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The Egyptian Journal of Surgery

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Therapeutic reduction mammoplasty techniques in management of breast cancer in large-breasted females – a comparative study between inferior and superior pedicle reduction mammoplasty Sherief M. Mohsen

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Background

Oncoplastic surgery for breast cancer in patients with macromastia is a new concept that has evolved to associate breast conserving surgery with techniques of breast reshaping. This study aims to compare the outcomes of therapeutic reduction mammoplasty in medium-sized to large-breasted females with breast cancer using superior pedicle versus the inferior pedicle mammoplasty for early stages of breast cancer.

Patients and methods

From January 2013 to January 2017, 50 females patients with medium-sized to large-sized breasts diagnosed with early breast cancer and suitable for breast conservation underwent reduction mammoplasty depending on either inferior pedicle (group 1) or superior pedicle (group 2). Patients with central breast cancer and inability to obtain free resection margin after excision were excluded from the study. Surgical outcomes, oncologic safety, and cosmetic result were assessed and compared between both techniques.

Results

There was no significant difference between the two groups regarding age and weight of the patients (median: 42 vs 40 years) (P>0.05). Most cases had a mass in the upper outer quadrant of the breast (60%). On follow-up, wound dehiscence occurred more frequent in the inferior pedicle group, which occurred in four (16%) cases, than in the superior pedicle group, which occurred in two (8%) cases. The cosmetic outcomes were assessed in inferior pedicle versus superior pedicle mammoplasty groups, showing excellent results in 15 (60%) cases versus 16 (64%) patients, respectively. In a median follow-up of 24 months, no cases showed local recurrence.

Conclusion

Therapeutic reduction mammoplasty using inferior and superior pedicles was shown to be oncologically safer than traditional conservative surgery with more satisfactory esthetic outcome. Moreover, the superior pedicle mammoplasty yields a lower morbidity with better cosmetic outcome than inferior pedicle mammoplasty in large-breasted women with breast cancer.

Keywords:

breast cancer, conservation surgery, oncoplastic techniques, reduction mammoplasty

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Introduction

The surgical treatment of cancer in large ptotic breast has many difficulties for surgeons performing traditional breast conservative surgery and for the radiation oncologist owing to the heterogeneous distribution of the radiation dose [1].

The challenge is to perform a resection wide enough to provide the most favorable oncologic control but not to remove so much breast tissue as to leave a deformed breast. Oncoplastic surgery consists of a new concept that associates conservative breast surgery with the techniques of breast reshaping. It provides a proper opportunity to improve the final cosmetic results and to expand the indications for conservative treatment without decreasing oncological safety [2]. Additionally, in some circumstances, oncoplastic techniques allow a more radical tumor excision, which potentially reduces margin involvement. The capacity to remove a wider margin may be important in certain groups of patients such as those with ductal carcinoma in situ and larger tumors that would usually be treated by a more radical surgery [3]. This adds to the oncologic safety of breast conserving treatment (BCT), because a larger volume of breast tissue can be excised as a wider negative margin can be achieved. It is especially indicated for large tumors when standard

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BCT has a high probability of leaving positive margins [4].

Surgeons should not only understand the distribution of cancer within the breast at planning for an optimum surgical resection but also should know the degree to which imaging can accurately predict the exact histological extent and orientation of disease. There are multiple oncoplastic techniques that can be used for the treatment of each tumorspecific site in relation to the size of the breast [5]. The most commonly used techniques in largebreasted women especially in the upper outer quadrant of the breast are inferior and superior pedicle reduction mammoplasty [6,7].

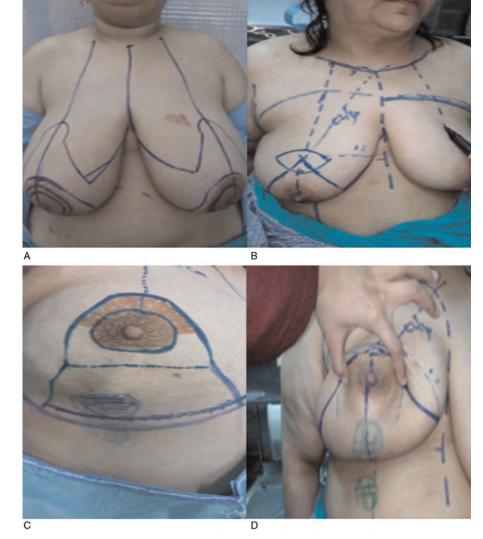
This study aims to compare the cosmetic outcome and oncologic safety in terms of conversion to mastectomy rate or necessity for repeated excision after therapeutic

Figure 1

reduction mammoplasty in large-breasted women with breast cancer using superior pedicle with the inferior pedicle mammoplasty within 3 months after the completion of the radiotherapy course. We also aim to assess the local recurrence within this short-term follow-up.

Patients and methods

Between January 2013 and January 2017, 50 females patients with medium-sized to large-sized breasts with early breast cancer admitted to Ain Shams University Hospitals and suitable for breast conservation participated in this comparative study. Ethical Committee approval was given for the study and written informed consent was obtained from all participants. Patients were divided into two equal groups: group 1 (inferior pedicle group; 25 patients) and group 2 (superior pedicle group; 25 patients). The



(A) marking of the inferior pedicle. (B) Marking of the superior pedicle while the patient in upright position. (C, D) Marked site of the tumor in the lower central pole of the breast.

choice of the procedure depends on the location of the tumor. The inferior pedicle procedure was suitable for lesions in the upper pole of the breast, whereas the superior pedicle procedure was suitable for lesions in the lower pole of the breast. It should be noted that both techniques are suitable for lesions in the upper outer quadrant of the breast, which is considered the most common site of breast cancer.

Exclusion criteria were central breast lesions, multicentric carcinoma, and patient's choice of involvement in the study. Inability to obtain tumorfree safety margins after repeated excision, the patient was excluded from the study and the technique was converted to mastectomy. All included patients provided written informed consent for the therapeutic procedures, and only two of them accepted to perform the same contralateral reduction technique in the same session, one from each group.

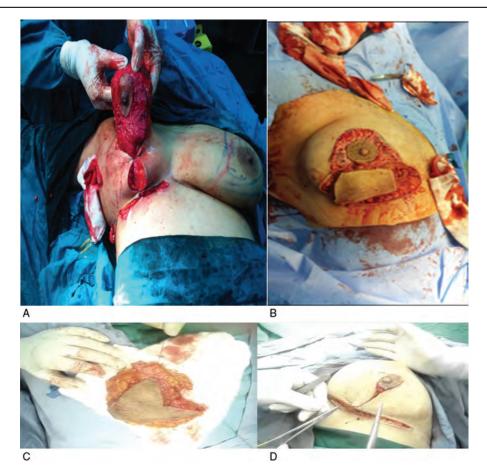
Surgical technique

Preoperative marking was performed according to the standard inverted T Wise pattern. The neo-nipple is

marked in the breast meridian $\sim 19-23$ cm from the sternal notch. The tumor defect location is anticipated, and an inferior or superior pedicle is drawn out ($\sim 8-10$ cm wide). The location of the pedicle can be adjusted to maximize width and blood flow depending on the tumor location and degree of breast ptosis. A similar pattern is drawn on the contralateral breast for symmetry, whenever indicated (Figs 1 and 2).

De-epithelialization of skin in the designed flap was done (Fig. 3). After tumor excision with a good safety margin (4–12 cm) (Figs 4–6), the specimen was marked with clips, weighed, and examined by frozen section to evaluate the safety margins. In our study, we started first with the diseased breast, and after assessment of adequate tumor-free safety margins, the same procedure in the contralateral breast was done to assure symmetry, whenever indicated.

During the hospital stay, patients were assessed for the onset of wound infection, dehiscence, nipple and areola necrosis, and hematoma formation.



(A) De-epithelialization of the inferior pedicle. (B) De-epithelialization of the superior pedicle and excision of the tumor with a good safety margin.
 (C) Specimen excised and margins are marked for frozen section examination. (D) Reshaping of the breast parenchyma and closure of the incisions.

Figure 2

Figure 3



Post-operative view after bilateral inferior pedicle reduction with excellent cosmetic outcome after 3 months.

Figure 4



Postoperative view after bilateral superior pedicle reduction with excellent cosmetic outcome after 3 months.

For 1 month postoperatively, the outpatient visits were done on a weekly basis, where assessment was made for presence of complications including wound infections and persistent seroma in the breast and axilla, and then the patients were followed up monthly till the next 3 months after completion of the radiotherapy course. All patients received radiotherapy and adjuvant chemotherapy according to stage and type of the tumor.

The cosmetic evaluation was performed 3 months after the completion of radiotherapy course and classified

Figure 5



Postoperative result 1 week after superior pedicle reduction without contralateral symmetry.

Figure 6



Postoperative result 1 week after inferior pedicle reduction without contralateral symmetry.

according to both surgeon and patient judgment as excellent, good, fair, and poor.

The patients were followed up for 1 year every 3 months and every 6 months for the second year with at least 1 year of follow-up (12 months).

Statistical analysis was done by SPSS version 17 (SPSS Inc., IBM, Chicago, Illinois, USA). Mann–Whitney test was used for age and weight. The median and the range were used as descriptive analysis for the age and weight, whereas the percentage was used for the incidence of complications and assessment of cosmetic outcome.

Results

The age of the patients ranged from 34 to 60 (median: 41) years. There was no significant difference between the two groups regarding age and weight (P>0.05). The age of the patients in group 1 ranged from 36 to 60 years with a median of 42 years, whereas in group 2, the range was from 34 to 56 years, with a median of 40 years. The size of the tumor ranged from 1 to 5 cm. Most patients (60%) had breast cancer located in the upper outer quadrant of the breast. Most of the patients (43)

patients) were diagnosed as having infiltrating ductal carcinoma. The weight of patients in the inferior pedicle group ranged between 60 and 90 kg, with a median of 80.90 kg, whereas in the superior pedicle group, weight of the patients ranged between 58 and 85 kg, with a median of 80.28 kg. (*P*=0.841). Patient and tumor characteristics are listed in Table 1.

Regarding inferior pedicle group, the size of the tumor ranged from 1 to 4 cm. Most patients were diagnosed as having infiltrating ductal carcinoma (22 patients, 88%). The weight of tissues removed ranged from 400 to 830 g. The tumor safety margins ranged from 2 to 7 cm. One patient had infiltrated margin at frozen section after an attempt of re-excision and mastectomy was made (conversion rate of 4%).

Table 1 Patient and tumor characteristics

	Group 1 (inferior pedicle)	Group 2 (superior pedicle)	Total
Patients			
Age	36–60 years Median: 42	34–56 years Median: 40	34–60 years Median: 41 <i>P</i> >0.05
Weight	60–90 kg Median: 80.9	58–85 kg Median: 80.2 <i>P</i> =0.841	
Tumor pathology			
DCIS	1	1	
Invasive ductal carcinoma	22	23	
Invasive Iobular carcinoma	1	1	
Mucinous carcinoma	1	0	
Tumor stage			
T stage			
T1	7	5	12
T2	20	18	38
N stage			
NO	10	6	16
N1	19	15	34
Tumor grading			
G1	10	9	19
G2	15	8	23
G3	4	4	8
Tumor location			
Upper outer quadrant	16	14	30
Lower outer quadrant	5	6	11
Upper inner quadrant	1	0	1
Lower inner quadrant	3	5	8

DCIS, ductal carcinoma in situ.

In the superior pedicle group, the size of the tumor ranged from 1 to 5 cm. Most of the patients were diagnosed as having infiltrating ductal carcinoma (23 patients, 92%). There was no need for conversion to mastectomy or repeated excision. The weight of tissue removed ranged from 600 to 1100 g. The tumor-free safety margins ranged from 3 to 10 cm.

It should be noted that only two patients accepted to perform simultaneous breast reduction in the contralateral breast, one patient from each group.

Wound dehiscence was the commonest postoperative complication after inferior pedicle mammoplasty. It occurred in four (16%) patients, which was minor and affecting less than half of the longitudinal scar in three patients, and was managed conservatively. One patient had secondary infection with dehiscence affecting more than half of the longitudinal scar and was managed by secondary suturing after infection control.

On the contrary, wound dehiscence was less common after superior pedicle mammoplasty (two patients representing 8%), with one patient requiring secondary suturing.

Moreover, partial areolar necrosis and fat necrosis were equal in the two groups. In each group, one patient developed partial necrosis of the areola (two patients, 8%); these were small areas and were managed by debridement and secondary suturing.

Another two patients developed a small firm area along the suture line 9 and 12 months postoperatively after inferior pedicle and superior pedicle mammoplasty, respectively, and were investigated by sonogram and tru-cut biopsy, revealing traumatic fat necrosis that was surgically excised. The overall complications are listed in Table 2.

Table 2 Ove	erall complication	rate
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	•	
	Inferior pedicle group [n (%)]	Superior pedicle group [n (%)]
Minor skin necrosis	1 (4)	1 (4)
Wound dehiscence	4 (16)	2 (8)
Infection	2 (8)	2 (8)
Fat necrosis	1 (4)	1 (4)
Partial areola necrosis	1 (4)	1 (4)
Total areola necrosis	0	0
Seroma	4 (16)	2 (8)

Seroma was noticed more frequent in the inferior pedicle group (four cases, 16%) than superior pedicle group (two cases, 8%).

Three months after completion of the radiotherapy course, the cosmetic outcome was evaluated. In the inferior pedicle group, 15 (60%) patients showed excellent results, seven (28%) women showed good results, two (8%) patients had satisfactory result, and one (4%) patient showed poor result.

On the contrary, assessment of the cosmetic outcome using the superior pedicle showed the following: 16 (64%) women showed excellent, eight (30%) women patients showed good results, and one (6%) patient rated the outcome as fair. There were better outcomes in the superior pedicle group than the inferior pedicle group. Regarding the two patients who accepted to perform simultaneous contralateral reduction (one patient from each group), the cosmetic outcome was rated as excellent, and the patients were greatly happy with the result. In both groups, no local recurrence or systemic metastasis was noticed during the follow-up period, which ranged from 12 to 36 (median 24) months (Fig. 5).

Discussion

Although simple lumpectomy in patients with macromastia may lead to good cosmetic results, breast reduction of both sides improves symptoms such as back and shoulder pain and may thus improve the quality of life. Moreover, the homogeneity of radiation dose distribution may be altered in large breasts. Chronic radiation-induced pain, fibrosis, and a poor cosmetic result after radiotherapy are frequent problems. Thus, breast reduction may improve adjuvant radiotherapy effects [8].

Appropriate surgical treatment of early breast cancer in a large-breasted woman who is a candidate for breast conservation therapy requires good knowledge of the basic mammoplastic techniques to deal with the various technical modifications needed for each individual case. Local control could be a determinant of survival in a percentage of affected women, and large free margins of resection are recommended by the pioneers of BCT [9,10].

Mastectomy is associated with an unacceptable asymmetry. If a large-breasted patient was to undergo complete mastectomy and decides not to undergo a reconstruction procedure, the contralateral breast could cause intolerable asymmetry and discomfort owing to the huge breast volume and weight [11]. Oncoplastic surgery has proven to be an oncologically safe procedure, with rates of local recurrence, metastasis, and death comparable to breast conservation surgery [12].

In this study, reduction therapeutic mammoplasty was used for the management of early breast cancer in large-breasted women, and we consider it to be a more conservative and less radical procedure.

In our study, the median age of the patients was 41 years, which is close to the study of Denewer *et al.* [6], who reported the median age of the patients to be 43 years, and comparable to the study by Antony *et al.* [13], who reported a median age of 30 years.

In our study, $\sim 60\%$ of tumors were found in upper outer quadrant, which is comparable to the study of Losken *et al.* [14] and Lee [15], who reported that onehalf of breast cancers affect the upper outer quadrant alone.

Moreover, also our result is similar to Roshdy *et al.* [16], who reported \sim 60% of the tumors were found in the upper outer quadrant of the breast.

Ideally, each patient case should have the specific reduction technique individualized to their needs, but more than half the surgeons reported using only the inferior pedicle and inverted T skin pattern, so this is not always possible [17].

In our study, we divided our patients into two equal groups : group 1 (inferior pedicle group; 25 patients) and group 2 (superior pedicle group; 25 patients). The choice of the procedure depends on the location of the tumor. The inferior pedicle procedure was suitable for lesions in the upper pole of the breast, whereas the superior pedicle procedure was suitable for lesions in the lower pole of the breast.

In our study, conversion to mastectomy was required in one (4%) case of our 50 patients with cancer treated with total radical mastectomy (TRM) owing to positive margin in frozen section inspite of repeated attempt to obtain free margin, which can be compared positively with other study, where Fitoussi *et al.* [18] in 2010 found a positive marginal rate was 18.9%, which led to mastectomy in 9.4% of the patients, with 540 patients in their oncoplastic surgery-related study [18].

In the study of Giacalone *et al.* [19] in 2006, positive surgical margin and re-excision rates are found to be lower in the oncoplastic surgery group, with 42

oncoplastic surgeries and 57 breast conserving surgery (BCS) applied patients.

In our series of inferior pedicle, one patient had infiltrated margin at frozen section after two attempts of excision and mastectomy was performed (conversion rate of 4%). In superior pedicle mammoplasty, there was no conversion to mastectomy owing to the easy attainment of tumor-free safety margins in all cases, because of wider excision being possible in large breasts.

McCulley and MacMillan [20] in 2005 reported a series of 50 patients with breast cancer treated with therapeutic mammoplasty, in which four (8%) patients required reoperation owing to surgical margin involvement. In these series, three different oncoplastic techniques were used.

Clough *et al.* [2] in 2003 found surgical margin involvements in 11 (10.9%) of their 101 patients with breast cancer whom were treated with oncoplastic surgery.

Regarding complications, in the literature, the complication rate for oncoplastic breast reduction ranges between 17 and 24%. Common complications include skin necrosis, infection, and partial or complete nipple areolar complex necrosis, according to Munhoz and colleagues reports [21–23].

Caruso *et al.* [24], evaluated the outcomes in 61 cases treated using reduction mammoplasty and reported five cases of skin complications and one case of partial nipple necrosis.

However, Munhoz *et al.* [25], reported an immediate complication rate of 17.6%, comprising skin necrosis (8.1%), infection (2.7%), partial necrosis of the nipple–areola complex (2.7%), dehiscence (1.35%), and total necrosis of the nipple–areola complex (1.35%).

Skin necrosis and wound dehiscence are the most often reported complications after therapeutic reduction mammoplasty [26].

Our complication rate is comparable to these result as in our study we reported complications as follow: 10 (20%) cases developed seroma, six (12%) cases developed wound dehiscence, four (8%) cases developed wound infection, and two (4%) case developed partial areolar necrosis. These complications neither affected the general health of any patient nor caused a delay in adjuvant treatment. It should be noted that the inferior pedicle technique shows a higher percentage of complications compared with the superior pedicle technique as listed in Table 2.

Our reported rate of patient satisfaction as excellent ranges between 15/25 women (60%) and 16/25 women (64%) after inferior pedicle and superior pedicle mammoplasty, respectively. In two patients who accepted to perform simultaneous contralateral reduction (one patient from each group), the cosmetic outcome was rated as excellent, and the patients were greatly happy with their result.

In comparison with other reports, Chang *et al.* [27] in 2004 evaluated the degree of patient satisfaction and cosmetic results, and 20/37 (54%) women and 14/20 (70%) women reported excellent results. No local recurrence was observed in follow-up period, which ranged from 12 to 36 (median 24) months [28].

Caruso *et al.* [24] in 2008 reported one (1.6%) case of local recurrence with a follow-up period of 68 months, and Chang *et al.* [27] showed a zero recurrence rate.

Long-term outcomes in larger scale multi-institutional studies investigating oncoplastic reduction mammoplasty as a curative surgical treatment of breast cancer remain a major issue for its oncologic radicality procedure in Egyptian women regarding the risk of local recurrence.

Conclusion

Therapeutic reduction mammoplasty using inferior and superior pedicle mammoplasty for early breast cancer in large-breasted women is a surgically and oncologically safe procedure. The superior pedicle mammoplasty has less postoperative morbidity and more satisfactory cosmetic outcome with lower morbidity than inferior pedicle mammoplasty.

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Conflicts of interest

There are no conflicts of interest.

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The outcome of using a prosthetic mesh in the repair of emergent abdominal midline incisional hernias: a prospective comparative study

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Objective

The aim of the study is to evaluate the efficiency and safety of mesh repair in emergent complicated midline incisional hernias as well as the impact on the early postoperative (PO) morbidity and mortality to implement the best patient management procedure.

Patients and methods

The study includes 60 patients with emergent midline incisional hernias. Patients were divided according to the type of closure of hernia defect into two groups, group A (30 patients) was managed with a prosthetic mesh repair and group B (30 patients) was managed by primary suture repair. We used the alternation method as an allocation process. Patients in both groups were monitored during operations and along the PO period. The data collected include the patients' condition at presentation, coexisting disease, operative data and PO complications, length of hospital stay, surgical site infection (SSI) and recurrence rates.

Results

A total of 60 patients underwent operations for emergent midline incisional hernias with (*N*=30) and without (*N*=30) the use of mesh repair. There is no significant difference between mesh and nonmesh groups about the mean operative time (*P*>0.05). Besides, there was no significant difference between both groups concerning the total hospital stay days. The SSI rate in the mesh repair group was 10%, while it was 6.7% in the primary suture repair group. The SSI rate was high among diabetic patients and those with chronic liver illness. The follow-up period ranged between 25 and 48 months with a significant difference between both groups regarding the recurrence rate (*P*<0.05).

Conclusion

Our prospective study offers an evidence that with adequate antiseptic precautions, it is possible and safe to use a nonabsorbable mesh in the repair of emergent abdominal wall midline incisional hernias with a significant decline in the recurrence rate.

Keywords:

emergent hernia, mesh repair, primary suturing, surgical site infection

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Introduction

Abdominal wall hernias were categorized as groin hernias (inguinal and femoral) and ventral hernias (epigastric, umbilical, incisional, port site and spigelian) [1]. A large percentage of abdominal hernias necessitate emergency intervention where operations were accompanied with a greater rate of postoperative (PO) morbidities [2]. An incarcerated hernia is a hernia in which the contents have converted irreducible due to sac adhesions or a narrow defect; it can be complicated by a bowel obstruction [3]. In the strangulated hernia, the blood supply of the hernia contents (gut and/or omentum) becomes compromised and necessitate urgent surgery [3]. It carriages a major hazard to emergency hernia repair, as there is a higher incidence of surgical field contamination as well as PO infection [4].

Bacteria colonize all surgical wounds, but only a few of these lead to infection. Host defenses are capable of eradicating microbes at the surgical site. Inserting a foreign material as mesh may lead to a reduced threshold for infection [5,6]. Biologic mesh declines the immune response against the foreign body, as well as declining the incidence of fibrosis, erosion and fistula formation [7].

The first use of mesh for hernia repair was in 1958 by Usher and colleagues, with the debut of polyethylene mesh [8]. The usage of the mesh has considerably

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diminished hernia recurrence in comparison with primary repair [9]. There has been a higher dependence on the mesh in hernia repair, either for supporting the abdominal wall or bridging the wall defect. Numerous studies display strong advantages of mesh use in elective cases, where the infection is scarce. According to the World Society of Emergency Surgery, limited studies have examined the outcome of mesh repair in an emergency situation [1]. From this point, we performed our present work to evaluate the usage of synthetic mesh in the repair of emergent midline incisional hernias.

Patients and methods

The current study implemented in the General Surgery Department, Banha University Hospital, Egypt and King Saud Hospital in Saudi Arabia since August 2013 till August 2017. Our study included 60 patients with emergent abdominal wall midline incisional hernias after approval of the study protocol by the local ethics committee. Patients were familiar with the potential hazards and benefits of both options (mesh repair and primary suture repair) and obtained fully informed written consent for participation in the study; patients were admitted and were clinically evaluated. An extra consent was taken for the surgical operation. Patients enrolled in the study if they fulfilled our inclusion criteria.

We defined emergent hernia repair as any repair that was done in a nonelective approach, within 24h of the patient presentation to our emergency department, suffering from acute pain, vomiting, absolute constipation and unable to reduce the hernia manually, as it was previously. Inclusion criteria for our study were: Complicated midline incisional hernias necessitating emergent open surgical repair, age at least 18 years and up to 70 years, BMI less than 35 kg/m², the patient capability to offer informed consent and undergo the study procedure, and American Society of Anesthesiology (ASA) score of I-III. Exclusion criteria include participation in an additional device or drug study, clinically infected hernia site, notable psychiatric disease, ASA score of at least IV, and purulent peritonitis due to gangrenous gut.

Patients were divided into two groups (30 patients in each group) according to the type of closure of hernia defect as either mesh repair (group A) or primary suturing (group B). In our study, we used the 'alternation' method as an allocation process, which is not relying on anyone's individual decision. In this distribution method, we did mesh repair to the first patient who was involved in the study, then primary suturing to the second patient, then mesh repair to the third patient, and so on. The primary endpoint was the evaluation of procedure time and the early PO complications with secondary endpoint including hernia recurrence within the four years of the study. Data were collected from each participating hospital.

Preoperative preparation

All included patients were examined clinically for demographic data including age, sex, BMI, coexisting morbidities and the type of hernia complications. All patients underwent routine laboratory investigations, ECG, abdominal radiographs in erect and supine positions and abdominal ultrasonography with a duplex study to check hernia contents viability. Patients received prophylactic intravenous antibiotic (metronidazole 500 mg and ceftriaxone 1 g) 1 h before surgery.

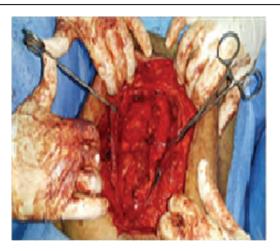
Operative technique

Operations were done under general anaesthesia. A long incision was made in the overlying hernial sac with the removal of the old scars. The hernial sac dissected and opened at the neck, with suction of any fluids inside the sac. The deficit widened in strangulated hernias to release the constriction, release of adhesions between the contents and around the hernia defect. The viability of the sac contents was evaluated, suspicious bowel covered with warm wet towels for 15 min while gangrenous contents resected and bowel continuity held. The hernial sac was preserved for a probable need for closure, flaps were raised by separation of the subcutaneous (SC) tissue from the anterior rectus sheath. Irrigation of the SC tissue was done at the surgical sites with 10% povidone iodine solution (1% available iodine) for 60 s, followed by copious amounts of warm normal saline 0.9% to wash out any residual infection or any minute tissue debris before mesh implantation. Change of surgical gloves, towels, drapes and contaminated instruments should be done.

In the mesh repair group, a bilateral tunnel was fashioned in the recuts sheath through dissection of the posterior rectus sheath from the rectus muscles. Edges of the posterior layers of right and left rectus sheaths were sutured to each other's (Fig. 1). A polypropylene mesh was inserted behind both rectus muscles, extended for at least 5 cm on both sides, cranial, and caudal of the suture line. The mesh was fixed to the anterior rectus sheath with interrupted nonabsorbable polypropylene sutures passing through the rectus muscle (Fig. 2). The anterior layers of the rectus sheath on both sides were sutured to each other with a running nonabsorbable suture (Fig. 3). Hernias with a large defect managed by either bilateral component separation with an approximation of the two recti or by use of the hernial sac medially as an interposition between the polypropylene mesh and bowel loops. Then, an onlay mesh was inserted and fixed in both conditions. The skin closed over SC 18 Fr suction drain (Fig. 4).

In the primary suturing group, after irrigation of the SC tissue at the surgical sites, the two recti were sutured to each other with a running nonabsorbable suture enforced with interrupted sutures. Large hernias (Fig. 5) were managed with bilateral component separation (Fig. 6) to allow closure of the defect with a running nonabsorbable suture enforced with

Figure 1



Posterior layers of rectus sheaths were sutured to each other.

Figure 2



Mesh inserted behind both recti, fixed to anterior rectus sheath with interrupted sutures through rectus muscle.

multiple simple sutures without tension. The kin closed over SC 18 Fr suction drain.

Figure 3



Anterior layers of both rectus sheathes were sutured to each other's.

Figure 4



An onlay synthetic mesh with 18 Fr suction drains.

Figure 5



An obstructed large midline incisional hernia.

Figure 6



Multiple release incisions through the exsternal oblique muscle.

Postoperative follow-up

- (1) Patients were encouraged for early ambulation with a proper abdominal binder.
- (2) The intra-abdominal tension assisted through a urinary bladder catheter if abdominal hypertension was suspected. However, in all cases, we did not record any noticeable increase in the intraabdominal pressure.
- (3) Drains were removed after 2 days or when it became minimal (<50 ml in 24 h).
- (4) On discharge from the hospital, patients were instructed to avoid lifting heavy objects and rapid treatment of constipation and cough. There was outpatient clinic follow-up every week after discharge for the first month, then every 3 months during the first year.
- (5) Follow-up ranging from 25 to 48 months.
- (6) Wound infection [surgical site infection (SSI)] recognized as a pussy discharge/collection as well as redness related to the operation site and fever or leucocytosis. However, seroma was determined during the outpatient clinic visit when there is a sterile serous fluid collected in the operative field subsequent to drain removal. Abdominal wall ultrasonography was done when there is any swelling related to operation field.
- (7) During the first PO month, three patients of the mesh repair group were readmitted due to fever, leucocytosis and wound infection, which subsided in two patients with IV antibiotics and local dressing. However, the third patient did not respond to conservative management and reoperated 25 days PO for drainage of a deep settled infection, an onlay mesh was removed, the wound was irrigated and kept open for frequent dressing and for secondary suture 2

weeks later. On the other hand, two patients of group B were readmitted due to wound infection, they responded to conservative management.

- (8) Seroma was aspirated in the outpatient clinic by using a 50 ml sterile syringe under aseptic condition with the guidance of ultrasonography.
- (9) Hernia recurrence was confirmed by an abdominal ultrasonography after taking a proper history and clinical examination.

Statistical analysis

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

Results

The study comprised 60 patients with emergent midline incisional hernias. Patients were divided into two groups (30 patients in each group) according to the type of closure of hernia defect as either mesh repair (group A) or primary suturing (group B). There were no difference between both groups regarding age, sex, BMI, and ASA score distribution or medical history. Patients' demographic data are clearly shown in Table 1.

The mainstream of patients in both groups passed the operations easily without intraoperative complications. The mean operative time with the mesh repair group was higher 110±20.91 compared with 95±18.07 in the primary suturing group; however, there was no significant difference in operative time between both groups. No significant difference between both groups regarding total ICU admission days and total hospital stay days. The details of the operations and PO period are summarized in Table 2.

Within a mean follow-up period of 35 ± 7.26 months, the total number of PO complications was the same in the two groups. There were no significant differences regarding SSI and seroma formation between both groups. However, there was a significant difference (P=0.041) regarding recurrence rate between both groups. The rate of SSI was slightly higher among patients managed with mesh repair than primary suturing repair (10 vs. 6.6%, respectively). Details of PO complications are mentioned in Table 3.

Data	Strata	Mesh repair group	Primary suturing group	P-value
n (%)	60	30 (50)	30 (50)	
Age (years)		45.73±13.31 (20-70)	43.70±13.62 (19-69)	0.229
Sex	Males	14 (46.7)	15 (50)	NS
	Females	16 (53.3)	15 (50)	NS
BMI (kg/m ²)		30.33±2.73 (26-35)	31.26±3.09 (25–33)	0.508
ASA score		1.66±0.71 (1–3)	1.60±0.81 (1-3)	0.365
Coexiting disease ^a	Diabetes	9 (30)	8 (26.6)	NS
	Hypertension	8 (26.6)	6 (20)	NS
	IHD	5 (16.6)	4 (13.3)	NS
	Chronic liver disease	9 (30)	7 (23.3)	NS
	Chronic lung disease	6 (20)	8 (26.6)	NS
	CRF	1 (3.3)	1 (3.3)	NS
Type of hernia complications	Irreducible	4 (13.3)	6 (20)	NS
	Incarcerated	6 (20)	5 (16.7)	NS
	Obstructed	11 (36.7)	8 (26.6)	NS
	Strangulated	9 (30)	10 (33.3)	NS

Table 1 Patients' demographic data

Data are presented as mean±SD and numbers; ranges and percentages are in parentheses; ASA, American Society of Anesthesiologists; CRF, chronic renal failure; IHD, ischemic heart disease; ^aSome cases had more than one coexisting disease.

Table 2 Operative and 30 days postoperative data

Data	Strata	Mesh repair group (n=30)	Primary suturing group (n=30)	P-value
Operative time (min)		110±20.91 (80–190)	95±18.07 (60-150)	0.103
Intraoperative blood loss		148±44.9 (100-250)	139±44.50 (50-250)	0.318
Bowel resection		6 (20)	7 (23.3)	NS
ICU admission (days)	Total (days)	2.00±1.22 (1-4)	4.6±3.05 (1-8)	0.251
Hospital stay (days)	<5	12 (40)	14 (46.7)	
	5–7	10 (33.3)	11 (36.7)	
	8–10	5 (16.7)	3 (10)	
	>10 days	3 (10)	2 (6.6)	
	Total (days)	6.73±4.63 (3–23)	6.00±4.12 (2-20)	0.223
Reoperation	Due to SSI	1 (3.3)	0.0	NS
Readmission	Due to SSI	3 (10)	2 (6.6)	NS
	Due to medical morbidities	1 (3.3)	3 (10)	NS

Data are presented as mean±SD and numbers; ranges and percentages are in parentheses; PO, postoperative; SSI, surgical site infection.

Table 3 Postoperative complications

Strata	Mesh repair group (n=30)	Primary suturing group (n=30)	P-value
Hematoma/bleeding	2 (6.7)	1 (3.3)	NS
SSI	3 (10)	2 (6.6)	NS
Seroma	2 (6.7)	2 (6.7)	NS
Hospital acquired chest infection	0.0	1 (3.3)	NS
Recurrence	2 (6.6)	5 (16.6)	0.041
Total events	13	13	NS

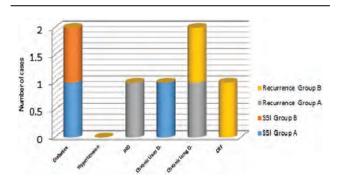
Data are presented as n (%) are in parentheses; SSI, surgical site infection.

