipple distance more than 4 cm, no multicentric tumour, absence of lymph node involvement, peripheral and not central tumour and absence of subareolar tumour involvement (LVI). This coincides with Kim *et al.* [24], Gerber *et al.* [25], Petit *et al.* [26], Benediktsson and Perbeck [27] and Simmons *et al.* [17].

Conclusion

According to our study NAS mastectomy is ideal for patients fulfilling the following criteria:

(1) Clinically normal NAC
(2) Tumour–nipple distance more than 4 cm.
(3) No multifocal/multicentric tumour.
(4) No lymph node invasion.
(5) Tumour grade I or II.
(6) Peripheral and not central tumour.
(7) No LVI.
(8) ER receptor positive.
(9) PR receptor positive.
(10) HER2 negative.

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Conflicts of interest

There are no conflicts of interest.

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Short-term outcome of infrapopliteal percutaneous transluminal angioplasty for isolated infrapopliteal lesions in patients with critical limb ischemia

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Objective
The aim of this study was to evaluate the efficacy of percutaneous transluminal angioplasty for isolated infrapopliteal (IP) arterial disease in patients with critical limb ischemia (CLI).
Patients and methods
This prospective study included all CLI patients with IP disease who underwent primary IP angioplasty between January 2014 and January 2016 in our institution. Study endpoints were technical success rate, primary patency, secondary patency, limb salvage, and wound healing.
Results
The mean age of patients was 64.6±13.5 years, with 23 74% men. Twenty limbs were identified as Rutherford category 4 (48%), 16 limbs as Rutherford category 5 (38%), and six limbs as Rutherford category 6 (14%). Initial technical success was 90.5%. Among 38 limbs with initial technical success, primary patency and secondary patency rate were, respectively, 60.5 and 75% at 1 year. Limb salvage rate was 86.8% at 1 year. Wound healing rate was 76.3%. Wounds were completely healed in 15.8%, improved in 60.5%, stable in 13.2%, and worse in 10.5%.
Conclusion
Percutaneous transluminal angioplasty is effective and preferred procedure for IP angioplasty for patients who presented with CLI.

Keywords:
angioplasty, critical limb ischemia, isolated infrapoplital angioplasty

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1110-1121

Introduction

Critical limb ischemia (CLI) is a condition that represents the most advanced form of peripheral artery disease [1]. The recent reports showed that about half of CLI was due to isolated infrapopliteal (IP) lesions [2]. CLI attributable to pure IP lesions might be thought as the most severe form of the peripheral artery disease [3]. Patients with CLI due to infrapopliteal arterial occlusive disease are a high-risk group in which the current reported amputation and mortality rates at 1 year are 25% and 20–25%, respectively [4]. Endovascular treatment is increasingly being used as the preferred method of revascularization in patients with infrapopliteal arterial disease suffering from CLI [5].

The aim of this prospective study was to evaluate the efficacy of percutaneous transluminal angioplasty (PTA) for IP arterial disease in patients with CLI. This aim is proved by detection of short-term results of primary patency, secondary patency, limb salvage, and healing rate.

Patients and methods

This prospective study was carried out in the Vascular Surgery Department, Faculty of Medicine, Sohag. All patients gave their formal consent. The protocol was approved the Ethical committee of the faculty. The study included all CLI patients with IP disease who underwent primary IP angioplasty between January 2014 and January 2016.

Exclusion criteria

(1) CLI patients presenting with functionally unsalvageable limbs with spreading ischemic ulcer or gangrene past the ankle requiring primary major amputation.
(2) CLI patients with iliac artery lesions or femoral artery lesions or multilevel lesions.

The institutional review board has approved the study and written informed consent was obtained from all patients before the procedure.

Preprocedure assessment

All patients were subjected to history taking, clinical examination, and radiological imaging.

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Preprocedure medication

Dual antiplatelet therapy [aspirin (100 mg/day), clopidogrel (75 mg/day), or cilostazol (200 mg/day)] was initiated for all patients 1 week before PTA.

Technique

Six French sheath was placed after ipsilateral puncture of the common femoral artery under local anesthesia. Intra-arterial bolus of 5000 IU of heparin was given. Infrapopliteal lesions were passed with a 0.018 hydrophilic guide wire. Balloon angioplasty was performed using 2.5 mm diameter balloon to avoid arterial injury and the diameter was increased to 3 or 3.5 mm according to the diameter of the artery.

When multiple stenosis or occlusions were noted in below-the-knee arteries, the aim was to dilate all arteries. However, if it was difficult to open all infrapopliteal arteries, the priority was to achieve direct flow to the tissue site based on the angiosome concept.

Postprocedure angiography

Completion angiography was performed immediately after the angioplasty procedure.

Debridement of extensive gangrene was mostly performed immediately after the end of the angioplasty procedure.

Postprocedure medication

The patients were given dual antiplatelet therapy for 3 months after PTA.

Follow-up

Before the patient's discharge from the hospital and at 1, 3, 6, and 12 months after PTA, all patients were evaluated with clinical examination and duplex imaging.

On clinical examination I looked for the following:

(1) Wound healing.
(2) Absence of rest pain.
(3) Absence of tissue necrosis and gangrene.

On duplex imaging I looked for target vessel restenosis, which was diagnosed by measuring the peak systolic velocity (PSV) in the target segment of the vessel and compared with the PSV in the preceding normal segment of the same vessel. A focal increase in PSV in the target segment of the vessel of at least 140% greater than the preceding normal segment was considered indicative of more than 50% restenosis at that site.

CTA was performed for patients who presented with return of symptoms of CLI associated with restenosis or occlusion of the treated arterial segment for more detailed anatomical information needed for reintervention (Figs 1 and 2).

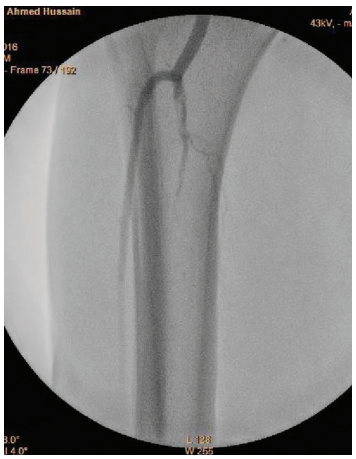
Endpoint

Primary endpoints were technical success rate, primary patency, and secondary patency.

Secondary endpoints were limb salvage and wound healing.

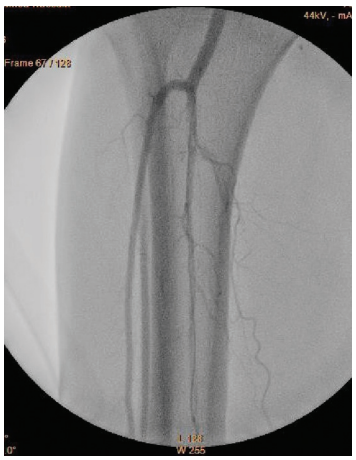
Technical success was defined as a residual stenosis less than 30% with sufficient antegrade flow and achieving straight-line flow from the aorta down to either a patent dorsalispedis or plantar artery at final angiography [6].

Figure 1



Pre intervention angiography

Figure 2



Post intervention angiography

Primary patency was defined as the absence of occlusion or significant restenosis within the treated segment [7].

Secondary patency was defined as patency that was achieved utilizing secondary endoluminal procedures, which involved recanalizing occluded arterial segments [5,8].

Limb salvage was defined as prevention of major amputation [9].

Major amputation was defined as limb loss below or above the knee [9].

Minor amputation was defined as a transmetatarsal amputation or more distal level amputation of the lower extremity [9].

Wound healing was documented as complete, improved, stable, or worse [10].

Statistical analysis

Data are presented as mean±SD for continuous variables and data are presented as counts (percentages) for categorical variables. The primary patency rate, the secondary patency rate, and the limb salvage rate were estimated using the Kaplan–Meier method.

Results

During the study period, 31 patients underwent PTA for 42 limbs. The baseline characteristics of the study patients are shown in Table 1. The mean age of the study population was 64.6±13.5 years, with 23 (74%) men. Many patients had significant comorbidities, including hypertension (68%), diabetes mellitus (71%), cerebrovascular stroke (13%), coronary artery disease (55%), and renal failure (16%). Moreover, 19 (61%) patients had a history of smoking. Twenty limbs were identified as Rutherford category 4 (48%), 16 limbs as Rutherford category 5 (38%), and six limbs as Rutherford category 6 (14%).

Table 1 The baseline characters of the study patients

Total number of patients	31
Demographic characteristics of patients	
Age	64.6±13.5
Male	23 (74)
Comorbid disease of patients	
Hypertension	21 (68)
Diabetes mellitus	22 (71)
Cerebrovascular stroke	4 (13)
Coronary artery disease	17 (55)
Chronic renal failure	5 (16)
Smoker	19 (61)
Clinical category of limbs (42)[a]	
Rutherford criteria+ 4	20 (48)
Rutherford criteria+ 5	16 (38)
Rutherford criteria+ 6	6 (14)

Data expressed as the mean±SD or *n* (%) of patients. [a]Rutherford classification reference [7].

Angiographic findings of the study patients

Angiographic findings of the study patients are shown in Table 2. A total 91 lesions were treated in 42 limbs of 31 patients. Anterior tibial artery was the most commonly affected artery with 45 (49.5%) lesions, followed by the posterior tibial artery with 27 (29.7%) lesions, the peroneal artery with 16 (17.5%) lesions, and, lastly, the tibioperoneal trunk with three (3.3%) lesions. Sixty-five of total 91 (61.5%) lesions were stenotic lesions. The lesion length was 9.7±7.8 cm.

Outcome variables of the study patients

Outcome variables of the study patients are shown in Table 3. Initial technical success was achieved in 38 (90.5%) limbs. Among 38 limbs with initial technical success, primary patency and secondary patency rates were, respectively, 60.5 and 75% at 1 year. During the follow-up, eight patients underwent successful repeated angioplasty.

Limb salvage rate was 86.8% at 1 year. During the follow-up, five patients required major amputation. Amputation was performed for two patients after intervention at 30 days and for the three other patients amputation was performed later. Four of

Table 2 Angiographic findings of the study patients

	n (%)
Affected arteries	
Anterior tibial art	45 (49.5)
Posterior tibial artery	27 (29.7)
Peroneal artery	16 (17.5)
Tibioperoneal trunk	3 (3.3)
Type of lesions	
Stenosis	56 (61.5)
Occlusion	35 (38.5)
Lesion length (cm)	9.7±7.8

Table 3 Outcome variables of the study patients

Outcome of the study patients	*n*/*N* (%)
Technical success	38/42 (90.5)
Primary patency	23/38 (60.5)
Secondary patency	6/8 (75)
Limb salvage	33/38 (86.8)
Wound healing	29/38 (76.3)

these patients presented with thrombosis of the treated artery and one patient presented with wound infection despite patent treated arteries. Wound healing rate was 76.3%. Wounds were completely healed in 15.8%, improved in 60.5%, stable in 13.2% and worse in 10.5%.

Discussion

The development of the endovascular techniques has resulted in an increase in the endovascular infrapopliteal revascularization. Endo vascular treatment (EVT) has become commonplace as the revascularization strategy for infrapopliteal lesions in patients with CLI [11].

Balloon angioplasty remains the most appropriate endovascular treatment modality for infrapopliteal disease, even with severe disease and suboptimal runoff [12].

In this study, we intentionally selected CLI patients with IP disease to demonstrate the efficacy of angioplasty alone on this type of arterial disease and demonstrate its effect on the healing process. The primary patency rate and secondary patency rate in this study were, respectively, 60.5 and 75% at 1 year.

Our results in terms of primary patency rate and secondary patency rate can be considered comparable to those reported in the literature [13]. Romiti *et al.* [13] reported in meta-analysis study including 30 studies (2557 cases) published between 1990 and 2006, dealing with PTA performed for IP lesion, a primary patency rate 58% and a secondary patency rate 74% at 1 year.

Our results are lower than those reported by Tartaglia *et al.* [14] and included 101 diabetic patients who underwent infrapopliteal angioplasty. Tartaglia *et al.* [14] reported that the primary patency rate and secondary patency rate were 67 and 83% at 1 year, although diabetes as a risk factor was present in all cases of Tartaglia *et al.* [14] study, it was present only in 71% of patients in this study. This can be explained by comparing the lesion length in the two studies. The mean length of lesions in this study is 9.7 cm, but in the study by Tartaglia *et al.* [14] it was 4.5 cm.

Moreover, our results are lower than those reported by Ryu *et al.* [9]. Ryu *et al.* [9] reported that, among 82 CLI who underwent infrapopilteal angioplasty with initial technical success, the primary patency rate was 70.7% at 1 year; however, the secondary patency rate was not delineated. Rye *et al.* [9] did not demonstrate the lesion length in the treated arteries to know the severity of the atherosclerotic disease of the treated arteries.

Our results are higher than those reported by Giles *et al.* [10], which included 176 consecutive limbs that underwent infrapopliteal angioplasty for CLI. Giles *et al.* [10] used stents for lesions refractory to PTA. The primary patency rate at 1 year in the study by Giles *et al.* [10] was 53%; however, the secondary patency was not delineated. Giles *et al.* [10] attributed the low patency rate in their study to presence 29% of patients with TASC D lesion, which had adverse impact on restenosis, as reported by Kudo *et al.* [15].

Moreover, our results are higher than that reported in the study by Fernandes *et al.* [6], which included 54 limbs of isolated tibial disease. The primary patency rate and secondary patency rate at 1 year were 37 and 65%, respectively.

The incidence of limb salvage in the current study was 86.8%, at 1 year. Our result in terms of limb salvage can be considered comparable to those reported in the literature [10,13,14]. Romiti *et al.* [13] reported that the limb salvage rate was 85% at 1 year. Giles *et al.* [10] and Tartaglia *et al.* [14] reported that the limb salvage rate was 84% at 1 year. Our result is lower than that reported by Rye *et al.* [9]. Rye *et al.* [9] reported that the limb salvage rate was 97.6% at 1 year. In contrast, our result is higher than that reported by Fernandez *et al.* [2]. Fernandez *et al.* [2] reported that the limb salvage rate in the group of isolated tibial disease was 81 and 74.8% at 9 and 12 months, respectively.

The healing rate in the current study was 76.3% at 1 year. According to wound healing classification documented in our study, the incidence of complete wound healing was 15.8%, that of improved wound healing was 60.5%, stable wound size with no healing was 13.2%, and worse wound healing was 10.5%. Healing rate in the current study can be considered comparable to that reported in the literature [14]. Tartaglia *et al.* [14] reported that the healing rate was 78% at 1 year. According to the Armstrong classification, healing rate was 100% when wound depth was grade 1, 91% when grade 2, 88% when grade 3, and 30% when grade 4. Our results are higher than those reported in other studies [8,10]. Giles *et al.* [10] reported that the healing rate was 57% at 1 year. According to wound healing classification documented in the study by Giles *et al.* [10], complete wound healing was 0%, improved wound healing was 57%, stable wound size with no healing was 22%, and worse

wound healing was 21%. Moreover, Fernandez *et al.* [2] reported that wound healing or improvement was 69% in the isolated tibial arteries group. The mean overall follow-up was 12.6±5.3 months.

Study limitations

First, this study was conducted in a single center and with a relatively small study population. Further multicenter studies with large numbers of patients are required to confirm the present results. Second, this is a short-term follow-up study. Further long-term follow-up study of the patients should be considered.

Conclusion

PTA is an effective procedure for IP angioplasty for patients who presented with CLI and gives good results in terms of primary patency, secondary patency, limb salvage, and healing rate along short-term follow-up. These results encourage the usage of PTA as a preferred procedure for IP angioplasty, but more studies with long-term follow-up are needed.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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Laparoscopic purse-string suture sac closure is appropriate procedure for children with unilateral indirect inguinal hernia: comparative study versus laparoscopic sac excision and closure procedure

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Objective
Evaluation of immediate and 6-month postoperative (PO) outcomes of laparoscopic repair of unilateral indirect inguinal hernia (IIH) and comparison of outcomes of purse-string versus stitch closure of the deep inguinal ring (DIR).
Patients and methods
The study included 84 children who had unilateral IIH, and they were randomly divided into two groups: group I included patients who underwent sac disconnection and stitch closure, and group II included patients who underwent purse-string suture closure of DIR without manipulation or sac dissection. PO pain sensation was evaluated using the observational pain-discomfort scale. Time till first oral intake, length of PO hospital stay, and immediate and 6-month PO outcomes were determined.
Results
One patient in group I was converted to open procedure and another patient in group II required sac disconnection. Patients of group II had significantly shorter operative time, lower collective observational pain-discomfort scale pain score, and shorter time till first oral intake and duration of PO hospital stay compared with patients of group I. A total of three (3.6%) patients developed port site wound infection. At the end of follow-up, in group I, one patient developed hydrocele and three patients developed recurrent hernia, for a 6-month PO complication rate of 9.8%. In group II, one (2.4%) patient developed recurrent hernia.
Conclusion
Application of laparoscopic purse-string suture closure of the DIR shortens operative time, time till first oral intake, and home return of children with unilateral IIH with low 6-month recurrence rate than disconnection and stitch closure of the DIR (2.4 vs. 7.3%).

Keywords:
children, laparoscopic purse-string suture deep ring closure, recurrence rate, unilateral indirect inguinal hernia

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Introduction

Repair of an indirect inguinal hernia (IIH) is one of the most common operations performed around the world by pediatric surgeons [1]. Inguinal hernia in children is traditionally repaired through a groin incision by dissecting the hernia sac from the spermatic cord and suture ligating its base [2]. However, inguinal hernia repair (IHR) with opening of the external ring, hernia sac twisting, and double ligation of the processus vaginalis confers no advantage for repair [3].

The application of laparoscopic surgery to the treatment of inguinal hernia is a revolution in IHR surgery [4]. Laparoscopic hernia repair has emerged as an alternative technique for traditional open hernia repair in children [5].

Many techniques have been developed for a simplified and safe procedure with a low recurrence rate, and good cosmetic result is the main concern [6], and various methods of repair have been described especially concerning suture ligation of the neck of the hernia sac at the deep ring with or without its transection[7], use of periperitoneal stitching or purse-string suture [8], and whether to apply intracorporeal or extracorporeal suturing [1].

Hypothesis

Purse-string suture deep inguinal ring (DIR) closure without any further manipulation will improve immediate postoperative (PO) outcome without

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compromising 6-month PO outcome of laparoscopic repair of unilateral IIH in children.

Objective

The objective is to evaluate the immediate and 6-month PO outcomes of laparoscopic repair of unilateral IIH and to compare outcomes of purse-string versus stitch closure of the DIR.

Design

This was a prospective single-blinded two-armed comparative study.

Setting

The study was conducted in El-Minia University Hospital, Egypt.

Patients and methods

The current study was conducted at Department of General Surgery, Faculty of Medicine, El-Minia University, from March 2015 until October 2016, to allow a minimum follow-up period of 6 months for the last case operated up on. The study protocol was approved by the local ethical committee. Parents of enrolled patients had to sign a written fully informed consent concerning the study plan and the laparoscopic approach. The study was conducted on 84 cases – 69 males and 15 females – with mean age range of 1–3 years.

Patients requiring additional surgical procedures at the same setting, had complicated IIH, recurrent inguinal hernia, umbilical hernia, other indications for open laparotomy, contraindication for pneumoperitoneum, or bleeding diathesis were excluded from the study. Moreover, patients whose parents refused to sign the consent form or could not attend the follow-up visits were excluded from the study. All patients underwent full clinical examination for assurance of inclusion and exclusion criteria and were evaluated on the night of surgery by anesthetist in charge.

Operative procedure

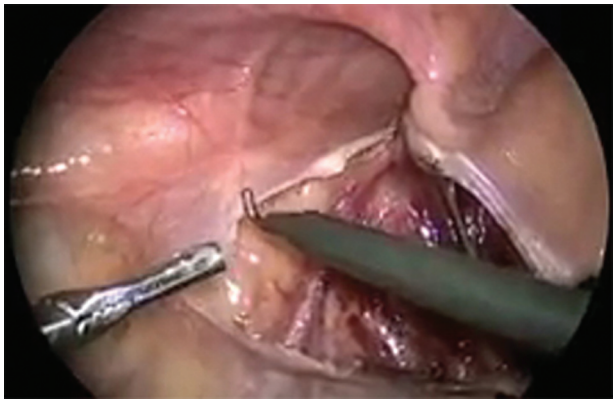
Patients were randomly, using sealed envelopes prepared by blinded assistant and chosen by parents of enrolled children, divided into two groups according to mode of the DIR closure. All patients received general anesthesia with nasal tracheal intubation and received one intravenous injection of third generation cephalosporin at dose of 50 mg/kg body weight.

Primary umbilical port (5 or 10 mm) was inserted by open cannulation, and pneumoperitoneum was created at a pressure of 10 mmHg. Inguinal anatomy was assessed with a straight telescope for assurance of indication and exploring the competence of the other inguinal ring. Two 5-mm working ports were inserted one on each side of the umbilicus. A hernia was defined as an open DIR of any size. The peritoneum was incised, both testicular vessels and vas deference were identified, and then the peritoneal incision was completed circumferentially to excise the sac tissue. The resultant peritoneal defect was closed by a stitch of 4/0 vicryl using intracorporeal knotting in patients of group I (Fig. 1). In patients of group II, no manipulation or dissection of vas deferens, testicular vessels, or sac was performed; a purse-string suture including 5–6 bites using 4/0 vicryl was inserted in the periorifical peritoneum (Fig. 2a) and tightened with intracorporeal knotting (Fig. 2b).

Postoperative care

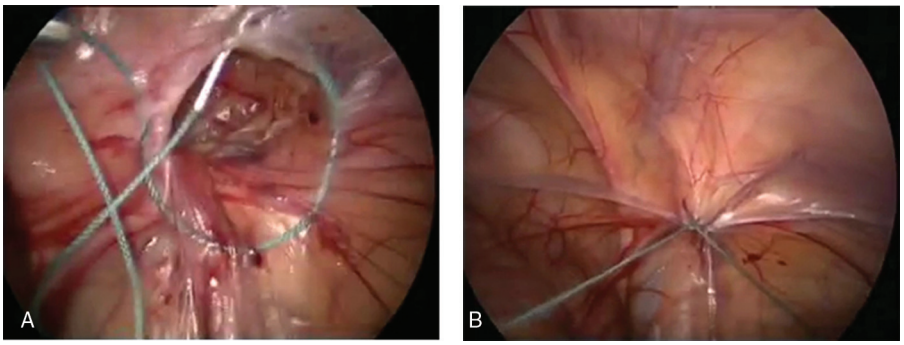
All patients received their immediate PO care at pediatric postanesthetic care unit. Pain sensation was evaluated using the observational pain-discomfort scale (OPS) [9] which assesses behavioral objective parameters, namely crying, facial expression, position of torso, position of the legs, and motor restlessness using a three-point scale, with 1=none, 2=moderate, and 3=severe to give a cumulative score of 5–15, and analgesia was provided in the form of paracetamol suppository (30 mg/kg) at OPS was more than 11 on two subsequent observations 10 min apart. Mean OPS score was recorded at 30, 60, and 90 min PO, and frequency of rescue analgesia administrations was also recorded. Time till first oral intake and duration of PO length of hospital stay were determined. Parents were asked to attend the outpatient clinic for follow-up at twice a weekly for 1 month and at 3 and 6 months PO. Follow-up examination included determination of the frequency of wound infection, development of

Figure 1



Laparoscopic sac dissection in cases of the first group

Figure 2



a: Insertion of a purse string suture in the periorificial peritoneum. b: Tightening of purse string suture and intracorporeal knotting.

secondary hydrocele, testicular atrophy, or hernia recurrence.

Statistical analysis

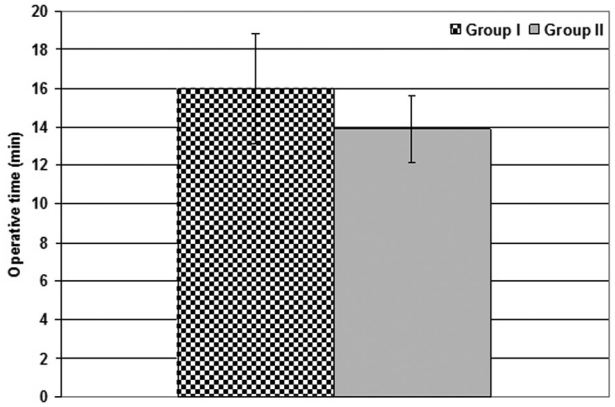
Obtained data were presented as mean±SD, ranges, numbers, and ratios. Results were analyzed using one-way analysis of variance with post-hoc Tukey HSD test and χ^2-test. Statistical analysis was conducted using the SPSS (version 15, 2006; SPSS Inc., Chicago, Illinois, USA) for Windows statistical package. *P* value less than 0.05 was considered statistically significant.

Results

The study included 84 patients who had unilateral IIH; 69 were males and 15 females, with mean age of 2.1± 0.8 years and range of 1–3 years, with nonsignificant difference ($P>0.05$) between both groups. One patient in group I showed adhesions between sac wall and vas deferens that was difficult to be dissected laparoscopically for fear of vas injury, so this patient was converted to open procedure and vas was completely dissected, and surgery was completed uneventfully for an open conversion rate of 2.4% in group I; no patient in group II required open conversion, so the open conversion rate for total study population was 1.2%. Another patient in group II required sac disconnection because of sac tearing during dissection, and surgery was completed uneventfully for a decision–conversion rate of 2.4%. Mean operative time for cases that underwent complete laparoscopic repair was significantly ($P=0.001$) shorter in patients of group II compared with patients of group I (Fig. 3). Intraoperative blood loss was minimal in both groups with nonsignificant difference ($P>0.05$) (Table 1).

The OPS scores determined at 30-min PO were significantly ($P=0.001$) lower in patients of group II compared with patients of group I. Mean OPS determined at 60 and 90-min PO were nonsignificantly lower in patients of group II compared with those of group I, but collective OPS pain score was significantly ($P=0.001$) lower in patients

Figure 3



Operative time (mean±SD) for laparoscopic repair of unilateral indirect inguinal hernia in both groups

Table 1 Preoperative and operative data of patients of studied groups

Data	Group I [*n* (%)]	Group II [*n* (%)]	*P* value
Preoperative			
Age (years)			
1	14 (33.3)	8 (19)	NS
2	13 (31)	22 (52.4)	
3	15 (35.7)	12 (28.6)	
Mean±SD	2±0.8	2.1±0.7	NS
Sex			
Male	34 (81)	35 (83.3)	NS
Female	8 (19)	7 (16.7)	
Operative			
Operative time (min)	16±2.8	13.9±1.7	0.001
Open conversion	1 (2.4)	0	NS
Decision–conversion	0	1 (2.4)	NS

Data are presented as numbers and mean±SD. Percentages are in parenthesis. NS, nonsignificant difference between both groups. $P<0.05$, significant difference between both groups.

of group II compared with group I. A total of 49 patients required rescue analgesia once, whereas 35 patients required it for two times, with significantly (P=0.046) lower frequency of patients who received rescue analgesia once in group II compared with group I (Fig. 4).

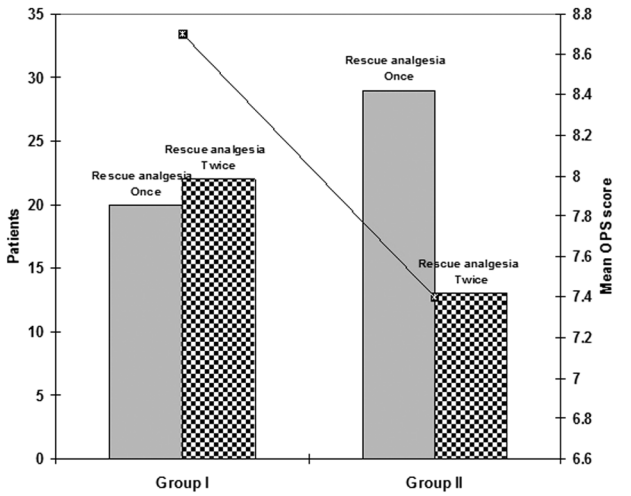
Patients of group I received their first oral intake significantly (P=0.005) earlier, with significantly higher frequency of patients who received their first oral intake within 60 min in group II than patients of group I. Mean PO hospital stay was significantly shorter, with significantly (P=0.033) higher frequency of patients discharged within 3 h PO in group II compared with patients of group I (Fig. 5). A total of three (3.6%) patients developed port wound infection – two in group I and one in group II – with nonsignificant (P>0.05) difference between both groups despite being in favor of group II. At the end of follow-up, in group I, one patient developed hydrocele and three patients developed recurrent hernia for a long-term complication rate of 9.5%. On the contrary, in group II, only one patient developed recurrent hernia, for a 6-month PO complication rate of 2.4%, with nonsignificantly (P>0.05) higher frequency of 6-month PO complication among patients of group I (Fig. 6 and Table 2).

Discussion

The study included 84 children with unilateral IIH, and diagnosis was ensured during laparoscopic examination to assure competent contralateral inguinal orifice. In line with laparoscopic diagnosis conformation of hernia laterality, Mortellaro *et al.* [10] reported minimal risk of infection or recurrence following unilateral IIH repair, and this risk is not increased with the use of contralateral exploration using laparoscopy.

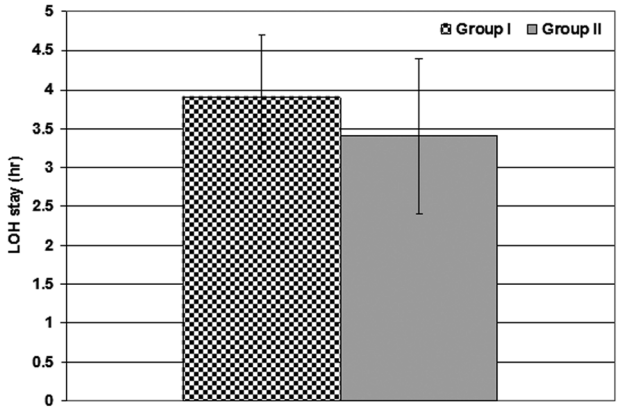
The current study was biarmed: the first for evaluation of outcome of laparoscopic indirect inguinal hernia repair (IIHR) and the second for evaluation of outcome purse-string suture closure versus stitch closure of DIR. Regarding the first arm outcome, only one patient of the total study population required open conversion for dissection of dense adhesions between vas and sac for an open conversion rate of 1.2%. A total of three patients developed port site wound infection for a rate of 3.6%. Concerning long-term complications, five patients developed PO complications for a rate of 6%; one developed hydrocele and four developed recurrent hernia.

