The Egyptian Journal of Surgery

The official organ of the Egyptian Society of Surgeons

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EGYPTIAN JOURNAL OF SURGERY

Egyptian Journal of Surgery - Published Quarterly
Egyptian Journal of Surgery is the Offical Journal of the Egyptain Society of Surgeons.

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Last updated September 2014

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The Egyptian Journal of Surgery is published four times a year; in January, April, July and October. The annual subscription fees are as follows: Members of ESS: L.E. 100
Institutions: L.E.100
Issues will be mailed to subscribers only.

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The Egyptian Journal of Surgery

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Vol. (36), No. (3), July-September 2017

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Original articles

Abstracts

Wolters Kluwer

Medknow

Burst abdomen: should we change the concept, preliminary study

Hesham Amer, Sherif M. Mokhtar, Shady E. Harb

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Received 7 November 2016
Accepted 22 November 2016

The Egyptian Journal of Surgery
2017, 36:199–207

Background
Burst abdomen represents one of the most frustrating and difficult postoperative complications encountered by surgeons who perform a significant volume of surgery. Burst abdomen occurs because of various preoperative, operative and postoperative factors, which can be prevented to some extent by being aware of them. The choice of incision for laparotomy depends on the area that needs to be exposed, the elective or emergency nature of the operation, and personal preference. Type of incision may, however, have an influence on the occurrence of postoperative wound complications, which is discussed in our study. There is little consensus in the literature as to whether a particular incision confers any advantage.

Objective
The purpose of this study was to provide an evidence-based consensus regarding the patients who underwent laparotomy for various intra-abdominal conditions included in our inclusion criteria and who developed burst abdomen in relation to the type of abdominal incision (vertical vs. transverse), as well as to know the rates of incidence, morbidity and mortality due to burst abdomen, and study other variables within the scope of postoperative complications. Other variables within the postoperative complications spectrum were also studied alongside the main one, burst abdomen.

Patients and methods
This is a prospective, randomized study (by card picking under supervision of the ward nurse) that compared the postoperative complications (mainly burst abdomen) after two main types of abdominal incisions, vertical and transverse, within a period of 12 months from October, 2015 to October, 2016. The study was conducted at the Emergency Unit, General Surgery Department, Kasr Al Ainy University Hospital, Faculty of Medicine, Cairo University. Sixty patients underwent open abdominal operations (exploration) after following distinctive inclusion and exclusion criteria. Thirty patients underwent vertical and thirty patients underwent transverse incisions. The main outcome measures were early complications such as burst abdomen, pulmonary complications and hospital stay.

Results
The transverse incision offers as good an access to most intra-abdominal structures as a vertical incision. The incidence of burst abdomen is higher in the vertical incision (midline) group, with 71.4% of the total patients suffering a burst abdomen. Respiratory complications occurred significantly in cases of burst abdomen ($P<0.001$). Hence, hospital stay was longer in cases of burst abdomen ($P<0.001$), which added to the economic burden.

Conclusion
Transverse incisions in abdominal surgery are based on better anatomical and physiological principles. It should be preferred, as the early postoperative period is associated with fewer complications (burst abdomen and pulmonary morbidity). A midline incision is still the incision of choice in conditions that require rapid intra-abdominal entry (such as trauma with suspected intra-abdominal haemorrhage).

Keywords:
burst abdomen, respiratory complications, transverse incision, vertical incision

Egyptian J Surgery 36:199–207

1110-1121

Introduction

Major abdominal surgery is an important part of current medical practice. The surgery is common, and is also responsible for significant utilization of hospital resources both in terms of funding

 DOI: 10.4103/1110-1121.211706

and in terms of bed usage. Postoperative surgical complications represent one of the most frustrating and difficult outcomes experienced by surgeons who perform a significant volume of surgery [1].

The occurrence of burst abdomen increases the cost of treatment and is associated with lost work productivity, disruption of normal family life, and unanticipated stress to employers and society in general. This complication can present for a variety of reasons. A surgeon can perform a technically perfect operation in a patient who is severely compromised by the disease process and still encounter a complication. Similarly, surgical technical errors or choices may account for this operative complication [2].

In clinical practice the choice of incision is usually based on surgical preference rather than on patient criteria. Surgically, ease of access, time to open and close the abdomen, and incidence of postoperative complications (burst abdomen, wound infection, postoperative pulmonary complications and incisional hernias) are important. For the patient, however, pain and rapid return to normal function are important. From an economical point of view, the duration of operation and duration of hospital stay determine the cost [3].

The recent interest in accelerated discharge after abdominal surgery highlights the importance of a comparison of incision types as there is an assumption that transverse incisions contribute to more rapid recovery [4].

Surgical practice has evolved to include a variety of incisions to gain access to the abdominal cavity. Midline and transverse incisions are the two most common forms of incision used [5].

The Emergency Unit, Department of Surgery, at Kasr Al Ainy University Hospital, Faculty of Medicine, Cairo University, faces the problem of burst abdomen frequently. This has led us to implement a different type of laparotomy incision to reach a better outcome. We also intended to evaluate the frequency of other variables within the scope of postoperative complications that are commonly encountered in our university hospital and could be related to the surgical procedure.

Patients and methods

A prospective, randomized study (by card picking under supervision of the ward nurse) was conducted on 60 patients who underwent exploratory laparotomy at the Emergency Unit, General Surgery Department, Kasr Al Ainy University Hospital, Faculty of Medicine, Cairo University, over a period of 12 months, from October, 2015 to October, 2016. The study cases were 30 patients who underwent vertical abdominal incision and another 30 patients who underwent transverse abdominal incision.

All patients were given an explanation of the study and about the investigative and operative procedures along with their merits and demerits, expected results and possible complications. The study did not involve any additional investigation or any significant risk as we followed the inclusion and exclusion criteria strictly. It did not impose an economic burden on the patients.

Selection of patients was based on certain inclusion criteria: all adult patient candidates for exploratory laparotomy aged 16 years and older with expected pathological and traumatic (whether blunt or penetrating abdominal trauma) aetiology of acute surgical abdomen that could withstand the longer duration of transverse incision were selected for the study. The patients' general condition was evaluated through haemodynamics, including the suspected upper and lower intra-abdominal pathology to evaluate the accessibility to different intra-abdominal organs. However, that was not the main outcome of our research. Trauma patients with haemodynamic instability and patients who had undergone a previous laparotomy were excluded. Those with trauma and hemodynamic instability were explored to control any source of bleeding. The paediatric age group was excluded from our study population. Primary outcome measures were surgical site infection, burst abdomen, respiratory complications and hospital stay. The data collection sheets were filled in by the investigators themselves. These sheets were designed to cover all aspects needed to be studied.

The patients' name, age, sex and address were noted. History of special habits of medical importance (smoking, hashish and tramadol addiction) and history of comorbidities in the form of diabetes mellitus, hypertension, cardiac condition, hepatic affection, renal impairment, asthma and BMI for morbid obesity were noted. Further, the date of admission, date of operation and date of discharge/ morbidity were recorded.

In each patient, detailed history taking was carried out for origin, duration and progress of the illness, past history and treatment. A complete physical examination was performed, and vital data and other

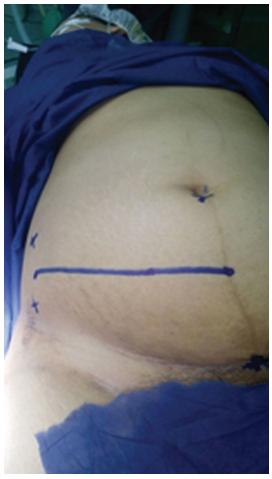
physical findings were obtained. A thorough systemic examination of the abdomen was performed. Patients were diagnosed on the basis of clinical symptoms, physical examination, haematological investigations, total lymphocyte count, haemoglobin, platelet count, serum creatinine, serum albumin and radiological investigations according to the need for each patient.

In each patient, the type of operative procedure starting from the type of abdominal incision, whether vertical or transverse (our main point of comparison in relation to burst abdomen incidence), and intraoperative findings were noted (Fig. 1). Postoperative complications such as acute systemic constitutional manifestations, surgical site infection, burst abdomen, respiratory complications, need for re-exploration, and mortality were noted, together with postoperative hospital stay.

Planning of the level of transverse incision was a little challenging as regards a supraumbilical or an infraumbilical approach to access the suspected site of pathology (upper or lower intra-abdomen), taking into our consideration the possibility of stoma. Stoma site selection whether in the upper or lower flap was not difficult as bowel exposure and resection procedure were technically attainable, giving good length to have a healthy and functioning stoma (Figs 2–4).

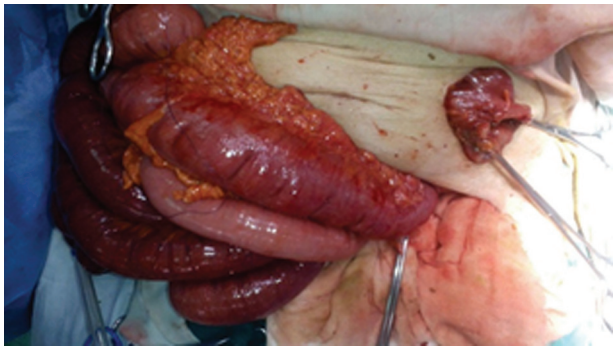
All midline vertical incisions were closed by continuous suture of mass closure using Prolene no. 1, reinforced by interrupted sutures of mass closure using Vicryl no. 1 or 0 with no peritoneal closure. We followed the recommended stitch interval and the tissue bite size to be 1 cm average with a range between 1 and 2 cm together with suture-length to incision-length ratio almost 4 : 1 or greater for this continuous mass closure. The subcutaneous tissue was closed using Vicryl 2/0 on a rounded needle and finally the skin was closed using interrupted sutures of silk 2/0. Transverse incisions were closed (with no peritoneal

Figure 1



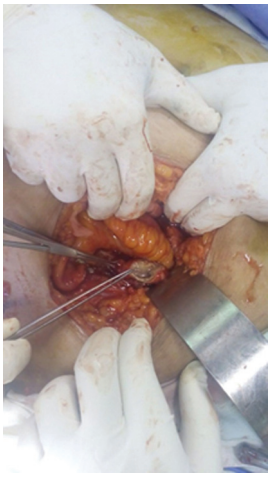
Marking of the site of transverse incision preoperatively.

Figure 2



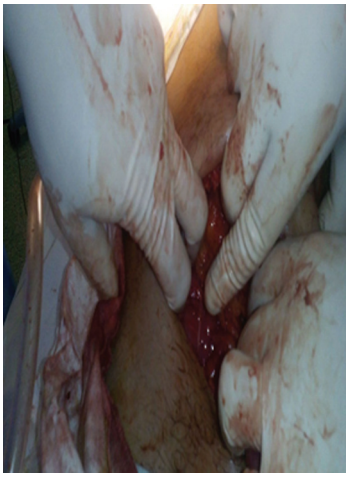
Stoma formation through the upper flap of a supraumbilical incision.

Figure 3



Complicated acute appendicitis with transverse incision.

Figure 4



Hepatic flexure exposure through transverse incision.

closure) using continuous suture of Vicryl no. 1 for the muscles and posterior rectus sheath and continuous suture of Prolene no. 1 for the anterior rectus sheath. The rest of the layers were closed as previously mentioned in closing the vertical incision. The same steps that were followed in vertical incisions as regards the stitch interval and the tissue bite size together with suture-length to incision-length ratio were followed in transverse incisions.

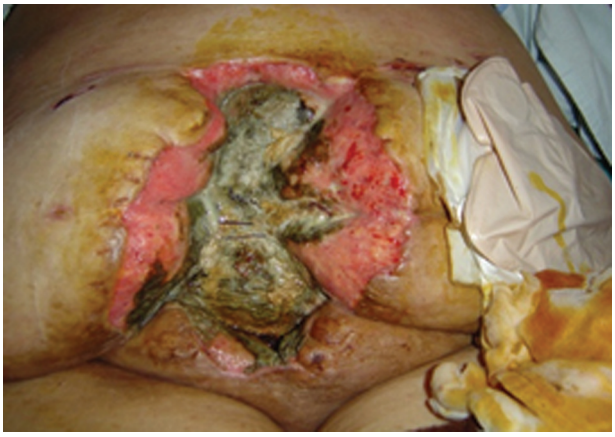
During the postoperative period all patients were closely monitored every day until discharge from the hospital. If any symptom or sign of infection appeared during this period, proper investigation was conducted. If any collection of pus was noted, it was drained out and sent for culture and sensitivity testing. Proper antibiotic was given to every patient preoperatively (prophylactic antibiotic for all cases was Ceftriaxone) and postoperatively. The antibiotic was changed when necessary after getting the report of the culture and sensitivity tests. The main outcome of the study was observation of the occurrence of burst abdomen after following proper operative steps and precautions (Fig. 5).

Statistical methods

The collected data were coded, tabulated and statistically analysed using IBM statistical package for the social sciences (SPSS) statistics software (version 22.0, 2013; IBM Corp., Chicago, Illinois, USA).

Descriptive statistics were analysed for quantitative data as minimum and maximum of the range, as well as mean±SD for quantitative normally distributed data and median and first and third interquartile range for quantitative non-normally distributed data. Qualitative data were presented as number and percentage. Inferential analyses were conducted for quantitative variables using the independent *t*-test in cases of two independent groups with normally distributed data and the Mann–Whitney *U*-test in cases of two independent groups with non-normally distributed data. In qualitative data, inferential analyses for independent variables were performed using Fisher's exact test for variables with small expected numbers. The level of significance was taken at *P* value of less than 0.05.

Figure 5



Burst abdomen in midline vertical incision.

Results

This prospective, randomized study was conducted to find a consensus on which exploratory abdominal incision is better (vertical or transverse) and its repercussion on the incidence of burst abdomen as the main dependent variable in our study. This would go alongside reporting of other postoperative complications.

Demographic distribution of the patients

The ages of the studied patients ranged from 16 to 75 years (mean age 33 years). BMI ranged between 29 and 42, with a mean of 33.1. Male sex represented 38 (63.3%) patients, whereas female sex represented 22 (36.7%) patients. Special habits recorded were smoking, hashish and tramadol addictions (Table 1).

Out of 60 patients, only 18 had comorbidities, which included hypertension, diabetes mellitus, chronic obstructive pulmonary disease, cardiovascular disease, liver disease, asthma and morbid obesity (Table 2).

Table 1 Demographic and special habits among the studied cases (total=60)

Variables	Mean±SD (range) or *n* (%)
Age (years)	33.0±12.7 (16.0–75.0)
BMI (kg/m^2)	33.1±3.2 (29.0–42.0)
Sex	
Male	38 (63.3)
Female	22 (36.7)
Smoking	25 (41.7)
Hashish	12 (20)
Tramadol	6 (10)

Table 2 Comorbidities at admission among the studied cases (total=60)

	N (%)
HTN	5 (8.3)
DM	5 (8.3)
Liver disease (HCV, cirrhosis)	2 (3.3)
COPD	2 (3.3)
CVD	3 (5)
Morbid obesity	1 (1.7)

COPD, chronic obstructive pulmonary disease; CVD, cardiovascular disease; DM, diabetes mellitus; HCV, hepatitis C virus; HTN, hypertension.

Patients presented as either pathological or traumatic. Different types of procedures were included in the study. Appendectomy was the most commonly encountered procedure, with an incidence of 38.3% (23 patients). Regarding the type of the incision used, midline laparotomy was equal to transverse incision as it was planned from the beginning of the study. Wound classes included in the study were I and II. Class II wounds were the most prevalent (51 patients) (Table 3).

The most frequent complication was discharge, followed by surgical site infection (SSI) and respiratory complications (Table 4 and Fig. 6).

Table 5 and Fig. 7 show that burst abdomen cases had significantly higher BMI compared with Non-burst abdomen cases.

Table 3 Surgical details among the studied cases (total=60)

Variables	*N* (%)
Indications	
Pathology	58 (96.7)
Trauma	2 (3.3)
Incisions	
Transverse	30 (50)
Midline	25 (41.7)
Lower mid	4 (6.7)
Right paramedian	1 (1.7)
Procedures	
Appendectomy	23 (38.3)
Intestinal resection	20 (33.3)
PU patch	3 (5)
Adhesiolysis	3 (5)
Herniorrhaphy	3 (5)
Delivery	4 (6.7)
Oophorectomy	3 (5)
Milking FB	1 (1.7)
Diversions	
Any	9 (15)
Lower flab	4 (6.7)
Left	5 (8.3)
Wound classes	
I	9 (15)
II	51 (85)

FB, foreign body, PU, peptic ulcer.

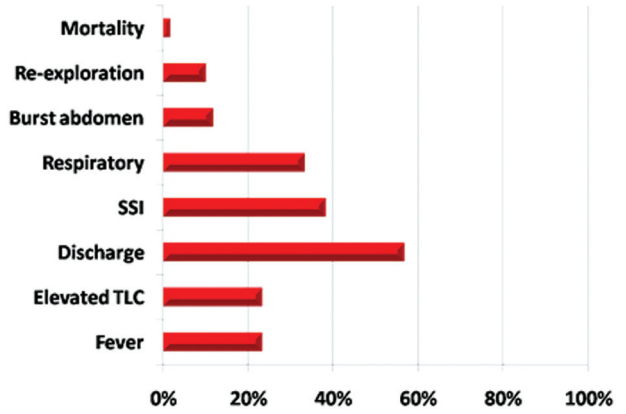
As shown in Table 6, DM was present in two cases out of seven that had burst abdomen, meanwhile, one case showed morbid obesity. Table 7 represents the following results, burst abdomen occurred in seven patients out of 60 and was higher in cases that were explored through vertical (midline) incision, with an incidence of 71.4%. Also, the incidence of burst abdomen in relation to surgical procedure was highest in cases with intestinal resection (71.4%). As regards the

Table 4 Complications after surgery among the studied cases (total=60)

Variables	*N* (%) or median (IQR) (range)
Fever	14 (23.3)
Elevated TLC	14 (23.3)
Discharge	34 (56.7)
SSI	23 (38.3)
Respiratory	20 (33.3)
Burst abdomen	7 (11.7)
Re-exploration	6 (10.0)
Mortality	1 (1.7)
Fever day	4.0 (3.0–7.5) (3.0–10.0)
Elevated TLC day	4.5 (3.8–7.0) (2.0–10.0)
Discharge day	4.0 (0.0–6.0) (0.0–10.0)
SSI day	5.0 (4.0–8.0) (3.0–10.0)
Stay	5.0 (3.0–9.0) (1.0–36.0)

IQR, third–first interquartile range; TLC, total leucocyte count.

Figure 6



Complications after surgery among the studied cases. TLC, total leucocyte count.

Table 5 Comparison between cases with and without burst abdomen regarding demographic data and special habits

Variables	Burst (*N*=7)	Not (*N*=53)	*P*	OR (95% CI)
Age (years)	35.6±15.2	32.7±12.4	0.575[a]	–
BMI (kg/m^2)	35.9±4.0	32.8±2.9	0.013[a*]	–
Sex [*n* (%)]				
Male	6.0 (85.7)	32 (60.4)	0.246[b]	3.94 (0.44–35.09)
Female	1 (14.3)	21 (39.6)		
Smoking [*n* (%)]	3 (42.9)	22 (41.5)	1.000[b]	1.06 (0.21–5.20)
Hashish [*n* (%)]	2 (28.6)	10 (18.9)	0.619[b]	1.72 (0.29–10.18)
Tramadol [*n* (%)]	1 (14.3)	5 (9.4)	0.541[b]	1.60 (0.16–16.10)

CI, confidence interval; OR, odds ratio. [a]Independent *t*-test. [b]Fisher's exact test. [*]Significant.

Table 6 Comparison between cases with and without burst abdomen regarding comorbidities at admission

Variables	Burst (*N*=7) [*n* (%)]	Not (*N*=53) [*n* (%)]	*P*[a]	OR (95% CI)
HTN	0 (0.0)	5 (9.4)	1.000	–
DM	2 (28.6)	3 (5.7)	0.099	6.67 (0.89–49.83)
CLD	0 (0.0)	2 (3.8)	1.000	–
COPD	0 (0.0)	2 (3.8)	1.000	–
CVD	0 (0.0)	3 (5.7)	1.000	–
Morbid obesity	1 (14.3)	0 (0.0)	0.117	–

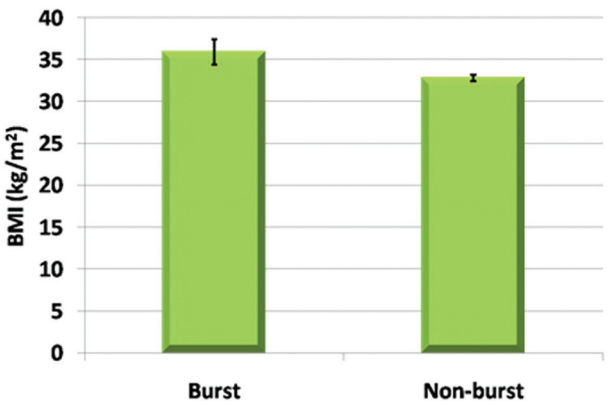
CI, confidence interval; COPD, chronic obstructive pulmonary disease; CLD, chronic liver disease; CVD, cardiovascular disease; DM, diabetes mellitus; HTN, hypertension; OR, odds ratio. [a]Fisher's exact test.

Table 7 Comparison between cases with and without burst abdomen regarding surgical details

Variables	Burst (*N*=7) [*n* (%)]	Not (*N*=53) [*n* (%)]	*P*[a]	OR (95% CI)
Indications				
Pathology	6 (85.7)	52 (98.1)	0.221	0.12 (0.01–2.09)
Trauma	1 (14.3)	1 (1.9)		
Incisions				
Transverse	2 (28.6)	28 (52.8)	0.424	0.36 (0.06–2.01)
Midline	5 (71.4)	20 (37.7)	0.117	4.13 (0.73–23.30)
Lower mid	0 (0.0)	4 (7.5)	1.000	–
Right paramedian	0 (0.0)	1 (1.9)	1.000	–
Procedures				
Appendectomy	1 (14.3)	22 (41.5)	0.233	0.23 (0.03–2.09)
Intestinal resection	5 (71.4)	15 (28.3)	0.036*	6.33 (1.11–36.28)
Perforated peptic ulcer	0 (0.0)	3 (5.7)	1.000	–
Adhesiolysis	1 (14.3)	2 (3.8)	0.315	4.25 (0.33–54.17)
Herniorrhaphy	0 (0.0)	3 (5.7)	1.000	–
Delivery	0 (0.0)	4 (7.5)	1.000	–
Oophorectomy	0 (0.0)	3 (5.7)	1.000	–
Milking FB	0 (0.0)	1 (1.9)	1.000	–
Diversions				
Any	4 (57.1)	5 (9.4)	0.007*	12.80 (2.21–74.22)
Lower flab	1 (14.3)	2 (3.8)	0.315	4.25 (0.33–54.17)
Left	3 (42.9)	3 (5.7)	0.017*	12.50 (1.88–83.31)
Wound classes				
I	1 (14.3)	8 (15.1)	1.000	0.94 (0.10–8.86)
II	6 (85.7)	45 (84.9)		

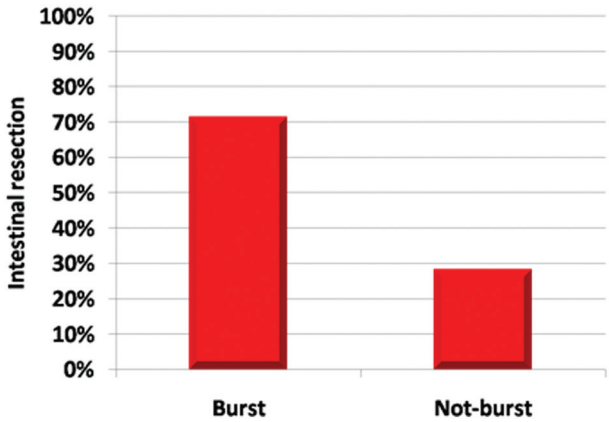
CI, confidence interval; OR, odds ratio. [a]Fisher's exact test. *Significant.

Figure 7



Comparison between cases with and without burst abdomen with regard to BMI.

Figure 8



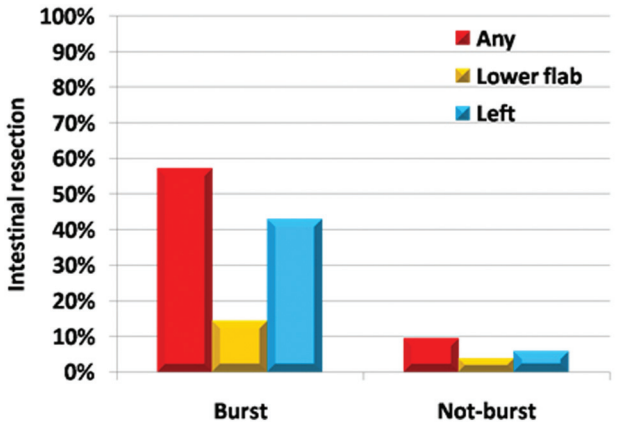
Comparison between cases with and without burst abdomen with regard to intestinal resection.

Table 8 Comparison between cases with and without burst abdomen regarding complications after surgery

Variables	Burst (*N*=7) [*n* (%)]	Not (*N*=53) [*n* (%)]	*P*	OR (95% CI)
Fever	5 (71.4)	9 (17.0)	0.006[*,a]	12.22 (2.04–73.19)
Elevated TLC	6 (85.7)	8 (15.1)	<0.001[*,a]	33.75 (3.57–319.13)
Discharge	7 (100.0)	27 (50.9)	0.016[*,a]	–
SSI	5 (71.4)	18 (34.0)	0.095[a]	4.86 (0.86–27.57)
RR (95% CI)				
Respiratory	7 (100.0)	13 (24.5)	<0.001[*,a]	–
Re-exploration	2 (28.6)	4 (7.5)	0.140[a]	3.60 (0.88–14.69)
Mortality	1 (14.3)	0 (0.0)	0.117[a]	–
Fever day	4.0 (3.0–4.0)	4.0 (3.5–9.5)	0.220[b]	–
Elevated TLC day	4.5 (3.5–7.0)	4.5 (3.3–8.8)	0.312[b]	–
Discharge day	4.0 (4.0–6.0)	4.0 (0.0–6.0)	0.417[b]	–
SSI day	5.0 (4.0–7.5)	5.0 (4.0–10.0)	0.706[b]	–
Stay	30.0 (23.0–35.0)	4.0 (3.0–7.5)	<0.001[*,b]	–

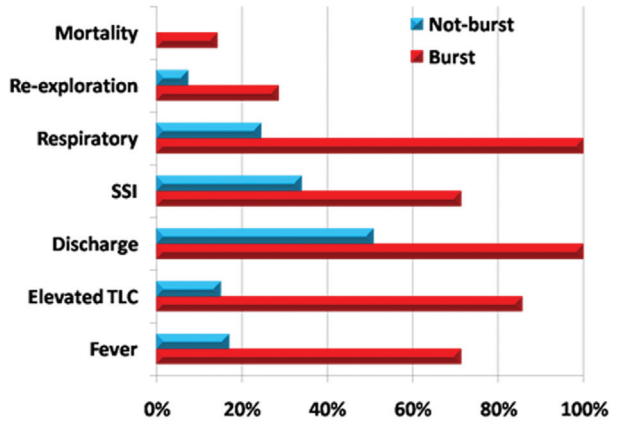
CI, confidence interval; OR, odds ratio; RR, relative risk; TLC, total leucocyte count. [a]Fisher's exact test. [b]Mann–Whitney test. [*]Significant.

Figure 9



Comparison between cases with and without burst abdomen with regard to diversion.

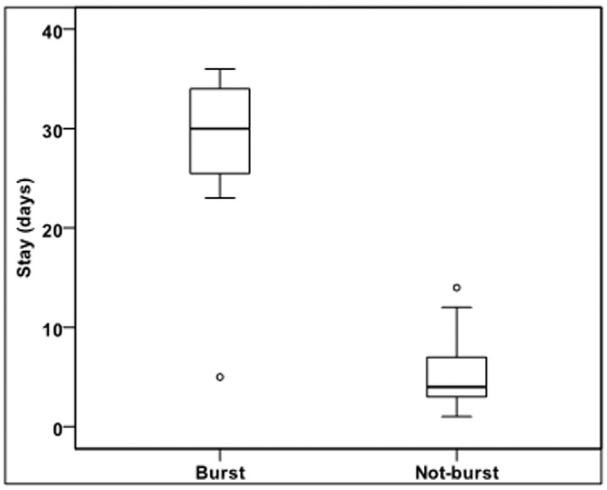
Figure 10



Comparison between cases with and without burst abdomen with regard to complications after surgery. TLC, total leucocyte count.

percentage of wound class II represented in cases of burst abdomen, it was 85.7%. Figs 8 and 9 show that burst abdomen caseshad significantly more frequent intestinal

Figure 11



Comparison between cases with and without burst abdomen with regard to hospital stay.

resection anddiversion compared with non-burst abdomen cases.

Table 8 and Figs 10 and 11 show that burst abdomen patients had fever significantly more frequently, elevated total leucocyte count, discharge and respiratory complications and significantly longer duration of hospital stay than did Non-burst abdomen cases.

Discussion

The choice of incision for abdominal access is controversial. Although many randomized controlled trials have favoured a transverse or oblique incision over a midline incision in terms of complication rates and recovery, the individual study results are by no means universal. Data suggest that a transverse incision may result in fewer complications [1].

The midline incision is generally preferred by surgeons because of its ease, speed and excellent exposure. However, as was evidenced in our current study, midline incision is associated with increased post-operative complications compared with transverse incision. This is evidenced in our study by having seven cases of burst abdomen out of 60 cases and is higher in cases that were explored through vertical (midline) incision (five cases) with a 71.4% incidence among burst abdomen cases. This result concurs with that of Burger *et al.* [6], who found that vertical abdominal incision is associated with more post-operative complications in terms of burst abdomen and respiratory complications.

On the other hand, Grantcharov and Rosenberg [3] stated that their initial review suggested that other short-term and long-term complications of surgery showed no difference between vertical and transverse incisions; however, the inclusion of more recent trials on cadavers and animals suggested that a transverse incision is more resistant to rupture. The updated review continues to illustrate a trend to a lower rate of wound dehiscence with transverse incisions. Additionally, Hoer *et al.* [7] suggested that it takes more than 2 years for 75% of incisional hernias to occur. The review now includes three trials with longer (but not necessarily sufficient) follow-up [2,8,9].

The incidence of burst abdomen in relation to the surgical procedure was highest in patients who had undergone intestinal resection (71.4%) (P=0.036) among our study cases. The percentage of wound class II represented in cases of burst abdomen was 85.7%. Furthermore, we found that burst abdomen had a significantly greater relation to intestinal resection and diversion than did patients who had not experienced burst abdomen. However, a larger study is required that concentrates on specific procedures and specific opening and closing techniques. It is very difficult to standardize these parameters. Proske *et al.* [10] discussed the impact of surgical procedure on the incidence of burst abdomen and emphasized the difficulty in standardization of the parameters impacting the outcome as regards complications.

The effects of transverse approach on pulmonary function appear to be real. Further data available from more recent trials add to the evidence, with all studies that analysed pulmonary function showing the advantage of a transverse incision approach [11]. This goes alongside the results of our study, as respiratory complications showed up in the seven cases of burst abdomen (P<0.001); five out of them were explored through vertical midline incision.

However, Mimica *et al.* [11] discussed the pulmonary compromise and whether it could be related to the cranial extent of the upper midline incision for abdominal surgery. This cranial extent of the incision may be an alternative explanation to the heterogeneity seen in some comparisons. This was suggested as a relevant topic for future work, particularly if a transverse incision allows a significantly lower incision and a more effective block with the common use of epidurals for pain relief. Such a study has now been carried out and adds to the evidence that upper abdominal incisions are more painful and affect respiratory function more than do lower abdominal incisions.

There are possible explanations for the high wound dehiscence and burst abdomen rate after midline laparotomy. First, contraction of abdominal wall muscles retracts wound edges laterally. Second, the avascular nature of the midline incision may impair wound healing. Third, the fibres of the linea alba, which are continuous with abdominal wall muscle aponeuroses, cross the midline mostly in transverse or oblique directions. Therefore, a vertical incision cuts most of them perpendicularly [6].When a transverse incision is used, Langer's lines of cleavage are followed, as well as the direction of most oblique and transverse muscle fibres, nerves and segmental blood vessels. Therefore, dissection of segmental blood vessels and nerves is limited. Further, contraction of the abdominal wall muscles (due to coughing or vomiting) does not increase tension on the wound as these forces parallel the transverse operational wound. In addition, unlike the midline incision wound, the transverse incision wound is situated in richly vascularized muscular tissue, which may benefit wound healing [6]. The updated review continues to show a trend towards a lower rate of wound dehiscence with transverse incisions, bearing in mind the data from Hoer *et al.* [7].

Conclusion

The use of a transverse or midline incision remains the choice of the individual surgeon. A midline incision is still the incision of choice in an emergency situation, allowing rapid entry into the peritoneal cavity and access to all organs. It is also the incision of choice in patients with an increased probability of relaparotomy or when a potential stoma site would be compromised by a transverse incision in a patient who is likely to need one. However, the

increased incidence of wound dehiscence and burst abdomen should influence the surgeon to favour a transverse incision. Also, the possible increased pain and compromise on pulmonary function with a midline incision may prompt the operating surgeon to use a transverse incision in high-risk patients, particularly in obese patients or in those with chronic obstructive airway disease.

Recommendations

A larger study is required that concentrates on specific procedures and specific opening and closing techniques. It is, however, very difficult to standardize these parameters. The effect of incision on patients with chronic obstructive airway disease has not been studied fully. These are the patients most likely to develop respiratory compromise after abdominal surgery and indeed wound rupture and it may be in this group that a large difference in complications is seen.

Acknowledgements

The authors thank all surgeons and patients who participated in the investigation.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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Short-term surgical and functional outcome of laparoscopic ventral mesh rectopexy for management of complete rectal prolapse

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Received 12 December 2016
Accepted 26 December 2016

The Egyptian Journal of Surgery
2017, 36:208–216

Background
There is no clear treatment of choice for the problem of complete rectal prolapse (CRP). The treatment of CRP in adults is essentially surgical. Surgical management is aimed at restoring physiology by correcting the prolapse and improving continence and constipation with acceptable mortality and recurrence rates.
Objectives
The aim of this study was to determine the safety and outcome of laparoscopic ventral mesh rectopexy (LVMR) for the management of patients with CRP.
Patients and methods
The study included 33 patients with CRP: 20 females and 13 males. Female patients were significantly obese than male patients were; however, male patients were significantly older. A total of four female patients had associated vaginal vault prolapse. All patients underwent LVMR. Surgical outcome included intraoperative, postoperative, and follow-up data. Functional outcome was assessed at 6- and 12-month postoperatively and compared versus preoperative evaluation for severity of fecal incontinence (FI) using Vaizey score, frequency, and severity of constipation using Cleveland Clinic Constipation score, and effect of FI on patient's quality of life (QOL) using the Fecal Incontinence Quality of Life Scale score.
Results
All patients passed smooth uneventful operative and immediate postoperative course. No patient required conversion to laparotomy. Mean operative time was 151.9±31.6 (range: 120–240)min, and mean amount of intraoperative blood loss was 75.2±16 (range: 50–130)ml. Laparoscopic surgery provided its usual advantages concerning low postoperative pain score, and early ambulation, oral intake, and hospital discharge. Only three (9.1%) patients developed immediate postoperative complications. All patients showed significant functional improvement manifested as a significant decrease of Vaizey FI and Cleveland Clinic Constipation scores with a significant increase of Fecal Incontinence Quality of Life Scale score at 6-month postoperatively, and these scorings were progressively improved till 12-month postoperatively. Throughout the course of the 12-month postoperative follow-up, two female patients developed recurrent rectal prolapse for a frequency of 6.1%.
Conclusion
LVMR is a safe procedure for management of CRP within reasonable operative time and with minimal immediate postoperative morbidities. LVMR provided significant improvement of CRP-associated FI and constipation and its effect on patients' QOL. LVMR was associated with low frequency of postoperative recurrence throughout the 12-month follow-up.

Keywords:
complete rectal prolapse, functional outcome, laparoscopic ventral mesh rectopexy, quality of life

Egyptian J Surgery 36:208–216

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Introduction

The term rectal prolapse (RP) includes three different entities: full-thickness RP, mucosal prolapse, and internal prolapse (rectal intussusception).

Complete rectal prolapse (CRP) is defined as the circumferential full-thickness protrusion of the rectal wall through the anus [1]. Straight rectum, a lack of rectal fascial attachments to the sacrum, a redundant sigmoid colon, levator ani diastasis, an abnormally deep Douglas pouch, and a patulous anus may be considered either anatomical predisposing factors for the development of CRP or the result of prolapsing rectum [2,3].

 DOI: 10.4103/ejs.ejs_174_16

The treatment of CRP in adults is essentially surgical. Surgical management is aimed at restoring physiology by correcting the prolapse and improving continence and constipation with acceptable mortality and recurrence rates [4].

Numerous surgical procedures have been suggested to treat RP; however, the controversy regarding 'which operation is appropriate?' cannot be answered definitely [5]. According to the approach used to repair the RP, surgical treatments can be divided into two categories: abdominal procedures, which are generally better for young fit patients, and perineal procedures, which are preferable for patients who are not fit for abdominal procedures, such as elderly frail patients with significant comorbidities. The abdominal procedures have a lower recurrence and a higher morbidity rate than the perineal procedures [4].

Laparoscopic RP surgery including both rectopexy and resection rectopexy can cure prolapse with good results and can be performed safely in older and debilitated patients [6]. Although both techniques offer significant improvements in functional symptoms, laparoscopic resection rectopexy had a higher complication rate than laparoscopic rectopexy did. [7].

Because of the acceptable anatomical results, fewer complications, low recurrence rate, good functional results, and low mesh-related morbidity in the short to medium term, laparoscopic ventral mesh rectopexy (LVMR) has been popularized in the past decade. LVMR is performed for patients with CRP and internal prolapse [8].

The current study aimed to determine the safety and outcome of LVMR for the management of patients presented with CRP.

Patients and methods

The current prospective study was conducted at Department of General Surgery, Benha University Hospital, and Al-Adwani General Hospital, Taif, KSA, after obtaining approval from the local ethical committee and after fully informed written consent was signed by the patients. This study was carried out on 33 consecutive adult patients with CRP since January 2012 till June 2016.

All patients underwent clinical examination including collection of demographic data and past medical history and obstetric history for female patients. All patients underwent laboratory and radiological workup for assuring the diagnosis and defining other prolapsed organs, and also to assure inclusion criteria and fitness for surgery. Then, patients were prepared and underwent preoperative flexible colonoscopy.

Patients with recurrent RP, colorectal malignancy, ulcerative colitis, previous laparotomy for any previous cause, contraindication for abdominal insufflation, or bleeding diathesis were excluded from the study.

Operative procedure

All patients received general inhalational anesthesia with endotracheal intubation. Using the 4-port technique, the camera is placed at the umbilicus, and two 5-mm trocars are placed in the left and right lower quadrants at the midclavicular lines. A 12-mm trocar is inserted in the suprapubic region just to the right of the midline. After pneumoperitoneum conduction up to 15 mmHg, patients were positioned in Trendelenburg position, and the small intestine is retracted cephalad. The rectosigmoid junction was identified and retracted to the left. A peritoneal incision was performed extending from the right side of the sacral promontory to the anterior peritoneal reflection distally (Fig. 1a); then, the right hypogastric nerve and ureter were identified and safeguarded (Fig. 1b). Using combined blunt and sharp dissections, a wide plane was developed in the rectovaginal/rectovesical space (Fig. 1c). Prolapsed rectum was reduced, but no posterior rectal mobilization or lateral dissection was conducted (Fig. 1d). After completion of dissection (Fig. 1e), a strip of Prolene Mesh (Ethicon Endosurgery, Blue Ash, Ohio, USA), ~3×17 cm, was prepared and inserted into the pelvic cavity through the 12-mm trocar site. One end of the mesh was fixed to the anterior surface of the most distal part of the rectum and to pelvic floor muscle laterally using polypropylene sutures (Fig. 1f). Full-thickness bite into the rectal wall was avoided to prevent mesh contamination. Finally, the proximal end of the mesh was fixed to the sacral promontory using Tackers (Covidien, Dublin, Ireland). During fixation of the mesh, proximal traction on the rectum is avoided, as the rectum should not be placed under tension. In female patients, the distal part of the mesh was also fixed to the posterior vaginal fornix for correction of vaginal vault prolapse if present. The peritoneum was then reapproximated to completely cover the mesh (Fig. 1g).