In our study, the SSI appears to be more frequent among diabetic patients, while other PO complications were not related to any of the chronic comorbidities. The frequency of PO complications was related to the chronic coexisting diseases (Fig. 7). The least number of PO complications was recorded among patients with irreducible hernias, there is only one recurrent case. The frequency of PO complications was related to the type of hernia complication (Fig. 8). Besides, we found that the hazard for SSI was slightly higher among cases of bowel resection in the mesh repair group (two out of six) compared with (one out of seven) cases in the primary suturing group. The frequency of PO complications in relation to bowel resection in strangulated hernias was shown in Fig. 9.

Discussion

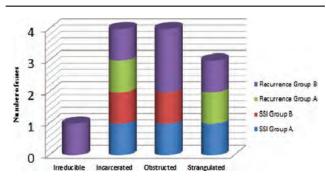
Numerous studies have shown a clear worldwide approval about the benefits of mesh repair in elective

Figure 7



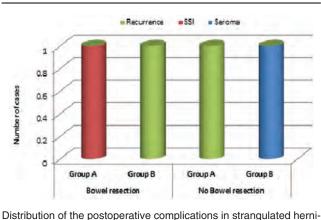
The frequency of postoperative complications in relation to the chronic coexisting diseases. CRF, chronic renal failure; IHD, ischemic heart disease; SSI, surgical site infection.

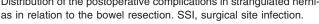
Figure 8



The frequency of postoperative complications in relation to the type of hernia complication. SSI, surgical site infection.

Figure 9





cases, where the infection is unusual and mesh significantly decreases the rate of recurrence, yet it has low complication rates [10]. On the reverse, limited researches have studied the outcome of mesh use in an emergency situation, where there is frequently surgical field contamination due to bowel involvement [3]. Approximately 5–15% of all patients with abdominal wall hernias were operated in emergent conditions [11]. Approximately 20% of all patients with complicated hernias require bowel resection due to gangrene caused by strangulation [12]. Propylene material was selected for the synthesis of surgical meshes due to its property of resistance to infection. It is a monofilamentous structure and wide pores allow infiltration of immune cells and antibiotics [13]. Up to date, the mesh is not habitually used in the repair of emergent hernias and most surgeons depend on primary suture repair for management of such conditions; this may be attributed to the panic of PO wound complications, especially in cases in which bowel is strangulated in the hernial sac and there is a need for resection [14]. For this reason, we aimed to study the consequence of acutely complicated abdominal wall hernias repaired with nonabsorbable mesh.

The rate of SSI in our study was higher among patients managed with mesh repair than the primary suturing repair group (10 vs. 6.6%, respectively). Moreover, we found that the hazard for wound infection was slightly higher among cases of bowel resection in the mesh repair group (two out of six) compared with one out of seven cases in the primary suturing group. In our study, the SSI appears to be more frequent in diabetic patients, while other PO complications were not related to any of the chronic comorbidities. This goes with Cavallaro et al. [14] who mentioned that for patients with incarcerated hernia and no signs of bowel strangulation or coexisting bowel resection, the surgical area is maintained clean and the infectious hazard for the inserted synthetic mesh is low. The study justifies this as the lack of bowel ischaemia renders patients less subjected to bacterial translocation, which may lead to contamination of the surgical field. Massimo and colleagues [1,15] also concluded that in patients with bowel strangulation and/or simultaneous bowel resection (potentially contaminated field), the primary suture is suggested when the hernia defect is small (<10 cm). However, the biological mesh repair can be implemented with caution. Xourafas et al. [16] studied the influence of mesh use on ventral hernia repairs with concurrent gut resections; they found a significantly greater incidence of PO infection in patients with mesh repair compared with those without mesh. They documented that the use of a mesh was the only significant risk factor regardless of other variables such as defect size, bowel resection or drain use. Besides Choi et al. [17] reported that, compared with clean cases, clean-contaminated cases showed a significantly higher chance of SSIs, wound disruption and sepsis. On the reverse, other studies have declared that mesh repair of

abdominal hernias can be securely performed together with simultaneous colonic operations. Antonopoulos *et al.* [18] reported that mesh repair is safe and effective in managing infected or contaminated hernias in kidney transplant patients. This is after taking into consideration wound irrigation with normal saline, repair with primary fascial approximation, prosthetic mesh reinforcement, large-bore drains and PO broad-spectrum antibiotics.

According to Kassem and El-Haddad [19], onlay positions are the favourite mesh positions in complicated ventral hernias. However, we believe that the inlay positioning of a synthetic mesh has many benefits; avoid hazards of intraperitoneal mesh on the bowel, away from possible SC tissue infection and escape the wide SC dissections to raise the flaps. This has also been reported in many other studies. The sequelae of wound infections in the present study are relatively minor. Most wound infections in the mesh repair group responded to conservative management (antibiotics and/or regional wound dressings) and were discharged home in decent clinical condition. Single and infected onlay mesh was removed at the operating theatre 25 days following mesh repair of a strangulated incisional hernia. The comparatively low percentage of infectious complications in our study can be referred to the strict aseptic precaution done before mesh placement, preoperative and PO use of broad-spectrum antibiotics and exclusion of cases with septic peritonitis as well as morbidly obese patients. Also, bowel resection was done in merely 20 and 23.3% of mesh repair and primary suturing group, respectively. Our findings correspond to the report of Hasbahceci and Basak [20], who found the same low rates of wound infections after usage of prosthetic mesh in the repair of acute hernias. On the other hand, 13.3% established different degrees of seroma; aspiration for variable volumes of seroma was performed under complete aseptic conditions in an outpatient clinic, and culture obtained from the aspirated fluid; however, no organism detected in all cases. To diminish the hazard of seroma, we recommend some rules that should be followed including kind dissection, slight use of diathermy, accurate hemostasis and prolonged times of drainage. Inlay and retrorectal mesh positions helped to reduce dissection and this leads to lower incidence of seroma formation in our study since this way creates a potential space in which a seroma can form. Montgomery [7] agree with us and mentioned that seroma was somewhat more with the onlay mesh associated with SC dissection.

Recurrence rates in our study are significant in nonmesh compared with the mesh group (P=0.041).

Recurrence rates were 6.7 versus 20% in mesh repair and primary suturing, respectively, after a mean followup period of 35±7.26 months. The overall low recurrence rates may be attributed to the low rate of infection and proper surgical techniques. This goes with the results of Sorour [21]; however, they referred low recurrence rate to the adequate overlap of the mesh over the hernia defect for at least 5 cm and low wound infection rates. Lukasiewicz and Drewa [12] suggested that leaving a dead space, incorrect mesh placement and fixation are important factors for recurrence.

Conclusion

This prospective study provides confirmation that it is possible and safe to use a prosthetic mesh in the repair of emergent complicated abdominal wall midline incisional hernias, permitting reinforcement of the abdominal wall, even if the operation is associated with simultaneous bowel resection. The adequate antiseptic precautions and suitable surgical techniques should be taken into consideration.

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Conflicts of interest

There are no conflicts of interest.

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Value of cluster of differentiation 56, Hector Battifora mesothelial-1, and cytokeratin 19 expression in predicting the risk of papillary thyroid carcinoma occurrence in Hashimoto's thyroiditis patients, which will advise early total thyroidectomy in those patients

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Background

There were no previous studies that have tried to find the prediction of papillary thyroid carcinoma (PTC) occurrence in Hashimoto's thyroiditis (HT) that will advise early thyroidectomy in HT cases with high risk of progression to PTC.

We aimed to use a panel of cluster of differentiation 56 (CD56), Hector Battifora mesothelial-1 (HBME-1), and cytokeratin 19 (CK19) to detect their predictive ability for HT progression into PTC.

Patients and methods

We included five groups of paraffin blocks that were retrieved from 70 patients. The first group included 20 cases of PTC, the second group included 20 samples from the same cases previously diagnosed as HT, the third group included 30 cases of HT, the fourth group included 30 samples from the same cases previously diagnosed as HT, and the fifth group had 20 cases of PTC without a history of HT. The sections were stained by CD56, HBME-1, and CK19 using immunohistochemistry.

Results

There is a significant difference between the second (HT that will be transformed to PTC) and the fourth (HT that will not be transformed to PTC) groups as regards CD56, HBME-1, and CK19 expression (P=0.012).

For the differentiation between HT that will be transformed to PTC from HT that will not be transformed to PTC, negative CD56 expression was of highest sensitivity (90%) and diffuse positive HBME-1 expression was of highest specificity (95.7%).

Conclusion

A combination of negative CD56 expression and diffuse positive HBME-1 could be used with high sensitivity and specificity in predicting PTC occurrence in certain cases of HT and these patients will be advised to early total thyroidectomy to avoid PTC occurrence in the future.

Keywords:

cluster of differentiation 56, cytokeratin 19, Hashimoto's, thyroiditis, Hector Battifora mesothelial-1, immunohistochemistry, papillary thyroid carcinoma, total thyroidectomy

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Introduction

The most common thyroid malignancy is the papillary thyroid carcinoma (PTC) that forms about 80% of thyroid malignancies [1]. The most common autoimmune disease of the thyroid gland is Hashimoto's thyroiditis (HT) which the commonest cause of hypothyroidism [2]. The association and pathogenic relations between HT and PTC remains controversial and still need further qualifications [3]. Dailey *et al.* [4] first described that there is a relationship between both thyroid lesions in 1955 and since then, there are many researchers who have tried to cover such scientific point but they provided

conflicting results. It is essential also to mention that molecular analyses have indicated that PTC had a high amount of lymphocytic infiltration that suggested the role of immunological factors in malignant progression [5,6]. The management of HT patients is mostly conservative with L-thyroxine [7]. Moreover performing total thyroidectomy is not preferred for such patients due to

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the presence of inflammatory response that surrounds the thyroid gland and leads to more difficult surgical resection [8]. There are few indications for early surgical intervention in HT patients, for example worsening of clinical symptoms that are related to the disease, malignancy suspicion, or a goiter with marked increase in size [8-10]. Although a plethora of studies have identified the indications of surgery in patients with HT [11], performing early thyroidectomy is still a controversial method for their management. So it would be beneficial to use the available biomarkers to predict the cases of HT that will have a high liability of progression to PTC, which will be helpful in performing early thyroidectomy for those patients even if there are no marker disfigurement or marked pressure symptoms.

An increasing number of promising biomarkers have emerged for differentiation between benign and malignant thyroid lesions, for example cluster of differentiation 56 (CD56), Hector Battifora mesothelial (HBME-1), and cytokeratin 19 (CK19). CD56 is an adhesion molecule that is present in the neural cells [12]. It is expressed in normal nonneoplastic thyroid follicular cells with decreased expression in thyroid malignancies mainly PTC [13]. HBME-1 exists in the microvilli of tracheal epithelium and mesothelial cells [14]. There are many previous studies that have clarified the role of HBME-1 expression in thyroid malignancies like PTC [15]. CK19 is an intermediate filament protein of type I that is widely expressed in normal epithelial cells [12]. A lot of researchers have clarified its strong and diffuse positivity in PTC [16]. Many of all those studies have assessed only the expression of a single marker of them in benign and malignant thyroid lesions, but only few of them have explored the value of their combined expression [17,18]. Moreover, most studies have assessed the roles of such markers in PTC diagnosis or to distinguish HT from PTC, but we noticed that there are no previous study which tried to assess the value of using such markers in the prediction of PTC occurrence in HT patients that will advise performing early thyroidectomy in HT cases with high risk of progression to PTC before its occurrence which will subsequently decrease the malignancy risk in such patients.

Therefore, we aimed in the present study to evaluate the usefulness of using a panel of the most sensitive and specific markers for PTC, as previously mentioned, for example CD56, HBME-1, and CK19 individually and in combination, to detect their ability to differentiate HT from PTC and detect their value in the prediction

of malignant progression of certain cases of HT to PTC.

Patients and methods

In the period between January 2012 and December 2016, 200 consecutive patients with either solitary thyroid nodule or multinodular goiter underwent total thyroidectomy in the General Surgery Hospital, Oncology Unit, Faculty of Medicine, Zagazig University and El Mansura University. We include in our study 70 patients that had a previous history of subtotal thyroidectomy. Our cases were divided into 20 cases of PTC with a previous history of HT, 20 cases of PTC without a previous history of HT, and 30 cases that was diagnosed as HT in the Pathology Department, Faculty of Medicine, Zagazig University. Data from all patients were retrospectively obtained from the files of the shared departments. All the 70 thyroidectomy samples are processed and subjected to routine hematoxylin and eosin stain. We ordered all cases to bring their paraffin blocks that was acquired by subtotal thyroidectomy to do our research on them and on blocks retrieved from the total thyroidectomy samples. In such a method the results classification comprises five groups. First group - 20 paraffin blocks of total thyroidectomy specimen that were recently diagnosed as PTC. Second group - 20 paraffin blocks of the same cases historically diagnosed as HT by subtotal thyroidectomy since variable periods. Third group – 30 paraffin blocks of total thyroidectomy specimen that were recently diagnosed as HT. Fourth group - 30 paraffin blocks of the same cases historically diagnosed as HT by subtotal thyroidectomy since variable periods. Fifth group - 20 paraffin blocks of that were diagnosed as PTC without a previous history of HT.

The collection and subsequent analysis of patients' data was duly approved by the IRB Committee in Faculty of Medicine, Zagazig University. The gross and histopathological features of each case were evaluated independently by two pathologists before arriving at the final diagnosis. We used the tumor, node, and metastasis staging system modified by the American Joint Committee on Cancer – Cancer Staging, seventh edition for surgical staging of PTC [19].

Immunohistochemical staining

Sections from paraffin blocks that were retrieved from the five groups were deparaffinized in xylene and rehydrated in absolute alcohol. Antigen retrieval in citrate buffer was used after the sections were treated in a microwave at 8 W for 6 min, and the sections were then left to cool for 20 min.

Peroxidase blocks were done. After that we incubated the slides with the primary anti-CD56 (clone 123C3, 1 : 100; DakoCytomation, Glostrup, Denmark); anti-HBME-1 (clone HBME-1, 1: 50; DakoCytomation), and anti-CK19 (1: 100; DakoCytomation) antibodies at room temperature, and then washed them lightly in PBS, at a pH of 7.6. Subsequent to this incubation with the secondary biotin-conjugated antibody for 1 h was done and then with peroxidase-conjugated streptavidin. Diaminobenzidine tetrachloride was added for 25 min, and finally the slides are counterstained in hematoxylin, then we dehydrated the slides, cleaned, and mounted them [20]. Positive and negative control slides were included. Positive controls were sections from neuroblastoma, mesothelioma, and skin for CD56, HBME-1, and CK19, respectively. Negative controls were done by the removal of primary antibodies and their replacement with PBS [21].

Interpretation of immunohistochemical (IHC) staining of the studied markers:

- (1) Membranous expression with or without cytoplasmic staining of the cells qualified the case as positive for CD56 and CK19 [16,21].
- (2) Cytoplasmic expression with or without membranous staining of the cells qualified the case as positive for HBME-1 [22].

Scoring for the immunomarkers by semiquantitative assessment of marker expression:

- (1) For all antibodies, immunoreactivity was considered positive if more than 10% of follicular epithelial cells were stained [32].
- (2) The immunoreactivity was scored as negative, focally positive (+: <25%), positive (++: 25–50%), or diffusely positive (+++: >50%), based on the extent of the reaction [21–23].

Statistical analysis

Quantitative data were expressed as the mean±SD and median (range), and qualitative data were expressed as absolute frequencies (number) and relative frequencies (percentage). Categorical data were compared using χ^2 -test or Fisher's exact test when appropriate. Paired categorical variables were compared using McNemar's test. All tests were two sided. A *P* value of less than 0.05 was considered statistically significant. Validity IHC was calculated using diagnostic performance depending on sample 2×2 contingency tables generation using the histological examination as the reference (gold) standard. The sensitivities, specificities, positive predictive values, negative predictive values, and accuracies, with their respective 95% confidence intervals were calculated. All data were collected, tabulated, and statistically analyzed using SPSS 20.0 for windows (SPSS Inc., Chicago, Illinois, USA) and MedCalc 13 for windows (MedCalc Software byba, Ostend, Belgium).

Results

Patients criteria

The clinical data of the patients are summarized in Table 1

Our study included 10 (14%) men and 60 (86%) women with age ranged from 29 to 51 years for patients with PTC with a history of HT, 29–52 years for patients with PTC without a history of HT, and 22–40 years for patients with HT.

- (1) First group: 20 paraffin blocks of total thyroidectomy specimen that were recently diagnosed as PTC, included two (10%) men and 18 (90%) women.
- (2) Second group: 20 paraffin blocks of the same cases historically diagnosed as HT by subtotal thyroidectomy for variable periods.
- (3) Third group: 30 paraffin blocks of total thyroidectomy specimen that were recently diagnosed as HT included three (10%) men and 27 (90%) women.
- (4) Fourth group: 30 paraffin blocks of the same cases historically diagnosed as HT by subtotal thyroidectomy for variable periods.
- (5) Fifth group: 20 paraffin blocks that were diagnosed as PTC without a previous history of HT included five (25%) men and 15 (75%) women.

Immunohistochemical expression in the studied thyroid

CD56 expression in the studies lesions

Among the first group, negative CD56 expression was detected in 16 (80%), focal positive CD56 expression was observed in two (10%), and diffuse positive CD56 expression was found in two (10%) of the cases of PTC that was on top of HT (Tables 1 and 2, Figs. 1e, f, 2e and 3c.

Among the second group, negative CD56 expression was detected in 10 (50%), focal positive CD56 expression was observed in eight (40%), and diffuse positive CD56 expression was found in two (10%) of the cases of HT that were found to be transformed into PTC later on.

Among the third group, negative CD56 expression was detected in five (16.7%), focal positive CD56

					P value	
	PTC with HT (N=20)	PTC without HT (N=20)	HT (<i>N</i> =30)	P ₁	P ₂	P ₃
Sex						
Male	2 (10)	5 (25)	3 (10)			
Female	18 (90)	15 (75)	27 (90)			
Age (years)						
Mean±SD	40.75±7.12	41.20±8.04	31.06±4.89			
Median (range)	38.50 (29–51)	38.50 (29–52)	30 (22–40)			
HBME-1 (historical H	IT)					
Negative	4 (20)		22 (73.3)	<0.001 ^a		
Focal positive	8 (40)		7 (23.3)			
Diffuse positive	8 (40)		1 (3.3)			
HBME-1 (recent)						
Negative	2 (10)	3 (15)	22 (73.3)	<0.001 ^a	0.619 ^a	<0.001 ^a
Focal positive	4 (20)	6 (30)	7 (23.3)			
Diffuse positive	14 (70)	11 (55)	1 (3.3)			
P value	0.031 ^b		1.000 ^b			
CK19 (historical HT)						
Negative	4 (20)		21 (70)	<0.001 ^a		
Focal positive	5 (25)		7 (23.3)			
Diffuse positive	11 (55)		2 (6.7)			
CK19 (recent)						
Negative	3 (15)	5 (25)	21 (70)	<0.001 ^a	0.717 ^a	<0.001 ^a
Focal positive	4 (20)	4 (20)	7 (23.3)			
Diffuse positive	13 (65)	11 (55)	2 (6.7)			
P value	0.375 ^b		1.000 ^b			
CD56 (historical HT)						
Negative	10 (50)		5 (16.7)	0.012 ^a		
Focal positive	8 (40)		12 (40)			
Diffuse positive	2 (10)		13 (43.3)			
CD56 (recent)						
Negative	16 (80)	17 (85)	5 (16.7)	<0.001 ^a	0.834 ^a	<0.001 ^a
Focal positive	2 (10)	2 (10)	12 (40)			
Diffuse positive	2 (10)	1 (5)	13 (43.3)			
P value	0.070 ^b		1.000 ^b			

Table 1 Comparison between studied	groups as regards demographic and	immunohistochemical staining

Categorical variables were expressed as number (percentage); continuous variables were expressed as mean±SD and median (range); CD56, cluster of differentiation 56; CK19, cytokeratin 19; HBME-1, Hector Battifora mesothelial-1; HT, Hashimoto's thyroiditis; PTC, papillary thyroid carcinoma; P_1 , papillary thyroid carcinoma with Hashimoto's thyroiditis versus Hashimoto's thyroiditis; P_2 , papillary thyroid carcinoma with Hashimoto's thyroiditis; P_3 , papillary thyroid carcinoma without Hashimoto's thyroiditis versus Hashimoto's thyroiditis; a_{χ}^2 -test; ^bMcNemar's test; P < 0.05, significant.

expression was observed in 12 (40%), and diffuse positive CD56 expression was found in 13 (43.3%) of cases of HT that was not transformed into PTC later on.

Among the fourth group, negative CD56 expression was detected in five (16.7%), focal positive CD56 expression was observed in 12 (40%), and diffuse positive CD56 expression was found in 13 (43.3%) of cases of HT that was not transformed into PTC later on.

Among the fifth group, negative CD56 expression was detected in 17 (85%), focal positive CD56 expression was observed in two (10%), and diffuse positive CD56 expression was found in one (5%) of the cases of PTC with no history of HT.

HBME-1 expression in the studied lesions HBME-1 signal was detected predominantly in the cytoplasm

Among the first group, negative HBME-1 expression was detected in two (10%), focal positive HBME-1 expression was observed in four (20%), and diffuse positive HBME-1 expression was found in 14 (70%) of cases of PTC that was on top of HT (Tables 1 and 3, Figs. 1a, b, 2a, b and 3a).

Among the second group, negative HBME-1 expression was detected in four (20%), focal positive HBME-1 expression was observed in eight (40%), and diffuse positive HBME-1 expression was found in eight (40%) of cases of HT that were found to be transformed into PTC later on.

Among the third group, negative HBME-1 expression was detected in 22 (73.3%), focal positive HBME-1

	Table 2 Change in cluster of diffe	rentiation 56 immunohistochemistry be	etween historical specimen an	d recent specimen
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CD56 IHC in historical specimen		CD56 IHC in recent specimen	men	Total
	Negative	Focal positive	Diffuse positive	
PTC with HT				
Negative	10 (50)	0 (0)	0 (0)	10 (50)
Focal positive	6 (30)	1 (5)	1 (5)	8 (40)
Diffuse positive	0 (0)	1 (5)	1 (5)	2 (10)
Total	16 (80)	2 (10)	2 (10)	20 (100)
HT				
Negative	5 (16.7)	0 (0)	0 (0)	5 (16.7)
Focal positive	0 (0)	12 (40)	0 (0)	12 (40)
Diffuse positive	0 (0)	0 (0)	13 (43.3)	13 (43.3)
Total	5 (16.7)	12 (40)	13 (43.3)	30 (100)

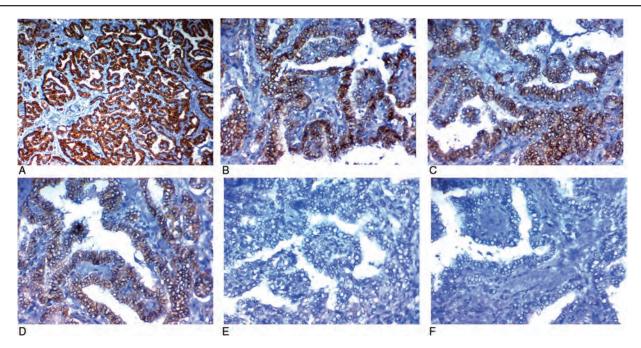
Categorical variables were expressed as number (percentage); CD56, cluster of differentiation 56; HT, Hashimoto's thyroiditis; IHC, immunohistochemistry; PTC, papillary thyroid carcinoma.

Table 3 Change in Hector Battifora mesothelial-1	immunohistochemistry between historica	I specimen and recent specimen

HBME-1 IHC in historical specimen		HBME-1 IHC in recent spe	cimen	Total
	Negative	Focal positive	Diffuse positive	
PTC with HT				
Negative	2 (10)	0 (0)	2 (10)	4 (20)
Focal positive	0 (0)	4 (20)	4 (20)	8 (40)
Diffuse positive	0 (0)	0 (0)	8 (40)	8 (40)
Total	2 (10)	4 (20)	14 (70)	20 (100)
HT				
Negative	22 (73.3)	0 (0)	0 (0)	22 (73.3)
Focal positive	0 (0)	7 (23.3)	0 (0)	7 (23.3)
Diffuse positive	0 (0)	0 (0)	1 (3.3)	1 (3.3)
Total	22 (73.3)	7 (23.3)	1 (3.3)	30 (100)

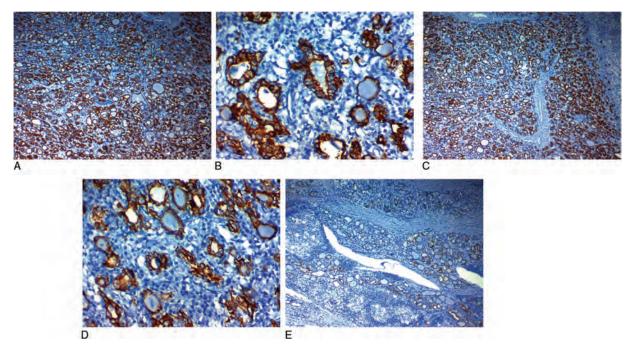
Categorical variables were expressed as number (percentage); HBME-1, Hector Battifora mesothelial-1; HT, Hashimoto's thyroiditis; IHC, immunohistochemistry; PTC, papillary thyroid carcinoma.

Figure 1



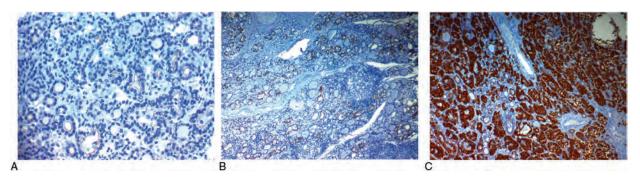
Papillary thyroid carcinoma immunohistochemistry. (a) PTC on top of HT showed diffuse positive HBME-1 expression (×100). (b) PTC without previous history of HT showed diffuse positive HBME-1 expression (×400). (c) PTC on top of HT showed diffuse positive CK19 expression (×400). (d) PTC without previous history of HT showed diffuse positive CK19 expression (×400). (e) PTC on top of HT showed negative CD56 expression (×400). (f) PTC without previous history of HT showed negative CD56 expression (×400). CD56, cluster of differentiation 56; CK19, cytokeratin 19; HBME-1, Hector Battifora mesothelial-1; HT, Hashimoto's thyroiditis; PTC, papillary thyroid carcinoma.

Figure 2



Hashimoto's thyroiditis that was transformed to papillary thyroid carcinoma immunohistochemical expression. (a) Diffuse positive Hector Battifora mesothelial-1 expression (×100). (b) High power of the previous image showed diffuse positive Hector Battifora mesothelial-1 expression (×400). (c) Diffuse positive cytokeratin 19 expression (×100). (d) High power of the previous image showed diffuse positive cytokeratin 19 expression (×400). (e) Negative cluster of differentiation 56 expression (×400).

Figure 3



Hashimoto's thyroiditis that was transformed to papillary thyroid carcinoma immunohistochemical expression. (a) Negative Hector Battifora mesothelial-1 expression (x400). (b) Negative cytokeratin 19 expression (x100). (c) Diffuse positive cluster of differentiation 56 expression (x100).

expression was observed in seven (23.3%), and diffuse positive HBME-1 expression was found in one (3.3%) of cases of HT that was not transformed into PTC later on.

Among the fourth group, negative HBME-1 expression was detected in 22 (73.3%), focal positive HBME-1 expression was observed in seven (23.3%), and diffuse positive HBME-1 expression was found in one (3.3%) of cases of HT that was not transformed into PTC later on.

Among the fifth group, negative HBME-1 expression was detected in three (15%), focal positive HBME-1 expression was observed in six (30%), and diffuse positive HBME-1 expression was found in 11 (55%) of cases of PTC with no history of HT.

CK19 expression in the studied lesions CK19 expression was detected in the cell membrane with or without the cytoplasm

Among the first group, negative CK19 expression was detected in three (15%), focal positive CK19 expression was observed in four (20%), and diffuse positive CK19 expression was found in 13 (65%) of cases of PTC that was on top of HT (Tables 1 and 4, Figs. 1c, d, 2c, d and 3b).

Among the second group, negative CK19 expression was detected in four (20%), focal positive CK19

Table 4 Change in cytokeratin 19 immunohistochemisti	y between historical specimen and recent specimen
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CK19 IHC in historical specimen	CK19 IHC in recent specimen			Total
	Negative	Focal positive	Diffuse positive	
PTC with HT				
Negative	3 (15)	1 (5)	0 (0)	4 (20)
Focal positive	0 (0)	2 (10)	3 (15)	5 (25)
Diffuse positive	0 (0)	1 (5)	10 (50)	11 (55)
Total	3 (15)	4 (20)	13 (65)	1 (100)
HT				
Negative	21 (70)	0 (0)	0 (0)	21 (70)
Focal positive	0 (0)	7 (23.3)	0 (0)	7 (23.3)
Diffuse positive	0 (0)	0 (0)	2 (6.7)	2 (6.7)
Total	21 (70)	7 (23.3)	2 (6.7)	30 (100)

Categorical variables were expressed as number (percentage); CK19, cytokeratin 19; HT, Hashimoto's thyroiditis; IHC, immunohistochemistry.

expression was observed in five (25%), and diffuse positive CK19 expression was found in 11 (55%) of cases of HT that were found to be transformed into PTC later on (Fig. 1a).

Among the third group, negative CK19 expression was detected in 21 (70%), focal positive CK19 expression was observed in seven (23.3%), and diffuse positive CK19 expression was found in two (6.7%) of cases of HT that was not transformed into PTC later on.

Negative CK19 expression was detected in 21 (70%), focal positive CK19 expression was observed in seven (23.3%), and diffuse positive CK19 expression was found in two (6.7%) of cases of HT that was not transformed into PTC later on. Among the fifth group, negative CK19 expression was detected in five (25%), focal positive CK19 expression was observed in four (20%), and diffuse positive CK19 expression was found in 11 (55%) of cases of PTC with no history of HT.

No statistically significant difference was found between the first and fifth groups, second and fifth groups, third and fourth groups as regards all marker expressions and (first and second groups as regards CD56 and CK19 expression.

There is a highly significant statistical difference found between the second and fourth groups as regards CD56, HBME-1, and CK19 expression (P=0.012, 0.000, respectively).

There is a significant statistical difference found between the first and the second group as regards HBME-1 expression (P=0.031).

There is a highly significant statistical difference that was found between the first and fourth groups, first and

third groups, fifth and third groups, and fifth and fourth group as regards all marker expressions (P=0.000).

Specificity and sensitivity of each marker

Diagnostic validity of CD56 was of highest sensitivity (90%) in differentiating HT that will be transformed to PTC from HT that will not be transformed to PTC (Table 5).

Diagnostic validity of HBME-1 was of highest specificity in differentiating HT that will be transformed to PTC from HT that will not be transformed to PTC.

Discussion

A plethora of researchers have assessed the association between HT and PTC, some of them found a significant positive correlation [2,3], but others have not found any correlation between both conditions [24]. The importance of finding such association is that the presence of goiter of any size in a patient with HT should raise the possibility of developing PTC later on, and also indicated the need for deeper investigations to exclude the coexistence of malignancy in such cases.

The most recent hypothesis that we tried to prove here in our study is if we can predict the liability for malignant progression of certain cases of HT to PTC that will be of great help to the patient as we will advise the surgeon to do early total thyroidectomy for those HT cases with more liability for malignant progression.

Akhtar and Scognamiglio [25] found that HT and PTC have the same pluripotent stem cell origins, which proved that the association between conditions is antibody specific and may have an oncogenic role [26]. It was found that the elevated

Groups	IHC	ЧL	님	TN	Ν	SN	SP	Accuracy	РРV	NPV
			-	6	6	CE (10 0 00 1)	0E 7 (00 0 100)	00 /76 1 0E 6/		00 0 /20 1 0E 0/
(2) that is not transformed to PTC vs. PTC		<u>+</u>	-	RV	٥	(1.9–90.1)	(001–Z.08) 1.08	00 (10.4-20.0)	83.3 (au.1-1uu)	02.3 (10.4-30.0)
	CK19 (diffuse=HT (1))	13	2	28	7	60 (44.1–85.9)	83.3 (84.4–90)	82 (71.4–90.6)	86.7 (69.5–100)	80 (66.7–93.3)
	CD56 (negative/focal=HT (1))	18	17	13	N	90 (76.9–100)	40 (25.6–55)	50 (48.5–70.5)	51.4 (34.9–68)	86.7 (38.9–74.4)
PTC vs. HT (1) same patients	HBME-1 (diffuse=PTC)	14	6	1	9	70 (49.9–90.1)	55 (33.2–76.8)	62.5 (47.5–77.5)	60.9 (40.9–80.8)	64.7 (42–87.4)
	CK19 (diffuse=PTC)	13	11	6	7	65 (44.1–85.9)	45 (23.2–66.8)	55 (39.6–70.4)	54.2 (34.2–74.1)	56.3 (31.9–80.6)
	CD56 (negative/focal=PTC)	18	18	N	N	90 (76.9–100)	10 (0–23.1)	50 (34.5–65.5)	50 (33.7–66.3)	50 (1–99)
PTC vs. HT (2)	HBME-1 (diffuse=PTC)	14	÷	29	9	70 (49.9–90.1)	96.7 (90.2–100)	86 (76.4–95.6)	93.3 (80.7–100)	82.9 (70.4–95.3)
	CK19 (diffuse=PTC)	13	N	28	7	65 (44.1–85.9)	93.3 (84.4–100)	82 (71.4–92.6)	86.7 (69.5–100)	80 (66.7–93.3)
	CD56 (negative/focal=PTC)	18	17	13	2	90 (76.9–100)	43.3 (25.6–61.1)	52 (48.5–75.5)	51.4 (34.9–68)	86.7 (38.9–74.4)
CD56, cluster of differentiation 56; CK19, cytokeratin 19; FN, false negative; FP, false positive; HBME-1, Hector Battifora mesothelial-1; HT, Hashimoto's thyroiditis; NPV, negative predictive value HT that is transformed into PTC=(2); PPV, positive predictive value; PTC, papillary thyroid carcinoma; SN, sensitivity; SP, specificity; TN, true negative; TP, true positive.	(19, cytokeratin 19; FN, false negativ, not transformed into PTC=(2); PPV, j	e; FP, f ^c positive	alse pos predicti	itive; HE ve value	BME-1, »; PTC,	Hector Battifora me	sothelial-1; HT, Hashii rcinoma; SN, sensitivit	moto's thyroiditis; NPV iy; SP, specificity; TN,	 v, negative predictive true negative; TP, tru 	value HT that is e positive.

levels of TSH in HT patients could be also be risk factors for cancer [27].