Figure 4



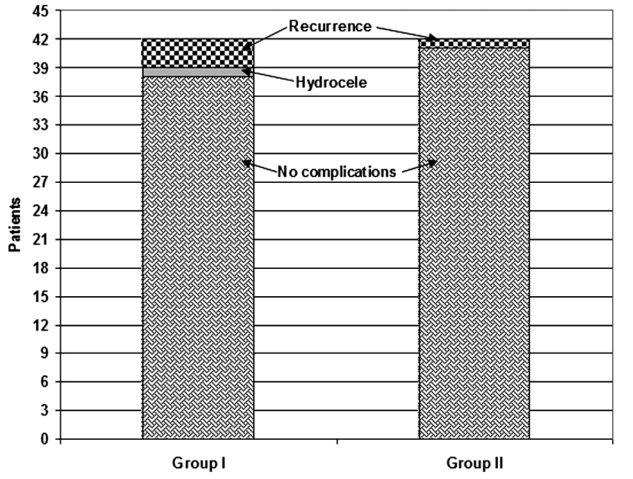
Mean observational pain-discomfort scale (OPS) pain score and frequency of requests of rescue analgesia by patients of both groups

Figure 5



Length of hospital stay (LOH) (mean±SD) of patients of both groups

Figure 6



Long-term outcomes of patients of both groups

Table 2 Postoperative immediate and 6-month postoperative outcomes of patients of studied groups

Data	Group I [*n* (%)]	Group II [*n* (%)]	*P* value
Immediate outcome			
Pain score			
30 min	10.3±2.7	7.6±4.1	0.001
60 min	8.1±3.5	7.6±3.7	0.542
90 min	7.8±3.8	6.8±4.1	0.263
Mean score	8.7±1.6	7.4±1.5	0.001
Frequency of rescue analgesia administration			
Once	20 (47.6)	29 (69)	0.046
Two times	22 (52.4)	13 (31)	
Time till first oral intake			
≤60	2 (4.8)	8 (19)	0.043
>60	40 (95.2)	34 (81)	
Mean	85.4±12.1	77.8±13.4	0.008
LOH stay			
2 h	0	7 (16.7)	0.033
3 h	15 (35.7)	20 (47.6)	
4 h	16 (38.1)	8 (19)	
5 h	11 (26.2)	7 (16.7)	
Mean	3.9±0.8	3.4±1	0.005
Port site wound infection	2 (4.8)	1 (2.4)	0.556
6-month PO outcome			
Hydrocele	1 (2.4)	0	0.456
Port site hernia	0	0	0
Hernia recurrence	3 (7.1)	1 (2.4)	0.306

Data are presented as numbers and mean±SD. Percentages are in parenthesis. LOH, length of hospital stay; NS, nonsignificant difference between both groups; PO, postoperative. $P<0.05$, significant difference between both groups.

The reported collective outcome of laparoscopic IIHR goes in hand with literature [2,11–16] which previously reported varied figures for open conversion, regarding short-term and long-term complications. Moreover, the reported figures coincided with that recently reported, in 2017, by Gause *et al.* [17], Zhao *et al.* [18], and Davies *et al.* [19] who found laparoscopic unilateral IIHR demonstrated shorter operative time [17,19] and was associate with a lower recurrence rate and lower PO complications [18] and concluded that minimally invasive IIHR is safe and effective [19].

In support of the efficacy of laparoscopic IIHR, multiple previous trials concluded that laparoscopic herniorrhaphy is a good alternative option in recurrent childhood hernia [20], to avoid the difficulties of redo surgery in scarred operative field with delicate structures liable [21], in bilateral hernias [22,23].

Intracorporeal knotting was used for tightening of the stitch applied after sac disconnection in group I or the purse-string suture in group II. In support of the use of intracorporeal knotting, Shalaby *et al.* [24] compared intracorporeal versus extracorporeal knotting of purse-string suture around the internal inguinal ring and reported significant differences in the operative time, recurrence rate, and cosmetic results between the studied groups.

Patients of group II who had DIR closure using purse-string periorificial peritoneum stitching did favorably better than patients who had sac disconnection and stitch closure of DIR in terms of significantly shorter operative time, lower PO pain scores, earlier resumption of oral intake, and shorter PO hospital stay. Moreover, only one patient developed PO port site wound infection and another developed recurrent hernia for PO complications rate of 2.4%. In line with these findings, Montupet [25] using a purse-string suture around the periorificial peritoneum after sac sectioning reported a recurrence rate of 1.5%. Moreover, Wheeler *et al.* [26] documented that laparoscopic pediatric IIHR with transperitoneal division of the hernia sac and purse-string closure of the proximal peritoneum allows for a minimally invasive option for pediatric IIHR with high parent satisfaction, minimal scarring, and good cosmetic results. Thereafter, Cho *et al.* [27] in a series of laparoscopic pediatric IHR using intracorporeal knotting of purse-string suture at sac neck reported a recurrence rate of 1.8% and PO groin swelling that resolved spontaneously in 1.8%, but iatrogenic PO cryptorchidism requiring subsequent orchidopexy was reported in 2.7% of patients. Moreover, Shalaby *et al.* [28] found that during follow-up period of 10–140 months, the recurrence

rate ranged between 0 and 1.13%, hydroceles occurred in 0.58%, and no occurrence of testicular atrophy or iatrogenic ascent of the testis after laparoscopic IIHR using transperitoneal purse-string suture technique. Moreover, Lee *et al.* [29] suggested that the laparoscopic purse-string suture of internal inguinal opening of hernia sac could be a safe, effective, and reliable alternative for management of pediatric inguinal hernia, and McClain *et al.* [30] using extra corporally tied purse-string suture reported that during laparoscopic unilateral IIHR, mean operating time was 20.5 min with PO minor complication rate of 4% and recurrence rate of 0.56%. Thereafter, Steven *et al.* [16] compared surgical outcomes for a simple purse-string method of laparoscopic IIHR with traditional open IIHR in children and found recurrence and overall complication rates were 2.9 and 7.8%, respectively, with laparoscopic, but were 3.9 and 9.9%, respectively, with open. Recently, in 2017, Esposito *et al.*[31] performed purse-string suture on periorificial peritoneum in inguinal orifice diameter more than or equal to 10 mm and N-shaped suture in orifices less than or equal to 5 mm and reported a recurrence rate of 0.3% and complication rate of 1.5%.

Conclusion

Laparoscopic purse-string suture closure of the DIR shortens operative time, time till first oral intake, and home return of children with unilateral IIH with low 6-month recurrence rate than laparoscopic sac disconnection and DIR stitch closure (2.4 vs. 7.3%).

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Conflicts of interest

There are no conflicts of interest.

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Endovascular management of Trans-Atlantic Inter-Society Consensus C and D aortoiliac occlusive disease as a feasible, effective, and durable intervention

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Context
The progress and innovations in endovascular tools have replaced standard surgical intervention with endovascular intervention, including long, complex lesions.
Aim
The aim of the study was to evaluate the results of endovascular management as the first-approach intervention for symptomatic extensive Trans-Atlantic Inter-Society Consensus (TASC) C and D aortoiliac disease.
Patients and methods
This was a prospective study. Fifty patients with long, complex TASC C and D aortoiliac lesions underwent revascularization by endovascular-first approach. Technical success and follow-up results after 6, 12, and 24 months were documented. SPSS software version 18 was used for statistical analyses.
Results
Of the 50 patients, 84% were male. All the patients had TASC C and D lesions and 66% of them had critical limb ischemia. All the patients were treated by endovascular-first approach. A total of 92 stents were used, of which 66.3% were balloon mounted, and they were located in the common iliac artery.
The technical success rate was 90%, and the ankle–brachial (A/B) index improved significantly (P=0.0001). The primary patency rates were 100, 81.8, and 80% at 6, 12, and 24 months, respectively. A total of 6.6% of patients developed major complications, which were successfully managed. Mortality rate was 2.2%, which was not procedure related.
Conclusion
The endovascular-first approach could be a good alternative and replace the standard surgical management for long, complex aortoiliac occlusive disease.

Keywords:
angioplasty, aortoiliac disease, endovascular intervention

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Introduction

Peripheral arterial disease (PAD) is pandemic, affecting 200 million people worldwide [1]. Aortoiliac occlusive disease represents 30% of all patients with PAD [2]. Atherosclerosis is the most common cause of occlusive disease affecting aortoiliac segment. It induces ischemia either by flow reduction to the distal arterial bed or by breaking down with embolization of its fragment occluding distal arterial vessels [3]. Atherosclerosis is the third leading cause of cardiovascular morbidity reducing quality of life even in patients classified as asymptomatic [4]. Endovascular approach recomended as a first intervention for aortoiliac occlusive disease by the the Society for Cardiovascular Angiography and Interventions (SCAI) [5], Trans-Atlantic Inter-Society Consensus (TASC) [6], and the American College of Cardiology and American Heart Association (ACC/AHA) guidelines, for TASC A and B [7]. Endovascular interventions performed in the aortoiliac segment offer a good technical success (>90%), low complication rate (2.7%) as compared with the standard surgical intervention, and good durability rate [8]. The aim of this study was to prospectively evaluate the technical and clinical success and patency rate over 24 months of endovascular intervention-first approach for symptomatic extensive TASC C and D aortoiliac disease.

Patients and methods

This was a prospective clinical study conducted at Kasr Ani University Hospital and National Institute of Diabetes and Endocrinology Disease over a 2-year

period starting from September 2014 till the end of September 2016.

This study was approved by the ethical committee of the Department of Vascular Surgery on 2014. All patients were informed about the risks and benefits of the procedure, and the written informed consents were obtained before enrollment.

The number of patients enrolled in this study was 50. All patients had PAD affecting the aortoiliac segment, which could be classified anatomically into either TASC II class C or D aortoiliac lesions. The recruited patients had incapacitating claudication in the buttock, thigh, and calf; ischemic rest pain (Rutherford class IV); tissue loss in the form of small ulcer (Rutherford class V); or gangrene (Rutherford class VI).

Patients who had limbs requiring primary amputation, patients with TASC II A or B aortoiliac lesions, patients who needed extra anatomic procedures for their lesions, patients with all arterial lesions associated with arterial–venous malformation, patients with all arterial lesions associated with aneurysmal dilatation, patients with connective tissue disorder or immunological disease, and patients who refused to participate were excluded from the study. All risk factors including smoking, diabetes, hypertension, ischemic heart disease, renal impairment, and cerebrovascular disease were determined and successfully controlled.

Interventions

All procedures were carried out under local anesthesia except for patients who experienced rest pain; the procedures for those patients were carried out under conscious sedation (midazolam, 1–2.5 mg) and intravenous analgesia.

The types of access were retrograde ipsilateral femoral, contralateral femoral with up and over the aortic bifurcation alone or in combination with antegrade brachial, or bilateral retrograde femoral. A 6-F sheath (Avanti, Cordis; Johnson and Johnson Company) was used; for contralateral cross-over aortic bifurcation approach the sheath was 45 cm long and for straight sheath through the brachial artery it was 90 cm long.

No re-entry devices were used. Hydrophilic normal-angled tip (0.035 or 0.018 inch, 260 cm) (Terumo guidewire; Terumo, Boston Scientific) was used to cross the lesion.

Predilatation was carried out using aortic balloon; 12–16 mm in diameter and 30–60 mm in length for aortic lesions and 5–8 mm in diameter and 20–80 mm length for iliac lesions. Inflation time ranged from 15 to 60 s. Balloon-expandable stents were inserted in the aortoiliac lesions and self-expandable stents in external iliac artery (EIA) lesions.

Technical success was assessed based on the presence of pulse distal to the treated segment. Angiographic success was assessed based on the good flow through the stented segment with no flow-limiting dissection or residual stenosis of more than 30%.

Sheath was removed immediately after the procedure using manual compression for 15–20 min. Patients was prescribed clopedogrel 75 mg once daily and acetylesalsylic acid 75 mg once daily on discharged. Patients were followed up for 1, 3, 6, and 12 months by clinical examination and duplex ultrasonography study. Restenosis was assessed using completion computed tomography angiography; reintervention was done when there was clinical indication.

Data analysis and statistical methods

Technical success was defined as good refilling in completion angiography with no residual hemodynamic (significant stenosis $\leq$30%), return of distal pulse or increase in ankle–brachial (A/B) index by 1.

Primary patency and limb salvage were determined. Loss of primary patency rate was determined based on the loss of previous palpable pulse and duplex ultrasonography findings.

The collected data were tabulated and statistically analyzed using statistical package for the social sciences (SPSS) software (version 18; SPSS Inc., Chicago, Illinois, USA). For quantitate data, mean, SD, median, and range were calculated. For qualitative data, number, percent, and distribution were calculated. Paired *t*-test was used to calculate the difference in the mean values of A/B index before and after intervention. For interpretation of the significance of the results, significance was adopted at *P* value less than or equal to 0.05.

Results

Over a period of 20 months, a total of 50 patients were prospectively enrolled in the treatment of aortoiliac lesions. At 12 months, clinical and duplex ultrasonography follow-ups were obtained for all patients.

Patients demographic, indication, and comorbidity

The number of patients eligible for this study, who fulfilled the inclusion criteria, was 50; of which 42 (84%) were men and 8 (16%) were women (Fig. 1). Their age ranged from 40 to 90 years, with a mean± SD of 58.7±8.9 years. Table 1 summarizes demography and comorbidity in the patients. A total of 22 (44%) patients presented with incapacitating claudication (Rutherford class III), 18 (36%) presented with rest pain (Rutherford class IV), seven (14%) presented with nonhealing ulcer (Rutherford class V), and three (6%) presented with gangrene proximal to metatarsal bone (Rutherford class VI) (Fig. 2).

The frequency of TASC II C and D is illustrated in Fig. 3. The total number of lesions was 113 in 50 patients, of which 86 lesions were total occlusion, whereas 27 were stenosis. Seven (14%) patients had aortic involvement, 13 (26%) had their common iliac artery (CIA) totally occluded, and 22 (44%) had had occlusive lesions involved both EIA and CIA (Table 2).

Technical details

Access

The types of access were single access in 12 (24%) patients, ipsilateral retrograde femoral approach in two (4%), contralateral cross-over approach in four (8%), and brachial approach in six (12%). Double access was used in 35 (70%) patients; bilateral femoral access was used in 21 (42%) patients, whereas combined femoral and brachial access was used in 14 (28%) patients. For three (6%) patients, triple access was used: bilateral femoral, popliteal, and brachial approaches. Hybrid technique was used in two (4%) patients (Table 3).

Crossing the lesion

In 20 (40%) patients lesions were crossed intraluminally and in 26 (52%) patients lesions were crossed subintimally, whereas in four patients lesions were failed to be crossed and they were excluded from further patency and follow-up analyses (Table 3). No re-entry devices were used.

Table 1 Summarizes demography and comorbidity in the patients

Variables	*N* (%)
Smoking habits	
Smoker	29 (58.0)
Nonsmoker	16 (32.0)
Ex-smoker	5 (10.0)
HTN	40 (80.0)
IHD	38 (76.0)
DM	38 (76.0)
Dyslipidemia	15 (30.0
CVS	8 (16.0)
Renal impairment	3 (6.0)

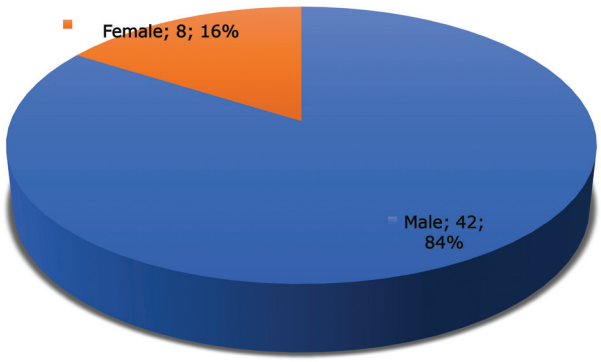
CVS, cerebrovascular stroke; DM, diabetes mellitus; HTN, hypertensive; IHD, ischemic heart disease.

Table 2 Summarizes different locations of the occlusive lesions and its percentages

Lesion positions	*N* (%)
CIA occlusion	13 (26.0)
Unilateral	2 (15.4)
Bilateral	11 (84.6)
CIA and its branches (EIA, CFA)	22 (44.0)
Unilateral	15 (68.2)
Bilateral	7 (31.8)
Occlusion below CIA (EIA, CFA, IIA)	8 (16.0)
Right	7 (87.5)
Left	1 (12.5)
Diffuse occlusive disease including aorta and iliac vessels	7 (14)

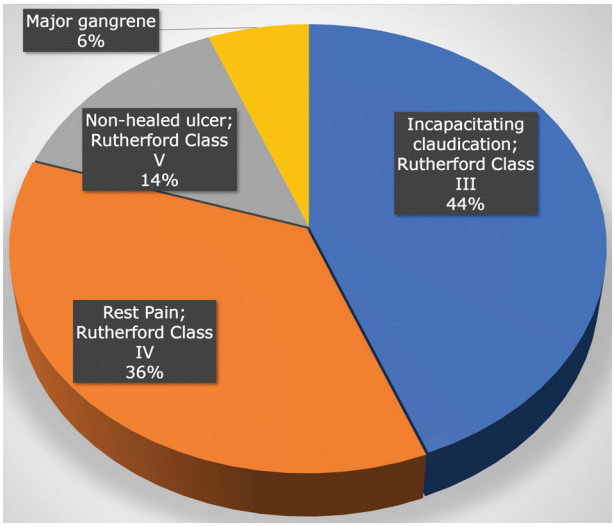
CFA, common femoral artery; CIA, common iliac; IIA, internal ilac artery.

Figure 1



Illustrates demography of the study group.

Figure 2



Illustrates the percentage of patients according to TASC classification.

Angioplasty and stenting

Balloon angioplasty was performed for all cases. A total of 95 stents were inserted in 50 patients; of which 63 (66.3%) stents were balloon-expandable and 25 (26.3%) were self-expandable stents inserted in iliac lesions. One of those stents was covered stent, which was inserted after the artery was injured during angioplasty. Seven (7.4%) stents were self-expandable stents inserted in the aortic lesions (Fig. 4).

Table 3 Illustrates details of intervention; access site location, method of recanalization, and the procedure done

Variables	*N* (%)
Number of access [median (range)]	2 (1–3)
Used access	
Ipsilateral femoral only	2 (4.0)
Contralateral femoral only	4 (8.0)
Brachial access only	6 (12.0)
Two access	
Bilateral access	21 (42)
Femoral/popliteal+brachial	14 (28)
Three access	3 (6)
Crossing the lesion	
Subintimal	26 (52.0)
Intraluminal	20 (40.0)
Failed to cross the lesion	4 (8.0)
Angioplasty	
Done	47 (94.0)
Failed	3 (6.0)

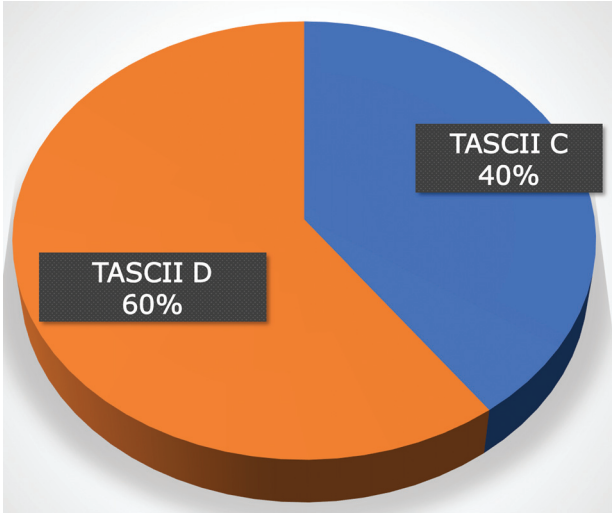
Success rate

Technical success was achieved in 45 of 50 (90%) patients (Table 4). All 45 patients completed follow-up of 6 months, 33 patients completed follow-up of 12 months, and 10 patients completed follow-up of 24 months (Fig. 5). The primary patency rates were 100, 81.8, and 80% for 6, 12, and 24 months, respectively (Table 5). Limb salvage rate was 91.1% (Table 6) and the A/B index increased significantly from 0.39±0.07 to 0.73±0.08 ($P \leq 0.0001$) (Table 7). Three of 50 (6.6%) patients experienced major complications including acute renal failure (2.2%) and retroperitoneal hematoma (2.2%). Eleven of 50 (22.2%) patients had minor complications: 8.9% had access-site hematoma and 13.3% had minor dissections, which were treated with prolonged balloon inflation and/or stenting (Table 8).

Table 4 Illustrate percentage of both technical and clinical success rates

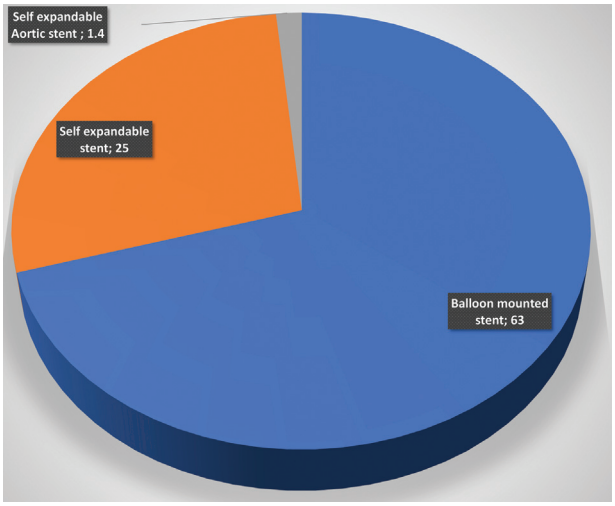
Variables	*N* (%)
Technical success	
Regain femoral pulse in one limb	18 (36.0)
Regain femoral pulse in both	27 (54.0)
Failed	5 (10.0)
Clinical success	
Successful	45 (90)
Failed	5 (10)

Figure 3



The frequency of TASC II C and D.

Figure 4



Percentage of type of inserted stent.

Table 5 Illustrate the patency rate in the follow up period

	Follow-up period				
	1 month	2 months	6 months	12 months	24 months
N	45	45	45	33	10
Patency rate [*n* (%)]	45 (100)	45 (100)	45 (100)	27 (81.8)	8 (80)

Discussion

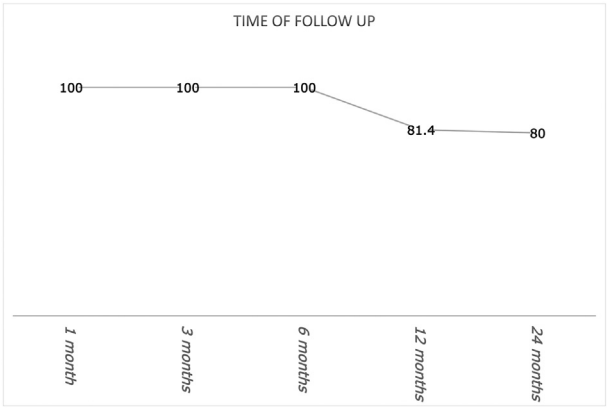
Although endovascular approach as the first approach for aortoiliac atherosclerotic occlusive disease is the standard, TASC II recommends surgical intervention for TASC C and D lesions, which are long, complex, and extensive, because of its durability [9]. Multiple meta-analysis studies encourage endovascular intervention for long, complex TASC C and D lesions. These studies as well as other studies have documented high technical success rate and good primary and secondary patency rate [4], which was comparable to the results of this study.

Sophisticated analysis of the results of this study confirmed better technical and clinical success and extended primary patency rate up to 24 months; and limb salvage rate was better than what published in literature insite of the high percentage of patients had critical limb ischemia (CLI) (66%) included in this study compared to what published literature (20–42%) [10,11]. In this study the limb salvage rate was high (91.1%) and the A/B index significantly improved after intervention (P=0.0001). The prognosis of diagnosed patients with CLI is dismal; the rate of major amputation and limb loss is about 10% per year. All-cause mortality rate is very high and reaches up to 26.8% in 2 years [12]. Endovascular-first approach improved the rate of limb loss (2.2%) and mortality (4.4%) in the population of this study.

Ante-grade approach was preferred in complex lesions (where distal aorta involved in the occlusive lesion); recanalization using brachial access allows successful recanalization, with less complication at the targeted segment and the access site [10,13–16]. In spite that recanalization devices were not used, the technical success rate was 90%. Failure rate was due to complete total occlusion (CTO) lesion in CIA with no proximal stump, and heavily calcified aorta precluded retrograde ipsilateral femoral access in those patients.

EIA perforation and retroperitoneal hematoma occurred in 2.2% of cases, which was managed using

Figure 5



Illustrates the follow up patency rate.

Table 6 Illustrate the limb salvage rate

Limb salvage	*N* (%)
Limb salvage	41 (91.6)
Metatarsal amputation	3 (6.7)
Above-knee amputation	1 (2.2)

Table 7 Illustrate the significance of improved Ankle/brachial index with the intervention

	Ankle–brachial index
Preintervention	0.39
Postintervention	0.73
P value	0.0001

Table 8 Illustrates the percentages of morbidities in the study group

Variables	Cases with success (*N*=45) [*n* (%)]	Cases with failure (*N*=5) [*n* (%)]
Major morbidities	6.6	
No major morbidities	42 (93.4)	4 (80.0)
Retroperitoneal hematoma and perforation	1 (2.2)	0 (0.0)
Thrombosis and intestinal ischemia	0 (0.0)	1 (20.0)
Acute stent thrombosis	1 (2.2)	0 (0.0)
ARF	1 (2.2)	0 (0.0)
Minor morbidities	22.2	
No minor morbidities	35 (77.8)	4 (80.0)
Dissection	6 (13.3)	1 (20.0)
Access hematoma	3 (6.7)	0 (0.0)
Access hematoma and dissection	1 (2.2)	0 (0.0)
Mortality		
Alive	43 (95.6)	5 (100.0)
Dead (cases of multiple organ failure, MI)	2 (4.4)	0 (0.0)

MI, myocardial infarction.

covered stent. One case developed extensive dissection in the aortoiliac segment, which was later complicated by acute ischemia, for which the patient was transferred to surgery. A total of 13.3% of the treated vessels had minor dissection managed with stent deployment. Access-site hematoma was seen in 8.9%, which was managed conservatively. The increasing innovations in endovascular tools extend the application of endovascular intervention, encourage surgeon, and release their fear of surgical conversion in cases where endovascular complications occur.

Conclusion

Endovascular-first approach for the management of complex aortoiliac lesions is effective, feasible, with high success rate and less complication rate. Endovascular management of TASC C and D iliac lesions could be an alternative to standard surgical approach. The evolution in endovascular tools and expertise allow successful management of complicated revascularization of aortoiliac segment.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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Radiofrequency ablation (RFA) for primary varicose veins: a feasible day-case procedure with good surgical and functional outcomes

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Objective
The aim of this study was to find out surgical and functional outcomes of the feasible day-case radiofrequency ablation (RFA) procedure for primary varicose veins (VV).
Background
Management of VV has changed rapidly in recent years. RFA being less invasive alternative to vein stripping can be done by percutaneous catheter-based closure without the necessity of incision.
Patients and methods
This prospective randomized controlled study was conducted on 26 patients (31 limbs) with primary VV; all patients were treated with RFA using VNUS closure under tumescent anesthesia. Patients were randomly allocated into two groups according to the performed RFA technique: group A: 'standard technique' [16 (51.6%) limbs] and group B: 'modified technique' [15 (48.4%) limbs]. Follow-up period was 6 months.
Results
There were satisfactory results with no complications in both groups at 3–6 months of follow-up (93.3% in group A and 86.7% in group B) and marked improvement of patients symptoms (P=0.011). The mean operative time was 62.9±5.4 min in group A and 51.8±3.2 min in group B. Patients in both groups were discharged within hours and returned to work within few days. On 1-week postoperative follow-up, minor complications were observed that disappeared with time, except for one (3.3%) limb with deep venous thrombosis, which was reported in group B.
Conclusion
Endovenous RFA and foam sclerotherapy, whichever is the performed technique, have shown to be very promising techniques as they are minimally invasive and highly effective, with high patient satisfaction and quality of life, better cosmetic results, and fewer days off work.

Keywords:
outcomes, primary varicose veins, radiofrequency ablation

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Introduction

Varicose veins (VV) are veins (usually in the legs) that have lost their elasticity and bulge with blood as a result. They occur if the valves in the veins become weak and let the blood go the 'wrong way' back through the veins. Over time, the veins become wider to cope with the extra blood, and this eventually leads to loss in elasticity. People with VV can feel pain in the affected area, their legs can feel tired and can swell, the skin can start to look different, and ulcers can appear in the area [1–3].

Chronic venous insufficiency (CVI) of the lower limbs is a common condition afflicting 25% of women and 15% of men, with venous reflux at the sapheno-femoral junction (SFJ) being the most common cause leading to VV. Long standing CVI can result in skin changes, including eczema, pigmentation, liposclerosis, and ulceration. Cosmetic concerns relate to the VV themselves and any associated skin changes. Surgical treatment of VV has been the gold standard for many years [4–6].

Multiple techniques for treating saphenous reflux have been developed over the years, including high ligation of the saphenous vein, saphenous vein stripping, and ultrasound (US)-guided sclerotherapy, as well as various combinations of these procedures. Most recently, endovenous thermal ablation has also been identified as a viable treatment option for patients with saphenous reflux [6,7].

Over the past decade, technological progress has enabled the development and application of new minimally invasive therapies such as VNUS closure

endovenous radiofrequency ablation (RFA) and endolaser [8–10].

RFA is a minimally invasive technology that provides efficacious treatment of venous reflux with minimal discomfort and 'downtime' for patients. One of the primary advantages of RFA is that the current procedure can be performed in an outpatient office setting with the use of local tumescent anesthesia [11]. The RFA technique has been used to treat VV, and it has several improvements over the original technology and features a 'segmental ablation' method using the Covidien (formerly VNUS) ClosureFAST catheter that is designed for treating both the great saphenous vein (GSV) and small saphenous vein (SSV). The ClosureFAST catheter is constructed with a 7-cm bipolar electrode affixed to its distal end [12–14].

RFA of a varicose vein involves using radiofrequency (RF) energy to heat the vein wall so that it collapses. Blood is redirected through nearby healthy veins as a result. For a varicose vein in the leg, the heating device is inserted either through a small cut in the skin made above or below the knee (depending on the area to be treated) or through a sheath that is run into the vein under the skin. Once in place in the vein, the device is slowly pulled back through the vein so that it heats and seals the vein as it goes [15,16].

The RFA mechanism is such that the electrode must make direct contact with the vein wall to deliver RF energy. Contact with the wall results in destruction of the endothelium, occlusion by contraction of vein wall collagen, and thrombus formation. Eventually, fibrosis occurs within the vein as well as the formation of new collagen matrix, which further constricts the vein lumen and successfully occludes the vein [17,18].