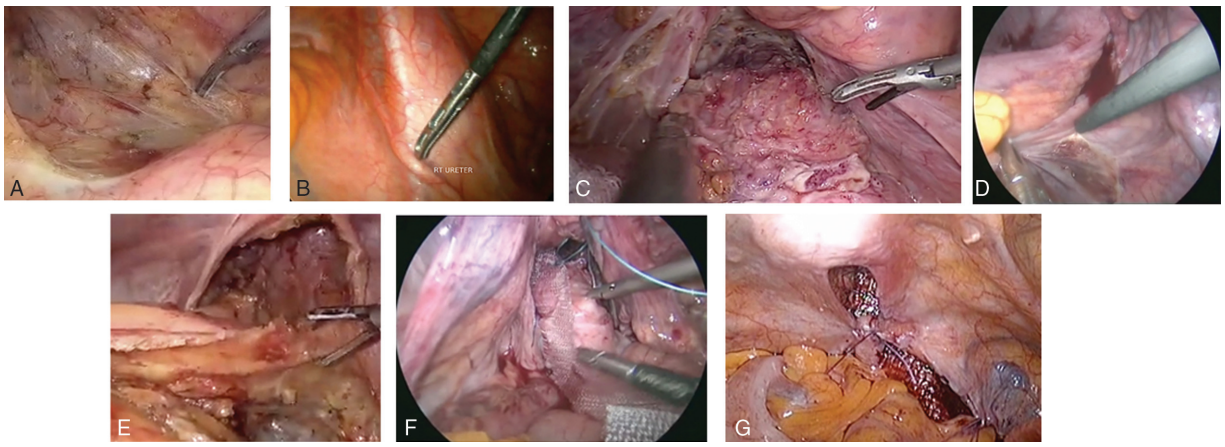
Study outcome

(1) Surgical outcome
   (a) Intraoperative collected data included conversion rate to laparotomy, operative time, intraoperative blood loss, and frequency of intraoperative complications.
   (b) Postoperative data included pain assessment using 1–10 pain visual analogue scale scoring, time till first ambulation and oral feeding resumption, postoperative hospital stay, and frequency of postoperative complication.
   (c) Postoperative follow-up extending for 12 months for frequency of recurrence, partial or complete
(2) Functional outcome was assessed at 6- and 12-month postoperatively and compared versus preoperative evaluation for the following:
   (a) The severity of fecal incontinence (FI) was evaluated using Vaizey score [9] for a total score ranging between 0 (perfect continence) and 24 (total incontinence). Details of Vaizey score are shown in Table 1.
   (b) Evaluation of frequency and severity of constipation was done using Cleveland Clinic Constipation (CCC) score [10] for a total score ranging between 0 (no constipation) and 25 (severe constipation since long duration). Details of items are shown in Table 2.
   (c) The effect of FI on patient's quality of life (QOL) was done using the Fecal Incontinence Quality of Life Scale (FIQL) [11], which consists of four subscales – lifestyle, coping/behavior, depression/self-perception, and embarrassment – including 29 questions. Responses to the questions are graded from 1 'strongly agree' to 4 'strongly' disagree. The obtained numerical values of all responses were added and then divided by the number of items. Higher scores indicate a better QOL.

Statistical analysis

Obtained data were presented as mean±SD, median, range, numbers, and percentages. Results were analyzed using one-way analysis of variance with post-hoc Tukey's honest significant difference test

Figure 1



(a) Peritoneal dissection down to the sacral promontory. (b) Dissection of the right ureter. (c) Dissection of the peritoneal reflection of the rectovesical pouch. (d) Reduction of the prolapsed rectum. (e) Complete peritoneal dissection down to the sacral promontory and preparation of the cavity. (f) Application and spreading of the Prolene Mesh to the rectum. (g) Closure of the peritoneal reflection after assurance of fixation and hemostasis.

Table 1 Vaizey incontinence score [9]

Items	Never	Rarely	Sometimes	Weekly	Daily
Incontinence for solid stool	0	1	2	3	4
Incontinence for liquid stool	0	1	2	3	4
Incontinence for gas	0	1	2	3	4
Alteration in lifestyle	0	1	2	3	4
Items	No	Yes			
Need to wear a pad	0	2			
Taking constipating medicines	0	2			
Lack of ability to defer defecation for 15 min	0	4			

Never, no episode in the past 4 weeks; rarely, one episode in the past 4 weeks; sometimes, more than one episode in the past 4 weeks, but less than one /week; weekly, more than or equal to one episode/week, but less than one episode/day; daily, more than or equal to one episode/day; minimum score=0 (perfect continence); maximum score=24 (totally incontinent).

and c^2 test. Statistical analysis was conducted using the SPSS (version 15, 2006) for Windows statistical package. *P*-value less than 0.05 was considered statistically significant.

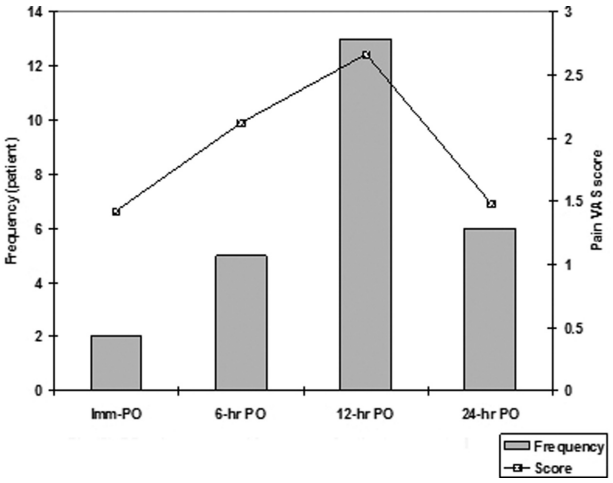
Results

The study included 33 patients who had CRP with a mean age of 59.5±14.5 (range: 25–78) years. There were 20 females and 13 males, with mean BMI of 27.4±2 (range: 23.4–30.8)kg/m^2. Female patients were significantly obese than male patients were; however, male patients were significantly older. A total of four female patients had associated vaginal vault prolapse. Overall, 10 patients had additional morbidity with nonsignificantly higher frequency in female than in male patients. Details of patients' enrollment data are shown in Table 3.

All patients passed smooth uneventful operative and immediate postoperative course. No patient required conversion to laparotomy. All surgeries were conducted through a mean operative time of 151.9±31.6 (range: 120–240)min. Laparoscopic surgery provided its usual advantages regarding low postoperative pain scores and a minimal number of patients requesting rescue analgesia (Fig. 2), and early ambulation, first oral intake, and hospital discharge as shown in Table 4.

Only three (9.1%) patients developed immediate postoperative complications: one diabetic patient developed hyperosmolar ketoacidotic coma on the second postoperative day and required admission to general ICU to receive intensive insulin therapy. She was discharged from the ICU after 3 days after proper adjustment of her blood glucose and was discharged uneventfully on the eighth postoperative day. Another 67-year-old patient developed acute myocardial infarction, which necessitated immediate ICU admission; fortunately, the patient responded well to thrombolytic therapy and stayed for 2 days and completed his immediate postoperative care free of complications and was discharged on the ninth

Figure 2



Postoperative pain scores and frequency of patients requested rescue analgesia throughout the first 24 hours postoperatively.

Table 2 Cleveland Clinic Constipation score [10]

Items	0	1	2	3	4	5
Frequency (times of bowel movements)	1–2/1–2 days	2/weeks	1/weeks	<1/weeks	<1/month	–
Difficulty (painful evacuation effort)	Never	Rarely	Sometimes	Usually	Always	–
Feeling incomplete evacuation	Never	Rarely	Sometimes	Usually	Always	–
Abdominal pain	Never	Rarely	Sometimes	Usually	Always	–
Time (min in lavatory/attempt)	<5	5–10	10–20	20–30	>30	–
Assistance (type of assistance)	Without	Laxative	Digital/enema	–	–	–
Failure (unsuccessful evacuation attempts/24 h)	Never	1–3	3–6	6–9	>9	–
Duration of constipation (years)	–	0	1–5	5–10	10–20	>20

Table 3 Patients' enrollment data categorized according to sex

	Total	Males	Females	*P*-value
n (%)	33 (100)	13 (39.4)	20 (60.6)	–
Age (years)	59.5±14.5	66±11.3	55.4±15	0.037
Body weight (kg)	81.1±5.8	78±5.4	83.2±5.2	0.010
Body height (cm)	172±4.1	173.7±4.3	170.9±3.6	NS
BMI (kg/m^2)	27.4±2	25.9±1.8	28.5±1.5	0.001
Associated comorbidities				
Vaginal vault prolapse	4 (12.1)	0	4 (20)	NS
Diabetes mellitus	7 (21.1)	2 (15.4)	5 (25)	
Hypertension	3 (9.1)	2 (15.4)	1 (5)	

Data are presented as numbers and mean±SD; percentages are in parenthesis.

postoperative day. The third patient had a delayed return of intestinal motility and developed manifestations of intra-abdominal infection. Computed tomography imaging defined pelvic collection that was drained laparoscopically. The patient was maintained on intravenous fluid and supportive therapy with appropriate antibiotic therapy; he responded to the applied therapy, and constitutional manifestations completely resolved. He was discharged on the tenth postoperative day to be re-evaluated for his prolapse. No operative or immediate postoperative mortality was reported.

All patients showed progressive improvement of their functional complaints. FI evaluated using Vaizey incontinence score showed a progressive significant decrease compared with the preoperative scoring. At the end of the 12-month postoperative follow-up, only five (15.2%) patients were still complaining of liquid and gas incontinence, which occurred rarely, but for the fear of soiling, they were still taking constipating drugs and wore pads. Details of frequency among incontinence scores determined at 6- and 12-month postoperative compared with preoperative frequency are shown in Table 5. Total incontinence scores calculated at 6- and 12-month postoperatively were significantly decreased compared with preoperative score, with significantly lower 12-month postoperative score compared with 6-month score as shown in Fig. 3.

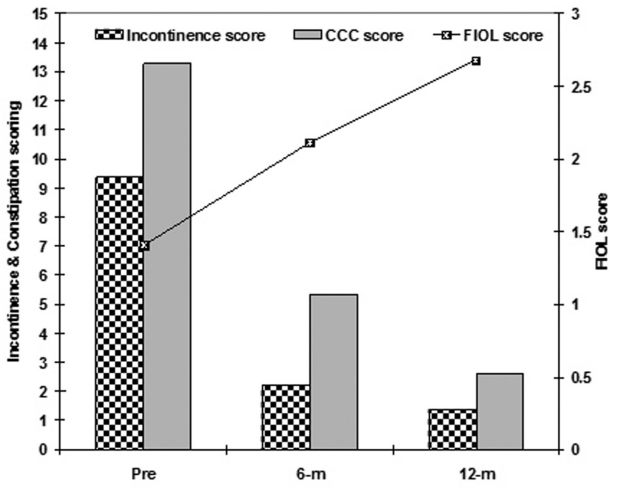
Table 4 Operative and immediate postoperative data

Data	Findings
Operative time (min)	
≤180	26 (78.8)
>180	7 (21.2)
Total	151.9±31.6
Operative blood loss (ml)	
≤100	31 (93.9)
>100	2 (6.1)
Total	75.2±16
Time till first ambulation (h)	
<6	5 (15.1)
6–12	25 (75.8)
>12	3 (9.1)
Total	10±2.3
Time till first oral intake (h)	
24–36	17 (51.5)
12–24	9 (27.3)
<12	7 (21.2)
Total	40.7±13.4
PO pain	
Immediate PO	
Median (range) VAS score	1 (0–4)
n (%)[a]	2 (6.1)
6-h PO	
Median (range) VAS score	2 (0–4)
n (%)	5 (15.2)
12-h PO	
Median (range) VAS score	3 (0–4)
n (%)	13 (39.4)
24-h PO	
Median (range) VAS score	1 (0–4)
n (%)	6 (18.2)
PO hospital stay (days)	
2–3	26 (78.8)
4–6	4 (12.1)
>6	3 (9.1)
Total	3.6±1.9

Data are presented as numbers and mean±SD; percentages are in parenthesis. PO, postoperative; VAS, visual analogue scale.
[a]Number of patients requested rescue analgesia.

A total of 23 (69.7%) patients complained of preoperative constipation with varying degrees of difficulty in evacuation and sense of incomplete evacuation since a median duration of constipation of 3 years (range: 0–13) years. Postoperatively, all patients showed progressive improvement of their constipation. At the end of 12-month follow-up, only 14 (42.4%) patients still had constipation of score 1, and 10 (30.3%) of them still had an occasional failure of evacuation and six (18.2%) of them were still using laxatives. Details of frequency among CCC scores determined at 6- and 12-month postoperatively compared with preoperative frequency are shown in Table 6. Total CCC scores calculated at 6- and 12-month postoperatively were significantly decreased compared with preoperative score, with significantly lower 12-month postoperative score compared with 6-month score as shown in Fig. 3.

Figure 3



Mean functional evaluation scoring of studied patients at 6- and 12-month postoperatively compared with preoperative scoring. CCC, Cleveland Clinic Constipation; FIQL, Fecal Incontinence Quality of Life Scale.

Table 5 Patients' frequency according to Vaizey incontinence score determined at 6- and 12-month postoperatively compared with preoperative frequency

Score items	Items											
	Solid stool incontinence			Liquid stool incontinence			Incontinence for gas			Lifestyle alteration		
	Preoperative	6 months	12 months	Preoperative	6 months	12 months	Preoperative	6 months	12 months	Preoperative	6 months	12 months
Never	21	33	33	5	26	28	0	14	23	4	19	24
Rarely	12	0	0	6	7	5	13	13	10	14	13	8
Sometimes	0	0	0	7	0	0	10	6	0	8	1	1
Weekly	0	0	0	5	0	0	10	0	0	7		0
Daily	0	0	0	10	0	0	0	0	0	0		0

Items	Items											
	Need for pad			Taking constipating medicines						Inability to defer defecation		
	Preoperative	6 months	12 months	Preoperative	6 months	12 months				Preoperative	6 months	12 months
	20	27	28	12	26	28				23	33	33
Yes	13	6	5	21	7	5				10	0	0

CRP-associated FI and constipation had a bad effect on patient's QOL; however, the applied surgical procedure induced significant improvement of patient's QOL as manifested by significantly higher FIQL score determined at 6- and 12-month postoperatively compared with preoperative FIQL score, with significantly higher score at 12-month compared with score determined at 6-month postoperative as shown in Fig. 3.

Throughout the 12-month postoperative follow-up, two patients developed recurrent RP for a frequency of 6.1%. One female patient developed recurrent vaginal vault prolapse, cystocele, and partial rectocele secondary to committing an obstructed labor despite the instruction not to have a vaginal delivery. Another female patient developed recurrence of CRP secondary to getting excessively obese owing to her sedentary life. One male patient died secondary to developing acute myocardial infarction that failed to respond to treatment.

Discussion

The current study reported a significantly higher frequency of female patients among the studied patients, and four (20%) female patients had an associated vaginal vault prolapse. The reported higher frequency of CRP among female patients could be attributed to previous obstetric trauma-inducing weakness of pelvic floor with subsequent laxity of suspensor ligaments leading to pelvic descent and organ prolapse. The reported association of vaginal vault prolapse and CRP goes in hand with Adjoussou *et al.* [12] who reported that colorectal symptoms, such as defecation dysfunction and anal incontinence occurred in 25.1 and 18.5% of women with genital prolapse, respectively. Also, Meister *et al.* [13] identified the duration of pushing during vaginal delivery and infant births weight as significant risk factors for sustaining laceration and obstetric anal sphincter injury, predisposing to genitourinary and RP.

Interestingly, studied females were more obese with significantly higher BMI than males; this implies a relationship between obesity and development and/or aggravation of RP. In support of this concept, Cuicchi *et al.* [14] found that after a mean BMI reduction of 10 kg/m^2, the prevalence of pelvic floor dysfunction decreased to 48%, and the rates of resolution of urinary incontinence, FI, and pelvic organ prolapse were 84, 85, and 74%, respectively. Also, multiple recent studies [15–17] documented that urinary incontinence, FI,

Table 6 Patients' frequency according to Cleveland Clinic Constipation score determined at 6- and 12-month postoperatively compared with preoperative frequency

Items	Score																	
	0			1			2			3			4					
	Preoperative	6 months	12 months	Preoperative	6 months	12 months	Preoperative	6 months	12 months	Preoperative	6 months	12 months	Preoperative	6 months	12 months	Preoperative	6 months	12 months
Frequency	12	11	19	10	16	14	11	6	0	0	0	0	0	0	0	0	0	0
Difficulty	0	16	16	16	11	15	8	6	2	9	0	0	0	0	0	0	0	0
Incomplete evacuation	0	6	18	15	19	12	9	5	3	6	3	0	3	0	0	0	0	0
Abdominal pain	15	8	25	0	17	8	18	4	0	12	4	0	3	0	0	0	0	0
Time (min/attempt)	18	16	23	12	17	10	3	0	0	0	0	0	0	0	0	0	0	0
Assistance	12	10	27	8	23	6	13	0	0	0	0	0	0	0	0	0	0	0
Failure of evacuation	15	17	22	11	16	10	7	0	0	0	0	0	0	0	0	0	0	0
Duration of constipation	10	–	–	13	–	–	6	–	–		–	–	4	–	–		–	–

and sexual dysfunction are more prevalent in patients with obesity, and weight loss by surgical and nonsurgical methods plays a major role in the improvement of these symptoms in such patients.

All surgeries were conducted uneventfully with no intraoperative morbidities, mortality, or conversion to laparotomy within appropriate operative time (151.9±31.6 min) and with minimal blood loss (75.2± 16 ml). Moreover, laparoscopic surgery provided its usual advantages concerning low postoperative pain score, and early ambulation, oral intake, and hospital discharge. Similarly, Magruder *et al.* [18] reported that patients who undergo laparoscopic rectopexy have a shorter length of hospital stay and lower surgical site infection rate than patients who undergo other abdominal procedures for RP repair. Bjerke and Mynster [19] reported a median operative time of 135 min (range: 90–215)min, a median length of stay of 2 days (range: 1–14) days, and 30-day morbidity and mortality rates of 15 and 4%, respectively, after LMVR.

The reported surgical data coincided with that recently reported by Chandra *et al.* [20] who reported a median operative time of 200 min (range: 180–350)min, median postoperative hospital stay of 4 days (range: 3–12) days, and no operative mortality or mesh-related complication was encountered after LVMR. Also, Pucher *et al.* [21] documented that LVMR had safety learning course and is an effective and safe treatment for RP with in-hospital morbidity and mortality rates of 3.2 and 0%, respectively. Keskin *et al.* [22] also documented that laparoscopic rectopexy should be considered as the first option in the treatment RP owing to its favorable early-term outcomes and acceptable rate of long-term recurrence.

In support of the favorable outcome of LMVR, Liu *et al.* [23] retrospectively compared laparoscopic versus open mesh rectopexy for total RP and reported insignificant intergroup differences in operative duration, postoperative complication, rate of long-term recurrence, and improvement of incontinence and constipation, but perioperative blood loss, time to first flatus, and hospital stay were significantly shorter in the laparoscopic rectopexy group.

Moreover, the applied surgical procedure induced significant functional improvement manifested as a significant decrease of FI and CCC scores with significant increase of FIQL score at 6-month postoperatively, and these scorings were progressively improved till 12-month postoperatively. The reported

functional improvement is similar to that stated by Consten *et al*. [24] in their report where the rates of FI and obstructed defecation decreased significantly after LVMR compared with the preoperative incidence (11.1 vs. 37.5% for FI and 15.6 vs. 54.0% for constipation); they concluded that LVMR is safe and effective for the treatment of different RP syndromes.

The obtained results are also in line with that recently documented in literature, wherein Chandra *et al*. [20] reported that at a median follow-up of 22 months, Wexner constipation score improved significantly from 17 to 6 and FI severity index score from 24 to 2 with no de-novo constipation or FI during the follow-up, and all patients expressed satisfaction with the outcome of their treatment; therefore, Chandra *et al*. [20] concluded that LVMR is an effective surgical option for CRP especially in patients having a bulky redundant colon. Also, Tsunoda *et al*. [25] reported improved incontinence and constipation in 77 and 59% of patients, respectively; significantly reduced FI severity index and Constipation Scoring System scores; and significantly improved scale scores on the three kinds of QOL instruments compared with the preoperative scores at 1 year after LVMR, and they concluded that LVMR improves both generic and symptom-specific QOL with good functional results. Moreover, Horisberger *et al*. [26] documented that 2 years after LVMR, constipation and QOL improve significantly in patients with complex pelvic organ prolapse.

In support of the reported advantages of LVMR, Bloemendaal *et al*. [27] documented that laparoscopic RP correction following emergency admission is both feasible and safe, so it can be considered for both recurring cases and cases with multiple comorbidities. Also, Ahmed[28] reported improvement in incontinence and constipation in 60 and 75% of patients, respectively, with no recurrence detected 6 months after single-port LVMR.

From the obtained results, we conclude that LVMR is a safe procedure for the management of CRP within reasonable operative time and minimal immediate postoperative morbidities. LVMR provided significant improvement of CRP-associated FI and constipation and its effect on patients QOL. LVMR is associated with low frequency of postoperative recurrence throughout the 12-month follow-up.

Financial support and sponsorship
Nil.

Conflicts of interest
There are no conflicts of interest.

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Laparoscopic left lateral bisegmentectomy for hepatocellular carcinoma: moving from peripheral to anatomical

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This study was previously presented at a meeting at the Doha HCC Meeting, Hammad Hospital; Doha, Qatar; 4–5th March 2016.
Received 2 January 2017
Accepted 30 January 2017

The Egyptian Journal of Surgery
2017, 36:217–221

Context
The use of the laparoscopic approach for liver resections became popular worldwide and is now of increasing popularity in Egypt. The growing experience in laparoscopic liver resections has made it more applicable in cirrhotic livers with hepatocellular carcinoma.
Aim
The aim of this study was to assess the feasibility and safety of laparoscopic left lateral liver resections in a tertiary centre in Egypt.
Patients and methods
A retrospective analysis of laparoscopic liver resections was undertaken in patients with preoperative diagnoses of a hepatocellular carcinoma with compensated cirrhosis. Surgical technique included CO_2 pneumoperitoneum and liver transection with a harmonic scalpel and laparoscopic Habib 4X sealer without portal triad clamping or hepatic vein control. Portal pedicles and large hepatic veins were stapled. Resected specimens were placed in a bag and removed through a separate incision, without fragmentation. Nonparametric data were presented as medians (range), and categorical data as frequency and proportion (%). *P* value less than 0.05 was considered statistically significant. Statistical analyses were performed using the IBM SPSS software, version 23.
Results
From August 2008 to February 2016, 38 liver resections were included. Eleven patients with a diagnosis of HCC were planned for laparoscopic left lateral resection. The mean tumour size was 5.6±2.1 cm. There were five conversions to laparotomy: two cases because of bleeding, one because of stapler failure, one because of accessibility failure, and one because of failure to extract the specimen. Mean blood loss was 150±75 ml. Mean surgical time was 160±40 min. There were no deaths. Complications occurred in two patients: only one patient developed postoperative ascites and the other developed bile leak.
Conclusion
Laparoscopic left lateral bisegmentectomy is feasible and safe in selected patients with adequate training and preparation.

Keywords:
hepatocellular carcinoma, laparoscopic, liver resection, surgery

Egyptian J Surgery 36:217–221

1110-1121

Introduction

This study tries to assess the feasibility and safety of laparoscopic Lt. lateral liver resections in a tertiary centre in Egypt. Liver resection is a well-established therapeutic option in the treatment of both benign and malignant hepatic lesions. In the era of minimally invasive surgery, laparoscopic liver resection (LLR) has rapidly been evolved with increased interest and practice since the first publication in 1991 [1]. Thereafter, LLR has been mounted from wedge resections and minor hepatectomies into anatomical and major resections. As in all less invasive procedures, LLR has the advantage of shorter hospital stay, earlier recovery, and rapid return to work. Nonetheless, LLR is a very demanding procedure necessitating a high level of experience in both laparoscopic and liver surgery, as well as a sophisticated laparoscopic setup [2].

After the introduction of LLR in the treatment of hepatocellular carcinoma (HCC), several

 DOI: 10.4103/1110-1121.211711

studies have reported that LLR is associated with similar disease-free survival and overall survival rates to open liver resection in patients with HCC [2–6].

Patients and methods

This study included a retrospective cohort analysis of 38 patients with HCC who underwent LLR. This study highlights the progression of our learning curve from nonanatomical wedge resection to more formal anatomical resection starting from August 2008 to February 2016 at the Department of Surgery, National Liver Institute, Menoufia University, Egypt. Retrospective analysis of their data was done over the next 6 months. The study was approved by the National Liver Institute Ethical Committee. Informed consent was taken from all patients. Data were extracted from our database system as follows: demographic date, underlying liver status and the aetiology of liver disease. The liver status was assessed by Child–Turcotte–Pugh and Model of End-Stage Liver Disease scores. The tumour characteristics were extracted, especially size, number, segmental location, satellites, vascular invasion, regional lymph nodes, tumour stage, preoperative management, comorbidities, imaging studies and serum tumour markers.

Operative data were recorded, including the extent of LLR (wedge, nonanatomical and left lateral bisegmentectomy), vascular occlusion if performed (Pringle manoeuvre), the volume of blood loss and blood transfusion, total operating time and open conversion rate. Postoperative data were collected, including hospital stay and in-hospital mortality (30-day mortality). The postoperative complications were recorded. Histopathology data were collected to confirm tumour size and tumour characteristics.

Follow-up data were collected for at least 6 months postoperatively. A follow-up computed tomography scan and α-fetoprotein measurements protocol were performed at 3, 6 and 12 months. The follow-up data included the patient's clinical status, recurrence and its treatment, and death and its cause.

Surgical technique of laparoscopic left lateral bisegmentectomy

The laparoscopic approach adopted in this study was a multiport technique. The patient was placed supine and general anaesthesia was introduced. A supraumbilical approach (either closed or open) was done for pneumoperitoneum and laparoscopy insertion. The second port was introduced in the left midclavicular line through which the abdomen was explored and the liver examined by an intraoperative laparoscopic ultrasound (a laparoscopic probe of BK Medical; Ethicon Endosurgery, New York, USA). Demarcation of the transaction line on the liver surface was done as guided by intraoperative laparoscopic ultrasound using an electrocautery. Pringle manoeuvre was used only in some cases. The hepatic parenchyma transection was then performed with various devices including the Harmonic Scalpel (Ethicon Endosurgery, New York, USA) or Lap. Habib 4X Sealer (AngioDynamics, New York, USA) depending on the individual's surgical experience or preference. Large pedicles (vascular and biliary) were controlled either by clipping or staplers. The resected specimen was enclosed in a plastic bag and removed through a small incision. Hemostasis of the transection line is then performed using bipolar electrocautery, argon beam coagulation, as well as Surgicel application (Fig. 1).

Statistical analysis

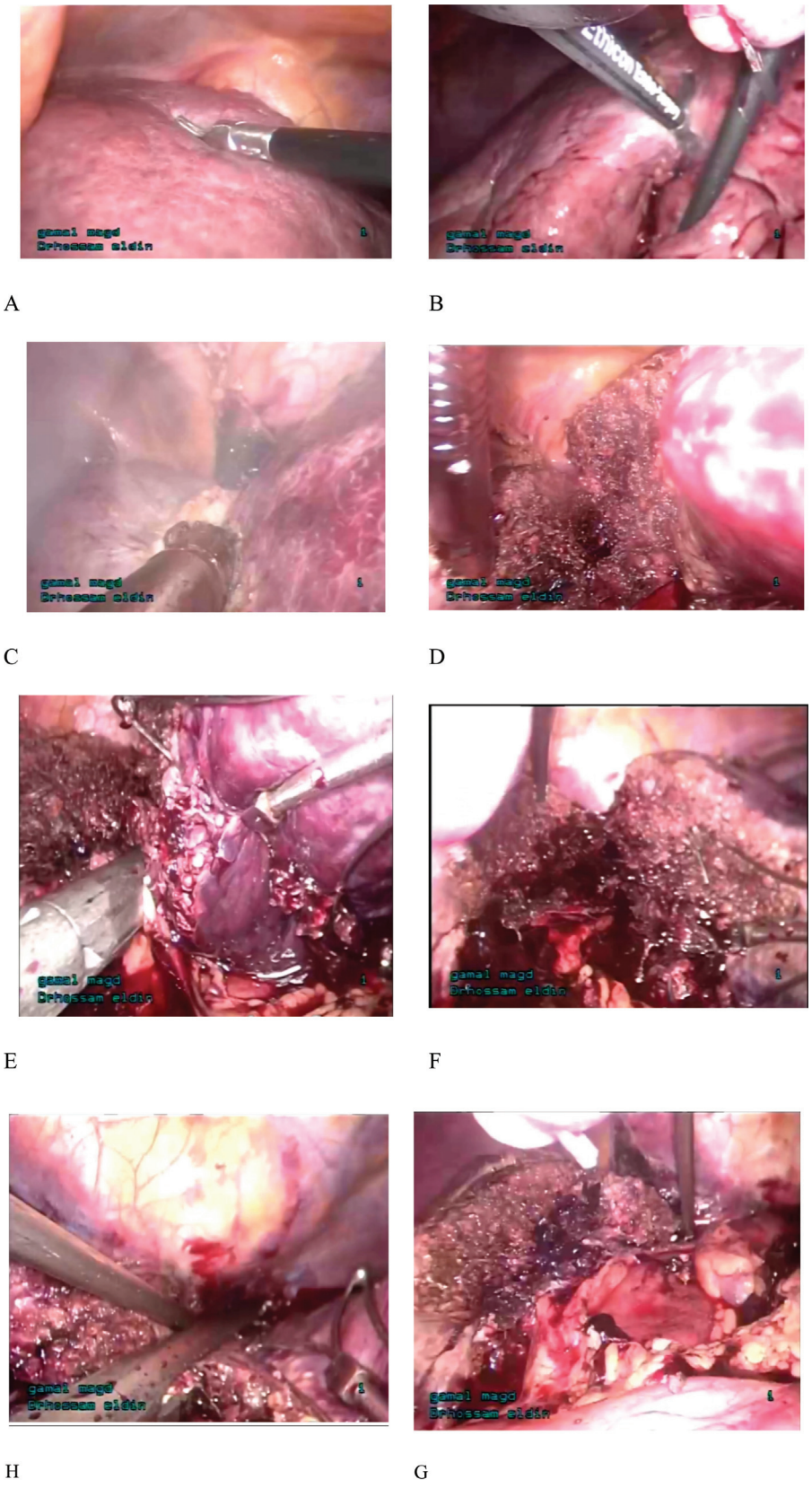
Nonparametric data were presented as medians (range), and categorical data as frequency and proportion (%). P value less than 0.05 was considered statistically significant. Statistical analyses were performed using the IBM SPSS software, version 23 (IBM Inc., Armonk, New York, USA).

Results

Thirty-eight patients underwent LLR, divided into two periods. From August 2008 to February 2016, 27 patients underwent nonanatomical resections (these focal lesions were peripherally located at segments III, IVb, V, VI and VII), and they were compared with another 11 patients who underwent laparoscopic left lateral bisegmentectomy (LLLBS), starting in February 2013 to the end of February 2016 (Fig. 2). This period division of patients was aimed for accurate comparison of our results of LLR and thus conveying the status of our learning curve and experience.

According to our HCC multidisciplinary committee, the selection criteria for laparoscopic resection were compensated cirrhosis (Child–Turcotte–Pugh class A, no signs of portal hypertension and Model of End-Stage Liver Disease score <9), single lesion and absence of a contraindication to laparoscopy. The exclusion criteria were multiple or bilobar HCC, decompensated cirrhosis and extrahepatic disease. The type and extent of laparoscopic resection were determined according to the anatomical location of

Figure 1

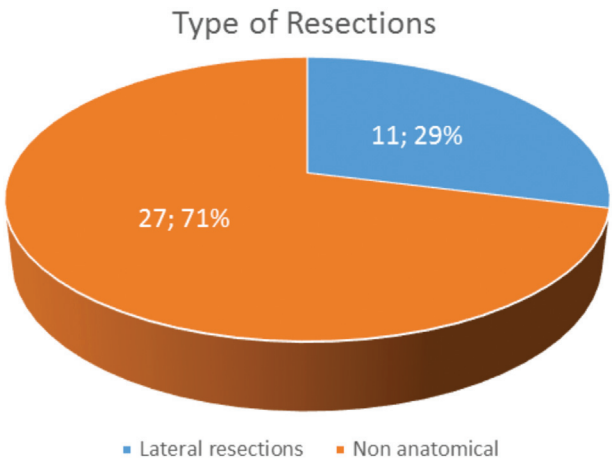


Technical steps of LLLBS. (a) A mass in S-II confirmed by ILUS. (b) The transection line is demarcated. (c) The line is burned by lap. Habib 4X. (d) The line is cut by Harmonic Scalpel. (e) The pedicle is divided using stapler. (f) After division of the inflow structures. (g) Cutting line after hemostasis. (h) Division of the LHV using stapler.

HCC, quality and volume of the remaining liver parenchyma, and the scheduled resection plan.

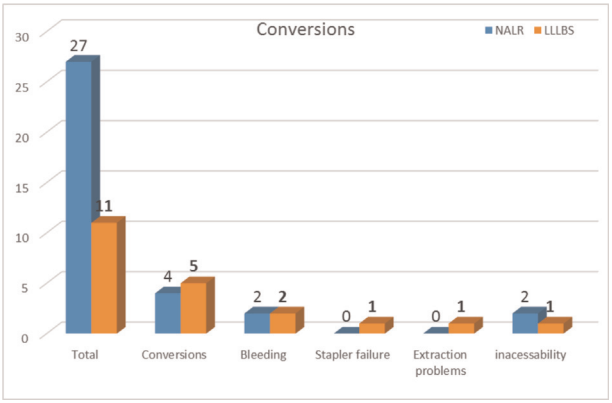
The demographic and operative data of the nonanatomical laparoscopic liver resection (NALLR)

Figure 2



Types of resections in both groups

Figure 3



Comparison of both groups for operative complications and conversions

Table 1 The operative and clinical characteristics of patients

	NALLR	LLLBS
No (%)	27 (71%)	11 (29%)
Age	53.2±4.5	52.5±3.5
Male	22 (81.48%)	9 (81.8%)
Female	5 (18.52%)	2 (18.2%)
Tumour size (cm)	3.1±2.4	5.6±2.1 cm
Operative time (min)*	120±20	160±40
Blood loss (ml)*	75±50	150±75
Blood transfusion (unit)	<1	2
Hospital stay (days)*	4±1	6±2

LLLBS, laparoscopic left lateral bisegmentectomy; NALLR, nonanatomical laparoscopic liver resection. *Statistically significant results.

versus LLLBS is demonstrated in Table 1. There was a statistically significant difference as regards operative time, blood loss and hospital stay.

Conversion to open technique was resorted to in five patients in group of LLLBS due to intraoperative bleeding in three patients, one of them due to stapler failure, fourth conversion was due to extraction difficulty because of a large left lateral segment size and the fifth conversion in this group was due to difficulty in the access of the superior part because of the large size of the tumour. On the other hand, four patients were converted into open resection in the NALLR group (Fig. 3). The causes of these conversions were operative bleeding with the failure of laparoscopic control in two patients and the difficulty of accessibility of the mass in segment VII in another two cases. However, most of these conversions occurred at the beginning of our experience. There was no statistical difference between the two groups. The overall conversion rate was statistically significant between both groups ($P<0.05$).

Postoperative outcome

The median hospital stay was comparable for both groups (Table 1), ranging from 3 to 10 days. Two patients in each group developed postoperative complications with an overall complication rate of 10.52%. In the LLLBS group, one patient developed significant ascites and the other had bile leak that was originating from the left duct stump and was treated by ERCP and stent. In the NALR group, two patients developed significant ascites postoperatively; those patients had operative bleeding and conversion. Another patient developed gastric fistula because of an overlooked iatrogenic radiofrequency injury. This was followed by peritonitis, sepsis and liver failure. There were no biliary complications in this group.

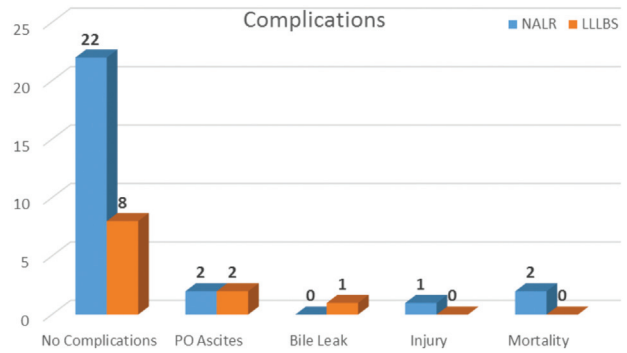
No patients died in the LLLBS group. However, two patients died in the NALLR group (Fig. 4). The first mortality was due to liver failure complicating the intraoperative bleeding and conversion, whereas the second had a gastric injury and uncontrolled septicaemia. The overall operative mortality rate was 5.26%. The 6-month tumour-free survival was 94.7%.

Discussion

Laparoscopic surgery has gained global acceptance over the past 20 years. The advantages of laparoscopic surgery in terms of surgical stress, abdominal wall trauma, respiratory complications, hospital stay, immunologic status and overall surgical-act-related morbidity [7] have been studied and demonstrated [1].

Laparoscopic minor liver resections are considered to be safe and reproducible techniques that were even superior to the open approach in recent meta-analyses gathering the results of retrospective comparisons [2–4]. A common

Figure 4



Post-operative complications in both groups. LLLBS, laparoscopic left lateral bisegmentectomy; NALLR, nonanatomical laparoscopic liver resection

indication for LLR is a solitary liver metastasis from colorectal cancer, but it may also be used for HCC and for benign liver tumours or cysts [8].

The evolution of our experience in laparoscopic resection occurred over 7 years. However, the evolution of LLLBS occurred over a 3-year period, and most of the conversion occurred in our early experience aiming for more patient safety. One study of 55 patients reported that there was no difference in the overall patient survival rate or disease-free survival rate between LLR and open resection. In five studies [2–5,8] that compared LLR with open resection in patients with malignant tumours, there were no statistically significant differences in the extent of the resection margins. Four of six nonrandomized comparative studies reported that the postoperative hospital stay was significantly shorter after LLR (mean stay: 4–15 days) than after open liver resection (mean stay: 8–22 days) [2–5,8]. All of the studies reported the rate of conversion to laparotomy, which ranged from 0% (0/30) to 15% (2/13). In LLR, blood transfusion was necessary during in 0–13% of patients. Postoperative complications included chest infection in 15% (2/13), liver failure in 8% (1/13), ascites in 8% (1/13), atelectasis of the left lower pulmonary lobe in 8% (1/13) and biliary leak in 5% (1/21) of patients. The potential adverse effects included death due to uncontrollable haemorrhage, bile leakage, gas embolism, deep-vein thrombosis and infection [9].

From the beginning of our experience, any incident that might compromise patient safety led to prompt conversion to open technique. Accordingly, there was urgent conversion of nine patients to an open approach. The complexity of the procedure may partially explain the high conversion rate in the LLLBS group, giving first priority to the issue of the patient's safety.

Finally, according to the learning curve exhibited by our team, we believe that preliminary experience, especially in the last five cases, may also improve these results with improvement of learning curves. However, there are adequate data that analyzed laparoscopic versus open left lateral sectionectomies for other indications and showed the superiority of the laparoscopic approach in terms of blood loss, postoperative pain, hospital stay and cost, with no significant difference in overall morbidity [8–12].

Conclusion

With development of experience in hepatic and laparoscopic surgery, the laparoscopic approach for liver resection is safe and feasible for selected patients with HCC in compensated liver cirrhosis.

Acknowledgements

This study was supported by National Liver Institute, Menoufia University.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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Efficacy of endovenous laser ablation (endovenous laser ablation) versus conventional stripping in the treatment of great saphenous vein reflux

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Received 4 January 2017
Accepted 2 February 2017

The Egyptian Journal of Surgery
2017, 36:222–232

Purpose
The purpose of this study was to find out the advantages and efficacy of endovenous laser ablation (EVLA) versus conventional stripping in the treatment of great saphenous vein (GSV) reflux.
Background
Varicose vein treatment places a considerable strain on the medical system, with long waiting time for operation in the public hospital system. EVLA allows efficient treatment of many patients on an outpatient basis.
Patients and methods
This prospective study included 44 patients with primary varicose veins. Patients were randomly allocated into two groups according to the intervention performed – group A: conventional surgical stripping of the GSV [22 (50%)], and group B: EVLA ablation [22 (50%)]. All patients underwent clinical evaluation, routine hematological tests, and venous duplex of both lower limbs. The follow-up period was 6 months.
Results
There were satisfactory results in the EVLA group (group B); in about 20 (90.8%) cases of this group the procedure was performed under tumescent anesthesia with less mean postoperative time, 69.1±3 min, less postoperative pain rate, 4.05±1.23, less 1-week complications limited to Bruising and Ecchymosis in five (23.8%) cases, superficial phlebitis in three (14.28%) cases, developed thrombosis in two (9.52%) cases, or skin burn in one (4.76%) case. Rapid return to normal activity (5.8 ±1.5) and overall results were better in group B, 19 (90.47%), compared with group B, 14 (66.66%), with a *P*-value of 0.001.
Conclusion
EVLA of GSV, being simple to perform and well accepted by patients, is a safe and effective method with low rate of complications, one-day hospitalization, short recovery time, and quick return to professional activities. For these reasons, this method is considered a very promising technique especially in female patients for cosmetic reasons as compared with surgical stripping.

Keywords:
efficacy, endovenous laser ablation, great saphenous vein reflux, stripping

Egyptian J Surgery 36:222–232

1110-1121

Introduction

There is no universally accepted definition of a varicose vein; however, the following definition incorporates the important element – a superficial vein of the lower limb, which has permanently lost its valvular efficiency and as a product of the resultant venous hypertension in the standing position becomes dilated, tortuous, and thickened. This definition excludes the muscular veins in thin patients who simply have prominent but normally functioning veins without venous reflux [1].