So many previous researchers have tried to differentiate PTC from HT by IHC and have succeeded in such issue using certain available sensitive and specific markers, but there are no previous study that tried to use such IHC markers to predict the progression of HT to PTC, which could identify a group of patients that will be in a certain need to do early total thyroidectomy for the management of HT to avoid malignant transformation into PTC later on.

CD56 has been found to be related to follicular epithelium differentiation, and many previous authors reported high CD56 expression in normal non-neoplastic thyroid tissue and some benign thyroid lesions [13,28]. In accordance with those studies, we currently report a high positive CD56 expression in 83.3% of HT cases that found to not transform to PTC. On the other hand, negative CD56 expression was observed in 80–85% of PTC that has occurred on top of HT and that has occurred *de novo*, respectively, and we have detected highly significant difference between PTC and HT cases that was not transformed to PTC (P<0.001). Similarly, previous studies reported negative CD56 expression in most of their studied PTC cases [28,29].

We found that negative CD56 expression was detected in 10 (50%); focal positive CD56 expression was observed in eight (40%), and diffuse positive CD56 expression was found in two (10%) of cases of HT that found to be transformed into PTC later on. There was no statistically significant difference between CD56 expressions in PTC cases and HT cases that was transformed into PT later on, but CD56 distinguished the HT group that did not transform into PTC later from the HT group that was transformed into PTC later, so it can be used to categorize HT into cases with high incidence of malignant transformation into PTC and cases with low in incidence of such transformation. The sensitivity and the specificity for CD56 in distinguishing the HT group that did not transform into PTC later from the HT group that was transformed into PTC later were 90 and 40%, respectively, so CD56 was of highest sensitivity as a negative marker in differentiating HT that will be transformed to PTC from HT that will not be transformed to PTC which will be very helpful to us in the prediction of cases with high incidence of malignant transformation into PTC and cases with low incidence of such transformation.

HBME-1 is a component of the microvilli that is located on the surface of mesothelial cells [15]. Previous studies demonstrated that HBME-1 overexpression as detected by IHC, was observed in thyroid cancers and it was a sensitive marker for PTCs [30,31].

That was similar to us as we proved that HBME-1 was positive in 85-90% of cases of PTC that has occurred de novo and that has occurred on top of HT, respectively, whereas it was negative in most cases of HT (73.3%) that was not transformed to PTC later on and we have detected a highly significant difference between PTC and HT cases that was not transformed to PTC (P<0.001). Our results proved that HBME-1 has been reported to be one of the most promising markers [17,32,33] of HBME-1 positivity in 70% classic PTC, and Prasad et al. [17] demonstrated HBME-1 expression in 85% PTC. This was slightly different from Arturs et al. [29] who detected negative HBME-1 expression in all benign lesions, whereas they observed its positive expression in all cases of PTC.

In our study when we used HBME-1 in the prediction of HT to PTC, we found that the sensitivity and the specificity for HBME-1 in distinguishing the HT group that did not transform into PTC later from the HT group that was transformed into PTC later were 65 and 95.7%, respectively, so HBME-1 was of highest specificity in differentiating HT that will be transformed to PTC from HT that will not be transformed to PTC that will be very helpful to us in the prediction of cases with high incidence of malignant transformation, and this was in agreement with Husain *et al.* [16], who showed that HBME-1 was a sensitive and specific marker to differentiate benign from malignant lesions which was higher than any markers.

We found that negative HBME-1 expression was detected in four (20%); focal positive HBME-1 expression was observed in eight (40%), and diffuse positive HBME-1 expression was found in eight (40%) of the cases of HT that were found to be transformed into PTC later on, and there was no statistically significant difference between HBME-1 expression in PTC cases and HT cases that was transformed into PT later on, but HBME-1 expression distinguished the HT group that did not transform into PTC later from the HT group that was transformed into PTC later, so it can be used to categorize HT into cases with high incidence of malignant transformation into PTC and cases with low incidence of such transformation.

CK19 (keratin 19) is a keratin family member that plays an essential role in the structure and integrity of most epithelial cells, but its role in the diagnosis of PTC is still a point of research [24–36].

Some studies have found that negative CK19 expression was found in all benign thyroid lesions [18], whereas Cheung *et al.* [33] demonstrated that 20% of benign thyroid lesions were focally CK19 positive. The study by Nasr *et al.* [32] also noted a 68% CK19 positivity in benign lesions, but staining intensity was weak. In all these cases, CKI9 staining was patchy and moderate. Zhu *et al.* [37] suggested that CK19 was not a specific marker of PTC.Sahoo *et al.* [38] and Guyetant *et al.* [39] have demonstrated that all cases of PTC showed strong CK19 positivity.

Prasad *et al.* [17] showed a high sensitivity and specificity of CK19 in PTC, so the chief benefit of CK19 lies in its diagnostic ability of PTC and its negative staining is a sign against PTC. Negative staining for CK19, therefore, is strong evidence against PTC. We have proved results similar to most of these previous studies as we found that CK19 was positive in 75–85% of cases of PTC that has occurred *de novo* and that has occurred on top of HT, respectively, whereas it was negative in most cases of HT (70%) that was not transformed to PTC later on and we have detected a highly significant difference between PTC and HT cases that was not transformed to PTC (P<0.001).

The sensitivity and the specificity for CK19 in distinguishing the HT group that did not transform into PTC later from the HT group that was transformed into PTC later were 60 and 83.3%, respectively.

CH-19 was of moderate sensitivity and specificity in differentiating HT that will be transformed to PTC from HT that will not be transformed to PTC that will be also helpful in addition to HBME-1 and CD56 to us in the prediction of cases with high incidence of malignant transformation into PTC.

In contrast to our results that HT increased the risk of PTC occurrence, Segal *et al.* [40] suggest that HT does not increase but rather delays PTC occurrence due to the presence of circulating antibodies which may be a significant factor which could prevent cancer development and also hinder nodal metastases in transformed cases. These results are in contrast to the investigations by Di Pasquale *et al.* [41], who proved a strong autoimmune background in all cases of PTC coexisting with HT. So further studies are needed to prove and clarify our results.

In summary

- (1) The most common thyroid malignancy is PTC and the most common autoimmune disease of the thyroid gland is HT.
- (2) The association and pathogenic relations between both HT and PTC remains controversial.
- (3) ?Dailey and colleagues first described that there is a relationship between both the thyroid lesions and since then, there are many conflicting results regarding such issue.
- (4) Management of HT patients is mostly conservative and performing total thyroidectomy is not preferred due to the presence of inflammatory response that surrounds the thyroid gland which can lead to more difficult surgical resection.
- (5) Although a plethora of studies have identified the indications of surgery in patients with HT, performing early thyroidectomy is still a controversial method for their management.
- (6) It would be beneficial to use the available biomarkers to predict the cases of that HT will have a high liability of progression to PTC which will be helpful in performing early thyroidectomy for those patients even if there is no marker disfigurement or marked pressure symptoms.
- (7) We used the biomarkers that have emerged for differentiation between benign and malignant thyroid lesions, e.g. CD56, HBME-1, and CK19.
- (8) Most studies have assessed the roles of such markers in PTC diagnosis or to distinguish HT from PTC, but we noticed that there are no previous studies which tried to assess the value of using such markers in the prediction of PTC occurrence in HT patients that will advise performing early thyroidectomy in HT cases with high risk of progression to PTC before its occurrence which subsequently will decrease the malignancy risk in such patients.

Conclusion

We detected that a panel of CD56 negative expression and HBME-1 diffuse expression is considered the most sensitive and specific for the prediction of PTC occurrence in certain HT cases.

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Conflicts of interest

There are no conflicts of interest.

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Value of laparoscopic exploration of penetrating abdominal trauma Ahmed A. Al Aziz

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Objective

The aim was to evaluate the role of laparoscopy in the management of patients with penetrating abdominal trauma.

Patients and methods

This prospective study included 60 hemodynamically stable patients with penetrating abdominal trauma presenting to the Casualty Department. The patients were subjected to routine investigations including routine laboratory and radiological investigations and were randomly divided into two groups: local wound exploration (LWE) group (n=30) and laparoscopy group (n=30). In the LWE group, the patients were subjected to LWE under local anesthesia followed by laparotomy if the wound penetrated the deep fascia. In the laparoscopy group, the patients were subjected to diagnostic laparoscopy and managed laparoscopically or converted to laparotomy according to the circumstances. Otherwise, the patient was discharged within 24 h.

Results

In the LWE group, six (20%) patients were discharged as having intact peritoneum; one of them was back 2 days later, had exploratory laparotomy and a small bowel injury was repaired. A total of 24 (80%) patients with perforated peritoneum proceeded to laparotomy; 17 (56.7%) of them had negative laparotomy. In the laparoscopy group 18 (60.0%) patients showed negative laparoscopy, four (13.3%) patients were managed laparoscopically, and eight (26.7%) were converted to laparotomy.

Thus, 33 laparotomies were performed; the rate of complications was 39.4% with significant difference between negative and therapeutic cases (P=0.619). The operative time and hospital stay were significantly longer in cases of laparotomy compared with laparoscopy (P<0.001).

Conclusion

Routine laparotomy has a negative rate of 57%. Laparoscopy did not miss intraabdominal injuries, was therapeutically effective in 12%, and was negative in 60% of cases.

Keywords:

abdominal trauma, laparoscopic exploration, penetrating

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Introduction

In the emergency department, the management of a patient with penetrating abdominal trauma (PAT) is always considered a diagnostic and therapeutic challenge. There is almost a consensus that immediate laparotomy (LAP) is mandatory for cases presenting with peritonitis, hemodynamic instability, or evisceration [1].

However, how to evaluate a stable patient without peritonitis is still a matter of debate for many reasons. In modern practice, the surgeon must balance the risks and the benefits of variable diagnostic and therapeutic procedures within the context of patient safety [2]. Mandatory laparotomy was considered the standard of care for the evaluation and treatment of abdominal trauma for decades, but it results in negative laparotomy rates in 12–40% of cases [3,4]. Despite decreasing the risk of missed injury to near zero, exploratory laparotomy has been associated with a complication rate of 15–50% and prolonged hospital stay [3].

Negative laparotomy cannot be accepted as an inevitable consequence of a sole management policy in today's environment. Therefore, laparotomy should be reserved for those patients who will get clear benefits. Noninvasive procedures such as computed tomography (CT) and abdominal sonography can deliver critical information with lower risk and little discomfort for the patient. Nevertheless, these methods may miss a serious intra-abdominal injury with subsequent increased

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morbidity, mortality, and cost [5]. Diagnostic peritoneal lavage (DPL) is another option that can accurately detect intraperitoneal hemorrhage or a ruptured hollow viscus [6].

In the last decade, laparoscopy attained a wider role in the evaluation and treatment of patients with abdominal trauma [2]. Laparoscopy has been utilized for both blunt and penetrating injuries, but it has gained more prevalent acceptance for the management of patients with penetrating abdominal injuries [7]. Several studies have reported good results of laparoscopic procedures in abdominal trauma in terms of high sensitivity and specificity for the diagnosis of intra-abdominal injuries, low rate of missed injuries, and few complications [8–11]. The laparoscopic approach avoided nontherapeutic laparotomies in ~60% of patients with abdominal stab wounds (SW) [8,11].

The aim of this study was to evaluate the role of laparoscopy in the management of hemodynamically stable patients with PAT compared with exploratory laparotomy.

Patients and methods

This comparative prospective study was conducted in Kasr Al-Ainy Hospital from April 2013 to August 2013. All the patients gave informed written consent and complied with the management and follow up regimen. It included 60 patients with PAT [SW and gunshot wounds (GSW)] presenting to the Casualty Department. The patients were eligible if they were hemodynamically stable, defined as systolic blood pressure more than or equal to 100 mmHg, diastolic blood pressure more than or equal to 60 mmHg, heart rate less than 110 bpm, and minimal requirements for crystalloid resuscitation (<2 l). Patients with GSW who were thought by physical examination to likely have tangential passage of the missile through the abdominal wall without peritoneal penetration were included.

Exclusion criteria included those who were hemodynamically unstable, patients with peritonitis or evisceration, and those in whom laparoscopy was contraindicated.

Patients were subjected to routine investigations including routine laboratory and radiological investigations such as abdominopelvic ultrasonography, CT scan, and plain erect abdominal radiographic, each case according to its requirement to reach diagnosis. Data collected included the mechanism of injury, anatomical site of penetration, injuries found and their management, operative time, postoperative complications, and hospital stay.

The patients were randomly divided into two groups: local wound exploration (LWE) group (n=30) and laparoscopy group (n=30). In the LWE group, the patients were subjected to LWE under local anesthesia to assess the extent of penetration. If the wound penetrated the deep fascia, formal laparotomy, and management was done. If not, the wound was sutured and the patient discharged. In the laparoscopy group, the patients were subjected to diagnostic laparoscopy (DL). If it proved to be penetrating, the management will be conducted either laparoscopically or the operation was converted to laparotomy according to the circumstances. Otherwise, the patient was discharged within 24 h.

Negative laparotomy was defined as the absence of intra-abdominal injury. Nontherapeutic laparotomy was defined as finding an organ injury that did not require intervention, e.g. nonbleeding minimal liver or spleen injuries. Therapeutic laparotomy was defined as an organ injury that required surgical correction. Therapeutic laparoscopy was defined as an organ injury that was surgically repaired through laparoscopy.

Statistical methods

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

Results

Table 1 shows the age and sex distribution of the two groups. GSW were observed in few patients of the two groups.

Results of evaluation of local wound exploration group During primary LWE, the peritoneum of six (20%) patients was judged to be intact and the primary suture was done and then the patients were discharged. One of these six patients was back 2 days later with signs of peritonitis and went through an exploratory laparotomy where a small bowel injury was found and repaired. The remaining 24 (80%) patients with perforated peritoneum proceeded to laparotomy. Seven out of 24 (23.3%) had positive laparotomy findings and were managed accordingly. In 17 (56.7%) patients, laparotomy yielded negative findings. The results and management of the LWE group in relation to the mechanism of injury are shown in Table 2. One of the two positive GSW cases had liver lacerations associated with mesenteric and small bowel injury. The other patient had spleen lacerations associated with omental and left colon injury. The five injuries in SW patients are shown in Table 2.

 Table 1 Age and sex distribution and mechanism of injury of the two studied groups

	LWE group (<i>n</i> =30)	Laparoscopy group (<i>n</i> =30)	P value
Age (years)	28.8±9.1	27.2±6.8	0.444
13–19	3 (10.0)	0 (0.0)	0.125
20–30	12 (40.0)	15 (50.0)	
31–40	8 (26.7)	12 (40.0)	
41–50	7 (23.3)	3 (10.)	
Sex (male/female)	28/2	29/1	1.000
Mechanism of injury			
Gunshot	3 (10.0)	6 (20.0)	0.472
Stab wound	27 (90.0)	24 (80.0)	

LWE, local wound exploration.

Table 2 Results of evaluation of loca	I wound exploration group (n=30)
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Results of evaluation of the laparoscopy group

A total of 18 (60.0%) patients showed negative laparoscopic exploration and were discharged within 24 h. Four (13.3%) patients were managed laparoscopically according to their findings (Table 3). Eight (26.7%) patients were converted to laparotomy and managed accordingly. Two of these eight patients needed laparotomy as a result of laparoscopic complications.

Technical laparoscopic complications

- (1) The first complication occurred in a patient with an SW. While running the small bowel, an enterotomy was made with a grasper. Laparotomy was required for small bowel repair, and the patient had no other injuries.
- (2) The second patient sustained a right-sided thoracoabdominal GSW and had a chest tube placed preoperatively. During CO₂ insufflation for laparoscopy, the patient became acutely hypotensive and the systemic oxygen saturation dropped. A diagnosis of tension pneumothorax was made and a second chest tube was inserted with immediate relief of tension and normalization of blood pressure and oxygenation; the initial chest tube had occluded by angulation.

	Gunshot wound (n=3) [n (%)]	Stab wound (n=27) [n (%)]	Total (n=30) [n (%)]
Negative LWE	1 (33.3)	5 (16.7)	6 (20.0)
Positive laparotomy	2 (66.7)	5 (73.3)	7 (23.3)
Liver lacerations	1 (33.3)	1 (3.7)	2 (6.7)
Spleen lacerations	1 (33.3)		1 (3.3)
Gastric lacerations		1 (3.7)	1 (3.3)
Omental injury	1 (33.3) ^a	2 (7.4) ^a	2 (6.7) ^a
Mesenteric injury	1 (33.3) ^a	2 (7.4) ^a	3 (10.0) ^a
Diaphragmatic injury	2 (66.7) ^a	1 (3.7)	3 (10.0) ^a
Small bowel injury	1 (33.3) ^a	2 (7.4)	3 (10.0)
Colonic injury	1 (33.3) ^a	1 (3.7) ^a	2 (6.7) ^a

^aAssociated injuries.

Table 3 Results of evaluation of	the laparoscopy group (<i>n</i> =30)
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	Gunshot wound ($n=6$) [n (%)]	Stab wound (n=24) [n (%)]	Total (n=30) [n (%)]
Negative laparoscopy	2 (33.3)	16 (66.7)	18 (60.0)
Positive laparoscopy	4 (66.7)	8 (33.3)	12 (40.0)
Liver lacerations	2 (33.3)	1 (4.2)	3 (10.0)
Spleen lacerations		1 (4.2)	1 (3.3)
Gastric lacerations	1 (16.7)ª	1 (4.2)	2 (6.7)
Omental injury		1 (12.5)	1 (3.3)
Mesenteric injury		1 (4.2) ^a	1 (3.3) ^a
Diaphragmatic injury	2 (33.3)		2 (6.7)
Small bowel injury	1 (16.7) ^a	2 (8.3)	3 (10.0)
Colonic injury		1 (4.2)	1 (3.3)

^aAssociated injuries.

Laparotomy was performed with repair of a 1-2 cm diaphragm laceration and cauterization of a superficial liver injury.

Classification of wounds according to the site of entrance

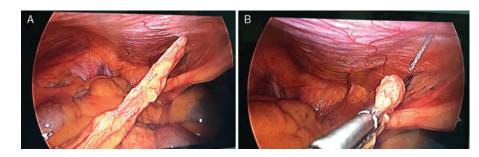
- (1) Thoracoabdominal: four patients out of the 60 (6.7%) presented with thoracoabdominal penetrating wounds. One patient with GSW had a diaphragmatic tear repaired laparoscopically. Another patient was subjected to laparotomy due to the excessive bleeding that was coming out through the SW and had negative findings. The muscular bleeding was controlled and a chest tube was inserted due to hemothorax.
- (2) Anterior abdominal wall: 55 (91.6%) patients presented with penetrating wounds in the anterior abdominal wall: 48 SW and seven GSW. Five patients with negative wound exploration were discharged.
- (3) Lateral abdominal wall: a case of lateral abdominal wall SW was discharged at the same day after being subjected to LWE which was negative. Figures 1

and 2 show the fate of the 60 patients in the two groups in relation to the wound site.

Collectively, 33 laparotomies were performed; three for thoracoabdominal wounds and 30 for anterior abdominal wall wounds. Out of these 33 laparotomies, 17 (51.5%) were negative. All of these 17 cases had routine laparotomy. Table 4 shows complications of the laparotomies. The rate of complications was 39.4%. There was no significant difference between negative and therapeutic cases regarding the rate of complications (P=0.619). Operative time and hospital stay were significantly longer in cases of laparotomy compared with laparoscopy (P<0.001) (Table 5).

Discussion

The results of this study demonstrated that management of stable patients with PAT with routine laparotomy yielded negative findings in 56.7%. LWE before laparotomy missed a case with perforated peritoneum among six patients who were discharged based on having intact peritoneum. On the other hand, laparoscopic exploration was negative in



Fate of the 30 patients in the local wound exploration group in relation to the wound site. LWE, local wound exploration.

Table 4 Postoperative complications in cases of laparotomy (n=33)

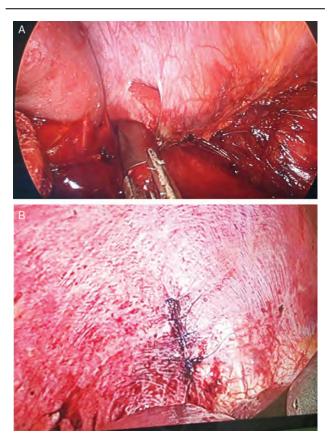
	Negative laparotomy (n=17) [n (%)]	Therapeutic laparotomy (n=16) [n (%)]	Total (n=33) [n (%)]
Wound infection	3 (17.6)	2 (12.5)	5 (15.2)
Wound dehiscence	0 (0.0)	1 (6.2)	1 (3.0)
Pneumonia/chest infection	2 (11.8)	2 (12.5)	4 (12.1)
lleus	1 (5.9)	2 (12.5)	3 (9.1)
All complications	6 (35.3)	7 (43.8)	13 (39.4)

Table 5 Operative time and hospital stay in cases of laparoscopy and laparotomy

	Lapa	roscopy	oscopy Laparotomy		Laparotomy	
	Negative (n=18)	Therapeutic (n=4)	Negative (n=17)	Therapeutic (n=16)		
Operative time (r	min)					
Mean	27.3±2.5	77.5±18.6	65.	3±32.4		
Range	20–30	40–120	20–180			
Hospital stay (da	ays)					
Mean	1.4±0.7	2.1±0.8	5.1±1.3	6.2±3.2		
Range	1–2	1–4	2–7	2–15		

Figure 1

Figure 2



Fate of the 30 patients in the laparoscopy group in relation to the wound site.

60% of cases; and management was possible in 12% of cases. Technical complications of laparoscopic exploration were met in only two cases. Laparotomy was associated with a postoperative complication rate of 39.4%; the rate in negative laparotomy was 35.3%. Laparoscopy significantly decreased the operative time and hospital stay.

PAT continues to represent a challenge for emergency surgeons. Traditionally, exploratory LAP was the main management option. However, the high negative laparotomy rate and associated postoperative morbidity had driven the trend toward selective nonoperative management strategy [12]. Actually, recent reports have shown that 30–50% of all SW do not penetrate the peritoneum and 20–40% with peritoneal penetration do not involve significant injuries [13,14].

The available diagnostic methods including DPL, focused abdominal sonography for trauma, and CT are not satisfactory enough to determine the presence and severity of intra-abdominal injuries caused by penetrating wounds. Laparoscopy has been safely and effectively used for patients with PAT for diagnostic and therapeutic purposes [13,15].

In the current study, the use of laparoscopy was relatively safe, and was successful for the treatment of four patients with intra-abdominal injuries. It reduced unnecessary laparotomies from 57 to 0% with shortening of the operative time and hospital stay. Six (20%) patients of the laparoscopy group were converted to laparotomy for the management of major injuries with 100% sensitivity.

An evidence-based review has reported that DL in trauma patients spares 17–89% of nontherapeutic laparotomy [16]. In predicting the need for LAP, DL was reported to have sensitivity, specificity, and diagnostic accuracy ranging from 75 to 100%; the rate of missed injuries was less than 1% [17].

In asymptomatic patients with abdominal GSW, Sosa *et al.* [3] reported a drop in negative laparotomy rate from 12.4 to 4.7% when routine DL was started. In a retrospective cohort study, laparoscopy decreased the nontherapeutic laparotomy rate from 57.9 to 0%, shortened hospital stay and operative time [8].

A systematic review included one randomized, controlled trial and eight observational studies comparing the outcomes of laparoscopy with laparotomy in PAT. Laparoscopy was associated with a significantly lower risk of wound infection and pneumonia and a significantly shorter hospital stay and procedure time [18].

In addition to diagnostic capabilities, laparoscopy has a considerable therapeutic potential with certain cases depending on the experience of the surgeon in advanced laparoscopic techniques [9]. In the current study, four patients were managed laparoscopically; one of them had a gunshot injury involving the diaphragm which was repaired.In fact, optimal management of asymptomatic patients with penetrating abdominal wounds has yet to be determined. Many guidelines are now available [13,15,19]. Biffl and colleagues suggested an algorithm for nonoperative management of stable patients with anterior abdominal SW. In this algorithm, patients undergo LWE with subsequent discharge if penetration is excluded. Otherwise, in-hospital serial clinical assessments were done. Afterwards, operative management or further investigations were done according to the patients' status. According to this algorithm, serial clinical assessments resulted in avoidance of the added expense of CT, DPL, or laparoscopy [20]. However, other investigators prefer DL to LWE. This is based on the advantages of immediate laparoscopy including reduced morbidity, accuracy in detecting diaphragmatic and

intestinal injuries, reducing hospital stay, and increased cost effectiveness [21].

The results of the current study indicate a clear benefit of LWE under local anesthesia; it correctly identified 16.7% of patients who have intact peritoneum and consequently did not need further management. The main drawback is a missed case of small peritoneal tear that was wrongly discharged. Unnecessary laparotomy rate was rather high (57%). On the other hand, laparoscopy did not miss any case with intraabdominal injury and was therapeutically effective in four patients. The rate of negative cases is still high (60%). Therefore, we recommend LWE as the first step in hemodynamically stable patients followed by serial clinical assessments for 24 h. If the patients' status is still doubtful, we can proceed to DL.

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Conflicts of interest

There are no conflicts of interest.

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Assessment of limb salvage in single peroneal runoff versus single tibial runoff in patients with critical limb ischemia having complex lesions

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Introduction

The value of peroneal artery revascularization has always been debatable, especially in patients with tissue loss. As one of the most important factors of wound healing is the establishment of in-line flow to the foot, the role of peroneal angioplasty has to be defined.

Aim

The aim was to assess the adequacy of single peroneal vessel runoff in endovascular revascularization of patients with TASC C-D lesion and critical limb ischemia (CLI) as infrapopliteal disease.

Patients and methods

This is a prospective study involving patients with TASC C-D lesions presenting with CLI along 1 year. Patients were stratified into two groups according to their runoff states. Group P includes patients with single peroneal vessel runoff, whereas group T includes patients with single tibial runoff other than peroneal. Patients with two or three vessel runoff were excluded from the study.

Results

The study included 180 patients, with age ranging from 42 to 86 years; 55% were male patients. Of the 180 patients, 60 patients had single peroneal vessel runoff (group P) whereas 120 patients had a single tibial runoff (group T). The mortality rate along 2 years was 10 and 5% in groups P and T, respectively. Limb salvage rate along 2 years was 68.8% in group P and 79.8% in group T (P<0.036). The primary and secondary patency rates over 2 years in group P were 31.3 and 54.2%, respectively, and in group T were 47.7 and 62.4%, respectively.

Conclusion

In patients having CLI with TASC C-D lesion, although single peroneal runoff showed slightly lower limb salvage rate compared with single tibial runoff, it is valuable in patients with no other alternative for revascularization. We think that further studies are required to examine the importance of presence of direct pedal communication and its effect on the clinical success (limb salvage and disappearance of rest pain) of peroneal artery angioplasty.

Keywords:

critical limb ischemia, infrapopliteal disease, limb salvage, peroneal angioplasty

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Introduction

The value of peroneal artery (PA) revascularization has always been debatable, especially in patients with tissue loss. As one of the most important factors of wound healing is the establishment of in-line flow to the foot, the role of peroneal angioplasty has to be defined.

The PA is relatively spared from the terminal stages of atherosclerosis and is often the last tibial vessel to become occluded in diabetes or end-stage vascular disease. The main prejudice, on the contrary, against its use in distal revascularizations is that the perfusion of the foot is indirect, via collaterals from its anterior and posterior branches, despite an extensive collateral arterial bed, so the target vessel may be inadequate for treating a septic or gangrenous foot [1]. The aim of this study was to assess the adequacy of single peroneal vessel runoff in endovascular revascularization of patients with TASC C-D lesions having critical limb ischemia (CLI).

Patients and methods

This is a prospective study that included 180 patients with infrainguinal TASC C-D lesions presenting with CLI between June 2014 and June 2016. Patients were stratified into two groups according to their runoff states. Group P includes patients with single peroneal

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vessel runoff, whereas group T includes patients with single tibial runoff other than peroneal.

Patients with two or three vessel runoff were excluded from the study. All patients were reviewed regarding age, sex, risk factors, primary and secondary patency, limb salvage, and mortality. All patients were followed up at 1, 3, 6, 12, and 24 months by both clinical and duplex examinations.

patients underwent clinical A11 assessment, preprocedural investigations, selection criteria for this study, technique, procedural outcome, procedural complications, and postprocedural management.

Clinical assessment

History taking and clinical examination were done for all patients, which included age and sex and major risk factors for atherosclerosis, including diabetes mellitus, smoking, hypertension, cardiac diseases, chest diseases, renal insult, and stroke. Clinical categorization of chronic lower limb ischemia was done in accordance to the categorization by Rutherford-Baker scale of severity of peripheral arterial disease for chronic lower limb ischemia.

Preprocedural investigations

- (1) Routine laboratory tests: they included complete blood picture, kidney and liver function tests, coagulation profile, lipids profile, and blood glucose level.
- (2) Duplex scanning: patients were scheduled for duplex scanning before intervention, and at 6, 12, and 18 months of follow-up.

Selection criteria for our study

Inclusion criteria

The study included patients with critical chronic lower limb ischemia with lesions involving the infrapopliteal vessels with or without proximal lesions and presenting with the following:

- (1) Ischemic rest pain (category 4, grade II Rutherford classification).
- (2) Minor tissue loss as nonhealing foot ulcers or focal gangrene (categories 5 and 6, grade III Rutherford classification).

Exclusion criteria

The following exclusion criteria were applied:

(1) Patients with claudication either capacitating or incapacitating.

- (2) Patients with more than two runoff tibial vessels.
- (3) Aneurysmal disease and AVF.
- (4) Known intolerance to study medications or contrast agents.
- (5) Nonatherosclerotic infrapopliteal disease.

Technique

Preprocedure preparations

Patients were admitted either 1 day before or on the day of the procedure. A loading dose of clopidogrel 300 mg was given the night of the procedure.

Access site

Femoral artery access was used either ipsilateral antegrade or retrograde fashion based on the lesion site in the femoropopliteal segment from the finding of the duplex or diagnostic angiographic study. Ipsilateral antegrade femoral access was used in lesions involving the mid to distal femoropopliteal or infrapopliteal arteries. Contralateral retrograde femoral access was used in atherosclerotic lesions of the iliac, common femoral artery, ostial lesion of the profunda femoris or proximal superficial femoral artery, and obesity. Anatomic and fluoroscopic localization of the common femoral artery was done for all patients.

For every patient, the following data were recorded:

- Indications of the procedure.
 Risk factors, for example, diabetes mellitus, cardiac disease, hypertension, and renal failure.
- (3) Access method.
- (4) Type of the guide wire.
- (5) Size of the balloon (diameter and length).
- (6) Lesions were categorized as stenoses, occlusions, or both.

Procedural outcome

The procedure was considered to be successful depending on the following:

- (1) Immediate success, that regain of is, pulse, revascularization warmness, edema, and disappearance of rest pain.
- (2) Clinical improvements should include symptomatic improvement and change of at least one category according to categorization of Rutherford-Baker scale of severity of peripheral arterial disease for chronic lower limb ischemia.
- (3) Angiographic success was defined as less than 30% residual stenosis measured at the narrowest point of vascular lumen.

Procedural complications

Complications were divided into major and minor. Major complications included death, need for emergency surgery, major bleeding, or acute thrombotic occlusion. Minor complications included hematoma, peripheral emboli, or spasm of the tibial vessels after posterior tibial artery (PTA).

Approval from the ethical committee in Cairo University, Vascular Surgery Division of General Surgery Department, was taken before the beginning of the study.

Primary outcome included primary and secondary patency rates and limb salvage rate.

Secondary outcome included amputation-free survival and mortality rate.

Data analysis

The data were analyzed with SPSS 16.0 for Windows (SPSS Inc., Chicago, Illinois, USA). Numerical data are expressed in mean and SD. Analysis of variance *t*-test is used to compare the three groups. *P* value is significant when below 0.05.

Results

This prospective study included 180 patients, with age range from 42 to 86 years and mean age of 62 years; 55% were male patients. Of the 180 patients, 60 patients had single peroneal vessel runoff (group P), whereas 120 patients had a single tibial runoff (group T). Most of the patients are diabetics and male (demographic features and co-morbidities are shown in Table 1. The main presentation is Rutherford V (Table 2).

Table 1 Co-morbidities in each group

Risk factors and co-morbidities	Peroneal (N=60) [n (%)]	Tibial (<i>N</i> =120) [<i>n</i> (%)]
Diabetes	52 (86.6)	117 (97.5)
HTN	43 (71.6)	97 (80.8)
Smoking	38 (63.3)	47 (39.1)
Cardiac	26 (43.3)	45 (38.8)
COPD and asthmatic	1 (1.6)	3 (2.5)
Renal disease	1 (1.6)	2 (1.6)
Stroke	3 (5)	8 (6.6)

COPD, chronic obstructive pulmonary disease; HTN, hypertension.

Table 2 Presentations of different groups

Clinical presentation	Peroneal [n (%)]	Tibial [<i>n</i> (%)]
Rutherford IV	10 (16.6)	15 (12.5)
Rutherford V	27 (45)	77 (64.2)
Rutherford VI	23 (38.3)	28 (23.3)

The mortality rate along 2 years was 10 and 5% in groups P and T, respectively. Limb salvage rate along 2 years was 68.8% in group P and 79.8% in group T (P<0.036). The primary and secondary patency rates over 2 years in group P were 31.3 and 54.2%, respectively, and in group T were 47.7 and 62.4%, respectively (Table 3 and Figs. 1–5).