RFA of the GSV was described by [19]. The manufacturer suggests that the technique is suitable for ablation of a nontortuous GSV of less than 12 mm diameter and is thus applicable in 30–58% of patients with varicose vein. Although there are anecdotal reports of its use in larger veins, there is no published data to confirm that [19].

The current prospective study is aimed to find out surgical and functional outcomes of the feasible day-case RFA procedure regarding being less pain, early return to normal activities, fewer days off work, and better cosmetic results.

Patients and methods

After approval from the local ethical committee of Benha University, written fully informed consent was obtained from each patients. The current study was conducted at the Vascular Unit of General Surgery Department, Benha University, from October 2015 till June 2017 so as to allow 6-month follow-up period for last case operated on. This prospective randomized controlled study was conducted on 26 patients (31 limbs): 21 patients with unilateral limb and five patients with bilateral limbs with primary VV. All patients were treated with RFA using the VNUS RF generator and the ClosureFast catheter (VNUS Medical Technologies, San Jose, California, USA) under duplex scan guidance and by using tumescent anesthesia. Its safety limits were 30–35 mg/kg body weight. Patients were randomly allocated by using a computer generated random number table into two groups according to the performed RFA technique: group A: 'standard technique' [16 (51.6%) limbs] and group B: 'modified technique' [15 (48.4%) limbs].

Patients included in this study were adults experiencing symptomatic primary VV, CEAP c_2 grade or above (Clinical, Etiological, Anatomical, Pathological classification), and either unilateral or bilateral VV. All were fit for regional/general anesthesia. Patients were excluded from this study if they had previously undergone varicose vein surgical stripping, were experiencing secondary VV or had vein diameter more than 1.2 cm or less than 0.2 cm, had tortuous veins that were considered to be unsuitable for RFA, had coagulation disorder, had peripheral arterial diseases, were pregnant, were unable to ambulate, or were extremely obese.

All patients presenting to the vascular unit of general surgery ward were admitted and underwent clinical evaluation, routine hematological tests, and venous duplex of both lower limbs to mark the highest point of reflux. After this, the patients were posted for intervention. On the day of the procedure, the patients were well hydrated to achieve maximum vein distention. The patients were kept warm, and the US gel was heated before placing it on the leg to avoid venospasm.

Radiofrequency ablation procedure

The procedure was performed under general, regional, or tumescent local anesthesia. The access site was detected ultrasonographically, and the procedure was initiated at or just below the popliteal area. In the reverse Trendelenburg's position, lidocaine was administered at the selected site, and a percutaneous

technique with Seldinger needle was used to gain access under U/S guidance. A small cutdown was used in few cases. A 0.035-inch guide wire was inserted into GSV and the needle was removed. Next, a 6F×10-cm or 8F×10-cm sheath was advanced over the wire and the VNUS catheter was inserted and advanced over the wire to the predetermined point. Optimal positioning of the catheter tip was 2 cm peripheral to the SFJ, which was done under U/S guidance.

Tumescent anesthesia was administered under US guidance using 22-gauge spinal needle connected to pump delivery system along the entire target treatment length to create a fluid layer around the GSV. Sufficient anesthesia was instilled to create a 10-mm diameter around vein, hence forming a distance of 10 mm between the targeted vein and the skin. A representative mixture includes 50 ml of 1% lidocaine with 1 ml epinephrine (1 : 100 000) in 450 ml of normal saline, neutralized with 5 to 10 ml of 8.4% sodium bicarbonate. Delivery of the tumescent anesthetic was helped by tourniquet application and was applied perivenously, and patient was placed in Trendelenburg's position to achieve maximum vein collapse.

Positioning of the catheter tip was reconfirmed with US before treatment is commenced. After that the generator was turned on. Then, either the "standard technique", where heating treatment is done at 85°C, in which the first 5.0 cm of saphenous vein was ablated at 1.0 cm per minute followed by the remainder of the GSV being ablated at 1 cm per 30 s, or "modified technique," in which the first 5.0 cm of saphenous vein was heated and ablated at 1.0 cm per minute with the generator set at 90°C after which the catheter is slowly and continuously pulled back at a rate 1 cm per 20 s that maintains a vein wall temperature of 90°C, was used. In both techniques, there was 0.5-cm overlap of each pair of segments and the pulled back was continuous until the desired vessel length was treated. When the final segment was treated, pulling of heating element of the catheter was avoided into the sheath because it might melt the sheath. The generator was turned off and sheath and closure catheter were then removed and hemostasis was obtained with manual compression over the access site.

Further treatment by US-guided sclerotherapy for the residual tributaries was performed immediately at the end of the RFA procedure. The sclerosant used in this study was aethoxysklerol (2%). The areas of concern were disinfected with a Povidone iodine solution 10%, then sclerosing agent solution was prepared for foam sclerotherapy (FS). It was aspirated in a 10-ml syringe and connected to a three-way cannula with a 10-ml syringe containing 7 ml of air; the syringes were rapidly depressed sequentially to create the foam sclerosant to air volume ratio (1 : 3).

A vein light was used to identify the reticular vein that was less than 5 mm, and a 26-G needle was placed into the vein with return of blood confirmed. The foam was injected through the needle while observing the foam displace the blood from the vein; the needle was removed at the end of the injection. In some cases, injection of the foam was done through multiple cannula inserted in the dilated tributaries. After all injections were completed, pressure dressings were placed on the veins treated, and simultaneously, the leg was elevated to achieve 90° of hip flexion. Thigh and knee were wrapped with an elastic compression bandage for 5 days continuously, taking it off only to shower. Thereafter, thigh high class II graduated compression stocking was applied for 2 weeks to minimize postprocedure bruising.

Clinical evaluation was performed for all patients at 1 week, 3 months, and 6 months. Patients were asked about symptomatic relief at follow-up visits, particularly improvement or resolution of lower extremity pain associated with venous insufficiency. Improvements in the appearance of the leg including reduction in visible varicosities, swelling, pigmentation, or other skin changes secondary to CVI were assessed by the patients, with direct comparison with pretreatment photographs obtained from all patients undergoing treatment. Patients were evaluated for possible adverse reactions caused by RFA at each follow-up visit. Minor complications were defined as those that had no significant clinical sequelae such as bruising. Major complications were defined as those necessitating an increased level of care, surgery, or hospitalization.

Outcome items

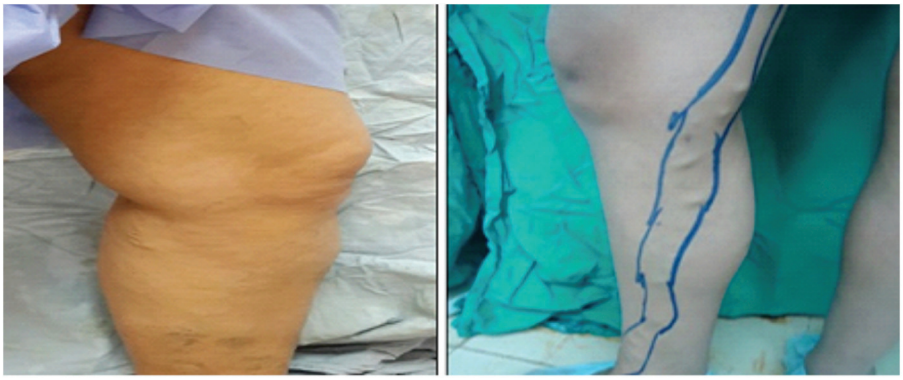
Patients were discharged 1–3 days after intervention and were followed up for 1 week for vessel perforation, nerve injury (manifesting as numbness, decreased or altered sensation or paresthesia), thrombosis [superficial thrombophlebitis or deep venous thrombosis (DVT)], thermal skin injury, and return to daily activities, and postoperative (PO) pain was evaluated using a Visual Analog Score (VAS). Patients ranked the level of pain from 0 (no pain) to 10 (very severe pain). Patients completed questionnaires dealing with analgesic use to detect the level of pain over the previous 24 h. Then, patient satisfaction and quality of life were evaluated using the Venous Clinical Severity Score (VCSS), which is composed of 10 parameters (pain, VV, edema, pigmentation, inflammation,

induration, number of ulcers, duration of ulcers, size of ulcers, and compressive therapy) and are graded 0–3 (absent, mild, moderate, and severe) [20]. To assess PO outcome, Duplex US examination was performed to confirm a successful obliteration procedure and to rule out any potential DVT or extension of thrombus from the saphenous vein into the femoral vein (Figs 1–6).

Statistical analysis

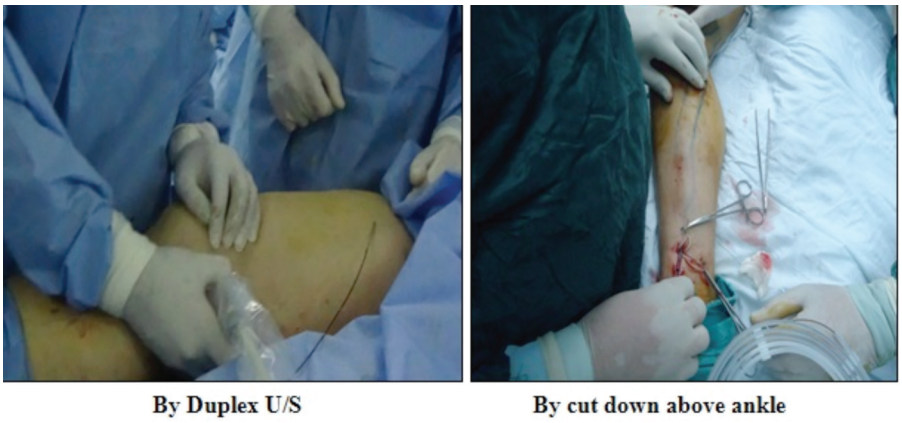
Analysis of data was done by using SPSS, version 16 (SPSS Inc., Chicago, Illinois, USA). Means of all

Figure 1



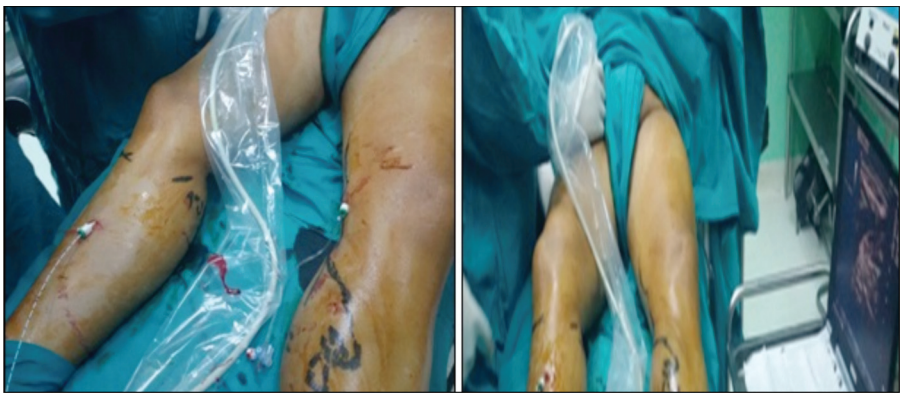
Preradiofrequency ablation photos.

Figure 2



Identification of the great saphenous vein.

Figure 3



Bilateral radiofrequency ablation (RFA) of great saphenous vein by sheath 6F: below right knee, above left knee; with identification of sapheno-femoral junction during introduction of RFA catheter to avoid deep vein injury.

continuous variables were compared by appropriate parametric or nonparametric tests (SD<50% mean). Categorical variables and proportions were analyzed using χ^2 and Fisher's exact tests. Results were expressed as medians, percentages, and mean±SD.

Steps of RFA of the GSV with immediate FS injection of the residual tributaries are shown in Figs 1–6.

Results

This prospective study was conducted on 26 patients with duplex US features of primary VV (31 limbs): 21 patients with unilateral limb and five patients with bilateral limbs. They were divided into two groups according to the performed RFA technique: group A: 'standard technique' [16 (51.6%) limbs] and group B: 'modified technique' [15 (48.4%) limbs]. Patients included 20 (76.9%) women and six (23.1%) men, with the following age strata – 25–35 years: seven (26.9%), 36–45 years: 14 (53.8%), and older than 45 years: five (19.3%) (Table 1 and Graph 1).

The most common symptoms were pain and visible veins which were present in almost all patients. Other

Table 1 Patients' demographic data

Data	Findings [*n* (%)]
Age (years)	
Strata	
25–35	7 (26.9)
36–45	14 (53.8)
>45	5 (19.3)
Sex	
Females	20 (76.9)
Males	6 (23.1)
Clinical categories	
C_2: varicose veins	17 (65.4)
C_3: varicose veins with edema	4 (15.4)
C_4: VV with skin changes without ulcer.	4 (15.4)
C_5: VV with healed ulcer.	1 (3.8)
C_6: VV with active ulcer.	0 (0)
Presenting symptoms	
Restless leg (heaviness)	26 (100)
Visible varicose vein	25 (96.2)
Skin discoloration	5 (19.3)
Night cramps	2 (7.7)
Bleeding	1 (3.8)
Total	26 (100)
Treated limbs (31)	
Right	9 (34.6)
Left	12 (46.1)
Bilateral	5 (19.3)
Total	31 (100)
Performed technique (limbs)	
Group A: 'Standard technique'	16 (51.6)
Group B: 'Modified technique'	15 (48.4)

VV, varicose veins.

Figure 4

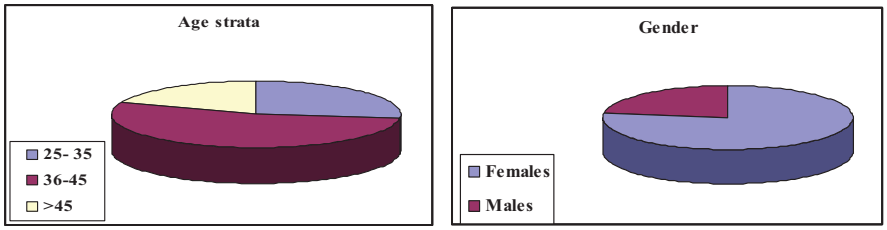
Radiofrequency apparatus VNUS type used in the present study.

Table 2 Vein characteristics: (*N*=31 limbs in 26 patients)

Data	Findings *n* (%)/mean±SD (range)
Anatomical	
GSV along the whole length	17 (54.8)
GSV above the knee	13 (41.9)
SSV	1 (3.3)
Vein reflux	
GSV reflux	30 (96.7)
SSV reflux	1 (3.3)
Diameter of GSV (mm)	
At 3 cm Below SFJ	10.2±0.4
At Mid-thigh	7.3±0.2
GSV puncture	
At the level of the knee	20 (64.5)
At the level of the ankle	10 (32.3)

GSV, great saphenous vein; SSV, small saphenous veins.

Graph 1



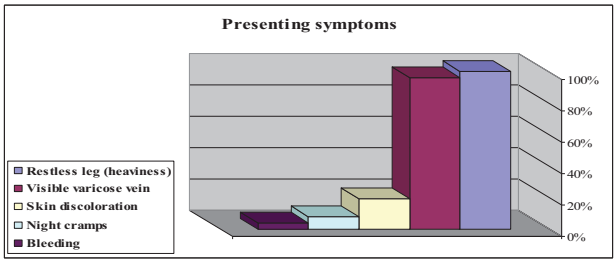
Patients' demographic data (age and sex).

symptoms included night cramps, bleeding, and skin discoloration. The studied patients were classified according to CEAP classification, which entails clinical, etiological, anatomical, and pathophysiological classification (Table 1, Graphs 2 and 3).

Upon review of characteristics of the affected veins, anatomical classification of VV of the studied 26 patients (31 limbs) was mainly seen in GSV reflux using duplex US that was used also to determine the site of puncture of GSV at either the level of the knee or the ankle and to detect site of SFJ (Table 2).

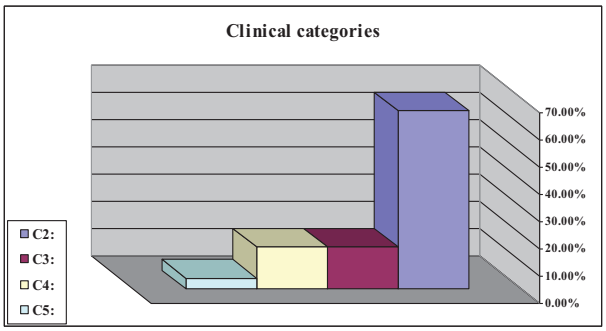
Tumescent anesthesia was used in all patients beside general or spinal anesthesia especially in irritable patients. All patients passed uneventful intraoperative course without complications. Mean operative time was 62.9±5.4 in group A, with a range of 51–87 min, and 51.8±3.2 in group B, with a range of 45–72 min.

Graph 2



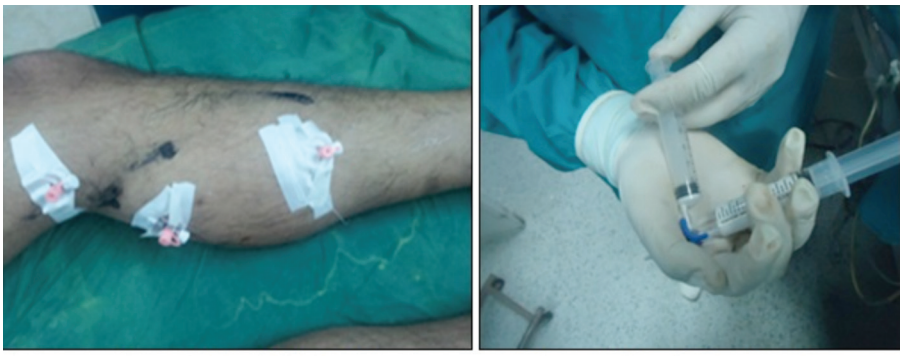
Presenting symptoms.

Graph 3



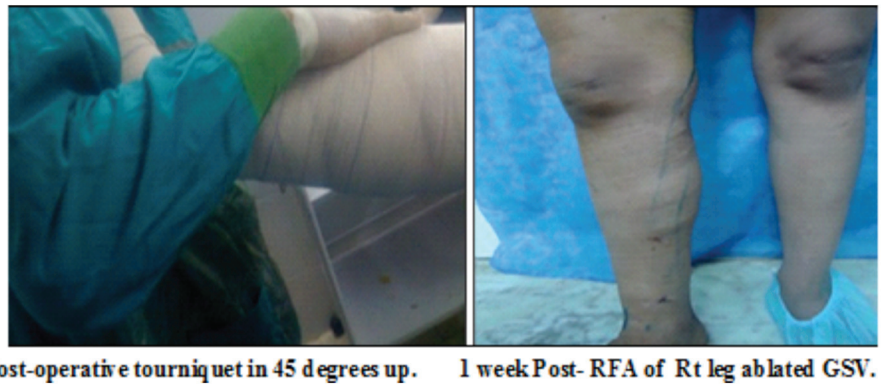
Clinical categories.

Figure 5



Technique for foam sclerotherapy injection.

Figure 6



Postoperative photos: immediate and after 1 week.

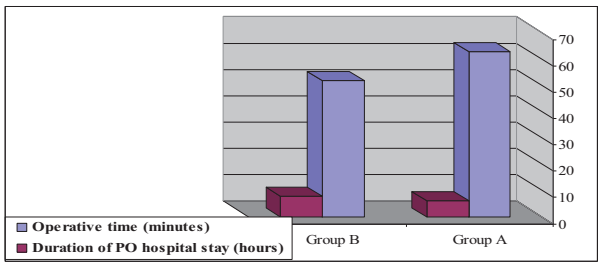
Patients in group A were discharged 6.2±1 h PO, whereas in group B, they were discharged 7.9±2 h PO (Table 3 and Graph 4).

Chemical sclerotherapy was performed for some patients of this study with residual dilated tributary after RFA. This was usually performed in the same session of RFA; the rate of injection in patients is shown in Table 4.

On using a VAS, patients in both groups experienced significantly less PO pain on first 2 days (VAS: 2.09 ±0.3 vs. 3.05±0.01; *P*=0.001) and seventh day (VAS: 0.9±1.1 vs. 1.51±0.9; *P*=0.001) (Table 5 and Graph 5).

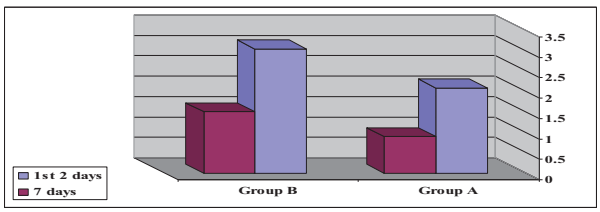
No mortality was recorded; however, one patient of SSV reflux did not come for follow-up, and data collection was applied on 25 patients (30 limbs) only, with 15 limbs in each group. At 1-week PO, erythema, hematoma, and bruising and ecchymosis were present in group A in one (3.3%), one (3.3%), and two (6.6%) limbs, respectively, versus two (6.6%),

Graph 4



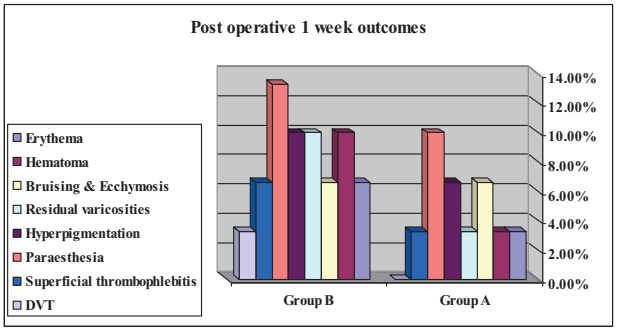
Operative and immediate postoperative (PO) data.

Graph 5



Postintervention pain assessment using a Visual Analog Score.

Graph 6



Postoperative 1-week outcomes. DVT, deep venous thrombosis.

Table 3 Operative and immediate postoperative data

Variables	Group A [16 (50.6%)]	Group B [15 (48.4%)]	*t*	*P* value
Operative time (min)				
Mean±SD	62.9±5.4	51.8±3.2	3.6	0.000 (HS)
Range	51–87	45–72		
Duration of PO hospital stay (h)				
Mean±SD	6.2±1	7.9±2	4.6	0.001 (HS)
Range	5–12	6–14		

HS, highly significant; PO, postoperative. Statistically significant difference was observed using unpaired *t*-test.

Table 4 Sclerotherapy in the studied patients: (*N*=31 limbs in 26 patients)

Types of varicose vein	Type of procedure	*n* (%)
GSV reflux without dilated tributary	RFA alone	24 (77.4)
GSV reflux with dilated tributaries	RFA with injection sclerotherapy	6 (19.3)
SSV reflux without dilated tributary	RFA alone	1 (3.3)

GSV, great saphenous vein; RFA, radiofrequency ablation; SSV, small saphenous veins.

Table 5 Pain assessment using a visual analog score

Variables	Mean±SD		*t*	*P* value
	Group A [16 (50.6%)]	Group B [15 (48.4%)]		
First 2 days	2.09±0.3	3.05±0.01	4.6	0.001 (HS)
7 days	0.9±1.1	1.51±0.9	3.9	0.001 (HS)

HS, highly significant. Statistically significant difference was observed using unpaired *t*-test.

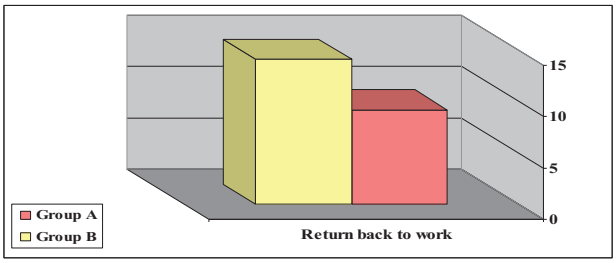
three (10%), and two (6.6%) limbs, respectively, in group B. Residual varicosities that appeared in both groups were treated immediately by FS. Thermal skin burn and superficial thrombophlebitis was observed in three (10%) limbs: one (3.3%) in group A versus two (6.6%) in group B. Only one (3.3%) limb with DVT was reported in group B. Hyperpigmentation and paresthesia were observed in two (6.6%) and three (10%) limbs in group A versus three (10%) and four (13.3%) limbs in group B (Table 6 and Graph 6).

The mean time to return to work in group A was 9.2 ±1.7 days and in group B was 14.1±1.6 days. Group B had slightly longer duration till return to work (Table 7 and Graph 7).

At 3–6-month postoperative follow-up, skin discoloration (pigmentation) was noticed in three (10%) limbs: one (3.3%) in group A versus two (6.6%) in group B. Residual varicosities was noticed only in two (6.6%) limbs in group B and treated by FS. Recurrence was noticed only in one (3.3%) limb in group A. Paresthesia was markedly declined and observed in three (10%) limbs: one (3.3%) in group A versus two (6.6%) in group B. The overall complications were less in group A [14, 93.3%) limbs] (Table 8 and Graph 8).

Patient satisfaction and quality of life were evaluated using the VCSS preoperative, third month and sixth month. There were marked improvement of patients' preoperative symptoms by 3 months after treatment and more significant improvement in the appearance of VV by 6 months after initial treatment; χ^2=5.391, *P*=0.011 (Table 9 and Graph 9).

Graph 7



Return to work.

Table 6 Postoperative 1-week outcomes: (*N*=30 limbs in 25 patients)

Variables	Group A [15 (50%)]	Group B [15 (50%)]	χ^2	*P* value
Erythema	1 (3.3)	2 (6.6)	21	0.01 (Significant)
Hematoma	1 (3.3)	3 (10)		
Bruising and Ecchymosis	2 (6.6)	2 (6.6)		
Residual varicosities	1 (3.3)	3 (10)		
Hyperpigmentation	2 (6.6)	3 (10)		
Paresthesia	3 (10)	4 (13.3)		
Superficial thrombophlebitis	1 (3.3)	2 (6.6)		
DVT	0 (0)	1 (3.3)		
Thermal Skin burn	1 (3.3)	2 (6.6)		
No complications	12 (80)	11 (73.3)		

Data are presented as *n* (%) and by using χ^2-test. DVT, deep venous thrombosis.

Table 7 Return back to work

Variables	Group A [15 (50%)]	Group B [15 (50%)]	*t*	*P* value
Mean±SD	9.2±1.7	14.1±1.6	8	0.001 (HS)
Range (days)	7–14	10–17		

HS, highly significant. Statistically significant difference was observed using unpaired *t*-test.

Table 8 Post-operative 3–6 months outcomes: (*N*=30 limbs in 25 patients)

Variables	Group A [15 (50%)]	Group B [15 (50%)]	χ^2	*P* value
Paresthesia	1 (3.3)	2 (6.6)	20	0.01 (Significant)
Skin pigmentation	1 (3.3)	2 (6.6)		
Residual varicosities	0 (0)	2 (6.6)		
Recurrence	1 (3.3)	0 (0)		
No complications	14 (93.3)	13 (86.7)		

Data are presented as *n* (%) and by using χ^2-test.

Discussion

During the past decade, new less invasive methods have been developed as alternatives to conventional high ligation/excision in the treatment of GSV incompetence, including RFA, endovenous laser therapy, and FS [21].

RFA involves the use of high-frequency alternating current delivered by a bipolar catheter, placed intraluminally under duplex guidance, to obliterate the vein lumen. The current causes ionic agitation and local heating, resulting in venous spasm and irreversible denaturation of collagen with intimal destruction [22].

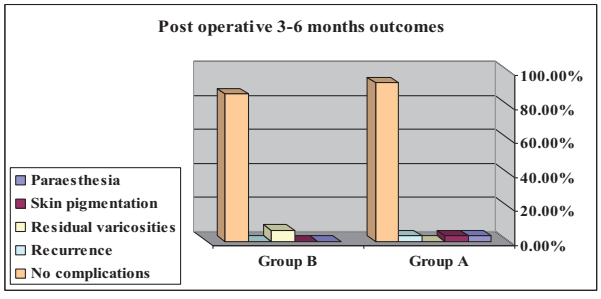
This produces a fibrotic luminal seal with minimal thrombus formation. Proper administration of tumescent anesthesia was a critical component of the procedure, because it not only serves as an anesthetic but also compresses the vein around the catheter and protects the surrounding tissue from heat damage. For the closure procedure, a bloodless field is desirable, as the closure catheter works by conducting RF energy through the vein wall. Blood within the field can coagulate on the tines of the closure catheter, increasing the impedance and diminishing the effectiveness of the heat deposition [23].

The present study was performed using VNUS closure as a closure system under tumescent anesthesia. It included 26 patients (31 limbs) divided into two groups according to the technique performed, and the mean follow-up period was 6 months. It included 20 (76.9%) women and six (23.1%) men, with the following age strata: 25–35 years: seven (26.9%), 36–45 years: 14 (53.8%), and older than 45 years: five (19.3%). This was a smaller study than the one done by Merchant *et al.* [13] who studied 858 limbs with RFA using ClosurePLUS catheter (Covidien, Mansfield, Massachusetts, USA). However, the sample size was similar to the study done by Dzieciuchowicz *et al.* [24] who performed their study on 161 limbs in 154 patients, including RFA in 43 extremities, and was similar to an earlier study done by Almeida [25], who performed his study on 69 patients, including RFA in 43 extremities.

In this study, classification of VV was based on CEAP classification by Bergan *et al.* [26] and revision of the CEAP classification by Eklöf *et al.* [27]. According to the clinical part of the CEAP classification, patients with CVI were categorized in percentage as done by Dzieciuchowicz *et al.* [24]. Moreover, our CEAP classification was comparable to another study published by Michael *et al.* [28].

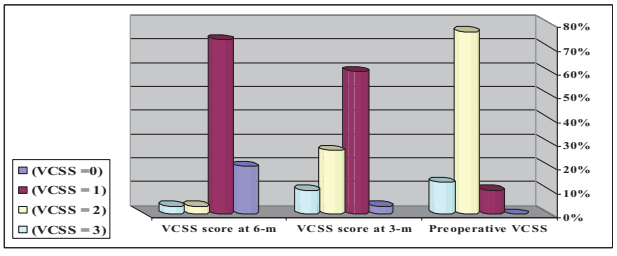
The presenting symptoms of patients were as follows: pain [26 (100%)], visible varicose vein [25 (96.2%)], night cramps [two (7.7%)], bleeding [one (3.8%)], and skin discoloration [five (19.3%)]. This was comparable to the study done by Halil *et al.* [29] that was performed on 90 patients and showed the following data: 90 (100%) patients complained of pain, 64 (71%) patients complained of night cramps, 12 (13%) patients

Graph 8



Postoperative 3–6 months outcomes.

Graph 9



Venous Clinical Severity Score (VCSS) at third and sixth month postoperatively.