Common symptoms include aching, heaviness, ankle swelling, pruritus, and, sometimes, muscle cramps. These symptoms are often made worse by prolonged standing or warm weather; an increase in referrals for varicose vein treatment has been noted in summer months [2].

Varicose veins are a common problem and cause disfigurement, disability, and impairment in the quality of life. The advent of endovenous ablation techniques has expanded the surgical options for patients requiring treatment [3].

Definitive treatment of varicose veins aims at abolishing sources of venous reflux, and removing long refluxing segments and varicose reservoirs can be achieved by conventional surgery or by endovenous ablation techniques [4].

 DOI: 10.4103/ejs.ejs_7_17

Fortunately, the pathophysiology of venous disease may lend itself to surgical treatment, which historically has centered on high ligation of the sapheno–femoral junction (SFJ) and/or stripping of the great saphenous vein (GSV). High ligation alone leads to unacceptably high recurrence rates; the addition of GSV stripping decreases recurrence, but with additional morbidity [5,6].

The cooperation between physics and phlebology has opened doors that one alone never could even have unlocked. If the already proven 'fruitful' cooperation between doctor and physicist continues, this already good therapy can reach the status of excellence [7].

Endovenous laser ablation (EVLA) is a minimally invasive percutaneous technique using laser energy to ablate incompetent superficial veins. EVLA is used primarily to treat venous insufficiency of the axial veins (i.e. great, small, or accessory saphenous veins) [8,9].

Boné, 1999, first reported on the delivery of endoluminal laser energy. Since then, an EVLA method for treating the entire incompetent GSV segment has been described. EVLA with a 980 nm diode laser system is clinically safe, feasible, and well-tolerated technique without scar and allows people to return to their normal daily activities rapidly. EVLA, which received approval from the United State Food and Drug Administration in January 2002, allows delivery of laser energy directly into the blood vessel lumen [10–12].

EVLA can be carried out under local or general anesthesia. EVLA involves delivery of laser energy into the blood vessel lumen. Non-thrombotic vein occlusion is achieved by heating the vein wall. Different wavelength, different energies, and pulsed or continuous light have been used; there is no feedback control as with radiofrequency ablation, and thus energy is delivered at a predetermined rate with sufficient heating of the vein wall where there is endothelial denudation and collagen contraction [13].

Endovenous procedures allow more efficient management of large numbers of patients with outpatient treatment. EVLA is simple to perform, well accepted by patients, and relatively a traumatic and safe procedure [8,9].

The current prospective selective study aimed to find out safety, efficacy, benefits, advantages, and outcomes of EVLA as compared with conventional venous stripping of incompetent GSV.

Patients and methods

After approval from the local ethics committee of Benha University and obtaining written fully informed patient consent, the current study was conducted at the Vascular Unit, General Surgery Department, Benha University and a private hospital from September 2015 until January 2017, so as to allow a 6-month follow-up period for the last case operated on. This prospective randomized controlled study was conducted on 44 patients with primary varicose veins. Patients were randomly allocated by using a computer-generated random number table into two groups according to the intervention performed – group A: conventional surgical stripping of GSV [22 (50%)], and group B: EVLA [22 (50%)].

Patients included in this study were suffering from symptomatic GSV incompetence, pain (44, 100%), visible varicose vein [42 (95.4%)], night cramps [two (4.5%)], restless leg [38 (86.4%)], bleeding [four (9.1%)], and skin discoloration [eight (18.2%)], and patients were having GSV with reflux more than 1 s on duplex ultrasound (US), GSV incompetence along its whole length with or without active ulcer, and Clinical, Etiological, Anatomical, Pathological (CEAP) C_2, C_3, C_4, C_5 grade (Clinical, Etiological, Anatomical, Pathological classification). All were fit for regional/general anesthesia. However, patients who were suffering from current deep vein thrombosis or acute superficial vein thrombosis, post-thrombotic syndrome, GSV or Short Saphenous Vein (SSV) less than 3 mm or greater than 15 mm in diameter, tortuous veins that were considered to be unsuitable for EVLA, coagulation disorder, peripheral arterial diseases, pregnant woman, those who were unable to ambulate, and those with extreme obesity were excluded from this study.

All patients presenting were admitted at the Vascular Unit, General Surgery ward, for clinical evaluation, routine hematological tests, and venous duplex of both lower limbs. After this, the patient was posted for intervention.

Interventions

In both groups, patients were operated under general, regional, or local anesthesia on a morning list. Preoperative marking of the patient in the standing position with an indelible marker was important in any case in which stab phlebectomy or direct perforator ligation was contemplated in group A and foam injection sclerotherapy was done in group B. Such marking was essential because visualization of varicose tributaries may be impossible once the patient was

prepared and the leg elevated. Patients were to be shaved immediately preoperatively with a clipper, and the leg was cleansed with an appropriate surgical preparation – i.e. aqueous povidone iodine 10% solution – and draped with the entire leg exposed from above the groin to just above the ankle. After gaining the GSV either in group A by venostripper or in group B by laser fiber and catheter, tumescent anesthesia was used (200–500 ml) to fully surround the saphenous vein. A combination of 25–40 ml of 1–2% lidocaine with 1 ml of epinephrine (1 : 100 000), 10 ml of sodium bicarbonate, and 450 ml of cold (4C°) normal saline in the tumescent mixture was administered perivenously under duplex scanning using an infusion pump until collapse of the GSV and nonechogenic halo of fluids were observed around the main trunk of GSV. Most of the interventions in group B were performed under local tumescent anesthesia; however, light intravenous sedation or spinal anesthesia might be used in some of the patients who could not tolerate pain, especially in group A [14,15].

Technique of surgical stripping

The GSV was most easily approached through an oblique incision 1 cm above and parallel to the groin crease. This location provided the best cosmetic results and the most reliable access to the SFJ. The incision started over the palpable femoral artery and extended medially to balance the better cosmesis of limited incisions with the necessity to ensure appropriate visualization of the SFJ and its tributaries to be ligated. High double ligation of the GSV was performed close to the femoral vein, with the second ligation being a suture ligature. Care was taken to avoid narrowing the femoral vein and to avoid leaving a long stump with a risk for thrombus formation and potential embolism [16,17].

Next, GSV stripping was performed using wire strippers or disposable plastic strippers to strip the vein from the knee to the groin by performing another incision; this standard stripping was the central component of the classic operation for varicose veins. Recurrence rates were markedly reduced when the GSV was stripped as opposed to when high ligation was performed alone. Associated varicosities if present were removed by multiple phlebectomies through small incisions. All legs were dressed postoperatively (PO) with cotton padding applied externally over the length of the GSV track, which was secured using a crepe bandage [18,19].

Technique of endovenous laser ablation

The patients were placed in antitrendelenburg position to minimize shrinkage of the vein, and EVLA was performed with FOX Diode ARC Laser system (Fox^{TM}, Cherolase^{TM} of ARC Laser Systems, Germany) and protective eye glasses. Laser 980 nm bare fiber was performed under tumescent anesthesia for all 22 patients. Mapping of GSV was mandatory by preoperative duplex US examination from SFJ until below the knee. Next, GSV was accessed using direct US guidance and micropuncture technique. If vasospasm occurred before successful cannulation, application of tourniquet proximal to the access site in conjunction with dependent positioning of the leg could be helpful or finally direct cut-down over GSV could present itself; in these techniques, lidocaine 1% was infiltrated over the site, a 1 cm small skin incision was made over the GSV, and then cannulation was proceeded under direct visualization. The ideal point of entry was caudal to most caudal point of reflux but not more than 10–15 cm below the knee (below which point saphenous nerve lies in close proximity to the vein) [20,21].

Then, a calibrated 40-cm-long vascular sheath 6 Fr was introduced to extend from the venotomy site to 5 cm below SFJ over the 0.35 j-tip 55 cm guide wire. This calibrated marking on the sheath was useful during laser fiber pullback under US guidance and was used to aid the passage of the bare-tipped laser fiber inside A 4-Fr guide catheter over the wire. The distal tip of the laser fiber was positioned 2–3 cm below SFJ, before inserting the laser fiber and catheter into the vein, the optimal laser fiber length was determined outside the body, the laser fiber was introduced into the catheter and positioned so as to protrude 2.5 cm from the distal end of the catheter, the stopper at the proximal end of the catheter was firmly tightened onto the fiber, and the fiber (with properly positioned and secured stopper) was removed from the catheter; this step ensures that the fiber protrudes correctly from the catheter inside the vein. The laser fiber tip was positioned caudal to the SFJ just caudal to the epigastric vein before activation to minimize the risk of developed thrombosis (DVT) or injury to the central veins [22].

Once the device is appropriately placed for ablation, the patient is placed in Trendelenburg position to facilitate vein emptying and perivenous tumescent anesthesia that was administered along the entire length of the GSV, as described before. After tumescent anesthetic had been administered, the entire course of the GSV was evaluated with US to confirm that it was completely surrounded by anesthetic fluid at all levels but was not occluded completely, as it is desirable and necessary with laser treatment to maintain a small volume of blood within the lumen of the vein, as blood is the chromophore for the

absorption of the laser energy to transfer heat to the vein wall and cause injury to the vein wall. Next, correct positioning of the laser fiber tip was again verified and adjusted as necessary. The catheter fiber was then energized in a continuous manner and was slowly withdrawn in wide sections of the vein at a velocity of 1 mm/s and faster in narrow sections at a velocity of 3 mm/s under US guidance until it reaches a distance of 2/2.5 cm from the puncture site of GSV; this is done with manual pressure, which assists vein wall apposition. The pullback rate is monitored by assessing the calibrated marks on the sheath. The rate of pullback was adjusted to maintain an energy transfer of 60–90 J/cm^2 at 12–14 W within the vein. The linear endovenous energy density values were used to calculate the laser energy based on the GSV diameter 1.5–2 cm distal to SFJ. For GSV diameters between 4.5 and 6.9 mm 60/70 J/cm^2 of energy was used and for GSV diameter between 7 and 10 mm 80/90 J/cm^2 energy was used [23].

After the catheter or fiber has been withdrawn to the venotomy site, the saphenous vein is again evaluated with US. Typically, one identifies vessel wall thickening, concentric narrowing, and absence of flow, indicating a successful endovenous saphenous vein obliteration procedure. The common femoral vein is also evaluated for compressibility and the absence of thrombus. The laser unit was turned off and sheath and laser fiber was then removed and hemostasis was obtained with manual compression over the access site. Simultaneously, the leg is elevated to achieve 90° hip flexion. Thigh and knee were wrapped with an elastic compression bandage for 3 days, and then thigh high class II graduated compression stocking was applied for 2 weeks to facilitate GSV closure and minimize post-procedure bruising [24,25].

Postintervention follow-up

PO pain was assisted for both groups by using The '0–10 Numeric Pain Rating Scale' and relating doses of analgesic drug. The patient was asked to make three pain ratings, corresponding to current, best, and worst pain experienced over the past 24 h. The average of the 3 ratings was used to represent the patient's level of pain over the previous 24 h (0=no pain, 1–3=mild pain, 4–6=moderate pain, and 7–10=severe pain).

Patients were discharged 1–3 days PO. Both groups were followed up for 1 week for bleeding, hematoma in the subcutaneous tissue along the stripped vein or in the groin, bruising and ecchymosis, wound infection, nerve injury (manifesting as numbness, decreased, or altered sensation or paresthesia), superficial thrombophlebitis, DVT, and skin burn, and at 3 and 6 months for skin discolouration or pigmentation, residual varicosities, scarring and recanalization 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 especially in group B. Bruising was assessed in the thigh along the stripping or ablation line and not in the calf where any bruising would be related to the avulsions (Fig. 1a–f).

Statistical analysis

Analysis of data was done by using statistical package for the social sciences version 16 (SPSS; SPSS Inc., Chicago, Illinois, USA). Quantitative data were presented as mean and SD and were analyzed by using one-way unpaired *t*-test to compare quantitative variables, in parametric data (SD<50% mean). Qualitative data were presented as numbers and percentages and were analyzed by using χ^2 and Fisher's exact tests. *P*-value less than 0.05 was considered significant, whereas *P*-value less than 0.01 was considered highly significant. However, *P*-value greater than 0.05 was considered insignificant.

These data are shown in Fig. 1a–f.

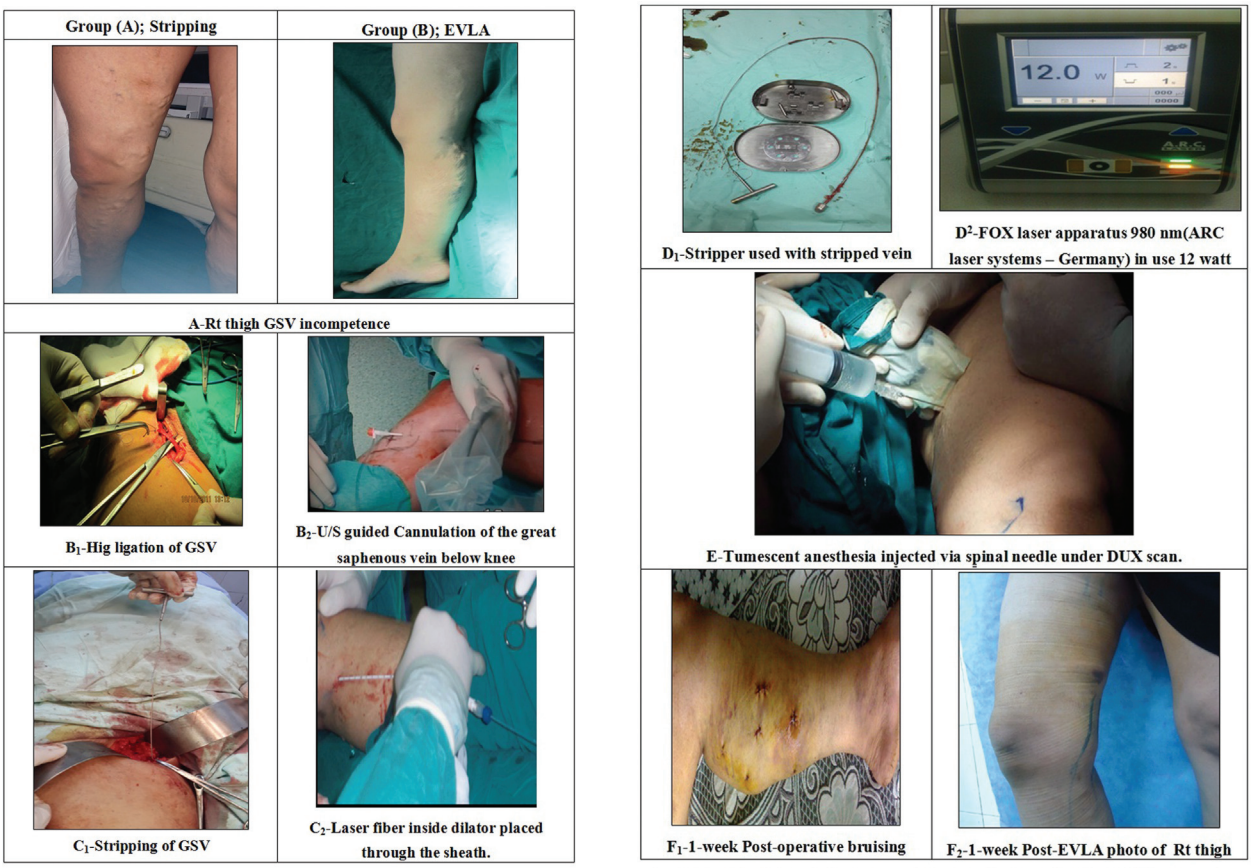
Results

This prospective study included 44 patients with duplex US features of GSV reflux more than 1 s along its whole length, who were divided into two groups according to the intervention performed – group A: conventional surgical stripping of GSV [22 (50%)], and group B: EVLA [22 (50%)]. The age of studied cases ranged from 24 to 59 years; mean age in group A was 32.6 years and in the group B it was 34.2 years. There were 13 female patients and nine male patients in group A, whereas in group B there were 14 female and eight male patients. There was no statistical difference between both groups in demographic data (Table 1 and Figure 2).

The presenting symptoms of GSV reflux were pain [44 (100%)], visible varicose vein [42 (95.4%)], night cramps [two (4.5%)], restless leg [38 (86.4%)], bleeding [four (9.1%)], and skin discoloration [eight (18.2%)] (Table 2 and Figure 3).

As regards the type of anesthesia used in this study in the surgical group spinal and general anesthesia were used in 15 (68.1%) and five (22.7%) patients, respectively, and tumescent anesthesia combined

Figure 1



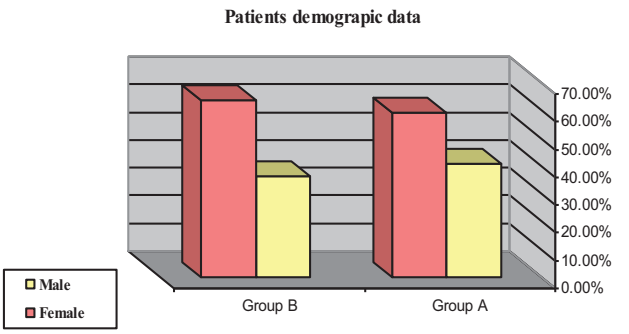
Steps of great saphenous vein stripping and endovenous laser ablation for right lower limb great saphenous vein incompetence. EVLA, endovenous laser ablation; GSV, great saphenous vein; US, ultrasound

Table 1 Patients' demographic data

Variables	Group A [22 (50%)]	Group B [22 (50%)]	*P*-value
Age (years)	32.6±3	34.2±2.5	0.44 (NS)
Sex			
Male	9 (40.9)	8 (36.4)	0.23 (NS)
Female	13 (59.1)	14 (63.6)	

Data are presented as numbers and mean±SD; percentages and ranges are given in parentheses.

Figure 2



Patients' demographic data

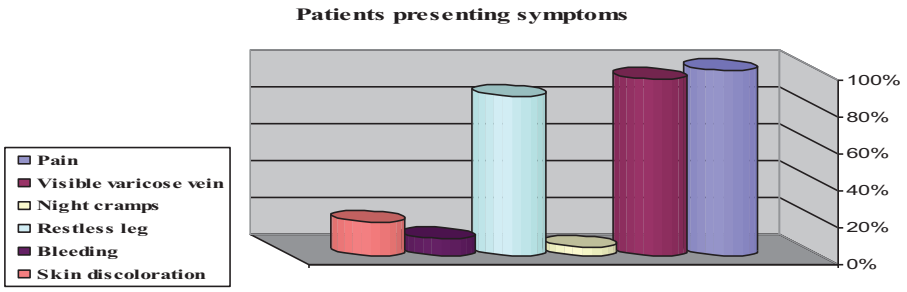
Table 2 Patients' presenting symptoms

Variables	Findings
Presenting symptoms [*n* (%)]	
Pain	44 (100)
Visible varicose vein	42 (95.4)
Night cramps	2 (4.5)
Restless leg	38 (86.4)
Bleeding	4 (9.1)
Skin discoloration	8 (18.2)
Duration of symptoms [mean±SD (range)] (years)	1.6±0.2 (0.5–3)

Data are presented as numbers and mean±SD; percentages and ranges are given in parentheses.

with spinal or general anesthesia was tried in two (9.2%) cases, whereas in the EVLA group tumescent anesthesia was used in all cases (100%) besides general or spinal anesthesia. There was a statistically significant difference between both groups; a *P*-value of 0.001 was considered highly significant (Table 3 and Figure 4).

Figure 3



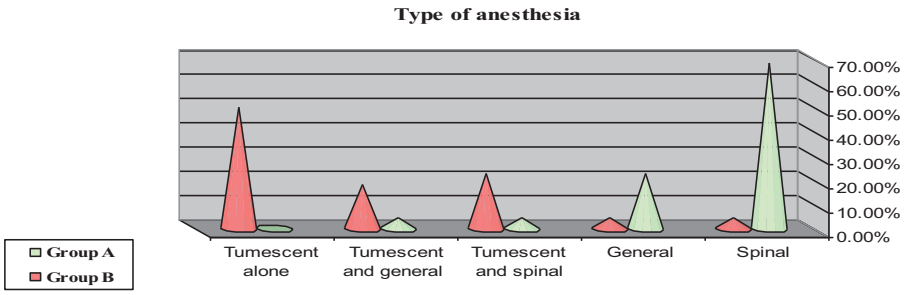
Patients' presenting symptoms

Table 3 Types of anesthesia

Variables	Group A [22 (50)]	Group B [22 (50)]	χ^2	*P*-value
Spinal	15 (68.1)	0	25	0.001 (HS)
General	5 (22.7)	0		
Tumescent and spinal	1 (4.6)	6 (27.3)		
Tumescent and general	1 (4.6)	5 (22.7)		
Tumescent alone	0	11 (50)		

Data are presented as percentages and by using χ^2-test. HS, highly significant.

Figure 4



Type of anesthesia

All patients passed uneventful intraoperative course without complications, except one case with femoral vein injury and bleeding. Mean operative time was 76.8 ±4, ranging from 60 to 91 min, in group A and 69.1±3, ranging from 53 to 79 min, in group B. Mean intraoperative blood loss was 56±5.5, ranging from 50 to 60 ml, in group A and 47.2±5.1, ranging from 40–50 ml, in group B. Patients in group A were discharged 1–3 days PO, but patients in group B were discharged 1–2 days PO (Table 4 and Figure 5).

Upon review of the results in this study, PO pain was assisted for both groups by using the (0–10) Numeric Pain Rating Scale and relating doses of analgesic drugs; a highly significant difference between both groups was noticed: in group A the average dose was 12.3±1.9 and pain rate was 6.05±1.099 and in group B the average dose was 5.4±2.1 and pain rate was 4.05 ±1.23, with t=10.9 and t=4.5, respectively, and a *P*-value of 0.001; surgical stripping had moderate to severe pain and received more analgesic drugs than EVLA patients who had mild to moderate pain (Table 5 and Figure 6).

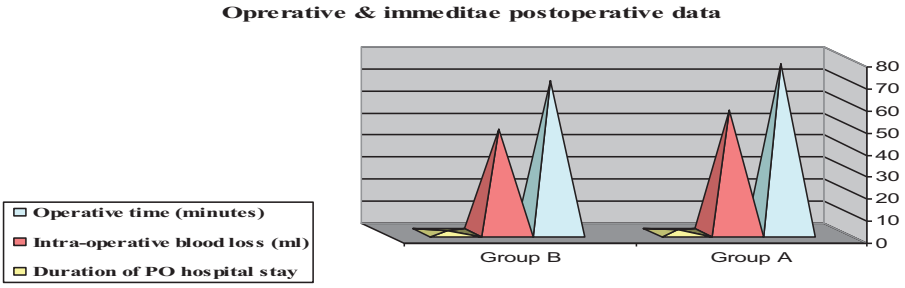
No mortality was recorded, but two patients did not come for follow-up, and data collection was applied on 42/44 patients only, 21/22 in each group. At 1 week PO, in group A, there was bleeding due to femoral vein injury at the SFJ during surgery, which was due to slipped ligature by retractor and discovered intraoperatively in one (4.76%) case, and the vein was repaired by continuous prolene 6/0; hematoma was noticed in the subcutaneous tissue along the stripped vein and in the groin in six (28.57%) cases; bruising and ecchymosis in seven (33.33%) cases; and wound infection and nerve injury in two (9.52%) cases (but there were no superficial thrombophlebitis, DVT or skin burn). In group B, there were complications limited to bruising and ecchymosis in five (23.8%) cases, superficial thrombophlebitis in three (14.28%)

Table 4 Operative and immediate postoperative data

Variables	Group A [22 (50)]	Group B [22 (50)]	*t*	*P*-value
Operative time (min)				
Mean±SD	76.8±4	69.1±3	3.5	0.000 (HS)
Range	60–91	53–79		
Intraoperative blood loss (ml)				
Mean±SD	56±5.5	47.2±5.1	8	0.001 (HS)
Range	50–60	40–50		
Duration of postoperative hospital stay (days)				
Mean±SD	1.8±0.5	1.2±0.4	4.1	0.001 (HS)
Range	1–3	1–2		

Data are presented as numbers and mean±SD; ranges are in parentheses and statistically significant difference by using unpaired *t*-test. HS, highly significant.

Figure 5



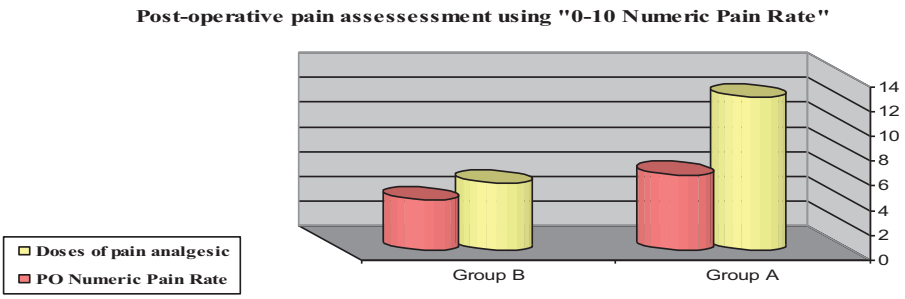
Operative and immediate postoperative data. PO, postoperative

Table 5 Postoperative pain assessment using '0–10 Numeric Pain Rate'

Variables	Group A [22 (50)]	Group B [22 (50)]	*t*	*P*-value
Doses of pain analgesic (mean±SD)	12.3±1.9	5.4±2.1	10.9	0.001 (HS)
Postoperative numeric pain rate (mean±SD)	6.05±1.099	4.05±1.23	5.4	0.001 (HS)

Data are presented as numbers and mean±SD; ranges are in parentheses and statistically significant difference by using unpaired *t*-test. HS, highly significant.

Figure 6



Postoperative pain assessment using '0–10 Numeric Pain Rate'. PO, postoperative

cases, DVT in two (9.52%) cases, or skin burn in one (4.76%) case. Residual varicosities that appeared in both groups were treated by foam sclerotherapy (Table 6 and Figure 7).

As regards returning back to normal activity, the mean time to return to normal activity in the surgical group was 8.5±2.4, which is higher than in the EVLA group, in which the mean time to return to normal activity was 5.8±1.5; therefore, there is a statistically significant difference between both groups (*P*=0.001) (Table 7 and Figure 8).

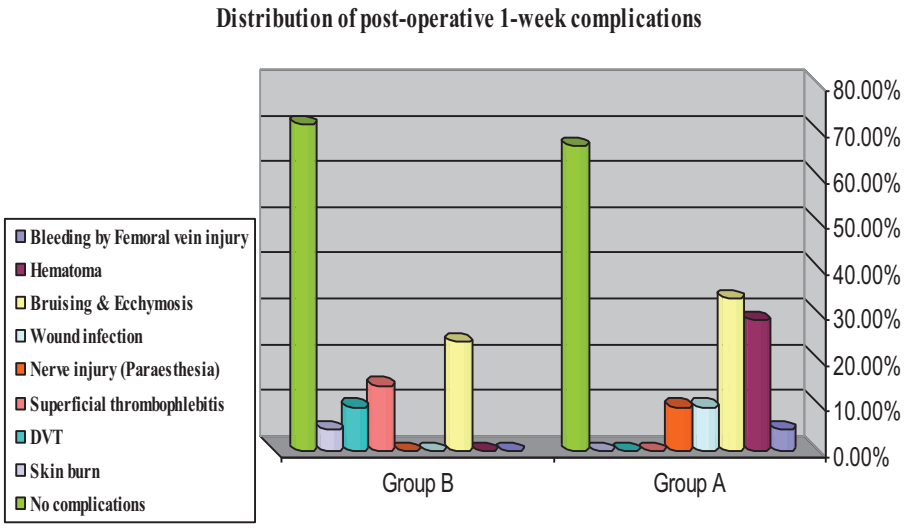
At the 3- and 6-month PO follow-up, there was skin discoloration (pigmentation) noticed in seven (33.33%) cases of group A and in only in one (4.76%) case of group B. Scarring was noticed only in group A in six (28.57%) cases and recurrence (recanalization) was

Table 6 Distribution of postoperative 1-week complications

Variables	Group A [21 (50)]	Group B [21 (50)]	χ^2	*P*-value
Bleeding by femoral vein injury	1 (4.76)	0	23	0.01 (significant)
Hematoma	6 (28.57)	0		
Bruising and ecchymosis	7 (33.33)	5 (23.8)		
Wound infection	2 (9.52)	0		
Nerve injury (paresthesia)	2 (9.52)	0		
Superficial thrombophlebitis	0	3 (14.28)		
DVT	0	2 (9.52)		
Skin burn	0	1 (4.76)		
No complications	14 (66.66)	15 (71.42)		

Data are presented as percentages and by using χ^2-test. DVT, developed thrombosis.

Figure 7



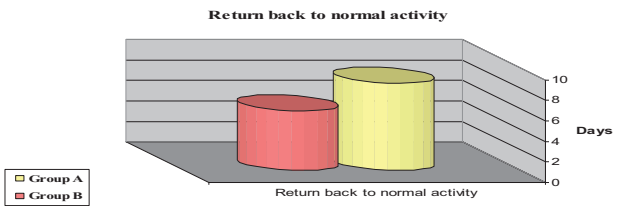
Distribution of postoperative 1-week complications. DVT, developed thrombosis

Table 7 Return back to normal activity

Variables	Group A [21 (50)]	Group B [21 (50)]	*t*	*P*-value
Mean ±SD	8.5±2.4	5.8±1.5	5.2	0.001 (HS)
Range	7–14	4–7		

Data are presented as numbers and mean±SD; ranges are in parenthesis and statistically significant difference by using unpaired *t*-test. HS, highly significant.

Figure 8



Return back to normal activity

noticed only in group B in two (9.52%) cases. The overall results were better in group B: 19 (90.47%) (Table 8 and Figure 9).

Discussion

Vein stripping and high ligation has been the standard of care for superficial venous insufficiency for many decades. Efficacy assessment of stripping and ligation was often performed by using varicose vein recurrence as the primary end point. Because of the wide availability of duplex US scanning has the significance of recurrent reflux been recognized. The prevalence of recurrent reflux increases over time, with a 28.8% incidence at 5 years and 60% at a mean follow-up of 34 years [26].

During the past decade, new less invasive methods have been developed as alternatives to conventional high ligation/excision (HL/S) in the treatment of GSV incompetence, including radiofrequency ablation, EVLA, and foam sclerotherapy. In the not so distant past, physicians did not perceive venous disease as a serious health risk. Typically, a patient would be treated with extremity elevation and compression for long periods, remaining severely debilitated [6].

This study was on the utilization of 'FOX' 980 nm diode laser system EVLA in the treatment of primary varicose veins group B compared with the stripping group A, which included 44 patients, and the mean follow-up period was 6 months, as regards the EVLA group (group B) that included 22 patients; this was smaller than recent studies conducted by Shi *et al.* [3], who studied 132 patients (156 limbs) with EVLA among a total of 311 patients (376 limbs) for a duration of 12 months, and Brittenden *et al.* [9], who treated 212 out of 798 patients in a long-term follow-up of 5 years duration.

The presenting symptoms of GSV reflux were pain [44 (100%)], visible varicose vein [42 (95.4%)], night cramps [two (4.5%)], restless leg [38 (86.4%)], bleeding [four (9.1%)], and skin discoloration [eight (18.2%)]. This was comparable to the study by Campbell *et al.* [27], who conducted a study on 151 limbs of 100 patients; the main presenting symptom was aching pain, which was present in 97 (64%) limbs, and the other symptoms included skin changes in 40 (26%) limbs, disfigurement in 32 (21%) limbs, heaviness in 18 (12%) limbs, phlebitis in 10 (7%) limbs, and bleeding in one (7%) limb. It is noteworthy that many patients reported more than one main symptom, and thus the total percentage exceeds 100% [27].

In this study, tumescent local anesthetic solution was used in all cases (100%) besides general or spinal anesthesia in group B and tried in combination with spinal or general anesthesia in two cases of group A. This technique provided excellent anesthesia and allowed, in group A, vein stripping to be performed under straight local anesthesia. In addition, the vasoconstriction from the epinephrine and the direct compressive effects of the instilled volume resulted in rapid hemostasis from the avulsed tributaries and a marked decrease in PO ecchymosis and pain and allowed, in group B, separation of the superficial aspect of the GSV by at least 1.0 cm deep to the skin surface along its entire length to reduce the likelihood of skin burns and collapse of GSV to improve the transfer of thermal energy to the vein wall, and the vasoconstriction from the epinephrine reduced incidence of hematoma and hyperpigmentation. The ability to perform the procedure under tumescent local anesthesia allows for an immediate return to daily activities with optimal medical and cosmetic results, as well as high patient satisfaction [14,15].

Table 8 Distribution of postoperative 3- and 6-month outcomes

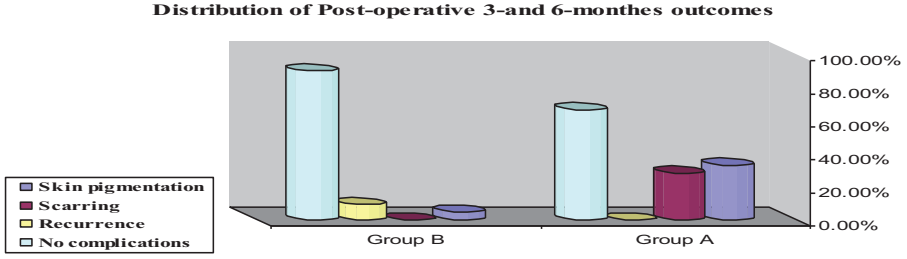
Variables	Group A [21 (50)]	Group B [21 (50)]	χ^2	*P*-value
Skin pigmentation	7 (33.33)	1 (4.76)	26	0.001 (HS)
Scarring	6 (28.57)	0		
Recurrence	0	2 (9.52)		
No complications	14 (66.66)	19 (90.47)		

Data are presented as percentages and by using χ^2-test. HS, highly significant.

In the present study, mean operative time was 76.8±4, ranging from 60 to 91 min, in group A and 69.1±3, ranging from 53 to 79 min, in group B. This is in contrast to the study by De Maeseneer *et al.* [28], who mentioned that the total theater time (between entry into and exit from the theater suite) was significantly longer for EVLA than for conventional surgery, owing to time consumed during marking the course of the GSV under duplex guidance in EVLA.

Upon review of the results in this study regarding PO pain, surgical stripping patients had moderate to severe pain and received more doses of analgesic drugs than EVLA patients who had mild to moderate pain – *P*-value of 0.001–and in EVLA patients there were no multiple skin incisions. Sharif and colleagues had reported that pain felt by patients occurred 5–8 days after the procedure and was related to the inflammation resulting from successful endovenous ablation but not related to ecchymosis nor damage to perivenous tissue [28,29].

Figure 9



Distribution of postoperative 3- and 6-month outcomes

At 1 week PO, in group A, there was bleeding due to femoral vein injury during surgery in one (4.76%) case and the vein was repaired by prolene 6/0; hematoma was noticed in the subcutaneous tissue along the stripped vein and in the groin in six (28.57%) cases; bruising and ecchymosis in seven (33.33%) cases; and wound infection (due to skin incision) and nerve injury (especially in cases with reflux of GSV >15 cm below knee stripping) in two (9.52%) cases (but there was no superficial thrombophlebitis, DVT, or skin burn) [28]. In group B, there were complications limited to bruising (occurred at the sites where the tumescent anesthesia has been instilled) and ecchymosis (most likely caused by laser-induced perforation of the vein wall, could be observed in every patient at the inner thigh and knee region from the next day to ~2 weeks later) in five (23.8%) cases, which improved spontaneously in the follow-up. There were three (14.28%) cases of superficial thrombophlebitis in the form of skin redness (topical anti-inflammatory was prescribed and rapid improvement was noticed in one case in the follow-up for this phlebitis) and the other two (9.52%) cases DVT, which was due to extension from superficial thrombophlebitis: in one case it was because of late ambulation and in the other case it was because the laser fiber was too close to the deep vein; these two cases were managed conservatively without sequelae or skin burn (most probably from inadequate administration of tumescent anesthesia), in one (4.76%) case. This was similar to Proebstle *et al.* [25] and Gibson *et al.* [30].

The mean time to return to normal activity in the surgical group was 8.5 days; this is higher than in the EVLA group, in which the mean time to return to normal activity was 5.8 days. Similar results were mentioned by De Maeseneer *et al.* [28], who reported that patients returned to their full level of normal household activities for driving and for work significantly more quickly after EVLA than after conventional surgery.

At the 3- and 6-month PO follow-up, there was skin discoloration (pigmentation) noticed in seven (33.33%) cases of group A and in only in one (4.76%) case of group B because the thrombotically occluded GSV was still present. Scarring was noticed only in group A because of skin incision, six (28.57%) cases, and recurrence (recanalization) was noticed only in group B, two (9.52%) cases. Recurrence of reflux at the SFJ is often blamed on operator failure during the first intervention, but it cannot always be explained by such technical inadequacy. Its development can be attributed to neovascularization in the granulation tissue around the ligated saphenous stump, as mentioned by Proebstle and colleagues [25,28].

The overall results were better in group B, 19 (90.47%), which is similar to promising results published by Shi *et al.* [3], as the technical success rate of EVLA was 100% in their evaluation of the Effect of EVLA of incompetent GSV in patients with primary venous disease.

Conclusion

EVLA of GSV, being simple to perform and well accepted by patients, is a safe and effective method with low rate of complications, requires one day of hospitalization, short recovery time, and quick return to professional activities. Therefore, this method is a very promising technique especially in female patients for cosmetic reason as compared with surgical stripping.

Acknowledgement

Author acknowledge Prof, Dr. Atef Abd-Elghani Youssef.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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Cholecystectomy for combined choledocholithiasis and cholelithiasis in elderly patients: do we need it?

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Received 7 January 2017
Accepted 30 January 2017

The Egyptian Journal of Surgery
2017, 36:233–238

Background
After endoscopic common bile duct (CBD) stone removal, physicians always recommend prophylactic cholecystectomy even in the absence of gall bladder (GB) stones to prevent further complications such as acute cholecystitis, recurrent CBD stones, or cholangitis despite the fact that management of GB after endoscopic stone removal remains a matter of debate. The main options in managing concomitant CBD stones and the GB stones include selective preoperative endoscopic retrograde cholangiopancreatography (ERCP), postoperative ERCP, open explorations, and laparoscopic common bile duct exploration.

Aim
The aim of this study was to assess the need for cholecystectomy after endoscopic sphincterotomy for CBD stones in elderly patients aged more than or equal to 70 years with coexisting cholelithiasis.

Patients and methods
A total of 336 patients who underwent successful endoscopic CBD stone removal at the endoscopy unit of the Medical Research Institute Hospital, Alexandria University from January 2013 to December 2015, were analyzed retrospectively. Patients were divided into three groups: the in-situ group comprised 168 patients with an intact GB, the cholecystectomy group comprised 72 patients who had cholecystectomy performed after ERCP, and the third group comprised 36 patients who had cholecystectomy before ERCP.

Results
After endoscopic CBD stone removal, 72 (30%) patients underwent subsequent cholecystectomy and 168 (70%) patients did not. There was no significant difference as regards morbidity and mortality among the study groups. Age was not a contraindication for surgery; however, the presence of multiple comorbidities, mainly diabetes and cardiac diseases, was a significant contraindication for prophylactic cholecystectomy.

Conclusion
A wait-and-see policy may be recommended for elderly patients with comorbidities and GB *in situ* taking in consideration regular follow-up for early detection of acute biliary complications.

Keywords:
cholecystectomy, cholecystitis, choledocholithiasis, common bile duct, endoscopic retrograde cholangiopancreatography

Egyptian J Surgery 36:233–238

1110-1121

Introduction

Over recent years, endoscopic retrograde cholangiopancreatography (ERCP) with endoscopic sphincterotomy (ES) is a widely accepted routine management for common bile duct (CBD) stones, with decreased morbidity and mortality since the introduction of new imaging techniques such as magnetic resonance cholangiopancreatography and endoscopic ultrasound with increasing accuracy of biliary system visualization without instrumentation [1–3], whereas laparoscopic cholecystectomy (LC) has largely replaced the open approach, with or without laparoscopic common bile duct exploration [4].

Subsequent cholecystectomy is usually advised to avoid serious complications such as acute cholecystitis or biliary pancreatitis [4,5], which might be fatal especially in old age with increased prevalence of comorbid conditions, such as cardiovascular disease, diabetes mellitus, and pulmonary diseases. However, these comorbidities may increase the operative risk and postoperative complications in elective surgery in elderly patients to about 21.2% compared with

 DOI: 10.4103/ejs.ejs_8_17

44.8% for emergency surgery [6–9], making post-ES cholecystectomy in the elderly a matter of debate [1,2,6,10].

The advancements of ERCP with ES markedly reduced their morbidity and mortality in elderly patients [11]. It has been shown that ES with or without an additional Cholecystectomy offers better protection than cholecystectomy alone in terms of reducing the number of recurrent biliary pancreatitis [12].

In elderly patients presenting with choledocholithiasis, it is important to clear the duct of stones, or at least establish an uninterrupted flow of bile. This can be effectively achieved by ES with stone extraction, mechanical lithotripsy, or simply by placing a plastic stent, which was proven to be quicker and cheaper, thereby very effective in the elderly population [13].