Discussion

To our knowledge, this is the largest series comparing the outcome in peroneal only angioplasty compared with other single tibial angioplasty in patients with infrapopliteal critical limb disease. The major finding in this study is that in patients having CLI with TASC C-D lesion, although single peroneal runoff showed slightly lower limb salvage rate compared with single tibial runoff, it is valuable in patients with no other alternative for revascularization. We think that further studies are required to examine the importance of presence of direct pedal communication and its effect on the clinical success (limb salvage and disappearance of rest pain) of PA angioplasty.

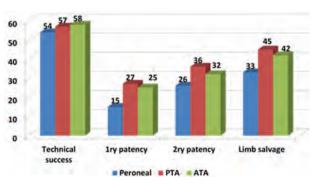
Using the PA angioplasty has been an argumentative issue. Some authors think that owing to the PA is

Table 3 Primary and secondary	patency and limb	salvage rate
(LSR) of different groups		

. ,	• •			
12 months	Peroneal [<i>n</i> (%)]	PTA [<i>n</i> (%)]	ATA [n (%)]	P value
Technical success	54 (90)	57 (95)	58 (96.6)	NA
Primary patency	15 (31.3)	27 (50)	25 (45.5)	0.044
Secondary patency	26 (54.2)	36 (66.6)	32 (58.2)	0.132
Limb salvage rate	33 (68.8)	45 (83.3)	42 (76.4)	0.036
Mortality rate	6 (10)	3 (5)	3 (5)	0.540

ATA, anterior tibial artery; PTA, posterior tibial artery.

Figure 1



Shows the differences in TS, 1ry patency, 2ry patency, LS.



Shows peroneal artery before dilatation.

usually the last and the least tibial vessel to be affected with atherosclerosis in diabetic or endstage tibial disease, in the meantime it has limitation in the form of indirect perfusion of the foot, in spite of an extensive collateral arterial bed, consequently it may be insufficient for treating a septic or gangrenous foot and this lead some authors to believe that it is an inappropriate outflow vessel [2–6].

On the contrary, long-term patency and limb salvage rate after PA angioplasty are mentioned by some authors to be as good as angioplasty to other tibial vessels angioplasty [1,6,7].

Although peroneal bypass surgery is the gold standard and it achieves a comparable hemodynamic result and limb salvage to other infrapopliteal bypass, provided a good quality vein is seen, its role in patients with extensive tissue loss and infection still needs to be clarified and is an arguable issue, and it is associated with considerable perioperative mortality and postoperative complications [6,8].

Review of literature revealed that no study has compared the angioplasty of peroneal only to other single tibial angioplasty. The only study that compared Figure 3



Shows peroneal artery after dilatation.

the adequacy of only peroneal runoff was done by Ballotta *et al.* [1] on surgical reconstruction to PA. They concluded that patency, LS, and wound healing after revascularization to the PA and other infrapopliteal arteries are comparable to each other, and this may provide an evidence that the influential outcome of the arterial reconstruction is not affected by outflow choice. Moreover, they found that PA contributes well to the tissue perfusion despite the lack of any direct communication between the PA and the major pedal vessels, and there is no reason to reject the PA as the last-choice outflow vessel for distal revascularization [1].

Other authors mentioned the importance of presence of wound blush after endovascular therapy in higher rates of limb salvage, and it may be a predictor of limb salvage in patients with CLI [9].

Although we did not study the effect of association between PA and other major pedal vessels, we think that it is important for optimal wound healing and different, at least in the hemodynamic effect, in angioplasty rather than surgery, and therefore, this issue should be elaborated more in angiolasty to study its effect on tissue healing.

Figure 4



Peroneal artery after dilatation communicating with ATA.

Graziani *et al.* [7] attempted to provide, by endovascular treatment, direct straight-line flow to the foot through a native tibial artery, selecting, whenever possible, the anterior tibial artery for ischemic forefoot lesions and the posterior tibial for calcanear lesions. If neither the anterior nor the posterior tibial artery can be treated despite several intraluminal and subintimal crossing attempts, the alternative treatment may consist of providing direct flow along the PA. They achieved good results in better healing and limb salvage [7].

As suggested by Faglia *et al* [10], the adequacy of a reconstruction with peroneal only runoff in some diabetic patients with infected gangrene and major tissue loss following debridement may not be adequate, and more direct blood flow to the involved angiosome may be necessary, either with additional endovascular recanalization or direct bypass. However, Dosluoglu *et al.* [6] found that as the major determinant of limb loss is the amount of tissue loss with extensive gangrene and overwhelming infection, limb loss may still be inevitable even if normal perfusion is restored in these patients.

Although the primary patency and limb salvage were statistically significantly higher in T group than

Figure 5



Peroneal artery after dilatation communicating with PTA.

P group, PA is still of a great value when revascularization to other tibial vessels fails by all means of intraluminal, subintimal, and retrograde recanalization or absent. This results may be attributed to the high percentage of severe tissue loss in this study (~85% of cases Rutherford V and VI).

Conclusion

In patients experiencing CLI with TASC C-D lesion, although single peroneal runoff showed slightly lower limb salvage rate compared with single tibial runoff, it is valuable in patients with no other alternative for revascularization. We think that further studies are required to examine the importance of presence of direct pedal communication and its effect on the clinical success (limb salvage and disappearance of rest pain) of PA angioplasty.

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Conflicts of interest

There are no conflicts of interest.

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Platelet-rich plasma for the treatment of diabetic foot ulcer: a randomized, double-blind study

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Background

Diabetic foot ulcer is a major complication of diabetes mellitus. Over the recent years, great progress has made in the techniques of wound healing, among which autologous platelet-rich plasma (PRP) has attracted the most substantial attention. Platelets are known to start the wound healing process through the release of locally active growth factors. The evidence from studies of autologous PRP to support its use in wound healing is not robust, and further rigorously designed blinded trials are needed. The aim of the study was to evaluate the efficacy and safety of the autologous PRP for diabetic foot ulcer in a randomized control multicenter double-blind design.

Patients and methods

The study included 50 patients with diabetic foot ulcers, who were divided into two groups: PRP and platelet-poor plasma (PPP) groups. The PRP group was treated with autologous PRP in gel form as a dressing. The PPP group was treated with autologous poor plasma as a dressing. The frequency of dressing change for each group was twice weekly.

Results

The healing rate of the PRP group was found to be significantly higher than that of the PPP group. The healing rate per week of the PRP group was significantly higher than that of the PPP group. The rate of complete healing was significantly higher in the PRP group than that of the PPP group.

Conclusion

Autologous PRP is effective and safe for treatment of diabetic foot ulcer.

Keywords:

diabetic foot ulcer, platelet-poor plasma, platelet-rich plasma

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Introduction

Diabetes is a major health problem that is currently showing an alarming rise in its prevalence [1]. Diabetic foot ulcer is a major complication of diabetes mellitus, and is the major component of the diabetic foot [2]. Alvarsson et al. [3] reported that up to 88% of all lower leg amputation is related to diabetic foot ulcer. The goal of the diabetic foot ulcer treatment is to obtain wound closure as expeditiously as possible [4]. Accepted therapeutic objectives and standards of care for diabetic foot ulcers include wound debridement, pressure relief in the wound area, appropriate wound management (e.g. moist wound healing), infection management, ischemia management, medical management of comorbidities, and surgical management as needed [5]. Over the recent years, great progress has been made in the techniques of wound healing, among which autologous platelet-rich gel has attracted the most substantial attention [6]. Platelets are known to start the wound healing process through the release of locally active growth factors [7-10]. The growth factors are able to produce granulation tissue and to induce epithelialization by

the production of neovessels, attraction of fibroblasts and mesenchymal cells, secretion of collagen fibers, and by proliferation of keratinocytes [11–14]. Plateletrich plasma (PRP) may also curb inflammation by suppressing cytokine release [15]. PRP has also been demonstrated to be of some antimicrobial properties against microorganisms, such as Escherichia coli, MRSA, Candida albicans, and Cryptococcus neoformans [16]. The evidence from studies of autologous PRP to support its use in wound healing is not robust, and further rigorously designed blinded trials are needed [17].

The aim of the study was to evaluate the efficacy and safety of the autologous PRP for diabetic foot ulcer in a randomized control multicenter doubleblind design.

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Patients and methods

This prospective, randomized, controlled, multicenter double-blind study was done in the Vascular Surgery Department of Sohag Faculty of Medicine and Vascular And Endovascular Units in Al Azhar Faculty of Medicine following approval by the Scientific Ethics Committee.

Inclusion criteria

- (1) Type 1 or 2 diabetes controlled by either medication or insulin.
- (2) Presence of a foot ulcer for at least 4 weeks to be considered chronic.
- (3) According to University of Texas Treatment-Based Diabetic Foot Classification System: ulcers included in this study are of grade 1A (wounds without tendon, capsule, or bone involvement, and also without associated infection or ischemia) or grade 1C (wounds without tendon, capsule, or bone involvement, and also, without associated infection but with ischemia). Patients with ischemia are allowed to be included but with ankle-brachial index (ABI) of greater than or equal to 0.6.

Exclusion criteria

- (1) Patient's blood vessels are noncompressible for ABI testing.
- (2) ABI of less than 0.6.
- (3) Evidence of gangrene in ulcer or on any part of the foot.
- (4) History of peripheral vascular repair within 30 days of randomization.
- (5) Patient has radiographic evidence consistent with diagnosis of acute Charcot foot.
- (6) Patient has known or suspected osteomyelitis.
- (7) Ulcer size area (length–width) of less than 2 cm^2 .
- (8) Diabetic foot ulcers that are clinically infected.
- (9) Patients having symptoms or signs suggesting general infection (fever, foot pain, hotness, and redness around the ulcer).
- (10) Ulcers that had exposed tendons, ligaments, or bone.
- (11) Patient who is currently receiving or has received radiation or chemotherapy within 3 months of randomization.
- (12) Screening serum albumin level of less than 2.5 g/dl.
- (13) Screening hemoglobin (Hb) of less than 10.5 mg/dl.
- (14) Screening platelet count of less than 100×10^{9} /l.

- (15) Patient undergoing renal dialysis, has known immune insufficiency, liver disease, active cancer, nutritional, hematologic, collagen vascular disease, rheumatic disease, or bleeding disorders.
- (16) Patient having inadequate venous access for blood draw.
- (17) Patients who did not complete their follow-up protocol.

This study was performed on 50 patients. The patient provides a written informed consent before enrolment in the study. All eligible patients were randomized into two groups according to the randomization schedule.

Randomization and blinding procedures

The randomization schedule was generated using the SPSS program (SPSS Inc., Chicago, Illinois, USA). The number and the type of dressing are provided to each vascular research center once the eligible case present there.

Each eligible study participant was assigned to one of the wo treatment groups: the PRP group or the platelet-poor plasma (PPP) group by receiving the next available consecutive randomization number and type of dressing according to the randomization schedule.

Each one of the two vascular research centers share in this research by two participating surgeons

The first participating surgeon (blind surgeon) select the eligible patients, prepared all wounds by removing the necrotic tissue, documented the size, site, and grade of the wounds and continued to follow the wounds during the outpatient visits, regarding the wound size. This surgeon was blind to the type of dressing.

The second surgeon (the unblind surgeon) know the number of the study patients and the treatment group of this patient according to an electronically generated randomization schedule. He also knows the type of the applied dressing and prepare dressings for the patients.

Eligible patients

- (1) PRP group (25 patients): the wounds in this group were covered with PRP as their dressing protocol.
- (2) PPP group (25 patients): the wounds in this group were covered with PPP as their dressing protocol.

Procedures

General measures

In both groups, surgical debridement of the wounds was done to freshen the wound bed and remove all necrotic tissue debris. The wound site, sizes (length, width, and depth), and grade were documented.

Platelet-rich plasma and platelet-poor plasma preparation

- Less than 20 ml of venous blood was drawn from the patients (depending on the wound size) into a tube containing an anticoagulant, to avoid platelet activation and degranulation.
- (2) Then the blood was centrifuged, the first centrifugation is called 'soft spin' (1000 rpm) for 7–10 min which allows the blood separation into three distinct layers:
 - (a) At the bottom of the tube, the red blood corpuscles (RBC) constitute 55% of total volume.
 - (b) At the top of the tube, the acellular plasma layer is mainly made up of circulating plasmatic molecules (in particular, fibrinogen) and is low in platelets. It is designated PPP and constitutes 40% of the total volume.
 - (c) Between the two, there is an intermediate PRP layer (5% of total volume) called the 'buffy coat'.
- (3) Using a sterile syringe, the PPP, PRP, and some RBCs (i.e. the upper two layers and very minimal 'unavoidable' amount of bottom layer) were transferred into another tube without an anticoagulant.
- (4) This tube underwent a second centrifugation (3000 rpm) for 10 min called 'hard spin.' This allowed the platelets (PRP) to settle at the bottom of the tube with very few RBCs.
- (5) The acellular plasma (PPP) (80% of the volume) was found on the top.
- (6) Most of the PPP was taken with a syringe and the remaining PRP was left in the tube.
- (7) At the time of application, the remaining PRP was mixed gently with calcium chloride 10% (0.1 ml) in a Petri-dish and left to rest for 10–15 min until the gel was formed.

Dressing protocol

- (1) PRP group (25 patients): The PRP was applied to the ulcer followed by Vaseline gauze and then sterile dressing. The frequency of change of dressing was twice weekly. The dressing protocol was performed for up to 12 weeks or stopped whenever healing occurred.
- (2) PPP group (25 patients): PPP was applied to the ulcer followed by Vaseline gauze and then sterile dressing. The frequency of change of dressing was twice weekly. The dressing protocol was

performed for up to 12 weeks or stopped whenever healing occurred. General rules regarding the use of offloading techniques for the prevention and healing of plantar foot ulcers in diabetic patients are provided by reducing plantar pressure at sites of ulceration.

Follow-up

Follow-up was twice per week for 12 weeks. The rate of healing of the ulcer was carried out by measuring the ulcer's dimensions (length, width, and depth) using metric tapes at initial visit and at each visit. Laboratory tests were performed for all patients in two groups every 4 weeks until the patients reach the endpoint.

Endpoints

The endpoints of the current analysis were ulcer healing or end of study occurred at completion of the week 12.

Statistical analysis

Data were analyzed using STATA (StataCorp LLC, College Station, Texas, USA) intercooled version 12.1. Quantitative data were represented as mean and SD. Data were analyzed using Student's *t*-test to compare the mean of two groups and paired *t*-test was used to compare data before and after producers in each group. Qualitative data were presented as number and percentage and compared using either χ^2 -test or Fisher's exact test. The *P* value was considered significant if it was less than 0.05.

Results

Between July 2016 and January 2017, 50 patients with diabetic foot ulcer met the inclusion criteria and enrolled in the current series in one of the two groups according to the randomization schedule, 25 patients in each group.

Baseline characteristics of the study patients

There was no significant statistically difference regarding demographic data, risk factors, laboratory parameters, ABI, and wound variables at the baseline for each group which are summarized in Table 1.

The baseline characteristics of diabetic foot ulcer are shown in Table 2 and Fig. 1. The ulcer's initial length ranged from 2 to 6.5 cm, the initial width ranged from 1.5 to 3.2 cm, the surface area ranged from 4 to 9.6 cm² with an average of 7.3 cm², and the volume ranged from 1.2 to 3 cm³ with an average of 1.97 cm³ in the PRP group. The majority of wound sizes in the PRP group (21 out of 25) were in the range of both less than or equal to 7.0 cm² in area and less than or equal to 2 cm³ in volume. Only four cases in the PRP group had areas of greater than 7 cm² and a volume of greater than 2 cm³.

The ulcer's initial length ranged from 2 to 6 cm, the initial width ranged from 1.5 to 3 cm, the surface area ranged from 4 to 9 cm² with an average of 7.08 cm², and the volume ranged from 1.4 to 3 cm³ with an average of 1.90 cm³ in the control group. The majority of wound sizes in the control group (23 out of 25) were in the range of less than or equal to 7.0 cm² in area and less than or equal to 2 cm³ in volume. The remaining two cases in the control group had areas of greater than 7 cm² and a volume of greater than 2 cm³. There were no statistically significant differences between the two groups regarding average length, width, surface area, and volume.

The ulcer healing rate in the PRP group is significantly faster than the control group. There was statistically significant difference between the PRP group and the

Table 1 The baseline characteristics of the study patients

Variables	PRP group	PPP group	P value
Number	25	25	
Age	56.88	55.8	0.76**
Male sex	16	14	0.56**
Risk factors			
Hypertension (%)	72	68	0.76**
Smoker (%)	48	40	0.57**
HbA1c	8.8	8.5	0.38**
Blood picture			
Hb	11.96	12.1	0.69**
Platelet count	258.8	265	0.81**
Blood chemistry			
Albumin	3.7	3.8	0.35**
ABPI	0.8±0.13	0.82	0.60**
Wound			
Area	7.3±1.6	7.08±1.27	0.57**
Volume	1.97±0.57	1.9±0.46	0.63**
Wound site	Foot	Foot	
Foot			
Right	14	12	0.57**
Left	11	13	

ABPI, ankle-brachial pressure index; Hb, hemoglobin; HbA1c, glycosylated hemoglobin; PRP, platelet-rich plasma; PPP, platelet-poor plasma. ${}^{**}P>0.05$, not statistically significant.

control group regarding the ulcer healing rate per week (Table 3).

There was statistically significant difference between the PRP group and the PPP group regarding the rate of completely healed ulcer at 10th and 12th weeks; however, the difference was insignificant at the eighth week (Tables 4 and 5, and Fig. 2).

There were no statistically significant differences between the PRP group and the PPP group from the baseline to the endpoint laboratory shift in blood picture (Hb and platelet count) and blood chemistry (albumin) (Table 4).

Discussion

This is a prospective, randomized, controlled, doubleblind multicenter trial on the use of PRP for the treatment of diabetic foot ulcer. The randomization in this study was generated using the SPSS program and the blindness involves the surgeon who takes the measurements and the patient to provide confidence in the results.

In this study, the majority of wound sizes in the PRP group (21 out of 25) and the PPP group (23 out of 25) were in the range of less than or equal to 7.0 cm^2

Figure 1



Predressing diabetic foot ulcer.

		PRP group		Control		rol group	
	Mean±SD	Minimum	Maximum	Mean±SD	Minimum	Maximum	
Length	3.912±1.2 cm	2 cm	6.5 cm	3.88±0.87 cm	2 cm	6 cm	0.92**
Width	1.96±0.39 cm	1.5 cm	3.2 cm	1.88±0.38 cm	1.5 cm	3 cm	0.39**
Area	7.3±1.6 cm ²	4 cm ²	9.6 cm ²	7.082±1.27 cm ²	4 cm ²	9 cm ²	0.57**
Volume	1.973±0.57 cm	1.2 cm ³	3 cm ³	1.90±0.46 cm ³	1.4 cm ³	3 cm ³	0.63**

PRP, platelet-rich plasma. **P>0.05, not statistically significant.

in area and less than or equal to 2 cm³ in volume. The remaining six cases, four in the PRP group and two in the PPP group, had areas of greater than 7 cm^2 and volume of greater than 2 cm^3 . The results of various studies suggest that a wound size of less than 7.0 cm^2 is most common [18–20]. The average baseline area in the majority of wounds was similar to that reported in many literatures. Driver et al. [4] reported that the majority of wounds (35 out of 40) met the criteria of wound area of less than or equal to 7.0 cm^2 and volume of less than or equal to 2.0 cm³. Lipkin et al. [21] reported in a tissueengineered product study in healing of diabetic foot ulcer that \sim 70% of the ulcers were less than 6 cm^2 . Another tissue-engineered product study in healing diabetic foot ulcer was done by Veves et al. [22]. Veves et al. [22] reported that the average wound size area in the graftskin group that included 112 patients was 2.97±3.10 and in the

Table 3 Comparison between the two groups according the healing area over time

Time	PRP group	Control group	P value
First week	0.6388±0.009	0.4892±0.008	<0.0001*
Fourth week	2.5552±0.035	1.9568±0.030	< 0.0001*
Sixth week	3.6168±0.152	2.9352±0.045	< 0.0001*
Eighth week	5.1018±0.065	3.9256±0.046	< 0.0001*
10th week	6.4786±0.042	4.892±0.078	< 0.0001*
12th week	7.8±0	5.87±0.12	< 0.0001*
Ulcer healing rate per week	0.66±0.04	0.49±0.03	<0.0001*

PRP, platelet-rich plasma. *P<0.05, statistically significant.

Table 4 Comparison between the two groups according to the rate of complete healed ulcer over time

Time	PRP group [<i>n</i> (%)]	Control group [n (%)]	P value
First week	0	0	
Fourth week	0	0	
Sixth week	0	0	
Eighth week	3 (12.00)	0	0.24**
10th week	11 (44.00)	1 (4.00)	0.002*
12th week	21(84.00)	13 (52.00)	0.02*

PRP, platelet-rich plasma. *P < 0.05, statistically significant. **P > 0.05, not statistically significant.

control group that included 96 patients was $2.83\pm$ 2.45. In a large study that was done by Margolis *et al.* [23] included 26 599 diabetic foot ulcer patients, about 60% of which had an wound area of less than 6 cm² that matched the majority of wound areas in the current study.

In this study, the ulcer healing rate in the PRP-treated wound group is significantly faster than that in the PPP group (0.66 ± 0.04 vs. 0.49 ± 0.03). This result is similar to that reported in many literatures.

Saad Setta *et al.* [24] reported in a randomized trial on the use of PRP on chronic diabetic foot ulcer on 24 patients that the healing of ulcer by PRP is significantly faster than by PPP.

Figure 2



Post dressing healed ulcer.

Table 5 Comparison of the laboratory investigation between PRP group and control group from the baseline to the endpoint

PRP	group	P value	Contro	l group	P value
Baseline	Endpoint		Baseline	Endpoint	
8.80±1.04	8.64±0.46	0.48	8.49±1.37	8.49±0.55	1.00**
11.96±1.06	11.98±0.77	0.87	12.08±1.08	12.16±0.99	0.53**
258.80±31.27	255.00±16.32	0.44	261.00±32.91	261.20±30.87	0.91**
3.77±0.010	3.75±0.12	0.35	3.79±0.07	3.79±0.09	0.52**
	Baseline 8.80±1.04 11.96±1.06 258.80±31.27	8.80±1.04 8.64±0.46 11.96±1.06 11.98±0.77 258.80±31.27 255.00±16.32	Baseline Endpoint 8.80±1.04 8.64±0.46 0.48 11.96±1.06 11.98±0.77 0.87 258.80±31.27 255.00±16.32 0.44	Baseline Endpoint Baseline 8.80±1.04 8.64±0.46 0.48 8.49±1.37 11.96±1.06 11.98±0.77 0.87 12.08±1.08 258.80±31.27 255.00±16.32 0.44 261.00±32.91	Baseline Endpoint Baseline Endpoint 8.80±1.04 8.64±0.46 0.48 8.49±1.37 8.49±0.55 11.96±1.06 11.98±0.77 0.87 12.08±1.08 12.16±0.99 258.80±31.27 255.00±16.32 0.44 261.00±32.91 261.20±30.87

HbA1c, glycosylated hemoglobin; PRP, platelet-rich plasma. **P>0.05, not statistically significant.

Kakagia *et al.* [25] reported in a randomized trial on chronic diabetic foot ulcers of 51 patients that the rate of healing for the combination of PRP and proteasemodulating matrix statistical is higher compared with protease-modulating matrix alone.

In 2001, a retrospective controlled study by Margolis *et al.* [26] on the use of platelet releasates on diabetic foot ulcer of 26 599 patients showed statistically significant higher rate of healing at 20th week after treatment by platelet releasates (50 vs. 41%; P<0.05).

In 2010, a systematic review and meta-analysis of Villela and Santos [27] showed that there is scientific evidence regarding favorable outcomes especially the healing rate with the PRP group that reflects the effectiveness of the use of PRP for the treatment of diabetic ulcers.

In this study, the rate of completely healed ulcer in the PRP group was statistically significantly higher than the PPP group at 10th week and at 12th week [11 (44.00%) vs. 1 (4.00%)] and [21(84.00%) vs. 13 (52.00%)] consequently. The result in this study is similar to the result reported by Driver *et al.* [4], Ahmed *et al.* [29], and Jeong *et al.* [28].

Driver *et al.* [4] published a randomized double-blind trial on the use of PRP on chronic diabetic foot ulcers and found a statistically significant difference regarding the rate of complete healing after treatment of diabetic foot ulcer by PRP (81.3 vs. 42.1%, *P*<0.05).

In 2010, the prospective controlled study of Jeong *et al.* [28] on 100 patients with chronic diabetic foot ulcers founds a statistically significant higher rate of complete healing (79 vs. 46%, P<0.05) after treatment using blood bank platelet concentrates.

In 2017, Ahmed *et al.* [29] published a randomized controlled trial on the use of PRP on diabetic foot ulcer of 56 patients and found a statistical difference regarding the rate of complete healing after treatment by PRP (86 vs. 68%, P<0.05). The periodic laboratory tests that were done for patients in this study to measure Hb, hematocrit, platelet counts, and albumin showed that the frequent small amounts of blood collection (\leq 20 ml) that was done on each visit did not reduce these blood elements. The result in this study is agreeable with that reported by Driver *et al.* [4]. Driver *et al.* [4] reported that there were no statistically or clinically significant differences noted between the PRP gel and control from baseline to endpoint laboratory shifts in hematology, clotting factors, and factor V tests. Also,

Driver *et al.* [4] reported that there were no clinical or statistically significant differences in chemistry test for sodium, potassium, chloride, bicarbonate, creatinine, or albumin. Serum glucose or glycosylated hemoglobin results showed that more patients shifted to high at endpoint in the PRP gel compared with the control group. These differences were not statistically significant or clinically meaningful.

Conclusion

The present study concludes that PRP is effective and safe for treatment of diabetic foot ulcer. PRP is effective where it significantly accelerates healing of diabetic foot ulcer and safe where it does not make significant changes on blood hematology or blood chemistry (albumin) in the patients.

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Conflicts of interest

There are no conflicts of interest.

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Endovenous radiofrequency ablation of lower extremity varicose veins: short-term outcomes of the initial experience

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Context

Radiofrequency ablation (RFA) has proven acceptable efficacy and safety in the treatment of truncal varicose veins. Faulty technique may, however, result in primary failure or serious complications, especially during the early time points of the surgeon's learning curve.

Aim

The aim of the present study was to evaluate the safety and effectiveness of RFA procedures in the treatment of great saphenous vein reflux during the initial experience in endovenous thermal ablation.

Materials and methods

A retrospective review was conducted on 47 patients with varicose veins of clinical, etiological, anatomical, physiological (CEAP) class 2–6 who received RFA at the Department of Vascular and Endovascular Surgery, Assiut University Hospitals, to treat refluxing great saphenous veins between 2014 and 2016. Outcome measures were technical success rate and perioperative complications. Short-term outcomes included complete occlusion of the ablated veins and symptom improvement at 1 year.

Results

RFA achieved a technical success rate of 97.9%. Perioperative complications were paresthesia (10.6%), ecchymosis (6.4%), phlebitis (6.4%), and hyperpigmentation (2.1%). No skin thermal injuries, hematomas, deep venous thrombosis, or endovenous heat-induced thrombosis were detected.

One-year complete occlusion rate was 87%. Vascular clinical severity score and venous disability score improved at 1 year to 1.08 ± 0.85 versus 4.03 ± 1.88 (P<0.0001) and 0.60 ± 0.545 versus 1.55 ± 0.552 (P<0.0001), respectively, compared with preoperative values. All treated CEAP-6 patients showed complete healing of their ulcers postoperatively.

Conclusion

RFA is an effective and safe procedure, with satisfactory technical success, closure rates, and symptom improvement. The procedure could be performed in centers with initial experience in endovenous thermal ablation, provided careful commitment to the procedure steps and guiding supervision.

Keywords:

Initital experience, radiofrequency ablation, varicose veins, venous reflux

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Introduction

Chronic venous disease (CVD) is a common health problem that affects approximately one-quarter of the adult population [1]. The increasing morbidity of untreated varicose vein disease can extend from the usual symptoms such as cosmetic disfigurement, leg pain, and edema to the most serious complications such as bleeding varices and venous ulcers. After decades of considering open surgery [ligation of the saphenofemoral junction (SFJ) and stripping of the great saphenous vein (GSV)] as the sole treatment of venous truncal reflux, the advent of the less invasive endovenous ablation has become the recommended first-line treatment of saphenous vein reflux if the patient is candidate for vein ablation [2-4]. Radiofrequency ablation (RFA) has many advantages over the conventional surgery as it can be safely performed in an office-based setting under local anesthesia with less postoperative pain, faster return to full activity [5], and excellent success rates [6]. RFA, however, has shown to have higher rates of primary failure and superficial thrombophlebitis than surgery [5,7,8], and it may develop serious complications such as skin burns especially during the learning curve of the surgeon's experience [9]. Therefore, the aim of the present study was to evaluate safety and effectiveness of

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RFA procedures in the treatment of GSV reflux during our initial experience.

Materials and methods Study setting

The present study is a retrospective review of the vascular registry at Assiut University Hospital (a tertiary referral hospital). The study was approved by the Institutional Review Board of the Faculty of Medicine, Assiut University. All study patients were informed and consented to the RFA procedure upon presentation for treatment.

Patients

The study included all patients with symptomatic lower extremity varicose veins of clinical, etiological, anatomical, physiological (CEAP) [10] class 2–6 who received endovenous RFA at the Department of Vascular and Endovascular Surgery, Assiut University Hospital, to treat refluxing GSVs between 2014 and 2016.

All patients underwent detailed clinical examination at the outpatient clinics to evaluate the severity of symptoms [including a baseline venous clinical severity score (VCSS) and venous disability score (VDS) assessment] [11]. Duplex ultrasound (DUS) examination of the superficial and deep venous systems in both lower limbs was done by the vascular surgeon to measure diameters of the GSV and their reflux time. Patients with suspected abdominal or pelvic venous pathology, deep venous reflux, superficial or deep venous thrombosis, reflux time shorter than 0.5 s, or saphenous vein diameters less than 5 mm or more than 12 mm were excluded from RFA. The study also excluded patients who received previous varicose vein procedures, GSVs that are located within 10mm distance under the skin, and patients with duplication of the GSV or concomitant reflux in the short or in the anterior accessory saphenous veins.

Procedural technique

Under direct supervision of experienced vascular surgeons in endovenous thermal ablation, all RFA procedures in the study were performed by vascular surgeons with a recent experience in endovenous thermal ablation. According to our protocol, RFA is done under local infiltration anesthesia in the operating rooms. We do not use a preoperative prophylactic heparinization. While patients are in supine position, an ultrasound (US)-guided puncture to the GSV is achieved percutaneously below or at the knee level using a micropuncture needle. Over a soft guidewire, a 7-French (F) sheath is secured into the GSV. RFA catheter (ClosureFast; VNUS Medical Technologies, San Jose, California, USA) is advanced from the knee level toward the groin. With the aid of US imaging, the catheter tip is positioned 2–3 cm distal to the SFJ. Tumescent anesthesia (500 ml of 0.9% saline, 50 ml of 1% xylocaine with 1 : 100000 epinephrine, 5 ml of 8.4% sodium bicarbonate 1%) is then injected with a spinal needle around the vein and along the segment to be ablated. The desirable amount of the injected tumescent anesthesia and its precise location in the saphenous compartment are guided by the US imaging.

While the vein is compressed by the DUS transducer probe, the vein is ablated in a groin-to-knee direction. The RF catheter heats a 7-cm segment of the vein to 120° in a 20-second cycle. The most proximal segment is treated with two heating cycles, whereas each distal segment is treated once. At the end of the procedure, a completion US examination of the ablated vein is done to confirm a complete closure of the vein and to exclude any thrombus protrusion into the deep veins. RFA was supplemented with phlebectomy of the small varicosities that were marked preoperatively.

Postoperative care

At the end of the procedure, a thigh-high class-3 graded compression stocking is applied. The patient is discharged to home on the same day. The patient is advised to ambulate early after the procedure and to use the stocking day and night for 2 days and then by day only for an additional week.

Follow-up

The first follow-up clinical and DUS examination is typically scheduled on the seventh postoperative day and then after 6 and 12 months postoperatively. Day 7 follow-up is aimed to assess technical success defined as complete ablation of the GSV starting at the 2 cm segment distal to the SFJ till the end of the treated vein with complete absence of color flow Doppler signals.

Partial technical failure is considered when the GSV is completely occluded with a residual patent vein stump of 3 cm or longer distal to the SFJ.

DUS follow-up (sixth and 12th month) examination of the treated vein is categorized into one of the following grades: (1) complete occlusion of the treated vein, (2) asymptomatic recanalization, where the treated vein shows one or more competent recanalization segments without clinical recurrence of varicose veins, (3)

Endpoints

Our primary end point is achievement of total closure of the ablated GSV (technical success). Failure to access the vein percutaneously or to pass the guidewire, or detection of postoperative residual patent vein segment of 5 cm length (or longer) is considered a technical failure and will be excluded from the follow-up analysis. Delayed patency of a vein segment after an initially successful occlusion is considered a recanalization.

Secondary endpoints included complications (sensory affection and wound and skin problems), improvement in VCSS and VDS values, appearance of varicose veins on follow-up, or the requirement for re-intervention to treat residual or recurrent varicose veins.

Statistical analysis

Statistical analysis was performed using SPSS 24.0 (SPSS Inc., Chicago, Illinois, USA). Descriptive statistics were used, with continuous variables expressed as mean \pm SD or median and interquartile range, and categorical variables as frequencies and percentages. Student's *t*-test was used to test the difference between the mean of VCSS and VDS score preoperatively and 1 year after the intervention. A value of *P* less than 0.05 was considered to be statistically significant. Freedom from any recanalization or symptom recurrence was assessed by Kaplan–Meier estimation.

Results

Between March 2014 and March 2016, 44 patients (47 limbs) underwent RFA procedures to treat symptomatic reflux of the GSV. All limbs that needed stab phlebectomies (n=22) were performed during the same RFA session. Baseline characteristics and CEAP classification for study patients are shown in Table 1.

Successful GSV closure using RFA was achieved in 46 limbs resulting in a technical success rate of 97.9%. Technical failure occurred in one limb, and the patient was successfully treated with surgical ligation of the SFJ and stripping of the GSV after 5 weeks.