Table 9 Venous Clinical Severity Score; at third m and sixth month postoperation

Descriptive items of VCSS	Preoperative VCSS	VCSS score at 3 m	VCSS score at 6 m
Absent (VCSS=0)	0 (0)	1 (3.3)	6 (20)
Mild (VCSS=1)	3 (10)	18 (60)	22 (73.4)
Moderate (VCSS=2)	23 (76.7)	8 (26.7)	1 (3.3)
Severe (VCSS=3)	4 (13.3)	3 (10)	1 (3.3)
Statistical analysis		χ^2=5.391, *P*=0.011	

Data are presented as *n* (%) and by using χ^2-test. VCSS, Venous Clinical Severity Score.

complained of edema, 14 (15.5%) patients complained of skin discoloration, two (2%) patients complained of bleeding, and six (6.5%) patients complained of varicose ulcer. Many patients reported more than one main symptom, so the total percentage exceeds 100%.

Duplex US was performed for all the studied patients. GSV reflux was found in 30 (96.7%) limbs, and SSV reflux was found in one (3.3%) limb. Similar ratios were obtained by Dzieciuchowicz *et al.* [24] who managed 147 of 185 (79.5%) GSV, 23 (12.5%) SSV, one (0.5%) Giacomini vein, eight (4.3%) anterior accessory saphenous vein, and six (3.2%) dilated thigh tributaries of GSV in 154 patients (171 limbs and 185 veins).

In the present study, despite the mean operative time being relatively long owing to time consumed during marking the course of the GSV under duplex guidance (62.9±5.4, range: 51–87 min, in group A and 51.8 ±3.2, range: 45–72 min, in group B), patients' hospital stay was short (in group A, patients were discharged 6.2±1 h PO, and in group B, they were discharged 7.9±2 h PO. This was mentioned by De Maeseneer [30]. The total theater time (between entry into and exit from the theater suite) was significantly longer for RFA.

In this study, six (19.3%) patients received foam sclerosant placed into them appropriately in the same session of RFA. Residual varicosities was noticed only in two (6.6%) limbs and treated by another session of sclerotherapy at third month. Ho *et al.* [31] similarly performed sclerotherapy in three (12.5%) patients of his 24 patients at eight week of follow-up and in one (4.1%) patient at sixth month.

Given the concern of postoperative pain, by using a VAS, patients in both groups reported significantly less PO pain at first 2 days (VAS: 2.09±0.3 vs. 3.05±0.01, P=0.001) and seventh day (VAS: 0.9±1.1 vs. 1.51±0.9, P=0.001). The results were to those obtained by Proebstle and Herdermann [18] who reported that the average pain score was 1.7±1.6 during the first 3 days. For patients who experienced limb pain at any time during the follow-up period, the maximum pain score was 2.8±1.6.

On review of the results in this study, at 1-week PO, erythema, hematoma, and bruising and ecchymosis were present in group A in one (3.3%), one (3.3%), and two (6.6%) limbs, respectively, versus two (6.6%), three (10%), and two (6.6%) limbs, respectively, in group B, which improved spontaneously in the follow-up. Residual varicosities appeared in both groups and were treated immediately by FS. Thermal skin burn and superficial thrombophlebitis was observed in three (10%) limbs (topical anti-inflammatory was prescribed and rapid improvement was noticed in the follow-up): one (3.3%) in group A versus two (6.6%) in group B. Only one (3.3%) limb with DVT was reported in group B. Hyperpigmentation and paresthesia were observed in two (6.6%) and three (10%) limbs, respectively, in group A versus three (10%) and four (13.3%) limbs, respectively, in group B. The reported figures for DVT were significantly superior to that obtained by Hingorani *et al.* [32] who reported that DVT subsequently developed in 16% of limbs treated with the ClosurePLUS catheter [32].

On the contrary, the results were comparable to Proebstle and Herdermann [18] who initially reported comprehensive findings from 6-month data showing a low rate of adverse effects: ecchymosis 6.4%, paresthesia 3.2%, hyperpigmentation 2.0%, hematoma 1.6%, erythema 1.6%, and phlebitis 0.8%. Thermal skin injury and DVT were not observed in the trial.

Patients were more comfortable with the earlier return to work following the intervention, but it remains a costly procedure. The mean time to return back to work was significantly more quickly following RFA: in group A, 9.2±1.7days, and in group B, 14.1±1.6 days. Group B had slightly longer duration, as the cause mentioned by De Maeseneer [30].

At 3–6-month post-operative follow-up, skin discoloration (pigmentation) was noticed in three (10%) limbs: one (3.3%) in group A versus two (6.6%) in group B. Residual varicosities were noticed only in two (6.6%) limbs in group B and were treated by FS. Recurrence was noticed only in one (3.3%) patient who was old and had large veins in group A). Paresthesia was markedly declined and observed in three (10%) limbs: one (3.3%) in group A versus two (6.6%) in group B. The overall complications were less in group A [14 (93.3%) limbs]. Similar results were published by Proebstle and Herdermann [18].

Residual varicosities and recurrence remain a significant problem after either RFA or open surgical ablation. Tielliu *et al.* [33] explained the cause of recurrence as follows: large veins may be less effectively treated by radiofrequency obliteration, and in elderly patients, possible alterations of the collagen fibrils' response

owing to the age of the patient might limit success of treatment. Neovascularization, presence of incompetent tributaries, and connection between remaining segment of GSV and new vessels or incompetent tributaries are another possible causes of recurrence [34].

The most important outcome for the patient with primary VV is satisfaction and quality of life. The current study indicates that RFA is an effective treatment for primary VV. Patient satisfaction and quality of life were evaluated using the VCSS. The components of the VCSS provide outcome analysis on many levels, including technical, patient reported, and clinical. The present study reported that there were marked improvements of patients' preoperative symptoms (χ^2=5.391, P=0.011). The obtained results coincided with that reported in literature, wherein Vasquez and Munschauer [35] examined the results of RFA on venous clinical severity score in 682 limbs treated with RFA. Overall mean baseline venous clinical severity scores were 8.8 at baseline and 3.6 at last follow-up visit, with $P<0.05$.

Proesbstle *et al.* [5] reported the average VCSS score was 1.5±1.8 at 6 months compared with 3.9±2.0 preoperatively. Kapoor and Mahajan [36] reported significantly reduced post-treatment VCSS scores at 3 months.

The reported PO results for RFA were better and showed a lower overall complication rate. Moreover, RFA was less invasive than the surgical approach. The present study showed a primary occlusion rate of 29/30 (96.7%). This is comparable to previous reports where Hingorani *et al.* [32] reported a 96% primary occlusion rate and Puggioni *et al.* [2] reported a 100% occlusion rate.

Conclusion

Endovenous, RFA, and sclerotherapy, whichever is the performed technique, have shown to be very promising techniques as they are minimally invasive and highly effective, with high patient satisfaction and quality of life, better cosmetic results, and fewer days off work. The most important thing is to choose the optimum one for each case to have good outcomes.

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Conflicts of interest
There are no conflicts of interest.

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Pattern of maxillectomies: an analysis of 44 cases in a tertiary referral hospital, Sokoto, Northwest Nigeria

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Background
The maxilla occupies a prominent and crucial position in the facial structure. Maxillectomy is an ablative surgical resection of the maxilla with attendant serious cosmetic deficit. There is paucity of data on the indications and pattern of maxillectomy in our centre. This study would help in better management of patients requiring this treatment.
Aim
The aim of this study was to determine the pattern of presentation of patients for maxillectomy at Usmanu Danfodiyo University Teaching Hospital, Sokoto, Nigeria.
Patients and methods
This study was a retrospective review of theatre records of the hospital between January 2007 and March 2017. Patients data were collected for sociodemographics (age and sex), indication(s), clinical presentations, diagnosis/histologic subtypes, and type of maxillectomy performed.
Result
During the 11-year study period, a total of 44 patients underwent maxillectomy, aged 4–77 years (mean±SD=37.6±19.6 years) with a modal age of 31–40 years [11 (25.0%)]. There were 26 (59.1%) male and 18 (40.9%) female patients (male : female=1.8 : 1). Overall, benign lesions accounted for 12 (27.3%) cases and malignant lesions for 32 (72.7%) cases. There was statistical difference between the ages of benign (mean±SD=24.9±16.2 years) and malignant lesions (mean ±SD=42.3±18.8 years) (t=–2.83, $d.f.$=42, P=0.0071). Benign lesions [11 (25.0%)] were commonly detected in those aged 40 years and younger, whereas malignancies [16 (36.4%)] were equally distributed across both divide. Total maxillectomy [34 (77.3%)] was the major surgical resection carried out, followed by subtotal maxillectomy [6 (13.6%)].
Conclusion
There is urgent need to focus on the prevention of orofacial malignancy to avoid surgery and complex rehabilitative expenses.

Keywords:
maxillectomy, orofacial malignancy, squamous cell carcinoma

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Introduction

The midface with complex anatomical landscape and components majorly occupies the middle third of the face [1]. It partakes in activities such as aesthetics, phonation, olfactory, breathing, mastication and swallowing [1,2]. These are crucial to the attainment of high quality of life and socioeconomic and psychological wellbeing. Anatomically, the maxilla is the largest and most prominent bone of the midface [1]. Together with the alveolus and teeth, it is often referred to as upper jaw. It bilaterally engages central position articulating in various directions with other contiguous bones and structures [1,3,4]. It also houses and supports delicate tissues and organs such as the eyes with other orbital contents: nasal cavity, the maxillary teeth and drainage channels such as nasolacrimal duct [3,4]. The paranasal sinuses are air filled epithelial-lined structures in the skull, of which the maxillary antrum is the largest and occupies a large central portion of the maxilla [1,3,4].

Primary benign and malignant tumours of the maxilla are not uncommon and are often the cause of partial or complete surgical removal of the maxilla [3–7]. These lesions could arise from the skin, nasal cavity, the maxillary sinus, oral mucosa, periodontium, minor salivary gland, bone, muscle, connective tissue, odontogenic epithelial remnants and others [3–5]. Secondary lesions could emerge as a result of

metastasis from other parts of the body such as breast, ovaries, uterus, prostate and others [8]. Maxillary tumours frequently remain asymptomatic, and hence late presentation persists, especially in low-income countries, with Nigeria inclusive [3–5,7,8].

Maxillectomy is an ablative surgical resection of the maxilla with or without removal of allied anatomic structures [3,7,9]. It results in significant compromise of sociopyschological status and functional issues such as sight, cosmetic, speech and mastication [3,4,10,11], and thus present tremendous prosthetic and reconstructive challenges [3,4,7,9–12].

There are various conflicting classifications and terms for maxillectomy, which include medial, low, high, limited, subtotal, total, hemi, extended, radical and others [3,4,7,9,12–17]. These classifications used several criteria – for instance, the nature of the maxillary lesion, site of maxilla involved, surrounding anatomical structures affected and prosthetic/reconstructive hurdles [9].

There is paucity of data on this pertinent topic in Nigeria, especially in North West region. Therefore, the aim of this study was to describe the pattern of maxillectomy at Usmanu Danfodiyo University Teaching Hospital, Sokoto, Nigeria.

Patients and methods

This was a retrospective study of clinical, theatre and histopathological records of the hospital between January 2007 and March 2017. Patients' data were collected for sociodemographics (age and sex), indication(s), clinical presentations, diagnosis/histologic subtypes and type of maxillectomy performed. Those with incomplete clinical and histological records were excluded from the study.

Maxillectomy was classified using Durrani *et al.*'s [12] classification.

(1) Alveolectomy involves removal of alveolar bone alone with no oronasal or oroantral fistula.
(2) Subtotal maxillectomy involves resection of the maxilla sparing the orbital wall of the maxilla but causing oronasal and oroantral fistula.
(3) Total maxillectomy involves complete removal of the maxilla, including the orbital wall, with preservation of the orbital contents.
(4) Radical maxillectomy involves complete removal of the maxilla and orbital contents.
(5) Composite maxillectomy involves removal of the facial skin, soft palate and/or any other part of oral cavity in addition to maxillary resection.

Data collected were entered into Microsoft Excel and subjected to statistical analysis using Analyze-it version 2.25 Excel 12+ (Microsoft Office, Washington, USA) (2013) and presented in frequencies and tables. χ^2-Test was applied to determine the differences between categorical variables. Paired *t*-test was used to check mean differences between the groups and *P* value 0.05 or less was regarded as statistically significance. Ethical clearance was obtained from Usmanu Danfodiyo University Teaching Hospital's Research and Ethics Committee.

Results

During the 11-year study period, a total of 44 patients underwent maxillectomy, aged 4–77 years (mean ±SD=37.6±19.6 years), with a modal age of 31–40 years [11 (25.0%)]. There were 26 (59.1%) male and 18 (40.9%) female patients (male : female=1.8 : 1) (Table 1). There was no sex difference in terms of age (*P*=0.9343). Many patients [43 (97.7%)] primarily presented for treatment at 6 months and above after the initial onset of the lesion.

Forty-three (97.7%) patients presented with swelling as the key primary clinical feature; however, a lot of patients had constellations of findings such as headache, pain, epistaxis, nasal obstruction, proptosis and visual loss. Others include malocclusion, limited mouth opening, dysphagia, bleeding, epiphoria and hyposuria.

Overall, benign lesions accounted for 12 (27.3%) cases and malignant lesions 32 (72.7%) cases (Fig. 1). There was statistical difference between the ages of benign (mean±SD=24.9±16.2 years) and malignant lesions (mean±SD=42.3±18.8 years) (*t*=−2.83, *d.f.*=42, *P*=0.0071). Benign lesions [11 (25.0%)] were commonly detected in those aged 40 years and younger, whereas malignancies [16 (36.4%)] were equally distributed across both divide (Table 2).

Table 1 Age and sex distributions of patients who underwent maxillectomy

Age groups (years)	Sex [*N* (%)]		Total [*N* (%)]
	Female	Male	
0–10	3 (6.8)	3 (6.8)	6 (13.6)
11–20	1 (2.3)	3 (6.8)	4 (9.1)
21–30	2 (4.5)	4 (9.1)	6 (13.6)
31–40	4 (9.1)	7 (15.9)	11 (25.0)
41–50	3 (6.8)	3 (6.8)	6 (13.6)
51–60	4 (9.1)	3 (6.8)	7 (15.9)
61–70	0 (0.0)	3 (6.8)	3 (6.8)
71–80	1 (2.3)	0 (0.0)	1 (2.3)
Total	18 (40.9)	26 (59.1)	44 (100)

χ^2=5.35. d.f.=7. *P*=0.6173.

Ossifying fibroma was the most prevalent benign histopathological finding [6 (13.9%)]. The prime malignancies were salivary gland lesions [12 (27.3%)] (mucoepidermoid and adenocystic carcinomas) and squamous cell carcinoma [11 (25.0%)] (Table 2). Total maxillectomy [34 (77.3%)] was the major surgical resection carried out, followed by subtotal maxillectomy [6 (13.6%)] (Table 3).

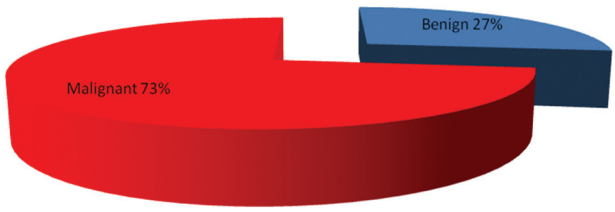
Discussion

The present study revealed a marginal male preponderance in concordance with earlier works from Lagos and Kaduna [4,18]. It, however, contradicts the findings of Eziyi *et al.* [7] from Ile-Ife that showed female dominance.

The fourth decade was the most predominant in this research, which does not resonate with earlier studies that showed that most lesions involving the maxilla occurred mostly among those above the age of 40 years [3–7,18–20]. This could be attributed to the fact that in this study those in this age group had a greater incidence of malignant salivary gland lesions such as mucoepidermoid carcinoma, which is more common in younger age bracket compared with Squamous cell carcinoma, which has a higher incidence in older age groups.

Studies have revealed that in developing countries a number of patients present late, making it challenging to ascertain the location of the initial site of origin of these maxillary lesions [3,4,7,20]. Hence, these lesions spread to adjoining anatomical sites such as orbit, nasopharynx, skull base and intracranium. Those located posterior tend to spread backward, and hence are not easily noticeable until clear signs such as nasal obstruction, epistaxis or visual impairments occur. In contrast, anterior lesions have propensity to grow forward involving the cheek and the oral cavity in many instances. Moreover, fast-growing lesions are aggressive and quickly expansile, thus becoming easily noticeable. In the present study, majority presented after 6 months, in agreement with various study across Nigeria and abroad [4,6–8]. In low-income sub-Saharan Africa, factors such as poor health-seeking behaviour, treatment default, preference for traditional care and poverty have previously been implicated [6,7,18]. Lack of information, poverty, inaccessibility to sound healthcare and inadequate manpower could also be contributory in perpetuating this scenario [18–20]. The literature has shown that as much 90% of those patients with malignancies presented at advanced stage of T3 and

Figure 1



Pie chart of tumour types detected

Table 2 Histopatholgic type and age category of patients who underwent maxillectomy

	Age category [*N* (%)]		Total [*N* (%)]
	≤40 years	>40 years	
Benign (*n*=12, 27.3%)			
Ameloblastoma	1 (2.3)	0 (0.0)	1 (2.3)
Ossifying fibroma	6 (13.6)	0 (0.0)	6 (13.6)
Dentigerous cyst	1 (2.3)	0 (0.0)	1 (2.3)
Neurofibroma	0 (0.0)	1 (2.3)	1 (2.3)
Pleomorphic adenoma	1 (2.3)	0 (0.0)	1 (2.3)
Osteolipoma	1 (2.3)	0 (0.0)	1 (2.3)
Rhinophycomycosis	1 (2.3)	0 (0.0)	1 (2.3)
Malignant (*n*=32, 72.7%)			
Non-Hodgkin's lymphoma	0 (0.0)	2 (4.5)	2 (4.5)
Olfactory neuroblastoma	1 (2.3)	0 (0.0)	1 (2.3)
Haemangiopericytoma	0 (0.0)	1 (2.3)	1 (2.3)
Osteogenic sarcoma	2 (4.5)	0 (0.0)	2 (4.5)
Mucoepidermoid	4 (9.1)	2 (4.5)	6 (13.6)
Burkitt's lymphoma	1 (2.3)	0 (0.0)	1 (2.3)
Rhabdomyosarcoma	1 (2.3)	0 (0.0)	1 (2.3)
Adenocystic carcinoma	4 (9.1)	2 (4.5)	6 (13.6)
Squamous cell carcinoma	3 (6.8)	8 (18.2)	11 (25.0)
Sinonasal carcinoma	0(0.0)	1 (2.3)	1 (2.3)
Total	27 (61.4)	17 (38.6)	44 (100.0)

χ^2=25.55. d.f.=16 *P*=0.0998.

Table 3 Distribution of sex and types of maxillectomy among patients

Types of maxillectomy	Sex [N (%)]		Total [*N* (%)]
	Female	Male	
Radical maxillectomy	1 (2.3)	3 (6.8)	4 (9.1)
Subtotal maxillectomy	3 (6.8)	3 (6.8)	6 (13.6)
Total maxillectomy	14 (31.8)	20 (45.5)	34 (77.3)
Total	18 (40.9)	26 (59.1)	44 (100)

χ^2=0.62. *d.f.*=2. *P*=0.7316.

T4 [4,7,8,18]. Sometimes regional lymph node metastases have been noticed in 3.3–26% of these patients [21].

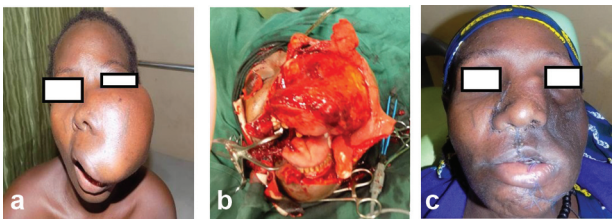
Swelling was the most common clinical finding in the current series. It is a distressing scenario that significantly attenuates aesthetics and could be linked to other clinical findings, including nasal obstruction, epistaxis, epiphoria, proptosis, malocclusion and others [4,6–8,20]. Anecdotally, many young patients, especially females found it quite depressing.

The histological diagnosis for maxillary lesions varies from one centre to the other [3,4,6,7,18–20]. The majority of reports have malignant tumours [4,6,18,19]. An earlier study by Ibikunle *et al.* [6,7] from our centre highlighted that the maxilla was the second most affected site for oral and maxillofacial malignancies with squamous cell carcinoma, mucoepidermoid carcinoma and Burkitt lymphoma predominating. Overall, over 4/5th of lesions identified in this work were malignant. These include epithelial malignant lesions, salivary gland lesions, sarcomas and lymphoma. Alcohol, tobacco and human papilloma virus have been linked to squamous cell carcinoma occurrence [6]. Workers in sectors such as textile, construction, petroleum, mining, smelting and woodworking are reported to be at high risk [3,20,21]. Inhaling toxic substances such as wood dust, leather dust, formaldehyde, paints, hydrocarbon, nickel, chromium, cement and some oils have been associated with sinonasal malignancies [8,20,21].

Our result revealed that the malignant salivary gland lesions were most dominant. This is in sharp contrast with several studies that mentioned squamous cell carcinoma as the principal lesion implicated [3,4,18,22].

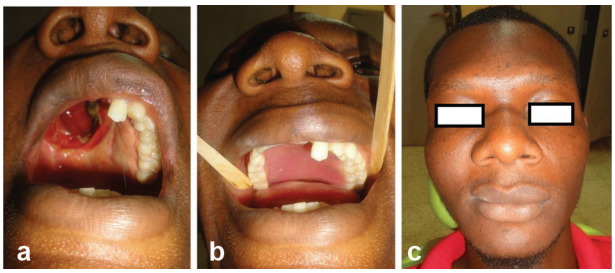
Ogunlewe *et al.* [4] from Lagos in a published series of 30 maxillectomy demonstrated that 26 (86.7%) were total maxillectomies; 10 maxillectomies were performed by Eziyi *et al.* [7] from Ife, six (60.0%) were total maxillectomies. The present study noted that 86.4% (*n*=38) of maxillectomies performed at least involved the total removal of the maxilla (Fig. 2a–c).

Figure 2



(a) Clinical photograph of a patient with maxillary tumour. (b) Intra-operative photograph exposing tumour for total maxillectomy. (c) Postoperative facial profile of patient

Figure 3



(a) Intraoral maxillary surgical defect. (b) Maxillary obturator *in situ* for oral rehabilitation. (c) Clinical photograph of patient after prosthetic rehabilitation

This is in accordance with earlier works from Lagos and Ile-Ife [4,7]. Costly prosthetic and surgical rehabilitation are often needed to restore aesthetics, function, confidence and quality of life of the patients. Controversies rages on whether prosthetic rehabilitation with obturator or reconstruction with microvascular flaps offers the patients the most benefits [23–25]. Our patients were provided with prosthesis (obturator) for rehabilitation and return to function (Fig. 3a–c). Surgical reconstruction of maxillectomy defects eliminates the need for engaging in lengthy fabrication processes of prostheses, which are often considered as bulky and cumbersome [9,10]. These prostheses may also be difficult to insert, especially in patients with trismus and may also be challenging to retain *in situ*. However, some authors have opined that surgical rehabilitation of maxillectomy defects is fraught with disadvantages such as the difficulty in monitoring of the surgical bed for recurrences and possibility of reduced drainage of fluids/mucus secretions [23–25]. Continuous accumulation of these secretions may result in emanation of unpleasant odours from the operative site [13]. Furthermore, surgically reconstructing the defect may entail having multiple surgeries, which may mean added costs and may necessitate the creation of multiple surgical sites [2,9,10].

Radiotherapy and local or systemic chemotherapy are often needed to increase the life expectancy to this group of vulnerable patients [4,7,8,21,22]. Many times the prognosis is guarded despite these treatments [4,22]. The availability and cost of these treatment modalities persistently challenge the healthcare system in Nigeria and other sub-Saharan African countries owing to chronic underfunding, lack of motivated manpower, corruption and others [3,4,22].

Conclusion

The present work showed a male preponderance, especially in the age group 31–40 years. Total maxillectomy was the most common surgical procedure performed. Therefore, this study highlights the importance of raising awareness about maxillary tumour and early diagnosis and create environment that will ensure prompt treatment and rehabilitation such as a national universal health insurance coverage. This will improve prognosis and reduce mortality.

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Conflicts of interest

There are no conflicts of interest.

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Management of difficult hepatic artery anastomosis in living donor liver transplantation: mansoura experience

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Background
One of the most difficult and important procedure in living donor liver transplantation (LDLT) is hepatic artery reconstruction. Difficult hepatic artery reconstruction may be because of pathological factor such as intimal dissection (ID) and anatomical variation. Difficult hepatic artery reconstruction is a risk factor for hepatic artery complications. This study was done to evaluate difficult hepatic artery reconstruction in LDLT at our center and its surgical outcomes.
Patient and methods
Consecutive patients who were treated for end-stage liver cirrhosis by LDLT were retrospectively reviewed. The management of hepatic artery with ID is carried out according to the extent of ID.
Results
Hepatic artery ID was found in 21/375 (5.6%) cases. Overall, seven (33%) cases were reconstructed with the graft hepatic artery after trimming the edge until reaching a healthy segment. A total of 11 (52.4%) cases were reconstructed with the graft hepatic artery after intimal fixation of ID. Moreover, three (14.3%) cases had severe ID and failed intimal fixation and were reconstructed with the recipient splenic artery. Biliary stricture developed in two patients who had severe ID, and three patients developed transient bile leak. No hepatic artery complications, graft failure, or mortality occurred.
Conclusion
Intimal fixation technique proved to be an effective technique in most of the cases, with good short-term and long-term follow-up results. In severe ID or failure of intimal fixation, alternative recipient arteries other than hepatic artery can be used.

Keywords:
biliary stricture, hepatic artery, intimal dissection, living donor transplant

Egyptian J Surgery 36:424–431

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Introduction

Living donor liver transplantation (LDLT) has obtained worldwide agreement, especially in countries that lacked deceased donors [1–3]. In many countries, the use of deceased donor liver transplantation (LT) has not been approved legally. Therefore, LDLT remains the only hope for management of patients with end stage liver disease (ESLD) [3–5]. One of the most difficult and important procedures in LDLT is reconstruction of the hepatic artery (HA) because the HA of the graft is usually short and small in diameter [6–8]. Moreover, the recipient artery is occasionally damaged and adds a more difficult scenario to an already existing one [9,10].

HA complications, including HA stenosis, hepatic artery thrombosis (HAT), bleeding from the anastomotic site, and rupture pseudoaneurysm, during LT can lead to increased morbidity and mortality in liver transplant recipients, and a retransplantation may be required in most of the cases [11,12]. The incidence of HA complications is 1.6–8% in adult recipients and 2–23.6% in pediatric recipients [5–8]. The causes of HA complications are multifactorial including technical, anatomical, pediatric LT, intimal dissection (ID), and pathological factors [7–12]. The incidence of HAT has reduced in recent years owing to improvement in surgical techniques, postoperative anticoagulants, and radiological modalities [9,13].

ID is one of the risk factors of HA complications. The intima of HA may be injured during dissection, during transarterial embolization (TAC), or because of atherosclerosis [8–10,14,15]. The ID was classified according to the extent of intimal injury into three grades: mild ID, when the extent of ID was less than one-quarter of the circumference of the HA; moderate ID, when it involved one-half of the circumference of the artery of the HA; and severe

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ID, when the extent of ID reached more than one-half of the circumference of the HA or the entire vessel wall [9,15]. The management of ID is performed according to the extent of intimal injury, by either trimming the edge until a healthy part of the artery is reached, fixation of the intima, or by using alternative vessels to replace the injured native HA [8–10,14–16]. The results of intimal fixation for ID of HA have not been fully elucidated. This study was done to evaluate the incidence and different management techniques of ID of HA and its outcome.

Patients and methods

Consecutive patients, who were treated for end-stage liver cirrhosis by LDLT at Gastroenterology Surgical Center, Mansoura University, Egypt, during the period from April 2004 to April 2015, were retrospectively reviewed. In this period, three cases were done for children who received the left lobe graft from their mothers. All data were reviewed from a prospectively maintained database on internal web-based registry system completed by paper records.

Preoperative assessment

Donor selection and workup

A multistep, multidisciplinary protocol was used for donor evaluation in our center, and it has been described elsewhere [4,5].

Recipient workup

Initial evaluation includes complete blood count (CBC), electrolytes, liver function tests (LFT), coagulation profile, viral serology, AFP, ABO blood typing, C-reactive protein, and renal function tests. The model for end-stage disease score was calculated. Radiographic studies including abdominal ultrasound (US) and triphasic computed tomography were used to assess the liver status and in case of hepatocellular carcinoma (HCC) to assess the number and size of the tumor.

Surgical procedures

Donor surgery

Surgery was performed through a right subcostal incision with midline extension. The operative details in our center were described elsewhere [4,5]. Overall, 100 IU/kg heparin was injected before HA clamping. The liver graft was flushed immediately with cold histidine-tryptophan-ketoglutarate solution through the portal vein on the back table. Cannulation and flushing of the artery was not performed to avoid damage to the intima of the HA. The diameter of middle hepatic vein (MHV) tributaries was rechecked on the back table, and those with a diameter of more than 5 mm were considered for reconstruction.

Recipient surgery

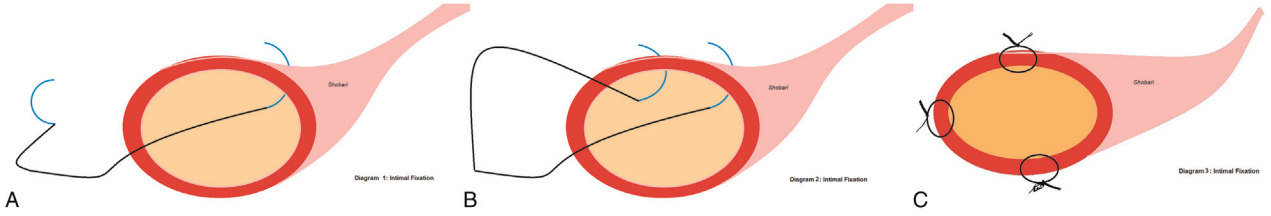
The abdomen was entered through a low subcostal incision with midline extension in all cases. The abdomen was thoroughly examined for any extrahepatic metastasis missed on preoperative imaging in cases with HCC. The liver was mobilized by dissecting all its ligaments. Hilar dissection was then approached with minimal dissection between arterial and biliary systems. Total hepatectomy was performed, preserving the inferior vena cava (IVC). The left hepatic vein (LHV) stump or the MHV/LHV stump was closed in most of the cases or used for MHV reconstructions.