Although ERCP has been proven to be a safe and effective option for extracting CBD stones in most cases, it also has some devastating adverse effects, as it may induce various postoperative complications, including bleeding, perforation, or pancreatitis [14].

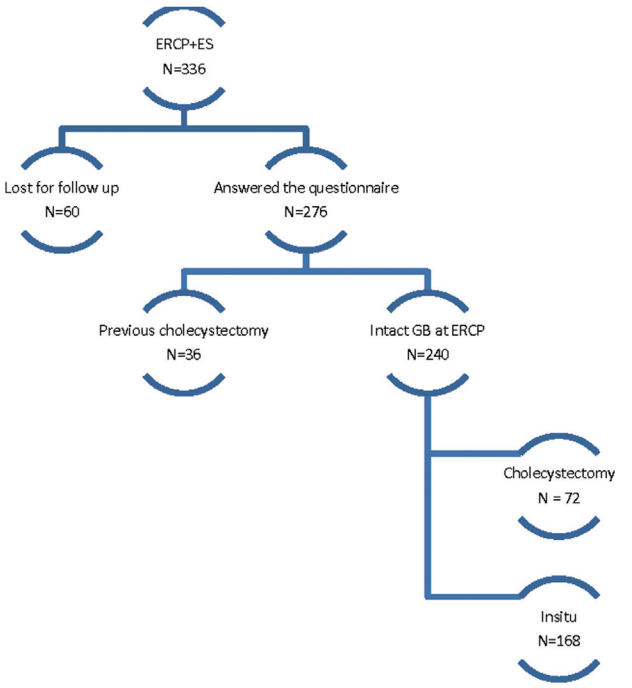
The aim of this study was to assess the need for cholecystectomy after ES for CBD stones in elderly patients aged more than or equal to 70 years with coexisting cholelithiasis.

Patients and methods

A phone number and mail address database was made for patients aged 70 years or more at Endoscopy Unit of the Medical Research Institute Hospital, University of Alexandria, who underwent ERCP and ES for choledocholithiasis during the time interval from January 2013 to December 2015. A total of 336 records from were eligible for the study. The research protocol was approved by the ethical committee of the Medical Research Institute.

ERCP with ES was performed in all cases. All ERCP procedures were performed by an expert endoscopist with more than 300 procedures annually, using side-viewing endoscope Olympus TJF-145 (Olympus, Japan; Industriestrasse 20, CH-8117 Fallanden, Switzerland). Stones were extracted by using retrieval baskets and/or balloon catheters after ES in all patients. If stones were too large to be extracted, either mechanical lithotripsy is performed or a plastic stent was inserted in the CBD to ensure free flow of bile.

Figure 1



Studied groups of patients.

After successful biliary drainage, cholecystectomy was recommended to all patients with intact gall bladder (GB) with explanation of all the possible risks, leaving the final decision to the patient and their referring physician.

All eligible patients were phone-called at least 6 months after their discharge, and according to the answers of a questionnaire, patients were divided into four groups (Fig. 1).

Group A comprised 168 patients, in whom the GB was intact and will be referred to as the in-situ group. Group B comprised 72 patients, in whom GB is surgically removed, and will be referred to as the cholecystectomy) group. Group C comprised 60 patients who were lost to follow-up. Group D comprised 36 patients who already had cholecystectomy at least 6 months before ERCP; this will be referred to in text as the previous group.

Statistical analysis

Statistical analysis was performed using IBM SPSS Statistics for Windows (version 20.0, 2011; IBM Corp., Armonk, New York, USA). Qualitative data were described using number and percent and was compared using χ^2-test, whereas normally quantitative data were expressed in mean±SD and

Table 1 Demographic and endoscopic procedures for all groups

	Lost to follow-up (*n*=60)	Previous (*n*=36)	In-situ (*n*=168)	Cholecystectomy (*n*=72)	*P*
Age (years)	74.7 (70–85)	75.9 (70–85)	76.5 (70–91)	76 (70–86)	0.131
Sex					
Male	29 (52)	16 (44)	79 (47	36 (50)	0.929
Female	31 (48)	20 (56)	89 (53	36 (50	
Follow-up period (days)	NA	474.2 (219–760)	515 (212–1103)	488 (219–1039)	0.347
Endoscopic procedure					
Stent	17 (28.3)	13 (36.1)	19 (11.3)	17 (23.6)	<0.05
CSE	38 (63.3)	20 (55.6)	142 (84.5)	54 (75)	<0.05
Crushing	5 (8.3)	3(8.3)	7 (4.2)	1 (1.4)	<0.05

CSE, complete stone extraction; NA, not assessed. Qualitative data were described using number and percent and were compared using χ^2-test or Fisher's exact test, whereas abnormally distributed data were expressed as median (minimum–maximum) and were compared using Mann–Whitney test.

Table 2 Showing relation between endoscopic interventions, demographics of in-situ and cholecystectomy groups and subsequent surgical procedures

	Endoscopic procedure		
	Crushing (*n*=8)	CSE (*n*=190)	Stent (*n*=36)
Age (years)	80.3 (72–86)	77.1 (70–91)	80.5 (72–91)
Sex			
Female	2 (25)	106 (54)	17 (47)
Male	6 (75)	90 (46)	19 (53)
Surgical procedure			
No	7 (87.5)	142 (72.4)	19 (52.8)
Yes	1 (12.5)	54 (27.6)	17 (47.2)
CBDE	0 (0)	0 (0)	15 (41.7)
CD	0 (0)	0 (0)	2 (5.6)
LC	1 (12.5)	28 (14.3)	0 (0)
OC	0 (0)	26 (13.3)	0 (0)
Recurrent symptoms			
Cholangitis	0 (0)	3 (1.5)	15 (41.7)
Recurrent jaundice	1 (12.5)	16 (8.2)	16 (44.4)
Death	0 (0)	10 (5.1)	8 (22.2)

Qualitative data were described using number and percent and were compared using χ^2-test or Fisher's exact test, whereas abnormally distributed data were expressed as median (minimum–maximum) and were compared using Kruskal–Wallis test or Mann–Whitney test. CBDE, common bile duct exploration; CD, choledochoduodenostomy; LC, laparoscopic cholecystectomy; OC, open cholecystectomy.

was compared using Student's *t*-test and was considered statistically significant at *P*-value less than or equal to 0.05.

Results

As regards demographic characteristics of all patients, there was no statistical difference between the four groups as regards age or sex distribution (Table 1).

The 'previous group' has shown that 36 patients have presented to our unit after a mean of 29 months, ranging from 6 to 72 months, of cholecystectomy complaining of jaundice, for 12 of whom jaundice was associated with cholangitis and all patients responded to medical treatment ERCP with biliary clearance.

The American Society of Anesthesiologists grading of all patients and their duration of follow-up are summarized in Table 3, with a statistically significant association between the American Society of Anesthesiologists of the patient and the mode of treatment followed. A significant association between the presence of comorbidities and the mode of management was found as well, with higher significance when multiple comorbidities are present.

All patients achieved biliary drainage with normalization of bilirubin level after ERCP. A total of 198 (82.5%) patients had CBD stone clearance, of whom eight (3.3%) patients required mechanical lithotripsy. In all, 42 (17.5%) patients achieved biliary drainage through placement of plastic stents. Seven patients reported post-ERCP complications; five reported mild pancreatitis with persistent vomiting associated with epigastric pain and elevated levels of amylase and lipase, and they responded well to conservative

Table 3 Mortality, morbidity, and comorbidities in the in-situ and cholecystectomy groups

	In-situ (*n*=168)	Cholecystectomy (*n*=72)	*P*
ASA			
I+II	138 (82.1)	50 (69.4)	0.029*
III	10 (6)	19 (26.4)	<0.001*
IV	20 (11.9)	3 (4.2)	0.062
Comorbidity	133 (79.2)	65 (90.3)	0.042*
Number of comorbidities			
0	35 (20.8)	7 (9.7)	
1	54 (32.1)	41 (56.9)	
2	48 (28.6)	23 (31.9)	<0.001*
3	18 (10.7)	0 (0)	
4	5 (3)	0 (0)	
Diabetes	56 (33.3)	36 (50)	0.015*
Hypertension	57 (33.9)	36 (50)	0.02*
Cardiac	39 (23.2)	6 (8.3)	0.007*
Bronchial asthma	9 (5.4)	4 (5.6)	1.000
Cirrhosis	16 (9.5)	1 (1.4)	0.024*
Renal	24	0 (0)	<0.001
Hypercoagulability and thrombotic complications	11 (6.5)	0 (0)	0.037*
Others	12 (7.1)	4 (5.6)	0.783
Recurrent symptoms			
Cholangitis	12 (7.1)	3 (4.2)	0.563
Recurrent jaundice	27 (16.1)	16 (22.2)	0.255
Death	11 (6.5)	7 (9.7)	0.392

Qualitative data were described using number and percent and were compared using χ^2-test or Fisher's exact test, whereas abnormally distributed data were expressed as median (minimum–maximum) and were compared using Mann–Whitney test. ASA, American Society of Anesthesiologists. *Mortality, morbidity, and comorbidities in the in-situ and cholecystectomy groups.

measures and completely resolved; and two patients complained of symptoms of upper gastrointestinal bleeding in the form of melena, and Oesophagodudenoscope (EGD) was performed and it revealed bleeding esophageal varices in one patient and bleeding from sphincterotomy site in the other one, which required hemostasis using monopolar cautery.

The relation between endoscopic interventions and demographics of all patients is summarized in Table 2.

The cholecystectomy group had 72 patients who underwent a post-ERCP cholecystectomy either alone or as a part of other operative procedures with a time interval between ERCP and cholecystectomy ranging between 1 and 300 days with an average of 55 days. In all, 29 patients had LC, 26 patients had open cholecystectomy, 15 had common bile duct exploration (CBDE) and stone extraction without insertion of T-tube, and two patients had choledochoduodenostomy. Six patients had postoperative complications; the first two had wound sepsis and responded to conservative measures and were discharged from the hospital 5 and 30 days postoperatively. The third one with uncontrolled diabetes also developed wound sepsis in association with diabetic keto acidosis (DKA), and septicemia; unluckily the patient died in the ICU on the 40th postoperative day. The fourth patient had bile duct injury with bile leak, and a choledochojujenostomy was performed after several trials for percutaneous drainage, and unfortunately the patient developed multiorgan failure and died on the 45th day postoperatively. The fifth patient developed duodenal fistula after choledochoduodenostomy with burst abdomen and died after 6 weeks. The last one developed ventricular arrhythmia intraoperatively with cardiac arrest, and cardiopulmonary resuscitation (CPR) was performed with return to sinus rhythm, the CBDE was completed, and the patient was transferred to ICU; however, he developed ventricular arrhythmia with subsequent cardiac arrest not responding to CPR measures. The other 63 patients had uneventful postoperative course, and the remaining three patients died for causes unrelated to operation (Table 3).

In the in-situ group, we had 11 mortalities, 10 of whom due to unrelated causes, and one due to severe sepsis owing to perforated GB after acute gangrenous cholecystitis, in whom the general condition was unfavorable to have cholecystectomy, and percutaneous cholecystostomy did not relieve the condition. In all, 13 patients complained at least once having signs and symptoms of biliary cholangitis relieved by antibiotics; 16 patients had

recurrent jaundice and required repeated ERCP and CBD clearance.

A logistic regression was performed to ascertain the effects of age, sex, complete stone extraction, and presence of comorbidities on the likelihood that patients have cholecystectomy. The logistic regression model was statistically significant, with *P*-value less than 0.0005. The model explained 36.1% (Nagelkerke's R^2) of the variance in cholecystectomy and correctly classified 78.3% of cases. Incomplete biliary clearance (stenting) is 9.7 times more likely to cause cholecystectomy, but the presence of more than one comorbidities, especially cardiac disease and history of thromboembolic complication or liver cirrhosis, was associated with a reduction in the likelihood of having cholecystectomy.

Discussion

ES and stone extraction has been recommended by many authors for the management of CBD stones, and if the CBD cannot be cleared a temporary plastic stent can be used to achieve biliary drainage until a surgical clearance with prophylactic cholecystectomy can be performed [5].

ES with a mortality of less than 2% has obvious advantages for managing CBD calculi in elderly patients if cholecystectomy is avoided [15,16], compared with 9.5% mortality in CBDE [17].

Despite marked improvement of endoscopic and laparoscopic techniques in the past decades, still the very conservative wait-and-see policy has a place for the management of many diseases especially in the elderly who must be individually assessed preoperatively in terms of the intended surgery, predicted morbidity and mortality, versus perceived benefit, as well as the influence of other coexistent medical conditions.

Post-ERCP prophylactic cholecystectomy is always recommend, in our department, for patients with combined cholelithiasis and choledocholithiasis. However, social and environmental factors usually influence the patient's decision, especially in the elderly patient. In our study, an overall of 28.3% of patients underwent prophylactic cholecystectomy after CBD drainage, 27% in complete CBD clearance, which rose to 47.2% in incomplete CBD clearance associated with insertion of plastic stent. The rate of cholecystectomy after ES and CBD stone extraction was in the range of 4.8–22% in various studies [2,18].

It is not clear whether cholecystectomy can prevent the development of secondary CBD stones. Lai *et al.* [19] conducted a study on 140 patients with a mean age of 69 years complaining of CBD stones with intact GB, who underwent ES for clearance of stones in the bile duct. Of the 140 patients, 32.8% underwent elective LC soon after ES and 67.2% did not. There was no statistically significant difference as regards recurrent complications between the two groups, concluding that elective cholecystectomy did not prevent recurrent biliary complications. Similar conclusions were drawn by Boytchev *et al.* [20].

The incidence of recurrent biliary symptoms after ES was shown to be about 10% in many retrospective and nonrandomized studies [21–23] with a recurrence rate of CBD stones after ES reported to be in the range of 6.5–17.4% in patients with GB *in situ* [1,24–27]. The recurrent biliary symptoms in our research were seen in 27 (16%) patients of the in-situ group and six (8.3%) patients in the cholecystectomy group; this was controlled by repeated ERCP and biliary clearance in case of recurrent stones, or systemic antibiotics, anticholinergic drugs, and other supportive measures in cholangitis and fatty dyspepsia.

The presence of comorbidity was significantly associated with patient's decision – the more comorbidities are found the more the likelihood that the patient will be in the in-situ group; on the other hand, age had no significant influence on decision-making. Similar reports have confirmed our results, showing that age alone should not be a contraindication to cholecystectomy in the elderly patient [18,28].

In summary, GB *in situ* was not associated with increased morbidity or mortality even in the presence of GB stones. A wait-and-see policy may be recommended for elderly patients with comorbidities and GB *in situ*, taking in consideration regular follow-up for early detection of acute biliary complications.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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How far is sleeve gastrectomy more effective than diet regimen in treating obesity-associated hyperlipidemia

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Received 9 January 2017
Accepted 4 February 2017

The Egyptian Journal of Surgery
2017, 36:239–245

Background
The global epidemic of obesity is one of the major health issues in the 21st century that influences many aspects of public health, including psychosocial and socioeconomic aspects. Hyperlipidemia is one of the health hazards associated with morbid obesity.
Patients and methods
This was a prospective study conducted in Kasr Al-Aini University Hospital (sleeve gastrectomy group) and the National Nutrition Institute (diet group) during the period from June 2015 till December 2015 with a follow-up of 12 months till December 2016 for both groups. One hundred patients were included in the study and were equally divided into two groups: group A (sleeve gastrectomy group) and group B (diet group).
Objective
The objective of this study was to compare the effects oflaparoscopic sleeve gastrectomy (LSG) and a dietary regimen on hyperlipidemia in morbidly obese patients.
Results
LSG significantly decreased total cholesterol in 70% of cases and triglycerides in 78% of cases; however, diet caused a decrease of total cholesterol in 30% of cases and triglycerides in 54% of case. Low-density lipoprotein was not significantly changed in both groups.
Conclusion
LSG is more effective than diet programs in treating obesity-associated hyperlipidemia due to more significant and sustained excess body weight loss.

Keywords:
diet, hyperlipidemia, morbid obesity, sleeve gastrectomy

Egyptian J Surgery 36:239–245

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Introduction

Obesity is now considered to be the second leading cause of preventable death after cigarette smoking [1]. It is associated with multiple comorbidities including type II diabetes mellitus, hyperlipidemia, obstructive sleep apnea, cardiovascular diseases, kidney diseases, gall bladder stones, gastroesophageal reflux disease, osteoarthritis, psychological disorders, metabolic syndrome, and obesity-related cancers [2]. Hyperlipidemia is defined as elevated levels of any or all lipids and/or lipoproteins in the blood [3]. It is a potent risk factor for cardiovascular diseases. Control of hyperlipidemia can be achieved by dietary fat control, regular exercise, and oral medications. Sleeve gastrectomy leads to long-term weight loss and improvement or resolution ofits associated comorbidities such as diabetes mellitus, hypertension, and hyperlipidemia [4]. The aim of this work was to compare the effects of laparoscopic sleeve gastrectomy (LSG) and dietary regimen on hyperlipidemia in morbidly obese patients.

Patients and methods

This was a prospective study conducted in Kasr Al-Aini University Hospi tal (sleeve gastrectomy group) and the National Nutrition Institute (diet group) during the period from June 2015 till December 2015, with a follow-up of 12 months till December 2016 for both groups. One hundred patients were included in the study and were equally divided into two groups: group A (sleeve gastrectomy group) and group B (diet group after exclusion of drop out cases).

Inclusion criteria included patients having BMI of at least 35 kg/m^2 and hyperlipidemia.

Exclusion criteria included the following:

(1) Endocrinal causes of obesity (hypothyroidism and Cushing disease).
(2) Pregnancy.
(3) Uncontrolled psychiatric disorders.

 DOI: 10.4103/ejs.ejs_10_17

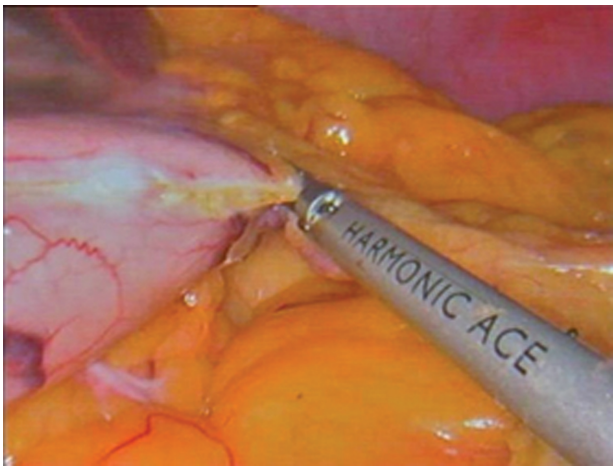
(4) Patients receiving treatment for hyperlipidemia to study the effect of only a single variable (sleeve or diet regimen) on hyperlipidemia.

All patients were subjected to proper history taking and complete physical examination. Preoperative investigations for group A included the following: complete blood count, coagulation profile, liver function tests, kidney function tests, fasting blood sugar, and the lipid profile including total cholesterol (TC), triglycerides (TG), high-density lipoprotein (HDL), and low-density lipoprotein (LDL). The thyroid profile was determined to exclude hypothyroidism. Chest radiograph as well as pulmonary function tests were performed to detect associated chest disorders. An abdominal ultrasound was performed to detect gall bladder stones. Cardiological assessment was done by ECG and echocardiography.

The aims of preoperative assessment were to detect and control associated comorbidities. Moreover, preoperative psychiatric and anesthetic consultations were conducted and an informed consent about the expected complications was signed. Patients were instructed to follow a carbohydrate-free and fat-free diet regimen for 2 weeks before surgery.

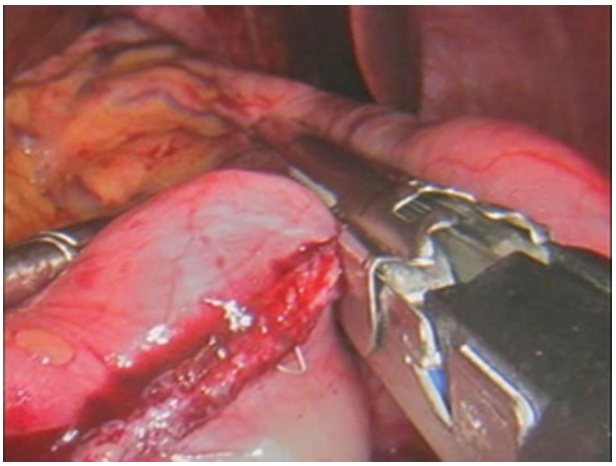
LSG was performed by mobilization of the greater curvature of the stomach proximal to the gastroesophageal junction and distally 6 cm proximal to the pylorus (Fig. 1). An orogastric 40-Fr bougie was passed till the first part of the duodenum. A 60-mm endoscopic gastrointestinal anastomosis stapler was used to divide the stomach along the line with the bougie creating a gastric tube about 20–25% of the original stomach (Figs 2 and 3).

Figure 1



Mobilization of the greater curvature of the stomach.

Figure 2



The endoscopic gastrointestinal anastomosis stapler dividing the stomach.

Postoperative care

In addition to the routine postoperative follow-up, the patients were instructed to receive the appropriate diet regimen in the form of sugar-free oral fluids for the first 3 weeks, and then sugar-free and fat-free semisolids were added, starting the fourth week. From the seventh week, they were allowed to have fat-free and carbohydrate-free steered food. Regular exercise (three times weekly-1 h each time) was strictly advised.

Diet group

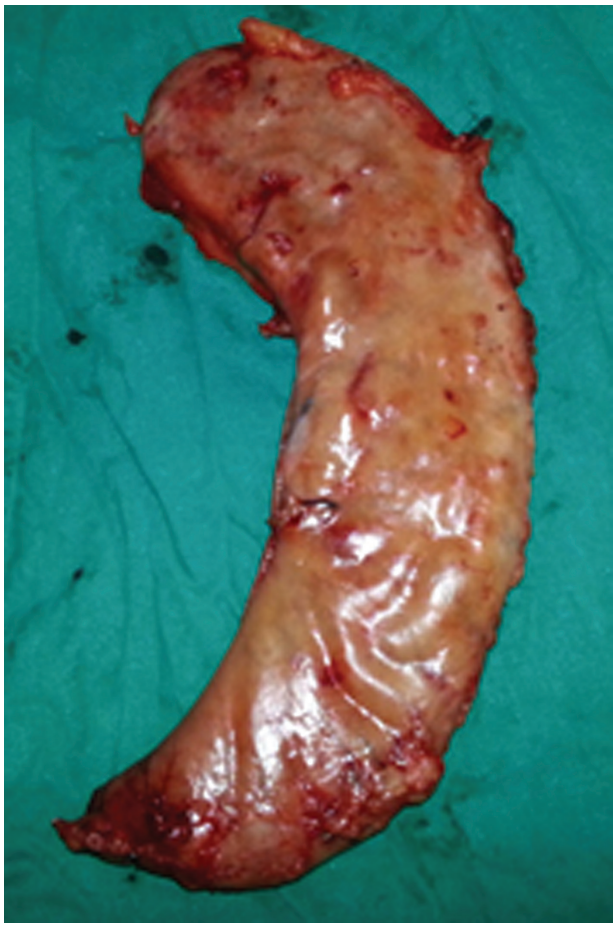
Patients in this group were subjected to a specific diet regimen at the outpatient clinic of the National Nutrition Institute in Cairo. This regimen was about 1800–2000 calories for male patients and 1400–1600 calories for female patients. The diet regimen consisted of 55% carbohydrates, especially the complex form, 25% proteins, especially plant-based proteins, and 20% fats. Less than 7% of the fat percentage is derived from saturated fats, and the rest was mainly monounsaturated fatty acids. Dietary cholesterol did not exceed 200 mg daily. Other therapeutic lifestyle changes included an increase in dietary fiber intake (>8 g/day), omega-3 supplementation, and cessation of smoking. Regular physical exercise (three times weekly – 1 h each time) was encouraged.

Assessment of the lipid profile for both groups was performed at the start of the study as well as at 3, 6, and 12 months. The term hyperlipidemia refers to elevated lipid levels in the body including high cholesterol (total, LDL, and low HDL) and high TG levels.

Statistical analysis

Results are expressed as numbers (%). Comparison between categorical data was performed using χ^2-test. The statistical package for social science

Figure 3



The excised part of the stomach.

computer programs (version 19, Windows) (IBM Inc., Chicago, Illinois, USA) was used for data analysis. *P* value less than or equal to 0.05 was considered significant.

Results

One hundred morbidly obese patients were included in this prospective study and were equally divided into two groups: group A (sleeve gastrectomy group) and group B (low-carbohydrate and low-fat diet group). Table 1 shows the demographic data of the patients in both groups.

At the start of the study, in the sleeve group, 45 (90%) patients had hypercholesterolemia, which was the same as that in the diet group. After 3 months in the sleeve group, hypercholesterolemia improved in 15 (30%) patients, whereas in the diet group, it improved in five (10%) patients. Six months after surgery, 35 (70%) patients had a normal serum cholesterol level (60% resolution), whereas 17 (34%) patients had a normal serum cholesterol level in the diet group (resolution in 24%) within the same period. Sleeve gastrectomy caused complete resolution in 70% of patients with

Table 1 Demographic data of both groups

	Sleeve group	Diet group
Range of age (years)	25–55	28–50
Sex [*n* (%)]		
Male	15 (30)	12 (24)
Female	35 (70)	38 (76)
Range of BMI (kg/m^2)	36–60	35–53
Associated comorbidities		
Hypertension	5 cases	8 cases
Diabetes	6 cases	5 cases
Total number of cases	50	50

hypercholesterolemia 12 months after surgery, whereas the diet regimen corrected hypercholesterolemia in 30% of patients after the same period. Table 2 shows the changes in the serum cholesterol level in both groups.

LSG significantly normalized serum TG in 24, 58, and 78% of patients after 3, 6, and 12 months, respectively, whereas the diet regimen improved TG in 10, 30, and 54% of patients within the same period. Table 3 illustrates the changes in serum TG levels in both groups.

At the start of the study, in the sleeve group, 47 (94%) patients had low serum HDL. Sleeve gastrectomy caused improvement in 37 (74%) patients after 1 year. However, in the diet group, improvement occurred in 31 (62%) patients during the same period. Table 4 shows changes in serum levels of HDL in both groups.

Unfortunately, sleeve gastrectomy did not lower the serum level of LDL significantly after 1 year. Improvement occurred in 8% of the cases only and this was twice that in the diet group. Table 5 shows changes in serum levels of LDL in both groups.

In the sleeve group, we did not experience weight loss failure and the excess body weight loss (EBWL) ranged from 60 to 80%, whereas in the diet group, EBWL ranged from 30 to 45% after 1 year.

Discussion

The global epidemic of obesity is one of the major health issues in the 21st century, which influences many aspects of public health including psychosocial and socioeconomic aspects. According to the latest report of the WHO, in 2011, people with BMI of more than 30 kg/m^2 reached up to10% of the world population. It is worth noting that the percentage of people with morbid obesity has almost doubled during

Table 2 Serum total cholesterol level at different time intervals in both groups

Total cholesterol	*n* (%)				P value
	Sleeve group		Diet group		
	Normal	Elevated	Normal	Elevated	
At the start	5 (10)	45 (90)	5 (10)	45 (90)	1.000
After 3 months	20 (40)	30 (60)	10 (20)	40 (80)	0.029*
		15/50 (30)		5/50 (10)	
After 6 months	35 (70)	15 (30)	17 (34)	33 (66)	0.001*
		30/50 (60)		12/50 (24)	
After 12 months	40 (80)	10 (20)	20 (40)	30 (60)	0.001*
		35/50 (70)		15/50 (30)	

P>0.05, not significant. **P*<0.05, significant.

Table 3 Serum triglyceride level at different time intervals in both groups

Triglyceride	*n* (%)				*P* value
	Sleeve group		Diet group		
	Normal	Elevated	Normal	Elevated	
At the start	8 (16)	42 (84)	10 (20)	40 (80)	0.603
After 3 months	20 (40)	30 (60)	15 (30)	35 (70)	0.295
		12/50 (24)		5/50 (10)	
After 6 months	37 (74)	13 (26)	25 (50)	25 (50)	0.013*
		29/50 (58)		15/50 (30)	
After 12 months	47 (94)	3 (6)	37 (74)	13 (26)	0.006*
		39/50 (78)		27/50 (54)	

P>0.05, NS. **P*<0.05, significant.

Table 4 Serum high-density lipoprotein level at different time intervals in both groups

HDL level	*n* (%)				*P* value
	Sleeve group		Diet group		
	Normal	Low	Normal	Low	
At the start	3 (6)	47 (94)	2 (4)	48 (96)	0.646
At 3 months	10 (20)	40 (80)	7 (14)	43 (86)	0.424
		7/50 (14)		5/50 (10)	
At 6 months	17 (34)	33 (66)	15 (30)	35 (70)	0.668
		14/50 (28)		13/50 (26)	
At 12 months	40 (80)	10 (20)	33 (66)	17 (34)	0.115
		37/50 (74)		31/50 (62)	

HDL, high-density lipoprotein. *P*>0.05, NS.

Table 5 Serum low-density lipoprotein level at different time intervals in both groups

LDL level	*n* (%)				*P* value
	Sleeve group		Diet group		
	Normal	High	Normal	High	
At the start	40 (80)	10 (20)	41 (82)	9 (18)	0.799
At 3 months	40 (80)	10 (20)	41 (82)	9 (18)	0.799
		0/50 (0)		0/50 (0)	
At 6 months	42 (84)	8 (16)	43 (86)	7 (14)	0.779
		2/50 (4)		2/50 (4)	
At 12 months	44 (88)	6 (12)	43 (86)	7 (14)	0.766
		4/50 (8)		2/50 (4)	

LDL, low-density lipoprotein. *P*>0.05, NS.

the last 30 years [5]. In Egypt, 30.3% of the adult population is considered to be obese according to the latest figures [6].

Unfortunately, obesity has a variety of adverse health consequences associated with a high rate of death, such as type 2 diabetes mellitus, hyperlipidemia, hypertension,

metabolic syndrome obstructive sleep apnea, certain types of cancer, gall bladder stones, steatohepatitis, gastroesophageal reflux, arthritis, polycystic ovary syndrome, psychological instability, and infertility [7].

The term hyperlipidemia refers to the elevated lipid levels in the body including high cholesterol (total, LDL, and low HDL) and high TG levels [8]. Common causes of hyperlipidemia include cholesterol-rich food, overweight, alcohol abuse, diabetes, stress, and lack of exercise [9]. Hyperlipidemia is a potent risk factor for developing atherosclerosis, hypertension, cardiovascular strokes, gall bladder stones, hepatosteatosis, and a variety of cardiac diseases [9]. High cholesterol levels is a modifiable risk factor causing 4.4 million deaths annually [10,11].

Hyperlipidemia can be controlled by weight loss, decreasing dietary fat, regular exercise, and medications. These modalities of treatment decrease TC, LDL, and TG as well as increase the serum level of HDL cholesterol [10].

Currently, medications from five major classes of drugs have been reported to treat people with detrimental lipid levels, which include statins, nicotinic acid derivatives, fibric acid derivatives, bile acid-binding resins, and cholesterol absorption inhibitors [11]. Side effects of these medications include anorexia, nausea, vomiting, headache and dizziness, flushing, constipation, and joint pain [12].

LSG, or longitudinal/vertical gastrectomy, has recently gained popularity and acceptance as a single effective procedure for the treatment of morbid obesity and resolution or significant improvement of obesity-associated comorbidities including hyperlipidemia. It is an example of restrictive bariatric surgery. The procedure is relatively safe with low morbidity and mortality sleeve gastrectomy works by the standard principle of restriction and the removal of the anorexigenic cells that produce the hormone ghrelin, in the fundus of the stomach [13].

Complications of sleeve gastrectomy include hemorrhage, gastric leakage, gastroesophageal reflux disease, gall bladder stones, nutritional deficiency, weight loss failure, deep venous thrombosis, gastric obstruction, chest complications, abdominal collection, visceral injury, and port-site hernia [13].

Different types of diet programs are available for the treatment of obesity and its associated comorbidities. The most commonly used diet regimens are low-carbohydrate diet, low-fat diet, high-protein diet or a combination of these regimens. A single or a combined regimen can be applied. The term 'low-carbohydrate diet' is generally applied to diets that restrict carbohydrates to less than 20% of the caloric intake [14]. It is used to treat morbid obesity and control obesity-associated health hazards mainly metabolic syndrome [15]. Low-carbohydrate diet appears to be at least as effective as low-fat diet in inducing weight loss for up to 1 year [16]. Carbohydrate restriction may help prevent obesity and type 2 diabetes mellitus as well as atherosclerosis [17]. A low-fat diet restricts fat and often also saturated fat and cholesterol. It is intended to reduce diseases such as heart disease and obesity [18]. Lowering fat intake from 35–40% of the total calories to 15–20% of total calories has been shown to decrease total and LDL cholesterol [19].

Hady *et al.* [20] conducted their study including 130 patients who underwent LSG with a follow-up period for 1 year. They achieved a decrease in LDL cholesterol (20% of cases), TG (95% of cases), and TC (40% of cases) as well as an increase in HDL cholesterol (65% of cases). However, short-term results (before the third month after surgery) were not satisfying. The results obtained indicate that bariatric surgery may effectively control obesity-associated hyperlipidemia [20].

Schauer and Ikramuddin [21] conducted a study including 20 morbidly obese patients with hyperlipidemia, and concluded that 1 year after LSG, there was a significant increase of HDL cholesterol levels (72% of cases), with a significant decrease in TG (90% of cases), and LDL remained unchanged.

Wong *et al.* [22] studied the lipid profile of 37 patients who underwent LSG. The follow-up period was 9 months. They reported a significant improvement in parameters of lipid profile after LSG. However, compared with our results, they reported improvement not only in HDL (60% of cases), TG (75% of cases), and TC (20% of cases) but also in LDL cholesterol (20% of cases) [22].

Razak *et al.* [23] reported that a short period after LSG (6 months – 33 patient), there is a decrease in TC cholesterol (55% of cases), TG (90% of cases), and HDL (30% of cases), but LDL also unchanged.

In 2011, Marek Bužga and colleagues summarized that 6 months after LSG, 33 patients showed an increase in HDL cholesterol levels (40% of cases) and a reduction

Table 6 Lipid profile changes after laparoscopic sleeve gastrectomy in different studies

References	Number of patients and follow-up period	Cases (%)			
		Decrease in TC	Decrease in TG	Decrease in LDL	Increase in HDL
Schauer and Ikramuddin [21]	20 (12 months)	Unchanged	90	Unchanged	72
Wong *et al*. [22]	37 (9 months)	20	75	20	60
Buzga *et al*. [24]	35 (6 months)	Unchanged	85	Unchanged	40
Razak *et al.* [23]	33 (6 months)	55	90	Unchanged	30
Hady *et al.* [20]	130 (12 months)	40	95	20	65
Boza *et al.* [25]	50 (12 months)	70	100	Unchanged	Unchanged
This study	50 (12 months)	70	78	8	74

HDL, high-density lipoprotein; LDL, low-density lipoprotein; TC, total cholesterol; TG, triglycerides.

Table 7 Lipid profile changes after diet regimen in different studies

References	Number of patients and follow-up period	Type of diet	Cases (%)			
			Decrease in TC	Decrease in TG	Decrease in LDL	Increase in HDL
Nordmann *et al.* [26]	20 (12 months)	LC	Unchanged	85	Unchanged	70
Shai *et al.* (2011)	50 (6 months)	LC	5	Unchanged	Unchanged	40
Hu *et al*. 2012 [28]	40 (6 months)	LC	Unchanged	55	Unchanged	63
	70 (6 months)	LC	Unchanged	58	Unchanged	62
	40 (6 months)	LC	25	52	Unchanged	35
This study	50 (12 months)	LC+LF	30	54	4	62

HDL, high-density lipoprotein; LC, low carbohydrate; LDL, low-density lipoprotein; LF, low fat; TC, total cholesterol; TG, triglycerides.

in TG level (85% of cases), whereas LDL and TC remained unchanged [24].

Boza *et al*. [25] followed the lipid profile of 50 patients after LSG for 1 year, and concluded that there was a significant decrease in TG cholesterol levels (100% of cases), with a significant decrease in TC (70% of cases), whereas LDL and HDL remained unchanged [25].

In our study, 50 patients underwent LSG and their lipid profile was followed for 1 year. Sleeve gastrectomy significantly decreased TC (70% of cases), TG (78% of cases), and LDL (8% of cases). HDL increased in 74% of cases. Table 6 summarizes the changes in lipid profile after LSG in our study as well as others.

Low-fat diets had the most favorable effects on TC and LDL cholesterol levels, whereas low-carbohydrate diets had the most favorable effects on TG and HDL cholesterol levels [26].

Shai *et al*. [27] found that the total-to-HDL cholesterol ratio was reduced by 20% in participants after a low-carbohydrate diet compared with a 12% reduction in those following a low-fat diet; this was a statistically significant difference.

In 2012, Hu and colleagues compared low-carbohydrate diets with low-fat diets, and found that participants on low-carbohydrate diets had greater increases in HDL cholesterol (63%) and greater decreases in TG (95%), but experienced less reduction in total (22%) and LDL (12%) cholesterol compared with those on low-fat diets [28].

Exercise plus a low-saturated fat diet reduced LDL cholesterol levels by 7–15% and TG levels by 4–18%, while increasing HDL cholesterol levels by 5–14%. Exercise plus nutritional supplements reduced LDL cholesterol levels by 8–30% and TG levels by 12–39%, while increasing HDL cholesterol levels by 2–8%. Therefore, combining diet and exercise interventions appears to be additive or at least synergistic [29].

In our study, 50 patients followed low-carbohydrate and low-fat diet programs for 1 year, which caused a decrease in TC (30% of cases), TG (54% of cases), and LDL (4% of cases). HDL cholesterol increased in 62%

of cases. Table 7 summarizes changes in the lipid profile in the diet group in our study as well as others.

Conclusion

LSG is an effective and reliable solution for morbid obesity as well as its associated comorbidities including hyperlipidemia. LSG is more effective than diet programs at achieving such goals due to significant and sustained EBWL. LSG significantly improved TC and TG, whereas LDL was not significantly changed in both groups, emphasizing the importance of prophylaxis against cardiovascular risks.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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Transhernial diagnostic laparoscopy for detection of contralateral subclinical patent processus vaginalis in cases with negative preoperative ultrasound

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Received 25 January 2017
Accepted 21 March 2017

The Egyptian Journal of Surgery
2017, 36:246–248

Introduction and objective
Bilateral inguinal hernias are relatively common in children; this fact has led to a controversy about the necessity of bilateral surgical exploration during the repair of unilateral inguinal hernia in children. The aim of our study is to evaluate transhernial laparoscopy as a tool for the detection of subclinical contralateral patent processus vaginalis (CPPV) in cases with negative preoperative ultrasound (US).
Patients and methods
This prospective study included 60 kids who underwent unilateral herniotomy in the period from October 2015 to October 2016 at Pediatric Surgery Unit, Sohag University Hospitals, Sohag, Egypt. Ethics committee approval was obtained. Patients with bilateral hernia and those with detected subclinical CPPV by preoperative US all were excluded. Two parameters were used for evaluation of subclinical CPPV, using transhernial diagnostic laparoscopy technique: the first was inflation of the contralateral scrotal compartment in males or labia in females and the second was laparoscopic visualization (exploration) of contralateral internal ring. Demographic data, laparoscopic operation time, difficulties in the procedure, and results were all reported and analyzed.
Results
Of 60 patients, 48 were male and 12 were female. Laparoscopic operative time ranged from 5 to 12 min. Hernia side was right in 40 patients (32 male and eight female) and left in 20 patients (16 male and four female). Subclinical CPPV was proved, using transhernial diagnostic laparoscopy technique in five patients and the procedure was completed by contralateral herniotomy.
Conclusion
Transhernial diagnostic laparoscopy, for cases with negative preoperative US regarding CPPV, is a feasible, rapid, safe, accurate method, with easy technique and it seems to be more sensitive than preoperative US.

Keywords:
herniotomy, laparoscopic visualization, subclinical contralateral patent processus vaginalis

Egyptian J Surgery 36:246–248

1110-1121

Introduction

Concurrent contralateral inguinal exploration in children with unilateral hernia or hydrocele is a subject of considerable debate. Historically, reported incidence of contralateral hernia was documented to be up to 30%. In addition, prophylactic contralateral exploration was recommended in all cases [1]. However, recent studies and meta-analysis revealed that the risk of contralateral hernia ranges only between 5.7 and 9.5% [2,3]. Therefore, it is widely considered that contralateral groin exploration is not justified in children with unilateral disease because of the low incidence of contralateral hernia and the potential for operative complications.

To avoid unnecessary contralateral inguinal exploration, several preoperative diagnostic tools, such as physical examination, preoperative ultrasound (US), and herniography, have been used. However, these tests have low accuracy rates and high false positive rates [4]. In 1992, laparoscopy (umbilical port) was introduced as a tool for the diagnosis of subclinical contralateral patent processus vaginalis (CPPV) [5]. If CPPV is observed laparoscopically, the patent processus vaginalis can be repaired through a groin incision or laparoscopy. Transinguinal laparoscopy (inguinoscopy) has been shown to be a safe, accurate, and effective method of evaluating CPPV [6].

Objective

The objective of this study was to evaluate transhernial laparoscopy as a tool for the detection of subclinical CPPV in cases with negative preoperative US.