Our perioperative complications (Table 2) included postoperative paresthesia in five (10.6%) limbs,

ecchymosis in three (6.4%), phlebitis in three (6.4%), and hyperpigmentation in one (2.1%). There was no postprocedural deep venous thrombosis, endovenous heat-induced thrombosis (EHIT), pulmonary embolism, or procedure-related mortality. None of the patients experienced postprocedural skin thermal injuries, hematomas, infections, or required hospitalization beyond the day of intervention.

A total of 38 (40 limbs) patients completed the 1-year follow-up. Symptom relief at 1 year was judged by the significant improvement in VCSS and VDS scores as compared with their preoperative values (1.08 ± 0.85 vs. 4.03 ± 1.88 , P<0.0001, and 0.60 ± 0.545 vs. 1.55 ± 0.552 , P<0.0001, respectively). All five patients with active venous ulcers showed a complete ulcer healing on follow-up, with a mean ulcer healing time of 2 months.

Follow-up DUS examination was done to the treated limbs to assess the rate of GSV recanalization after

Table 1 Baseline patient characteristics and distribution
according to clinical, etiological, anatomical, physiological
classification

Characters	n (%)
Number of patients (limbs)	44 (47)
Number of bilateral procedures	3
Age (mean±SD) (years)	33.19±8.1
Sex	
Males	26 (59.1)
Females	18 (40.9)
Side	
Right	26 (55.3)
Left	21 (44.7)
GSV diameter (mm)	
Mean±SD	7.85±1.18
Median (IQR)	8 (1)
CEAP class	
Varicose veins (C2)	28 (59.6)
Swelling (C3)	7 (14.9)
Hyperpigmentation and/or lipdermatosclerosis (C4)	6 (12.8)
Healed ulcer (C5)	1 (2.1)
Active ulcer (C6)	5 (10.6)

CEAP, clinical, etiological, anatomical, physiological; GSV; great saphenous vein; IQR, interquartile range.

Table 2 Periprocedural complications of radiofrequency ablation-treated limbs

	n (%)
Postoperative paresthesia	5 (10.6)
Ecchymosis	3 (6.4)
Phlebitis	3 (6.4)
Hyperpigmentation	1 (2.1)
Skin burns	0 (0)
Heat-induced deep vein thrombosis	0 (0)
Pulmonary embolism	0 (0)
Mortality	0 (0)

Follow-up time point	Number (at risk)	Any recanalization (limbs)	Symptom recurrence	Additional treatment
Seventh day	46	0	0	No
6 months	42	2	1	Foam sclerotherapy
12 months	40	4	2	Foam sclerotherapy

Table 3 Outcome of radiofrequency ablation-treated limbs on duplex follow-up examination

RFA procedures (Table 3). At 6 months, 40 limbs (of 42) continued to have total occlusion of the treated GSV. Of the two GSV racanalizations, one limb was symptomatic with recurrent leg varicosities (Fig. 1) and was successfully treated with duplex-guided foam sclerotherapy. The other limb showed an asymptomatic recanalization of a vein segment that did not require any further treatment.

At 1 year, 36 limbs of the examined 40 limbs maintained a complete closure of the GSV, resulting in a cumulative complete occlusion rate of 87% (Table 3, Fig. 2). Two limbs showed asymptomatic reflux in recanalized vein segments (grade 2) and required no additional treatment. The remaining two limbs showed recurrent varicosities (Fig. 1) owing to recanalization of vein segments (grade 3) and were all treated with duplex-guided foam sclerotherapy.

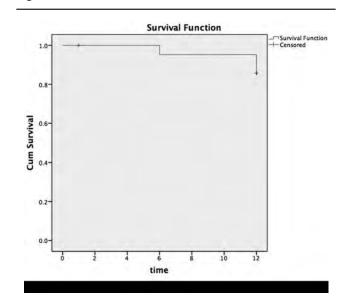
Overall, throughout all time points of follow-up in the study, there were six limbs that were found to have delayed recanalization after an initially successful RFA procedure. Of those, only three limbs that had grade 3 recanalization associated with symptom recurrence and were successfully retreated with duplex-guided foam sclerotherapy.

Discussion

Endovenous thermal ablation of incompetent GSV has been met with widespread consideration by vascular interventionists. Newer catheter generations, improved technical expertise, and available patient reimbursement all contributed to increased number of these minimally invasive procedures. The scientific evidence for the treatment of refluxing GSV in patients with CVD strongly recommends endovenous thermal ablation in preference to surgery as demonstrated in clinical practice guidelines of the Society of Vascular Surgery, the American Venous Forum [3], the European Society for Vascular Surgery [4], and NICE guidelines [12].

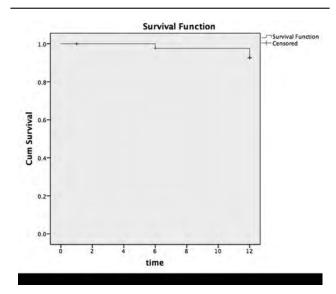
The current study is a retrospective analysis of patients presented with CVD who underwent RFA of incompetent GSV at a tertiary referral hospital. The aim was to evaluate short-term outcomes of this technique performed by interventionists in early time





Kaplan–Meier survival curve demonstrating probability of great saphenous vein recanalization associated with symptom recurrence.





Kaplan–Meier survival curve demonstrating probability of great saphenous vein freedom from any recanalization.

points of their learning curve. However, all procedures were performed under direct supervision of experienced vascular surgeons.

A total of 47 limbs received RFA treatment of refluxing GSV in the current series. Concurrent phlebectomy

The reported total occlusion rate using the firstgeneration RFA device ranged from 75 to 92%, with a partial occlusion rate of between 7 and 26% [13–15]. Previous studies demonstrated early occlusion rates of 99.6% using the ClosureFast device in 194 patients [16], 88.7% at 1 year [17], and 92.4% at 180 days [18]. Nicolini reported a total occlusion rate of 81% and varicose vein free rate of 90.1% at 1 year after RFA using the first-generation device in 330 limbs [19].

Of the ablated 47 veins in the current study, one limb failed the RFA procedure and was treated with surgical ligation of the SFJ and stripping of the GSV. Technical failure could be attributed to following a wrong technique or missing steps starting with detailed preoperative duplex vein mapping, ideal catheter positioning with optimal visualization, effective tumescence application around all vein segments, and inadequate limb position trying to empty the vein from blood.

In the current cohort, duplex follow-up demonstrated that recurrent varicose veins were noticed in relation to recanalization of incompetent vein segments with absence of neovascularization at the groin. Few studies described neovascularization as an important risk factor for symptom recurrence following high SFJ ligation and GSV stripping operations that may reach 45% at 2 years [20,21].

Our most frequent complication was paresthesia (10.6%), ecchymosis (6.4%), phlebitis (6.4%), and hyperpigmentation (2.1%). We have not observed any incidents of EHIT or pulmonary embolisms in our patients. Reported EHIT varies from 0 to 16% [22]. Its risk is higher in patients with documented thrombophilia, previous history of DVT, obesity, or old age [22,23]. The newer ClosureFast catheter (VNUS Medical Technologies) and early ambulation were linked to fewer adverse effects [24].

The current study patients demonstrated a significant clinical improvement after RFA as seen with healing of venous ulcers along with the improvement of VCSS and VDS score from 4.03 ± 1.88 to 1.08 ± 0.85 , *P* value less than 0.0001, and from 1.55 ± 0.552 to

 0.60 ± 0.545 , *P* value less than 0.0001, respectively. Our results compare favorably with reported results in several studies [25–27].

Our study limitations could be the small sample size and the short follow-up period as we are reporting our initial experience. The retrospective design limited the availability of our retrieved data. We have not included analysis for pain assessment either intraprocedurally or postprocedurally, mean BMI, or for the proximity of the closure level to the SFJ, which is considered as an important factor for EHIT.

Conclusion

RFA is a simple and safe procedure. The technique is effective with satisfactory technical success and closure rates leading to a significant symptomatic improvement. The procedure could be performed in centers with initial experience in endovenous thermal ablation, provided careful commitment to the procedure steps and the guiding supervision.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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Portal vein thrombosis with cirrhosis: is it an indication for early liver transplantation?

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Introduction

Portal vein thrombosis (PVT) is an independent risk factor for perioperative mortality and graft loss but not long-term outcomes in patients with cirrhosis after LT.

The aim of this study was to assess the effect of timing of Living Donor Liver Transplantation (LDLT) on early results in patients with cirrhosis with PVT and decompensated liver (early vs. late). This was a retrospective study.

Patients and methods

This study included 24 patients with cirrhosis with PVT who underwent LDLT between January 2015 and June 2017 in Ain Shams University Hospitals. Fifteen patients were Child C and Model for End stage Liver Disease (MELD) more than 15 (group A) at time of transplantation and nine patients were transplanted early (Child B and MELD <15) owing to other indications, for example, Hepato Celluluar Carcinoma (HCC) (group B). Comparisons were done between both groups regarding operative data and perioperative mortality.

Results

Both groups were comparable in age, sex, etiology of liver disease, and presence of HCC. Operation in group B was easier than in group A, with statistically significant difference regarding operative time (7.4±1.2 vs. 10±2.1 h, *P*=0.002), need for blood transfusion (55.6 vs. 100%, *P*=0.005), and amount of blood transfusion [2 U (0–6) vs. 3 U (1–10) (*P*=0.048)]. Blood loss was only significantly lower in group B at 1900 ml (700–2600) versus 3000 (1000–6000) in group A (*P*=0.073). No statistically significant differences in ICU stay (*P*=0.570), hospital stay (*P*=0.432), and perioperative mortality (22.2 vs. 26.7%) were observed in group B and group A (*P*=0.562).

Conclusion

LDLT in patients with cirrhosis with PVT is technically more feasible when done early (Child B and MELD <15), but this is not associated with better outcome. PVT in patients with cirrhosis is not an indication for early transplantation.

Keywords:

indication, LDLT, portal vein thrombosis with cirrhosis

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Introduction

The prevalence of portal vein thrombosis (PVT) varies from 5 to 20% in patients with cirrhosis [1]. Notably, most patients have Child-Pugh classes A and B [2]. The development of PVT is associated with a decreased portal flow caused by splanchnic vasodilatation and the liver architectural derangement [3]. Furthermore, there is presence of systemic thrombotic risk factors and changes of the coagulation and anticoagulation factors in liver cirrhosis [4]. In the past, Liver Transplantation (LT) was forsaken for patients with PVT. Currently, however, PVT is no longer a contraindication owing to the development of various surgical and medical strategies. In a retrospective analysis of 21 673 LT recipients using the United Network for Organ Sharing registry, the presence of PVT was identified as an independent risk factor for post-transplant early mortality [5]. PVT is a risk factor for early mortality and graft loss but not long-term outcomes in patients undergoing LT [6]. The aim of this study was to compare the early results (90 days) of Living Donor Liver Transplantation (LDLT) in patients with PVT transplanted early (Child B and Model for End stage Liver Disease, MELD <15) and patients transplanted late (Child C and MELD >15).

Patients and methods Patients

Between January 2015 and June 2017, 112 LDLT were done in Ain Shams Centre for Organ Transplantation. Twenty-four (21.4%) patients had PVT either diagnosed

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preoperatively by radiology or was an incidental intraoperative discovery. Of the 24 patients, 15 were transplanted for end-stage liver disease (Child C and MELD score >15) and nine patients were transplanted for other indications, mostly Hepato Celluluar Carcinoma (HCC) (Child B, or MELD <15). For patients with HCC, exclusion of malignant PVT depends on the relation of tumor to portal vein, lack of vascularization of the thrombus in arterial phase of triphasic computed tomography (CT), and absence of disruption of vessel wall or arteriovenous fistula. Ultrasound (US)-guided biopsy and pathological assessment is the most accurate form of examination but is invasive and carries a high risk of complication in such patients, so it is avoided in this study.

Preoperative workup

All patients undergoing transplant were subjected to the following:

- (1) Full clinical assessment.
- (2) Laboratory investigations: complete blood count, coagulation profile, liver function tests, kidney function tests, lipid profiles, diabetes profile, serum electrolytes, viral markers, tumor markers, and assessments for bilharzias, autoimmune disease, and metabolic liver disease. All patients with PVT diagnosed preoperatively were investigated for hypercoagulable state with protein C, protein S, antithrombin III, lupus anticoagulant, anticadiolipin IgG and IgM, factor V Leiden mutation, prothrombin G20210A mutation, JAK2V617F mutation, and MTHFR C677T gene mutation.
- (3) Radiological investigations: triphasic pelviabdominal CT with portography, venography, and arteriography. Bone scan and CT chest were done for HCC staging.
- (4) Endoscopy: upper gastrointestinal endoscopy and colonoscopy.
- (5) Medical consultations: cardiology, chest, psychological, ENT, dental, gynecological consultations, and others according to patient condition.
- (6) Calculation of MELD and Child score.

Only two cases of known patients with PVT had pretransplant trial of management of PVT with anticoagulant. Thrombolysin or transjugular intrahepatic portosystemic shunt was not done in any patients.

Intraoperative

All patients were treated with portal vein eversion thrombectomy with adequate flow and direct anastomosis of recipient portal vein with donor portal vein. There was no need for any other treatment options (jumping graft, renoportal with graft, portocaval hemitransposition, or portal vein arterialization).

At the end of the operation, if portal vein velocity by Doppler US was less than 50 (steel phenomenon), ligation of collateral was done (one patient) or exposure of left renal vein with clamping and re-measure PV velocity, if increased ligation of left renal vein at its termination in inferior vena cava were done (five patients).

Postoperative workup

(1) All patients with PVT started anticoagulation with enoxaparine therapeutic dose (1 mg/kg/12 h) as soon as the patient's condition allows (INR <2, platelet count >30×10⁹/l, and drain color to be serous). In patients with renal impairment, dose adjustment was done. In patients without increased systemic risk of hypercoagulable state, enoxparine was continued for 1 month. For patients with systemic risk, enoxparine was continued for 1 month and then shifted to oral anticoagulant (warfarin), and follow-up was done to maintain INR between 2 and 3 forever.

Early workup (first 3 months)

- (1) Follow-up included laboratory investigation and Doppler US daily for 2 weeks, then twice weekly for 2 weeks, and then once weekly for 2 months.
- (2) For patients with incidental discover of PVT intraoperatively, investigations for inherited or acquired risk of hypercoagulable state were done, including protein C, protein S, antithrombin III, lupus anticoagulant, anticadiolipin IgG and IgM, factor V Leiden mutation, prothrombin G20210A mutation, JAK2V617F mutation, and MTHFR C677T gene mutation.

Later (after 3 months)

- Follow-up laboratory investigation and US every 2–4 weeks were done according to patient's demands.
- (2) Follow-up of tumor markers every 3 months and abdominal CT every 6 months was done for patients transplanted for HCC.

This study involves follow-up of 24 patients with PVT who underwent LDLT at Ain Shams University Hospitals. These patients were classified into two groups:

- (1) Group A: patients with Child C and MELD up to 15.
- (2) Group B: patients with Child B and MELD less than 15.

Comparison between the two groups was done using the following:

- (1) Preoperative data.
 - (a) Demographic data.
- (2) Operative data.
 - (a) Blood loss.
 - (b) Cell saver and blood transfusion.
 - (c) Operative time.
- (3) Short-term results.
 - (a) Perioperative mortality (90 days).

Statistical analysis

Data were collected, revised, coded, and entered to the statistical package for the social sciences (IBM SPSS) version 20. The comparisons between the two groups with qualitative data were done by using χ^2 -test and/or Fisher exact test, which was used instead of χ^2 -test when the expected count in any cell was found less than 5.

The comparisons between two independent groups regarding quantitative data with parametric distribution were done by using independent *t*-test.

The comparison between two independent groups regarding quantitative data with nonparametric distribution was done by using Mann–Whitney *U*-test.

The confidence interval was set to 95% and the margin of error accepted was set to 5%. So, the *P*-value was considered significant as the following:

- (1) P>0.05: nonsignificant.
- (2) *P*<0.05: significant.
- (3) P < 0.01: highly significant.

Results

This study include patients transplanted between January 2015 and June 2017 with PVT (24/112 patients, 21.4%). PVT was diagnosed either preoperatively by radiology or was an incidental discovery intraoperatively. Group A included 15 patients of 24 who were transplanted for end-stage liver disease (Child C and MELD score >15) and group B included nine patients transplanted for other indication, for example, HCC and refractory ascites but were still early regarding Child and MELD (Child B, or MELD <15).

Group A included 12 (80%) male and three (20%) female patients in comparison with nine (100%) male with no female patients in group B, which was statistically not significant (P=0.151). The median age in group A was 55 years (ranging between 35 and 62 years) and 59 years (ranging between 34 and 68 years) in group B (statistically not significant P=0.446). There was no statistical significant difference regarding etiology of liver disease. All patients in group A were transplanted owing to HCV, whereas seven (77.8%) patients of nine in group B were because of HCV, one (11.1%) patient was owing to autoimmune hepatitis, and one (11.1%) patient was owing to cryptogenic cirrhosis (statistically not significant, P=0.162). Overall, 40% of the patients in group A and 33% in group B had HCC at the time of transplantation (statistically not significant, P=0.744) (Table1).

Comparison was done between both groups regarding operative data, and there was a statistically significant difference in operative time and blood transfusion (incidence and amount). Blood loss was lower in group B at 1900 ml (range between 700 and 2600) than in group A at 3000 ml (range between 1000 and 6000), but the difference tended to be significant but not statistically significant (P=0.073). Blood transfusion happened in all patients (100%) in group A but only in five (55.6%) patients in group B (statistically high significant, P=0.005), and also the number of unit of blood was higher (3U, ranging between 1 and 10U) in group A than in group B (2U, ranging between 0 and 6U) (statistically significant, P=0.048). Cell salvage (autologous blood transfusion) was done in all patients of both groups except patients transplanted for HCC (40% in group A and 33.3% in group B) (statistically not significant, P=0.744). The median amount of blood retransfused was 800 ml (0.0-3000 ml) in group A versus 700 ml

Table 1	Comparison	between	demographic	data of the
patients	5			

	Group A (Child C, MELD >15) [<i>n</i> (%)]	Group B (Child B, MELD <15) [<i>n</i> (%)]	Р
Age	55 (35–62)	59 (34–68)	0.446
Sex			
Female	3 (20.0)	0 (0.0)	0.151
Male	12 (80.0)	9 (100.0)	
Etiology of cirrh	nosis		
HCV	15 (100.0)	7 (77.8)	0.162
AIH	0 (0.0)	1 (11.1)	
Cryptogenic	0 (0.0)	1 (11.1)	
HCC			
Negative	9 (60.0)	6 (66.7)	0.744
Positive	6 (40.0)	3 (33.3)	

AIH, auto immune hepatitis. This table shows no statistically significant difference between the groups regarding age, sex, etiology of liver disease, and HCC incidence.

(0.0–1250 ml) in group B (statistically not significant, P=0.411). The mean operative time was 10 ± 2.1 h in group A in comparison with 7.4 ± 1.2 h in group B (statistically highly significant, P=0.002) (Table 2).

Postoperative data of both groups regarding ICU and hospital stay were nearly similar. Mean ICU stay was 6 days in both group A (ranging between 5 and 12 days) and group B (ranging between 4 and 8 days) (P=0.570). The median hospital stay in group A was 28 days (ranging between 21 and 46 days), which was slightly higher than group B at 24 days (ranging between 20 and 38 days) (P=0.432) (Table 2).

There was no significant difference in early postoperative mortality between both groups (P=0.562). Four patients of 15 (26.7%) died early in group A. Two patients died owing to portal vein rethrombosis. One of them showed very early occlusion, on day 2. Patient explored with thrombectomy and good intraoperative Doppler followed by rethrombosis within 3 days. The other presented with sudden deterioration with marked elevation of liver enzymes on day 14 postoperatively. The patient needed vasopressor and mechanical ventilation, with Doppler showing complete occlusion of portal vein and inhomogenous graft. One patient died of hepatic artery (HA) thrombosis, and last one died of uncontrolled sepsis (pneumonia with bilateral patches). In group B, two patients of nine (22.2%) died of portal vein rethrombosis and HA thrombosis. The patient with portal vein rethrombosis was explored with thrombectomy and collateral ligation, but had unsatisfactory weak portal flow. The patient with HA

 Table 2 Intraoperative and postoperative data of both groups

thrombosis was explored twice with reconstruction of HA anastmosis with re-occlusion within less than 12 h between transplantation procedure and each exploration (Table 2).

Discussion

The prevalence of PVT in patients with cirrhosis ranges from 5 to 20%. This heterogeneity is owing to the different diagnostic modalities used in different studies (autopsy, surgery, and US) and the exclusion or inclusion of HCC. The severity of liver dysfunction might influence the incidence of PVT in liver cirrhosis [1]. In a prospective study by Zocco *et al.* [3], 49% (36/73) of patients with PVT had MELD score of more than 13.

In our study, incidence of PVT was 21.4% (24/112 patients). Nine (37.5%) patients were Child B and MELD less than 15 and 15 (62.5%) patients were Child C and MELD more than 15.

Song *et al.* [7] showed that the packed red blood cell transfusion amount of PVT group was not different from that of no-PVT group, unlike most publications where the transfusion requirement and operation time was significantly greater in the PVT group compared with no-PVT group [8–10].

In our study, the procedure technically was more easier in group B with low Child and MELD in comparison with group A with higher Child and MELD score with less operative time (7.4 \pm 1.2 vs. 10 \pm 2.1 h, *P*=0.002), need for blood transfusion (55.6 vs. 100%, *P*=0.005),

	Group A (Child C, MELD >15) [n (%)]	Group B (Child B, MELD <15) [n (%)]	Р
Blood loss [median (range)] (ml)	3000 (1000–6000)	1900 (700–2600)	0.073 ^a
Blood transfusion			
Yes	15 (100)	5 (55.6)	0.005 ^b
No	0 (0)	4 (44.4)	
Blood transfusion (U)	3 (1–10)	2 (0.0–6)	0.048 ^a
Cell salvage			
Yes	9 (60)	6 (66.7)	0.744 ^b
No	6 (40)	3 (33.3)	
Cell salvage [median (range)] (ml)	800 (0.0–3000)	700 (0.0–1250)	0.411 ^a
Operative time (h)	10±2.1	7.4±1.2	0.002 ^a
ICU stay (days)	6 (5–12)	6 (4–8)	0.770 ^a
Hospital stay (days)	28 (21–46)	24 (20–38)	0.432 ^a
Perioperative mortality (90 days)			
Living	11 (73.3)	7 (77.8)	0.562 ^b
Dead	4 (26.7)	2 (22.2)	
Cause of death			
НАТ	1 (25)	1 (50)	0.431
PVT	2 (50)	1 (50)	
Sepsis	1 (25)	0 (0)	

HAT, hepatic artery thrombosis; PVT, portal vein thrombosis. ^aMann–Whitney U-test. ^bFisher's exact test.

and amount of blood transfusion [2 U (0–6) in group B vs. 3 U (1–10) in group A] (P=0.048).

PVT was associated with worse outcomes after LT, especially with high Yerdel grade (III and IV) in which thrombosis extended below the splenic and superior mesenteric veins confluence [11]. However, some single-center studies have described no effect on survival, particularly if physiological portal vein reconstruction is achieved [12–14]. Despite the debate about LT results in patients with PVT, LT carries a favorable survival benefit in these patients [15].

In our study, perioperative mortality in all patients was 25% (six patients out of 24 patients) which is definitely high. Comparison between the effects of different grades on survival was very important but was not applicable owing to the small sample size. Unfortunately, better general condition of patients when transplanted early (Child B, MELD <15) was not associated with better outcome. Perioperative mortality was nearly similar (26.7% in group A vs. 22.2% in group B, P=0.562).

In LDLT for patients with PVT, not only PV-related complications but also HA-related complications are prone to develop because HA injury can often occur during dissection of hepatic hilum when pericholedochal varix or cavernous transformation of hepatic hilum is present, and alternative available arterial inflow vessels or interposing fresh cadaveric iliac artery that have small branches corresponding to graft HA are usually absent. Particularly in patients with extensive PVT, including grades 3 and 4, we have to perform meticulous dissection to reduce HA injury such as direct arterial wall injury or intimal dissection from mural hematoma propagation [16].

In our study, two patients (33% of mortality) died owing to HA problems, with one in each group: One of them may be related to technical problem, but the other was related to hypercoagulable state with recurrent rapid rethrombosis even after reconstruction twice.

Conclusion

Living donor liver transplantation in patients with cirrhosis with PVT is technically more feasible when done early (Child B and MELD <15), but this is

not associated with better outcome. PVT is not an indication for early transplantation.

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Conflicts of interest

There are no conflicts of interest.

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Negative pressure wound therapy for chronic venous ulcer: a randomized-controlled study

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Objective

The purpose of this study was to evaluate the efficacy of negative pressure wound therapy (NPWT) in promoting wound healing of venous leg ulceration.

Patients and methods

This study was designed as a single-center randomized-controlled trial. Patients with venous leg ulcer of at least 3 months in duration were enrolled in this study. The first group (NPWT group) was treated by NPWT using standardized method. Intermittent negative pressure at -100 to -150 mmHg was applied, and the dressings were changed every 48–72 h. The second group (control group) was treated by conventional daily dressing using normal saline.

Results

After 15 days of treatment, significant differences in ulcer size and percent of ulcer healing were detected between the two treatment groups. The wound healing rate was 13.1 and 2.8 mm²/day in NPWT group and control group, respectively. After 30 days of treatment, 17 (68%) ulcers revealed 90% healing in NPWT group, with mean duration of 24 days needed for healing. None of the ulcers in control group completed 90% healing after the 30 days of treatment.

Conclusion

NPWT improved wound healing and may be considered as treatment for venous leg ulcer.

Keywords:

chronic venous insufficiency, negative pressure wound therapy, venous ulcer

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Introduction

Venous leg ulcers (VLUs) represent the most severe manifestation of chronic venous insufficiency and account for most lower extremity ulcerations [1]. VLU has been estimated to affect 500 000–600 000 people annually in the USA and is the most common leg ulcer treated in wound care centers. Furthermore, it has been stated that ~1% of all adults will develop a VLU at some point in their lives [2]. These ulcerations are known to be difficult to heal leading to negative effect on the patient's quality of life, with a significant economic burden on the healthcare system [3].

Negative pressure wound therapy (NPWT) was developed as an alternative to standard wound management incorporating the use of intermittent negative pressure to optimize wound healing conditions with positive results [4]. NPWT consists of a wound filler material covered with an adherent airtight drape connected to a source of negative pressure such as a pump [5].

NPWT appears to act through multiple mechanisms including exudate management, removal of edema, promoting tissue perfusion, and stimulation of granulation tissue formation [6]. NPWT has been used for different types of wounds with promising results; however, only a few studies have evaluated its role in VLU. Therefore, the purpose of this study was to evaluate the efficacy of NPWT in promoting wound healing of VLU.

Patients and methods

This study was designed as a single-center randomized-controlled trial at the Department of General Surgery Menoufia University, with prior approval from our Institution's Ethics Review Board.

Inclusion criteria

Patients with VLU of at least 3 months in duration were enrolled in this study. The diagnosis of VLU was made by the associated clinical manifestation of primary or secondary venous disease and confirmed by duplex ultrasound.

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Exclusion criteria were patients with reflux at the saphenofemoral junction, long saphenous vein or saphenopopliteal junction, absent pedal pulse, age younger than 18, poorly controlled diabetes mellitus, recent history of chemotherapy, and patients with active cancer. Patients with severe anemia, those with hypoalbuminemia, or immunocompromised patients were also excluded.

After written informed consent, eligible patients were randomized using a computerized list into two groups. The first group (NPWT group) was treated by NPWT using standardized method. Sterile, open-cell foam dressing was gently placed into the wound cavity; a fenestrated evacuation tube was then embedded in the foam and connected to vacuum pump that contains a fluid collection canister; the site is then sealed with an airtight adhesive drape. Intermittent negative pressure at -100 to -150 mmHg was applied, and the dressings were changed every 48-72 h. The second group (control group) was treated by conventional daily dressing using normal saline. Patients with bilateral leg ulcers were randomized separately for each leg.

The wound size was evaluated before initiation of treatment and during follow-up. The elliptical method described by Shaw *et al.* [7] and the mathematical formulae described by Johnson [8] were used for wound measurement. Wound healing rate, defined as absolute area healed per day, was recorded in both groups. Ulcer healing was the outcome of interest in this study, and the endpoint was 30 days of treatment or 90% healing of the index ulcer.

Statistical analysis

Statistical analysis was performed using SPSS, version 24.0 (IBM Corp., Armonk, New York, USA). Discrete variables were presented as numbers (counts) and percentage. Continuous variables were presented as mean and SD. Student's *t*-test was used for intergroup comparisons to test the significance of difference between two different variables. *P* value less than 0.05 was considered statistically significant.

Results

From March 2016 to October 2017, 50 patients were eligible to participate in this study. They were randomly assigned into two groups, each containing 25 patients.

Baseline patient characteristics are shown in Table 1. The two groups were comparable regarding ulcer size, chronicity, history of diabetes, and deep venous thrombosis at randomization.

Ulcers size was evaluated after 15 days of treatment, and significant differences in ulcer size and percent of ulcer healing were detected between the two treatment groups, as shown in Table 2. The mean ulcer size was reduced from 3.58 to 1.63 cm² (56% healing) in NPWT group, whereas in the control group, the size was reduced from 3.12 to 2.71 cm² (14% healing), with significant statistical difference between the two groups.

The wound healing rate was 13.1 and 2.8 mm²/day in NPWT group and control group, respectively. After 30 days of treatment, 17 (68%) ulcers revealed 90% healing in NPWT group (Figs 1 and 2), with mean duration of 24 days needed for healing. None of the ulcers in control group completed 90% healing after the 30 days of treatment. The remaining eight (32%) ulcers of NPWT group showed mean healing percentage of 70% of original ulcer size (Figs 3 and 4).

	Negative pressure wound therapy (<i>n</i> =25)	Control (n=25)	P value
Male/female (n)	15/10	18/7	0.54
Age (years)			0.15
Range	25–55	29–61	
Mean±SD	38.2±5.8	40.7±6.3	
Ulcer size (cm ²)			0.11
Range	2.24-8.7	2.51-7.33	
Mean±SD	3.58±1.2	3.12±0.9	
Ulcer chronicity (months)			0.28
Range	3–9	3–7	
Mean±SD	5.1±1.4	4.7±1.2	
Diabetes	7	4	0.49
History of deep venous thrombosis	16	11	0.26

	Negative pressure wound therapy (n=25)	Control (n=25)	P value
Ulcer size after 15 days (mean±SD) (cm ²)	1.63±0.42	2.71 ±0.56	0.001
Ulcer healing after 15 days (%)	56	14	0.004
Healing rate at 15 days (mm ² /day)	13.1	2.8	0.001
No healed ulcer (90% healing) after 30 days [<i>n</i> (%)]	17 (68)	0 (0)	0.001
Days needed for 90% healing	24	0	0.001

Figure 1



Ulcer before treatment

Figure 2



90% healing after 19 days of NPWT.

Discussion

Chronic VLUs represent a great challenge to vascular surgeons worldwide because of their notoriously slow healing and high recurrence rates. VLUs pose significant physical, emotional, and socioeconomic costs to patients, families, and the healthcare system [9].

NPWT has become a major component of wound care therapy and has been shown to be effective in the treatment of acute and chronic wounds. Whether used as an end therapy or a bridge to surgery, evidence shows NPWT to be effective in reducing wound exudates and increasing granulation tissue formation [10].

The application of NPWT in treatment of VLUs has been reported in few studies, and owing to a variety of chronic leg ulcers, no randomized-controlled study was conducted on venous ulcers only.

Figure 3



Large ulcer before treatment.

Figure 4



70% healing after 30 days of treatment by NPWT.

In this study, the effectiveness of NPWT on VLUs was evaluated. The NPWT group did show a significant reduction in wound size after 15 days of treatment when compared with the control group. Significant difference in the number of ulcers reached 90% healing also was detected with superiority of NPWT. Owing to different wound sizes between patients, the absolute area healed per day, wound healing rate, was evaluated in both groups, and NPWT showed a significantly higher healing rate.

Supporting our results, Yao *et al.* [11] reported that NPWT has been demonstrated to accelerate wound healing successfully in patients with low extremity ulcers including venous ulcer. In a study by Vuerstaek *et al.* [12], NPWT also had a better effect on healing of different types of leg ulcers when compared with moist wound treatment. Conflicting with our results, Capobianco and Zgonis [13] summarized that NPWT has proved to be an effective modality for wound therapy in several areas, most notably diabetic foot ulcers, open fractures, and skin grafts. However, the use of NPWT on venous stasis ulcers and burns in particular has been less than satisfactory [13].

Clinical practice guidelines of the Society for Vascular Surgery and the American Venous Forum suggested against routine primary use of NPWT for VLUs (grade – 2; level of evidence – c); however, they had explained this recommendation by absence of enough information to support the primary use of NPWT for VLUs, although evidence supports positive effects with the use of negative pressure therapy for wound healing in general [14].

All these studies either supporting or opposing our results had not addressed the VLU as a separate problem in a randomized-comparative study which may be necessary before recommending or opposing NPWT as a treatment to VLUs.

A drawback of our study is that we compared the NPWT to conventional dressing and not to the compression therapy which represents the standard treatment of VLU now in clinical practice [15]. However, we had tried in this study to evaluate the NPWT in a randomized study, and we considered conventional dressing as a placebo treatment to VLU, and with these encouraging results of the NPWT, we are planning to conduct a randomizedcomparative study between NPWT and compression therapy with a longer duration and a larger scale of patients.

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Conflicts of interest

There are no conflicts of interest.

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Bougie size 32 versus 40 french in laparoscopic sleeve gastrectomy Medhat Helmy

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Background

Laparoscopic sleeve gastrectomy (LSG) is considered as one of the most popular bariatric procedures worldwide. Although LSG appears simple, there is still no standard procedure across different surgical teams. The most debatable issue in sleeve gastrectomy is the gastric pouch size; by changing the size of the bougie, we can create different volumes of the stomach tube.

Aim

The aim was to compare the outcome following LSG results when using 32 versus 40-Fr bougie as regards the effects of each on the clinical outcome: weight loss of the patients and possible complications.