The right hepatic vein (RHV) plasty was done routinely. The RHV of the patient and the liver graft are anastomosed in an end-to-end fashion using running 4/0 prolene sutures, leaving a loose stitch for venting of blood. Portal vein reconstruction was done using prolene 6-0. After venting of 300 ml of blood, the loose suture in the hepatic venous anastomosis was tied and the graft was reperfused.

Hepatic arterial reconstruction was performed using interrupted 8/0 Prolene sutures under 4.5 loupe magnification using midposterior wall first technique. Our policy is to anastomose either the right or left branch of the HA to the donor artery.

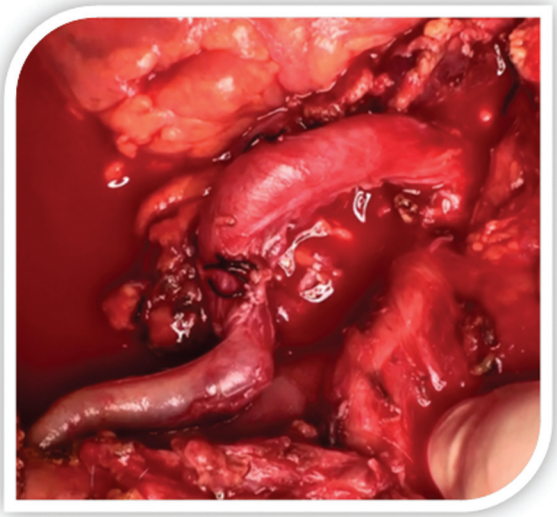
The management of HA with ID is carried out according to the extent of intimal injury; in cases with mild or moderated ID, trimming the edge was done until reaching a healthy part of the artery. Intimal fixation was performed with either 1, 2, 3 or even 4 quadrants and then proceed to anastomosis in cases of moderate or severe ID. We use double needle 6-mm 8/0 Prolene suture from inside out 2 mm away from the edge to fix the intima to adventitia to facilitate the anastomosis, and then ligation outside (Fig. 1a–c). All interrupted stitches of the anastomosis were carried out from the inside of the artery to the outside. The total number of stitches range from eight to 12 according to the arterial caliber. The recipient artery used for reconstruction were hepatic arteries, except in a few cases where the HA was severely damaged, in which the splenic artery was used for reconstruction (Fig. 2). Intraoperative Doppler was done for all cases at the end of the procedure to assess the vascular patency and blood flow in RHV, portal vein (PV), and HA. Duct-to-duct biliary anastomosis is performed using 6/0

Figure 1



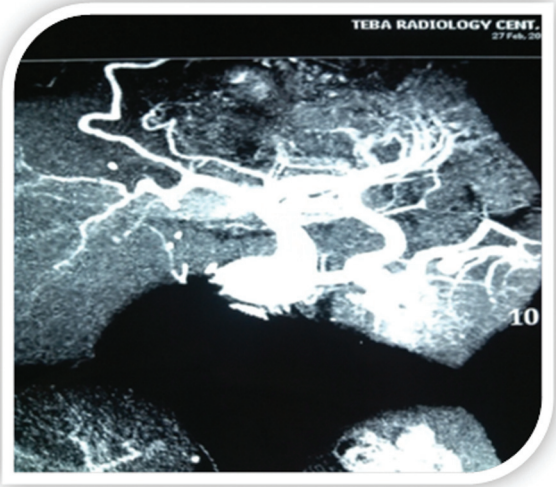
(a–c) Intimal fixation was performed with either 1, 2, 3 or even 4 quadrants using double needle 6 mm 8/0 prolene suture from inside out, 2 mm away from the edge then ligation outside.

Figure 2



Splenic artery used as an alternative to hepatic artery.

Figure 3



Angiography revealing patent hepatic artery was performed 6 months after liver transplantation after IF.

polydioxanone suture (PDS) or Maxon 6/0 in an interrupted fashion, over an indwelling 4–5 Fr catheter. This stent emerges from either CBD or cystic duct stump. Three drains were placed in right subphrenic space, cut margin of the graft, and pelvis.

Postoperative management

All patients were managed in the ICU before transfer to the ward. All patients received prophylactic antibiotics intraoperatively and postoperatively. Anticoagulant was not given postoperatively. Routinely all patients were given intravenous infusion of magnesium and phosphate until tolerating diet. The drain was removed if the amount was less than100 ml/day after 1 week and if there was no bile leak, or pus. Complete blood picture, liver function tests, serum electrolytes, creatinine and C-reactive protein findings were monitored daily.

Vascular patency was followed up using Doppler ultrasonography (DUS) daily for 2 weeks, weekly till discharge, and then monthly till 6 months. Computed tomography angiography was performed 6 months after LT (Fig. 3). A measurable velocity flow on DUS was considered an indicator of patency.

Immunosuppressive treatment started intraoperatively after arterial reconstruction and consisted of steroid and Simulect. The regimen consisted of tacrolimus and cellcept from the fourth day postoperatively. Initial rejection was treated by adding steroid.

The decision of discharge from hospital was based on patient's general condition, clinical parameters, absence of complication, and imaging study.

Follow-up and data collection

Donors and recipient were followed up after hospital discharge with laboratory investigation, abdominal US, and Magnetic Resonance Cholangiopancreatography (MRCP) in selected cases every month for the first month, then every 6 months, and then every year postoperatively. Follow-up visits included clinical examination, laboratory investigation, doses of

immunosuppressive, radiological examination, and DUS. All preoperative, operative, and postoperative data were recorded retrospectively from a prospectively maintained database on internal web-based registry system completed by paper records.

Data analysis

Continuous variables are expressed as median. Categorical variables were expressed as numbers and percentages. Analysis was performed with SPSS program 17 for Windows (SPSS Inc., Chicago, Illinois, USA). Comparison of variables was done by independent student *t*-test for continuous variables and χ^2-test for categorical variables. A *P* value less than 0.05 was considered statistically significant. Variables with *P* less than 0.1 were entered into a logistic regression model to determine independent risk factors for postoperative complications.

Results

From May 2004 to July 2015, 375 cases of living donor liver transplantation (LDLTx) for adult were done in Gastroenterology Surgical Center, Mansoura University, Egypt. Single arterial anastomosis was done in 372 cases, and double arterial anastomosis was performed in three cases. The median diameter of donor HA is 2 mm (1–3 mm). A total of 326 cases were anastomosed to right HA branch and 49 to left HA branch. Preoperative data of patients with HA ID are shown in Tables 1 and 2.

HA ID was found in 21 (5.6%) cases. Trimming of the edge of recipient HA was performed in five cases had mild ID and two cases had moderate ID and were reconstructed with graft HA. Revision of anastomosis was carried out in the same setting in four cases of them, as DUS showed no flow. Intimal fixation using 8/0 Prolene double needle of 6 mm was done in 11 (52.4%) cases (six cases had moderate ID and five cases had severe ID). Intimal fixation was done as four fixation sutures in five cases, three fixation sutures in one case, and the remaining five cases by two fixation sutures. Revision of anastomosis was performed after intimal fixation (IF) in two cases of them, as DUS showed no flow. Trial splenic artery replacement was done in four cases when HA was severely damaged and was successful in three of them. In case of failed splenic artery replacement because splenic artery, in this case, was short and unsuitable, soothe left HA was used after IF (Tables 3–5).

All cases showed excellent Doppler wave intra-operatively, with average resistive index of 0.69. Long-term follow-up using Doppler and in suspected cases computed tomography angiography showed good patency in all cases. HAT, stenosis, or pseudoaneurysm did not occur in any case. No graft failure or mortality occurred.

A total of five patients developed biliary complications. Biliary stricture developed in two patients who had severe ID and was managed by IF: one of them requiring seven sets of ERCP for dilatation and US-guided tubal drainage for the biliary collection, and the other one developed very tight stricture and failed to pass the guide wire by ERCP, so hepaticojejunostomy was done for him. Moreover, three patients (one had severe ID and was managed by IF, the second had severe ID and was managed by splenic artery replacement, and the third had mild ID and was treated by trimming the edge) developed transient bile leak; two of them were managed conservatively and one by ERCP (Tables 4 and 5)

The severity of ID affected the surgical outcome and development of biliary complications, as four of five cases that developed biliary complications had severe ID (P=0.06) (Tables 5 and 6).

Discussion

HA reconstruction is a challenging point in LDLT because the artery has small caliber and short stump and is a technically complicated procedure [7–10]. Complications of HA reconstruction are one of the leading causes of graft failure and mortality after LDLT. HA complication after LDLT includes HAT, HA stenosis, and HA pseudoaneurysm [8–14]. The early complications of HA are usually because of technical, anatomical, or pathological factors including small diameter, pediatric recipient, prolonged clamping of the artery, kinking of a long artery, hematoma of the artery wall, severe hypotension, prolonged cold ischemia, acute rejection, and ID [7–11].

ID is one of the risk factors of development of complications after HA reconstruction[9,14,15]. The intima of HA may be injured owing to atherosclerosis, prolonged clamping, vigorous traction, and grasping of HA during dissection or during pretransplant TAC for hepatocellular carcinoma [13–17]. To minimize the incidence of ID, careful atraumatic dissection and preparation of artery is mandatory. The management of ID is performed according to the extent of intimal injury, by either trimming the edge until a healthy part of artery is reached, fixation of the intima, or by using alternative vessels to replace the injured native HA

Table 1 Preoperative patient details

Patients nos	Age (years)		Sex		BMI		Diameter of HA (mm)		Primary disease
	D	R	D	R	D	R	D	R	
12	20	40	Male	Male	29.7	25.6	2	3	HCV cirrhosis
40	21	52	Male	Male	28.7	27.7	2	3	HCV cirrhosis
96	41	47	Male	Male	29	31.8	3	3	HCV cirrhosis
103	24	56	Male	Male	19.4	28.7	2	4	HCV cirrhosis
104	41	49	Male	Male	27.1	29.1	3	3	HCC on HCV cirrhosis
110	35	45	Female	Male	29.6	32	3	2	HCV cirrhosis
116	25	57	Male	Male	22.2	28.4	2	4	HCV cirrhosis
120	24	59	Male	Male	22	23.9	2	2	HCV cirrhosis
132	31	47	Male	Male	26.8	25.5	3	2	HCC on HCV cirrhosis
140	34	49	Male	Male	24.2	32	2	3	HCV cirrhosis
147	39	49	Male	Male	30.3	40	2	3	HCV cirrhosis
166	26	58	Male	Male	23	36.6	2	4	HCV cirrhosis
211	24	48	Male	Female	25.9	36.9	2	2	HCV cirrhosis
257	23	53	Male	Male	21	28.1	3	3	HCV cirrhosis
267	26	58	Male	Male	24.5	24.4	2	2	HCV cirrhosis
289	20	51	Male	Male	20.4	33	2	2	HCC on HCV cirrhosis
291	34	43	Female	Female	28.3	32	2	2	HCV cirrhosis
312	22	46	Male	Female	20.4	23.9	2	2	HCV cirrhosis
334	27	45	Male	Female	32.2	40	3	3	HCC on HCV cirrhosis
345	20	45	Male	Female	20.4	23.9	2	2	HCV cirrhosis
369	23	55	Female	Male	28.5	26	2	3	HCV cirrhosis
Median/ frequency	25 (20–41)	49 (40–59)	Male/female: 18/3	Male/female: 16/5	25.9 (19.4–32.2)	28.7 (23–40	2 (2–3)	3 (2–4)	HCV: 17 (80.95%)HCC on top of cirrhosis: 4 (19.05%)

HA, hepatic artery; HCV, hepatitis C virus.

Table 2 Demographic data

Variables	Number of cases [*n* (%)]/median (range)
Number of cases with hepatic artery intimal dissection	21/375 (5.6)
Median age (years)	
Donor age	25 (20–41)
Recipient age	49 (40–59)
Sex	
Donor male/female	18/3
Recipient male/female	16/5
Median BMI	
Donor BMI	25.9 (19.4–32.2)
Recipient BMI	28.7 (23–40)
Median hepatic artery diameter (mm)	
Donor hepatic artery diameter	2 (2–3)
Recipient hepatic artery diameter	3 (2–4)
Primary disease	
Hepatitis C virus	17 (80.95)
Hepatocelullar carcinoma on top of cirrhosis	4 (19.05)

including splenic, right gastroepiploic, left gastric, or gastroduodenal artery [14–19].

Lin *et al*. [15] classified the ID into three grades according to the extent of ID, and their management depended on the grade of ID. In mild and moderate ID, the HA can be used after trimming the edge till reaching a healthy part, but in severe ID, alternative recipient arteries other than HA were used. They found that 23 of 40 (57.5%) patients developed ID after TAC. Overall, nine patients had mild ID and six had moderate ID, and they were managed by trimming of the edge; eight had severe ID, and they were managed by alternative vessels other than HA. Two incidences of HAT developed postoperatively. No graft failure or mortality occurred.

Banshodani *et al*. [9] reported that when ID occurred, intimal fixation was performed at four points, and all stitches were carried out from inside to outside of the artery to facilitate good intimal fixation (intraluminal stitching technique). Intraoperative DUS was used to confirm adequate blood flow. Postoperative anticoagulant was given for 3 days. This technique was used in eight cases with ID, except in two cases with severe ID, and the recipient's right gastroepiploic artery was used. Reanastomosis in primary operation was done in three cases, thrombectomy using Fogarty catheter was performed in one case, and thrombolytic agent was used in one case.

For ideal arterial reconstruction, careful dissection and preparation of recipient artery with intimal adaptation must be done. When there is neither an atherosclerotic change nor ID, each stitch is performed from the

Table 3 Intraoperative data

Patient nos	Artery used	Grade of ID	Site	Management	CIT 35 (14–120)	WIT 37 (25–93)	Duration 165 (75–350)	Number of revision
12	RHA to SA	Severe	Recipient	Failed IF Using SA	120	60	250	2
40	RHA to LHA	Severe	Recipient	Trial SA IF (4)	80	70	350	2
96	RHA to RHA	Severe	Recipient	IF (4)	60	65	120	0
103	RHA to RHA	Severe	Recipient	IF (4)	35	35	110	0
104	RHA to RHA	Moderate	Recipient	IF (2)	48	44	130	0
110	RHA to RHA	Severe	Recipient	IF (4)	29	31	165	1
116	RHA to RHA	Moderate	Recipient	IF (2)	30	36	78	0
120	RHA to RHA	Severe	Recipient donor	IF (4)	25	37	75	0
132	LHA to RHA	Mild	Recipient	Trimming the edge	39	45	140	1
140	RHA to RHA	Mild	Recipient donor	Trimming the edge	40	93	119	0
147	RHA to RHA	Moderate	Recipient	Trimming the edge	35	27	170	1
166	RHA to RHA	Mild	Recipient	Trimming the edge	35	27	110	0
211	RHA to RHA	Moderate	Recipient	Trimming the edge	36	43	170	0
257	RHA to LHA	Mild	Recipient	Trimming the edge	30	49	271	3
267	RHA to RHA	Mild	Recipient	Trimming the edge	35	75	318	1
289	RHA to LHA	Moderate	Recipient	IF (2)	40	33	135	0
291	RHA to LHA	Moderate	Recipient	IF (2)	40	29	128	0
312	RHA to SA	Severe	Recipient	Failed IF Using SA	30	25	220	2
334	RHA to LHA	Moderate	Recipient	IF (2)	14	43	207	0
345	RHA to SA	Severe	Recipient	Failed IF Using SA	30	31	315	2
369	RHA to CHA	Moderate	Recipient	IF (3)	44	26	276	0

CHA, common hepatic artery; CIT, cold ischemia; ID, intimal dissection; LHA, left hepatic artery; RHA, right hepatic artery; SA, splenic artery; WIT, warm ischemia duration.

Table 4 Postoperative data

Patient number	Doppler US	Postoperative complications	Management
12	Patient with normal RI	No	–
40	Patient with normal RI	No	–
96	Patient with normal RI	Biliary stricture	Seven sets of ERCP for US tubal drainage
103	Patient with normal RI	Biliary stricture	Failed ERCP hepaticojejunostomy
104	Patient with normal RI	No	–
110	Patient with normal RI	Biliary leakage	ERCP
116	Patient with normal RI	No	–
120	Patient with normal RI	No	–
132	Patient with normal RI	Biliary leakage	Conservative
140	Patient with normal RI	No	–
147	Patient with normal RI	No	–
166	Patient with normal RI	No	–
211	Patient with normal RI	No	–
257	Patient with normal RI	No	–
267	Patient with normal RI	No	–
289	Patient with normal RI	No	–
291	Patient with normal RI	No	–
312	Patient with normal RI	No	–
334	Patient with normal RI	No	–
345	Patient with normal RI	Biliary leakage	Conservative
369	Patient with normal RI	No	–

RI, resistive index; US, ultrasound.

outside to the inner side of the artery using an 8/0 Prolene suture. In case of ID, double needle 6-mm 8/0 Prolene suture was used from inside out to fix the intima to adventitia, and then ligation outside. All interrupted stitches of the anastomosis were carried out from the inside of the artery to the outside [9,15]. In the present study, five cases had mild ID and two cases hade moderate ID, and they were reconstructed with the graft HA after trimming the edge till reaching a health segment. Moreover, six cases had moderate ID and five cases had severe ID, and they were reconstructed with the graft HA after intimal

Table 5 Operative and postoperative data

Variables	Number of cases [*n* (%)]/median (range)
Number of cases with hepatic artery intimal dissection (ID)	21/375 (5.6)
Severity of ID	
Mild	5 (23.8)
Moderate	8 (38.1)
Severe	8 (38.1)
Management	
Trimming the edge	7 (33.3)
Intimal fixation	11 (52.4)
Using Splenic artery	3 (14.3)
Number of revision	
0	12 (57.14)
1	4 (19.05)
2	4 (19.05)
3	1 (4.8)
Median duration of hepatic artery reconstruction (min)	165 (75–350)
Median cold ischemia duration (min)	35 (14–120)
Median warm ischemia duration (min)	37 (25–93)
Median resistive index	0.67 (0.59–0.71)
Postoperative patency	21 (100)
Postoperative complications	
Biliary complication	5 (23.8)
Biliary stricture	2 (9.5)
Biliary leak	3 (14.3)
Hepatic artery thrombosis	0 (0)
Hepatic artery stenosis	1 (4.8)

Table 6 Univariate and multivariate analyses of variables affecting postoperative surgical outcome

Variables	Univariate analysis (*P* value)	Multivariate analysis (*P* value)
Age (years)	0.33	–
Sex of the donor	0.67	–
Sex of recipient	0.82	–
BMI of the donor	0.81	–
BMI of recipient	0.44	–
Severity of ID	0.06	0.81
Type of management of ID	0.75	–
Number of revision	0.83	–
Duration of hepatic artery reconstruction (min)	0.68	–
Cold ischemia duration (min)	0.74	–
Warm ischemia duration (min)	0.73	–
Hepatic artery diameter of the donor	0.08	0.75
Hepatic artery diameter of the recipient	0.69	–

ID, intimal dissection.

fixation of dissected HA. A total of three cases had severe ID and failed intimal fixation and were reconstructed with the recipient splenic artery.

ID of HA may be a risk factor that leads to severe arterial complications such as HAT and subsequent graft failure and mortality [15,19,20]. In recent years, the arterial complications rate in LDLT was reduced to 3.5–6% owing to improvement of techniques, careful atraumatic dissection and preparation of the artery, introduction of microsurgical techniques [7–9,13,20]. Early diagnosis of HA complications based on serial DUS, even in asymptomatic patients, during the first 14 days is very important to decrease the incidence of biliary complications and graft failure because of early intervention. Urgent thrombectomy and revascularization have replaced retransplantation for early HAT [18–21].

Iida *et al*. [12] reported that HA complications occurred in 43 (6.4%) of 673 adult recipient. Postoperative biliary complications after hepatic arterial complications were found in 17 (39.5%) of the 43 cases. They were seven patients who developed biliary leak, six had hepatic pyogenic abscesses, and four patients had biliary strictures. Wang *et al*. [19] reported that five patients of 126 patients required an HA alternative using gastric arteries owing to ID of the recipient HA, which was found during primary transplant. Biliary complications developed in three patients: one patient had biliary stricture requiring percutaneous biliary drainage and two patients had bile leak. The indication of one bile leak recipient resolved conservatively. The other one had graft failure owing to leak and sepsis. In our study, five patients developed biliary complications. Biliary stricture was developed in two patients. One of them required seven sets of ERCP for dilatation. The other one developed very tight stricture and failed to pass the guide wire by ERCP, so hepaticojejunostomy was done for him. Three patients developed transient bile leak, two of them managed conservatively and one by ERCP.Several studies found that extra-anatomical HA reconstructions are strategy in cases with severe ID of HA and can save hepatic graft using other arteries, such as recipients' gastric arteries, gastroduodenal artery, and splenic artery, instead of unusable HA [9,17,21,22]. However, the anatomical anastomosis must be the first choice for the HA reconstruction because extra-anatomical HA anastomosis was a risk factor for development of HA complications, biliary complications, and for taking longer time [12–15,17]. When using splenic artery, ligation of the distal part of the artery may lead to splenic infarction in some cases [23]. In the current study, trial splenic artery replacement was done in four cases with severe ID and was successful in three of them. Biliary complication developed in

one case of them in the form of transient bile leakage and passed conservatively.

Conclusion

ID is one of the risk factors of development of complications after HA reconstruction in LDLT. To minimize the incidence of ID, careful atraumatic dissection and preparation of the artery is mandatory. Intimal fixation technique proved to be a simple and effective technique in most cases, with good short- and long-term follow-up and decreased shift to extra-anatomical reconstruction. In severe ID or failure of intimal fixation, alternative recipient arteries other than HA can be used.

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Conflicts of interest

There are no conflicts of interest.

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Laparoscopic sleeve gastrectomy compared with Roux-en-Y gastric bypass surgery: 2-year outcome of body weight, obesity-associated comorbidities, and quality of life

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Objective
The objective is to check the efficacy and safety of two operative techniques designed for treating morbidly obese patients: laparoscopic sleeve gastrectomy (LSG) and laparoscopic Roux-en-Y gastric bypass (LRYGB).

Patients and methods
The study includes 72 morbidly obese patients, who were divided into two groups: group A, 40 (55.5%) patients treated using LSG, whereas group B, 32 (44.5%) patients managed by LRYGB. Operations were completed according to the rules of laparoscopic surgery. Collected operative data included operative time, intraoperative complications, postoperative (PO) complications, ICU, and hospital stay. All patients were monitored throughout the first 2 PO years at 3rd, 6th, 12th, and 24th PO months.

Results
There is a significant difference between both groups regarding operative time. The rates of early PO complications were higher in LRYGB than LSG group. Both groups showed a significant weight loss at the first 12 months postoperatively. The mean BMI dropped from 39.5±3.03 to 33.10±3.56 kg/m^2 among LSG patients compared with 40.18±3.18 to 30.23±2.64 kg among LRYGB patients. However, at the end of the second PO year, no difference in patients' weight, BMI, The percentage of excess weight loss (%EWL), or EBMIL was noticed in both groups. At the end of the first PO year, a dramatic improvement in both groups was seen about frequency and severity of associated comorbidities except for gastroesophageal reflux disease. At the end of the second PO year, all comorbidities showed prominent remission among patients of LSG group. Patients of LRYGB showed complete resolution of type 2 diabetes mellitus, obstructive sleep apnea, and depression.

Conclusion
Both LSG and LRYGB are safe bariatric surgical procedures that deliver convenient outcomes in weight loss and resolution of most obesity-associated comorbidities.

Keywords:
body mass index, laparoscopic sleeve gastrectomy, morbid obesity, Roux-en-Y gastric bypass

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Introduction

Worldwide, the obesity epidemic is considered as one of the most frustrating medical, social, psychological, and economic burden [1]. Obesity is associated with many comorbidities, such as type 2 diabetes mellitus (T2DM), hypertension, heart disease, dyslipidemia, joint disease, back pain, gall bladder stones, gastroesophageal reflux disease (GERD), and obstructive sleep apnea (OSA) as well as an increase in rates of early death [2]. None of the accessible conservative measures (e.g. lifestyle changes, medications, and behavioral therapy) have succeeded to qualify persons for attaining weight loss and concurrently to treat the comorbidities associated with obesity [3].

Nowadays, bariatric surgery is the most effective way of achieving these goals [3]. Three mechanisms are considered for surgical weight loss: restriction, malabsorption, or combination of both. Restrictive procedures [laparoscopic adjustable gastric banding (LAGB) and laparoscopic sleeve gastrectomy (LSG)] lead to early satiety and reduced caloric ingestion because of a decrease in the gastric size [4]. Malabsorptive procedures (biliopancreatic diversion with or without duodenal switch) lead to a reduction in bowel absorption through by passing a long segment of the small bowel [4]. Roux-en-Y gastric bypass (RYGB) is the operation that includes the two mechanisms: malabsorption and restriction [5]. Although RYGB operations are useful

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for patients, they have variable ranks of success and drawbacks that are unique to each operation [4]. For a long time, RYGB has been considered the surgical management of choice for obesity, with a satisfactory decline of associated comorbidities [6].The rising prevalence of obesity has led to the appearance of alternative tactics such as the LSG, which was defined by Regan *et al.* [7]. LSG showed certain advantages over the laparoscopic Roux-en-Y gastric bypass (LRYGB), as the bowel passage remains intact, endoscopy of the residual stomach and duodenum is still possible, and no threat of postoperative (PO) internal hernias [8]. The American Society for Metabolic and Bariatric Surgery in 2012 suggested LSG as a legal substitute to LRYGB, but still, there is skepticism between surgeons about long-term outcomes of LSG in comparison with the reputable outcomes of LRYGB [9,10]. Several studies have been done recently evaluating the efficacy and safety of LSG. We decided to present our study for evaluation of the outcomes of LSG and LRYGB.

Patients and methods

The current study was conducted in the general surgery and internal medicine departments of Banha University Hospital, Egypt, and King Saud Hospital, Saudi Arabia, from April 2013 to April 2017. Our study includes 72 morbidly obese patients. After approval of the study protocol by the Ethical Committee, patients were acquainted with the details of the possible hazards and benefits of both the procedures, fully informed written patients' consent forms were obtaining for participation in the study. For patients admitted for clinical evaluation, extra consent form was taken for the surgical operation. The patients were assessed by a multidisciplinary team (physician/endocrinologist, nutritionist, psychiatrist, and surgeon) and enrolled in the study if they fulfilled the inclusion criteria. BMI was calculated as weight (kg)/height (m^2) [11]. BMI was graded according to WHO classification as follows [11]: underweight: less than 18.5 kg/m^2, average weight: 18.5–25 kg/m^2, overweight: 25–30 kg/m^2, and obese: over 30 kg/m^2. Obesity was classified as obese class I (moderately obese) with BMI more than 30 to less than 35 kg/m^2, obese class II (severely obese) with BMI 35 to less than 40 kg/m^2, and obese class III (very severely obese) with BMI at least 40 kg/m^2. Only cases of BMI more than 35 kg/m^2 were included in the study. All cases were assessed preoperatively for the presence and severity of comorbidities, and routine laboratory investigations and evaluation of fasting blood glucose (FBG) and serum insulin levels for calculation of Homeostasis Model Assessment of Insulin Resistance were done [12]. All patients underwent abdominal ultrasonography and upper gastrointestinal endoscopy for detection of reflux esophagitis, hiatus hernia, and gastric or duodenal ulcers as well as esophageal manometer and upper gastrointestinal series.

Comorbidities were determined by using universal standards (T2DM: FBG≥126 mg/dl or 2-h plasma glucose ≥200 mg/dl through oral glucose tolerance test (GTT) or antidiabetic medication with or without insulin treatment; impaired glucose tolerance: 2-h plasma glucose ≥140 and ≤200 mg/dl during oral GTT; hypertension: systolic blood pressure 140 mmHg or more and/or diastolic blood pressure ≥90 mmHg or antihypertensive medications; OSA: repeated upper airway occlusion during sleep with or without sleepiness and high apnea/hypopnea index and the need for continuous positive airway pressure during sleep; GERD: necessity for PPI therapy and/or esophagitis detected by endoscopy and/or atypical manometry; arthralgia: through clinical examinations and radiological results; and dyslipidemia: fasting high-density lipoprotein <40 mg/dl for males, <50 mg/dl for females, and/or triglycerides >150 mg/dl and/or low-density lipoprotein >100 mg/dl or the use of statins).

Inclusion criteria for our study were as follows: (a) BMI more than 40 or BMI more than 35 with at least one major comorbidity related to morbid obesity (T2DM, dyslipidemia, OSA, hypertension, and arthralgia), (b) age between 18 and 60 years, and (c) failed conservative treatment)adequate diet and exercise program) over 2 years. Exclusion criteria were major abdominal surgery, noteworthy psychiatric disease, active peptic ulcer disease, patients with giant hiatal hernia, major eating disorder (binge eating), challenging GERD (not respond to medications), patients with inflammatory bowel disease (IBD), former bariatric surgery (apart from gastric banding), and active alcohol or substance abuse.

All included patients were examined clinically for demographic data including age, sex, anthropometric measurements, and accompanying comorbidities. Patients were classified according to the type of management provided as either LSG (group A) or LRYGB (group B). Operative and PO data were collected.

Preoperative assessment and preparation

Preoperative management was personalized based on patient history, physical examination, and investigations. Diabetic patients were kept on subcutaneous injection of regular insulin per 6 h, dose adjusted according to regular plasma and urine examination for

glucose to keep up FBG level less than 160 mg/dl, without ketonuria. Hypertensive patients were kept on β-adrenergic agonists and Ca-channel blockers to keep systolic arterial pressure (SAP) less than or equal to 130 and diastolic arterial pressure (DAP) less than or equal to 90 mmHg. Patients with COPD were kept on bronchodilators and β-adrenergic agonists.

Operative techniques

Laparoscopic sleeve gastrectomy

Under general anesthesia, with the patient in reverse Trendelenburg position, the surgeon while standing between the patient's legs performed the operation with a three-port technique. The greater omentum was dissected from the greater curvature of the stomach with division of the gastrocolic and gastrosplenic ligaments. Dissection was done close to the gastric wall using ultrasonic dissection or a bipolar sealing device. The left crus of the diaphragm was totally dissected and the angle of His defined. Hiatal hernias were explored and repaired with a posterior closure of the crura. The Posterior wall of the stomach was clearly visualized, and adhesions between it and pancreas were dissected. A 36-Fr (12 mm) stomach calibration tube (bougie) was inserted up to the pylorus. After leaving 7 cm of antrum from the pylorus, the sleeve of the stomach was created using a linear cutting (60 cm cartridge length, 4.1-mm staple-height) (Endo GIA stapler; Covidien, Mansfield, MA, USA). Reinforcement of the stable line was done by monofilament absorbable sutures to avoid the risk of PO leakage. The methylene blue test was done to detect any leak. The resected part of the stomach was extracted. Cholecystectomy was done for cholelithiasis. Nasogastric tube (NGT) was left in place, with no drains.