 DOI: 10.4103/ejs.ejs_12_17

Patients and methods

This prospective study included 60 patients who underwent unilateral herniotomy, with negative preoperative ultrasonographic finding regarding CPPV, in the period from October 2015 to October 2016 at Pediatric Surgery Unit, Sohag University Hospital, Sohag, Egypt. Patients with bilateral clinically patent processus vaginalis or those with detected CPPV by US all were excluded from this study.

After acceptance of the scientific and ethics committee of our institution, the surgical procedures were fully explained to the parents and a written informed consent was obtained from parents.

Pediatric patients with clinically and sonographically unilateral patent processus vaginalis were admitted and routine investigations were done; inguinal incision, identification of the spermatic cord or round ligament, dissection of the sac, and opening of the sac were performed, and at this step a 5-mm laparoscopic trochar cannula was introduced through the sac. Insuflation of the abdomen by CO_2 was done at a flow rate of 1 l/min to a pressure of 8–10 mmHg. A 30° angled 5 mm telescope was then introduced and patients were repositioned at trendelenberg position for better visualization of the pelvis.

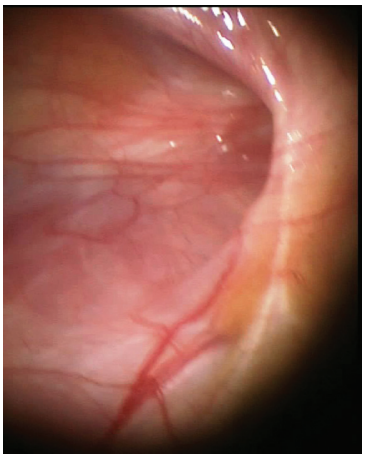
Two parameters were used for evaluation of subclinical CPPV, using transhernial diagnostic laparoscopy technique: the first was inflation of the contralateral scrotal compartment in males or labia in females and the second was laparoscopic visualization of patent contralateral internal ring. Accordingly, contralateral processus was considered patent in the presence of at least one of them. Deflation of the abdomen and herniotomy is completed. In cases with patent contralateral processus viginalis, a contralateral herniotomy is completed. Data were analyzed statistically using STATA intercooled version 9.2; STATA 9.2 software (Stata Corp LP, College Station, USA) was used for statistical analysis. Quantitative data were analyzed using Student's *t*-test to compare mean of two groups as data were normally distributed. Qualitative data were compared using χ^2-test. *P* value was considered significant if it was less than 0.05.

Results

Of 60 patients, 48 (80%) were male and 12 (20%) were female, with a male : female ratio of 4 : 1. Age ranged from 10 weeks to 8 years (mean=3.4 years and median=3.5 years). Prematurity was reported in 18 (30%) patients. The hernia was right in 40 (67%) patients (32 male and eight female) and left in 20 (33%) patients (16 male and four female).

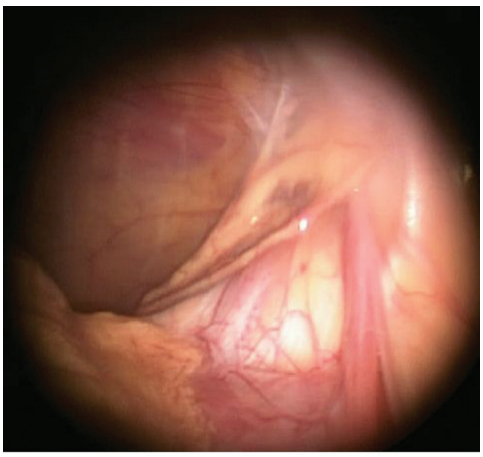
Laparoscopic operative time, calculated from introduction of the trochar cannula to extraction, ranged from 5 to 12 min (mean=8.2 min and median=8.5 min). Patent contralateral side was established in five (8.3%) patients where the procedure was completed by contralateral herniotomy (Fig. 1). Diagnosis depended on both inflation and visualization in four cases. Failure of visualization of the contralateral internal ring occurred in three (5%) cases: one because of adhesions and the other two cases because of peritoneal veil, which partially cover the internal inguinal ring and obscure its visualization (Figs 2 and 3). One of those cases had patent contralateral processus depending on inflation of the contralateral scrotal compartment. No intraoperative complications were reported during the inguinoscopy.

Figure 1



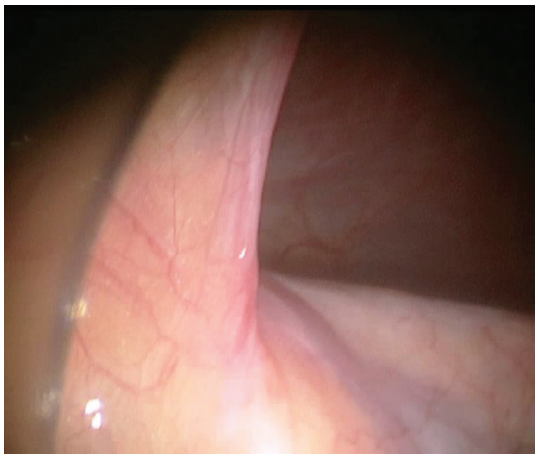
Patent contralateral internal ring

Figure 2



Adhesions obscure visualization of the contralateral internal ring

Figure 3



Peritoneal veil

Discussion

The advantages of contralateral inguinal exploration include prevention of additional anesthesia and surgeries, minimizing parental and patient inconvenience, elimination of the possibility of incarceration, and reduced costs [7]. The dissenting opinion is that the true incidence of contralateral inguinal hernia is low [8].

Many authors used preoperative US for evaluation of subliminal CPPV with documented accuracy rate ranging from 91.6 to 95%, which was confirmed by diagnostic laparoscopy or surgical exploration [9–11].

Laparoscopic examination is introduced as a tool for the diagnosis of CPPV. It enables the direct visualization of anatomic defects of the contralateral internal inguinal ring. Studies have shown that the additional time required for laparoscopic inspection is only 2–17 min [12]. In our study, the range of additional time was 5–12 min.

However, inguinoscopy has certain limitations. Since the peritoneal veil sometimes partially covers the internal inguinal ring, a direct view of the inguinal ring can be interrupted. The failure rates are reported as 3–8% [4]. On the other hand, failure to visualize the internal ring was reported in 5% of our cases. In addition, when it is difficult to observe the opened ring directly, bulging of the contralateral scrotum during gas inflation or air bubbles from the inguinal canal during scrotal manipulation are also evidence of patent processus vaginalis, which was documented in one case of our series. Thus, it is considered that these diagnostic observations can overcome the limited visibility.

Conclusion

Transhernial diagnostic laparoscopy, for cases with negative preoperative US regarding CPPV, is a feasible, rapid, safe, accurate method, with easy technique, and it seems to be more sensitive than preoperative US.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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Posterior hyoid space; a brilliant concept in managing thyroglossal duct cyst (TGDC)

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Received 31 January 2017
Accepted 3 May 2017

The Egyptian Journal of Surgery
2017, 36:249–253

Introduction
Thyroglossal duct cyst and/or fistula represent the most common congenital anomalies of the neck. Many procedures have been described for excising thyroglossal cysts. These procedures vary from simple cyst excision to anterior block neck dissection.
Objective
The aim of the paper was to evaluate the concept of posterior hyoid space according to the Maddalozzo modification of the Sistrunk operation.
Patients and methods
This prospective study was carried out at the general surgery departments of Benha and Zagazig University Hospitals. Twenty-eight patients diagnosed with primary thyroglossal duct cyst were included in this study. The surgical technique used was that described by Maddalozzo *et al.*
Results
Twenty (71%) patients had anterior neck cystic swelling and eight (29%) patients had neck fistula. After histopathological examination, the tract passed in front of the hyoid bone in all cases (100 %), whereas ectopic thyroid follicles were detected ventral to the hyoid bone in 11 (39%) cases, behind the hyoid bone in three (11%) cases, and in four (14%) cases, it was found in both the ventral and the dorsal position.
Conclusion
Our results were promising, and this approach of posterior hyoid space should be studied more extensively for assessment of its efficacy and benefits. This method should also be used to evaluate the possible role of ectopic thyroid tissues in recurrence with the use of the classic Sistrunk procedure.

Keywords:
posterior hyoid space, Sistrunk operation, thyroglossal cyst

Egyptian J Surgery 36:249–253

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Introduction

The thyroid gland originates at the foramen cecum and descends anterior to the pharynx to its final position close to the larynx [1]. During the second gestational month, this pathway is divided by the hyoid bone into upper and lower segments. The failed thyroglossal tract obliteration, or retained epithelial cysts, gives rise to thyroglossal duct cysts (TGDCs) [2]. Knowledge of the thyroglossal tract exact path, especially in relation to the hyoid bone, remains the most important factor in determining the optimum treatment for TGDCs [3]. Although extensive descriptive data on the operative treatment and the pathology of surgical specimens of TGDCs are available today, only limited and contradictory information on the anatomic course of the thyroglossal tract in relation to the hyoid bone can be found in the literature [4–7].

Some debate persists around The topographic course of thyroglossal tract. Sprinzl *et al.* [8] used – for the first time – serially step-sectioned histologic autopsy specimens for the assessment of thyroglossal tract remnants. They reported that 41.3% of specimens (24/58 specimens) showed remnants of the thyroglossal tract or ectopic thyroid tissue. Four specimens showed complete thyroglossal tracts and ectopic thyroid tissue. The tract remained ventral to the hyoid bone in all planes. However, they found ectopic thyroid follicles alone in 20 specimens. The thyroid follicles were located in ventral, dorsal, and a combination of ventral and dorsal positions in 11, three, and six specimens, respectively.

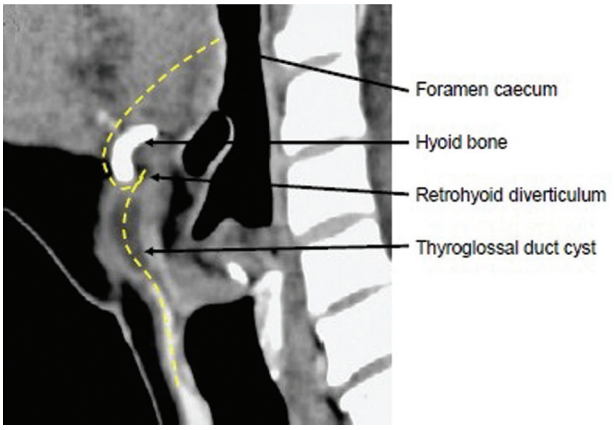
Other authors believed that a persistent thyroglossal duct courses anterior to, and rarely through, the hyoid body, and often has a diverticulum that hooks below and behind the hyoid bone [9] (Fig. 1). This variation

in understanding the embryological development is reflected in the mode of excision of the cyst.

A wide range of procedures have been described for the management of thyroglossal cysts. These procedures vary from simple cyst excision to anterior block neck dissection. A simple cystectomy showed a higher recurrence rate [10]. In 1893, Schlang [11] described a procedure to remove central part of the hyoid bone in continuity with the main cyst. In 1920, Sistrunk [12] described aprocedure of excision of the cyst in continuity with the central part of the body of the hyoid bone and the core of the tongue muscle up to the foramen cecum. The use of the Sistunk procedure led to a lower recurrence rate (about 4–14%) and is considered the gold standard for the treatment of thyroglossal cysts [13,14].

Maddalozzo *et al*. [15] modified the Sistrunk approach to include skeletonization of the thyroid cartilage to identify the alae and notch of the cartilage (Fig. 2). The thyrohyoid membrane is then identified and used to locate the posterior aspect of the hyoid bone and to evacuate the posterior hyoid space (PHS).

Figure 1



Course of the thyroglossal tract

The PHS is outlined inferiorly by the inferior margin of the hyoid, superiorly by the superior margin of the hyoid and thyrohyoid membrane, anteriorly by the posterior surface of the hyoid, and dorsally by the thyrohyoid membrane (Fig. 3). This approach facilitates complete resection of the hyoid and exposure of the PHS, enabling evacuation of abnormal tissue from this area [15].

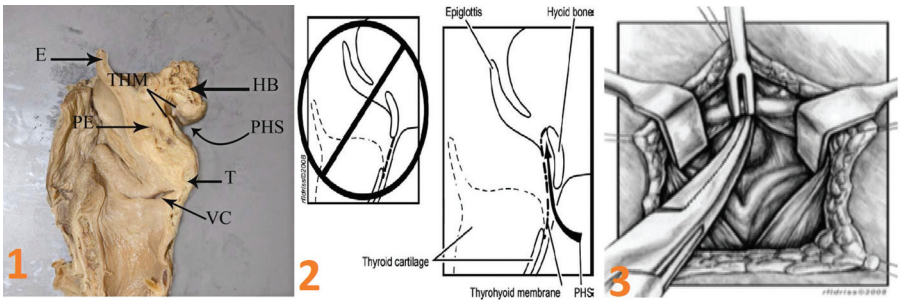
The aim of this study is to evaluate the concept of the PHS according to the Maddalozzo modification of the Sistrunk operation.

Patients and methods

This prospective study was carried out at general surgery departments of Benha and Zagazig University Hospitals after obtaining approval from the local ethical committee and after a fully informed written consent was signed by the patients' parents. This study was carried out from April 2013 to November 2016. This duration (about 44 months) allowed for patients' selection and at least a 12-month follow-up period from the last case operated upon.

Twenty-eight patients diagnosed with primary TGDC were included in this study after proper treatment of recent infection to ensure that they did not have infection for at least 6 weeks before surgery. The diagnosis of a TGDC was made on the basis of a thorough assessment of history and a physical examination (midline neck mass, which moves with deglutition and with tongue protrusion). Recurrent cases were excluded from this study. Also, patients with pathology other than TGDC were retrogradely excluded. Neck ultrasonography is a routine investigation method for cyst assessment and to visualize the thyroid gland in its normal position. Routine preoperative laboratory tests were also performed for all cases. Thyroid function tests were

Figure 2



Autopsy and diagrams showing posterior hyoid space

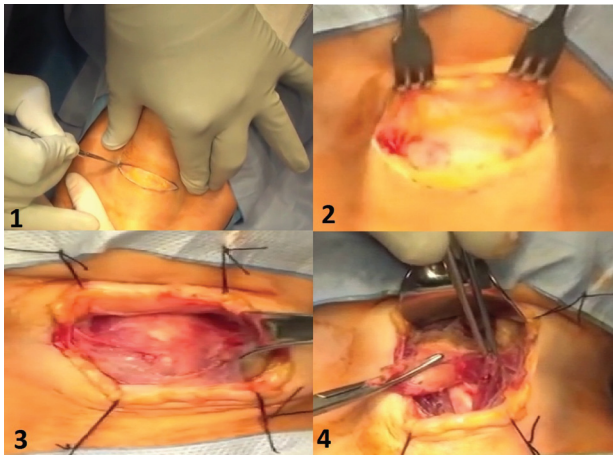
not performed routinely in cases of thyroglossal cysts if the patient was clinically euthyroid.

Surgical technique

The surgical technique as described by Maddalozzo *et al.* [15] was used. A horizontal incision approximately 4 cm in length was made in a skin crease inferior to the lesion and carried through subcutaneous tissue and platysma. Upper and lower flaps were created in the subplatysmal plane. Superiorly, the flap was elevated up to the inferior part of the submental triangle of the neck. Inferiorly, the flap was extended to expose the thyroid cartilage (Fig. 3). The strap muscles were retracted along the midline and dissection was extended to the level of the thyroid cartilage. The alae and notch of the thyroid cartilage were exposed. The thyrohyoid membrane was exposed (Fig. 4) and dissection was carried out superficially until identification of the posterior aspect of the hyoid bone and the space between the bone and membrane (PHS). The hyoid bone could then be clearly visualized and grasped with an Allice clamp and transected medial to the tendon of the digastric muscle. Further suprahyoid dissection was carried out to remove a core of tissues up to lingual musculature where the specimen was transected (Fig. 5). The tongue defect was repaired and the wound was drained before closure.

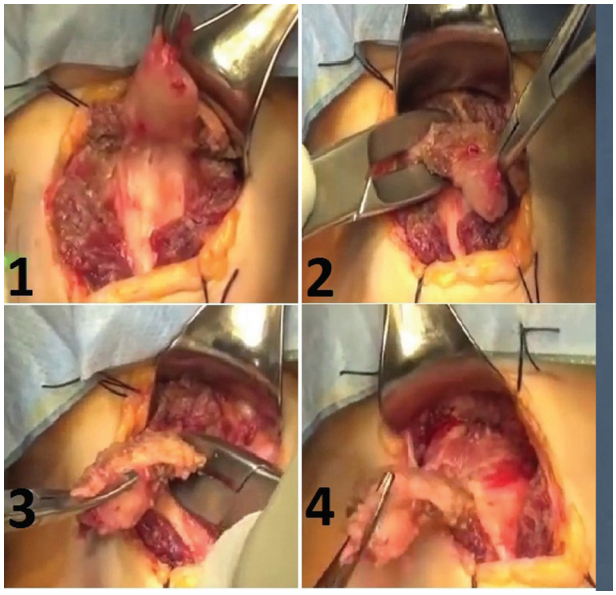
All patients received aprophylactic antibiotics. All specimens were examined histopathologically to locate the thyroglossal tract with or without ectopic thyroid tissues. Also, the relation of these tissues (tract

Figure 3



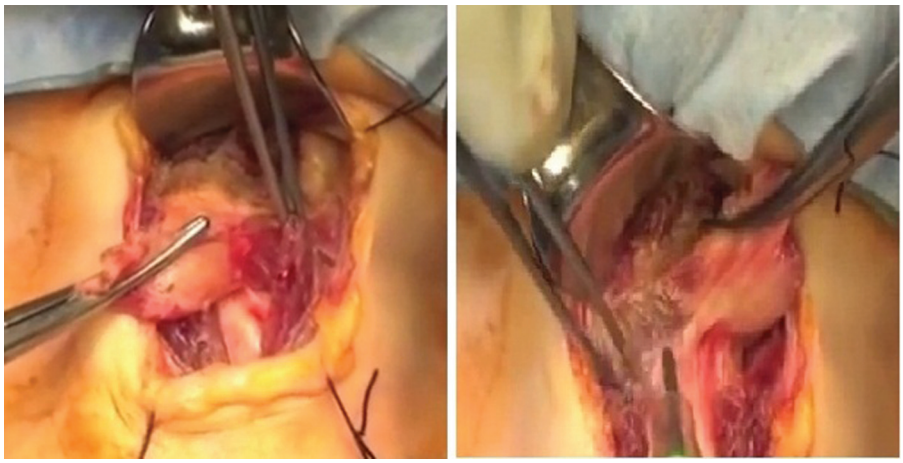
Surgical steps: 1, incision; 2, subplatysmal plane; 3, raising flaps; 4, strap muscles retraction

Figure 5



Surgical steps: 1, entry into posterior hyoid space; 2,3, cutting of the hyoid bone; 4, suprahyoid dissection

Figure 4



Exposure of the thyrohyoid membrane

and ectopic thyroid tissues) to hyoid bone was determined.

Results

The study group included 28 patients, 16 (57%) males and 12 (43%) females, with a mean age of 5.3 years (2.9–17.2 years) (Table 1). The history of the disease varied from 3 months to 2.7 years. Twenty (71%) patients had anterior neck cystic swelling and eight (29%) patients had neck fistula (Table 2).

After a histopathological examination, the tract passed in front of the hyoid bone in all cases (100 %), whereas ectopic thyroid follicles were detected in 18 (64%) patients (Fig. 6). Eleven (39%) patients had ectopic thyroid tissues ventral to the hyoid bone, in three (11%) cases, ectopic thyroid tissues were behind the hyoid bone, and in four (14%) cases, ectopic thyroid tissues were found in both the ventral and the dorsal position. In all cases, during perihyoid dissection, we found a single tract. However, suprahyoid dissection was carried out as an enblock excision of 1 cm core of tissues till lingual musculature, without any trial of skeletonization of the suprahyoid portion of the tract. Only two (7%) patients had a superficial wound infection, and this was treated successfully by oral second-generation cephalosporin. No other complication or recurrence was reported during the follow-up period (Table 2).

Table 1 Demographic data (original)

Age (years)	2.9–17.2 (5.3)	
Sex		
Male : female [*n* (%)]	16 (57)	12 (43)

Table 2 Clinical and pathological findings (original)

	n (%)
Presentation	
Cysts	20 (71)
Fistula	8 (29)
Track (single or multiple) (%)	
All cases had a single track	100
Relation to hyoid bone (%)	
All tracks were ventral to the hyoid bone	100
Ectopic thyroid tissues (*N*=28)	
Number of cases detected in patients	18 (64)
Cases (ventral to the hyoid)	11 (39)
Cases (dorsal)	3 (11)
Cases (combined ventral and dorsal)	4 (14)
Postoperative complications	
Cases of wound infection	2 (7)
No recurrence (%)	0

Discussion

TGDC and/or fistula represent the most common congenital anomalies of the neck, representing more than 70–75% of congenital midline neck masses. Post mortem examination of adult larynges suggested that TGDC remnants may be present in 7% of the population [15].

Management varies widely, ranging from simple drainage, cystectomy, tract excision, tract plus hyoid bone excision to extended excision or even anterior block neck dissection [10–12,16].

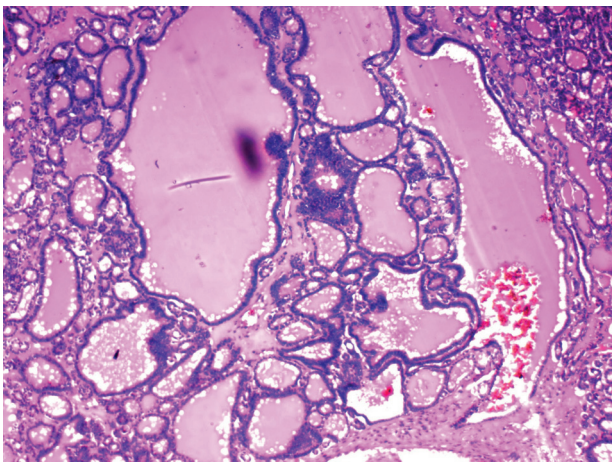
A simple cystectomy was associated with a high recurrence rate (50%). Schlang [11] carried out hyoid bone excision and found a significant reduction in the recurrence rate to 20%. Sistrunk [12] followed the same Schlang principles and also performed suprahyoid dissection; he reported a greater reduction in the recurrence rate (4–14%) [17].

Moreover, the extended dissection approach was described by Valentina and Fabio [16], but they limited the indication of this technique to recurrent cases.

Maddalozzo *et al.* [15] created a brilliant technique between all these modifications of the Sistrunk operation. They introduced the concept of the PHS, which is an anatomically undescribed area. This concept not only ensures complete tract excision but also eradication of abnormal ectopic thyroid tissues.

Previously, it was believed that the main cause of recurrence is an unexcised residual part of the tract [18]. However, even after clear tract excision, recurrence still occurred.

Figure 6



Section from ectopic thyroid tissue showed thyroid follicles. Haemotoxylin and eosin, ×200

Sprinzl *et al.* [8], for the first time, used serially step-sectioned histologic autopsy specimens. They highlighted the perihyoidal distribution of abnormally ectopic thyroid tissues with a constant position of the tract anterior to the hyoid bone. The study of Sprinzl *et al.* [8] was a strong support to the concept of the PHS.

This study evaluated the PHS concept, and we found that it is an excellent modification of the Sistrunk operation. This approach leads to a complete eradication of a TGDC, tract, and hyoid bone and evacuation of the PHS with its possible contents of ectopic thyroid tissues and it is still a simple and easy to perform technique.

In this study, we found the thyroglossal tract at a constant position anterior to the hyoid bone. However, Chandra *et al.* [19] reported that in ~30% of cases, the tract has been found posterior to the hyoid bone.

In this study, we encountered no recurrence over the entire 12-month follow-up duration. Maddalozzo *et al.* [15] used the same technique that was described here, and reported a 1.05% recurrence rate in a series of 95 patients. Their results still showed a significant reduction in the recurrence rate compared with the use of the classic Sistrunk operation. As reported by Mondin *et al.* [20], in their extensive 2008 review, they carried out a meta-analysis to combine the recurrence rates of TGDC after a classic Sistrunk operation from 13 reported series involving 950 patients. They reported a recurrence rate of 6.6% [20].

Also, pathological studies reported the constant position of TGDC and the tract ventral to the hyoid bone with the plane of cleavage in between. Moreover, we also highlight the important possible role of ectopic thyroid tissues that were found in the perihyoid area. Ectopic thyroid tissues were found in 64% of cases. the relation of ectopic thyroid tissues with hyoid bone was anterior, posterior, and combined anterior and posterior to the hyoid bone in 39, 11, and 14% of cases, respectively. These results are comparable with those reported by Sprinzl *et al.* [8], they found that ectopic thyroid tissues were 55, 15, and 30% in anterior, posterior, and combined anterior and posterior positions in relation to the hyoid bone [8]. It is still unclear to consider ectopic thyroid tissues a cause of recurrence of thyroglossal cysts. For further evaluation, subsequent researches should be carried out on a wide scale.

Our results were promising as we encountered no recurrence over a follow-up period of 12 months. The relatively small number of cases in this study is a limiting factor, and this approach of PHS should be studied more extensively for assessment of its efficacy and benefits. Also, the possible role of ectopic thyroid tissues in recurrent cases with the use of the classic Sistrunk procedure should be studied.

Financial support and sponsorship
Nil.

Conflicts of interest
There is no conflict of interest.

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Predictors of occult nipple–areola complex involvement in breast cancer patients: clinicopathologic study

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Received 3 February 2017
Accepted 26 March 2017

The Egyptian Journal of Surgery
2017, 36:254–259

Context
Although oncoplastic breast-conserving surgery is a standard approach for treatment of breast cancer patients, mastectomy is still performed in 20–30% of patients undergoing surgeries. Nipple-sparing mastectomy provides a cosmetic and psychological outcome for patients; however, the oncologic safety of nipple–areola complex (NAC) sparing is a major concern.
Aim
The focus of this study was to determine the predictive factors of NAC involvement to define the indicators for NAC preservation.
Patients and methods
We analyzed NAC involvement in 180 patients during the period between October 2013 and December 2016 as regards the relation between the pathological affection of the NAC and clinical criteria, pathological and molecular features of the tumor (size, site, tumor–nipple distant, nodal affection, and molecular classification of breast cancer).
Results
Among 180 patients, 38 (21.1%) demonstrated NAC involvement, and it was mostly associated with tumor size 4 cm (P=0.047), tumor–nipple distant of 2.5 cm (P=0.003), positive lymph node (P=0.05), negative estrogen receptor (P=0.00013), negative progesterone receptors (P=0.000001), and HER2 receptor overexpression (P=0.001). Triple-negative breast cancer was significantly associated with increased risk of NAC involvement followed by HER2/neu-enriched subtype (P=0.001).
Conclusion
Tumor–nipple distant, tumor size and state of lymph nodes are the most important clinical predictors of nipple involvement and should be considered as risk factors. At the pathological and molecular level, triple-negative breast cancer is the worst subtype. The presence of one or more of these factors indicates high risk of occult nipple invasion.

Keywords:
nipple involvement, nipple-sparing mastectomy, predictive factors

Egyptian J Surgery 36:254–259

1110-1121

Introduction

Although oncoplastic breast-conserving surgery is a standard approach for treatment of breast cancer patients, mastectomy is still performed in 20–30% of patients undergoing surgeries [1,2].

Skin-sparing mastectomy and nipple-sparing mastectomy (NSM) are examples of mastectomy techniques that were originally employed for benign lesions [3,4].

Skin-sparing mastectomy requires the removal of the nipple–areola complex (NAC) by considering the fact that the nipple contains the terminal ducts that may contain tumor cells or a certain amount of breast tissue that carry a risk of developing subsequent cancer [5].

There are many problems with reconstructed nipples, including lack of projection, shape, size, color mismatch, and position. Hence, there is increasing interest in preservation of the NAC in the hope of achieving better cosmetic and functional outcomes [6–9].

NSM includes removal of all breast tissue with preservation of the entire skin of the breast and NAC [10,11].

Risk factors for NAC involvement with tumor are still not well defined. Therefore, selection criteria for NSM in breast cancer patients have not been well established [12].

We intended to investigate the frequency of occult NAC involvement and the clinicopathologic factors most frequently associated with it.

Aim

The focus of this study was to determine the predictive factors of NAC involvement to define the indicators for NAC preservation.

Patients and methods

This study was conducted at Zagazig University Hospital between October 2013 and December 2016. The study was approved by local ethical committee of our faculty and the technique was discussed with all patients and informed consent was obtained. In this study, we analyzed NAC involvement in 180 patients as regards the relation between the pathological affection of the NAC and clinical criteria of the tumor [size, site, tumor–nipple distant (TND), and nodal affection].

Inclusion criteria

All female patients with breast cancer with healthy non invaded skin and grossly free NAC and who were not candidates for oncoplastic surgery.

Exclusion criteria

(1) Grossly and radiologically involved NAC.
(2) Inflammatory breast cancer.
(3) Breast cancer patient subjected to chemotherapy or radiotherapy.
(4) Skin involvement.

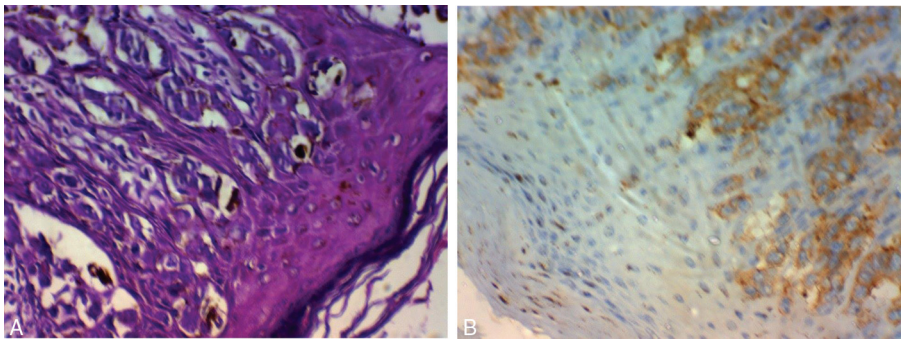
All patients diagnosed with breast cancer by history taking, clinical examination and investigation in the form of breast ultrasound, mammography and biopsy [Fine needle aspiration cytology (FNAC), true cut or excisional]. For staging of the disease chest radiography, pelvic abdominal ultrasound and bone scan were carried out. MRI was performed for all patients to measure TND (distant between the center of the nipple and nearest margin of the lesion).

After diagnosis of early breast cancer, our patients were prepared and consented for modified radical mastectomy (MRM).

Clinical criteria of the patients that were taken into consideration throughout our study included age, tumor size, tumor site, lymph node status (palpable or not palpable) and TND. Breast ultrasonography plays an important and more precise role in determining tumor size and infiltration of axillary lymph nodes.

The resulting specimens after MRM were subjected to histopathological examination for nipple invasion (lymphatic and vascular invasion of the subareolar region) (Fig. 1) shows histological type [Invasive ductal carcinoma (IDC), invasive lobular carcinoma (ILC), ductal carcinoma insitu (DCIS) or any combination], tumor grade (I, II or III), pathological lymph node affection (positive or negative) and immunohistochemistry for molecular classification: (i) luminal A tumors that showed an IHC profile of high Estrogen receptors (ER), progesterone receptors (PR) expression, negative HER2 and low Ki67; (ii) luminal B is ER+, PR+, HER2– and Ki67 greater than or equal to 14%; (iii) luminal HER2 is ER+, PR+ and HER2+; (iv) HER2-enriched subtypes are ER–, PR–, HER2+ and (v) triple-negative breast cancer (TNBC): ER-, PR- and HER2-. Immunohistochemistry was performed on paraffin sections using anti-ER antibody (clone D07, DAKO) and anti-PR antibody ((PR 636, Dako at 1 : 50 dilution). Polyclonal HER2 antibody in the Herceptin kit (HercepTest, DAKO) was used according to the manufacturer's instructions and

Figure 1



A: Skin of NAC are infiltrated by malignant ductal epithelial cells (H&E x400). B: Skin of NAC are infiltrated by malignant ductal epithelial cells (IHC, Her2-neu x400).

Ki67 antibody (clone MIB-1, 1 : 50 dilution; Dako) was utilized by using the Envision system for detection. For ER and PR expression, moderate to strong nuclear staining in ≥1% of tumor cells was considered positive. HER2/neu was considered positive if at least 10% of tumor cells exhibited 3+ cell membrane staining. Cutoff point for ki67 expression was 14%.

Statistical analysis was performed to compare tumors with or without nipple involvement.

Results

Patient age

Age distribution along the examined group is shown in Table 1

Lymph nodes examination

In our study, preoperative examination of axillary lymph nodes revealed that the majority of cases had impalpable nodes, but on testing the relation of having infiltrated axillary LNs to having an NAC devoid of malignancy, this relation was found to be strongly statistically significant as *P* value was less than 0.05 (χ^2 test was used) (Table 2).

Tumor–nipple distant

In our study, preoperative measuring of the distant from the outer mass margin to the center of the nipple was recorded in a trial to find the safe distance at which the NAC was devoid of malignancy. Patients were divided into groups as shown in the following table; thereafter, every 2 successive groups were compared statistically to record this safe distance, and at least 2.5 cm was found to be the statistically significant safe distant for having an NAC free of malignancy. *P* value was 0.003 (χ^2 test was used) (Table 3).

Table 1 Age distribution along the examined group

Age	NAC positive	NAC negative	Total	χ^2	*P* value
<30	0	4	4	1.129	0.769
30–<40	8	31	39		
40–60	21	75	96		
>60	9	32	41		
Total	38	142	180		

NAC, nipple–areola complex.

Tumor size

In our study, tumor size at the maximal diameter was recorded in a trial to find the safe size at which the NAC was devoid of malignancy. Patients were divided into groups as shown in the following table; thereafter every 2 successive groups were compared statistically to record this safe size and 4 cm at maximal diameter for the tumor mass was found to be the statistically significant safe size for having an NAC free of malignancy. *P* value was 0.047 (χ^2 test was used) (Table 4).

Other pathological features

In our study, certain pathological factors were recorded in a trial to outline the pathological features at which the NAC was devoid of malignancy. These factors were as follows:

(1) Histopathological type of the tumor.
(2) Histological grade.
(3) Histopathological status of lymph nodes.
(4) Molecular classification of breast cancer.

It was found that histopathological type of the tumor, histological grade or histopathological status of lymph nodes cannot affect the malignancy-free condition of the NAC, as *P* values for them were 0.687, 0.084, and 0.08,

Table 2 State of lymph nodes

Clinical examination of lymph nodes	NAC positive	NAC negative	Total	χ^2	*P* value
Clinically positive	29	36	65	33.748	<0.05 (too low)
Clinically negative	9	106	115		
Total	38	142	180		

NAC, nipple–areola complex.

Table 3 Tumor–nipple distant

Tumor–nipple distant (cm)	NAC positive	NAC negative	Total	χ^2	*P* value
<2	19	20	39	41.2	0.0001
2–<2.5	18	28	46		
2.5–<3	1	20	21		
3–<3.5	0	41	41		
3.5–<4	1	20	21		
>4	0	12	12		
Total	38	142	180		

NAC, nipple–areola complex.

Table 4 Tumor size

Tumor size (cm)	NAC positive	NAC negative	Total	χ^2	*P* value
<1	0	13	13	25.1	0.00004
1–<2	2	15	17		
2–<4	9	66	75		
4–<5	12	34	46		
>5	15	14	29		
Total	38	142	180		

NAC, nipple–areola complex.

Table 5 Pathological finding

Pathological findings	NAC positive	NAC negative	Total	χ^2	*P* value
Histopathological type					
IDC	34	120	154	0.749	0.687
ILC	1	8	9		
IDC+DCIS	3	14	17		
Total	38	142	180		
Histological grade					
Grade I	1	17	18	4.94	0.084
Grade II	19	80	99		
Grade III	18	45	63		
Total	38	142	180		
Pathological lymph nodes					
Positive	24	67	91	3.06	0.080
Negative	14	75	89		
Total	38	142	180		
Estrogen receptors					
Positive	16	106	122	14.537	0.00013
Negative	22	36	58		
Total	38	142	180		
Progesterone receptors					
Positive	11	102	113	23.593	0.000001
Negative	27	40	67		
Total	38	142	180		
HER2 overexpression					
Positive	23	46	69	10.036	0.001
Negative	15	96	111		
Total	38	142	180		

NAC, nipple–areola complex.

Table 6 Molecular classification of the cases

	NAC positive	NAC negative	Total	*P* value
Luminal A	4	66	70 (38.9)	0.001
Luminal B	4	36	40 (22.2)	
Luminal HER2	3	27	30 (16.7)	
HER2 enriched	11	11	22 (12.2)	
TNBC	16	2	18 (10)	
Total	38 (21.1)	142 (78.9)	180	(100)

NAC, nipple–areola complex; TNBC, triple-negative breast cancer.

respectively. In contrast, estrogen and progesterone receptors status and HER2 overexpression were found to strongly and significantly affect the malignancy-free condition of the NAC, as *P* values for them were 0.00013, 0.000001 and 0.001, respectively (χ^2 test was used), as shown in Table 5. TNBC was significantly associated with increased risk of NAC involvement followed by HER2/neu-enriched subtype (*P*=0.001) as shown in Table 6.

Discussion

Surgical treatment of early breast cancer has rapidly evolved from radical mastectomy to more cosmetic

procedures like breast-conserving surgery and NSM with NAC preservation.

All patients in our study were subjected to MRM, because we included patients who were not candidates for oncoplastic surgery (patient preference was the main cause) and to enable us for NAC resection and histopathological examination.

Most breast cancer patients ask for both better cosmetic appearance and oncological safety. The majority of patients are interested in preserving the nipple during surgical resection of the tumor.

Preoperative detection of NAC invasion helps the surgeon to choose the most suitable surgical procedure that achieves both cosmetic and oncological satisfaction.

Factors that predict NAC invasion are not fixed in all studies, and to preserve the NAC we must be sure that it is free from malignancy.

The rate of NAC involvement has shown a wide range of involvement varying from 0 to 58% [13,14]; hence, the safety of the NSM remains controversial. NAC involvement was defined by the presence of invasive carcinoma and/or ductal carcinoma *in situ* at the subareolar margin. In this work we tried to predict factors that determine NAC involvement. In the current study NAC involvement was 21.1%; however, Andersen and Pallesen [15] have reported a rate of 50% of NAC involvement.

Many studies reported a lower rate of recurrence; Laronga *et al*. [16], have reported a 5.6% rate of recurrence, whereas Jianli *et al*. [17] reported a 9.5% rate of recurrence. This discrepancy between different rates of recurrence may be due to a peripherally located tumor in some studies and the sampling technique of the nipple, whether it was a sagittal section, or multiple coronal or vertical sections.

Site of the tumor, size of the tumor, and the state of the lymph nodes are the most important clinical factors associated with NAC involvement [18,19]; this was confirmed in the current study.

In our study, TND was the most important risk factor for nipple invasion; tumor distance less than 2.5 cm from the nipple was predictive for NAC involvement, and this is in agreement with Gerber *et al*. [9] and Vyas *et al*. [20], but in contrast with Sacchini *et al*. [7] who report that the cutoff value of TND was 1 cm.In this study, the risk of NAC invasion is directly proportionate with tumor size; tumor size less than 4 cm in our study was predictive for NAC involvement, and this is in agreement with Garcia-Etienne *et al*. [21].

In our study, breast ultrasonography plays an important and more precise role in determining axillary lymph nodes infiltration; positive lymph nodes were predictive for NAC involvement.

Breast cancer is a heterogeneous tumor that reveals several different molecular profiles with different biological behaviors; triple-negative subtypes present poorly differentiated tumors lacking ER, PR, and HER2 on immunohistochemical assay, and they are characterized by an increased rate of proliferation and increased invasiveness. In this work, this subtype was associated with increased risk of NAC involvement followed by HER2/neu-enriched subtype and this is in agreement with Petit *et al*. [22].

Conclusion

Tumor nipple distant, tumor size and state of lymph nodes are the most important clinical predictors of nipple involvement and should be considered as risk factors. At the pathological and molecular level, TNBC is the worst subtype. The presence of one or more of these factors indicates high risk of occult nipple invasion.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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Negative-pressure wound therapy in pediatric extremity trauma: a single-institution experience

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Received 19 February 2017
Accepted 27 March 2017

The Egyptian Journal of Surgery
2017, 36:260–264

Background
The value of negative-pressure wound therapy as a bridge to definitive closure of traumatic extremity wounds has been established in adults. Negative-pressure wound therapy has been used to assist granulation tissue formation and promote closure of wounds. In this study, we evaluated our experience with negative-pressure wound therapy for pediatric extremity wounds requiring delayed closure.
Patients and methods
A prospective study was conducted on 20 pediatric patients presenting with extremity injuries involving soft-tissue defects not suitable for immediate primary closure. Initial evaluation of the traumatized patient, wound irrigation, debridement, and antibiotic therapy were carried out and a plan for each case was outlined. Negative-pressure wound therapy was established using the vacuum-assisted closure system and dressings were changed every 3 days before definitive closure either by skin graft, Integra dermal matrix followed by skin graft, or local flaps.
Results
Granulation tissue was noted in all wounds by day 3. The mean duration of vacuum therapy was 12±3.3 days in patients whose wounds were closed by local flap advancement (n=4), 9±3.6 days in patients whose wounds were closed by skin grafts (n=8), and 6±4.8 days in patients whose wounds were closed by Integra dermal matrix (n=8). There was no incidence of skin graft or Integra losses. All local flaps healed completely. The mean follow-up period was 18±6.8 months, during which no complications were noted.
Conclusion
As a relatively atraumatic wound care technique with little complications, negative-pressure wound therapy provides a highly effective option as a bridge for soft-tissue management of extremity trauma in pediatric patients.