Patients and methods

Our study is a prospective, comparative study of 60 patients, who underwent LSG between 'March 2015 and March 2016' with a 1-year follow-up. The patients were classified into two groups: group A (n=30) who underwent LSG using a bougie size of 32 Fr and group B (n=30) who underwent LSG using a bougie size of 40 Fr. We recorded the operative time, hospital stay, and intraoperative and postoperative complications.

Results

A total of 60 patients [17 (28.3%) men and 43 (71.7%) women] underwent LSG. Patients had a mean age of 35 ± 10 years (range: 18–58 years). The mean;Deg;BM; Deg;I was 46.66 ± 4.30 kg/m² (range: 34.6-57.5 kg/m²); the duration of hospital stay in group A was 56 ± 28.07 h, with group B being 36.4 ± 10.68 . As regards the weight loss both groups had the same excess weight loss over 1 year; postoperative persistent vomiting was in favor of group A with four (13.3%) patients, two of them required intervention either by endoscopy or conversion to bypass, in comparison to one patient in group B who was managed conservatively.

Conclusion

The use of bougie size 32 Fr did not result in significant excess weight loss differences than bougie size 40 Fr; however, more complications were observed.

Keywords:

bariatric procedure, bougie size, laparoscopic sleeve gastrectomy, morbid obesity

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Introduction

Laparoscopic sleeve gastrectomy (LSG), first described as a modification of the biliopancreatic diversion with duodenal switch, is emerging as a popular operation for the treatment of morbid obesity, with acceptable morbidity, and long-term weight loss compared with the laparoscopic Roux-en-Y gastric bypass and laparoscopic adjustable gastric band [1].

Although LSG appears to be a simple procedure, there is still no standard procedure across different surgical teams [2]. The gastric pouch size usually varies from 60 to 120 ml yet by many factors, by changing the size of the bougie, we can create different volumes of the SG [3].

So, bougie size is considered one of the debatable issues in sleeve gastrectomy. To illustrate that Parikh *et al.* [4] reported the calculated volumes of a cylindrical tube according to varying bougie sizes, consider 25-cm-long sleeve, and revealed that the difference in sleeve volume created by a 40 and 32-Fr bougie would be about 6 cm³. Talking about bougie size opens the discussion to know how it is measured, what is meant by the unit of measurement (French) unit. Knowing that 1 Fr is equivalent to 0.33 mm. Therefore, 32 Fr bougies have a 1.1-cm diameter, those of 36 Fr have 1.2 cm, and those of 40 Fr have 1.3 cm. Considering that most authors who perform LSG use catheters between 32 and 40 Fr, is it possible that there are so many differences among patients treated with these types of catheters when the difference between their sizes is minimal? Some authors believe that the diameter of the

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catheter is a determining factor in the amount of excess weight loss (EWL) [5].

In the current study, we address these observations for procedural optimization regarding the proper bougie size and hopefully improvement in patients' outcome.

Aim

The aim of the study was to compare the outcome following LSG results when using 32 versus 40-Fr calibrated bougie as regards the effects of each on the clinical outcome: weight loss of the patients and possible complications.

Patients and methods

Our protocol included a prospective, comparative study of 60 patients who underwent LSG between 'March 2015 and March 2016' with 1-year follow-up. Patients were chosen randomly from Ain Shams University Hospital bariatric clinic. Randomization was done by Card Selection method. Ethical approval from Ain Shams University Hospitals' ethics committee and informed consent from all patients including approval of protocol of treatment were obtained. The 60 morbidly obese patients were classified into two groups:

- Group A: this group is composed of 30 morbidly obese patients who underwent LSG using bougie size 32 Fr.
- (2) Group B: this group is composed of 30 morbidly obese patients who underwent LSG using bougie size 40 Fr.

Inclusion criteria

Age: more than 16 years. Sex: both sexes. BMI greater than 40 kg/m^2 or greater than 35 kg/m^2 with comorbidity.

Bulky eaters.

No endocrinal causes for obesity. Psychologically stable.

Exclusion criteria

Pregnant or breastfeeding patients.

Patients suffering from any severe psychiatric illness. Patients with significant, long-standing heart/lung disease or other severe systemic diseases.

All patients in this study were subjected to preoperative assessment to figure out any associated comorbidities, proper history taken, preoperative investigations, and psychological and nutritional evaluation were done. All the patients were admitted on the day of the surgery.

Main steps of our standardized technique

The patient under general anesthetic position is supine with split legs. The patient is secured to the table not to slide during positioning of the table throughout the procedure. The surgeon stands between the patient's legs with two assistants on each side.

For pneumoperitoneum, our preferable technique is through introduction of the first supraumbilical 12 mm visiport, slightly to the left, under direct vision. Inflating the peritoneal cavity with CO_2 up to a pressure of 15 mmHg is usually enough.

Following pneumoperitoneum and under vision we continue by insertion of four more ports, ideally 5–10 mm port is placed in the epigastrium for liver retraction and two 12–15 and 12 mm disposable working ports are placed in the right and left midepigastrium. Finally, a 5-mm port is placed in the left upper quadrant for lateral gastric retraction.

Using a 30° scope, first, laparoscopic exploration of the abdomen was performed. The first step was to identify the pyloric ring. Then we started dissection 3–4 cm from the pylorus near the greater gastric curvature along the gastrocolic ligament using laparoscopic Harmonic device or LigaSure.

Dissection is continued upwards toward the left crus of the diaphragm dividing the gastrosplenic ligament and coming through the short gastric vessels till freeing the whole fundus from its attachments. This step was very important for complete resection of the fundus in the subsequent steps. We continued to free all the posterior adhesions between the gastric wall and the pancreas up to the lesser curvature posteriorly.

The bougie was then inserted into the stomach; the anesthesiologist inserted the 32-Fr bougie (for group 1) or 42-Fr bougie (for group 2) under laparoscopic vision. The first fire is started 3–4 cm proximal to the pylorus using 60–4.8 mm (green reload), endo-GIA stapler (Autosuture Bariatrics/Covidien, USA). After applying the stapler and before firing we make sure that the bougie moves freely in and out; this is to be repeated before all the subsequent firings. Subsequent firing is done using 60 mm, 3.5 mm (blue reload), endo-GIA stapler (Autosuture Bariatrics; Covidien). We ensured that the transection is symmetrical all the way between the anterior and the posterior gastric wall and close enough, however, allowing for smooth mobilization of the bougie during the

procedure. Transection then was continued along the stomach proximally while the bogie is in place. We ensured that the whole of the gastric fundus was resected.

Using methylene blue, staple line is checked for being watertight by filling the gastric tube through the bougie while obstructing the antrum using a long grasper. The resected stomach is extracted through the umbilical wound. Tube drain was inserted in all cases.

Postoperative care

Close observation for vital signs with ICU admission is essential. Encourage early mobilization with anticoagulants according to body weight such as deep vein thrombosis, prophylaxis, proper pain management, third-generation cephalosporins in the form of cefoperazone 1 g intravenously on induction of anesthesia and then twice per day till discharge; proton pump inhibitors such as omeprazole 40 mg intravenously twice per day and then by oral administration after discharge for at least for a month.

The patients were started oral fluids (if tolerated) 6 h postoperatively. Gastrogrifin swallow was performed if there was suspicion of leakage or potential acute stenosis. The drain was removed after tolerating oral fluid intake with no leakage or bleeding. All patients are to be discharged 24 h postoperatively after meeting the discharge criteria of no bleeding, no leakage, and no other complications. Some patients were discharged later than 24 h if there were any significant adverse outcomes.

All patients returned for their first outpatient clinic appointment in 10 days. For the diet, patients were advised to start clear fluid-only diet for 10 days which is then advanced gradually to a semisolid diet for 10 days, followed by mashed food for 10 days. They were then advanced to regular healthy diet thereafter. There were follow-up visits in the outpatient clinic at 1 month and then at 6 and 12 months.

Outcomes assessment

Many parameters are used to determine the differences between the two groups as operative time, intraoperative, postoperative complications (early or late), length of postoperative hospital stay, and weight loss which is assessed by the change in BMI and the change in %EWL measured at 6 and 12 months after surgery.

Assessment of weight loss

The BMI was calculated according to the following formula:

$$BMI = \frac{\text{weight}}{\text{height}^2 \left(\text{kg/m}^2\right)}.$$

The percentage of EWL was defined according to the following equation [6]:

% EWL =
$$\left(\frac{\text{preoperative weightfollow} - \text{up weight}}{\text{preoperative weightideal body weight}}\right) \times 100.$$

Ideal body weight (IBW) was defined by Miller's formula. This formula is different for men and women. Men: IBW (kg)=56.2+1.41 kg per inch over 5 feet. Women: IBW (kg)=53.1+1.36 kg per inch over 5 feet (1 m=3.28084 ft).

Data management and statistical analysis

The collected data were revised, coded, tabulated, and introduced to a PC using the Statistical Package for the Social Sciences (Released 2011, IBM SPSS Statistics for Windows, version 20.0; IBM Corp., Armonk, New York, USA). Data were presented and suitable analysis was done according to the type of data obtained for each parameter.

- (1) Descriptive statistics:
 - (a) Mean±SD and range for parametric numerical data.
 - (b) Frequency and percentage of nonnumerical data.
- (2) Analytical statistics:
 - (a) Student's t-test was used to assess the statistical significance of the difference between the two study group means.
 - (b) χ^2 -The test was used to examine the relationship between two qualitative variables.
 - (c) *P* value indicates the level of significance as in the following:
 - (i) *P* value of greater than 0.05: non-significant.
 - (ii) *P* value of less than 0.05: significant.
 - (iii) *P* value of less than 0.01: highly significant.

Results

A total of 60 patients [17 (28.3%) men and 43 (71.7%) women] underwent LSG between March 2015 and March 2016. All the patients were followed up for 1 year. Patients had a mean age of 35±10 years (range: 18–58 years). The mean BMI was 46.66±4.30 kg/m² (range: 34.6–57.5 kg/m²). The patients were classified into two groups: the characteristics of the patients of

each group are illustrated in Table 1. There was no statistically significant difference between the two groups as regards the baseline characteristics.

There was no statistically significant difference between the two groups as regards the operative time (Table 2).

As regards postoperative hospital stay, there was longer hospital stay in favor of group A with a bougie size of 32, which was 56 ± 28.07 h. The mean of each group was calculated, there is a statistically significant difference between the two groups as shown in Table 3. As regards the pouch shape Fig. 1 illustrates the shape of the pouch of both groups by GG early postoperatively. Body weight was measured and BMI at 1, 6, and 12 months. Figure 2 illustrates the mean BMI among both groups at 1, 6, and 12 months. Statistical analysis shows that there is no statistically significant difference between the two groups as regards BMI changes as shown in Table 4.

The mean of EWL was calculated at 6 and 12 months postoperatively. Statistical analysis conveys no significant difference between the two groups as regards %EWL (Table 5).

As regards postoperative bleeding, we reported three cases: Two patients in group A and one patient in group B, as shown in Table 6. One patient managed conservatively as the patient's hemodynamics improved

Table 1	Baseline c	haracteristics	of the	patients	before	surgery

Variables	Group A (Bougie 32 F) (N=30)	Group B (Bougie 40 F) (N=30)	P value	Significance
Age				
Mean±SD	36.57±11.52	33.93±8.47	0.317•	NS
Range	18–58	22–53		
Sex [n (%)]				
Males	7 (23.3)	10 (33.3)	0.390*	NS
Females	23 (76.7)	20 (66.7)		
Preoperative weig	Jht (kg)			
Mean±SD	132.37±14.76	133.60±10.47	0.710•	NS
Range	100–160	117–161		
Preoperative BMI	(kg/m ²)			
Mean±SD	46.50±4.35	46.82±4.25	0.772•	NS
Range	34.6–55.4	40.9–57.5		

•Independent *t*-test; χ^2 -test.

Table 2 Mean operative time among both groups

Variable	Group A (Bougie 32 F) (N=30)	Group B (Bougie 40 F) (N=30)	P value	Significance
Operative time (min)				
Mean±SD	107.93±18.10	111.17±15.46	0.460	NS
Range	88–160	90–140		

Table 3 The hospital length of stay among the two groups

Variable	Group A (Bougie 32 F) (N=30)	Group B (Bougie 40 F) (N=30)	P value	Significance	
Postoperative hospital length of stay (h)					
Mean±SD	56±28.07	36.4±10.68	0.05	Significance	
Range	24–120	24–72			

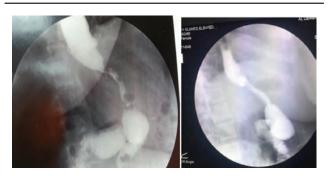
Table 4 A comparison between group A and group B as regards preoperative BMI and postoperative BMI at 1, 6, and 12 months

Variables	Group A (Bougie 32 Fr) (<i>N</i> =30)		Group B (Bougie 40 Fr) (<i>N</i> =30)		P value	Significance
	Mean±SD	Range	Mean±SD	Range		
Baseline BMI	46.50±4.35	34.6–55.4	46.82±4.25	40.9–57.5	0.772	NS
BMI 1 month	43.31±3.72	36.5–51.2	43.38±4.33	38.1–55.3	0.642	NS
BMI 6 months	34.21±3.85	27.6-41.5	35.51±4.66	30.1–48	0.243	NS
BMI 12 months	29.30±3.48	22.9–36.3	30.34±4.51	24.3–42	0.323	NS

when received 3 units of packed red blood cells and 2 units of fresh frozen plasma. The bleeding stopped on the third postoperative day.

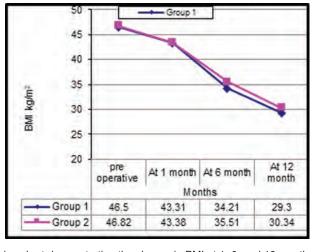
Two patients required reoperation. The first patient was from group A, had bleeding 1 h postoperatively as 500 ml fresh blood was noticed in the drain along with

Figure 1



GG postoperatively, the right one for group A with bougie size 32, the left for group B with bougie size 40.

Figure 2



Line chart demonstrating the change in BMI at 1, 6, and 12 months.

hemodynamic instability. The patient was rushed to the operating theater and opened to find the bleeding vessel from the greater epiploic arcade. It was controlled and the postoperative course passed uneventful. The second patient was from group B, presented by postoperative hemodynamic instability and fresh bleeding on post operative day (POD) 1. Re-exploration on the same day, evacuation of hematoma, and peritoneal lavage was done. However, there was no definitive source of bleeding.

In terms of leakage there was only one patient, who was in group A; his clinical examination revealed tachycardia POD 1, confirmed by the positive gastrografin study which showed leakage in gastro-oesphogeal junction (GEJ). The patient was re-explored laparoscopically on the same day; intraoperative methylene blue leak test was positive for leakage at GEJ. Laparoscopic primary repair was done and omental patch was placed over the site of repair (Fig. 3). The patient was given total parenteral nutrition postoperatively. Few days later, gastrografin study was done and was negative for leakage. Gradual oral feeding started following the same protocol without other events.

We reported five patients who were presented with postoperative vomiting among both groups: four cases in group A (bougie 32 Fr.) and one case in group B (bougie 40 Fr), as shown in Table 6. As regards group A, the first patient was woman, 22 years old and who had uneventful LSG. However, on POD 2 the patient complain of difficulty of any oral fluid intake with persistent vomiting. The patient was readmitted on regular intravenous antiemetic therapy (primperane and ondansetron) and intravenous fluids. The patient had their condition gradually improved giving her ability to tolerate oral fluid along with improving her vomiting. She was discharged asymptomatically and followed up on outpatient basis.

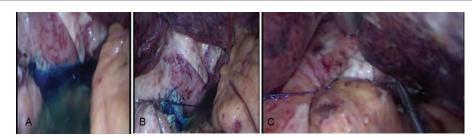
Parameters	Group A (Bougie 32 Fr) (N=30)		Group B (Bougie 40 Fr) (N=30)		P value	Significance
	Mean±SD	Range	Mean±SD	Range		
%EWL at 6 months	51.60±11.00	24.29-71.68	46.50±8.83	26.2-60.06	0.052	NS
%EWL at 12 months	71.65±11.06	51.13–96.53	67.76±11.78	41.41-89.29	0.193	NS

EWL, excess weight lost.

Table 6 Statistical analysis of the complications among both groups

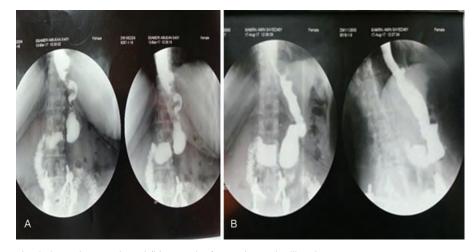
	Group A (Bougie 32) [n (%)]	Group B (Bougie 40) [n (%)]	P value	Significance
PO bleeding	2 (6.66)	1 (3.3)	0.076	NS
PO leak	1 (3.3)	0 (0)	0.313	NS
PO vomiting	4 (13.3)	1 (3.3)	0.019	S
Portside hematoma	1 (3.3)	0 (0.0)	0.313	NS

PO, postoperative.



(a) Positive methylene blue test and (b) laparoscopic primary repair of gastric perforation, (c)omental patch over the repair.

Figure 4



(a) Stenosis at the proximal sleeved stomach and (b) 1 week after endoscopic dilatation.

The second patient was presented with postoperative bleeding which was controlled conservatively. However, on POD 20 as the patient started to introduce meshed food when she complained of severe dysphagia and persistent vomiting, which gradually progressed even with oral fluid which was previously tolerated. Upper gastrointestinal endoscopy showed stenosis in the upper sleeve and dilatation of the stenotic region was done. Gastrografin study 1 week later showed free flow of the dye (Fig. 4). The patient reports gradual improvement of her symptoms.

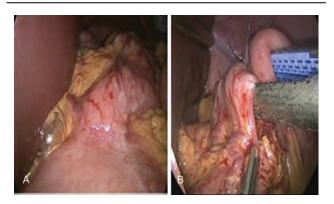
The third patient was presented 5 months after with uneventful LSG by 1 month history of dysphagia to solids with ability to tolerate only liquids, occasional vomiting, and upper colicky abdominal pain. Gastrografin series was done and showed mild kinking in the midsleeve. The patient was admitted on intravenous fluid therapy, antispasmodics, and antiemetics. She showed improvement of her symptoms thereafter.

The fourth patient was discharged on POD 1 after uneventful LSG. However, she presented with persistent vomiting as well as intolerability for solids more than fluid diet. She had frequent hospital readmissions, due to severe dehydration and anemia, with intravenous fluids, total parenteral nutrition, parenteral antiemetics, and sometimes packed red blood cells transfusion. GG study revealed kinking and stenosis at the incisura, and UGI endoscopy confirms the site of the stenotic; there was an obvious stenosis site with poststenotic antral dilatation. The decision was to go for Roux-en-Y gastric bypass with gastrojejunal anastomosis applied above the site of the stricture (Fig. 5).

As regards group B (bougie 40 Fr), we have one patient who presented by postoperative persistent nausea and vomiting on POD 2. The GG study showed narrowing in midsleeve at the level of incisura. The patient was discharged on regular antiedematous and antiemetic therapy on POD 3. On follow-up 7 days later, the patient reported improvement of her manifestations. Gastrografin study was done and revealed free flow of the dye.

As regards other complications, we reported on the case of portside hematoma in group A (bougie size 32 Fr) and one case of symptomatic

Figure 5



(a) Stenosis site with poststenotic antral dilatation and (b) gastrojejunal anastomosis.

Table 7 Range of MOOREHEAD-ARDELT Quality of Life Questionnaire after 1-year follow-up

M-A QoLQ range
2.5–3
2.5–3

M-A QoLQ, MOOREHEAD-ARDELT Quality of Life Questionnaire.

cholelithiasis 1 month postoperatively for which she had laparoscopic cholecystitis (bougie size 40 Fr). None of these complications showed statistically significant difference between the two groups (Table 6).

To assess the patient quality of life in both groups after 1-year follow-up we used the original MOOREHEAD-ARDELT Quality of Life Questionnaire (M-A QoLQ) [7], which is a one-page questionnaire using simple drawings to offer answer options in each of the five important quality of life domains such as self-esteem, physical activity, social life, work conditions, and sexual activity. We found differences between the two groups as shown in Table 7.

Discussion

Sleeve gastrectomy is one of the restrictive procedures for the management of morbid obesity and metabolic syndrome which is gaining increasing popularity nowadays [8]. Despite its ongoing popularity, LSG still exhibits technical variations; many are still debatable issues in International Consensus Summit on Sleeve Gastrectomy (ICSSGs) and American Society of Metabolic and Bariatric Surgery (ASMBS) meeting. The main technical point beyond controversy adopted by most bariatric surgeons is the standardization of LSG diameter and hence volume with a bougie or orogastric tube [9].

On one hand, there is concern that the wider the initial LSG, the more likely it is to stretch, resulting in

long-term sleeve dilation and weight regain. In addition, theoretically with a wider bougie, a larger part of gastric fundus, with its content of ghrelinproducing cells, may be retained. Currently, however, there is no scientific evidence showing lower satiety scores and increased hunger scores associated with wider diameter bougies [10].

On the other hand, smaller-sized bougies causing greater restriction may result in maladaptive eating and adoption of increased intake of sweets, highcalorie liquids, and meltable calories making it more likely that the patients regain weight in the long term [11].

In this study, we aimed to compare the effect of bougie sizes of two different diameters on the final outcome of LSG as regards postoperative weight loss as well as the complications rate. It is a prospective comparative study which was done between March 2015 and March 2016 at Ain Shams University Hospital, Cairo, Egypt. The study included 60 obese patients, 30 of them underwent LSG using bougie 32 Fr and other 30 patients underwent LSG using bougie 40 Fr.

We present our data as regards %EWL. At 6 months, mean %EWL for group A (bougie size 36 Fr) is 51% ranging from 24 to 71%. For group B (bougie size 46 Fr), the mean %EWL was 47% ranging from 26 to 60%. At 1 year, we obtained %EWL which exceeds 70% with the range between 51 and 96%. For group B (bougie size 40 Fr), the mean %EWL reached 67% ranging between 41 and 89%. And these differences in mean %EWL between the two groups were statistically nonsignificant.

Similar to our data, Spivak et al. [11] found no significant difference in BMI, EWL, or change in comorbidities at 1-year postoperatively when retrospectively comparing a group of patients who had LSG with a 42 Fr versus those who in whom a 32 Fr bougie was used [11]. Moreover, in a large metaanalysis of 9991 cases conducted by Parikh et al. [12], there was no significant difference in weight loss in the first 36 months when patients who had LSG calibrated with bougies of size less than 40 Fr were compared with those with a bougie size of more than or equal to 40 Fr. However, they identified that utilizing a bougie greater than or equal to 40 Fr may decrease leak without impacting %EWL up to 3 years [12]. Spivak et al. [11] conveyed the message; the size of the calibration bougie (42 vs. 32 Fr) has no predictive value at least in the first year, in regard to weight reduction and resolution of comorbidities, as these were identical

for the two groups and comparable to other reported data. Hawasli *et al.* [13] compare between bougie sizes 32 and 36 Fr and concluded that the bougie size used during sleeve gastrectomy does not affect the long-term %EWL with greater than 70% reduction in excess weight after 1 year using a bougie size of 40 Fr.

In contrast, data from the Spanish registry has shown that a smaller bougie size (32–36 Fr) had initial better weight loss outcomes compared with 38–60 Fr of up to 12 months after LSG, without a difference in complication rate. However, there was no significant impact on weight loss beyond 12 months in the two groups [14].

In addition it is well known that 1 Fr is one-third of a millimeter. Thus, the 8 Fr difference in the bougie size makes 40 Fr to be just 2.6 mm bigger in diameter than 32 Fr. This would explain the negligible difference in the effect on the long-term weight loss between bougie sizes around 40 Fr.

In our study, the overall incidence of leakage was 1.66% which is close to the incidences reported in the literatures. We have one case of leakage in group A (bougie size 32 Fr), while we did not report any case of leakage in group B (bougie size 40 Fr). Although this finding did not reach statistical significance, this may be attributed to low statistical power.

It was suggested by Gagner *et al.* [15] that these small bougies were related to an increase in the rate of leakage [16]. This suggestion was later potentiated by a systematic analysis performed by Aurora *et al.* [17], who concluded that the use of bougies with diameter 40 Fr or more resulted in decreased instances of staple line leakage compared with the use of bougies with a diameter of less than 40 Fr.

Moreover, Yuval *et al.* [18] published a review that recommend against the use of the smallest bougie because the risks of leak may outweigh the benefits (0.9% leaks with bougies \geq 40 Fr vs. 2.9% leaks with bougies <40 Fr; *P*<0.05). They conclude that larger size bougies are associated with a significant decrease in the incidence of leak.

Among the complications, the most commonly recognized and major early complication is certainly the postoperative bleeding which can occur in up to 16% of patients with a reported average of 3.6% [19]. Frezza [20] observed that the risk of postoperative bleeding after LSG is between 1 and 6%.

We suffered three (5%) cases of postoperative bleeding with average rate among the series. Of our three cases, one case detected 1 h postoperatively and underwent laparotomy to find a bleeding vessel from the caudal gastroepiploic arcade. One patient who was hemodynamically stable was managed conservatively. One patient, who was hemodynamically unstable, was re-explored laparoscopically, evacuation, and lavage of hematoma without identifying obvious source.

This was similar to the approach of managing bleeding following sleeve gastrectomy as described by Weiner *et al.* [21]. They advised to control bleeding by surgical intervention (hematoma evacuation, oversewing, and drainage) in hemodynamically unstable patients. In hemodynamically stable patients, conservative methods with fluid resuscitation, blood transfusion (if necessary), and careful observation usually succeed to control the hemorrhage. Our data have shown that the smaller bougie could have an impact on increasing incidence of persistent postoperative vomiting. We reported five patients among our series that complained of persistent postoperative vomiting, four of them in group A (bougie size 32 Fr) and one in group B (bougie size 40 Fr). Although we did find a statistically significant difference among both groups, however, the higher incidence in group A (bougie 32 Fr) could be attributed to other factors rather than the bougie size solely.

Among the cases, one patient had early postoperative hematoma that was complicated 2 weeks later by postoperative stenosis and kink that was relieved by endoscopic dilatation. The hematoma, which was managed conservatively, could have induced scarring that lead to retraction along the part of the staple line. This possibly produced a kink that lead to obstruction. Zundel et al. [22] have reported a case of acute obstruction and after laparoscopic exploration, a large hematoma was found compressing the gastric tube. A more close pathological circumstance was described by Paikh et al. [12] as they reported a case of symptomatic stenosis that started 36 days after LSG. A large hematoma was found on the neo-greater curve of the mid-body of the sleeve as well as twisting of the gastric tube. In our case, however, one session of endoscopic dilatation, without the need for surgical intervention, relieved the kinked gastric tube with evidence of free flow of the dye through the previously seen stenotic part of the stomach.

In addition, we did report a significant increase in hospital length of stay in group A (bougie 32 Fr) which

could be related to the frequency of the morbidities that occurred among this group.

Hawasli *et al.* [13] evaluated the effect of bougie size in the immediate postoperative period after sleeve gastrectomy. They concluded that the smaller bougie size did have a significant effect on increasing postoperative hospital length of stay, which probably was, in part, due to the increase in nausea. The trend toward the increased use of this antiemetic drug was evident indirectly in the increase in hospital length of stay. They reported higher number of hospital readmissions among group of smaller bougie size. In addition, in their study, Hawasli *et al.* [13] believed that there was more dehydration in the smaller bougie group due to the increased pressure and decreased food intake from the smaller sleeve size.

Conclusion

The use of the calibrating tube in LSG is out of discussion. Over the years, LSG showed evolution into a tighter sleeve by decreasing the bougie size and other technical variabilities. The use of bougie size 32 Fr did not result in significant %EWL differences than bougie size 40 Fr. However, more complications were observed with the use of a bougie size of less than 40 Fr including postoperative leak, bleeding, and vomiting.

For instance, a larger scale study with a longer followup would illustrate the long-term clinical effects of bougie size on the outcome after LSG.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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Potassium titanyl phosphate 532 nm laser for treatment of facial vascular lesions: a prospective analysis of 27 cases

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Background

Facial vascular lesions are often disfiguring. Potassium titanyl phosphate (KTP) laser is an appropriate vascular-selective therapy. This prospective study was conducted in Mosul, Iraq, and intended to evaluate KTP laser in treating such lesions.

Patients and methods

The study involved infantile hemangioma smaller than 3 cm, port-wine stain (PWS), and telangiectasia in light-skin patients. Pretherapy pictures were taken. KTP laser (532 nm wavelength) with 1-mm spot size was used in multiple sessions under local or general anesthesia (for adults and children, respectively). Ice cubes were used for cooling. The immediate clinical endpoint in telangiectasia was blood vessels clearance. Post-therapy photographs were evaluated and improvement graded from poor to excellent.

Results

There were 27 patients (21 females) aged 7 months–50 years, with a mean of 15.2 ± 14.3 years. There were 15 (55.6%) PWSs, eight (29.6%) hemangiomas, and four (14.8%) telangiectasias. All hemangiomas were infantile. PWS, on the contrary, occurred in an age range of 3–36 years. Patients with telangiectasia were 11–50 years old. Near half of PWSs were in the maxillary region. The nose was a common site for both hemangioma (n=3) and telangiectasia (n=3). PWS had more treatment sessions (6.6) compared with hemangioma (4.25) and telangiectasia (4). Overall, 55.6% of patients had good to excellent results. The best results were obtained in telangiectasia and hemangioma. There were few transient complications, and the commonest was blistering (n=22, 82%).

Conclusion

KTP laser is an effective safe therapy for facial telangiectasia and hemangioma but is less satisfactory in PWS.

Keywords:

hemangioma, laser, port-wine stain, potassium titanyl phosphate, telangiectasia

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Introduction

LASER is an acronym of the words Light Amplification by Stimulated Emission of Radiation. Since its introduction in 1967, laser therapy has provided a great benefit to both patients and physicians [1,2]. In the late 1960s and early 1970s, laser treatment of vascular lesions used to be provided by continuous-wave lasers such as the Argon laser [3]. Despite their effectiveness, these lasers caused unacceptable adverse effects like scarring and dyspigmentation as laser energy was not confined to the target structure (blood vessels) but extended to surrounding tissues such as collagen and melanin [4,5].

In 1983, Anderson and Parrish have revolutionized the treatment of vascular lesions by introducing their theory of selective photothermolysis [2,3]. The theory dictates that laser energy can be specifically deposited within a target tissue (a chromophore) to result in controlled, thermal injury with minimal collateral destruction [3].

Intravascular oxyhemoglobin acts as a chromophore whose heating by laser results in vascular injury [4,5]. Potassium titanyl phosphate (KTP) laser system uses ND: YAG crystal with a KTP crystal that doubles the frequency emitting a wavelength of 532 nm [3,4]. It has the advantage of being small, portable, and appropriate for small vessels ablation [3,4]. However, it is only suitable for patients with light skin (Fitzpatrick type I–III) [3–5].

Patients with vascular lesions such as port-wine stain (PWS), hemangioma, and telangiectasia often seek treatment because of pain, bleeding, disfigurement, and/or psychological reason [3]. PWSs, also called capillary malformation, are composed of an abnormal

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dermal plexus of dilated capillaries $100-1000 \,\mu\text{m}$ underneath a normal epidermis [2,6]. Telangiectasias are small cutaneous vessels $0.1-1.0 \,\text{mm}$ in diameter [3]. Hemangiomas are vascular endothelial cell neoplasms characterized by early rapid proliferation and eventual regression [2].

Nowadays, plenty of laser devices are available, making selection of an appropriate laser system a bit confusing [3]. It is important to understand the basic features of the laser device and setting the parameters in accordance to the biology of the specific vascular lesion. To the best of our knowledge, there is only one study from Iraq using KTP laser for treatment of 10 PWSs [7]. The aim of this study was to evaluate the outcome of this type of laser in a group of Iraqi patients with vascular lesions of the face in view of the published literature.

Patients and methods

Over an 18-month period (30 October 2012–30 April 2014), 27 patients (21 females and six males) with three types of vascular lesions in the face (PWS, hemangioma, and telangiectasia) were admitted to Plastic Surgery Department/Al-Jumhori Teaching Hospital/Mosul/Iraq and received a laser therapy. The Ethical Committee of our hospital has approved doing this study. The patients in this prospective study were chosen as follows:

Inclusion criteria

The following were the inclusion criteria:

- (1) Of the six known types of skin [1], Fitzpatrick skin types I–IV were included. Type I is pale, porcelain, or ivory skin; type II is fair, beige, or cream colored; type III is light brown, golden, or olive; type IV is caramel or medium brown; type V is bronze or rich brown; and type VI is mahogany or dark brown.
- (2) Infants with facial hemangiomas less than 3 cm receiving no previous therapy were included.

Exclusion criteria

The following were the exclusion criteria:

- (1) Chronic dermatoses.
- (2) Tattoos at the treatment area.
- (3) Patients predisposed to keloid formation.
- (4) Previous herpes simplex infection.
- (5) Previous plastic surgery.
- (6) History of excessive sun exposure.
- (7) Pregnancy.
- (8) Epilepsy.

- (9) Allergy to local anesthesia.
- (10) Patients on anticoagulants.

Clinical evaluation

Clinical history, demographic features, and physical signs particularly the size of the vascular lesion and color of PWS (pink, red, or purple) were noted. Advantages and disadvantages of laser therapy were explained, and informed consents of the patients or their families were obtained. The number of treatment sessions and the anticipated outcome were also discussed. A pretherapy photograph was obtained for comparison with subsequent post-therapy photographs.

Equipment

Nuvolas KTP laser device was used (Fig. 1a). This is a diode-pumped solid-state frequency-doubled ND: YAG laser with a wavelength of 532 nm (green). For safety, the patients wore oculoplastic eye cup (Fig. 1b), whereas the surgeon and other personnel in the theater wore goggles (Fig. 1c). Corneal eye shields were unavailable; thus, lesions in the eyelids were excluded.

Anesthesia

General anesthesia was used for infants and children, whereas adults were treated under local anesthesia (local infiltration, nerve block, or topical anesthesia using lidocaine gel or EMLA (eutectic mixture of local anesthesia: 2.5% prilocaine and 2.5% lidocaine) cream. The gel or cream was applied 2 h before laser therapy.