Laparoscopic Roux-en-Y gastric bypass

Under general anesthesia, with the patient in supine position, while standing on the right side of the patient, the surgeon performed the operation with a 6-port technique and exposed the ligament of Treitz. Overall, 50 cm of the jejunum was measured from the ligament of Treitz. Then, the biliopancreatic limb and Roux-limb were created. The 'white vascular' cartridge (2.5-mm staple height, 60-mm cartridge length) was used. Roux-limb was measured 75 cm distally in all cases. An end-to-side jejunojejunostomy was performed with Endo-GIA stapler with the 60-mm white load. The patient was transferred to a steep reverse Trendelenburg position. Endo-GIA stapler with 60-mm blue loads was applied two to three times across the gastric cardia (1 cm from the gastroesophageal junction) toward the angle of His to create a gastric pouch of about 15 ml. The Roux-limb is then advanced toward the gastric pouch for an end-to-side gastrojejunal anastomosis using absorbable surgical suture. An omental patch (shower cap) was used to cover the gastric pouch to protect against leakage. Mesenteric defects were sutured with a non-absorbable surgical suture to protect against internal herniation. Cholecystectomy was performed for cases with cholelithiasis. A closed suction drain was placed behind the anastomosis.

Postoperative care

Patients were managed with modern enhanced recovery after-surgery protocols. Patients were encouraged to get out of the bed on the same day of surgery. Close observation of pulmonary function and continuous SpO_2 monitoring were performed. Patients with medical diseases were maintained on the same ranks of treatment given preoperatively. Thrombosis prophylaxis measures (mechanical and chemical) were performed according to the policy. Early enteral feeding was started. After LSG, patients were discharged home by the second PO day. For LRYGB, the drains were usually withdrawn from the third PO day, and then the patients were discharged home.

Follow-up monitoring

(1) Anthropometric measures were evaluated at 3, 6, 12, 18, and 24 months after surgery. The %EWL and percentage of excess body mass index loss (%EBMIL) were calculated as follows:

$$\%\mathrm{EWL} = \frac{\mathrm{Preoperative follow-up\ weight}}{\mathrm{Preoperative\ weight}} \times 100,$$

and

$$\%\mathrm{EBMIL} = 100\left(\frac{\mathrm{Follow-up\ BMI25}}{\mathrm{Preoperative\ BMI25}} \times 100\right).$$

(2) Associated comorbidities were evaluated at 6, 12, 18, and 24 months after surgery. Remission and improvement of comorbidities were defined by the physician/endocrinologist responsible for the follow-up.

(3) The Quality of life (QOL) was evaluated at the end of second PO year with the Moorehead-Ardelt QOL Questionnaire II [12].

Statistical analysis

Data were presented as mean±SD, ranges, numbers, and ratios. Results were analyzed using Wilcoxon's ranked test for unrelated data (Z-test) and χ^2-test for numerical data. Statistical analysis was conducted using the SPSS (version 21) for Windows statistical package (IBM Corp., Armonk, NY, USA). The P value less than 0.05 was considered as statistically significant.

Results

The study included 72 morbidly obese patients. They divided into two groups (A and B) according to bariatric operation offered to them. Group A contained 40 (55.5%) patients treated with LSG whereas group B contained 32 (44.5%) patients managed with LRYGB. There were no significant differences between both groups regarding age, sex, anthropometric measures, or associated diseases. Most enrolled patients experienced obesity-associated comorbidities. Patients' demographic data are clearly shown in Table 1.

Most patients in both groups passed the procedure smoothly without intraoperative complications or conversion to laparotomy. Details of the operations and PO periods are mentioned in Table 2. On discharge from the hospital, patients were instructed to stay on medications for control of their medical comorbidities according to the regimen stated by a multidisciplinary team. Three patients from LRYGB group were readmitted: one diabetic patient developed a wound infection and was admitted for control of blood sugar and wound infection, who responded to conservative therapy, whereas the second patient and the third patient had a severe asthmatic attack that

Table 1 Patients' demographic data

Data	Strata	LSG group	RYGB group	*P*-value
N (%)	72	40 (55.5)	32 (44.5)	
Age (years)	–	33.6±10.58 (20–55)	35.68±10.64 (23–59)	>0.05
Sex [*N* (%)]	Males	12 (30)	8 (25)	>0.05
	Females	28 (70)	24 (75)	>0.05
Anthropometric measures	Weight (kg)	122.5±7.58 (110–140)	123.2±8.83 (103–147)	>0.05
	Height (cm)	176±7.9 (157–188)	175.1±9.88 (151–192)	>0.05
	BMI (kg/m^2)	39.5±3.03 (35–46)	40.18±3.18 (35.3–47.8)	>0.05
Comorbidities	Hypertension	24 (60)	20 (62.2)	>0.05
	Diabetes	11 (27.5)	9 (28.2)	>0.05
	Dyslipidemia	26 (65)	18 (56.25)	>0.05
	GERD	15 (37.5)	14 (43.7)	>0.05
	OSA	18 (45)	15 (46.89)	>0.05
	Joint/back pain	27 (67.5)	20 (62.5)	>0.05
	Depression/anxiety	7 (17.5)	8 (25)	>0.05

Data are presented as mean±SD and numbers and ranges and percentages are in parentheses; GERD, gastroesophageal reflux disease; LSG, laparoscopic sleeve gastrectomy; OSA, obstructive sleep apnea; RYGB, Roux-en-Y gastric bypass.

Table 2 Operative and postoperative data

Data	Strata	LSG group	RYGB group	*P*-value
Operative time (min)	–	95±26.95 (55–140)	150±32.65 (135–190)	<0.05
Conversion to open	–	0	1 (3)	–
ICU admission (days)	1	2 (5)	1 (3)	
	2	1 (2.5)	1 (3)	
	3	0	2 (6)	
	Total (days)	1.3±0.58 (0–2)	2.4±0.89 (0–3)	>0.05
Hospital stay (days)	2–4	28 (70)	20 (63)	
	5–7	12 (30)	8 (25)	
	8–10	0	3 (9)	
	>10 days	0	1 (3)	
	Total (days)	3.87±1.52 (2–7)	7.06±1.95 (5–14)	<0.05
Reoperation	Owing to bleeding	0	1 (3)	NS
	Owing to leakage	0	1 (3)	
Readmission	–	0	3 (9)	NS
PO complication	Bleeding	2 (5)	1 (3)	
	Leakage	0	3 (9)	
	Infection	0	2 (6)	
	Dysphagia	1 (2.5)	3 (9)	
	Anastomotic stenosis	0	1 (3)	
	Total events	3	10	<0.05

Data are presented as mean±SD and numbers; ranges and percentages are in parentheses; GERD, gastroesophageal reflux disease; LSG, laparoscopic sleeve gastrectomy; PO, postoperative; RYGB, Roux-en-Y gastric bypass.

managed by the medical team. A total of four patients (one from LSG group and three from LRYGB group) developed dysphagia, and all responded well to medical therapy. At the sixth PO month, one patient from LRYGB group experienced repeated vomiting. Endoscopy revealed stenosis in the anastomotic line. Dilatation was done through endoscopy, and the patient's condition improved. More details are present in Table 2.

Patients in both groups showed a significant weight loss at the first 12 months of PO follow-up; however, the decreases in body weight and BMI were more prominent in LGRYB group compared with LSG group. The details of anthropometric measures of both groups throughout the follow-up period are mentioned in Table 3 and Figs. 1 and 2.

At the end of the second PO year, there was a dramatic improvement between patients of both groups in the frequency of obesity-associated comorbidities except for GERD. All details about PO changes in obesity-associated comorbidities are mentioned in Table 4 and Fig. 3.

Patients in both groups showed a marked PO improvement in QOL matched with the preoperative one. According to Moorehead-Ardelt QOL QuestionnaireII, 2 years postoperatively, the QOL was assessed as very good and good in 31 (77.5%) and 23 (72%) patients in LSG and LRYGB, respectively. Postoperatively, no patient was evaluated as very bad in both groups. Details of the QOL changes are shown in Fig. 4.

Discussion

Over the past decades, obesity represents an epidemic health problem all over the world. Surgical management of obesity till now is the gold standard for controlling excessive body weight [13]. Between all bariatric surgeries, LRYGB and LSG were the most popular operations [14]. In our study, we did not only report the results of each procedure

Table 3 Anthropometric measures of both groups throughout the follow-up period

	Time				
Data	Preoperative	3 months PO	6 months PO	12 months PO	24 months PO
Weight					
LSG group	122.5±7.58	118.2±4.36	113±4.67	104.5±3.41	102.58±3.45
RYGB group	123.2±8.83	115.6±5.23	109.4±2.65	100.32±6.51	98.95±3.26
BMI					
LSG group	39.5±3.03	37.15±4.81	35.65±5.24	33.10±3.56	32.30±3.15
RYGB group	40.18±3.18	37.98±5.02	34.5±4.23	30.23±2.64	29.75±6.40
%EWL					
LSG group	–	3.51±3.25	7.75±6.25	14.69±2.65	16.26±2.46
RYGB group	–	6.16±5.21	11.20±4.10	18.57±2.36	19.68±4.76
EBMIL					
LSG group	–	16.20±6.40	27.17±5.20	44.14±3.54	41.60±5.20
RYGB group	–	14.49±3.62	37.41±3.26	65.54±4.71	66.70±4.18

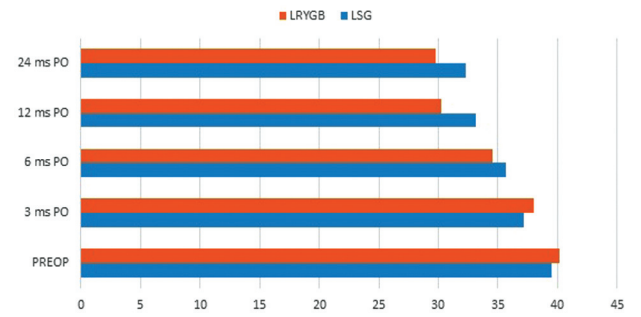
Data are presented as mean±SD; LSG, laparoscopic sleeve gastrectomy; PO, postoperative; RYGB, Roux-en-Y gastric bypass.

Table 4 The rates of resolved obesity-associated comorbidities throughout the postoperative follow-up period

Diseases	Groups							
	LSG group				RYGB group			
	Preoperative	6 months PO	12 months PO	24 months PO	Preoperative	6 months PO	12 months PO	24 months PO
Hypertension	24	7 (29.2)	16 (66.6)	21 (87.5)	20	7 (35)	15 (75)	18 (90)
Diabetes	11	4 (36.4)	8 (72.7)	10 (90.9)	9	4 (44.5)	8 (89.9)	9 (100)
Dyslipidemia	26	7 (27)	16 (61.5)	23 (88.5)	18	7 (39)	14 (77.8)	17 (94.5)
GERD	15	5 (33.3)	7 (46.7)	11 (73.3)	14	7 (50)	12 (85.7)	12 (85.7)
OSA	18	8 (44.5)	13 (72.3)	16 (88.9)	15	6 (40)	12 (80)	15 (100)
Joint /back pain	25	6 (24)	16 (64)	21 (84)	20	10 (50)	17 (85)	19 (95)
Depression/ anxiety	7	2 (28.6)	5 (71.4)	6 (85.7)	8	3 (37.5)	7 (87.5)	8 (100)

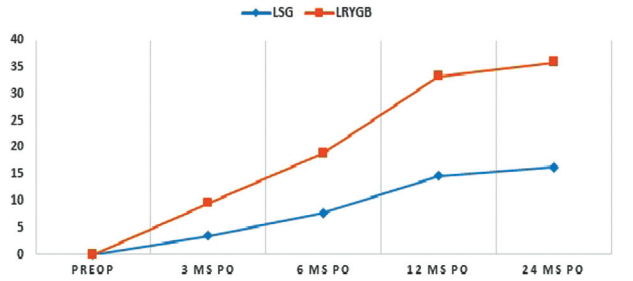
Data are presented as numbers and percentages; GERD, gastroesophageal reflux disease; LSG, laparoscopic sleeve gastrectomy; PO, postoperative; RYGB, Roux-en-Y gastric bypass; OSA, obstructive sleep apnea.

Figure 1



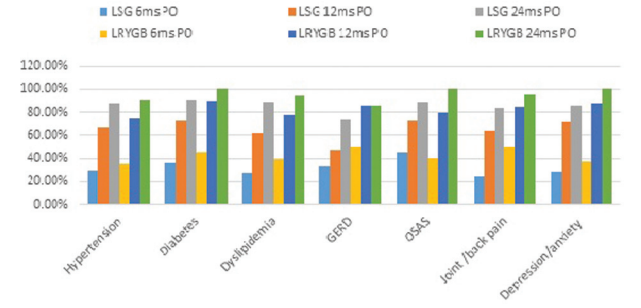
Frequency of changes in BMI throughout the follow-up period.

Figure 2



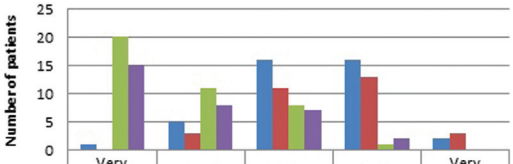
Frequency of changes in %EWL throughout the follow-up period.

Figure 3



The rates of cured obesity-associated comorbidities throughout the follow-up period.

Figure 4



QOL	Very good	Good	Medum	Bad	Very bad
Preoperative LSG	1	5	16	16	2
Preoperative LRYGB	0	3	11	13	3
Two years PO LSG	20	11	8	1	0
Two years PO LRYGB	15	8	7	2	0

The QOL changes as specified with the Moorehead-Ardelt QOL Questionnaire II.

separately as before, but we made a comparison between perioperative results and 2-year outcomes on body weight and obesity-associated comorbidities to share with our colleagues the best and safest way for reduction of excessive body weight.

In our study, the mean operative time for LRYGB was significantly (P<0.05) higher than LSG (50±32.65 vs. 95±26.95 min, respectively). Intraoperative complications were more prominent among patients treated with LRYGB, which obligated conversion of one (3%) case to an open procedure. During LSG, there was no intraoperative hazards or conversion. There is no doubt that the durability and complexity of LRYGB reflected on PO patients' condition and total hospital stay. This goes with the findings of Mingrone *et al.* [15] and Helmio *et al.* [16], who mentioned that LSG is considered a technically less challenging operation than the LRYGB, mirrored by smaller operation time and minor complication rate in the LSG group. The mean PO ICU admission in LSG group was much less than the LRYGB group. The mean total hospital stay for LSG patients was 3.87±1.52 days, and it is significantly lower than the LRYGB group, which was 7.06±1.95 days (P<0.05). This goes to some extent with the findings of Albeladi *et al.* [17], who stated that LSG is technically simpler than the LYRGB, which is reflected by shorter operative time. However, they found that these features are not interpreted into the shorter PO hospital stay. Early outcomes in our study reflect a significant difference (P<0.05) in PO morbidities between patients of both groups; compared with the LSG, LRYGB has a higher rate of bleeding, anastomotic leaks, dysphagia, infection, and fevers. This goes with Matthew *et al.* [18], who mentioned that, compared with LSG, LRYGB has a high rate of approximately all PO bariatric specific events requiring reoperation, readmission, or an intervention. Zhang *et al.* [19] reported that the complication rate was slightly higher among patients treated with LRYGB, with 13.2% for LSG and 26.5% for LRYGB. This also goes with Jurowich *et al.* [20] and Topart *et al.* [21], who mentioned that morbidity is lower in patients undergoing LSG; however, early and late complications in both groups showed no statistically significant difference (P>0.05).

In our present study, there was a significant drop in the mean body weight and mean BMI with a progressive elevation of %EWL and EBMIL among patients of both groups in the first PO year than after 24 months;

however, the decrease was prominent among patients treated with LRYGB than LSG. This goes to some extent with Ralph *et al.* [10], who mentioned that body weight markedly decreased in the first PO year nearly to the same extent in both groups, but there was no difference concerning weight loss or EBMIL between the two groups after 12 months. According to Boza *et al.* [22], the bariatric surgery was considered as successful only when the patients achieved a percentage of EWL of more than 50%. The results of our study showed that LRYGB and LSG were effective bariatric operations resulting in significant weight loss, with %EWL of 62.5% in LSG and 75% in LRYGB [22].

In this study, PO resolution of comorbidities was very favorable. Cure rates for patients undergoing LSG exceeded 70% among patients with T2DM in the first year and 90% after 24 months. Resolution rates of hypertension, dyslipidemia, OSA, joint/back pain, and depression/anxiety were between 60 and 70% in the first year and exceeded 80% after 24 months. On the contrary, the cure rates of obesity associated-comorbidities such as diabetes, hypertension, OSA, joint/back pain, and depression/anxiety among patients undergoing LRYGB were higher than the figures of LGS group, where the cure rates of LRYGB range from 75–90% in the first PO year. At the end of second PO year, all patients with diabetes, OSA, and depression/anxiety stopped medications completely. This goes in hand with Rao *et al.* [23], who mentioned that clinical studies with a 1–2-years follow-up showed that LSG produced greater remission in T2DM rates than those achieved after other bariatric techniques. Also, Benaiges *et al.* [24] noticed a high cure rate of T2DM among patients who were undergoing RYGB; this improvement happened soon after surgery even before significant weight loss had not yet been reached; this could be related to changes in the gut hormonal mechanisms. In patients undergoing LRYGB, GERD significantly improved in the first and second PO years by 87.5%; this may be attributed to the acceleration of gastric emptying, and weight loss may improve GER. On the contrary, GERD improvement was lower among patients treated with LSG, with 40 to 70% at the end of first and second years, respectively. This goes with de Groot *et al.* [25] who concluded that LSG may deteriorate gastroesophageal reflux owing to raised intragastric pressure, decreased gastric emptying, and reduced lower esophageal sphincter pressure. They also suggested that the use of LSG as a final technique for the surgical management of morbid obesity is a respectable option for the obese people who do not have GERD or a hiatus hernia [25]. In our study, patients from both groups showed a marked PO improvement in the QOL matched with the preoperative one. These findings are similar to the study by Zellmer *et al.* [26], in which the PO improvements in QOL even exceeded that of healthy people.

Conclusion

Our prospective study demonstrates that LSG and LRYGB are respectable options for the management of morbidly obese people. LRYGB is more effective than LSG for the rapid decrease of excessive body weight, surgical treatment of T2DM, improvement ofthe symptomized GERD, curing OSA, and control of metabolic syndrome. LSG is easier and safer and has a lesser rate of PO morbidity and mortality. However, further studies with longer follow-up periods and with a larger patient pool are mandated to give more reliable evidence before we can judge which operation should be considered as the gold standard bariatric procedure.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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Mesh or not in the repair of complicated umbilical hernia in cirrhotic patients with decompensated liver cell failure

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Background
Umbilical hernia had been found to occur in 20% of cirrhotic patients with decompensated liver cell failure who had ascites; in such patients, umbilical hernia had a marked liability for complications such as irreducibility, obstruction, and strangulation. Management of complicated hernias especially irreducible hernias in such patients could be done by excision of the hernial sac, closure of the defect and then fixation of the prolene mesh (hernioplasty), or by reduction and repair in two layers of continuous sutures using polypropylene sutures without mesh (herniorrhaphy).
Aim
The aim of our study was to compare hernioplasty with the use of prolene mesh and the conventional anatomical repair (herniorrhaphy) in complicated umbilical hernia in patients with decompensated liver cell failure.
Patients and methods
In our descriptive study, we included 101 cases who were followed up for a period of 24 months, and we divided them into two groups: group A contained cases who had complicated umbilical hernia and were managed by hernioplasty with the use of prolene mesh, and group B contained cases that had complicated umbilical hernia and were managed by reduction and repair in two layers of continuous sutures using polypropylene sutures without using a mesh (herniorrhaphy).
Results
We found a statistically significant difference between both groups regarding recurrence of the umbilical hernia and duration of hospital stay (days) (P=0.004).
Conclusion
Complicated umbilical hernia in cirrhotic patients with decompensated liver cell failure who were managed by hernioplasty with the use of prolene mesh showed lower incidence of recurrence than the conventional anatomical repair (herniorrhaphy).

Keywords:
ascites, cirrhotic patients, prosthetic mesh, umbilical hernia

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Introduction

The incidence of umbilical hernias is 3% in general and rises to 20% in patients having liver cirrhosis and ascites [1]. The major risk factors for the occurrence of umbilical hernias in cirrhotic patients are increased intra-abdominal pressure, the presence of ascites, malnutrition, and muscle wasting [2]. In addition, the umbilical hernias in cirrhotic patients had many complications – e.g. ulceration, acute rupture or gradual leakage with discharge of variable amounts of ascites, irreducibility, obstruction, and strangulation [3]. Management of cirrhotic patients who have umbilical hernia is a matter of controversy [4–6]. Such patients could be managed expectantly because of the higher rate of complication and recurrence of hernia [4]. However, the expectant management might lead to many complications – e.g. hernia incarceration and necrosis of the overlying skin that will be followed by evisceration, ascites, and peritonitis [5,6]. Recently, many studies found that the results of surgical repair might depend on the degree of ascites and liver functions [7–9]. Elective umbilical herniorrhaphy is a safe and effective method in a majority of cirrhotic patients in whom ascites is controlled adequately [9]. However, it is better to be avoided in patients with uncontrolled ascites. Recently, there is an absence of high-quality prospective study about management of cirrhotic patients having umbilical hernia to be sure of the right decision [10]. Indications, time, and technique of herniorrhaphy in such patients remain a matter of controversy [6,7]. The use of mesh and laparoscopic access is also subject to debate [11,12]. There is an increase in the recurrence rate of umbilical hernia following its correction in cirrhotic patients, and thus

hernioplasty with the use of prolene mesh in its repair has been introduced [13]. Previous studies have studied the hernia repair with mesh in comparison with the conventional anatomical repair (herniorrhaphy) and they found that it might reduce the recurrence rate of hernia, but may increase the risk of some complications – e.g. seroma and infection [14]. The technique of mesh repair, i.e., 'hernioplasty', involved either a mesh plug, which is put in the defect, or a flat mesh put over the defect with or without sutures to preserve the mesh secure. The most common mesh used is synthesized from polypropylene prosthetic material [15]. There are many conflicting results on whether the mesh should be used in umbilical hernia repair.

Our goal in this study was to explore the best surgical method for the open repair of primary umbilical hernias in cirrhotic patients by detecting the advantage of mesh use in repairing umbilical hernias.

The aim of our study was to compare hernioplasty with the use of prolene mesh and the conventional anatomical repair (herniorrhaphy) in complicated umbilical hernia in patients with decompensated liver cell failure.

Patients and methods

Study design

Location

We carried out this study in General Surgery Department, Zagazig University Hospitals, after local ethics committee and Institutional Research Board approval.

Sample size

A total of 101 cases were included in our study.

Patients criteria

Inclusion criteria – the inclusion criteria were as follows:

(1) All patients more than 18 years old.
(2) All men and women with complicated umbilical hernia with decompensated cirrhotic liver.
(3) Patients who want to undergo surgery for complicated hernia and accept participation in the study.

Exclusion criteria – the exclusion criteria were as follows:

(1) Lack of consent.
(2) Cases with incomplete data and those lost in follow-up were excluded.

Tools – all patients were subjected to the following:

(1) Full history taking as regards onset, course, duration, and manifestations of liver condition.
(2) Clinical examination.
(3) Full preoperative investigations, which include:
    (a) Complete blood count.
    (b) Liver function.
    (c) Kidney function.
    (d) Coagulation profile.
    (e) Blood glucose level.
    (f) ECG.
    (g) Viral markers.
    (h) Abdominal ultrasound.
    (i) Plain radiography erect and supine positions.

Operational design

The operational design was as follows:

(1) Type of study: descriptive study.
(2) An informed consent was taken for the type of surgery.
(3) Preoperative prophylactic intravenous broad spectrum antibiotic was given to all patients.
(4) All patients were divided into two groups:
    (a) Group A: this group included cases of complicated umbilical hernia, which were managed by reduction repair in two layers of continuous sutures using polypropylene sutures and insertion of nonabsorbable onlay prolene mesh (hernioplasty).
    (b) Group B: this group included cases of complicated umbilical hernia, which were managed by reduction repair in two layers of continuous sutures using polypropylene sutures without mesh (herniorrhaphy).
(5) For every patient the following was recorded:
    (a) The operative time.
    (b) The need for blood and plasma transfusion.
    (c) Oral feeding was started in patients of the first and second groups on first postoperative morning after restoration of bowel movement.
(6) All patients were followed up in the early postoperative period for the following:
    (a) The length of hospital stays (days).
    (b) Hemorrhage.
    (c) Wound infection.
    (d) Deep vein thrombosis/pulmonary embolism.
    (e) Ileus.
    (f) Leakage of fluid (ascetic leak).
    (g) Burst abdomen (partial and complete).
    (h) Postoperative pain.

All patients were followed up monthly for 6 months for recurrence.

Administrative design

The administrative design was as follows:

(1) Approval was obtained from the Surgery Department of Zagazig University.
(2) Approval was obtained from ethics committee of Faculty of Medicine.
(3) Approval was obtained from Institutional Review Board.
(4) Approval was obtained from all patients included in the study.

Statistical analysis

Continuous variables were expressed as the mean±SD and the categorical variables were expressed as a number (percentage). Continuous variables were checked for normality by using Shapiro–Wilk test. Independent Student's *t*-test was used to compare two groups of normally distributed data, whereas Mann–Whitney *U*-test was used for non-normally distributed data. Percentage of categorical variables was compared using χ^2-test or Fisher's exact test when appropriate. All tests were two-sided. *P* values less than 0.05 was considered statistically significant. All data were analyzed using statistical package for the social sciences for windows version 18.0 (SPSS Inc., Chicago, Illinois, USA).

Results

Preoperative characteristics of our patients are included in Table 1. Group A included 29 (54.76%) men and 24 (54.3%) women. Group B included 29 (60.4%) men and 19 (39.6%) women. Most of the patients in both groups are 50–60 years old. The following table shows the basic characteristics for the patients.

Preoperative results

There were statistically significant differences between both groups regarding the presenting complications of the hernia and model for end-stage liver disease score (P=0.021 and <0.001, respectively). There were no statistically significant differences between both groups regarding age, sex, associated comorbidities, Child classification, and the presence of ascites (Table 1).

There were statistically significant differences between both groups regarding type of anesthesia (P=0.004), content of the sac, resection and anastomosis, and type of the drain used (P<0.001) (Table 2).

Postoperative results

There were statistically significant differences between both groups regarding total length of hospital stay (P=0.004), length of ICU stay, and postoperative recurrence of the hernia (P<0.001) (Table 3).

There were no statistically significant differences between both groups regarding postoperative complications such as infection, seroma, hematoma, ascetic leak, and wound dehiscence.

Table 1 Preoperative characteristics of our patients

Basic characteristics	With mesh (*N*=53) [*n* (%)]	Without mesh (*N*=48) [*n* (%)]	*P* value
Sex			
Male	29 (54.7)	29 (60.4)	0.563‡
Female	24 (45.3)	19 (39.6)	
Age (mean±SD) (years)	56.32±9.28	56.60±11.08	0.762•
<50	7 (13.2)	8 (16.7)	0.802‡
50–60	32 (60.4)	26 (54.2)	
>60	14 (26.4)	14 (29.2)	
Comorbidity			
Any	20 (37.7)	24 (50)	0.214‡
Hypertension	17 (32.1)	23 (47.9)	0.104‡
DM	14 (26.4)	17 (35.4)	0.327‡
IHD	13 (24.5)	18 (37.5)	0.158‡
Renal	15 (28.3)	18 (37.5)	0.325‡
Chest infection	18 (34)	18 (37.5)	0.711‡
Pleural effusion	13 (24.5)	18 (37.5)	0.158‡
Child classification			
A	8 (15.1)	2 (4.2)	0.057‡
B	35 (66)	29 (60.4)	
C	10 (18.9)	17 (35.4)	
MELD score (mean±SD)	13.30±4.44	16.91±6.55	0.021•
Encephalopathy	0 (0)	2 (4.2)	0.223‡
Ascites			
No	6 (11.3)	2 (4.2)	0.021‡
Mild	18 (34)	6 (12.5)	
Moderate	25 (47.2)	36 (75)	
Tense	4 (7.5)	4 (8.3)	
Presentation			
Irreducible	0 (0)	18 (37.5)	<0.001‡
Obstructed	42 (79.2)	1 (2.1)	
Strangulated	1 (1.9)	29 (60.4)	
Ruptured	10 (18.9)	0 (0)	
Multiple air fluid level	10 (18.9)	25 (52.1)	<0.001‡

Quantitative data were expressed as mean±SD; qualitative data were expressed as *n* (%). DM, diabetes mellitus; IHD, ischemic heart disease; MELD, model for end-stage liver disease. ‡χ^2-Test. P<0.05, significant. •Mann Whitney U test.

Discussion

Our study included 101 cirrhotic patients with decompensated liver cell failure who were suffering from complicated umbilical hernia. Our results showed a male predominance among all patients, where group

Table 2 Operative characteristics of our patients

Operative data	With mesh (*N*=53) [*n* (%)]	Without mesh (*N*=48) [*n* (%)]	*P* value‡
Anesthesia			
Local	6 (11.3)	17 (35.4)	0.004
General	47 (88.7)	31 (64.6)	
Content of sac			
Loop	30 (56.6)	27 (56.3)	<0.001
Omentum	23 (43.4)	5 (10.4)	
Ascitic fluid	0 (0)	16 (33.3)	
Finding			
Viable	52 (98.1)	9 (18.8)	<0.001
Gangrenous	1 (1.9)	25 (52.1)	
Ascitic fluid	0 (0)	14 (29.2)	
R&A	1 (1.9)	25 (52.1)	<0.001
Pus	4 (7.5)	3 (6.3)	1.000
Clear ascites	46 (86.8)	45 (93.8)	0.325
Drain			
No drain	7 (13.2)	2 (4.2)	0.001
SC	21 (39.6)	5 (10.4)	
Abd.	10 (18.9)	20 (41.7)	
SC and Abd.	15 (28.3)	21 (43.8)	

Abd, abdominal; R&A, resection & anastomosis; SC, subcutaneous. Quantitative data were expressed as mean±SD; qualitative data were expressed as *n* (%). ‡χ^2-Test. $P<0.05$, significant.