Keywords:
extremity, negative-pressure wound therapy, vacuum-assisted wound closure

Egyptian J Surgery 36:260–264

1110-1121

Introduction

Pediatric extremity trauma is associated with unique challenges to wound management. The visual and emotional experience of a tragic injury demands an approach that lessens the daily trauma of wound care to the child. Soft-tissue management must be as atraumatic as possible with adequate pain management, especially in wounds that will heal by delayed primary or secondary intention requiring multiple and often painful dressing changes that add great anxiety to the pediatric patient's experience. Alternative methods for soft-tissue management are needed to promote wound healing before closure and to ensure patient comfort and minimize anxiety [1,2].

Negative-pressure wound therapy has been used to manage difficult wounds since 1985 and has focused the use of this tool to assist in the management of children with complex traumatic wounds since 2000. The application of negative pressure to wounds has been practiced for some time; however, the benefits of negative-pressure wound therapy were outlined in a series of clinical studies in Russia in the 1980s [3–6] and later in Europe [7–9]. In recent times, negative-pressure wound therapy has re-emerged as a way of removing exudate, cell debris, inflammatory factors, and microbes from the wound while maintaining a moist environment that supports granulation tissue formation. Negative-pressure wound therapy has been gaining acceptance in the USA, and has been used in a variety of patients and wound types. The utility of negative-pressure wound therapy specifically in the pediatric population has been described by several groups [10–12]. Negative-pressure wound therapy using the vacuum-assisted closure (VAC)

system has been described for the temporary treatment of open fractures in both adults [13] and children [11], to promote granulation tissue formation before definitive closure by flaps or grafts. In this study, we evaluated our experience with negative-pressure wound therapy for pediatric extremity wounds requiring delayed closure.

Patients and methods

A prospective study of 20 patients who presented with extremity injuries to Adan Hospital, Kuwait, between 2013 and 2015 was performed. This study was approved by the ethical committee of our institutions. Patient demographics are shown in Table 1. The study included patients with injuries that involved the loss of soft tissue that was contaminated or traumatized and was not suitable for immediate primary closure. We recorded the injury site, presence of fracture, duration of vacuum therapy, time to formation of a granulating wound bed, and method of closure. After initial debridement and antibiotic therapy, negative-pressure wound therapy was applied using the VAC system (Kinetic Concepts Inc., San Antonio, Texas, USA) [1]. The dressings were changed every 3 days in the operating room when debridement was required or at the bedside with conscious sedation when indicated. Methods of wound closure included skin grafts, Integra dermal matrix followed by skin graft, and local flaps.

Results

Negative-pressure wound therapy was used on 20 children. The ages of the patients ranged from 4 to 16 years. The mean age was 6.5±3.9 years. Twelve patients were treated for upper-extremity injuries, and eight were treated for lower-extremity injuries. Granulation tissue was noted in all wounds by day 3. The mean number of dressing change was 4.7±1.2.

Table 1 Patient demographics

Number of patients	20
Male : female	12 : 8
Lower-limb : upper limb	12 : 8
Age (mean±SD) (years)	6.5±3.9
Follow-up period (mean±SD) (months)	18±6.8
Number of dressing changes (mean±SD)	4.7±1.2

Table 2 Duration of negative-pressure therapy according to type of closure

	Local flap group (4 patients)	Skin graft group (8 patients)	Integra group (8 patients)
Duration of negative-pressure therapy (mean±SD) (days)	12±3.3	9±3.6	6±4.8

The mean duration of vacuum therapy was 12±3.3 days in patients whose wounds were closed by local flap advancement (n=4), 9±3.6 days in patients whose wounds were closed by skin grafts (n=8), and 6±4.8 days in patients whose wounds were closed by Integra dermal matrix (n=8) (Table 2). There was no incidence of skin graft or Integra losses. All local flaps healed completely. All patients were managed as inpatients and the wounds were closed at the time of discharge. The mean follow-up period was 18±6.8 months, during which no complications were noted.

Two cases selected from this study are described in Figs 1 and 2.

Discussion

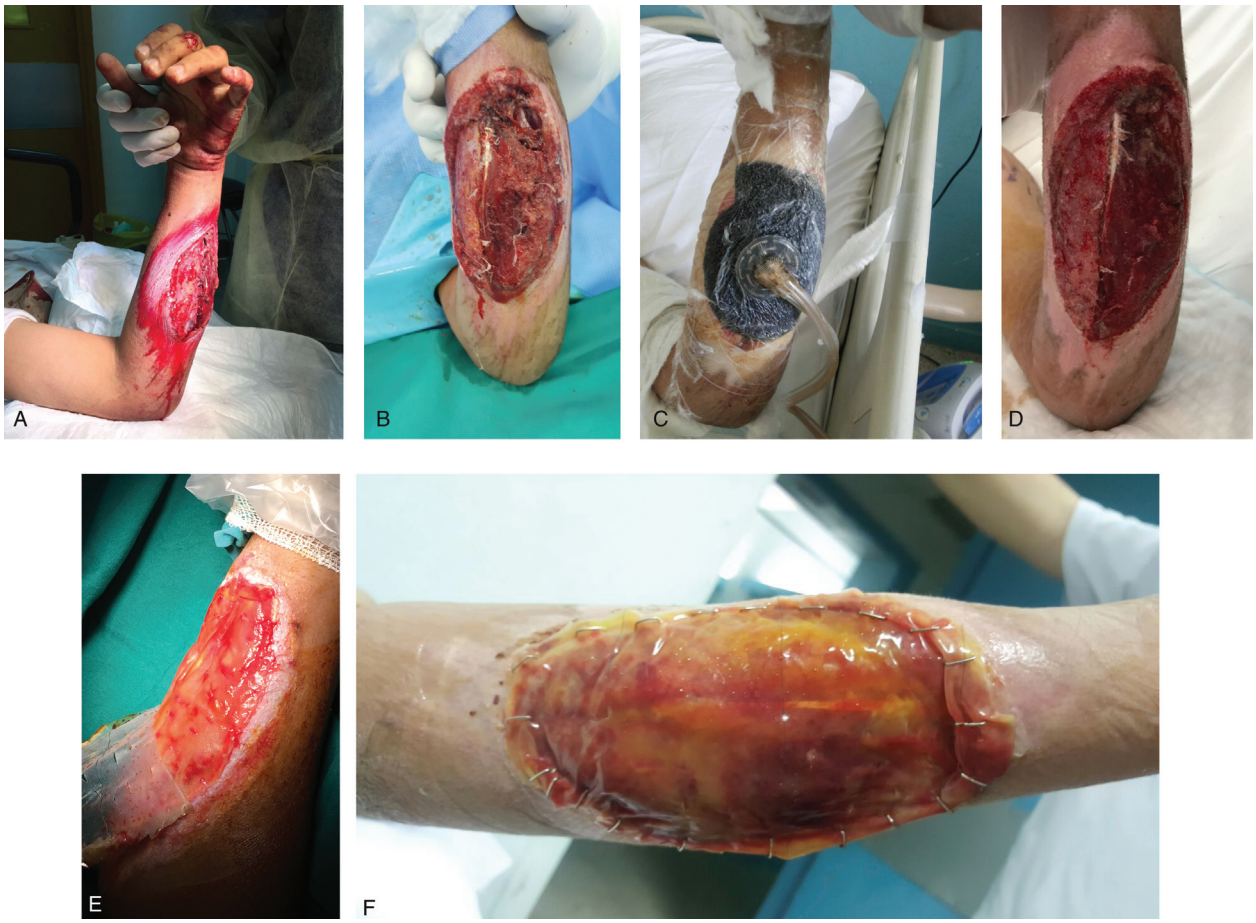
The use of vacuum dressing in the management of complex upper-extremity and lower-extremity injuries in the adult population has been clearly documented and is an effective tool in the management of open fractures complicated by soft-tissue loss [13–17]. Negative-pressure wound therapy is considered a bridge technique for soft-tissue management of traumatic extremity wounds, meaning that it is used to promote wound healing before closure, either by secondary intention or by grafting or flap placement [13–17].

Our protocol for closing traumatic extremity wounds are started at the initial operation. Once the wound is debrided, local flaps are used to decrease the wound size and to gain tension-free coverage of any exposed neurovascular structures, tendons, or bone. Once local flap coverage has been maximized, the wound is covered with the negative-pressure wound therapy dressing. This process is repeated at 3-day intervals until it is clear that all nonviable tissue has been removed. Once it is clear that further debridement is no longer needed, dressing changes can be performed at the bedside with conscious sedation. Once evidence of granulation tissue appears, wound closure can be performed.

In the present study, negative-pressure wound therapy was used as a means of preparing the wound for definitive closure in 20 pediatric patients with upper-extremity and lower-extremity injuries.

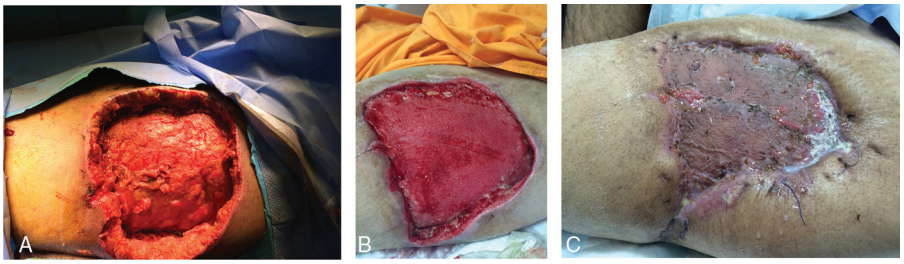
Studies on the role of vacuum therapy in adult and pediatric traumatic extremity wounds are infrequent. In pediatric patients, Mooney *et al.* [18] conducted a small retrospective study of 27 patients treated with VAC for various soft-tissue defects (11 of which were acute

Figure 1



Crushed forearm in a 10-year-old child.

Figure 2



Crushing injury to the thigh in a 14-year-old child.

extremity wounds secondary to trauma). There was a 56% closure rate after an average of 4.8 dressing changes performed approximately every 3 days [18]. Notably, no patients required free tissue transfer for definitive closure [18]. The authors described infrequent complications, which were primarily related to bleeding caused by disruption of the granulation tissue during dressing changes [18].

Another study has evaluated the efficacy of vacuum therapy in pediatric patients, specifically for traumatic extremity wounds [11]. Fifteen patients with type III open tibial shaft fractures underwent VAC with an average of 3.6 dressing changes before definitive wound closure or coverage, with only one patient requiring free tissue transfer [11].

Chariker *et al.* [2] have performed a retrospective review of 24 pediatric patients presenting with extremity injuries involving soft-tissue defects not amenable to immediate primary closure. They evaluated the efficacy of gauze-based negative-pressure wound therapy using the Chariker–Jeter technique. Granulation tissue was noted in all

wounds by day 4. The duration of vacuum therapy averaged 10 days in patients whose wounds were closed primarily (n=19) and 17 days in patients who were allowed to heal by secondary intention (n=5). Nine patients' wounds were closed with skin grafts and local flaps, eight were closed with local flaps only, and three were closed with free tissue transfer. There was no incidence of skin graft loss or flap failure. Follow-up evaluation of the wounds averaged 24 months, during which no complications were noted [2].

Notably, our study of negative-pressure wound therapy confirmed the major conclusion of these previous studies: that vacuum therapy allows the possibility of traumatic wound closure by secondary intention or with local flaps or grafts in extremity wounds that otherwise would require more complex microvascular procedures.

A similar conclusion was reached by the authors of five studies of VAC used to treat traumatic open-extremity wounds in adults [13–17]. In a series of 75 patients with open wounds of the lower extremity (of which 49 were the result of trauma), granulation tissue was present by day 4 of vacuum therapy, with decreased edema and bacterial counts [16]. No patients required free tissue transfer, and wound closures remained stable through a 6-year follow-up [16]. Another group reported their results in 21 consecutive patients with high-energy soft-tissue wounds who underwent vacuum therapy for an average of 19.3 days (4.1 dressing changes) [15]. Fifty-seven percent of wounds healed by secondary intention or were closed with a split-thickness skin graft, and 43% required free tissue transfer [15]. A similar study in 49 patients with grade III open tibia fractures found that vacuum therapy applied for an average of 12.7 days (2.9 dressing changes) was sufficient for wound closure or definitive coverage [13]. Only three patients required free tissue transfer, and 14 wounds were closed with rotational pedicled muscle flaps [13]. Bollero *et al.* [14] likewise reported rapid granulation tissue formation in 35 patients with lower-limb traumatic wounds who underwent vacuum therapy. After an average treatment time of 22 days, two-thirds of the wounds were able to be covered by split-thickness skin grafts, and 76% of patients had stable soft-tissue reconstruction after an average follow-up of 265 days [14]. The efficacy of intermittent vacuum therapy was assessed in a subset of patients with grade III tibia fractures whose wounds could not undergo immediate closure (within 7 days after trauma) [17]. Patients were treated with either subatmospheric pressure dressing therapy (n=17) or wet-to-dry gauze or a moist occlusive dressing (n=38) [17]. The average duration of subatmospheric pressure dressing therapy was 5.91 days [17]. Patients who received vacuum therapy had statistically significantly lower complication rates (35 vs. 53%; P=0.05) and decreased time to bony union (4.9 vs. 7.2 months; P=0.05) than those who did not receive vacuum therapy [17]. Furthermore, these complication and union rates were comparable to those of patients who were able to undergo free tissue transfer within the first 7 days after injury, suggesting that vacuum therapy is an effective option for extending the 'acute' period of traumatic wounds that cannot undergo immediate closure [17].

Our study findings in pediatric patients using negative-pressure wound therapy are thus highly consistent with the existing literature in that they support the use of subatmospheric pressure therapy as a 'bridging' wound care technique in traumatic extremity wounds that are not amenable to immediate closure. In others' and our studies, application of vacuum therapy decreased the need for more complex wound closure procedures, with many wounds able to be covered with grafts or local flaps or healed by delayed secondary intention.

Soft-tissue management in extremity wounds may be particularly challenging in pediatric patients, who may experience intensified anxiety regarding traumatic wounds and who may have a lower threshold for tolerating wound-associated pain and complications. Pediatric extremity trauma thus presents a unique constellation of challenges – anxiety management, pain management, consistent wound care, restorative reconstruction, and post-traumatic stress management – that must be addressed to ensure optimal outcomes [19]. Prevention of wound infection, moist wound care, and wound closure strategies must be both time efficient and relatively painless. The psychological and physical pain management of children requires a team approach involving nurses, anesthesiologists, physical therapists, and family support staff [19].

It is believed that negative-pressure wound therapy enables wound healing by at least three mechanisms. The first is by enabling moist wound healing with an occlusive dressing. Use of an occlusive dressing alone has been shown to increase epithelialization, increase granulation rates, and promote wound healing [20]. The second mechanism is wound drainage. The vacuum effect created under this occlusive dressing creates a highly effective drainage system whereby the products of cell turnover, bacteria, destructive

proteases, and harmful wound factors, and the alkaline drainage of a chronic wound or the acidic drainage of an enteric fistula, are removed [5]. This drainage facilitates the movement of a chronic wound along a dynamic healing curve of an acute wound. The third mechanism is the soft-tissue mechanical stress applied by the vacuum. Urschel *et al*. [21,22] estimated that mechanical stress leads to an upregulation of wound healing through increased cellular nutrition.

Conclusion

In conclusion, this study supports the efficacy of negative-pressure wound therapy as a relatively atraumatic temporary bridging technique to manage soft-tissue defects in complex extremity wounds in pediatric patients. The success of negative-pressure wound therapy depends on a comprehensive clinical judgment and an appropriate wound care regimen once granulation tissue has formed and negative-pressure wound therapy is stopped. More clinical trials are needed to confirm the clinical evidence base needed for this powerful wound care technique.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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Single-port laparoscopic-assisted appendectomy using the nephroscope for percutaneous nephrolithotomy at low cost

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Received 24 February 2017
Accepted 8 April 2017

The Egyptian Journal of Surgery
2017, 36:265–268

Context
Laparoscopic appendectomy had been accepted over the last years, as a goal of improved diagnostic accuracy and wound complication rate, over the open procedure. However, the new techniques require single port and manoeuverable instruments, which are expensive. In this study, the cost of single-port laparoscopic appendectomy is reduced through conventional instrumentation using a side-arm viewing operative laparoscope, which is the nephroscope used for percutaneous nephrolithotomy.
Aim
The aim of this study was to present the retrospective experience of reducing the cost of single-port laparoscopic-assisted appendectomy using the nephroscope for percutaneous nephrolithotomy.
Settings and designs
The study design was a retrospective case series one.
Materials and methods
Our study was conducted between December 2014 and August 2015. The study included 40 patients with clinical diagnosis of acute appendicitis. Patients with complicated appendicitis, obese patients (BMI $\geq$35 kg/m^2) and those who needed the insertion of another port were excluded from the study.
Statistical analysis
Continuous variables were expressed as mean and SD. Categorical variables were expressed as frequencies and percentage.
Results
The study included 40 patients, 24 (60%) male and 16 (40%) female. The mean operative time was 35±12 min. The age of participants ranged between 8 and 25 years. There was no significant perioperative morbidity or mortality. The mean follow-up period was 6 months.
Conclusion
Our experience with this technique of single-port laparoscopic-assisted appendectomy using the nephroscope for percutaneous nephrolithotomy demonstrates its feasibility and safety at a very low cost.

Keywords:
appendectomy, laparoscopic-assisted appendectomy, nephroscope, single-incision laparoscopy, single-port laparoscopy

Egyptian J Surgery 36:265–268
© 2017 The Egyptian Journal of Surgery
1110-1121

Introduction

Incisions used for open appendectomy vary widely, but the most common is proposed by McBurney (oblique incision in the right iliac fossa). The cosmetic result is poor when the incisions are oblique, horizontal, or vertical. Most appendectomies are performed in children and adolescents, and the cosmetic result is an important factor at these ages [1]. Scars remain lifelong and may change with the advancement of the age of the patient, becoming often unsatisfactory in appearance.

During the past two decades, general surgery had been shifted from open to minimally invasive surgery. This was aided by the development of laparoscopic technology, which enables surgeons to perform increasingly complex tasks through small incisions. Laparoscopic appendectomy (LA) was one of the first reported laparoscopic cases in general surgery by de Kok in 1977 [2].

Different techniques for the laparoscopic approach have been reported in the literature for better aesthetic results and reduction in hospital costs without compromising safety of the operation. The first LA performed using three ports was described by Semm in 1983 [3]. In 1992, a LA using a single umbilical puncture was proposed by Pelosi and Pelosi [4]. In 1998, Esposito reported an initial

experience in performing one-trocar appendectomy in children [5].

Ongoing active surgical research to further reduce the morbidity introduced novel endoscopic techniques such as SILS and NOTES [6]. The technique of NOTES is not yet widely accepted, as it requires opening of normal viscera with risk for contamination. Since the first report of single-incision laparoscopic surgery (SILS) for acute appendicitis, it had been proposed as the next evolution in minimally invasive surgery. The increased interest in single-incision laparoscopic appendectomy (SILA) had seemed to be primarily focused on better cosmesis (scarless abdominal surgery performed through an umbilical incision), less incisional pain and conversion to standard multiport laparoscopic surgery if needed [7].

The instruments that are needed for SILA include SILS port and specialized customized dissector and graspers. However, using these instruments in SILS might increase healthcare costs. To reduce costs, many authors have used their own tools for SILS [8]. In this report, we describe laparoscopic-assisted appendectomy through the use of a side-arm viewing laparoscope, which is the nephroscope that is used for percutaneous nephrolithotomy (Karl Storz, Tuttlingen, Germany). We conducted this study to present the retrospective experience of single-port laparoscopic-assisted appendectomy at low cost.

Materials and methods

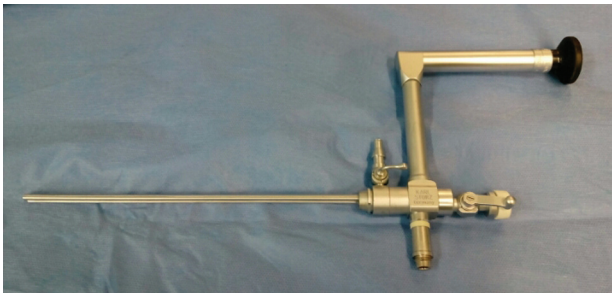
Our study is a retrospective study that was conducted between December 2014 and August 2015 after approval of the ethical committee. The study included 40 patients with acute appendicitis. The diagnosis of acute appendicitis was based on patient history, physical examination (abdominal pain in the right lower quadrant or migration of pain from the periumbilical area to the right lower quadrant, rebound tenderness, fever, elevated white blood cells count and elevated C reactive protein) and ultrasonographic (US) findings. Abdominal US was used as the first diagnostic tool.

Totally, 40 patients with acute appendicitis without suspicion of complications underwent laparoscopic-assisted appendectomy after obtaining informed consent. In four patients, in whom the appendectomy was considered impossible to be safely completed with transumbilical laparoscopic-assisted approach (TULAA) because of an inadequate exposition and exteriorization through the umbilical incision (severe inflammatory appendiceal adhesions, retrocecal with subserosal position of the appendix, obese patient with a BMI of 35 kg/m^2, short and fatty mesoappendix), two additional 5 mm trocars (one placed in the midline suprapubic and the other placed in the left iliac fossa) were introduced to perform a LA. Two patients with clinical and US diagnosis of acute complicated appendicitis (appendiceal abscess, diffuse peritonitis) underwent open appendectomy after trial of LA. The four patients who underwent LA and the two patients who underwent open appendectomy were excluded from the study.

Technique

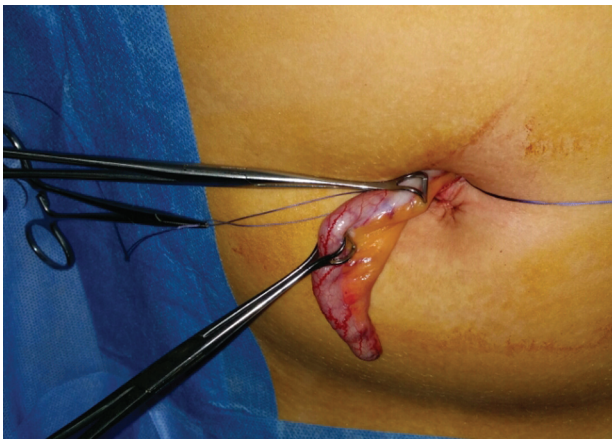
The patient is positioned in the supine position under general anaesthesia. A 10 mm trocar is inserted in 'open' technique through a transverse supraumbilical incision. The pneumoperitoneum is obtained by CO_2 insufflation. Systematic exploration of abdominal cavity is carried out using a side-arm viewing operative laparoscope, which is the nephroscope that is used for percutaneous nephrolithotomy (Karl Storz) (Fig. 1). Through the working channel of the nephroscope, the appendix is dissected free using a Maryland dissector. The tip of the appendix is grasped using a grasper and brought out through the umbilicus. The mesoappendix and appendix are then divided extracorporeally (Fig. 2).

Figure 1



The nephroscope for percutaneous nephrolithotomy

Figure 2



The mesoappendix and appendix are divided extracorporeally

The scope is then reinserted to ensure that there is no bleeding and then the port site is closed in layers. When the appendectomy is considered impossible to be safely completed with any laparoscopic technique, it was converted to an open surgery and excluded from the study.

Results

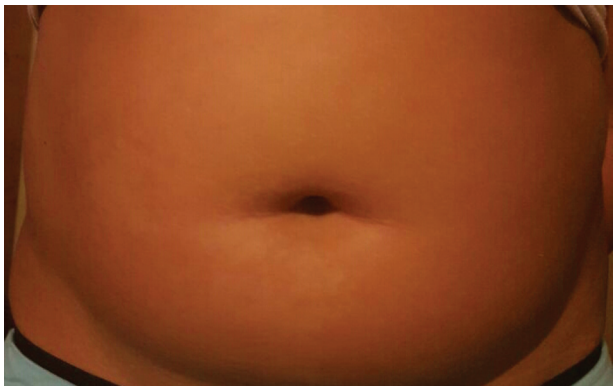
The study included 40 patients, 24 (60%) male and 16 (40%) female. The mean operative time was 35± 12 min; operative time was taken from the time of first skin incision to the complete skin closure. The age of participants ranged between 8 and 25 years with a mean age of 13.075 years. Delivery of the appendix through the umbilical incision was easy in 36 (90%) patients, whereas in four (10%) patients with less adequately movable caecum, delivery of the appendix was not easy and managed with retraction of umbilical incision towards the caecum to facilitate the appendiceal exposition and resection.

Postoperative pain was evaluated at 12 h, day 1 and day 2 postoperatively using a visual analogue scale, which ranged from 0 to 10, where 0 is no pain and 10 is extremely painful. The pain was most intense on day 0 and was controlled with simple analgesia. The mean hospital stay was 1.325 days; it ranged from 1 to 2 days, and it was calculated from the time of presentation at the casualty to the time of discharge.

Patients were evaluated during the postoperative period for complications such as bleeding, shoulder pain, postoperative ileus, vomiting, surgical site infection, intra-abdominal abscess or seroma and were discharged when deemed fit by the operating surgeon. There was no significant perioperative morbidity or mortality. The appendectomy specimen was histopathologically confirmed and was suggestive of appendiceal inflammation.

Patients were followed up at 1 week for wound examination and histopathology report analysis. At follow-up, two (5%) patients presented with wound infection and nobody presented with intraperitoneal abscess. The mean follow-up period was 6 months. Cosmetic results were considered good or excellent by parents in all patients, including those with wound infection (Fig. 3).

Figure 3



The wound after 6 months

Discussion

Single incision, transumbilical, laparoscopic assisted appendectomies have been well described in the literature and have been shown to be safe and effective alternatives to the traditional laparoscopic multiport appendectomy with a comparable postoperative complication rate [9–16]. With the new instrumentation, this procedure may now be easier and safer. This technique gives the surgeon the advantages of both open and laparoscopic approaches. The patient benefits from the decreased invasiveness of multiple ports placed in the conventional multiport LA, and also benefits from the single wound with less postoperative pain and better cosmetic result.

This method decreases the amount of equipment needed during the operation with only one instrument placed through the single port, and also it decreases the operating room time with only one incision to open and close; thus, it is much more cost-effective. Moreover, in a recent study, Montalto *et al.* [17] found a significant reduction in the postoperative cytokines in TULAA compared with open appendectomy, suggesting a less surgical trauma.

This operation is learned quickly and easily. The limitations include dense adhesions, perforated appendicitis, generalized peritonitis, or a retrocecal subserosal appendix, which may require the addition of an extra port or conversion to multiport LA. The conversion rate is much more in adults than in children because the distance between the caecum and umbilicus is shorter and the abdominal wall is suppler in children [11].

The aim of this study was to perform SILS at a very low cost. In this study, SILA was performed as an extra-abdominal procedure similar to the study carried out by Deie *et al.* [18], who had suggested that the extra-abdominal procedure is quicker and easy, and thus may lower overall costs. We used a single port and a single instrument through the working channel of the nephroscope (Karl Storz) similar to a study conducted by

Stylianos *et al.* [19]. The mean operative time was 35± 12 min; it was dependent on how easy it is to exteriorize the appendix. Reasons for the shorter operative time with TULAA include extracorporeal ligation of the mesoappendix and appendix, and easier laparotomy and closure of the umbilical incision compared with multiport LA, similar to the result published by Visnjic [20].

Postoperative pain was controlled with simple analgesia. It seemed to be less than that seen in open or conventional laparoscopic appendectomies; this may be due to a single small incision of 10 mm. There was no significant perioperative morbidity or mortality. At follow-up, two (5%) patients presented with wound infection. Cosmetic results were considered good or excellent by parents in all patients, including those with wound infection. TULAA provides nearly scarless surgery by placing a single incision within the umbilicus, which is in agreement with the study carried out by Stylianos *et al.* [19].

Conclusion

In conclusion, this technique is a safe, effective and feasible procedure with the advantages of combining open and laparoscopic techniques to provide a cost-effective treatment method with excellent cosmetic results. In TULAA, exteriorization of the appendix is a key component of its efficacy and cost-effectiveness. It is a practical procedure for patients who cannot afford expensive procedures and in resource-limited set-ups of developing countries. TULAA should be the initial procedure of choice for most cases of appendicitis.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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External laryngeal nerve to identify or not during thyroidectomy: a single-institute experience

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Received 26 February 2017
Accepted 28 March 2017

The Egyptian Journal of Surgery
2017, 36:269–273

Background
Iatrogenic injury to the external branch of the superior laryngeal nerve (ESLN) may occur during thyroidectomy because of its close proximity to the upper pole of the thyroid gland. Injury to the ESLN results in postoperative voice changes, which may be severe, especially in professional voice users. Although the main principle in neck surgery is proper dissection and identification rather than avoidance of important structures for their preservation, many surgeons do not routinely identify the ESLN during thyroidectomy because the nerve has variable anatomical courses. This encouraged us to conduct this study to evaluate the incidence of ESLN injury during thyroidectomy when superior thyroid vessels were ligated individually close to thyroid capsule without prior identification of the nerve.
Patients and methods
The present study included 200 patients with goiters who underwent either total or hemithyroidectomy at the Department of Surgery, Medical Research Institute Hospital, Alexandria University. In all patients, superior thyroid vessels were ligated in branches very close to thyroid capsule without prior positive search for the ESLN.
Results
In the present study, 185 (92.5%) patients underwent total thyroidectomy, whereas the remaining 15 (7.5%) patients underwent hemithyroidectomy. Transient ESLN injury occurred in 3% of patients, whereas 2% suffered from permanent nerve injury.
Conclusion
Preservation of the ESLN is necessary during thyroidectomy, especially in professional voice users. Ligation of superior thyroid vessels in branches close to thyroid capsule without prior identification of the ESLN is a safe procedure and does not increase the incidence of nerve injury.

Keywords:
cricothyroid muscle, external laryngeal nerve, thyroidectomy, voice changes

Egyptian J Surgery 36:269–273

1110-1121

Introduction

The rate of surgery of the thyroid gland has tripled over the last 30 years [1]. Many investigators have reported acoustic changes after surgery of the thyroid gland [2–8]. These changes can result from either laryngeal nerve injury or other events during thyroidectomy [2–8]. The importance of the external branch of the superior laryngeal nerve (EBSLN) has been overshadowed by the clinical significance of recurrent laryngeal nerve and it received little attention during surgery. The external laryngeal nerve is the sole motor nerve supply of the cricothyroid muscle, which is the tensor of vocal folds and raises the pitch of voice [9]. Post-thyroidectomy ESLN injury symptoms include voice fatigue, breathy voice, and a decrease in voice range [10]. This injury is important, especially in professional voice users such as singers and teachers and may impair the quality of their lives. The reported risk for ESLN injury is variable, ranging from 3 to 13% [11]. The ESLN is at risk for injury during dissection of upper thyroid pole, as it runs close to superior thyroid vessels [12–14]. Various techniques have been reported for preservation of the ESLN, including skeletonization and ligation of superior thyroid vessels in branches close to the thyroid capsule [15], visual identification of the nerve before ligation of the upper thyroid pole [11], and the use of either nerve stimulator [16] or intraoperative nerve monitoring (IONM) [17,18]. The best technique to avoid EBSLN injury is still debatable. Identification of any structure to preserve it is the main issue of any surgical intervention. However, many surgeons do not apply this principle to the ESLN, and hence we conducted this study to assess the incidence of ESLN injury during

 DOI: 10.4103/ejs.ejs_24_17

thyroidectomy when superior thyroid vessels are ligated individually in branches very close to thyroid gland capsule without prior identification of the nerve.

Patients and methods

This study was a prospective nonrandomized study. It included 200 patients with goiter who underwent either total or hemithyroidectomy in the Department of Surgery, Medical Research Institute Hospital, Alex University, from January 2014 to January 2016. Preoperative workup included full history taking, general and local clinical examination, routine laboratory investigations in addition to thyroid function tests and serum calcium level (total and ionized), and neck ultrasonography. Fine needle aspiration cytology was performed on selected basis (suspicious lesions). All patients in the study underwent videostroboscopy laryngoscopy examination before surgery to exclude vocal cord disorders (mobility disorders and lesions). Preoperative normalization of thyroid hormones and serum calcium levels were emphasized so as to avoid their effects on voice. Patients with a history of previous cervical or laryngeal operations, cervical radiotherapy, vocal cord disorders, preoperative voice changes, and those with thyroid malignancy with extrathyroid extension were excluded from the study.

Ethics

Before inclusion in the study, each patient signed an informed consent form, which included thorough information about his or her operation and the possible complications. This consent was approved by the Ethics Committee of the Medical Research Institute.

Outcomes

Primary outcome

The primary was to evaluate the incidence of post-thyroidectomy ESLN injury in the studied group.

Secondary outcomes

The secondary outcomes were operative time, post-operative recurrent laryngeal nerve injury, hypo-calcemia, and other postoperative complications.

Surgical technique

All patients in the study underwent either total or hemithyroidectomy using extracapsular dissection technique described by Shah and Patel [19]. Superior thyroid vessels were skeletonized and individually ligated distally very close to the thyroid capsule without prior identification of the external laryngeal nerve. Keeping cricothyroid muscles intact was emphasized during dissection. Integrity of strap muscles was restored if muscle cutting was performed. Closed negative suction drain was utilized routinely for every patient in the study.

Postoperative course

Operative and postoperative data of each patient were recorded, stressing upon operative time and postoperative complications. Videostroboscopy laryngoscopy was performed for each patient on the seventh postoperative day and any voice changes were assessed clinically with stress upon aphonia, hoarseness, voice fatigue, and inability to produce high-pitched voice. Laryngoscopic signs of external laryngeal nerve injury include inferior displacement of the affected cord leading to oblique glottic opening, irregular or wavy cord, flaccid and shorter than normal, bowing of the vocal cord, and or rotation of posterior glottis toward the site of lesion when using the voice at an extremely high pitch [20–25].

Follow-up

Follow-up of patients was carried out at the outpatient clinic at 7 days, 1 month, and 6 months after operation for the assessment of complications. Patients with voice changes, suspected nerve injury, and those with hypocalcemia were followed up every month for the detection of any improvement and better evaluation of their conditions.

Results

In the present study, preoperative data of the studied group are shown in Table 1. One hundred and eighty-five patients underwent total thyroidectomy and 15 patients underwent hemithyroidectomy with 385 ESLN at risk. Operative data of the studied group are shown in Table 2. In the present study, transient ESLN injury occurred in six (3%) patients, whereas permanent injury occurred in four (2%) patients. Other postoperative complications are shown in Table 3. Figures 1 and 2 show postoperative laryngoscopy for two patients with EBSLN injury.

Discussion

Voice changes after thyroidectomy may result from ESLN injury, and hence preservation of this nerve during thyroidectomy is necessary, especially in professional speakers such as teachers and singers. In the present study, transient ESLN injury occurred in 3% of patients and permanent injury occurred in 2% of patients. Aluffi *et al.* [20] in their study followed the

Table 1 Preoperative data of the studied group (*n*=200)

	N (%)
Sex	
Male	46 (23.0)
Female	154 (77.0)
Age (years)	
Min.–max.	14–65
Mean±SD	41.7±10.7
Type of goiter	
SMNG	125 (62.5)
Controlled Toxic	32 (16.0)
Malignant	21 (10.5)
STN	15 (7.5)
Thyroiditis	7 (3.5)
Comorbidities	
Hypertension	13 (6.5)
Cardiac	5 (2.5)
BA	7 (3.5)
DM	9 (4.5)

BA, bronchial asthma; DM, diabetes mellitus; max., maximum; min., minimum; SMNG, simple multinodular goiter; STN, solitary thyroid nodule.

Table 2 Operative data of the studied groups (*n*=200)

	Total thyroidectomy (*n*=185)	Hemithyroidectomy (*n*=15)
Operative time (min)		
Min.–max.	50–130	30–70
Mean±SD	91.4±14.9	48.4±10.8
Operative blood loss (ml)		
Median (min.–max.)	31 (10–250)	14 (10–70)
Mean±SD	50.8±43	18.4±15.3
Number of identified parathyroid glands		
Median (min.–max.)	4 (2–5)	2 (1–2)
Mean±SD	3.6±0.6	1.9±0.3
Weight of thyroid glands (g)		
Median (min.–max.)	39 (20–200)	17 (14.3–80.4)
Mean±SD	46.7±23.4	23.4±18

Max., maximum; min., minimum.

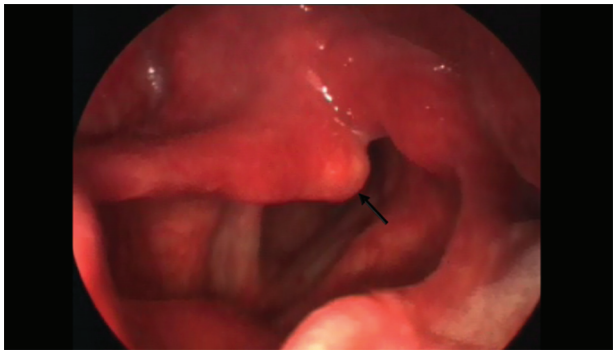
same surgical protocol for management of the ESLN during thyroidectomy as in the present study and reported 14% incidence for ESLN injury despite their small study population (45 patients). Teitelbaum and Wenig [26] also did not routinely identify the ESLN and reported a high permanent nerve injury (5%). The incidence of ESLN injury in the previous two studies was much higher than that in the present study. This may be attributed to the use of both laryngoscopy and electromyography of cricothyroid muscles for the diagnosis of ESLN injury in these two studies, whereas, in the present study, we used only laryngoscopy. Lekacos *et al.* [27] performed individual ligation of superior thyroid vessels without prior ESLN identification and

Table 3 Postoperative data of the studied groups (*n*=200)

	N (%)
ESLN injury	
Transient	6 (3.0)
Permanent	4 (2.0)
RLN injury	
Transient	6 (3.0)
Permanent	2 (1.0)
Hypocalcemia	
Transient	10 (5.0)
Permanent	5 (2.5)
Postoperative hematoma	8 (4.0)

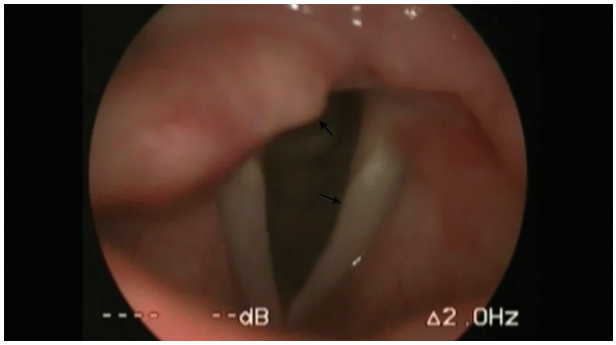
ESLN, external branch of the superior laryngeal nerve; RLN, recurrent laryngeal nerve.

Figure 1



Post-operative laryngoscopy showing severe deviation of posterior glottis to the left side denoting left ESLN injury.

Figure 2



Post-operative laryngoscopy for another patient showing bowing of left vocal cord with mild deviation of posterior glottis to the left side denoting left ESLN injury.

reported 0% ESLN injury with distal ligation close to thyroid capsule and 5.6% injury with high ligation. Evaluation of ESLN injury in their study was carried out using laryngoscopy. Likewise, Loré *et al.* [15] and Kierner *et al.* [28] reported that gentle mobilization of upper thyroid pole and individual ligation of superior thyroid vessels very close to thyroid capsule without systematic positive search for the ESLN may avoid nerve injury. Page *et al.* [29], studying over 50

thyroidectomies, also found no benefit of systematic search for the ESLN.

Some authors claim that it is important to positively identify the ESLN before ligation of superior thyroid vessels, especially type IIb nerve according to the Cernea classification (the nerve crosses superior thyroid vessels under cover of upper thyroid pole) [30]. Despite the rarity of this nerve type, it is the most dangerous type and is considered to be most at risk during ligation of superior thyroid vessels close to thyroid capsule [31]. Hurtado-Lopez *et al.* [32] found that patients who underwent thyroidectomies without positively searching for the ESLN had more voice changes compared with patients with thyroidectomies with intentional searching for the nerve (14 vs. 8%, respectively) and emphasized upon the importance of intraoperative identification. Bellantone *et al.* [33] conducted a study to compare visual identification of the ESLN before ligation of upper pole vessels (group A) with distal ligation of individual branches of superior thyroid vessels close to thyroid capsule without prior identification of the ESLN as in the present study (group B) as regards the incidence of ESLN injury. They found no significant difference between the two groups as regards ESLN injury and a significantly shorter operative time in group B. Kark *et al.* [23] reported an injury rate of 3% without nerve identification compared with 5% with the nerve search.