Procedure

Multiple sessions were required ranging from 1 to 10 spaced 4-6 weeks apart. Laser settings were adjusted according to the site, color, and depth of the lesion. In this study, a power of 8 Watts, energy of 61–81 J/cm², pulse duration of 60-80 ms, frequency of 1-2 P/s, and spot size of 1mm were chosen. A spot to spot technique was used. The handpiece was moved in a continuous manner to prevent pulse overlap that may result in scarring. The laser beam was directed toward the lesion perpendicularly to maintain fluency and effectiveness of laser. The immediate clinical endpoint in telangiectasia was clearance of blood vessels. In case of PWS, the edges were treated first to outline the lesion and avoid accidental shooting of normal skin. To decrease epidermal damage and permit using a high dose of laser, cooling was necessary. This was achieved by applying ice cubes held in gloves to the treated area.

Post-therapy care

Post-therapy care included the following:

- (1) Corticosteroid and antibiotic ointment (Zeta-Cort: betnosam+fucidin) three times/day for 3–5 days.
- (2) Cold sponging to alleviate pain and edema.
- (3) Analgesia (acetaminophen syrup for children and tablets for adults).
- (4) Washing of the area was allowed after 48 h using nonirritant soap.
- (5) Exposure to sun was permitted after the second week.
- (6) The patients were discharged home the same day and asked to come for follow-up 1 and 4 weeks later.

Evaluation of treatment outcome

Pretreatment and 3-month post-treatment photographs (Figs 2–5) of each patient were independently evaluated by a plastic surgeon and dermatologist. The lesion characteristics such as overall appearance, size, color lightening, texture, and boundaries were evaluated and

scored. Improvement was graded as poor (0-25%), fair (26-50%), good (51-75%), very good (76-95%), and excellent (more than 95%).

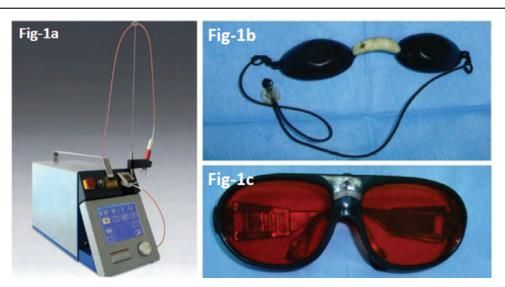
Results

Female-to-male ratio was 3.5:1. The mean age was 15.2 ± 14.3 years. The youngest patient was a 7-month-old male infant with a hemangioma of the nose and the oldest was a man of 50 years with telangiectasia of the nose. Table 1 displays the age and sex distribution of the patients.

Infants younger than 2 years (n=8) comprised 29.6% of the patients. The peak age was in the second decade (n=7, 26%).

Table 2 shows sex versus type of the lesions.

Figure 1



(a) Nuvolas potassium titanyl phosphate laser device. (b) Oculoplastic eye cup for the patient. (c) Goggles for the operator.

Figure 2



A 36-year-old woman with port-wine stain. (a) A pretreatment photograph. (b) A post-treatment photograph after three sessions of potassium titanyl phosphate laser treatment showing good result.

Figure 3



A 21-month-old male child with hemangioma of lower lip. (a) A pretreatment photograph. (b) A post-treatment photograph after 10 sessions potassium titanyl phosphate laser showing excellent result.

Figure 4



A 18-month-old girl with capillary hemangioma of the face. (a) A pretreatment photograph. (b) A post-treatment photograph after four sessions potassium titanyl phosphate laser treatment showing an excellent result.

More than half of the patients (55.6%) had PWS, mostly females (14 out of 15 patients), whereas telangiectasia constituted 14.8% of the patients, mainly males (3/4). Regarding hemangioma, three-quarters of patients (n=6) had superficial (capillary) and two had combined (superficial and deep) types. Likewise, there were six (75%) females. One case was noted at birth, four within 2 weeks, and three after 2 weeks. PWS lesions had a range of colors (pink, n=6; purple, n=5; dark purple, n=3 and red, n=1).

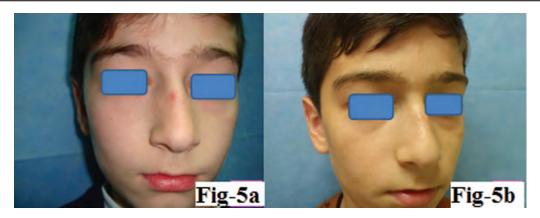
Table 3 displays the distribution of the vascular facial lesions by age.

All hemangiomas (n=8) were infantile (<2 years). PWS, on the contrary, occurred in an age range of 3–36 years, with a peak in the second decade. Patients with telangiectasia were 11–50 years old, distributed in the second and fifth decades.

Regarding the type of anesthesia, 13 adult patients received local anesthesia, whereas the remaining patients (14 infants and children) received general anesthesia.

Table 4 shows the distribution of vascular lesions in the face.

Figure 5



A 11-year-old boy with nasal telangiectasia. (a) A pretreatment photograph. (b) A post-treatment photograph after one session of potassium titanyl phosphate laser treatment showing excellent result.

Table 1 Age and sex distribution

Age	Female	Males	Total [n (%)]
6-12 months	3	1	4 (14.8)
13-24 months	3	1	4 (14.8)
3-10 years	4	0	4 (14.8)
11–20 years	6	1	7 (26)
21–30 years	3	0	3 (11.1)
31-40 years	2	1	3 (11.1)
41-50 years	0	2	2 (7.4)
Total [n (%)]	21 (77.8)	6 (22.2)	27 (100)

Nearly half of the PWS lesions (47%) were located in the maxillary region, whereas one-third of the lesions (n=5, 33.3%) were located in ophthalmic or ophthalmic and maxillary regions. The nose was a common site for both hemangioma and telangiectasia (three cases each). Table 5 shows the type of vascular lesion versus number of treatment sessions.

It seems that patients with PWS had a higher average number of treatment sessions (6.6) compared with those with hemangioma (4.25) and telangiectasia (4). Table 6 displays the outcome of laser therapy.

Overall, more than half of the patients (n=15, 55.6%) had good to excellent results. The best results were obtained in telangiectasia (Fig. 6a and b) and hemangioma (Fig. 7a and b) as almost all patients had good to excellent results, whereas with PWS had patients less satisfactory results (11 of 15 patients had poor to fair results vs. patients with good results) four (Fig. 8a and b). Table 7 shows the post-therapy complications.

The commonest complication was blistering (n=22, 82%), whereas the least common was

Table 2 Sex versus type of vascular lesions

Туре	Females	Males	Total [n (%)]
Port-wine stain	14	1	15 (55.6)
Hemangioma	6	2	8 (29.6)
Telangiectasia	1	3	4 (14.8)
Total [n (%)]	21 (77.8)	6 (22.2)	27 (100)

hypopigmentation (n=2, 7%). Most of these complications resolved within 1-week period.

Discussion

Vascular lesions of the face are often unsightly. Beside their negative cosmetic effect, they can cause pain and bleeding. Dermatologists and plastic and vascular surgeons are often consulted to provide a management. Selecting an appropriate therapeutic option for a particular patient is frequently influenced by many factors. The natural history of the lesion, its location, and severity of presenting symptoms and signs are few to mention. Management options may range from simple observation to open surgery.

In this study, three facial vascular lesions were managed by laser therapy. Since its early introduction in 1967, laser therapy has greatly benefited both patients and physicians [2]. It is important to take into account the specific characteristics of the vascular disorder when we select the appropriate laser device. Maximum destruction of the target 'chromophore' and minimal injury to adjacent structures can be achieved by properly manipulating the wavelength, pulse duration, energy density, and laser spot size [2,3].

More than half of our patients (n=15) had PWS. This is a congenital malformation that typically presents at birth with a prevalence of 0.3–0.5% [2,6,8–11]. Our patients

Table 3 Age versus type of vascular lesion

Age	Port-wine stain	Hemangioma	Telangiectasia	Total [n (%)]
6-12 months	0	4	0	4 (14.8)
13-24 months	0	4	0	4 (14.8)
3–10 years	4	0	0	4 (14.8)
11-20 years	5	0	2	7 (26)
21–30 years	3	0	0	3 (11.1)
31-40 years	3	0	0	3 (11.1)
41–50 years	0	0	2	2 (7.4)
Total [<i>n</i> (%)]	15 (55.6)	8 (29.6)	4 (14.8)	27 (100)

Table 4 Distribution of vascular lesions in the face

Port-wine stain in trigeminal ner	ve dermatomes	Hemangion	Telangiectasia	
Dermatome	n (%)	Region of face	n (%)	n (%)
V1 (ophthalmic region)	2 (13)	Forehead	0	1
V2 (maxillary region)	7 (47)	Cheek	2	0
V3 (mandibular region)	3 (20)	Nose	3	3
V1+V2	3 (20)	Lip	2	0
Total	15 (100)	Chin	1	0
		Total	8	4

Table 5 Type of vascular lesion versus number of treatment sessions

Type of lesions	Number of treatment sessions			าร	Range of sessions	Average number of sessions	Total number of patients						
	1	2	3	4	5	6	7	8	9	10			
Port-wine stain	0	0	3	2	0	3	1	1	1	4	3–10	6.6	15
Hemangioma	0	2	2	2	0	1	0	0	0	1	2–10	4.25	8
Telangiectasia	1	0	0	2	0	0	1	0	0	0	1–7	4	4
Total number of patients	1	2	5	6	0	4	2	1	1	5	-	_	27

Table 6 Outcome of laser therapy

Lesion	Poor	Fair	Good	Very good	Excellent	Total
Port-wine stain	3	8	4	0	0	15
Hemangioma	0	1	2	0	5	8
Telangiectasia	0	0	1	0	3	4
Total [n (%)]	3 (11.1)	9 (33.3)	7 (26)	0 (0)	8 (29.6)	27 (100)

aged 3-36 years close to that reported by Mahmood et al. [7] from Iraq whose patients aged 3–42 years. Most PWS cases in this series were females (14/15). This is similar to Mahmood et al. [7] who had nine females of 10 cases. In contrast, Cordoro et al. [9] found no sex predilection. Nearly half of PWS lesions (47%) were located in the maxillary region, whereas one-third of the lesions (n=5, 33.3%) were located in ophthalmic or ophthalmic and maxillary regions. Similar finding was observed by Cordoro et al. [9]. Unlike hemangioma, PWS never resolve spontaneously [2,5,7], and hence, therapy is needed. Being vascular selective, KTP laser (532 nm) has been considered an initial treatment choice for PWS and has been primarily studied for resistant and residual cases [9]. In this series, we observed that despite more laser treatment sessions, patients with PWS had less

satisfactory results when compared with other vascular lesions. Mahmood *et al.* [7], on the contrary, achieved better results (70% good–excellent results).

Hemangiomas are present in up to 3% of newborns and commonly present around 2 weeks after birth [2]. Most hemangiomas begin to slowly involute by 1 year of age [2,10]. In the present study, all hemangiomas (n=8) were infantile (<2 years); five developed within 2 weeks. They were located in prominent parts of the face (nose, lips, cheek, and chin). After an average of 4.25 treatment sessions, almost all patients (7/8) achieved good to excellent results.

The development of telangiectasia is connected to significant sun exposure, hormonal factors, or

Figure 6



(a) A pretreatment photograph of a 50-year-old man with perialar telangiectasia. (b) A post-treatment photograph of the same patient after four sessions of potassium titanyl phosphate laser treatment showing excellent result.

Figure 7



(a) A pretreatment photograph of a 10-month-old girl with upper lip hemangioma. (b) A post-treatment photograph after three sessions of potassium titanyl phosphate laser treatment showing excellent result.

Figure 8



(a) A pretreatment photograph of a 12-year-old girl with port-wine stain. (b) A post-treatment photograph after seven sessions of potassium titanyl phosphate laser treatment showing poor result.

Table 7 Post-therapy complications

Tuble 7 Tost therapy complications	
Complications	n (%)
Pain	10 (37)
Edema	16 (59)
Erythema	16 (59)
Blistering	22 (82)
Hypopigmentation	2 (7)
Atrophic scars	3 (11)

genetic predisposition [3]. KTP laser produces energy pulses with small spot sizes and therefore can be used in the treatment of smaller vessels such as facial telangiectasias. The target vessels are not ruptured during treatment; thus, much less purpura is noticed thereafter [3,4]. In this series, there were four cases of telangiectasia (three males), aged 11–50 years, located in the nose (n=3) and forehead (n=1). They responded very well to laser therapy; all achieved good-excellent results after an average of four sessions.

Regarding complications, the commonest was blistering (n=22, 82%), whereas the least was hypopigmentation (n=2, 7%). Only light-skinned patients were enrolled in this study. At the wavelength of 532 nm, there is significant energy absorption by melanin, which makes patients with dark skin (Fitzpatrick IV–VI) unsuitable for treatment with KTP laser, as they would develop long-lasting dyspigmentation if they were to receive such therapy [3–5].

Conclusion

KTP laser seems to be a safe and effective therapy for facial telangiectasia and hemangioma but is less satisfactory for PWS.

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Conflicts of interest

There are no conflicts of interest.

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Silver-coated graft as bailout option in managing femoral artery-infected pseudoaneurysm: a review of 30 patients Ahmed K. Allam^a, Ahmed K. Gabr^b, Mohamed Ismail^b

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Context

Femoral artery-infected pseudoaneurysm (fa-IPA) is very common in modern societies, and it represents a difficult problem to the vascular surgeon, as surgical management remains controversial, which ranges from ligation with debridement to extra-anatomical bypass. The present study was carried out to evaluate the outcome of silver-coated grafts used for the management of fa-IPA secondary to illegal drug injections.

Aim

To assess the outcome of silver-coated graft as bailout revascularization conduit in patients with infected pseudoaneurysm regarding success of the procedure, limb salvage, infection rate, and primary patency rate.

Settings and design

A prospective study was conducted.

Patients and methods

The study included 30 patients who presented with fa-IPAs and were admitted to Emergency Department of Benha University Hospital, Ain Shams University Hospitals, and Security Forces Hospital, Makkah, Saudi Arabia, during a 30-month period. Overall, 24 (80%) patients were male and six (20%) patients were female, with age range from 25–46 years. Twenty-one (70%) patients underwent surgical resection and immediate revascularization using silver collagen-coated polyester graft (InterGard Silver; Maquet), whereas nine (30%) patients underwent surgical ligation, with delayed revascularization in four (13.3%) patients through transobturator bypass using the same graft.

Results

Immediate revascularization using either in situ or extra-anatomic bypass is associated with risk of graft infection [early, five patients of 21 (23.8%); late, two patients of 21 (9.5%), with limb salvage rate of 86.7%].

Conclusion

However, no surgical treatment for fa-IPA has been proved to be safe in terms of the overall surgical complications. Our study shows promising results for possibility of using silver-coated grafts as bailout option for limb revascularization. Long-term antimicrobial therapy is advised, and longer follow-up periods are needed to provide accurate results.

Keywords:

femoral artery, intravenous drug abuse, mycotic aneurysm, pseudoaneurysm, silver-coated grafts

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Introduction

Mycotic aneurysms are defined as a localized and irreversible dilation of an artery caused by damage to the vessel wall by infection, which may originate following an infection of a previously healthy artery wall or through secondary infection of a pre-existing aneurysm. The name mycotic aneurysm was coined by Osler [1] to describe aneurysms associated with bacterial endocarditis. A primary mycotic aneurysm is due to infection of a normal arterial wall, whereas infection of a pre-existing aneurysm is defined as a secondary mycotic aneurysm [2]. In the postantibiotic era, arterial trauma has been replacing endocarditis as the most common cause of mycotic aneurysm [3]. This is believed to be owing to increased intravascular drug use and catheters for intravascular monitoring. Femoral mycotic aneurysms are associated with increasing percutaneous arterial access procedures and intravenous drug use [4]. Pseudoaneurysms result from a variety of mechanisms including infection, trauma, intra-arterial injection of illegal substances, arterial access for diagnostic and endovascular procedures, closure device infections,

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and synthetic graft infections [5]. Femoral arteryinfected pseudoaneurysm (fa-IPA) is more commonly seen in the intravenous drug using population owing to repeated nonsterile needle groin punctures. However, it may also complicate iatrogenic pseudoaneurysms [6]. Most of the patients with femoral pseudoaneurysms typically present with pain and swelling of the affected groin, along with a palpable mass, which may be pulsatile with a thrill or bruit. Foul smelling discharge and profuse bleeding are the classic presentation in infected groin abscess [7]. Clinical diagnosis can be difficult in those who are obese, where a high index of suspicion is required to prompt further investigation. Pseudoaneurysms that persist may enlarge and lead to complications related to compression of the adjacent femoral vein, nerve, and overlying skin. This can lead to leg swelling, deep vein thrombosis, compressive neuropathy, and skin necrosis [8]. Considering the aneurysmal abscesses remain the most common vascular complication with a potential risk of sepsis, hemorrhage, limb loss or even death, management of the fa-IPAs is still controversial, with no consensus among vascular surgeons on whether it is necessary to revascularize the endangered limb and, if so, the timing and method of revascularization [9].

Several techniques, including simple ligation without revascularization, primary and delayed vascular reconstruction, and revascularization in cases with signs related to ischemia, have been recommended [10]. The surgical care of the patient with fa-IFPA includes a series of well-defined steps, starting with control of hemorrhage (if present), taking wound cultures, and wound swabs of the hematoma and the aneurysm sac (including of purulent drainage, if present) must be routinely taken in every case [11]. Many authors have used more than one of the classical treatment options:

- (1) Primary amputation if reconstruction in any form is not feasible [12].
- (2) Primary repair with standard vascular techniques, together with extensive local debridement of all necrotic tissue [12].
- (3) Ligation and excision (Lig-Exc) of fa-IFPA and all infective tissues, followed by immediate (routine) arterial revascularization by either (i) an extraanatomic bypass through noninfected tissues (the most commonly used materials are manufactured from polytetrafluoroethylene, but autogenous vein or rarely cryopreserved arterial and venous conduits have also been used) or (ii) an in-situ autogenous repair (anatomical reconstruction), in the form of angioplasty or bypass [11].

- (4) Single Lig-Exc or triple Lig-Exc of the fa-IFPA together with aggressive local debridement, without arterial reconstruction. Revascularization is recommended if the pedal Doppler signals are absent after test clamping of the external iliac artery or ligation of the common femoral artery [9].
- (5) Lig-Exc of the fa-IFPA and all necrotic tissues, followed by a period of observation and selective (delayed) revascularization where the viability of the leg is in danger owing to critical limb ischemia [13].

Patients and methods

Our case study was conducted from November 2014 to May 2017 in the Vascular Unit, Department of Surgery, Benha University/Department of Vascular Surgery, Ain Shams University, and Department of Vascular Surgery, Security Forces Hospital, Makkah, Saudi Arabia, on 30 patients for 18 months, and they followed up for another 12 months from the last patient operated upon. All hemodynamically stable patients were evaluated according to our protocol by full laboratory investigations (complete blood count, Creactive protein, bleeding profile, kidney function test, and hepatitis and HIV markers) and duplex evaluation of arterial system that confirmed diagnosis of pseudoaneurysm with evaluation of ipsilateral, superficial, and deep venous system. Contrast-enhanced computed tomographic scan was performed for detailed anatomical evaluation of aneurysm extension with inflow and outflow vessels condition. Intraoperative selective angiography was done in three patients with renal impairment. All patients were on broad-spectrum antibiotics after blood cultures were drawn.

All patients were operated on under general anesthesia in a supine position. In patients with aneurysm size of at least 6 cm, a lateral abdominal pararectus incision was performed for retroperitoneal proximal control of the external iliac artery. Another separate skin incision was then made to the inguinal area for exposure and adequate control of the proximal part of the common femoral artery. Whenever possible, the superficial and profunda femoral arteries were also controlled. For patients with smaller aneurysm, direct inguinal vertical skin incision for exposure was used. Extensive debridement of the suppurative surgical field was performed, the groin mass was incised, and all necrotic material was excised. The cavity was then copiously irrigated with saline. Assessment of the arterial wall defect followed, and the decision for circulation restoration was made in 21 patients using

silver collagen-coated polyester graft (InterGard Silver; Maquet SARL, La Ciotat, France). Although decision was ligation and observation in nine patients, four of them were hemodynamically unstable owing to ruptured aneurysm and the other five patients owing to extensive abscess cavity; all excised masses were sent for culture and sensitivity.

In all immediately revascularized patients, graft was covered by sartorius muscle flap and skin closure over subcutaneous drain. All patients were on broad-spectrum parenteral antibiotics for 6 weeks and discharged from the hospital after screening for evidence of graft infection. Four patients of nine were operated upon for delayed revascularization through transobturator bypass using the same graft.

Results

Patient characteristics are shown in Table 1. Twentyfour (80%) patients were male, and six (20%) were female, with age range from 25–46 years. Twenty-three (76.7) fa-IPAs were on the right side, six (20%) were on

Table 1 Patient demographics and clinical characteristics

the left, and one (3.3%) was bilateral. Twenty-five (83.3%) fa-IPAs occurred owing to intravenous drug self-injection and five (16.7%) owing to femoral artery catheterization for coronary intervention. Twenty-one (70%) patients underwent immediate revascularization using silver collagen-coated polyester graft (InterGard Silver; Maquet); nine (30%) patients underwent surgical ligation, with above-knee amputation in two (6.7%) patients owing to acute limb ischemia with gangrene; and four (13.3%) patients had delayed revascularization by transobturator bypass owing to symptomatic disabling claudication. The duration of symptoms ranged from 5 to 31 days (median: 14 days). All patients had a workup and were initiated on broadspectrum antibiotics. The follow-up range was 6-12 months. In 14 cases, the pseudoaneurysm involved the bifurcation; in six, the mid; and in 10, the proximal common femoral artery (CFA) extending above the inferior border of the inguinal ligament. In 26 patients, the mass was pulsatile. Four (13.3%) patients were admitted with massive external bleeding from the right groin owing to a ruptured fa-IPA, whereas five (15.7%) patients were febrile on admission, those who

Patient nos	Age (years)	Sex	Presentation	Intraoperative culture
1	25	Male	Pulsatile groin mass	S. aureus
2	30	Male	Pulsatile groin mass, leg swelling, and DVT	S. aureus
3	27	Female	Pulsatile groin mass, leg swelling, and DVT	S. aureus
4	38	Male	Pulsatile groin mass	S. aureus (methicillin-resistant
5	40	Female	Pulsatile groin mass and leg swelling	Negative
6	33	Male	Pulsatile groin mass, leg swelling, and DVT	Streptococcus spp.
7	29	Male	Pulsatile groin mass, fever, and contained ruptured aneurysm	S. aureus, E. coli
3	45	Female	Pulsatile groin mass and leg swelling	Negative
9	40	Male	Pulsatile groin mass and leg swelling	Negative
0	26	Male	Massive external bleeding	S. aureus
11	31	Male	Pulsatile groin mass, leg swelling, and DVT	S. aureus
12	36	Male	Pulsatile groin mass, leg swelling, fever, and DVT	S. aureus (methicillin-resistant
13	25	Male	Pulsatile groin mass	S. aureus
14	26	Male	Pulsatile groin mass, fever, and contained ruptured aneurysm	S. aureus (methicillin-resistant
15	28	Male	Pulsatile groin mass, leg swelling, and DVT	Streptococcus spp.
16	33	Male	Massive external bleeding	S. aureus
17	42	Male	Pulsatile groin mass, and contained ruptured aneurysm	S. aureus, E. coli
18	27	Male	Pulsatile groin mass, leg swelling, fever, and DVT	S. aureus (methicillin-resistant
19	32	Male	Pulsatile groin mass, leg swelling, and DVT	Streptococcus spp.
20	30	Female	Pulsatile groin mass and leg swelling	S. aureus
21	39	Male	Pulsatile groin mass, leg swelling, and DVT	Negative
22	29	Male	Pulsatile groin mass	S. aureus
23	33	Male	Pulsatile groin mass and leg swelling	S. aureus
24	41	Male	Pulsatile groin mass, leg swelling, fever, and DVT	S. aureus (methicillin-resistant
25	36	Female	Pulsatile groin mass, leg swelling, and DVT	Negative
26	32	Male	Pulsatile groin mass	S. aureus
27	26	Male	Massive external bleeding	S. aureus, E. coli
28	28	Male	Pulsatile groin mass and leg swelling	S. aureus
29	38	Female	Pulsatile groin mass, leg swelling, and DVT	S. aureus (methicillin-resistant
30	31	Male	Massive external bleeding	Negative

DVT, deep venous thrombosis; E. coli, Escherichia coli; S. aureus, Staphylococcus aureus.

had abscess on exploration. In 24 (80%) patients, there were palpable pedal pulses. Skin involvement such as erythema, induration, or gangrene over the fa-IPA was present in 18 (60%) patients. Leg swelling was present in 18 (60%) patients, and 12 of 18 (66.7%) patients had chronic deep venous thrombosis (DVT): four patients at the ipsilateral popliteal vein and eight at the ipsilateral femoral vein. Overall, 20 (66.6%) patients had a damaged ipsilateral great saphenous vein (GSV) owing to previous superficial venous thrombosis. Fourteen (46.7%) patients were hepatitis C virus positive. Wound cultures showed Staphylococcus aureus in 18 (60%) patients (six methicillin resistant) and Streptococcus spp. in three (10%) patients, and three patients with S. aureus also had Escherichia coli (10%). No growth of any organisms was seen in six (20%) patient's culture. Five patients of 21 (23.8%) had a rupture of the proximal anastomosis of the iliofemoral synthetic graft on the 10th and 13th postoperative day. They were treated with graft excision and distal external iliac artery ligation. Two of five patients were operated upon for amputation owing to limb ischemia. Two of 21 (9.5%) patients presented with graft thrombosis six and seven months later with skin sinus owing to perigraft chronic abscess. Surgical drainage of abscess with restoration of flow in the thrombosed graft was done by catheter direct thrombolysis. Limb salvage was achieved in twenty six (86.7%) patients, whereas overall amputation was performed in four (13.3%) patients: two patients owing to ruptured infected graft and the other two patients owing to immediate ligation of ruptured fa-IPA. All 26 patients were ambulatory, and 20 revascularized patients (16 were immediate and four were delayed) were free of claudication symptoms during the longterm follow-up period (12 months) (Table 2).

Discussion

In the past two decades, the femoral artery has become the most common site for infected arterial aneurysms. fa-IPA formation is a well-documented complication of illicit drug use. These lesions are serious, having a definite threat to both life and limb, if left untreated. Their natural history is of rapid progression to rupture and hemorrhage [10]. There is no consensus regarding optimal management of fa-IPA, because results in most published series are based on small numbers of patients. Current treatment options include excision and debridement of the fa-IPA with ligation of the common femoral artery without revascularization and excision and debridement of the fa-IPA with routine or selective revascularization [14]. Primary repair with preservation of the native vessels is considered the

Table	2	Resu	lts
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Patients (n)	30
Age [n (%)] (years)	
25–30	13 (43.3)
31–40	14 (46.7)
41–46	3 (10)
Male [n (%)]	24 (80)
Female [n (%)]	6 (20)
The etiology [n (%)]	
Intravenous drug self-injection	25 (83.3)
Coronary catheterization	5 (16.7)
Clinical presentation [n (%)]	
Pulsatile mass	26 (86.7)
Size <6 cm	18 (60)
Size ≥6 cm	8 (26.7)
Massive bleeding	4 (13.3)
Contained rupture	3 (10)
Associated leg swelling	18 (60)
Associated DVT	12 (40)
Skin involvement	18 (60)
Fever	5 (16.7)
Damaged GSV	20 (66.6)
Hepatitis C	14 (46.7)
Angiographic pattern of aneurysm [n (%)]	
Proximal CFA	10 (33.3)
Mid CFA	6 (20)
Bifurcation of CFA	14 (46.7)
Wound culture growth [n (%)]	
S. aureus	12 (40)
S. aureus (methicillin-resistant)	6 (20)
Streptococcus spp.	3 (10)
S. aureus, E. coli	3 (10)
Negative growth	6 (20)
Surgical management technique [n (%)]	
Ligation and immediate revascularization	21 (70)
Ligation only	9 (30)
Delayed revascularization	4 (13.3)
Nonrevascularized	5 (16.7)
Results and complication [n (%)]	
Early graft infection and ruptured anastomosis	5 (23.8)
Graft thrombosis with chronic abscess	2 (9.5)
Overall amputation	4 (13.3)
Amputation in surgical ligation	2 (22.2)
Primary graft patency	14 (87.5)
Target graft revascularization	2 (12.5)
Limb salvage	26 (86.7)
Revascularized	20 (76.9)
Nonrevascularized	6 (23.1)

CFA, common femoral artery; DVT, deep venous thrombosis; E. coli, Escherichia coli; GSV, great saphenous vein; S. aureus, Staphylococcus aureus.

best option when the infection is limited. However, it is not recommended by some authors because the extended destruction of the arterial wall usually results in secondary hemorrhage and infection [15]. Padberg et al. [16] presented two cases of primary repair with excellent results. Reddy et al. [17] reported high rates of limb loss, up to 33% in triple ligation involving the

femoral bifurcation in a group of patients with bifurcation fa-IPA. However, single-vessel ligation in false aneurysm of the common, superficial, or profunda femoral artery had significantly better clinical outcome with no resultant amputations. In our study, the overall amputation rate (revascularized and nonrevascularized) was 13.3%, with amputation rate of 22.2% in nonrevascularized group (100% of them owing to triple-ligation), which is comparable to amputation rate in different studies evaluating the outcome of femoral vessel ligation in fa-IPA. Khan et al. [18] reported the surgical outcome after ligation of femoral vessels in intravenous drug users in 19 patients, and their results were entire limb survived in 11 patients, four had toe amputations, three ended in below-knee amputation, and one in above-knee amputation. The overall major amputation rate was 21%. Naqi et al. [19] studied 17 patients of femoral artery pseudoaneurysm during a 1-year period. Parenteral drug abuse was the most common etiological factor. The femoral artery was most commonly involved at its bifurcation. Sixteen (94%) patients had excision of the pseudoaneurysm with ligation of vessel and debridement without any revascularization and one (6%) patient had reverse saphenous grafting after excision and ligation of vessels. Four (23%) amputations were performed. Three (17%) were major limb amputations, which included one above-knee and two below-knee amputations. For fa-IPA involving the femoral bifurcation, immediate vein interposition grafting proves more satisfactory than simple Lig-Exc alone, with an amputation rate of zero. Placing a graft in an infected field is recognized as potentially dangerous, but this practice minimizes limb loss associated with arterial ligation [15]. Although the autogenous graft is more resistant to infection, it unfortunately is not always available. Damage of the superficial veins (especially the great saphenous vein) owing to recurrent attacks of phlebitis and obstructions owing to the injection of inflammatory agents over a prolonged period are other surgical challenges specific to management of this problem [15]. In our series, 20 of 30 patients had no usable GSV. Consequently, the use of prosthetic grafts for delayed or immediate arterial reconstruction seems unavoidable. However, attempts to use prosthetic materials in the bed of the resected fa-IPA have produced uniformly poor results [16]. The rationale of using antimicrobial vascular grafts is obvious: vascular graft infection will only occur if viable bacteria approach the surface of the graft, are able to attach to the prosthetic material, and start becoming metabolically active. If the antimicrobial compound

used in or on the graft is leaching, approaching bacteria will be killed off, while either a nonleaching antimicrobial graft will prevent formation of bacterial biofilm on its surface [20]. A vast number of different antimicrobial compounds, antibiotics, or antiseptics could be used to render a vascular graft antimicrobial. The antimicrobial compound must be toxicologically safe, should have no or very limited allergic potency, should possess a low rate of resorption, should not induce bacterial resistance, and must be antimicrobially active, even in the presence of organic load. Until now, the most frequently used antimicrobial compounds in vascular grafts are therefore the antibiotic rifampicin, antimicrobial elements such as silver, and the antiseptics triclosan and povidone iodine [20]. No RCT has proven the efficacy of silver grafts to prevent vascular graft infection. One retrospective study compares the performance of the InterGard Silver polyester graft (Maquet) with that of standard prostheses in routine use. The study showed good results with the silver prosthesis in the aortofemoral position, but it did not achieve a reduction of prosthetic infections in cases of femoropopliteal grafting [21]. Two recent clinical studies have shown the potential benefit of InterGard Silver grafts compared with arterial homografts in the treatment of infections of aortic prostheses. In the first study, Pupka et al. [22] evaluated the effectiveness of in-situ revascularization with the use of arterial homografts and silver-coated prostheses in the treatment of aortic graft infection. A total of 77 patients were studied. Patients were assigned to three groups: group 1 (n=24), fresh arterial homograft with subsequent immunosuppression; group 2 (n=26), fresh arterial homograft without immunosuppression; and group 3 (n=27), silvercoated prosthesis. After a mean follow-up of 22.8 ±10.1 months, the postoperative mortality rate in groups 1, 2, and 3 was 8, 23, and 11%, respectively. The postoperative morbidity was 35% in group 2, 16% in group 1, and 7% in group 3. This study suggests that silver-coated prostheses can be as effective as arterial allografts in the treatment of infections of vascular prostheses. Bisdas et al. [23] compared cryopreserved arterial homografts and silver-coated Dacron grafts for the treatment of abdominal aortic infections in a contaminated intraoperative field. Primary outcomes were survival and limb salvage, and secondary outcomes were graft patency and reinfection. The 30-day mortality rate was 14% in group A and 18% in group B (P>0.99), and 2-year survival rates were 82 and 73%, respectively (P=0.79). After 2 years, limb salvage was 96 and 100%, respectively (P=0.50), whereas graft patency was 100% for both groups.

Results showed comparable effectiveness between cryopreserved arterial homograft and silver-coated Dacron graft for the treatment of a rtic infection with positive evidence of micro-organisms. In our study, limb salvage was (86.7%), primary graft patency was (87.5%), and secondary patency was (100%). The overall postoperative morbidity in immediately revascularized patients was 33.3%. Early ruptured anastomosis owing to graft infection was (23.8), whereas late graft thrombosis was 9.5%. The use of bactericidal antibiotics together with early surgical intervention and long-term suppressive antibiotic therapy has led to improved survival and decreased amputation rates [24]. Highdose bactericidal therapy should be maintained for at least 6 weeks and longer if inflammatory biomarkers such as C-reactive protein level, erythrocyte sedimentation rate, and white blood cell count do not subside [24]. Our patients were treated with 6 weeks of high-dose intravenous antibiotics and remained well at follow-up of 1 year.