Table 3 Postoperative characteristics of our patients

Outcomes of treatment	With mesh (*N*=53) [*n* (%)]	Without mesh (*N*=48) [*n* (%)]	*P* value
Child classification			
A	7 (13.2)	4 (8.3)	0.106‡
B	36 (67.9)	26 (54.2)	
C	10 (18.9)	18 (37.5)	
MELD score (mean±SD)	13.81±4.07	17.12±5.63	0.031•
Complication			
Infection	4 (7.5)	6 (12.5)	0.512‡
Seroma	14 (26.4)	7 (14.6)	0.143‡
Hematoma	2 (3.8)	0 (0)	0.496‡
Ascites leak	7 (13.2)	5 (10.4)	0.665‡
Wound dehiscence	3 (5.7)	22 (45.8)	<0.001‡
Hematemesis	6 (11.3)	8 (16.7)	0.437‡
Coma	17 (32.1)	12 (25)	0.433‡
Total LOS (mean±SD) (days)	3.98±3.80	5.89±4.15	0.004•
In-ward stay (mean±SD) (days)	3.56±3.46	4.06±3.72	0.424•
In-ICU stay (mean±SD) (days)	1.62±2.82	3.29±3.26	<0.001•
Recurrence	5 (9.4)	24 (50)	<0.001‡
Mortality	0 (0)	12 (25)	<0.001‡

Quantitative data were expressed as mean±SD; qualitative data were expressed as *n* (%). LOS, length of hospital stay; MELD, model for end-stage liver disease. ‡χ^2-test. $P<0.05$, significant. •Mann Whitney U test.

A included 29 (54.76%) men and 24 (54.3%) women and group B included 29 (60.4%) men and 19 (39.6%) women.

Our results are similar to results of Chatzizacharias *et al.* [16], Sarit *et al.* [17], and Ammar [10], who stated that unlike the whole population in general, where female sex and obesity are risk factors for occurrence of umbilical hernia, men with ascites are the most common cirrhotic patients with umbilical hernias.

Our results are similar to those of the study by Yu *et al.* [18] that included 18 patients, in which the incidence of male patients was 61%.

Our results were different from the results of Maniatis and Christin [19], in which they found that female patients comprised 63.9% of all patients. Their results may be explained by the fact that women had more liability to obesity and weak abdominal musculature, which are risk factors for occurrence of umbilical hernia.

In our study, umbilical hernia irreducibility was the most common complication that formed 42.6% of cases, followed by strangulation, 29.7%, but results of the study performed by Ragab and Abdelaal [20] documented that strangulation was the most common complication that had occurred in 50% of their patients followed by irreducibility, which forms 27.3%, such discrepant results may be because of different time of hospital attendance and admission of the patients (early or delayed). Ruptured hernia was the first complication (38.2%) in the study performed by Andraus *et al.* [2], followed by irreducibility (29.4%).

The total number of our patients who had comorbidities form 37.7 and 50% of cases in group A and group B, respectively. The most frequent comorbidities were hypertension, diabetes mellitus, ischemic heart disease, renal impairment, and pleural effusion. On the basis of Child–Turcott's grading, child B formed the majority of cases (66%) in group A and (60.4%) group B. This is nearly similar to the result obtained by Ammar [10]. Sonography has been shown to be an accurate preoperative technique in adults for confirming hernias evident on clinical examination [21], which coincides with our results as sonography has been done for all cases and is helpful in accurate diagnosis.

The treatment of complicated umbilical hernia in cirrhotic patients remains controversial [22]. Some authors do not recommend urgent surgery in rupture umbilical hernia and suggest daily sterile dressing associated with intravenous antibiotics, correction of

fluid and electrolyte imbalance, correction of coagulopathy, and medical treatment of ascites. In addition, it has been shown that emergency operation, for hernia disruption in ascitic patients, did not appear to enhance survival [23]. On the other hand, other authors advocate rapid surgery, as conservative treatment may be associated with ascites super infection, a complication that carries a high mortality [24].

In our study, we have urgently operated all patients who had ruptured umbilical hernia, with no increase in operative or postoperative mortality. This might be explained by the observation that these patients had stable liver functions as indicated by their stable child class. Moreover, leakage of ascetic fluid acts as a sort of spontaneous paracentesis, thus controlling the amount of ascites and allowing for a better prognosis after surgery.

Strangulation is a life-threatening complication [24]. In this study, emergency surgical repair was performed for all these patients, and emergency operation did not result in an increased operative mortality. In addition 25 (25.7%) patients had resection anastomosis of small bowel. This did not increase the operative mortality or recurrence rate without any evidence of intestinal leak.

Recurrence rates of complicated umbilical hernia in cirrhotic patients have been reported to be as high as 20–30% [15]. In this current study, there was a statistically significant difference between the two groups including the use of mesh that decreased the postoperative recurrence only in 9.4% of cases. The use of mesh was not associated with increased incidence of postoperative infection rate. These results go favorably with those of Belghiti and Durand [25], where recurrence was documented in 12.5% of cases.

De la Pena *et al*. [26] reported the results of the use of mesh in 14 cirrhotic patients with complicated umbilical hernia. They reported no recurrence with very minimal postoperative complications during follow-up period of 32 months [25].

A meta-analysis performed by Aslani and Brown [27] concluded results similar to ours that there was a 10 times decreased recurrence risk in using mesh repair when compared with the use of primary suture repair, and rates of recurrence that were associated with primary tissue repair ranged from 15 to 40%.

Regarding mortality rate in this study, it was 11.9% of cases; this coincides with reports from other series such as O'Hara *et al*. [24] (16%), Lemmer *et al.* [3] (11.1%), and Teonetti *et al*. [28] (8.4%). Although this rate is higher than that of those undergoing elective umbilical hernia repair, these results may be explained by the presence of complications in decompensated patients with child class B and C, which constituted the main bulk of patients.

Several authors who performed complicated umbilical herniorrhaphy in cirrhotic patients have reported discrepant results. Mortality ranged from 0% by McAlister [29] to 31% by Belli *et al*. and Baron [30,31].

Conclusion

The development of umbilical hernia in cirrhotic patients with ascites should alert the physician to a potentially serious condition. Complicated umbilical hernia management in those patients is a matter of controversy. Regarding our study, complicated umbilical hernia should be urgently repaired as early as possible with available multidisplinary team formed of surgeon, anesthesiologist, and hepatologist for preoperative preparation, operative management, and postoperative monitoring of the patients. The use of a prosthetic mesh in complicated cases showed an advantage over the conventional techniques. However, the use of mesh needs to be investigated on a larger scale of patients in comparison with the conventional herniorrhaphy, and longer follow-up periods are needed to assess its influence on recurrence rates.

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Conflicts of interest

There are no conflicts of interest.

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The role of covering the facial nerve and parotid surface in prevention of the postparotidectomy complications

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Background
Few operations in the head and neck region present challenges such as parotidectomy. The tumors detected are usually benign and patients expect normal function postoperatively. Complications of parotidectomy can be divided into early and late complications. The most serious of late complications are Frey syndrome and cosmetic deformity. Our aim is to evaluate the role of dermal fat graft interposition in preventing postparotidectomy complications.
Patients and methods
This study included 72 patients with benign parotid tumors who were treated between May 2012 and December 2015 in the Department of General Surgery, Menoufia University Hospitals. These patients are randomly divided into two groups: group A (control group) included 36 patients treated with parotidectomy without using dermal fat graft, and group B (study group) included 36 patients treated with parotidectomy and interposition of dermal fat graft.
Results
Most of our patients were females in both groups (66.7 and 77.8%), respectively. The most common pathology was pleomorphic adenoma in both groups (61.1 and 66.7%). There are no statistically significant differences between both groups as regards the operative time and the incidence of facial nerve palsy. Group B (study group) had a significantly lower incidence of Frey syndrome compared with group A (control group) either by subjective or objective methods (P=0.011 and 0.002). There was also a significant reduction in the incidence of sialocele and cosmetic unsatisfaction in the study group (P=0.030 and 0.003, respectively).
Conclusion
The dermal fat graft is a simple idea for restoring facial contour and preventing the postoperative complications after parotidectomy.

Keywords:
dermal fat graft, Frey syndrome, parotidectomy

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Introduction

Few operations in the head and neck region present challenges such as parotidectomy. The tumors detected are usually benign and patients expect normal function postoperatively. However, complications may arise [1]. Numerous reports in the literature have described the surgical technique and the oncological outcome; however, few reports have documented the complications of parotid gland surgery [2].

Complications of parotidectomy can be divided into early and late complications. The early complications include facial nerve dysfunction, hemorrhage, infection, seroma, sialocele, and salivary fistula. The late complications included Frey syndrome and cosmetic deformity [3].

Raw gland surface, left after removal of a parotid tumor or a portion of the gland, contributes to postoperative salivary leakage in the form of sialocele or salivary fistula. In addition, raw gland exposed to skin provides a ready pathway for postganglionic parasympathetic fibers to migrate from salivary tissue and cross-innervate facial sweat glands, resulting in gustatory sweating (Frey syndrome). The clinical signs include flushing and sweating at the skin of the parotid region during eating. The reported incidence of Frey syndrome is around 20–68% overall. The subjective and objective incidences are 38 and 86%, respectively [4].

The surgical depression caused by removal of the parotid gland is most noticeable immediately after the operation, when the surrounding skin is slightly edematous, enhancing the contrast. The magnitude of this depression depends on the amount of gland removed [5]. The aim of this work is to evaluate the

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role of dermal fat graft interposition in preventing postparotidectomy complications.

Patients and methods

This study included 72 patients (aged 28–60 years) with benign parotid tumors who were treated between May 2012 and December 2015 in the Department of General Surgery, Menoufia University Hospitals.

These patients were randomly divided into two groups.

(1) Group A included 36 patients; parotidectomy was done without using dermal fat graft.
(2) Group B included 36 patients; parotidectomy was done with dermal fat graft.

All patients were examined thoroughly, investigated well, and informed consent was taken.

Surgical technique

The preauricular–submandibular S-shaped incision was used in all patients.

The skin flap was raised above the parotid fascia and beyond the tumor to ensure complete exposure of the tumor.

Superficial parotidectomy or partial superficial parotidectomy was done in a standard manner according to the pathology.

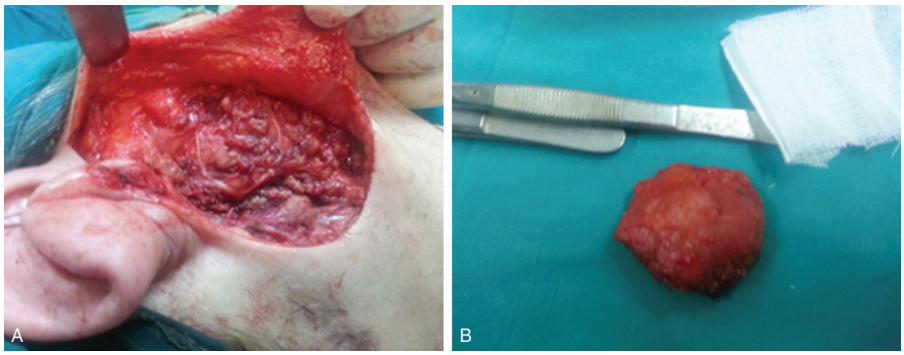
In partial superficial parotidectomy, only the tumor-bearing area of the gland parenchyma was excised with identification of the main trunk and adjacent branches of the facial nerve.

After complete removal of the tumor and involved parotid tissue, the size of the excised parotid and the cavity left after excision were roughly measured (Fig. 1).

In group B, dermal fat graft was harvested from the anterior abdominal wall and de-epithelized as usual. The size of the graft must be slightly larger (20%) than the excised part, because some shrinkage of the graft size occurred in the postoperative period (Fig. 2).

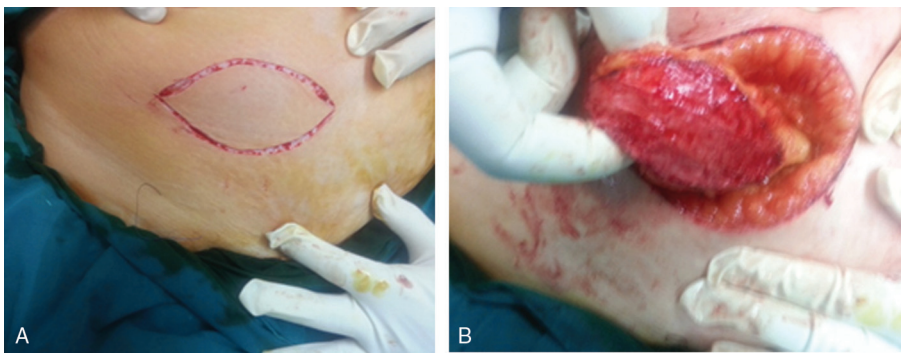
The parotid surface and the facial nerve were covered by the graft, which was sutured to the edge of the residual

Figure 1



(A) The cavity left after parotidectomy. (B) Estimation of the tumour size.

Figure 2



(A) Design of the graft. (B) Harvesting of the dermal fat graft.

parotid tissue by vicryl 4/0 to prevent graft displacement (Fig. 3).

Suction drain was placed and the skin and platysma were closed by vicryl 4/0 suture.

All patients were followed up in the immediate postoperative period and at follow-up visits for parotidectomy complications such as facial nerve palsy, seroma, sialocele, salivary fistula, wound infection, and Frey syndrome (Fig. 4).

Both subjective and objective (starch–iodine test) methods were used to assess the Frey syndrome.

Ethical considerations

This study had been conducted after taking approval from the ethical committee of Faculty of Medicine in Al-Menoufia University and the competent authority of Al-Menoufia University Hospitals. Written consent was obtained from every patient for publication of this research and accompanying images.

Results

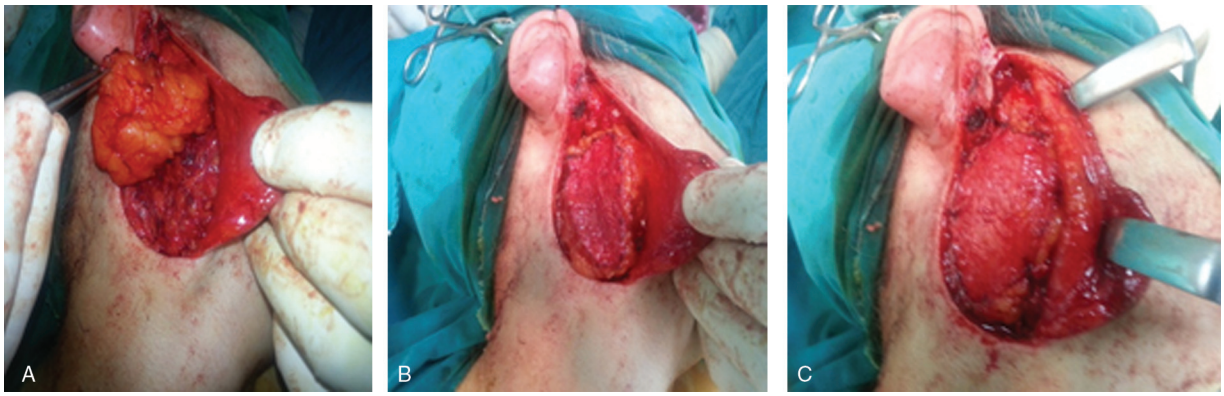
This study was conducted on 72 patients who complained of benign parotid swelling. The mean age was 40.77±5.26 and 40.30±4.92 years in control and study groups, respectively. In all, 22 (30.6%) patients were male and 50 (69.4%) patients were female. The most commonly encountered pathology was pleomorphic adenoma (50 patients, 69.4%). No significant difference as regards age, sex, and pathology were detected in both groups (Table 1).

Superficial parotidectomy was performed for 46 (63.9%) patients: 22 patients in the control group and 24 in the study group. Partial superficial parotidectomy was performed in 26 (36.1%) patients – 14 patients in the control group and 12 patients in the study group – with no significant differences between both groups (P=0.824) (Table 1).

There was no significant difference between both groups as regards the mean operative time. It was 97.0±8.14 and 100±6.79 min in the control and study groups, respectively (P=0.094) (Table 1).

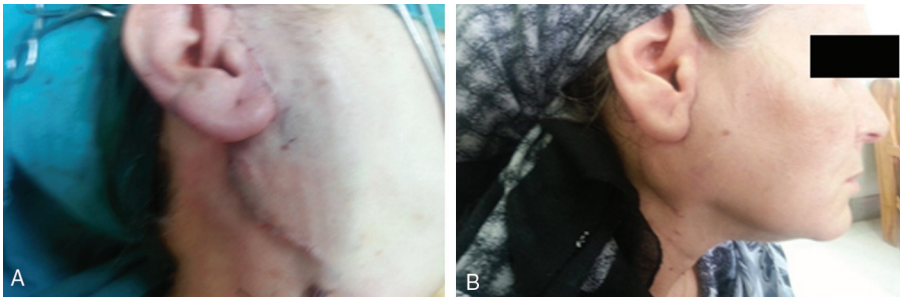
Transient facial nerve palsy occurred in seven (9.7%) patients; three of them were in the control group and four cases were in the study group, with no statistically significant difference between both groups. Sialocele occurred also in eight (11.1%)

Figure 3



(A) Placement of the graft. (B) The graft obliterates the cavity left after parotidectomy (C) Fixation of the graft by vicryl 4/0 to the residual parotid tissue.

Figure 4



(A) Immediate postoperative. (B) Two months postoperative.

Table 1 General and operative characteristics of the studied groups

	Groups (*N*=36)			*P* value
	Study	Controls	Test of significance	
Age (mean±SD)	40.30±4.92	40.77±5.26	*t*=0.39	0.696
Sex [*n* (%)]			χ^2=0.26	0.609
Male	10 (27.8)	12 (33.3)		
Female	26 (72.2)	24 (66.7)		
Pathological type [*n* (%)]			χ^2=0.48	0.923
Pleomorphic	26 (72.2)	24 (66.7)		
Wartin	4 (11.1)	6 (16.7)		
Lymphoepithelial	4 (11.1)	4 (11.1)		
Follicular hyperplasia	2 (5.6)	2 (5.6)		
Operation type [*n* (%)]			χ^2=0.24	0.824
Superficial parotidectomy	24 (66.7)	22 (61.1)		
Partial parotidectomy	12 (33.3)	14 (38.9)		
Operative time [mean±SD (range)] (min)	100.0±6.79 (95–130)	97.0±8.14 (90–120)	*t*=1.69	0.094

Table 2 Postoperative complications

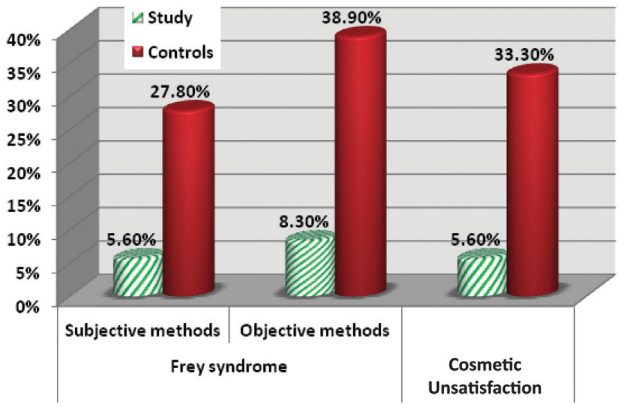
Complications	Groups (*N*=36)					*P* value
	Study		Control		Test of significance	
Sialocele	1	2.8	7	19.4	Fisher's exact test=5.06	0.030*
Facial nerve palsy	4	11.1	3	8.3	Fisher's exact test=0.15	1.0
Frey syndrome						
Subjective methods	2	5.6	10	27.8	χ^2=6.40	0.011*
Objective methods	3	8.3	14	38.9	χ^2=9.31	0.002*
Cosmetic unsatisfaction	2	5.6	12	33.3	χ^2=8.86	0.003*

*Significant.

patients; seven cases were recorded in the control group in comparison with one case in the study group, with significantly higher incidence in the control group than in the study group (*P*=0.030) (Table 2).

Frey syndrome was recorded, by subjective method, in 10 (27.8%) patients in the control group in comparison with two (5.6%) patients in the study group and by objective method in 14 (38.9%) patients in the control group in comparison with three (8.3%) patients in the study group. Incidence of Frey syndrome by subjective and objective methods was significantly higher in group A (control group) than in group B (study group) (*P*=0.011 and 0.002). Two patients in group B had soft tissue deficits (manifested as cosmetic depression at the operative site), whereas it occurred in 12 (33.3%) patients in group A with significant differences between both groups (*P*=0.003) (Table 2 and Fig. 5).

Figure 5



Frey syndrome and cosmotic unsatisfaction in the studiied groups.

Discussion

Salivary gland tumors mostly occur in the parotid gland (70–80%). Eighty percent of parotid tumors are benign and the most common benign tumor is pleomorphic adenoma [6]. Patients expect normal function and cosmosis postoperatively.

Complications of parotid surgery may be intraoperative or postoperative. Postoperative complications can be classified as early or late complications [7]. The late complications included Frey syndrome and cosmetic deformity [3].

One of the mechanisms of Frey syndrome is the aberrant regeneration of two different nerves because of defects in the parotid fascia after parotidectomy. The postganglionic parasympathetic nerve fibers connect with nerve fibers that innervate

the subcutaneous sweat glands, resulting in abnormal secretions from those glands during eating (flushing and sweating) [8].

Many flaps, including temporal fascia, fascia lata femoris, and sternomastoid myocutaneous flap, have been used as barriers between the parotid surface and the skin, but they had the disadvantage of the donor site morbidity. Synthetic materials, such as allogenic cellular matrix, have been used for the same purpose, but it is limited because its cost and its complications such as allergy [9].

In this study, attention was focused on the role of dermal fat graft in the prevention of postoperative complications.

In our study, by subjective method, the incidence of Frey syndrome was 27.8 and 5.6%, whereas by objective method the incidence was 38.9 and 8.3% in the control and study groups, respectively.

This is comparable to the studies conducted by Laccourreye *et al.* [10], Laskawi *et al.* [11], Hanna *et al.* [12], and Malatskey *et al.* [13], in which the incidence of Frey syndrome was 13, 11, 17, and 43%, respectively.

Incidence of Frey syndrome (by subjective and objective methods) was significantly higher in group A (control group) than in group B (study group).

In this study, the postoperative sialocele occurred in seven (19.4%) patients in the control group and in one (2.8%) patient in the study group. In the study by Rea *et al.* [14], 5.1% of their patients had sialocele and salivary fistula. The incidence of sialocele was significantly higher in the control group than in the study group. This is explained by the barrier effect done by the dermal fat graft in the study group, which decreases the incidence of Frey syndrome and sialocele.

As regards the cosmetic depression (soft tissue deficits), 12 patients in the control group had noticeable depression at the side of the face, whereas most of the patients in the study group noticed a mild elevation at the surgical site, which was related to the intended overcorrection by the dermal fat graft, as a portion of adipose tissue was shrinked over the few months after the operation and the patient restored the normal facial contour.

There was no significant difference between the studied groups as regards to the operative time and facial nerve palsy.

Conclusion

The dermal fat graft is a simple idea for restoring facial contour and preventing the postoperative complications after parotidectomy.

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Conflicts of interest

There are no conflicts of interest.

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A study on road traffic accidents in Arar, Saudi Arabia

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Background
Road traffic accidents (RTAs) are responsible for a substantial portion of morbidity and mortality and are responsible for more years of life lost than most human diseases.
Aim of the study
The aim of this study was to determine the type and contributing factors to RTAs in Arar, Northern Saudi Arabia.
Participants and methods
A cross-sectional study was carried out on randomly selected drivers in Arar city, Northern Saudi Arabia, KSA. Data were collected from 407 drivers aged between 18 and more than 55 years using predesigned questionnaires, which include questions designed to achieve the study objectives.
Results
RTAs were frequent with persons aged less than 20 years old, with a percentage of 36.9%, followed by 33.9% in the age between 20 and 35 years old and just 1.7% above 50 years. Distraction habits while driving were as follows: 49.6% use the cellphone while they drive and 30.5% smoke. Most of the RTAs happened during sunny weather (63.9%) and rainy weather (13.5%). The most frequent occurrences of RTAs were angle collision (40.8%), back collision (19.9%), and hitting a fixed object (13.3%). Place of accidents was main road in 43.2% followed by crossroad in 20.9 and 11.3% at traffic light site. Limbs, head, and upper body parts were the most injuries (35.1, 23.6, and 10.6%, respectively). After treatment, 3.4% of the injured drivers have distortion as a permanent disability, 2.9% have paralysis, and 2.5% have a limp. In all, 5.2% of the accidents resulted in one death, 2.5% resulted in two deaths, and 86% of the accidents did not result in any deaths.
Conclusion and recommendations
The findings of the present study will be helpful in the prevention of RTAs and its associated complications and hence will be vital for policymakers, health service managers, and stakeholders.

Keywords:
Arar, death, disability, distraction habits, driving, factors, Northern Saudi Arabia, road traffic accidents

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Introduction

Road traffic crashes (RTCs) are responsible for a substantial fraction of morbidity and mortality than most of the human diseases [1]. Road injuries occurred in almost 54 million people in 2013 [2]. This resulted in 1.4 million deaths globally in 2013, and up from 1.1 million deaths in 1990 [3]. Injuries resulting from RTCs are a major growing public health problem worldwide. RTIs are recognized as the most common cause of death, resulting in 1.26 million deaths each year globally, which accounts for 20.7% of all deaths from injuries [4]. Almost all high-income countries have decreased death rates, whereas the majority of low-income countries have increased death rates because of traffic accidents. Middle-income countries have the highest rate (with 20 deaths/100 000 inhabitants, 80% of all road fatalities by only 52% of all vehicles). While the death rate in Africa is the highest of all (24.1/100 000 inhabitants), the lowest rate is found in Europe (10.3/100 000 inhabitants) [5]. Many developing countries are still at low levels of motorization and the incidence of road traffic injuries (RTIs) in these countries is likely to increase. It is estimated that by 2020 road traffic accidents (RTAs) will be moved from

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ninth to third in the world disease burden ranking, as measured in disability-adjusted life years [6]. In addition, if present trends continue, road traffic injuries are predicted to be the third leading contributor to the global burden of disease and injury by 2020 [7].

A study conducted in Qatar [8] found that young drivers in the age group of 25–34 years had the highest prevalence of RTIs (35%). A significantly higher proportion of men had road traffic injuries when compared with women, with an incidence ratio of 1.4 : 1 (P=0.001), respectively. A large proportion of the injured drivers were involved in traffic violations within a year, especially violations such as exceeding speed limits (36.9%) and parking violations (18.1%). In all, 27.9% of injured drivers were distracted by eating or drinking, whereas 25.4% were distracted by using their mobile phone. The main types of crashes among drivers of Qatar were a result of overturn skid crashes (20.7%) followed by hitting fixed objects (15.1%). Those injured by both light vehicles and heavy vehicles reported the highest incidence of head injuries, with a combined percentage of 31.8% of all reported injuries.

Another study conducted in Northern Iran [9] showed that the prevalence of road traffic injuries in Guilan province was 31 in a population of 10 000. Of a total of 7671 accidents, 5976 (77.9%) were men and 1695 (22.1%) were women. Mean age of these victims was 33.3±17.289 years (32.64±16.939 for men and 35.62±18.312 for women). Most of them (32.5%) were 20–29 years old. Motorcycle–car accidents had the highest frequency followed by car–car crashes and car accidents involving pedestrians. Most of the patients (85.9%) were hospitalized and 280 (3.7%) injured died. Upper extremities were the most common sites of injuries. Male sex, length of hospital stay, multiple injuries, and increased age were associated with RTA-associated mortality.

Aim of the study

The aim of this study was to determine the type and contributing factors to RTAs in Arar, Northern Saudi Arabia, KSA.

Participants and methods

Study design and setting

This is a cross-sectional study carried out at five randomly selected Primary Health Care Centers in Arar city, Northern Saudi Arabia.

Study period and target population

The drivers were selected through systematic random sampling among patients registered for attending the Primary Health Care Centers during the study period. The study was conducted between 1 October 2016 and 30 April 2017, among drivers aged 18 years or above, who resided in Arar city. After obtaining informed consent, each participant was interviewed by a pretrained interviewer using a standard questionnaire. This questionnaire covered topics related to the sociodemographic, human behavioral factors of drivers, as well as environmental factors.

Sociodemographic information such as age, sex, and number of years that they have held a driving license, as well as type of vehicle driven, was obtained. Type of derived vehicle was light vehicles, which included the rest of the types of cars.

Sampling

The sample size was statistically calculated assuming a 50% prevalence of RTAs in Arar city, considering 5% bound on error of estimation and a 95% confidence level. The required minimum sample size for this study was 280. During the study period, 450 participants were approached, of whom 407 responded to the questionnaire, yielding a response rate of 90.4%.

Statistical analysis

Collected data were coded and analyzed using statistical package for social sciences (SPSS Inc., Chicago, Illinois, USA). Descriptive statistics for the qualitative and quantitative variables were used. The χ^2-test was used as a test of significance, and differences were considered significant at a P value of 0.05 or less.

Ethical considerations

Participants were informed that participation is completely voluntary, and written consent was obtained from each participant before being subjected to the questionnaire and after discussing the objective with the participants. No names were recorded on the questionnaires. Adequate training of data collectors took place to ensure protection of confidentiality, and all questionnaires were kept safe.