Patnaik *et al.* [34] conducted a study to evaluate the visual identification rate of the ESLN during 64 thyroidectomies in a tertiary care hospital. The nerve was identified and preserved in 83% of patients and could not be identified at all in the remaining patients (17%). None of these patients (17%) showed any symptoms and signs of ESLN paresis as their nerves were preserved using individual ligation of superior thyroid vessels close to thyroid capsule. Patnaik *et al.* [34] proposed that the ESLN was buried under inferior constrictor muscle fibers, and hence it was impossible to identify the nerve in the field of thyroidectomy. They concluded that trial of nerve identification if it is buried under inferior constrictor muscle fibers would take a longer period of time with more injury to surrounding structures and without any benefit as the nerve could be preserved with individual ligation of superior thyroid vessels close to thyroid capsule. Barczyński *et al.* [18] conducted a randomized study to compare surgical visualization with neuromonitoring (IONM) of the ESLN during thyroidectomy and concluded that the use of intraoperative neuromonitoring significantly improved intraoperative identification of the ESLN and decreased early postoperative voice changes with no significant difference in delayed postoperative voice changes between IONM and surgical visualization. Improvement in the identification rate of the ESLN by the use of IONM and thus limitation of the risk for nerve injury were confirmed in other several studies [35,36]. We propose that despite the benefit of IONM during thyroidectomy it could not be used routinely in developing countries because of deficiency of resources. According to the results of the present study, individual ligation of superior thyroid vessels close to thyroid capsule can be safe and save the cost and time of the use of IONM.

Injury and identification rates of the ESLN vary greatly from one study to another with identification rates varying from 33 to 93% and injury rates varying from 0 to 58% [10,16,17,23,26–28,37]. Lack of standard surgical technique for preservation of the ESLN may be responsible for this great variation in the results of various studies. Inaccuracy of diagnostic procedures of nerve injury used in some studies may play a role. Jansson *et al.* [10] reported that partial injury of the ESLN could not be diagnosed accurately with indirect laryngoscopy or voice symptoms alone. They propose that electromyography (EMG) of the cricothyroid muscle is very important for the definitive diagnosis of partial nerve injury. Most of the up-to-date studies do not use EMG when reporting injury rates of the nerve [15–17,23,27]. Another important factor is training level of the surgeon. Cernea *et al.* [37] reported 28% injury rate of the ESLN by resident compared with 12% injury rate by the senior author. The lack of consensus as regards the optimal surgical protocol for ESLN preservation is most probably due to variable anatomical courses of the nerve. Various classification systems have described the anatomical course of this nerve, such as Cernea, Kierner, and Friedman classification systems, in an attempt to facilitate ESLN identification and preservation [28,30,31,34,37].

Conclusion and recommendations

Preservation of the ESLN during thyroidectomy is necessary to avoid post-thyroidectomy voice changes, especially in professional voice users. Individual ligation of superior thyroid vessels close to thyroid capsule without prior identification of the ESLN is safe and may prevent ESLN injury. Larger numbers of patients with large goiters have to be evaluated in further studies for safety of this surgical technique as regards ESLN injury and to be compared with intraoperative neuromonitoring of the ESLN as regards the incidence of nerve injury and cost.

Financial support and sponsorship
Nil.

Conflicts of interest
There are no conflicts of interest.

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Surgical outcome of choledochal cysts in adults: a prospective cohort study

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Received 15 March 2017
Accepted 8 April 2017

The Egyptian Journal of Surgery
2017, 36:274–282

Background
Choledochal cysts (CCs) are cystic dilatation of the biliary ductal system. Adult cases comprise around 20% of all cases.
Purpose
The aim of this study was to integrate all possible technical methods to prevent complications arising from residual choledochal tissue by presenting our experience in adult patients.
Patients and methods
A prospective cohort study of 24 adult patients, who underwent surgery for CC, over a 4-year period from March 2013 to February 2017 at the Gastroenterology Surgical Unit, Faculty of Medicine, Alexandria University, Egypt, was carried out. Cysts were classified according to the Todani classification. Biliary anatomy was defined by intraoperative cholangiography.
Results
The present study included six males and 18 females. Their ages ranged from 18 to 43 years (mean 26.4 years). Pain was the most common symptom at presentation (20 patients, 83.3%). Eighteen patients (75%) had type I cysts. All patients underwent excision of the extrahepatic bile duct cyst. The mean follow-up period was 34.6 months.
Conclusion
The present study showed satisfactory medium-term results following surgical resection of adult CC. Our approach was effective, to a great extent, in preventing complications of residual cysts. Excision of the extrahepatic bile duct should be guided by intraoperative cholangiography and distal clips to avoid pancreatic duct injury.

Keywords:
adult choledochal cyst, hepaticojejunostomy, intraoperative cholangiography, mucosectomy

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Introduction

Choledochal cysts (CCs) are cystic dilatation of the biliary ductal system, which can be extrahepatic, intrahepatic, or both. The disease is usually diagnosed in the first decade of life; however, adults comprise a substantial number of cases [1]. These patients may initially be asymptomatic, with subclinical bile duct inflammation, but later they are susceptible to recurrent abdominal pain associated with cholangitis, cholelithiasis, pancreatitis, or biliary obstruction [2]. The increased incidence of associated biliary tract stone disease, stricture formation, and superimposed malignancy lead to challenges in management of the disease [3].

There is a well-known, long-term association between CCs and cholangiocarcinoma. The risk increases with age. The risk in children younger than 10 years is less than 1%, rises to 18% in adults, and becomes greater than 50% in patients over 50 years. On the basis of Asian literature, malignancy occurs more often in types I and IV cysts and rarely in types II and III [4].

Complete cystic excision with cholecystectomy is the standard surgical approach as it lowers the risk of complications [5,6]. Types I, II, and IVb can usually be managed in this manner. Superimposed malignancy necessitates more extensive surgery, such as Whipple's operation for distal cholangiocarcinoma or hepatectomy for proximal cancers. Operations for adult choleduchal cyst are more difficult than their pediatrics counterparts because of the concomitant problems of inflammatory adhesions, infection, stone disease, malignancy, and previous surgery [3].

The diseased mucosa of the residual cyst may be the cause for postoperative complications. For that reason, mucosectomy of the cyst wall was advocated to prevent such complications in type IVa cysts [7–9].

 DOI: 10.4103/ejs.ejs_27_17

The literature is deficient in terms of studies on complete eradication of adult CCs and most series are retrospective in nature. Thus, we aimed to integrate all possible technical methods to prevent occurrence of long-term complications arising from residual choledochal tissue by presenting our experience in these patients.

Patients and methods

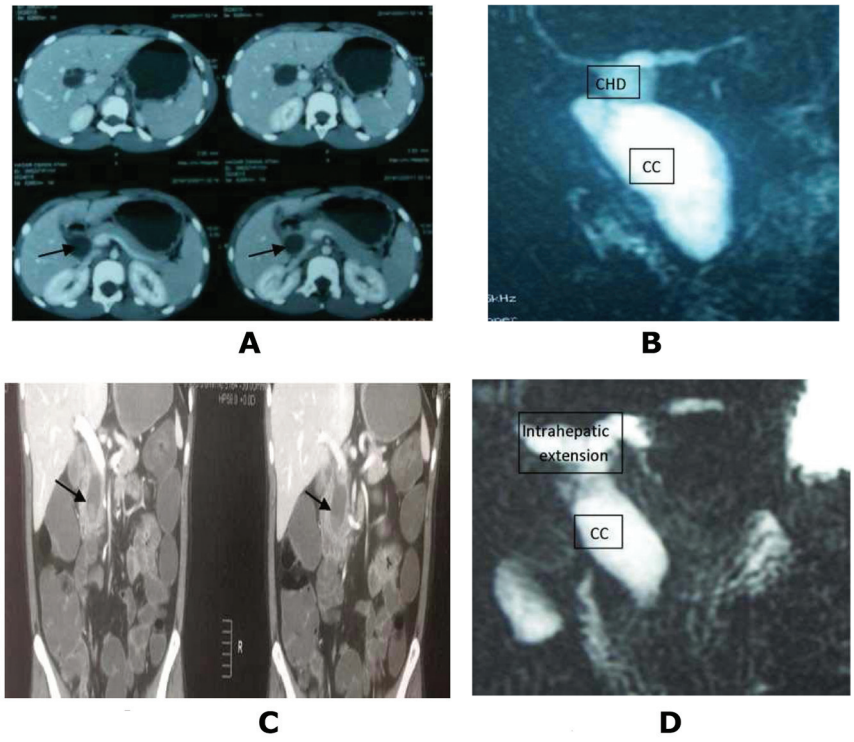
A prospective cohort study was designed including 24 adult patients who underwent surgery for CC during a 4-year period from March 2013 to February 2017 at the Gastroenterology Surgical Unit, Faculty of Medicine, Alexandria University, Egypt. Our center is the tertiary referral center of four major governorates (Alexandria, Beheira, Matrouh, and Kafr El-Sheikh). After obtaining approval of the local ethics committees, all patients were informed about the operative technique, and written consent was obtained. Patients were subjected to complete imaging starting with abdominal ultrasound; identified cysts were further delineated by both computed tomography scan and magnetic resonance cholangiopancreatography to estimate the size and extent of the disease and to assess for malignancy (Fig. 1). Endoscopic retrograde cholangiopancreatography was not included in the study protocol. Cysts were classified according to the Todani modification of the Alonso-Lej classification [10].

All patients received 1 g of third-generation cephalosporin and metronidazole at the time of induction of general anesthesia and then every 12 h for 5 days. A right subcostal incision was made. After dissecting the gallbladder, the hepatic flexure of the colon was mobilized, and the duodenum was kocherized. Biliary anatomy was defined by intraoperative cholangiography through a 8-Fr tube catheter introduced through the cystic duct. The length of the common channel between the distal end of the common bile duct (CBD) and the pancreatic duct, abnormal junction, or abrupt obstruction was recorded.

For types I and IVa, the choledochal dilatation is then dissected in an extramural plane between the peritoneum and the anterior wall. Dissection progressed across the lateral walls downwards, separating the cyst from the first part of the duodenum (Fig. 2).

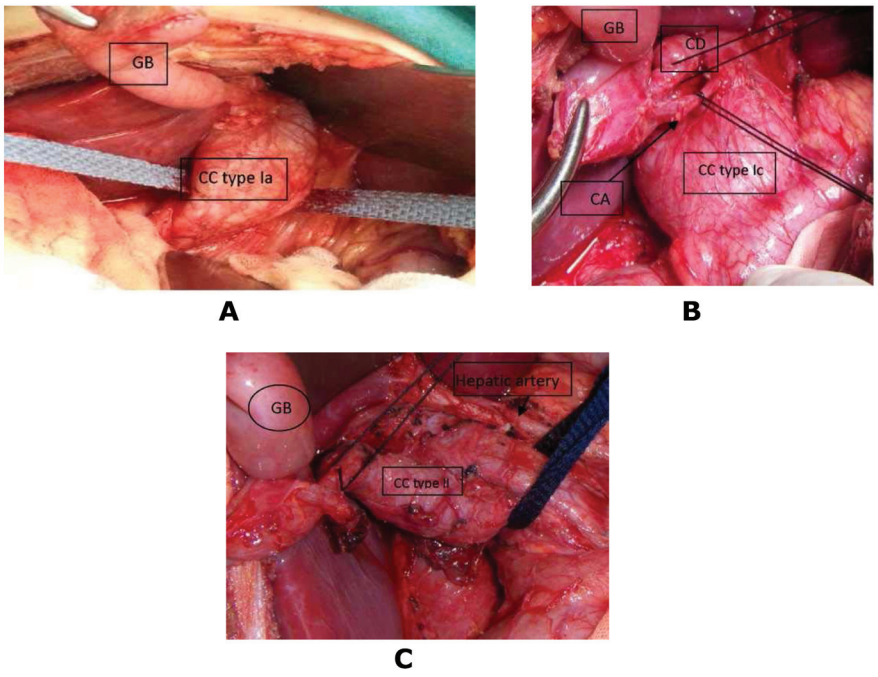
Next, a clip was tucked to the inspected distal limit of the CC, and a repeat cholangiography was carried out to check the accurate lower limit. If the cholangiogram showed distal extension of the cyst, the dissection continued further downwards (Fig. 3).

Figure 1



(a) Computed tomography scan of the abdomen showing type Ia choledochal cyst (black arrow). (b) Magnetic resonance cholangiopancreatography (MRCP) showing type Ia choledochal cyst (CC). (c) Coronal section showing type Ic choledochal cyst harbouring intracystic stone (black arrow), (d) MRCP showing type IVa choledochal cyst

Figure 2



(a) Type Ia CC involving extrahepatic bile duct. (b) Type Ic CC. (C) Type II CC. CA, cystic artery; CC, choledochal cyst; CD: cystic duct; GB, gallbladder

The distal bile duct was then over-sewed by propylene 3/0 sutures and transected just above the demarcated pancreatic duct within the head of the pancreas, to avoid leaving any intra-pancreatic part of the cyst (Fig. 4).

In case of difficulties caused by the close posterior proximity and adhesions of CC to adjacent structures in the hepatoduodenal ligament (mainly to the portal vein), the anterior cyst wall was incised allowing the technique of mucosectomy, formerly published by Lilly's, to be adopted (Fig. 5).

The proximal part was dissected until the level of the hilar bifurcation and then transected. Proximal intrahepatic ducts were cleared from debris by irrigation. If the mucosa of the residual intra-hepatic cyst wall was found to be inflamed and thickened, the mucosa was excised or stripped off like a sleeve. Bleeding from the exposed bile duct wall was controlled with bipolar diathermy or by compression.

A 40-cm retrocolic jejunal Roux loop was used to construct the end-to-side bilioenteric anastomosis using interrupted absorbable sutures (4/0 polyglactin) with accurate apposition. The anteroinferior wall of the extrahepatic segment of the left hepatic duct was incised for a spacious hepaticojejunal anastomosis. In cases where a narrow anastomosis was expected, a 10-Fr plastic biliary stent was inserted to prevent early stricture formation.

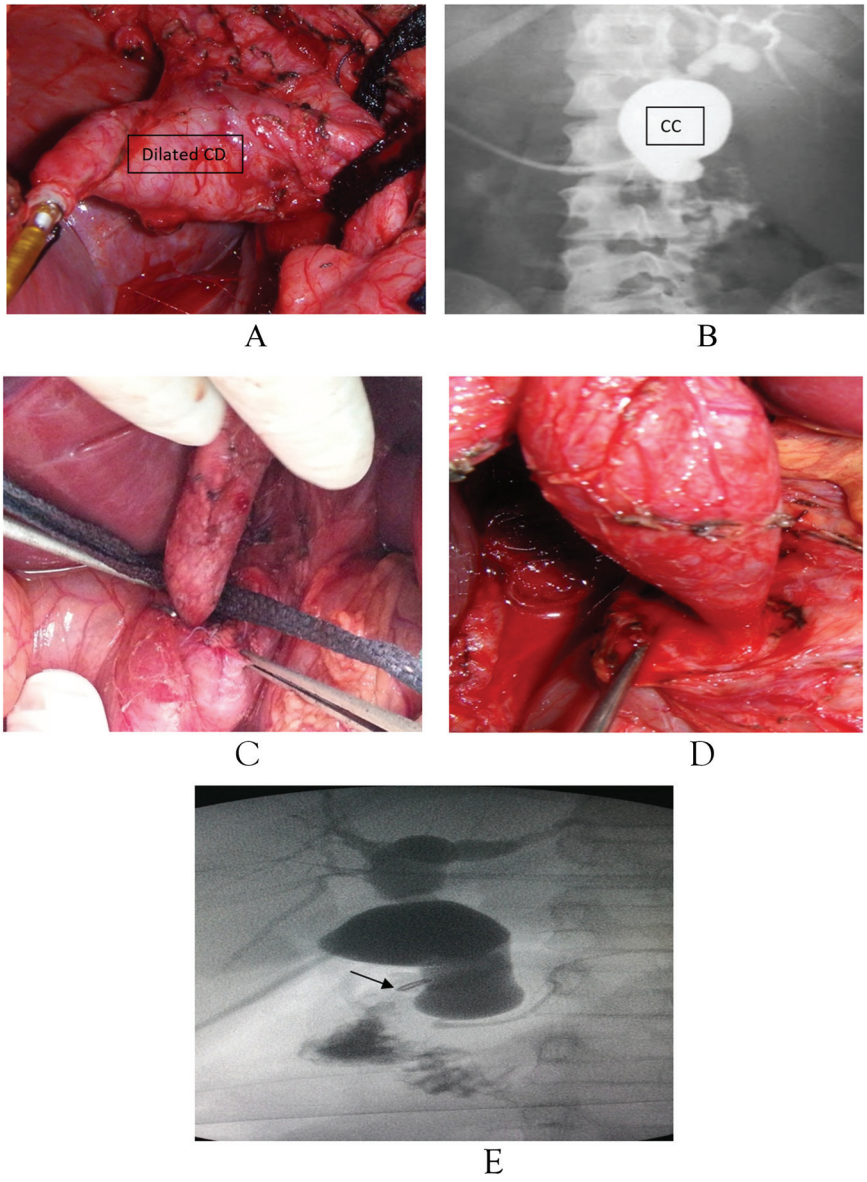
An abdominal drain was inserted in all cases. All resected specimens were sent for histopathological examination (Fig. 6). Patients resumed oral fluid intake after 3–5 days and then a soft diet when tolerated before discharge.

Operative/postoperative findings, pathology results, and follow-up outcomes were collected. Early and late postoperative complications were noted. All patients were seen in the outpatient clinic at 1 week, 1 month, and 3 months postoperatively, and at 6-month intervals thereafter. Data are presented using numbers, percentages, arithmetic means, and SD, and were analyzed using SPSS (Chicago, IL, USA) (version 15) statistical software.

Results

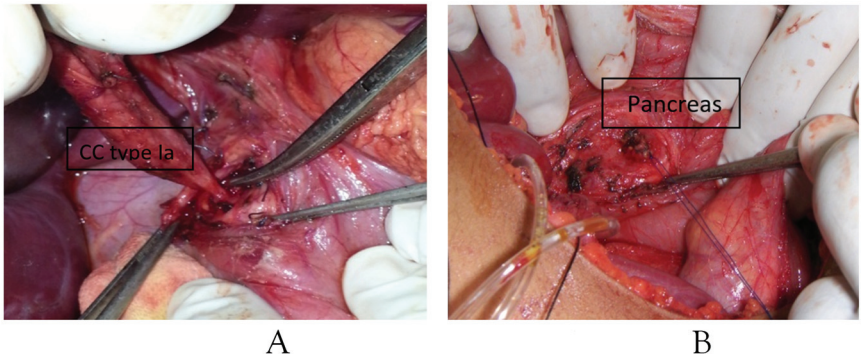
Twenty-nine adult patients with CC presented to us during the study period; three of them were excluded because of confirmed diagnosis of cholangiocarcinoma at the time of presentation. Two patients with Caroli disease were excluded as well because their treatment was medical and liver transplantation, which is still not feasible at our institution. Thus, 24 adult patients who underwent surgery for CC were included. There were six males (25%) and 18 females (75%) with a

Figure 3



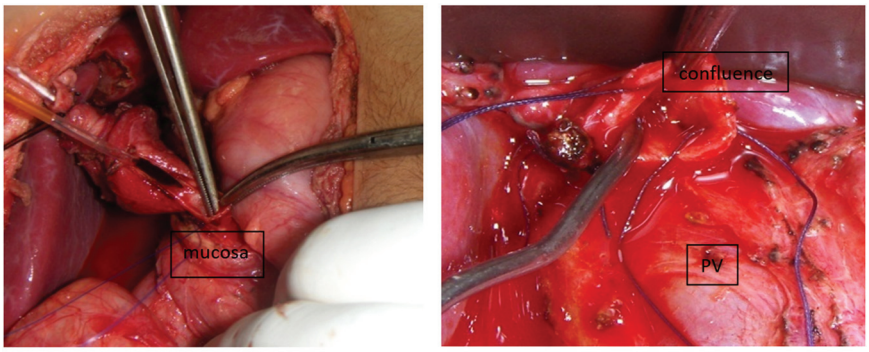
(a, b) Cystic duct catheterization and intraoperative cholangiography were performed, the cystic duct was dilated. (c, d) Operative image showing the distal clip tucked to the inspected lower level of the choledochal cyst (black arrow) and distal dissection was continued further (e) Operative cholangiogram of the same patient showing extension of type Ia choledochal cyst for 2 cm distal to clip tucked (black arrow) to the inspected lower level of the cyst

Figure 4



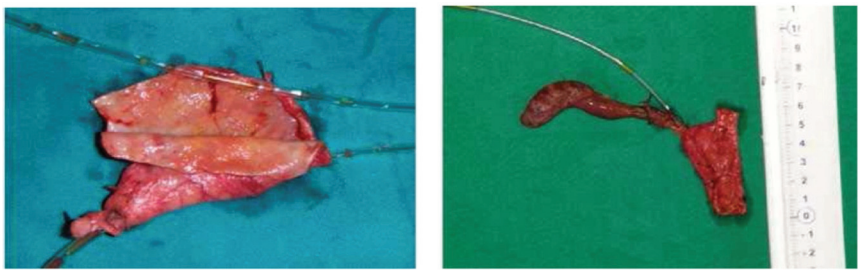
(a) Distal retroduodenal intrapancreatic dissection till normal diameter of common bile duct, checked by operative cholangiogram. (b) Suturing of lowermost level after transection of the choledochal cyst by prolene sutures away from pancreatic duct guided by intraoperative cholangiogram

Figure 5



(a) Distal mucosectomy of posterior wall of the cyst. (b) Opening of hepatic duct confluence after proximal transection of the cyst ready for hepaticojejunal anastomosis, the mucosa of the residual intrahepatic cyst wall was excised in piecemeal or stripped off (proximal mucosectomy)

Figure 6



(a, b) Resected specimens of type I choledochal cysts showing mucosal inflammation, thickening, and fibrosis

female-to-male ratio of 3 : 1. The age of patients at diagnosis ranged from 18 to 43 years (mean 26.4 years).

Epigastric dull aching pain was the most frequent symptom at presentation (20 patients, 83.3%) followed by nausea and vomiting (10 patients, 41.6%). One episode of cholangitis had been experienced by one-third of patients. Jaundice was found in seven patients (29%). A past history of pancreatitis was obtained from three patients (12.5%). The classic triad (abdominal pain, jaundice, and a palpable mass) was not seen in any patient. None of the patients had undergone previous surgery for CCs in their childhood.

On the basis of Todani's classification, 18 patients (75%) had type I CC (Figs 1 and 2), four cases (16.6%) had type IVa cysts (Fig. 1), and two cases (8.3%) had type II cysts (Fig. 2). In type IVa cysts (four cases), three cases were bilobar, and in one case it was confined to the left hepatic lobe. Regarding the presenting symptom compared with the type of cyst, abdominal pain was the main symptom in most types. Jaundice was seen in type I (four of 18 patients) and type IV (three of four patients) cysts.

Eight patients had biliary stones at presentation, including four cases with gallstones (16.6%), with three patients (12.5%) harboring stones in their extrahepatic CCs, and two of them (8.3%) having intrahepatic ductal stones (one patient had both intrahepatic and extrahepatic stones). In 17 patients (71%), abnormal pancreaticobiliary junction was demonstrated on intraoperative cholangiography. Sudden and severe narrowing denoting distal obstruction of terminal choledochus with normal pancreaticobiliary junction was seen in five (21%) patients. The clinical presentation, Todani classification, laboratory results, and morphological features are given in Table 1.

All patients underwent excision of the extrahepatic bile duct cyst (type I, II, and the extrahepatic part of type IVa) with reconstruction by a Roux en-Y hepaticojejunostomy in 22 patients. Three cases with type IVa cysts were not completely excised, although left hepatectomy was performed in one patient. There were two cases of type II cysts in our series – one of

Table 1 Clinical presentation, Todani's classification, laboratory results, and morphological features in the studied adults with choledochal cyst

Clinical presentation	*N* (%)/mean (range)
Abdominal pain	20 (83.3)
Nausea and vomiting	10 (41.6)
History of cholangitis	8 (34)
Jaundice	7 (29)
History of pancreatitis	3 (12.5)
Todani classification	
Type I	18 (75)
Ia	13 (72.2)
Ib	2 (11.1)
Ic	3 (16.6)
Type II	2 (8.3)
Type III	–
Type IVa	4 (16.6)
Type V	–
Laboratory results	
Serum albumin (g/dl)	3.48 (2.5–4.5)
Serum alkaline phosphatase (U/l)	304 (128–536)
Serum ALT (U/l)	63.58 (33–156)
Serum AST (U/l)	32.9 (13–58)
Serum bilirubin, total (mg/dl)	1.42 (0.3–5)
Morphological features	
APBJ	17 (71)
Distal obstruction	5 (21)
Bile sludge/stone formation	8 (33.3)
Accessory hepatic ducts	2

ABPJ, abnormal pancreaticobiliary junction; ALT, alanine aminotransferase; AST, aspartate aminotransferase.

them was managed by simple cyst excision and direct axial repair of the bile duct over a T-tube and the other by segmental resection of the CBD and choledochoduodenostomy.

Extensive adhesions with adjacent structures (mainly to portal vein) were noted in nine patients (37.5%), and in these cases a part of the cyst wall was left behind after excising the mucosa. The mean width of the hepaticojejunostomy was 40.5±6 mm (range 12–55 mm). The anstomosis was performed at the level of the carina or common hepatic duct (single duct anastomosis). The mean operating time was 185.3±46.9 min (range 120–240 min), and the mean operative blood loss was 175.3±50.7 ml (range 100–250 ml). The mean hospital stay was 11.3±4 days (range 5–21 days).

A subcutaneous hepaticojejunal access loop was made in one patient with type IVa having both intrahepatic and extrahepatic stones. The jejunal loop was marked by clipping the sutures holding the access loop in place.

As shown in Table 2, the total complication rate was 41.6% (10/24). Early complications were noted in six

Table 2 Distribution of patients according to early and late postoperative complications

Postoperative complication	*N* (%)
Early complications (*N*=6)	
Bile leak	1 (4.1)
Intra-abdominal collection	1 (4.1)
Wound infection	5 (20.8)
Wound hematoma	1 (4.1)
Total	8[a]
Late complications (*N*=7)	
Intrahepatic stones	1 (4.1)
Anastomotic stricture	3 (12.5)
Cholangitis	2 (8.3)
Pancreatitis	1 (4.1)
Incisional hernia	2 (8.3)
Total	9[a]

[a]Some patients had more than one complication.

patients (25%) including wound infection (five patients) and hematoma (one patient). A patient (4.1%) had biliary leak with subhepatic abscess, which resolved after 1 week of parenteral nutrition, intravenous antibiotics, and percutaneous drainage; enteral feeding was delayed for 10 days in this patient. One patient was found on postoperative ultrasound study to have minor fluid collection in the gallbladder fossa that resolved spontaneously on follow-up. No perioperative mortality occurred.

Seven patients (29.1%) had late postoperative complications: recurrent intrahepatic stones in one, anastomotic stricture in three, cholangitis in two, pancreatitis in one, and incisional hernia in two. Two patients developed cholangitis that resolved with medical treatment in one, and in the other patient percutaneous transhepatic drainage was performed. Three patients (two type I and one type IVa) developed anastomotic stricture. Two patients (type I) required percutaneous dilatation of the stricture and insertion of a biliary stent by the interventional radiologist. In the third patient, access to the biliary tree was achieved using the subcutaneous access limb. This patient also developed recurrent intrahepatic stones in the left lobe of the liver on top of the stricture. His condition was detected after 1.5 years. He had a type IVa cyst with intrahepatic and extrahepatic biliary stones. An end-viewing gastroscope was passed through the subcutaneous access limb (identified by clips on C-arm). After entering through the anastomosis, the hepatic ducts were reached, and a cholangiogram was performed. Dormia basket and extraction balloons were successfully used to extract calculi. A balloon catheter over a guide-wire was inserted through the working channel of the scope and then through the stricture

and inflated to 5 mm for 10 min to dilate the stricture. On completion, the ducts were flushed with saline, and the jejunal loop was closed.

Histopathological examination showed the presence of cyst wall inflammation in 22 (91.6%) and cholecystitis in 12 (50%) patients. Premalignant proliferative changes were detected in two cases.

On follow-up, patients were in an acceptable state of health. The mean follow-up duration was 34.6±13.2 months (median 1.5 years), ranging from 1 to 48 months. All patients were assessed by liver function tests and abdominal ultrasonography. No malignant disease was recorded.

Discussion

Bile duct cysts are one of the distinguished congenital disorders that cause dilatation mainly of the extrahepatic and sometimes the intrahepatic biliary tree. Despite being a rare pediatric disorder, we were able to find and manage 24 adults with CCs over a relatively short period. The number of cases of such a rare disease may be attributed to several factors: first, our center is a tertiary referral center serving four densely populated governorates. Second, the disease may be asymptomatic that adult presentation can exist in up to one-third of the cases of CCs [6–8]. Finally, symptoms are vague and nonspecific, and the low level of education and socioeconomic state of parents in some rural areas preclude early referral of their child for medical consultation till adulthood.

Abdominal pain was the most common complaint in this report (20 patients, 83.3%). It has been reported that the type of symptoms depends largely on the age at presentation – abdominal pain is the most frequent symptom in adults, whereas jaundice is the main presentation in children [8].

In this series, type I constituted the largest group, accounting for 75% of cases, followed by type IV (16.6%), similar to other studies [3,11–15]. In a North American series [16], type IVa was the predominant type, and the authors recommended routine intraoperative cholangiogram to reveal intrahepatic association in patients with type I.

Harsh difficulties were met during dissection in nine cases (37.5%). These surgical difficulties arose from severe adhesions to neighboring vital vessels, mainly the portal vein. Tsai *et al.* [15] reported that cyst excision was much more difficult in adults than their pediatric counterparts because of the presence of more intense pericystic inflammation with distortion of the anatomy and more bleeding during dissection. In practice, complete excision can be performed by careful dissection around the cyst towards the lowermost normal-diameter portion of the CBD with the help of traction, avoiding injury to the pancreatic duct. Incomplete excision results in retention of residual tissue that can give rise to complications such as stone formation, pancreatitis, and malignancy [3,6,7,11,13–19].

In the same way, we recommend proximal cyst resection till the ductal confluence, and reconstruction by an ample roux-en-Y wide hepaticojejunostomy. To prevent anastomotic strictures, many studies [6,16,20] recommended high, wide anastomosis. We recommend proximal anastomosis with a nonpathological part of common hepatic duct.

We encountered four patients (16.6%) with type IVa cysts. Type IVa cysts are recognized to be more common in adults with a reported prevalence ranging from 2 to 39% [21–23]. This wide range of type IVa cyst may be related to underestimation of the intrahepatic involvement. Therefore, accurate imaging of type I cysts in adults is of utmost importance. For these cases, the extrahepatic component was completely resected as for type I cyst. Unfortunately, three cases had diffuse cysts in both lobes of the liver that precluded liver resection, and therefore mucosectomy of intrahepatic ducts was performed. On follow-up magnetic resonance cholangiopancreatography, shrinkage of intrahepatic parts was identified in two cases. Huang *et al.* [14] and Dutta [7] stated that intrahepatic involvement in type IVa is confusing, and some of their patients showed regression of intrahepatic components after excision of extrahepatic CC and adequate drainage. In the same way, Koshinaga *et al.* [23] recognized that some barrel-shaped biliary dilatations vanished after total excision.

Excision of the inner layer of the cyst wall or mucosectomy provided a compromised solution for management of both hilar intrahepatic cysts and distal intrapancreatic extension. In this procedure, a plane was created between the pathological mucosa and the underlying wall of the cyst with difficulty. Curettage of the abnormal friable mucosa was also performed in some cases.

In the present study, anastomotic stricture developed in three patients after mucosectomy. We believe that ample-diameter hepaticojejunal anastomosis, with a mean of 40.5 mm, was crucial in lowering the risk of postoperative tight anastomosis. Cyst wall inflammation

in adults is intense, damaging the common hepatic duct that is used for hepaticojejunostomy [24]. Two patients with type I cyst underwent percutaneous balloon dilatation and insertion of a biliary stent. This concurs with other investigators who recommend this approach for anastomotic strictures [24,25].

Intraoperative cyst cholangiography allowed us to precisely excise the distal end of the cyst, without injuring the pancreatic duct as its opening can be identified, leaving only a minimal intrapancreatic terminal choledochus. During surgery, debris or protein plugs in the common channel were removed by irrigating normal saline. In agreement, Wiseman *et al.* [16] recommended the routine use of intraoperative cholangiogram to diagnose intrahepatic extension of the disease.

All possible surgical means were performed to avoid risks of remnant complications: distal clip-guided intraoperative cholangiography, mucosectomy at proximal, cystic, and distal levels, extensive intrapancreatic dissection, wide conduit, and the selective use of subcutaneous access limb in risky cases to aid further management.

Malignancy occurs in 2.5– 30% of patients with CC, and jaundice should raise suspicion of malignancy in adults [2,25–27]. Lee *et al.* [3] reported an incidence of malignancy of 20% in 25 adults. They suggested that a high degree of suspicion should be applied in older male patients and in the presence of impaired liver function. Pancreatic secretions regurgitating into the retained abnormal biliary tissue embedded in the pancreas may trigger malignant cells to proliferate [28].

In the present study, no malignancy has been detected in any of our cases until now. The mean age at presentation in this series was 26.4 years – an age with a relatively lower malignant risk than in those over 50 years. Delayed presentation without simultaneous cancer in an untreated adult warrants an eminent risk of future malignancy. Kobayashi *et al.* [29] reported that the epithelium of the retained bile duct may have already undergone genetic alterations to a premalignant stage at the time of surgery, and these genetic changes may continue during the postoperative period.

Two histopathological reports found premalignant changes in our series. Komi *et al.* [30] and Komuro *et al.* [31] highlighted increasing rates of premalignant changes in resected cysts with advancing age. Hence, long-term follow-up is considered. In this report, one patient had an episode of pancreatitis on follow-up. On the other hand, cholangitis was found in two cases; this may be explained by relative bile stasis and exposure to enteric milieu; 34% of adults in the retrospective series of Huang *et al.* [14] had severe late complications such as cholangitis, biliary cirrhosis, and strictures.

The small sample size from a single center, a medium-term follow-up period, and lack of feasibility to liver transplantation were noted limitations of this study.

Conclusion

The present study showed satisfactory medium-term results following surgical resection of adult CC. Our approach was effective, to a great extent, in preventing complications of residual cysts. Imaging is the cornerstone for the complete diagnosis and subsequent surgical management, notably for intrahepatic involvement. Excision of the mucosa of the intrahepatic cyst enables further resection of the affected mucosa with attendant risk of stricture. Excision of the extrahepatic bile duct should be guided by intraoperative cholangiography and distal ligaclips to avoid pancreatic duct injury. Long-term surveillance remains essential. Being an uncommon disease, larger-scale studies are required for more data and experience for optimum management.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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Stent fracture after provisional stenting using four brands of nitinol stents in trans-atlantic inter-society consensus c and d femoropopliteal lesions: in 1 year's follow-up

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Received 5 March 2017
Accepted 20 March 20017

The Egyptian Journal of Surgery
2017, 36:283–290

Introduction
Stenting Trans-Atlantic Inter-Society Consensus C and D lesions of the femoral–popliteal segment is still controversial. There is a wide range of stent fractures ranging between 2 and 62% with different clinical outcomes. This study aimed to investigate the clinical impact and outcome of stent fracture of complex lesions of the femoral–popliteal territory using four brands of stents after 1 year.
Patient and methods
This was a retrospective study on 102 limbs that had Trans-Atlantic Inter-Society Consensus C and D femoral–popliteal lesions. All of them were treated with balloon angioplasty with bailout stenting (self-expandable nitinol stents, Portege EverFlex, E-Luminexx, and Absolute Pro). Patients were followed up by clinical assessment, and duplex and biplane radiography to detect stent fracture.
Results
After a mean 9±5.6 months' complete follow-up of 150 stents in 102 limbs, mean length of the stented segment being 16.5±9.9 cm, the following results were obtained. An overall 78% of stents were fractured. An overall 88.2% of the treated limbs were occluded and presented with critical limb ischemia. The patency rate was 0% for type III and type IV stent fractures, 50% for type II stent fracture, and 6.25% for type I stent fracture. There was no correlation between the type of stent fracture and either stent location (proximal, mid, distal superficial femoral artery and supragenicular popliteal artery) or stent design (brand).
Conclusion
The patency rate for the stented femoral–popliteal segment was very poor, despite great advances in the designs of stents to withstand the highly varied forces applied to this segment. Stenting this segment should be the last option, in which surgery has a great risk (drug-coated balloon and/or atherectomy devices, failed or unavailable).

Keywords:
femoral–popliteal stenting, in stent occlusion, stent design, stent fracture

Egyptian J Surgery 36:283–290

1110-1121

Introduction

Everyday, advances in endovascular technology have encouraged intervention in long complex lesions with a high success rate [1,2]. Despite endovascular interventions in the superficial femoral artery (SFA), which accounts for more than 50% of all endovascular interventions, maintaining long-term patency after these interventions is still a challenging issue [3]. Although the main stream in the literature mentions that it is better to stent SFA lesions than perform percutaneous transluminal angioplasty (PTA) [4–11], the incidence and the clinical impact of stent fracture were still a controversy; some of the literature reported a high incidence rate of in-stent stenosis, occlusion, and thrombosis, and deterioration of the patient's clinical presentation, whereas the others did not [12–17]. SFA is located in the most dynamic portion of the body, exposing it to great cyclic forces in the form of compression, bending, and torsion [18–21]. Stent conformability is defined as the degree to which a stent can bend around its longitudinal axis after deployment, and this is attributed to stent design, which is determined by numbers and arrangement of the interconnectors between the stent struts, strut length and strut cross-sectional shape, strut angles, stent material, and manufacturing process [22]. Recently many stent designs have been developed to meet the requirement of SFA stenting. The aim of this study was to compare the incidence and the clinical impact of stent fracture in four designs of nitinol stents after they had been inserted in long complex SFA lesions as bailout procedures.

Patients and methods

This retrospective study was carried out between November 2013 and October 2015. It was ethical committee approved by the Department of Vascular Surgery in 2013. All patients were informed of the risks and benefits of the procedure and gave written informed consent to participate before enrollment. 'Endovascular first' concept was the policy in the management of chronic lower limb ischemia. Preoperatively, all risk factors were determined, such as diabetes, hypertension, renal impairment or ischemic heart disease.

Inclusion criteria

Patients with criteria of chronic lower limb ischemia were classified according to the Rutherford classification as follows: class IV (rest pain), class V (minor gangrene), or class VI (major gangrene).

Lesions were classified according to Trans-Atlantic Inter-Society Consensus (TASC) II which are as follows: TASC II (C) lesions, which are de-novo stenotic, occlusive to more than 15 cm, or restenotic lesions in the SFA after performing angioplasty twice, or TASC II (D) lesions, which cause chronic total occlusion (CTO) of CFA or SFA (>20 cm involving the popliteal artery) or CTO of the popliteal artery and proximal trifurcation vessels. The presence of adequate inflow and outflow, either pre-existing or re-established was an important factor. Outflow being through at least one tibial vessel ending in the foot.

Exclusion criteria

Patients who had sensitivity to contrast media, renal impairment (serum creatinine ≥2.0 mg/dl), extensive peripheral vascular disease that precluded safe insertion of an introducer sheath, lesions within or adjacent to an aneurysm, asymptomatic lesion, claudicating patients, and patients with acute ischemia or arterial thrombosis, or life expectancy less than 1 year were excluded from the study.

Intervention

All procedures were performed under local anesthesia, except in patients who had rest pain; the procedures were carried out under conscious sedation (midazolam 1–2.5 mg) and intravenous analgesia. Access was achieved by antegrade approach using a 6F sheath (Cordis Avanti; Johnson & Johnson), or contralateral crossover by the aortic bifurcation approach (8F 45 cm crossover sheath Cordis Avanti, Johnson & Johnson).

Retrograde access of popliteal or pedal vessels was obtained if antegrade attempt of crossing the lesion was unsuccessful. The choice of distal access depended on the extent of the lesion and the fitness of the patient; popliteal access was not preferred in obese patients. A micro puncture kit containing a 21 G needle and 0.018 in straight tipped wire was used to get access. After the distal access had been gained, a mixture of 100 μg of glyceryl trinitrates and 5000 IU of heparin (70–80 IU/kg) was administered. Lesions were crossed using the intraluminal method; angled hydrophilic Glide wire (Terumo Boston Scientific Corp, Natick, Mass/Vascular) was advanced to the level of occlusion under angiographic guidance. Other lesions were crossed using a subintimal method; the angled tip of the wire was directed to the wall, followed by advancing of the wire in the subintimal plan.

No re-entry device was used. Advanced techniques to cross CTO lesions were used when the previous conventional methods failed; subintimal arterial flossing with antegrade-retrograde intervention (SAFARI) technique or double balloon technique, in which two small balloons were inflated simultaneously with the intention to break the plaque and open the channel between the antegrade and retrograde wires, was used [17].

All the patients underwent PTA of the target lesions. Appropriate balloon sizes were determined on the basis of the diameter of the reference vessel adjacent to each lesion. Bailout stenting was used for residual stenosis of more than 30% or persistent dissection after prolonged inflation times (2–3 min). The stent dimensions were chosen by visual estimation to fit the vessel diameter. Adjacent stents were overlapped by 1 cm. Self-expandable Epic stent (Boston Scientific Corporation), E-LUMINEXX vascular stent (Bard Peripheral Vascular, Tempe, Ariz), and Absolute pro (Abbott; Abbott Vascular Inc, Menlo Park, CA) were used according to diameter and length availability. The used stent was of either 5, 6, or 7 mm in diameter. Stents were routinely postdilated to ensure optimal extension and apposition. The balloon (Wanda Boston Scientific Corp, Natick, Mass/Vascular) dimension and length were chosen not to exceed the length of the stent.

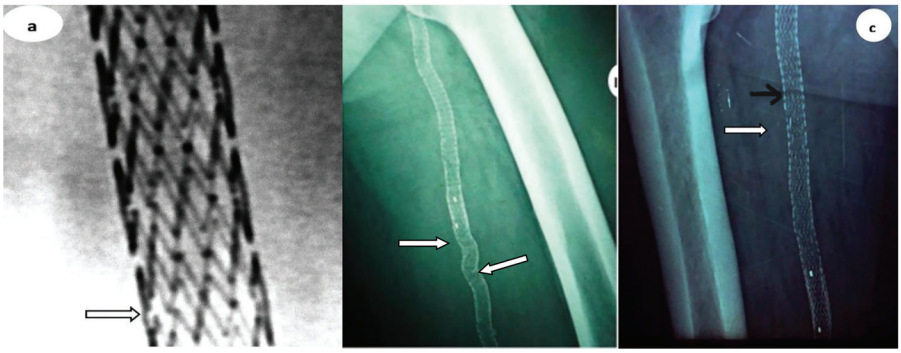
The technical results of the procedures were assessed by final angiography at the end of the procedures. Associated outflow lesions that were suspected to be involved in the disease were treated during the same procedure.

A prophylactic dose of low-molecular weight heparin was prescribed to the patients during hospitalization. Patients were continued on dual antiplatelet therapy with clopidogrel 75 mg once daily and aspirin of 75 mg once daily for at least 6 months.

Follow-up

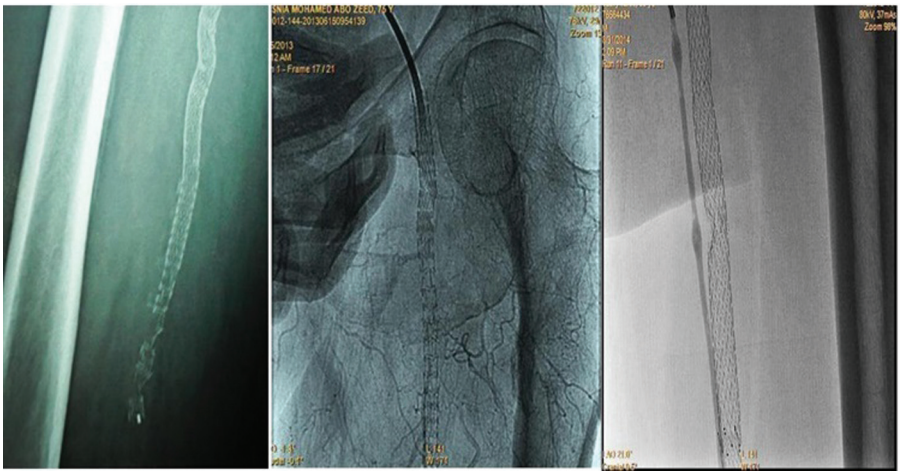
Clinical examination was performed by the surgeon at 1, 3, 6, and 12 months, postoperatively. Stent fractures were assessed by biplane radiography at 12 months with two different projections separated by at least 45° using the highest available magnification. Stent fracture was assessed and classified by a radiologist according to Poppa classification as type 1 (minor), type 2 (V-form), type 3 (complete separation without displacement), or type 4 (complete separation with displacement) (see Figs. 1 and 2). The exact site of each inserted stent was noted. The femoral–popliteal artery was divided into proximal femoral, midfemoral, distal femoral, supragenicular popliteal, and infragenicular popliteal parts. Length, diameter of each inserted stent, number of stents inserted, and total stented length per each patient were documented. In cases where stents fractured, the exact site of the fractured stent was noted – that is, proximal femoral, midfemoral, distal femoral, supragenicular popliteal, or infragenicular popliteal part. The type of stent fracture was noted; when several fractures were present on the same stent, only the most severe fracture was considered. Clinical impact evaluation including change of symptoms according to the Rutherford classification and duplex scan examination was performed at 1, 6, and 12 months and yearly. Duplex imaging of the revascularized vessel offers the best method of assuring the patency of the revascularization strategy and assessment of the degree of narrowing.The velocity criteria for determining stenosis vary; however, if the peak systolic velocity ratio was greater than 2.5, the degree of stenosis was considered significant enough to warrant further evaluation either with computed tomography angiography or magnetic resonance angiography or even direct angiography. Maintaining a close relationship with these patients was crucial, allowing the physician to identify and treat those patients who develop problems early, before the lesion progressed to a point where intervention became difficult.

Figure 1



Different types of fractured stent: (a) type I fracture, single struts fracture; (b) type II fracture, multiple stent fracture, V-shaped fracture; (c) type III fracture, transverse linear fracture.

Figure 2



Type IV fracture: type III with displacement.

Results

Over a period of 20 months, a total of 100 patients and 102 limbs were treated, in which 150 stents were inserted. They were retrospectively enrolled in the treatment of femoral–popliteal lesions. At 12 months' follow-up, radiography were obtained for all patients who attended the clinical follow-up.

Patients demographic, indication and comorbidity

Patients who were eligible for study and fitted the inclusion criteria were 100 in number [86 male individuals (85.3%) and 14 female individuals (14.7%)]. Their ages ranged from 42–80 years; the mean age was 58.8±9 years. Table 1 summarizes the demography and comorbidity of the patients. All treated patients presented with critical limb ischemia.

According to the TASC II classification, 79.4% patients presented with TASC II (C) lesions and 20.6% had TASC II (D) lesions. The median length for lesions in TASC II (C) and TASC II (D) was 143.45±97.6 and 220.6±55.7 mm, respectively. The mean stented length was 100.86 mm for TASC II (C) lesions and 170.96 mm for TASC II (D) lesions. The outflow tibial vessels for TASC II (C) and TASC II (D) were as shown in Table 2.

Concomitant tibial angioplasty was performed in 88% of the patients (88/100). The average number of stents was 1.5 stents inserted per patient. The number of stents inserted per limb (see Fig. 3) and the location of stents are shown in Fig. 4.

Table 1 Summarizes demography and comorbidity of patients

Age (years)	58.8±9
Sex (male : female) (%)	85.3 : 14.7
Diabetic (%)	61.8
Hypertensive (%)	38.2
Renal impairment (%)	14.7
Cardiac (%)	47.6
Previous iliac stent (%)	0
Rutherford classification (%)	
Class IV	38.1
Class V	26.5
Class VI	35.3

Table 2 Summarizes anatomic characteristics of the distal runoff of patients

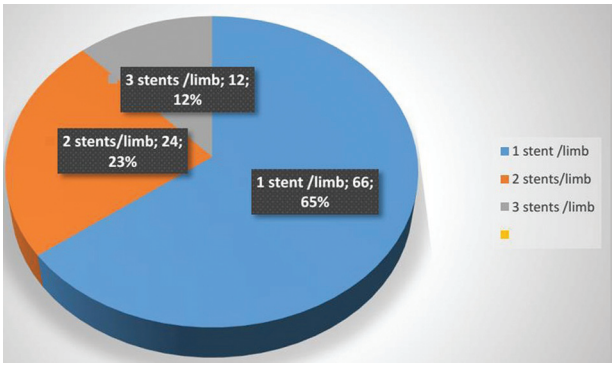
	TASC II C (%)	TASC II D (%)	*P*
Number of vessel runoff			
One vessel runoff	50.0	51.4	0.990
Two vessel runoff	41.7	40	
Three vessel runoff	8.3	8.6	
ATA	55.6	48.6	0.556
PTA	61.1	54.3	0.561
Peroneal	41.7	54.3	0.287

ATA, anterior tibial artery; PTA, percutaneous transluminal angioplasty; TASC, Trans-Atlantic Inter-Society Consensus.

Stent fracture

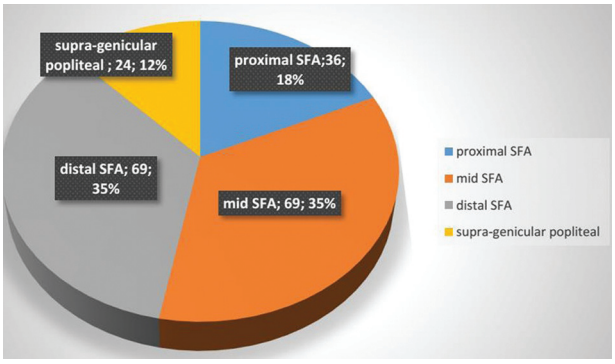
- An overall 78% of the stents (117/150) were fractured. Multiple stent fracture was seen in 40% of the stents (60/150).
- An overall 65% of the limbs (66/102) had one stent inserted, of which 89.3% of the stents (59/66) were fractured, and 53% of inserted stents were short stents less than or equal to 100 mm.
- An overall 23% of the limbs (24/102) had two stents inserted, of which 87.5% of stents (21/24) were fractured; in 11 limbs both stents were fractured and in ten limbs one stent only was fractured; 50% of the inserted stents were less than or equal to 100 mm long.
- An overall 11.8% of the limbs (12/102) had three stents inserted, of which 83.3% of the stents (10/12) were fractured; all the three stents were fractured in six limbs, whereas in four limbs only two stents were fractured. All stents inserted in those patients were more than or equal to 100 mm long.

Figure 3



The percentage of limbs according to number of stents inserted in each limb.

Figure 4



The percentage of stents according to their location.

- It was found that 56% of the stents were less than or equal to 100 mm in length (see Fig. 5).
- The location and distribution of fractured stents in different parts of the femoral–popliteal territory are shown in Fig. 6. The types of stent fracture are shown in Fig. 7.
- The patency rate of the fractured stent after 1 year's follow-up was 0% for type IV and III stent fractures, 50% for type II stent fracture, and 6.25% for type I stent fractures.
- Type II stent fracture was represented in 53% of all types of stent fracture. The mean stented length associated with type II stent fracture was 16.88±11.22 cm and 26.5% of type II fractures were located in the mid SFA (see Fig. 6). There was no significant difference between the locations where type II stent fractures occurred (P=0.118) or in the time elapsed for the type II stent fractures to be occluded (P=0.246) (see Table 3).
- Type III stent fracture was represented in 26% of all types of stent fracture. The mean stented length associated with type III stent fracture was 17.12 ±9.56 cm (see Fig. 6). There was no significant difference between the locations where type III stent fractures occurred (P=0.415) or in the time elapsed for the type III stent fractures to be occluded (P=0.168) (see Table 3).

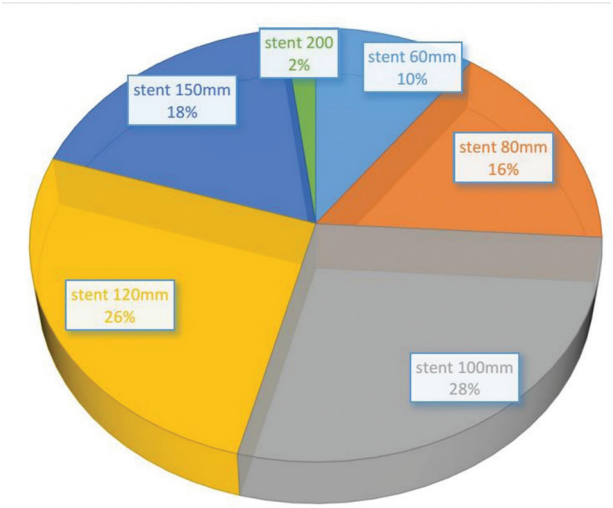
and

- There was no significant difference in stent fracture in the different stent brands (see Fig. 8). The incidence of stent fracture in the different stent brands Absolute pro, Portege EverFlex, E-Luminexx, and Epic was 8.8% (8/90), 26.6% (24/90), 22.2% (20/90), and 42.86% (38/90), respectively (P=0.258. 0.031, 0.191, and 0.034, respectively).
- The incidence of type II fracture in the different locations, that is, proximal, mid, distal, and supragenicular parts of the popliteal artery was insignificant (P=0.504, 0.124, 0.065, and 0.003, respectively).

Clinical impact of stent fracture

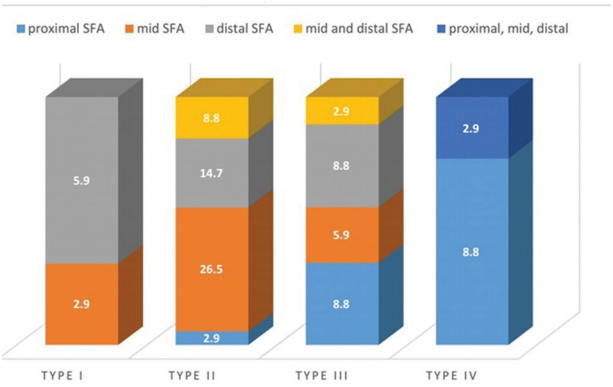
- An overall 88.2% of the limbs (90/102) were occluded and presented with critical limb ischemia, which ranged from rest pain to major gangrene.
- An overall 11.8% of the limbs (12/102) were patent; a total of 9/102 limbs had fractured stent and 3/102 limbs had no stent fracture.
- Of the patients in whom the stents were fractured, five patients had type I stent fracture and the patients were symptom free; three patients had type II stent fracture, and, despite the stented segment being patent, the patients presented with gangrene in their toes for which tibial angioplasty was performed.

Figure 5



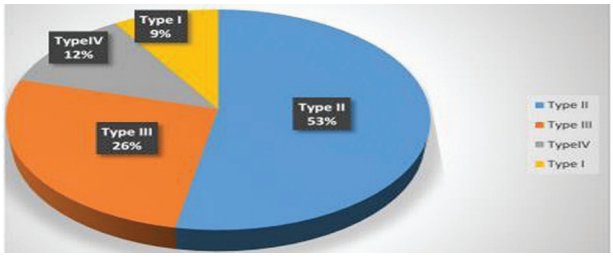
Length, number, and percentages of each inserted stent.

Figure 6



Distribution of different fracture types according to different segments of the femoral popliteal territory.

Figure 7



Percentages of different fracture types.

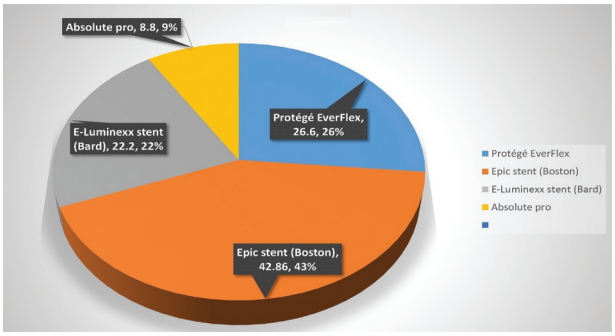
Table 3 Illustrates types II and III fracture to different stent locations and time elapsed for stent occlusion

	Mean stent length (*P* value)	Time elapsed for stent occlusion
Type II fracture		
P	0.415	0.168
Proximal SFA	20 cm	3 cm
Mid SFA	12.67 cm	7.67 months
Distal SFA	16.6 cm	7 months
Distal and upper pop	24.67 cm	14.76 months
Type III fracture		
P	0.118	0.246
Proximal SFA	9.33±3 cm	11.33±4 months
Mid SFA	19.33±15.56	7.5±7 months
Distal SFA	9.33±1.15 cm	9±2.65 months
Distal and upper pop	39 cm	28 months

SFA, superficial femoral artery.

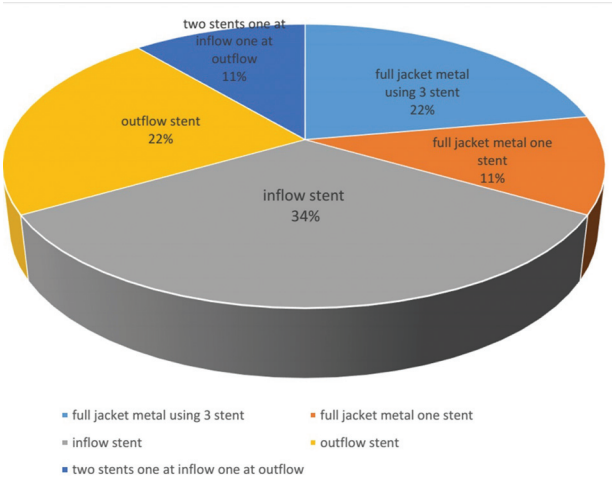
- One patient had type II stent fracture, and this patient presented with incapacitating claudication, which was associated with external iliac artery occlusion, as the patient improved after PTA to the external iliac artery lesion.
- In comparing the fractured stent group to the nonfractured stent group, there was no significant difference related to the age of the patients. The mean age of patients in the fractured stent group and nonfractured stent group was 57.89±8.66 and 62.83±10.57 years, respectively (*P*=0.23).
- The mean stented length in the fractured stent group and nonfractured stent group was 17.6±10.5 and 11.33±4.5 cm, respectively (*P*=0.139).
- An overall 84% of the limbs (75/90) underwent angioplasty; 51 limbs improved on PTA alone using a drug-eluted balloon, and 24 limbs underwent bailout stenting for residual lesions. In patients who needed bailout stenting, six limbs had full metal jacket (three limbs had three stents per limb to cover inflow, outflow, and in-stent lesions, and the other three limbs had a long stent covering inflow, outflow, and in-stent lesions). Three limbs had two stents inserted; one stent was at inflow and the other was at outflow of the lesion. Fifteen limbs had only one stent reinserted per limb, either at the inflow lesion or at the outflow lesion (see Fig. 9).
- An overall 13% of limbs (12/90) were transferred to surgery (see Fig. 10). Patients who were transferred to surgery had a relatively fair risk for surgery.
- An overall 3% of limbs (3/90) underwent above knee amputation, in which presentation was acute thrombotic ischemia. These patients' conditions were documented from the previous angioplasty they had undergone, which showed that they had a poor distal runoff and their presentation was late.

Figure 8



Percentage of stent fracture related to different manufacturers' stents.

Figure 9

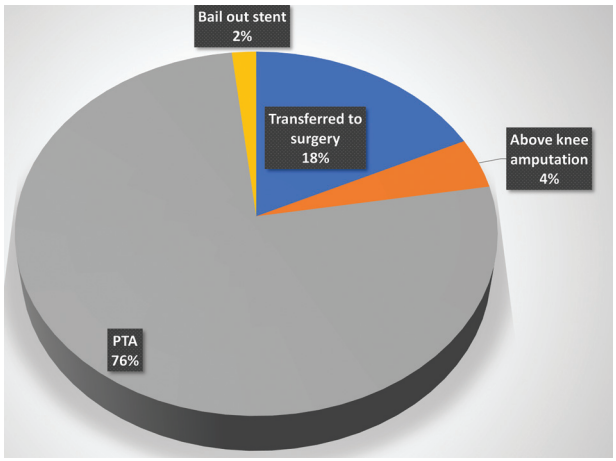


Different position of restenting.

Discussion

The stent fracture rate ranged between 2 and 65% in the literature with various factors influencing stent fracture rate [18,23]. Most studies report their stent fracture rate according to the number of treated limbs; in our opinion, the stent-based analysis seems more

Figure 10



Different modalities and their percentage in the management of occluded stented lesions.

relevant, particularly in long lesions with several implanted stents, in order to reflect the result of each implanted device.

This retrospective study reported the incidence of stent fracture and its clinical impact in four different designs of stents in patients with TASC II C and TASC II D lesions. In stent-based analysis, the incidence of stent fracture rate was 78%. In limb-based analysis, the incidence of stent fracture was 88.24%, and the incidence of symptoms recurrence was 79.4%.

Primary stenting was the protocol of management of long complete total occlusion in most reports in the literature [11,18,24], but the protocol for this study was provisional stenting for residual stenosis or dissection. As the length of the stent was directly proportional to the length of the lesion, [11,13,18,24,25] provisional stenting [for residual stenosis more than 30% or persistent dissection after many attempts of prolonged PTA (2–3 min)] was the protocol in this study to shorten the total stented length and provide a good prepared arterial segment for stenting.

The lesions in this sample were not long complete total occlusions, but they were hard, and sometimes calcified, needing nonconventional methods for recanalization. SAFARI technique and double balloon technique were the methods of recanalization in many lesions, which was contrary to what was reported in the literature [16,17,26]. It is thought that regions of high artery stress are the most susceptible to an adverse biological response. Thus, any chance to minimize such stresses while still maintaining arterial patency should be considered [19].

The high incidence of stent fracture rate observed in this study may be attributed to many factors such as the heterogeneity of stents (in design) being inserted in the same lesion, the use of multiple short stents with area of overlap in-between, and the patients recruited in the study being young.

Each stent brand possesses a unique stent design; strut cross-section shape, thickness of the struts, angle, number, length, and arrangement of interconnectors between these struts are all factors that affect the flexibility of each stent and its suitability for a certain lesion, which were improving overtime as the manufacturing process progressed. It was assumed that the evolution of design of E-Luminexx stent (first generation of self-expandable stent) to EverFlex, the second generation of slotted tube nitinol stents better flexibility; reducing the number of connections between cells or crowns and by plough configuring spiral orientation of these interconnections, decrease the incidence of stent fracture [27].The overlap of heterogeneous stents may exert an extra stress more than the localized rigidity and hinge point effect of the overlapped stent with the same design.

The mean age of the population in the published studies was 70, which was higher than that in this study population (58±9 years) [17,26]. Inserting stents in young active people subjected those stents to more bending, compression, torsion, and stretch forces [28].

The distal segment of the SFA (at the adductor hiatus) was considered to be the segment of the femoral–popliteal artery subjected to the most bending and tortuosity forces than other segments in the same territory [28–30], but, from this study, the incidence of the stent fracture was insignificantly related to the location where the stent was inserted.

The poor clinical outcome of this study population cannot be attributed to the incidence of stent fracture only but it may also be attributable to the high Rutherford grade at presentation; 50% had a patent single tibial vessel, and 50% of that single vessel was a peroneal artery that indirectly provided blood supply to the foot.

Conclusion

The incidence of stent fracture is high among different stent brands (design) and associated with worse clinical outcome. SFA and popliteal artery stenting should not be the first option for intervention except in those whose general health is at high risk for open surgical

bypasses. The new growing technology of drug-covered balloon or biodegradable stents should be compared with conventional stenting in its long-term patency rate and cost effectiveness.

Financial support and sponsorship
Nil.

Conflicts of interest
There are no conflicts of interest.

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Value of staging laparoscopy for the assessment of operability in periampullary cancer patients: a comparative study versus exploratory laparotomy

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Received 8 March 2017
Accepted 23 April 2017

The Egyptian Journal of Surgery
2017, 36:291–296

Objectives
The aim of this study was to evaluate the diagnostic yield of staging laparoscopy (SL) for patients with periampullary cancer with no signs of inoperability on computed tomography (CT) imaging.
Patients and methods
Thirty-eight patients with malignant obstructive jaundice were considered for this study. Only patients with no distant metastases and with lesions potentially resectable on CT criteria were included. Patients were randomized to two groups: group A included patients who underwent exploratory laparotomy (EL) based on CT findings, and group B included patients who were subjected to SL and then proceeded to laparotomy according to SL findings. Primary outcomes included the frequency of cancelled laparotomy and the frequency of positive laparoscopy, indicating inoperability or irresectability.
Results
EL confirmed CT findings in eight (42.1%) patients of the EL group. In total, resection was not indicated nor possible in 11 patients of the, Replace:= wdReplaceAll, Format:=True, Forward:=True, MatchWildcards:=False, Wrap:= wdFindStop EL group and were considered as false positive for CT. SL confirmed CT findings in seven (36.8%) patients of the SL group. SL detected signs of inoperability in 12 patients. In total, resection was not indicated nor possible in 13 patients of the SL group and were considered as false positive for CT. Collectively, CT could define operability and lesion resectability with a positive predictive value (PPV) of 36.8% and low specificity. However, preliminary SL could define operability and lesion resectability of patients with free CT with a PPV of 85.7% (95% confidence interval: 47.72–97.53) and specificity rate of 92.3% (95% confidence interval: 63.97–99.81).
Conclusion
Reliance on CT imaging alone for defining operability of patients with periampullary is accompanied by a relatively high unnecessary laparotomy rate. SL should be considered for defining inoperability with high PPV and specificity. SL could spare unnecessary laparotomy in around 50% and allowed shorter theater time and postoperative hospital stay for inoperable patients compared with EL.

Keywords:
malignant obstructive jaundice, periampullary carcinoma, staging laparoscopy

Egyptian J Surgery 36:291–296

1110-1121

Introduction

Periampullary cancer includes cancer of the head and neck of the pancreas, cancer of the distal end of the bile duct, cancer of the ampulla of Vater and cancer of the second part of the duodenum [1]. Surgical resection is the only potentially curative treatment for pancreatic and periampullary cancer.

Despite the availability of high-resolution computed tomography (CT) scans, occult distant metastases can still be found in 11% of patients during the operation [2] and a considerable proportion of patients undergo unnecessary laparotomy because of underestimation of the extent of the cancer on CT scanning [3], thus the accurate staging is becoming increasingly important [4].

Laparoscopy can detect metastases not visualized on CT scanning, enabling better assessment of the spread of cancer [3]. In the absence of reliable risk factors to predict distant metastases, staging laparoscopy (SL) should be offered to all patients with radiographic localized disease [2]. Moreover, SL is considered

useful for detecting peritoneal metastasis, a task that is difficult using conventional imaging modalities [5]. Moreover, SL allows avoiding laparotomy with unsuccessful resection, and can lead to rapid induction of chemotherapy for unresectable pancreatobiliary cancers [6].

SL has become routine in certain cancers, especially gastric cancer and hilar cholangiocarcinoma, and may play a role in hepatopancreaticobiliary malignancy; however, with ever improving radiology, its role remains controversial [4]. Thus, the current study aimed to evaluate the diagnostic yield of SL for patients with hepatopancreaticobiliary cancer with no signs of inoperability on CT imaging.

Patients and methods

The current randomized controlled trial was conducted at General Surgery Department, Cairo University Hospitals between January 2014 and July 2016. The study protocol was approved by the local ethical committee and in accordance with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Informed consent was obtained from all individual participants included in the study. Thirty-eight patients with malignant obstructive jaundice fit to undergo surgery were considered for this study. Only patients with no distant metastases and with lesions potentially resectable on CT criteria were included in this study. All patients underwent routine preoperative workup. Endoscopic Retrograde Cholangiopancreatography (ERCP) was routinely performed preoperatively. Biliary drainage could not be achieved in one patient only due to gastric outlet obstruction.

Using sealed envelopes, patients who agreed to take part in the study were randomized to two groups:

(1) Group A included patients who underwent exploratory laparotomy (EL) based on CT findings.
(2) Group B included patients who were subjected to SL and then proceeded to laparotomy according to SL findings.

SL was performed under general anesthesia using three 10–11-mm umbilical, left and right subcostal cannulas. The abdominal cavity was explored, using a 30° telescope, for ascites and peritoneal, omental and surface hepatic deposits. Ligament of Treitz and transverse mesocolon were visualized to look for peritoneal deposits specifically at these two areas. Any positive finding was confirmed with frozen section. Ascitic fluid, if present, was sent for cytology.

Study outcome

Primary outcome included the following items:

(1) The frequency of cancelled laparotomy.
(2) The frequency of positive laparoscopy, indicating inoperability assured by frozen section.

Secondary outcome

The secondary outcome included influence of adding SL on operative time.

Results

The study included 38 patients eligible for inclusion in the study. All patients presented with malignant obstructive jaundice with other varied manifestations, and their CT imaging assured operability of patients and resectability of the lesion. There was a nonsignificant ($P>0.05$) difference between patients enrolled in both studies as regards age, sex, and frequency of presenting manifestations, as shown in Table 1.

EL confirmed CT findings in eight (42.1%) patients of the EL group and proceeded to Whipple's procedure. These eight cases were considered as true positive for CT.

Three patients had locally advanced disease precluding completion of resection. All three patients had the plastic stents changed to metal stents before referring them to oncology for palliative chemotherapy.

Among the remaining eight patients in the EL group, three patients had small surface liver deposits, four patients had peritoneal nodules, and one patient had omental mass. Frozen section confirmed malignancy.

Table 1 Patients' enrollment data

Data	EL group (n=19)	SL group (n=19)
Age (years)	53.1±14.4	58.1±12
Sex		
Male	12 (63.2)	11 (57.9)
Female	7 (36.8)	8 (42.1)
Clinical manifestations		
Jaundice	19 (100)	19 (100)
Cachexia	11 (57.9)	10 (52.6)
Mass	3 (15.8)	1 (5.3)
Fever	12 (63.2)	11 (57.9)
Vomiting	8 (42.1)	6 (31.6)
Anemia	9 (47.4)	7 (36.8)

Data are presented as mean±SD and numbers. Percentages are given in parentheses. EL, exploratory laparotomy; SL, staging laparoscopy.

In total, resection was not indicated nor possible in 11 patients in the EL group and were considered as false positive for CT.

SL confirmed CT findings in seven (36.8%) patients of the SL group and proceeded to resection through laparotomy. Unfortunately, during laparotomy, one patient was found to have a locally advanced tumor more than that appreciated by laparoscopy. This patient was considered as false positive for both CT and SL. In the remaining six cases, Whipple's procedure was performed uneventfully, and these cases were considered as true positive for both CT and SL.

SL detected signs of inoperability in 12 patients (either peritoneal/omental deposits or surface liver deposits) (Figs 1–5). Laparotomy was cancelled and plastic biliary stents were changed to metal ones postoperatively. Laparoscopic gastrojejunostomy was performed for one patient with gastric outlet obstruction. This patient had a percutaneous transhepatic metallic biliary stent inserted postoperatively.

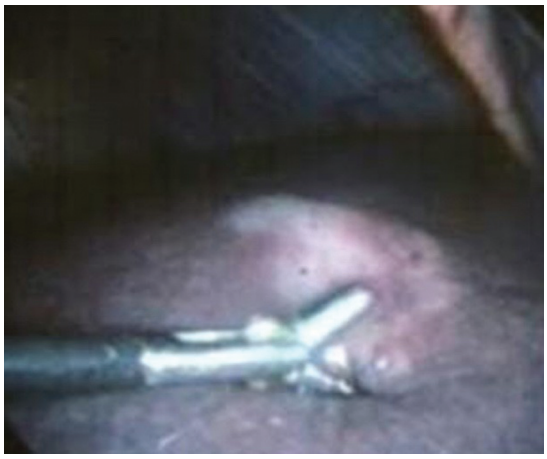
In total, resection was not indicated nor possible in 13 patients in the SL group and were considered as false positive for CT.

Collectively, CT could define operability and lesion resectability with a positive predictive value (PPV) of 36.8% and low specificity. However, preliminary SL could define operability and lesion resectability of patients with free CT with a PPV of 85.7% [95% confidence interval (CI): 47.72–97.53] and specificity rate of 92.3% (95% CI: 63.97–99.81).

Receiver operating characteristic curve analysis of SL and CT as predictor for operability defined SL as significant predictor with area under the curve (AUC) of 0.897 (95% CI: 0.769–1.005), whereas CT could not be the sole diagnostic modality as it showed an AUC of 0.5 with nonsignificant difference versus the null hypothesis (Fig. 6).

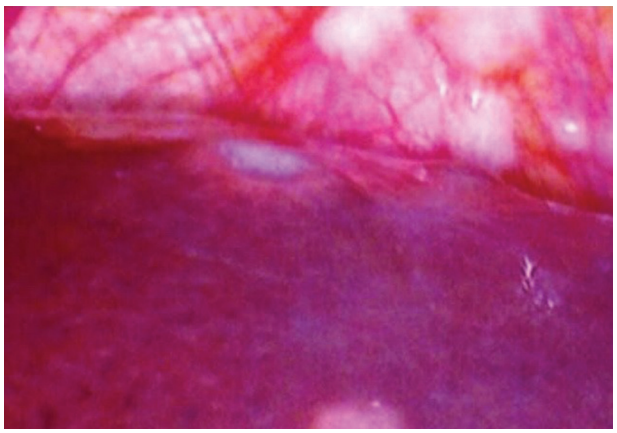
The mean operative time for patients found to be inoperable was significantly (P=0.003) shorter with SL compared with EL. However, mean total theater

Figure 1



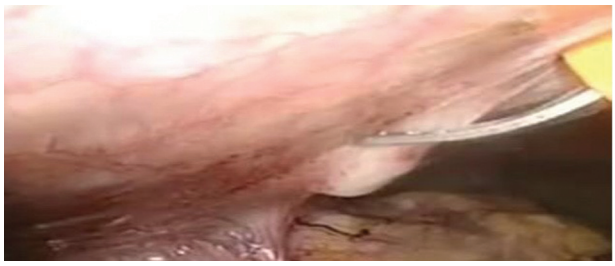
Surface liver deposits Segment V/VIII.

Figure 2



Surface liver deposits Segment II, III and deposits on Falciform ligament.

Figure 3



Peritoneal Nodules.

Table 2 Operative time and duration of hospital stay of patients according to operative approach and performed procedure

Findings	Inoperable patients		Operable patients	
	SL alone	EL alone	SL and completed laparotomy	Exploration and completed laparotomy
Number	12	11	6	8
Operative time (min)	28.3±3	35.7±6.9[a]	252.1±39.7	203.8±44.7[a]

Data are presented as mean±SD. EL, exploratory laparotomy; SL, staging laparoscopy. [a]Indicates significant difference versus counter group.

time for operable patients who were subjected to SL followed by open Whipple procedure was significantly (P=0.046) longer than that for patients who had completed EL (Table 2).

Cumulative 24-h postoperative pain VAS score was significantly (P=0.001) higher in patients who underwent laparotomy (3.4±0.6) compared with scores determined in patients who underwent laparoscopy (2.2 ±0.5). Moreover, patients who underwent laparotomy requested significantly higher rescue analgesia compared with laparoscopy patients (P=0.001). The mean number of times rescue analgesia was requested with laparotomy versus laparoscopy was 2±0.8 vs. 0.6±0.5, respectively.

Discussion

The study included 38 patients with malignant obstructive jaundice diagnosed using CT imaging as operable patients with resectable lesions. However, EL detected inoperability/irresectability of 12 patients (one had SL) and SL defined another 12 inoperable patients. Fourteen patients were considered as true positive for CT imaging that showed a PPV of 42.11% and AUC for predictability of operability of 0.5 with a nonsignificant difference versus area for the null hypothesis. However, SL spared laparotomy in 12 patients, but unfortunately underestimated local extent of the disease in one patient who underwent unnecessary laparotomy. Statistical analyses defined a PPV of 85.7% and specificity rate of 92.3% for SL for the identification of operable patients. Moreover, receiver operating characteristic curve analysis showed that SL is positive significant predictor for operability with AUC of 0.897.

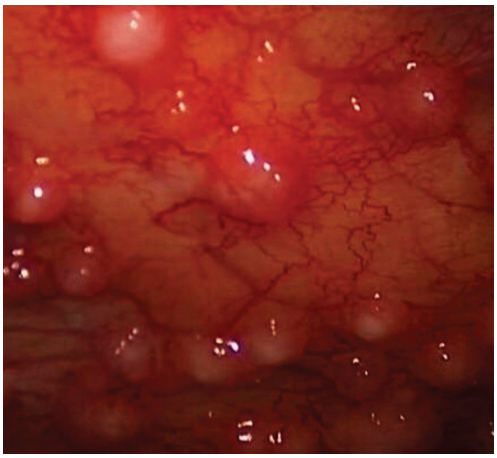
According to our study, 20 (52.6%) patients of 38 (eight in the EL group and 12 in the SL group) with potentially curable disease on CT criteria could potentially be spared a laparotomy.

Many hepatobiliary centers would consider SL as a routine step in the workup of gall bladder cancer (GBC) patients and Klatskin's tumor patients. However, SL is usually performed on selective basis in pancreatic cancer patients.

Zhuang *et al.* [7] found that SL in GBC is sensitive in detecting disseminated disease and increases the curative resection rate, shortens the recovery time, and has no negative implications on overall survival, and Agarwal *et al.* [8] also found that SL identified 94.1% of the detectable lesions, thereby obviated a nontherapeutic laparotomy in 55.9% of patients with unresectable disease and 23.2% of overall GBC patients.

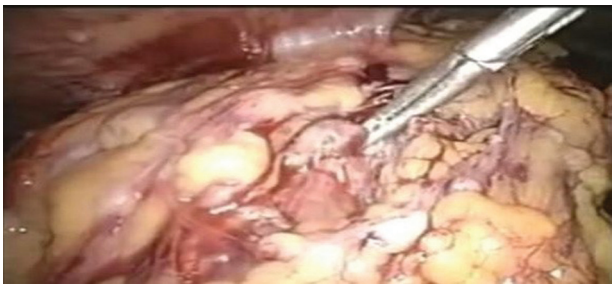
Bird *et al.* [9] reported that the accuracy for all-cause nonresection for SL was 66% with a PPV of progress to resection of 81% and concluded that SL proved useful

Figure 4



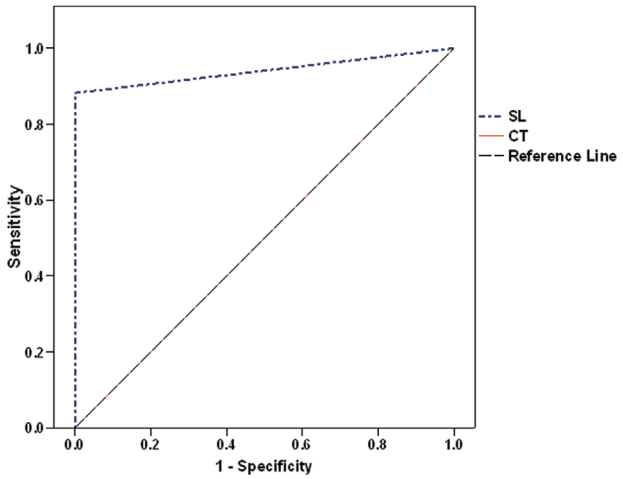
Omental deposits.

Figure 5



Omental mass and nodules.

Figure 6



ROC curve analysis of predictability of SL and CT for operability of patients had malignant obstructive jaundice.

in determining the presence of radiologically occult metastatic disease in perihilar cholangiocarcinoma (PHC). Moreover, Coelen *et al.* [10] found that the sensitivity of SL to detect unresectable disease in potentially resectable PHC patients ranged from 31.6 to 75% and the sensitivity was highest for peritoneal metastases (80.7%, 95% CI: 70.9–88.3). Recently, Tian *et al.* [11] through their meta-analysis including eight studies documented that 32.4% of patients with PHC and 27.6% of patients with GBC may avoid unnecessary laparotomy with the use of SL.

Königsrainer *et al.* [12] documented that in pancreatic cancer patients laparoscopy should be considered as an additional staging tool to rule out peritoneal carcinomatosis, and Sakamoto *et al.* [13] found that laparoscopic biopsy taking is a useful less-invasive procedure that allows obtaining sufficient specimen regardless of the location and size of the tumor and is more reliable compared with imaging-guided biopsy.

Bird *et al.* [9] reported that the sensitivity of SL for the detection of peritoneal disease was 71% in patients with PHC, and Karabicak *et al.* [14] documented that, in patients with radiographically defined locally advanced pancreatic ductal adenocarcinoma, SL detected peritoneal dissemination in 19% and liver metastasis in 15% of patients.

Moreover, cytological examination of peritoneal lavage samples obtained during SL detected malignant cells indicating the presence of metastatic lesion out of reach of SL and reliability of cytology for the diagnosis of inoperability of suspicious cases. Similarly, Karabicak *et al.* [14], in their series of patients with radiographically defined locally advanced pancreatic ductal adenocarcinoma, reported that SL detected positive peritoneal lavage cytology in 23% of patients. As regards operative time and total postoperative hospital stay of studied patients, SL significantly reduced theater time and hospital stay for patients diagnosed as inoperable compared with EL. Similarly, multiple previous studies documented that SL required a shorter operating room time, and a briefer hospital stay [4,7,15–17].

These results indicated the superiority of preliminary SL for defining operable cases and its ability to spare unnecessary laparotomy with its subsequent sequelae. In support of this assumption, Allen *et al.* [3,18] searched the Cochrane Central Register of Controlled Trials to determine the diagnostic accuracy of SL as an add-on test to CT scanning in the assessment of curative resectability in pancreatic and periampullary cancer and documented that SL with biopsy and histopathological confirmation of suspicious lesions before laparotomy would avoid unnecessary laparotomies in 21 [3] and 23% [18] of patients in whom cancer resection was planned.

The lack of consistency in CT reporting in this study may have contributed to the relatively high percentage of inoperable patients considered for surgery and then found to have peritoneal disease. However, this is more in favor of performing SL routinely in our setup.

Conclusion

Reliance on CT imaging alone for defining operability of patients with periampullary is accompanied by a relatively high unnecessary laparotomy rate. SL should be considered for defining inoperability with high PPV and specificity. SL could spare unnecessary laparotomy in around 50% of patients defined as operable using CT imaging. SL allowed shorter theater time and postoperative hospital stay for inoperable patients compared with EL.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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