Results

Table 1 illustrates the age group, nationality, history of chronic diseases, traffic violations within a year, and driving experience among the studied drivers. Saudi nationals constitute 89.7%. Regarding traffic violations within a year, 36.6% exceed the speed limit, 12.0% lost their driving license, 11.1% had stop or

yield violation, and only 5.4% had red light violation. Driving experience was more than 10 years in 59.2%, 5–10 years in 26.3%, and less than 5 years in only 14.5% of them. There were no chronic diseases in 65.4%, 16.7% were diabetics, and 8.4% were hypertensive. Table 2 illustrates age group, distraction habits while driving, weather at the time of accident, types of crashes, and place of accidents among studied drivers. Our study showed that RTAs were frequent with individuals aged less than 20 years old, with a percentage of 36.9%, followed by 33.9% in the age between 20 and 35 years old, and only 1.7% above 50 years. Regarding distraction habits during driving, our study found that 49.6% use the cellphone while they drive and 30.5% smoke. Most of the RTIs occurred during sunny weather (63.9%) and rainy weather (13.5%). The highest occurrences of RTC were angle collision (40.8%), back collision (19.9%), and hitting a fixed object (13.3%). Place of accidents was main road in 43.2% followed by crossroad in 20.9%, and 11.3% at a traffic light site. Table 3 illustrates the type and severity of injury, duration and type of treatment, presence of disability after treatment, and number of deaths due to studied accidents. In all, 51.6% of accidents were minor; limbs, head, and upper body parts were the most injuries (35.1, 23.6, and 10.6%, respectively). Duration of treatment was just 1 week in 46.9% of cases and the treatment was medical in 56.9% and surgical in 9.1%. As regards disability after treatment, 3.4% of the injured drivers suffered from distortion as a permanent disability, 2.9% suffered from paralysis, and 2.5% suffered from lame. Regarding deaths, 86% of the total crashes did not result in any deaths, whereas only 5.2% resulted in one death and 2.5% resulted in two deaths. Table 4 illustrates the relationship between age at the time of accident and traffic violations within a year, distraction habits while driving and type of crash among studied drivers (27.8% of the population aged <20 years, 40.6% aged 20–35 years, and 42.3% of the population aged 35–50 years exceeded the speed limit). In all, 61.4% of drivers aged less than 20 years use the mobile phone during driving, 57.1% of the drivers aged more than 50 years eat and/or drink, and 47.1% of drivers aged 35–50 years smoke during driving. Of drivers younger than 20 years, 39.9% had angle collision crash, whereas 19.0% of them had back collision, and only 11.4% of them hit a walking person. In addition, 39.1% of drivers aged 20–35 years had angle collision and 8.0% of them hit a walking person. There was a highly significant relationship between age group at the time of accident and distraction habits while driving ($P<0.000$).

Table 1 Age group, nationality, history of chronic diseases, traffic violations within a year, and driving experience among the studied drivers, Arar, 2016 (*n*=407)

	n (%)
Nationality	
Foreigner	42 (10.3)
Saudi	365 (89.7)
Traffic violations within a year	
No violation	103 (25.3)
Shading	39 (9.6)
Exceeding speed limit	149 (36.6)
Loss of driving license	49 (12.0)
Red light violation	22 (5.4)
Stop or yield violation	45 (11.1)
Driving experience (years)	
<5 years	59 (14.5)
5–10 years	107 (26.3)
>10 years	241 (59.2)
History of chronic diseases	
No	266 (65.4)
Bronchial asthma	9 (2.2)
Diabetes mellitus	68 (16.7)
Hypertension	34 (8.4)
Cardiac disease	30 (7.4)

Table 2 Age, distraction habits while driving, weather at the time of accident, types of crashes, and place of accidents among studied drivers, Arar, 2016 (*n*=407)

	n (%)
Age at the time of accident (years)	
<20	158 (38.9)
20–35	138 (33.9)
35–50	104 (25.6)
>50	7 (1.7)
Distraction habits while driving	
Use of mobile phone	202 (49.6)
Eating or drinking	81 (19.9)
Smoking	124 (30.5)
Weather at the time of accident	
Hot sunny	271 (66.6)
Foggy	28 (6.9)
Dusty	53 (13.0)
Rainy	55 (13.5)
Type of crash	
Hit a walking person	32 (7.9)
Hit a fixed object such as a parked vehicle	54 (13.3)
Car accident	34 (8.3)
Angle collision	166 (40.8)
Back collision	81 (19.9)
Collision head to head	40 (9.8)
Place of accidents	
Main road	176 (43.2)
Side road	70 (17.2)
Traffic light site	46 (11.3)
Roundabout	30 (7.4)
Crossroad	85 (20.9)

Table 3 Type and severity of injury, duration and type of treatment, presence of disability after treatment, and number of deaths due to studied accidents, Arar, 2016

	n (%)
Severity of injury	
Minor	210 (51.6)
Moderate	119 (29.2)
Sever	78 (19.2)
Type of injury	
Other sites	73 (17.9)
Limps	143 (35.1)
Abdomen	16 (3.9)
Head	96 (23.6)
Chest	43 (10.6)
Neck	36 (8.8)
Duration of treatment	
1 week	191 (46.9)
2 weeks	51 (12.5)
About 1 month	33 (8.1)
More than 1 month	60 (14.7)
No need	72 (17.7)
Type of treatment	
Surgical	37 (9.1)
Medical	232 (56.9)
Both	66 (16.2)
No need	72 (17.7)
Presence of disability after treatment	
No disability	345 (84.8)
Distortion	32 (7.8)
Limp paralysis	12 (2.9)
Lame	10 (2.5)
Limp loss	8 (2.0)
Number of deaths	
No deaths	368 (90.4)
One	21 (5.2)
Two	10 (2.5)
Three	4 (1.0)
Four or more	4 (1.0)

Discussion

Injuries are the main causes of mortality and morbidity in a majority of countries around the world [10,11]. RTIs are one of the leading causes of death, hospitalization, disability, and low socioeconomic status [12–15].

This is a cross-sectional study carried out in Arar city, Northern Saudi Arabia, KSA, throughout the period from 1 October 2016 to 30 April 2017 on random drivers using a predesigned questionnaire for data collection. The major purpose of this study is to determine the contributing factors to RTCs and RTIs in Arar, Northern Saudi Arabia KSA.

Our study revealed that RTAs were frequent among persons aged less than 20 years old, with a percentage of 36.9%, followed by 33.9% in the age between 20 and 35 years old. Another study [9] showed that the most and least traffic accidents belonged to the 20–29-year group and below 10-year group, respectively. Our results is supported by other studies in Mexico [16] and in Lazio, Italy [22]; they found that young people were the most common victims of road accidents [17–21].

Regarding driving experience, 59.2% had experience more than 10 years, which did not agree with another study [8] that found that RTC was more prevalent among drivers with 5 years of driving experience. However, this association is usually not apparent, and it invalidates the relationship between driving experience or age and crashes, resulting in the highest rate of crashes among very young and old drivers.

Regarding distraction habits while driving, our study found that 49.6% use the cellphone while they drive and 30.5% smoke. A study in Qatar [8] found that most (27.9%) of the injured drivers were distracted by eating or drinking while driving; this was followed by a large proportion of drivers (25.4%) who were using mobile phones (25.4%) or typing SMS/text messages (22.7%). Another study found that there was a 39% prevalence of distraction. The most prevalent distractions were due to interactions with another passenger and it was more prevalent among drivers below 30 years of age or older than or equal to 50 years of age [23]. Another study showed that distractions can have varying influences on crash type. More specifically, passenger-related and cellphone distractions are more likely in angular crashes, whereas for other electronic-device-related distractions the most probable type of crash is a single-vehicle crash [24].

A high percentage of those who were injured had committed traffic violations before; the main traffic violations included exceeding the speed limit (36.6%), parking violations (11.1%), and red light violations (5.4%). Another study [8] found that the main traffic violations included red light violations (13.4%), exceeding the speed limit (36.9%), and parking violations (18.1%). This is in agreement with the previous study [25], which has reported that an increase of 1 km/h in the mean traffic speed results in a 3% increase in the incidence of injury crashes and a 4–5% increase in fatal crashes.

The data presented in the current study revealed that most of the RTIs happened during sunny weather (63.9%) and rainy weather (13.5%). In fact, a study carried out in Saudi Arabia [26], which has a climate

Table 4 Relationship between age at the time of accident and traffic violations within a year, and distraction habits while driving among studied drivers, Arar, 2016

Variable	*n* (%)					*P* value
	Less than 20 (*n*=158)	20–35 (*n*=138)	35–50 (*n*=104)	More than 50 (*n*=7)	Total (*n*=407)	
Traffic violations within a year						
Shading	20 (12.7)	15 (10.9)	4 (3.8)	0 (0.0)	39 (9.6)	NA
Exceeding speed limit	44 (27.8)	56 (40.6)	44 (42.3)	5 (71.4)	149 (36.6)	
Loss of driving license	26 (16.5)	15 (10.9)	8 (7.7)	0 (0.0)	49 (12.0)	
Red light violation	7 (4.4)	11 (8.0)	4 (3.8)	0 (0.0)	22 (5.4)	
Stop or yield violation	8 (5.1)	11 (8.0)	24 (23.1)	2 (28.6)	45 (11.1)	
No violation	53 (33.5)	30 (21.7)	20 (19.2)	0 (0.0)	103 (25.3)	
Distraction habits while driving						
Use of mobile phone	97 (61.4)	77 (55.8)	26 (25.0)	2 (28.6)	202 (49.6)	0.000
Eating or drinking	22 (13.9)	26 (18.8)	29 (27.9)	4 (57.1)	81 (19.9)	
Smoking	39 (24.7)	35 (25.4)	49 (47.1)	1 (14.3)	124 (30.5)	
Type of crash						
Hit a walking person	18 (11.4)	11 (8.0)	3 (2.9)	0 (0)	32 (7.9)	NA
Hit a fixed object such as a parked vehicle	17 (10.8)	19 (13.8)	18 (17.3)	0 (0)	54 (13.3)	
Car accident	17 (10.8)	10 (7.2)	7 (6.7)	0 (0)	34 (8.3)	
Angle collision	63 (39.9)	54 (39.1)	46 (44.2)	3 (42.9)	166 (40.8)	
Back collision	30 (19.0)	28 (20.3)	20 (19.2)	3 (42.9)	81 (19.9)	
Collision head to head	13 (8.2)	16 (11.6)	10 (9.6)	1 (14.3)	4 (9.8)	

NA, not applicable.

similar to our study, also found that hot, sunny conditions increase RTI; this finding can be attributed to increased stress and decreased performance of tasks that require motor skills during hot weather. The study in Qatar [8] also agreed with these results; they found that most of the RTIs occurred during the hot climate (80.4%) and sunny days (87.5%), reflecting the unique climate and weather conditions of Qatar. This was not in agreement with findings of other studies that have reported increased incidences of RTIs and RTCs in rainy conditions particularly after long dry spells [26–28]. Another study found that the sequence of occurrence of crashes during different seasons from highest to lowest include sunny>rainy>foggy>snowy [29].

The most frequent occurrences of RTC were angle collision (40.8%), back collision (19.9%), and hitting a fixed object (13.3%). Another study [8] found that the highest occurrences of RTC were angle collision (21.2%) and overturn skid (20.7%) among the studied drivers. Meanwhile, the highest incidences of RTI were a result of overturn skid (18.6%) and hitting a fixed object (15.1%) among the drivers studied.

In our study, limbs, head, and upper body parts were the most common injuries (35.1, 23.6, and 10.6%, respectively). Another study [8] found that head, face, neck, and spine injuries were more common among RTCs and RTIs of heavy vehicle drivers and most of the injured drivers had been hospitalized for their injuries. However, in the study by Zahra and colleagues, the results showed that upper extremity injuries and upper body part injuries were the most important causes of hospitalizations, following head and neck and lower extremities. In men, 34.1% of injuries were in upper extremities, whereas in women head and neck were the most injured body organs (27.8%). In different ages, upper extremities and head and neck were the most injured parts, which were different from Belgium [30] and Shiraz study [17]. In Mexico [16], surface injuries had the highest frequency. In contrast, data from Riyadh and the Armed Forces Hospital Al-Aseer reported a lower number of all types, and particularly head and neck injuries during 2001–2006 [31].

Accidents are responsible for 10% of death in the world, even higher than that of AIDS, malaria, and tuberculosis [32]. In our study, 86% of the total crashes did not result in any deaths, whereas only 5.2% of the crashes resulted in 1 death and 2.5% resulted in two deaths. The Nigerian Federal Road Safety Corps estimated 3.7 deaths per 100 000 population for Nigeria in 2009 [33].

RTCs cause disability in the short and long term, they are the ninth leading cause in the world of disability-adjusted life years, and they generate 41.2 million years of healthy life lost, thus accounting for 2.7% of the total worldwide [31,34–36]. Our study estimated that 3.4% of the injured

drivers suffered from distortion as a permanent disability, 2.9% suffered from paralysis, and 2.5% suffered from lame. A study conducted in Spain showed that mobility disabilities were the most prevalent, vision disability 18.3%, and hearing disability 15.1% [29].

Conclusion and recommendations

The findings of the present study will be helpful in prevention of RTAs and its associated complications and hence will be vital for policymakers, health service managers, and stakeholders.

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Conflicts of interest

There are no conflicts of interest.

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Laparoscopic cholecystectomy for symptomatic multiseptate gallbladder

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Multiseptate gallbladder is a rare congenital anomaly that may be silent or with symptoms. Herein, we report a case of 12-year-old male child with abdominal pain associated with nausea and vomiting. The diagnosis of multiseptate gallbladder was settled at 6 months after the first episode of abdominal pain by screening ultrasound and was confirmed by magnetic resonance cholangiopancreatography. We performed laparoscopic cholecystectomy with complete resolution of preoperative symptoms. The patient was discharged on postoperative day 1. The postoperative course was uneventful without complications.

Keywords:
congenital anomaly, laparoscopic cholecystectomy, multiseptate gallbladder

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1110-1121

Introduction

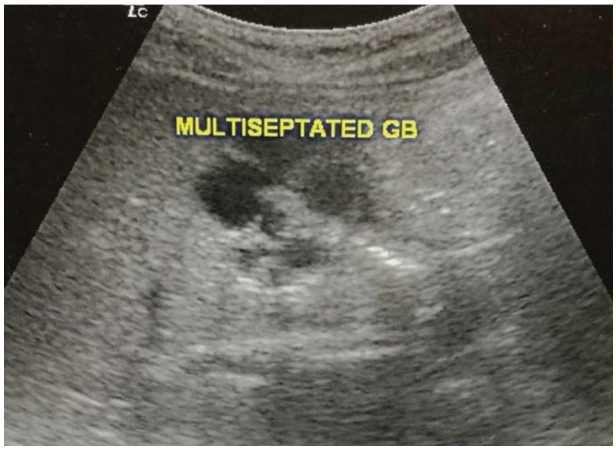
Multiseptate gallbladder is a very rare congenital anomaly, in which multiple septa of different sizes divide the gallbladder into intercommunicating chambers with faintly bosselated external surface. The gallbladder is usually normal in size and position. These septations may lead to bile stasis, stone formation, and recurrent abdominal pain, but this malformation may be asymptomatic [1]. Herein, we report a case of symptomatic calculous multiseptate gallbladder in a 12-year-old child treated by laparoscopic cholecystectomy (LC) with complete resolution of all preoperative symptoms.

Case report

A 12-year-old child was considered for LC due to multiseptate gallbladder. All Patients gave their formal consent. The protocol was approved the Ethical committee of Assiut University Hospital, Assuit Governate, Egypt. The diagnosis was pointed when the patient presented to our hospital with a 6-month history of recurrent right upper quadrant colicky abdominal pain. This was accompanied by nausea and vomiting. There was no fever or jaundice. Clinical examination and laboratory tests have shown normal findings (his hemoglobin concentration, white cell, and platelet counts were normal). Serum bilirubin concentration was 6 μmol/l, alkaline phosphatase 135 IU/1, γ-glutamyl transpeptidase 60 IU/l, aspartate transaminase 22 IU/1, albumin concentration 4 g/dl, and international normalized ratio of 1.02. Gall stones were the first clinical suspicious; however, abdominal ultrasound (US) scan showed no stones neither signs of inflammation, but multiple hyperechoic linear septa converting the gallbladder into a complex cystic structure (Fig. 1). For further confirmation of the diagnosis, magnetic resonant cholangiography (MRCP) was performed and showed a grape-like cluster of the gallbladder, with no associated abnormalities of the bile ducts (Fig. 2). The patient was scheduled for LC.

At laparoscopy, the gallbladder showed bosselated external surface, with delicate adhesion at the Hartman's pouch (Fig. 3a). The Calot's triangle was dissected; the cystic duct was very long (Fig. 3b).

Figure 1



Ultrasound showing multiple septa dividing the gallbladder into multilocular cysts. No stones or signs of inflammation.

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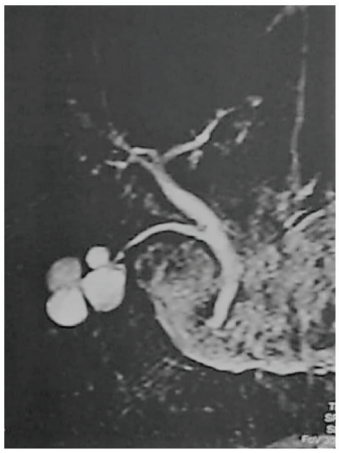
However, the cystic duct and artery were clipped and divided individually (Fig. 3c). The LC was completed with ease and without complications. The patient was discharged on the postoperative day 1. The 2-month postoperative course was uneventful, with resolution of all preoperative symptoms.

Figure 2

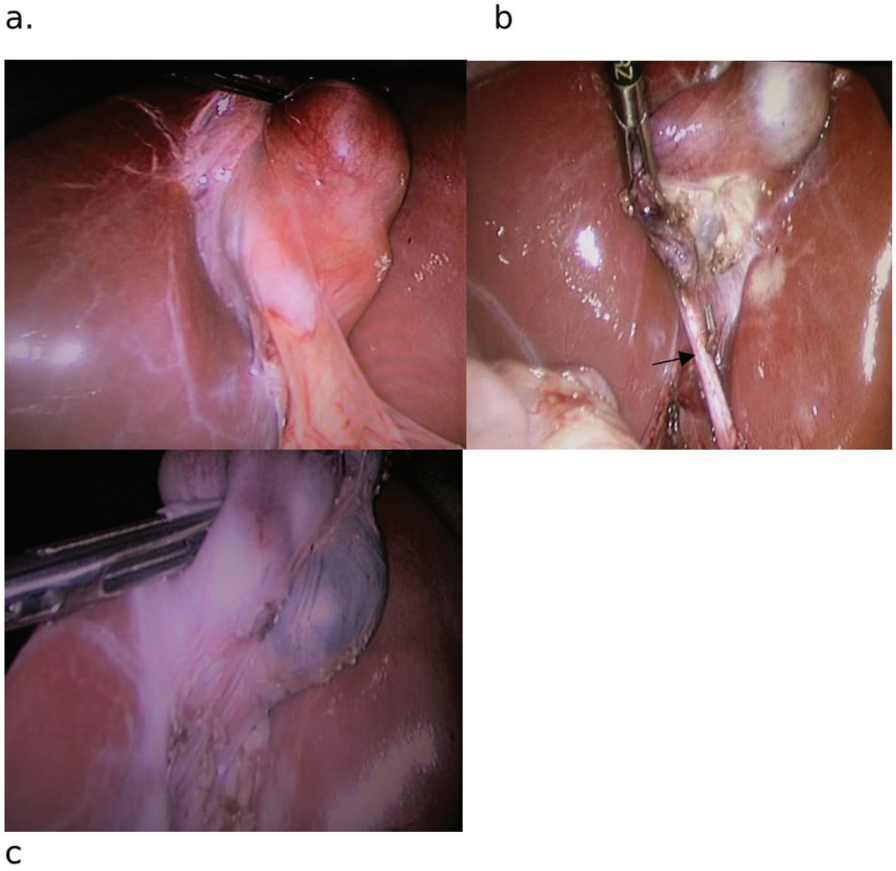


Magnetic resonant cholangiography confirmed the diagnosis of multiseptated gallbladder with delineation of normal bile ducts.

Discussion

Unlike anomalies of bile ducts and their associated blood vessels, gallbladder malformations are rare. The incidence of gallbladder anomalies was reported to be 0.1% [2]. These anomalies affect the size, shape, position, and number [3]. Multiseptate gallbladder is a rare anomaly of the shape which occurs due to incomplete vacuolization of the gallbladder bud [4]. Nevertheless, acquired multiloculate gallbladder due to inflammatory process has been reported previously [5,6]. Most cases are asymptomatic and discovered incidentally [1,7], whereas, in our patient, long-standing recurrent abdominal pain in the right hypochondrium was the main symptom, which might be due to impaired gallbladder motility, attributed to the presence of septa with subsequent bile stasis. Variant imaging modalities were used to diagnose the multiseptate gallbladder [8]. In our case, we used the safest and the least invasive modalities; the multiseptat gallbladder was demonstrated on the screening US as a honeycomb appearance (Fig. 1), which was further confirmed by the MRCP as a grape-like cluster; moreover, the

Figure 3



Intraoperative findings of laparoscopy. (a) The bosselated external surface; (b) long cystic duct (black arrow); and (c) separation of the gallbladder from its bed after division of the cystic duct and artery individually.

MRCP has the advantage to delineate the biliary tree and exclude the associated bile duct anomalies, with definite identification of the biliary anatomy which was of great importance during future cholecystectomy (Fig. 2). Cholecystectomy is a curative therapy for symptomatic septate gallbladder [9]. Herein, we performed LC, keeping in mind the principles of LC to prevent inadvertent injury [10]. Complete removal of the gallbladder was achieved, to avoid complications of remnant gallbladder, which could be a suitable seat for future stone formation and recurrence of symptoms.

Conclusion

In conclusion, multiseptated gallbladder is a rare anomaly that can be diagnosed by a combination of US and MRCP. Cholecystectomy should be considered for patients with symptomatic multiseptated gallbladder even in the absence of gall stones. In our patient, the abdominal pain and associated symptoms have resolved after surgery.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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Intestinal obstruction caused by mesenteric fat necrosis masquerading as small bowel malignancy

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Retractile mesenteritis had been described a century ago. However, the manifestations are variable and the diagnosis is difficult. We report a case presenting with a subacute intestinal obstruction. In conclusion, surgeons should add this variety in their differential diagnosis of bowel obstruction.

Keywords:
lipodystrophy, mesenteritis, panniculitis, sclerosis, small bowel obstruction

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1110-1121

Background

Mesenteric fat necrosis is a part of a larger disease spectrum called collectively as mesenteric sclerosis. It was first described in 1924 by the name retractile mesenteritis [1]. It mainly affects the mesentery of the small bowel, although it is claimed to involve the large bowel, especially the sigmoid mesentery, more frequently in Japanese [2].

Actually, the disease passes by three major stages: stage I (lipodystrophy), characterized by fat necrosis; stage II (panniculitis), characterized by a chronic inflammatory process; and finally stage III (retractile mesenteritis), characterized by extensive fibrosis and mass formation [3].

The disorder was considered by some authors as an IgG4-related disease or mimic, because of the associated high serum levels of the immunoglobulin and its presence within the inflammatory process [4].

Herein, we, up to our knowledge, describe the first case from Egypt, and the second from the Arab countries, with this rare disease manifesting by obstructive symptoms.

Case presentation

A 69-year-old woman with a recently discovered hypertension and dyslipidemia presented with a long history of abdominal discomfort and vomiting, but normally passing flatus and stool. She had a previous admission 1 month ago at an emergency hospital because of recurrent attacks of severe vomiting, where it was treated conservatively. She had no known allergies, nor significant family history, and a review of her systems was unremarkable.

Upon physical examination, the patient was obese (BMI: 35), in no acute distress, and had stable vital signs. She had a distended and tympanic abdomen with tinkling bowel sounds.

Laboratory data revealed a normal complete blood count, blood chemistry, and coagulation profile. She was referred for an outpatient colonoscopy, which passed up to the cecum, and revealed just a benign polypoidal lesion near the splenic flexure, which was excised and confirmed histopathologically. Computed tomography (CT) of the abdomen was performed using a slice thickness of 5 mm after oral and intravenous contrast administration. CT showed a diffuse thickening of small intestinal loops, which is associated with haziness of the surrounding fat planes, forming an exophytic mass lesion of 6.6×5 cm^2, query inflammatory or neoplastic, and an enlarged fatty liver. The proximal intestinal loops showed a moderate dilatation (Fig. 1).

Midline exploratory incision revealed a mass in the mesentery of the small bowel (ileum) with no evidence of hematoma or infarction (Fig. 2). There was moderate distension of the proximal intestinal loops. Segmental intestinal resection with primary anastomosis was performed, and the patient was discharged home 4 days later.

Grossly, the specimen consisted of 35 cm of small intestine excised with a single greyish yellow mass at

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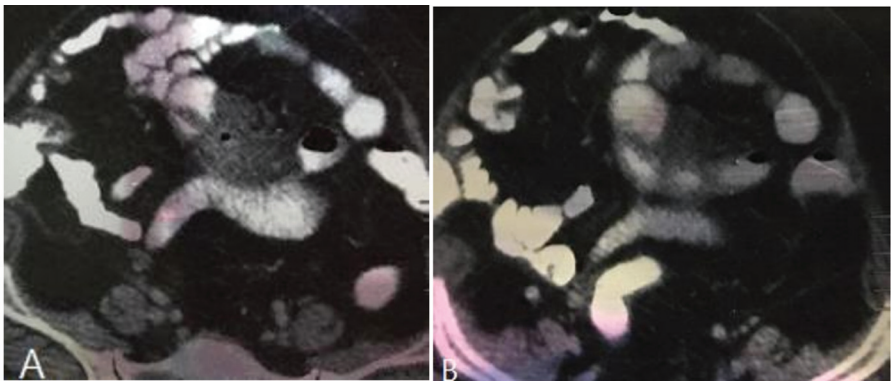
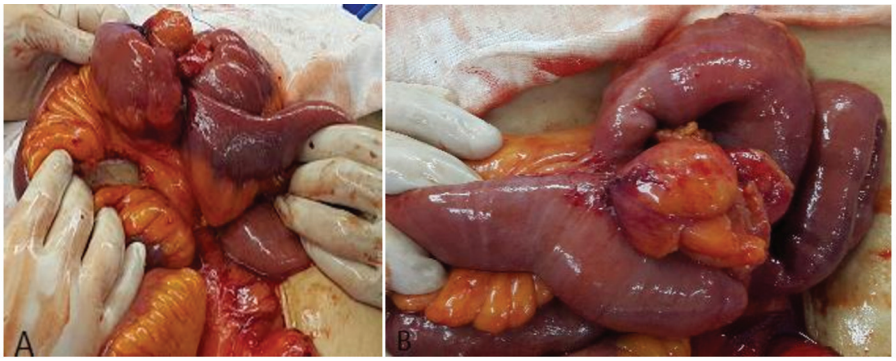
Figure 1



A transverse section of contrast computed tomography, (A) Showing a small intestinal ill-defined mass with surrounding haziness (B) Intestinal mass protruding through a small abdominal wall defect

Figure 2



The small intestinal mass as seen in exploration (A) Side view (B) Anterior view

the mesenteric side measuring 5×4×4 cm^3 compressing the intestinal wall with fibrous adhesion. Multiple mesenteric nodes, greyish yellow in color, were also seen. Microscopic examination revealed fat cells separated by fibrous septa (Fig. 3). Sections prepared from the mesenteric nodules revealed similar picture. Two lymph nodes showed a reactive hyperplasia. Final diagnosis was intestinal obstruction by mesenteric fat necrosis with fibrous adhesion.

Discussion

Sclerosing mesenteritis is a chronic, rare nonspecific inflammatory disease of adipose tissue in the intestinal mesentery with unrivalled criteria [5]. Although there is scarce disease description in Arab countries and Africa, Hammoud *et al.* [6] previously reported three cases from Lebanon, and Madubogwu [7] reported a case in Nigeria.

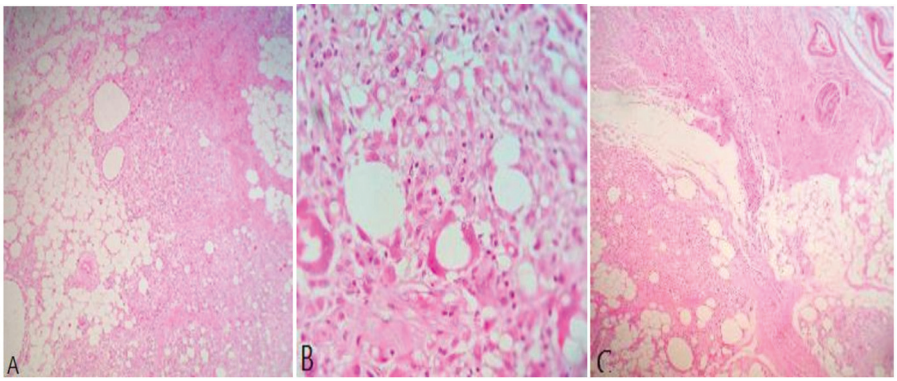
Association with previous surgery, trauma, autoimmune disease, and ischemic injury was frequently reported [8]. Other scholars had related the disease to glucose intolerance, but in a small series [9]. In two separate case reports and one case series, the disease was associated with Sjogren disease [10,11], one of them with multiple disease focuses [12]. In our case, none of the above association was detected. However, the only significant, may be related, disorder was dyslipidemia with the associated diffuse fatty infiltration of the liver.

The relation of the disease and malignancy (being a paraneoplastic syndrome), especially lymphoma, gastrointestinal tract adenocarcinoma, lung carcinoma, and prostatic carcinoma, was described [13,14]. Actual causation and the need for longer follow-up of those patients are still unclear.

The disease usually affects men in the 6th decade of life [15], in contrary to our patient, who is a female and a decade elder.

The disease diagnosis is another dilemma, and in many cases, as in our patient, it is impossible to obtain the diagnosis preoperatively. Mesenteric panniculitis is usually asymptomatic and discovered incidentally. If

Figure 3



Microscopic examination showing (A) Fat necrosis, ruptured fat cells with foam, macrophage and fibrosis (H&E X 40) (B) Ruptured fat cells with foam, macrphages and giant cells (H&E X 400) and (C) Fat cells variable in size and shape with intervening histiocytes, foreign body giant cell reaction, and areas of dense fibrosis (H&E X40)

symptomatic, patients may present with abdominal tenderness, a palpable mass, may be with systemic manifestations such as pain, fever, weight loss, and bowel disturbance of variable duration. Laboratory findings may include elevation in erythrocyte sedimentation rate, neutrophilia, and anemia [16,17]. However, radiologic signs were described, including fat ring encircling the mesenteric vessels and tumor pseudocapsule [3].

The disease is relatively indolent, with slow progression, and usually self-limited [8]. However, some authors documented that up to 20% had an aggressive pattern, which may be fatal [18].

Treatment of the disease seems mainly medical, unless obstruction, bleeding, or advanced chronic disease supervenes [15]. Otherwise, the main role of surgery is to biopsy the lesions to confirm the radiologic diagnosis. Drugs used in the therapy are Colchicine, Prednisolone, Tamoxifene, and Pentoxyphiline [8]. Some claim Prednisolone to be the first choice in case inflammatory symptoms dominate [19].

However, others claim the presence of the disorder as a part of Weber-Christian disease being associated with worse response to corticosteroids [12]. In our patient, the subacute intestinal obstructive symptoms, plus the uncertain preoperative diagnosis, made the surgical intervention as the only suitable treatment option. Afterwards, the patient had significantly improved symptoms.

Conclusion

Sclerosing mesentritis is a rare, poorly understood disease that may present with intestinal obstruction. The orientation of this entity among radiologist and surgeons may obviate the need for surgery in uncomplicated cases.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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