Conclusion

An infected femoral aneurysm is a challenging clinical entity that should be diagnosed and managed promptly, because it is associated with high mortality and morbidity, including limb loss especially with tripleligation of the aneurysm. However, no surgical treatment for fa-IPA has been proved to be safe in terms of the overall surgical complications. Our study shows promising results for possibility of using silvercoated grafts as bailout option for limb revascularization, with limb salvage rate of 86.7%. Long-term antimicrobial therapy is advised, and longer follow-up periods are needed to provide accurate results.

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Conflicts of interest

There are no conflicts of interest.

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Management of cholecystectomy-induced biliary injuries at Zagazig University Hospital

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Objective

To evaluate the management strategies following bile duct injuries.

Design and duration

This was a prospective analysis conducted from March 2015 to March 2017. **Setting**

The study was conducted at the Department of Surgery, Zagazig University Hospitals.

Patients and methods

The study included all patients who were admitted with iatrogenic biliary injuries during this period. The patients were evaluated according to their clinical features and certain laboratory and imaging investigations. After appropriate preparations, they were managed based on Bismuth Classification.

Results

A total of 27 patients presented with iatrogenic biliary injuries over a period of 2 years among all 420 cases that underwent cholecystectomy during this period. There were 16 females and 11 males, with a median age of 40 years. A total of 18 patients had laparoscopic cholecystectomy, whereas nine had open cholecystectomy. Twelve cases belonged to our unit whereas 15 were referred from other institutes. Four patients were detected intraoperatively, 15 patients presented with obstructive jaundice, four patients presented with biliary fistula, and four patients presented with collection. Of which, one had ultrasound-guided aspiration and five had endoscopic retrograde cholangiopancreatography (ERCP) stenting done, whereas two underwent peritoneal lavage with drain placement, 16 patients had hepaticojejunostomy, and one patient had choledechodoudenostomy. We had one postoperative mortality owing to hepatorenal failure.

Conclusion

Strategies need to be developed for dealing with bile duct injuries, with a view to reduce morbidity and mortality, as early recognition and timely management improve the outcome of these patients.

Keywords:

biliary strictures, cholecystectomy, hepaticojejunostomy, iatrogenic bile duct injuries

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Introduction

Surgery remains the gold standard treatment for the management of patients with symptomatic gallstone disease [1]. The universal implementation of laparoscopic cholecystectomy has brought significant advantages of shorter hospital stay, decreased postoperative morbidity and mortality, and quicker return to normal activity [2].

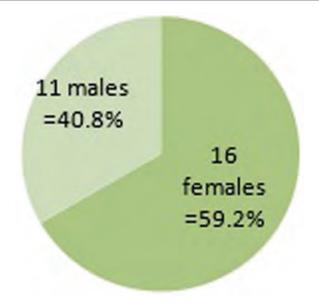
Major complications following cholecystectomy include bile leak, bile duct injury, and acute pancreatitis. Of these, biliary injuries are the most serious. Patients with biliary stricture may experience long-term problems with recurrent cholangitis and a risk of developing biliary cirrhosis [3]. Recent studies have shown that laparoscopic cholecystectomy has approximately twice the risk of bile duct injury as compared with the open procedure (0.6 vs. 0.3%), and this is attributed to the learning curve [4–6]. Early recognition of bile duct injury is essential to prevent major morbidity. This paper presents the management and outcome of bile duct injuries sustained during laparoscopic and open cholecystectomy.

Patients and methods

This study was conducted in the Surgical Department, Zagazig University. An analysis was done prospectively for iatrogenic biliary injuries after both open and laparoscopic cholecystectomy over a period of 2 years (March 2012 to March 2014). These patients were either operated in our unit or referred from other units.

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Male to female ratio.

Table 1 Timing of presentation

Time of presentation	n (%)
Intraoperative	4 (14.8)
<1 week	8 (29.6)
1 week to 1 month	12 (44.4)
1–3 months	3 (11.4)
Total	27 (100)

The criteria that were evaluated included presenting symptoms, nature and site of biliary tract injury, diagnostic modalities and treatment given and its outcome.

Inclusion criteria

All patients with postcholecystectomy biliary injury admitted at the Department of General Surgery, Faculty of Medicine, Zagazig University, during the study period (March 2012 to March 2014) were included.

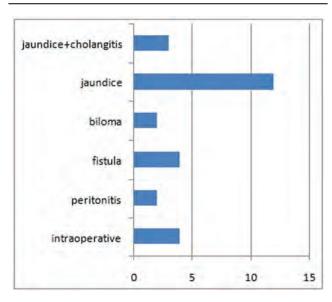
Exclusion criteria

Patients with any discovered growth in the gall bladder and those with traumatic injury to the biliary tract or injury sustained during some other procedure were excluded from the study.

Results

During the 2-year study period, 12 patients had iatrogenic biliary injuries in our department, whereas 15 cases were referred from elsewhere, thus making a total of 27 patients. Among these, 16 were females and 11 males, giving a female to male ratio of 1.4:1 (Fig. 1). Overall, 420 cases underwent cholecystectomy in this period.

Figure 2



Presentation of injured patients.

Table 2 Results of abdominal ultras	sound
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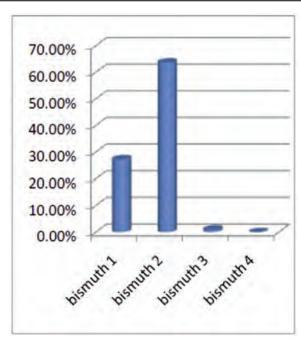
Finding	n (%)
Dilated intrahepatic biliary radicals	17 (73.9)
Collection	8 (34.6)
Negative	2 (8.6)

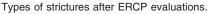
The mean age of the patients was 40 years (range: 15–55 years). Eighteen patients had cholecystectomy done laparoscopically, whereas the remaining underwent open procedure. The time of presentation of the biliary injuries varied from intraoperative to early postoperative (during the first week postoperatively) and late postoperative (after 1 week to 3 months) (Table 1).

Of the 23 patients who presented postoperatively, two presented with a biloma, two had biliary peritonitis, and four had continuous discharge of bile from the drains placed during surgery. Twelve cases presented with obstructive jaundice alone and three cases presented with jaundice with cholangitis (Fig. 2).

Ultrasound was carried out as the first-line investigation in all 23 patients presented post-operatively. It helped in detecting the site of injury and the extent of any collection, besides playing a therapeutic role in the aspiration of localized collections (Table 2).

Magnetic resonance cholangiopancreatography (MRCP) was carried out in eight patients who either presented late after surgery or had persistent symptoms despite the initial management. MRCP delineated the ductal anatomy and the site and extent of the lesion. Endoscopic retrograde cholangiopancreatography (ERCP) was done in fifteen





patients. In three cases, it showed the exact site of biliary leakage (which was the cystic duct stump in two cases and hepatic duct fistula in one case). Sphincterotomy and stent insertion was used with adequate drainage for the three cases. In 11 cases, it demonstrated ductal stricture or obstruction and the site of the distal stump. [stricture in the upper common bile duct (CBD) in three patients, stricture of hepatic duct in seven cases, and stricture of hepatic duct confluence in one case]. It was failed in one case where cannulation of the duodenal papilla could not be performed.

Types of strictures after ERC evaluation: after ERCP evaluation, the site of injuries were discovered, where stricture was seen in the upper CBD in three patients, stricture of hepatic duct in seven cases and stricture of hepatic duct confluence in one case (Fig. 3).

Percutaneous transhepatic cholangiography was performed in two cases. First case was the one with failed ERCP and the other one was unfit for anesthesia to do ERCP. In one case, it showed biliary stricture at the confluence of right and left hepatic duct (Bismuth type III). The other case of percutaneous transhepatic cholangiography (PTC) showed complete CDB obstruction at the level of entry of the cystic duct leaving a remnant of ~2.5 cm of the CBD (Bismuth type 1) (Fig. 4).

Two groups emerged from the point of management:

Figure 4



Percutaneous trans-hepatic cholangiography.

The first group was the one where injury was discovered intraoperatively in patients (n=4).

In one case, partial injury of the anterior wall of CBD was noticed and it was repaired primarily after T-tube insertion. In two cases, there were complete transections of the CBD. The proximal and distal stumps of the bile duct were easily approximated together without tension. T-tube insertion was done via separate incision. In one case, there was proximal CBD injury near the confluence of hepatic duct (Bismuth type 3), and an immediate Roux-en-Y hepaticojejunostomy was performed for the patient (Fig. 5).

The second group was the one where injury was discovered postoperatively in patients (n=23). The patients in this group were managed through the following two procedures:

(1) Patients managed with conservative treatment (six patients):

Ultrasound-guided drainage of the collected bile was performed in one case, that is, 4.3% of the cases. ERCP was used as a therapeutic modality in five patients of the 23 (21.7%) cases that presented with postoperative injury. Sphincterotomy and stent insertion was used with adequate drainage in three cases (60% of total cases) that presented with bile leakage. In two cases (40% of total cases), the presentation was obstructive jaundice. ERCP showed partial occlusion of the CBD denoting partial clipping or ligation. Balloon dilatation was done followed by sphincterectomy, and a stent insertion was done for this patient.

 (2) Surgical treatment (17 patients): Roux-en-Y hepaticojejunostomy was done for 16 patients whereas choledechodoudenostomy was done for only one patient.

Postoperative complications

The commonest early complications were wound seroma and infection, which occurred in five patients. Moreover, two patients developed a subphrenic collection, where in one of them, the collection responded to conservative management, and in the second one, catheter drainage under ultra sonography (US) guidance was needed. One patient developed a pelvic collection and had catheter drainage under CT guidance. Another patient developed deep vein thrombosis. Patient was obese with past history of deep venus thrombosis (DVT) 2 years ago (Table 3).

Table 3 Postoperative complications observed in this series

Postoperative complications	N=19 [n (%)]
Wound infection	5 (26.3)
Subphrenic collection	2 (10.5)
Peritonitis	1 (5.3)
Pelvic collection	1 (5.3)
DVT	1 (5.3)
Totals	10 (52.7)

DVT, deep venus thrombosis.

Figure 5

Postoperative investigations

An analysis of the changes in the liver function test preoperatively, within 5 days postoperatively, and then before hospital discharge has shown significant decrease in serum bilirubin and alkaline phosphatase. Serum transaminases levels, however, showed an insignificant change in the immediate postoperative period, and a significant change was observed only before hospital discharge (Figs 6 and 7). The average length of stay in hospital was 6 days. Nevertheless, we had one postoperative mortality owing to hepatorenal failure (3%).

Discussion

Injuries to the bile ducts during cholecystectomy represent a dreaded problem, which is easier to prevent rather than cure. The management of these injuries is difficult, and satisfactory results are not always obtained. The management of these problems provides an enormous challenge, even to experienced biliary surgeon. Major bile duct injury may require biliary enteric reconstruction. Many patients, their consultants and their lawyers believe that the treatment results in life time of disability. In this study, 27 patients with postcholecystectomy bile duct injuries were studied. There was a predominance of female, middle-aged patients, as they are classically the population group most susceptible to calcular gall bladder disease, which is, by far, the most common indication for elective cholecystectomy procedures performed for the patients presented in this study.

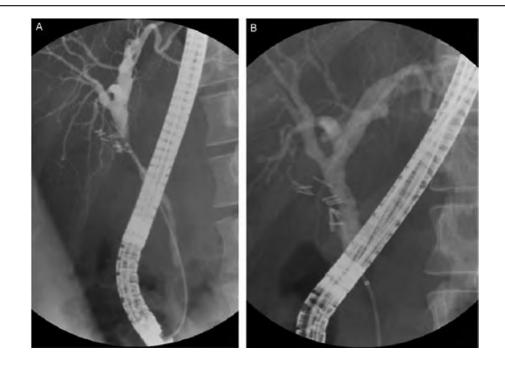
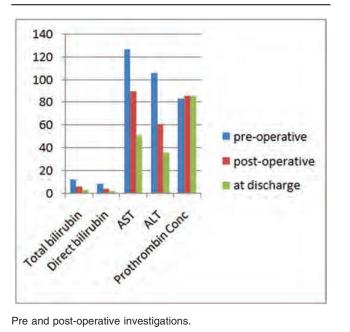
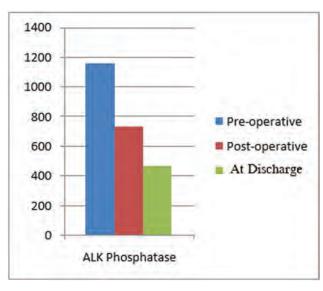


Figure 7



The risk of bile duct injury after open cholecystectomy varies between 0.2 and 0.5%. Recent large collective reviews have shown that there is approximately twice the risk (0.6 vs. 0.3%) of bile duct injury following laparoscopic cholecystectomy compared with open cholecystectomy. A recent international study by Barkun et al. concluded that 75% of all cholecystectomies performed now are laparoscopic. Therefore, it is a fact that the introduction of laparoscopic cholecystectomy increased the incidence of iatrogenic bile duct injuries. Detection of the injury intraoperatively during the cholecystectomy procedure is not easy and can easily be missed especially with partial duct injuries as the affected duct will cause leak later on or stricture even later. In our study, four (14.8%) patients were diagnosed intraoperatively, whereas 23 (85.2%) patients were diagnosed in the postoperative period.

Obstructive jaundice with or without cholangitis was the cardinal presentation of the patients in this study (56.7%). A variety of other presentations were present, including biliary fistula (13.3%), biliary peritonitis (6.6%) and biloma (6.6%). Our results are nearly similar to those of Cameron and Gadacz [7] where 50% of the patients in their study also presented with jaundice, with occasional cholangitis. Show *et al.* [8] showed marked prevalence of obstructive jaundice as the main presentation of the 50 patients in their study, accounting for 90% of patients, whereas only 4% presented with biliary fistulae. In our study, four injuries were discovered and managed intraoperatively. A recent study by Agabiti *et al.* [2], where 200 cases of





biliary injuries following open or laparoscopic were studied, showed that one-third of the lesions were discovered intraoperatively. In the mentioned study, the authors advocated the repair in the same setting. Early repair has its advantages, as the operative field is much clearer with exposed anatomy with the absence of fibrosis and adhesions. The time of presentation of patients following their original cholecystectomies in this study ranged from a few days to 3 months postoperative. This wide variation was owing to the different clinical presentations depending on the type of injuries. Most of patients with less than 1-week presentation had biliary peritonitis owing to major bile leak injuries, whereas those who presented after 1 week to few months had delayed bile duct strictures and external biliary fistulae. Show et al. [8] found that 54% of their patients presented in a period less than 1 month following their cholecystectomies whereas 36% presented in more than 1 month. Abdominal ultrasound was done as a routine primary investigation in our study. It detected dilatation of intrahepatic biliary radicles in 84% of patients (those who were presented with jaundice), whereas it confirmed the presence of intraperitoneal collections in 16% of the patients (those who presented with a biloma or biliary peritonitis).

In the study done by Chapman *et al.* [9], US showed biliary dilatation in 35% of patients whereas abdominal collections were detected in 30%. In our study, ultrasonography had a limited role in deciding the level of injury. This is owing to the established fact that ultrasound has poor visualization of the biliary tree, as intestinal gases largely obscure the biliary view



in US. In our study, only one patient underwent USguided aspiration of bile collection successfully. Show et al. [8] advocated this technique and considered it superior to doing an unnecessary laparotomy for the patients. ERCP was successfully preformed as a preoperative diagnostic investigation in 87.5% of the patients in our study. Similar results were seen in the study by Martin et al. [10], where 88% of their patients successfully underwent preoperative diagnostic ERCP. It was noticed in our study that ERCP failed in one patient to assess the biliary tree, most probably owing to extensive stricture of bile ducts with severe fibrosis which pulls the proximal stump to a much higher level and pulling the distal stump. Diagnostic workup and treatment of bile duct injuries need a multidisciplinary approach requiring gastroenterologists, radiologists, and surgeon. Three of our patients with diagnosed postoperative biliary injuries underwent ERCP and stenting of the common bile duct, and two cases had sphincterectomy and stenting. This offered a definite therapeutic measure for these patients as an alternative to surgical repair. It had a success rate of 88.9%. Similar results were seen in the study by Show et al. [8] in which seven of their 20 patients with biliary strictures were treated by ERCP and stenting, with a success rate of 85.7%. These results are also comparable with those of Martin et al. [10], who had a success rate of 89%.

The endoscopic treatment succeeded in all five patients to give the desired therapy with closure of the fistula and complete relieve of jaundice in all five patients within 2 weeks. The fistula was closed after 10 days in one patient, after 2 weeks in two patients, and after 20 days in other two patients. During the period of follow-up (mean 9 months), there was no recurrence of fistula or jaundice. The stent was removed after complete closure of fistula (after 3 months). Martin et al. [10] commented that it is unknown whether the results of stent therapy are improved by the use of large-diameter stents, and the optimal duration of stent therapy has not yet been established. In our study, PTC was used in limited numbers (two cases=8.6%) as a preoperative diagnostic, clearly delineating the proximal biliary tree and identifying the level of injury. In the study by Misra et al. [11], 32% of their patients successfully underwent PTC as the preoperative diagnostic measure. PTC is helpful in identifying the proximal extent of complete segmental and major bile duct injuries and obstruction but can cause complications such as cholangitis, bile leakage, and even hemorrhage. MRCP was done for eight (32%) patients in our study. (nevertheless, it was of excellent standard in determining the exact site of stricture and in demonstration of the exact anatomy of the proximal biliary tree). In our study, it had a diagnostic accuracy of 100%. In a study performed by Hakansson *et al.* [12], MRC provided additional information that may not be available by PTC in delineating complete anatomy and injury of biliary tract. In our study, 82% of the patients underwent surgical corrective procedures for their bile duct injuries. However, in the study by Li et al. [13], 96% of their patients underwent various surgical procedures of repair including Roux-en-Y hepaticojejunostomy in 72%, Roux-en-Y choledechojejunostomy in 18%, and choledechoduodenostomy in 6%. Study of 22 patients presented by Martin et al. underwent Roux-Y Hepaticojejunostomy. In our study, primary repair over T-tube was done in one patient and primary end-to-end repair was done in two patients, whose injury was discovered intraoperatively during cholecystectomy procedure. Pujahari [14] reported a 78% rate of stricture following attempts at end-to-end repair in accidental operative section of the common bile duct. However, a Roux-en-Y choledechojejunostomy or hepaticojejunostomy is the procedure of choice if the defect is more than 1 cm long or is detected a long time after the injury. Choledechoduodonostomy was performed for 1 patient in our study. This technique still has its advantages as it allows for later endoscopic access by ERCP to assess the efficiency of the anastomosis or to dilate any stricture that might develop. However, its disadvantage is that it may cause ascending cholangitis. Ascending cholangitis occurred in our study which was treated by conservative measures. Choledechoduodenostomy is more physiological, resulting in better digestion and avoiding peptic ulcer formation. It is easier and faster technique [15]. Most cases underwent hepaticojejunostomy, as most of the injuries presented were proximal. This may be owing to proximal traction on the upper stump by the formed fibrosis together with extending ischemia of the affected duct. The high approach was adopted in all the cases so as to perform the anastomosis with the optimum healthy proximal duct stumps as far as possible from any fibrosis or adhesions. Proper dissections of the hilar plate together with a sound mucosa-to-mucosa anastomosis are the key for a successful repair. Stenting after Roux-en-Y hepaticojejunostomy was performed in one case in our study. The role of stenting remains controversial. There has been an increasing trend away from stenting if an adequate wide anastomosis is done. The use based on each patient duct. Short-term postoperative morbidity of patients in our study had an overall rate of 20% (four cases) in surgically treated patients in the form of ascending cholangitis, and one (5%) case developed stricture at bilioduodenal anastomosis and resurgery was done. In our study, the morbidity rate was 4%, with one case of ascending cholangitis and one case of mild pancreatitis. Postoperative complications were 22%

wound infection, 4% subphrenic collection, 2% peritonitis, and 2% DVT.

We had one postoperative mortality owing to hepatorenal failure (3%). In the last decade, most series reported a mortality rate of less than 5%. The results of surgery were considered excellent if the patient remained symptoms free and required no further surgery. Patients were considered to have a good result if they had only mild symptoms including rare episode of cholangitis and did not require further surgery. Patients were considered to have a poor result if obstructive jaundice or severe cholangitis developed requiring reoperation, died within 30 days postoperative or died from biliary cirrhosis or liver failure. According to that the results in our study were as follow: the results of surgery were excellent in 76.5% compared with 60-90% in the reports of Bittner [6]. Those patients showed excellent final results as symptoms were relieved and liver function tests showed normal results. Overall, 11.7% of patients had good results compared with 8-12% in the previous reports. Poor results were 8% compared with 8-12% in the previous reports.

Conclusion and recommendations

Strategies need to be developed for dealing with bile duct injuries, with a view to reduce morbidity and mortality, as early recognition and timely management improve the outcome of these patients.

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Conflicts of interest

There are no conflicts of interest.

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Endovenous laser ablation versus conventional surgery in treatment of primary truncal varicosities

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Aim of the Work

In this study we compare the outcome of laser ablation and conventional surgery in treatment of patients with primary trunkal varicose vein with a period of one year. **Background**

It is estimated that varicose veins in the distribution of the great saphenous vein (GSV) are present in about 25% of women and 15% of men. Endovenous Laser Therapy (EVLT) is one of the most promising techniques in treatment of varicose veins.

Methods

This is a prospective randomized study. This study was conducted on 36 patients presented to our clinic in Mansoura university hospital (MUH) in the period from November 2015 to January 2017 with trunkal varicosities.

Results

In this study, female predominance was remarkable, with a 32 year old mean age. All patients in our study were presented by limb heaviness. Only 5 patients (13.8%) seeked intervention for varicose veins due to cosmetic issues. this study showed different results according to the operative time with 46 minutes difference in the mean operative time between both groups.

Conclusion

In our study we found that EVLA has the same results as surgical stripping regarding the efficacy and the recurrence rate, which was our primary outcome, so that we recommend EVLA as a main method for varicose vein treatment used in treatment of varicose veins with no scars or cosmetic discomfort.

Keywords:

aser ablation, cosmoses, stripping

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Introduction

Great saphenous vein (GSV) varicosities affect $\sim 25\%$ of women and 15% of men. It seems that the appearance and evolution of the disease occur owing to multiple factors but mainly the modern lifestyle, characterized by sedentarity, lack of exercise, and obesity [1].

Surgery is the gold standard in the treatment of varicose veins. For several decades, high ligation at the saphenofemoral junction and stripping of the GSV was the treatment of choice to eradicate the diseased vein. In the past years, in the era of minimally invasive surgery, new techniques in the treatment of varicose veins, such as the endovenous laser ablation (EVLA), have been introduced [2].

In this study, we compare the outcome of laser ablation and conventional surgery in the treatment of patients with primary truncal varicose vein with a follow-up period of 1 year.

Patients and methods

This is a prospective randomized study. This study was conducted on 36 patients with truncal varicosities who presented to our clinic in Mansoura University Hospital in the period from November 2015 to January 2017.

A total number of 175 patients visited the outpatient clinic in 2015, and one hundred of them were excluded as they did not match the criteria, whereas the other 75 patients were matched the inclusion criteria.

Moreover, 30 patients did not agree to the informed consent included in our study, and many of them claimed that the cost was too heavy on their pocket. In addition, nine patients were missed during the

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follow-up, so eventually, we had 36 patients in our study, who were divided into two groups.

Inclusion criteria

Patients presented with varicose vein symptoms affecting their quality of life such as heaviness sensation, fatigability, pain, and cosmetic concerns, with or without presence of skin manifestations such as eczema, pigmentations, lipodermatosclerosis, and healed or active ulcers were included in the study.

Anatomical criteria are mainly listed as having remarkable reflux shown byduplex ultrasonography (DUS) examination (reflux >0.5 s), straight vein segment, any vein segment intrafascially or epifascially which has the same criteria as it can be moved away from the skin by using tumescent injection, great saphenous vein diameter ranges from 4 to 17 mm, and predicted availability of the patient for the follow-up investigations.

Exclusion criteria

Patients primarily aged less than 16 years or more than 65 years, pregnant females, patients experiencing mental incapacitation, patients with obstructed deepvenous system either recanalized or not, patients with GSV diameter more than 17 mm, patients presented with SSV reflux, and patients with deepvein reflux were excluded from the study. Moreover, patients with tortuous veins were also not included as it makes the passage of an endovenous device impossible.

Randomization

Randomization was done before beginning of the procedure using a coin by a nurse who was blinded to the process. The patients were divided into two groups. Group A underwent conventional surgery and group B underwent laser ablation.

Procedure

The basic equipment and supplies for endovenous laser ablation (ELA) were prepared as follow: operating table which can move up and down with tilting to Trendelenburg and reverse Trendelenburg; DUS using transducer with 7.5 MHz; sterile gowns, gloves, masks, drapes, and gauze; ultrasonographic KY gel with sterile probe using wire shields; local anesthesia; scalpel blade (11); 18-G needle, blade (15), or punch biopsy device; 18–21-G needle for skin puncture; 21–25-G needle for tumescent injection; syringes; normal saline; elastic stockings; an EVLA device (Ceralas 1470 nm); and a catheter (ELVeS Radial, Bioletic, Bonn, Western Germany).

Preoperative preparation

All patients were subjected to provide a written consent with complete history taking. After that, full general and local examination was done, which was followed by full laboratory investigations and preoperative duplex scanning.

Treatment modalities

In the group that underwent EVLA, venous access was obtained while the patient lied in the supine position. In some cases, reverse Trendelenburg position was used to increase the venous hydrostatic pressure.

Spinal anesthesia was used in all patients. Skin nicking was done just to help the introduction of the sheath. We used an ELVeS Radial catheter in all cases. A specific mark on the tip of the catheter is usually present. After that, we fix the laser fiber manually and expose \sim 3 cm of the fiber by pulling the sheath backward. Then, weadjust the whole system according to the beginning point of thermal ablation.

The second group that was subjected to surgical stripping was managed preoperatively as usual. Then spinal anesthesia was used in all patients. A small transverse incision of 2 cm in width was done in the groin just medial to the palpable femoral pulsation. Delivery of the GSV and ligation of the tributaries was done surgically. A second small infragenicular incision was made handbreadth from the knee. Delivery of the vein was done surgically.

The stripper then was introduced from below upward. We used disposable metallic strippers. Then stripping was done by pulling the stripper from the incision below the knee.

The follow-up then was done with DUS 1 week later, and then follow-up was done at 1 month, 3 months, and 1 year postoperatively.

The primary outcome of the study was the recurrence rate documented by duplex ultrasound examination 6 months after the operation. The secondary outcomes were assessment of the patient satisfaction according to presence of failure rate, complications, postoperative scars, and the hospital stay as well as ambulation time that allows patients to return to normal activities they used to do before the procedure. Scars were defined by presence of any skin incisions more than 2 cm in the limb.

Patient satisfaction was assessed by Aberdeen Varicose Veins Questionnaire. A total of 13 questions were asked to all patients. The scoring system ranges from 0 point, which means no affection on patient's quality of life, to 100 points, which means severe affection.

Statistical analysis

Data analysis was performed using statistical package for the social sciences, version 21. Qualitative data was expressed as number and percent, and comparison between groups was done using χ^2 -test. The quantitative data were expressed as mean±SD. Independent sample *t*-test was used to compare two groups. Kaplan–Meier method was used for survival curves. *P* value of less than 0.05 was considered to be statistically significant (Figs. 1–8 and Tables 1–4).

Results

Demographic data

Our study was conducted on 36 patients presented with primary varicose veins, with 14 (38%) males and 22 (62%) females. The age of our patients ranged from 17 to 45 years old with mean age of 31 years for the laser group and 35 years for the surgical group.

Clinical presentation

All patients presented with heaviness sensation in the lower limb, 30 patients experienced lower limb pain, only four patients had ulcer, 23 patients had edema, and only five patients complained of cosmetic issues.

Operative techniques

There was a significant difference in the operative time in both groups, as the mean time in the laser group was 49.72 ± 27.78 min and in the surgical group was 96.67 ± 33.43 min, with *P* value less than 0.001.

Figure 1



Assessment of the saphenofemoral junction.

Postoperative hospital stay and complications

In the laser group, the hospital stay ranged from 1 to 2 days, but in the surgical group, it ranged from 2 to 3 days, except for one case, which stayed for only 1 day.

Moreover, there was a significant difference in the ambulation time after intervention in both groups. In laser group, ambulation after surgery was within 2 days, but in the surgical group, it ranged from 2 to 10 days.

Quality of life

Quality of life was assessed by documenting postoperative complications.

Figure 2

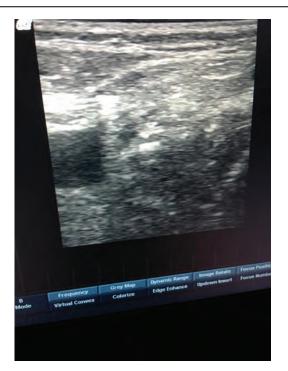


Insertion of 6 Fr sheath into the GSV.

Figure 3

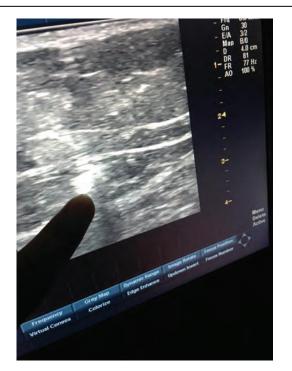


Introduction of the laser fiber through the sheath.



Thermal ablation of GSV.

Figure 5

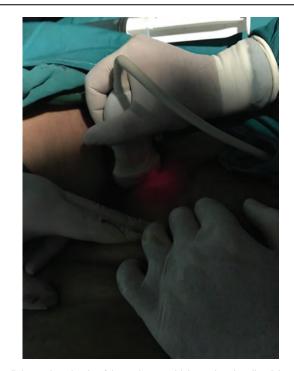


Another case for thermal ablation of GSV.

Discussion

In our study, female predominance was remarkable, as it represented ~61.1% of patients. This may be because of cosmetic point of views. These data are nearly similar to those of all recent studies.

Figure 6



The light mark at the tip of the catheter, which can be visualized through skin.

Figure 7



During removal of the sheath to start ablation for the infragenicular segment of GSV.

The mean age in our study was 32 years in patients underwent EVLA and 35 years in the surgical group. This was to some extent lower than most studies. In 2010, Christenson *et al.* [3] published their study on 200 limbs, with 100 limbs in each group, and the mean age was 45 years in the laser group and 46 years in the surgical group. There is no definite cause for this discrepancy between studies, but it may be related to social awareness about self-medications and periodic scanning about varicose veins [4].

All patients in our study were presented by limb heaviness. Lower limb pain was documented in 72% of patients who underwent laser ablation, and 95% of patients experienced pain in the surgical group. Only five (13.8%) patients seeked intervention for varicose veins owing to cosmetic issues, with four of them being female and only one male.

There was no significant difference in the operative time between laser and surgical groups in most of the studies published recently. Kalteis *et al.* [5] presented that the mean time was 67 min in laser ablation, which is more than the mean time of

Figure 8



Postoperative case after endovenous laser ablation.

surgical group at 60 min only. In Jan 2010, *Jan et al.* also documented that there was no remarkable difference in the treatment time between both groups, with a mean time of 31 min in the high ligation surgery and 32 min in the laser ablation.

However, our study showed different results regarding the operation time. In the laser group, the actual mean time was 50 min, whereas in the surgical group it was 96 min.

Unlike most of the studies, significant differences were recorded in our study according to hospital stay. The mean time in the laser group was 1.28 days, whereas in the surgical group, it was 2.11 days, with *P* value less than 0.001.

Although recent studies showed no difference between surgery and EVLA in the ambulation time, there was a significant difference in our study. Patients who underwent EVLA regained their normal activities after 1–2 days, with mean of 1.5 days, whereas in the surgery group, they returned to their work again after 7–9 days (7.39). *P* value was less than 0.001. This obvious variation may be owing to cultural factors, as

Table 1 Demographic data and clinical presentation inpatients with varicose veins

	Laser group (<i>N</i> =18)	Surgery group (<i>N</i> =18)	Р
Age	31.33±9.62	35.56±6.39	0.131
Male [n (%)]	6 (33.3)	8 (44.4)	0.494
Female [<i>n</i> (%)]	12 (66.7)	10 (55.6)	0.494
Clinical presenta	ation [<i>n</i> (%)]		
Pain	13 (72.2)	17 (95)	0.306
Edema	10 (55.6)	13 (72.2)	
Ulcer	1 (5.6)	3 (16.7)	
Heaviness	18 (100)	18 (100)	
Cosmetic	3 (16.7)	2 (11.1)	

Table 2 Operative time, intraoperative (IO) complications, hospital stay, and ambulation time

	Group	Group [<i>n</i> (%)]	
	Laser group (N=18)	Surgery group (<i>N</i> =18)	-
Intraoperative complications			
No	16 (88.9)	17 (94.4)	0.387
Failed infragenicular access with inaccessible cut down, and ligation with new supragenicular access	1 (5.6)	0 (0.0)	
Cut down	1 (5.6)	0 (0.0)	
Bleeding	0 (0.0)	1 (5.6)	
Operative time (min)	49.72±27.78	96.67±33.43	< 0.001
Stay (days)	1.28±0.46	2.11±0.47	< 0.001
Ambulation time (days)	1.50±0.51	7.39±2.30	< 0.001

Table 3 Postoperative	pain, complications,	and assessment
of quality of life		

	Group	Р	
	Laser group (N=18)	Surgery group (<i>N</i> =18)	-
Postoperative comp	olications		
No	13 (72.2)	8 (44.4)	0.178
Multiple scars	0 (0.0)	2 (11.1)	
Hematoma	0 (0.0)	1 (5.6)	
Edema	3 (16.7)	3 (16.7)	
Burn	2 (11.1)	0 (0.0)	
Scars	0 (0.0)	1 (5.6)	
Postoperative pain	3 (16.7)	12 (66.7)	0.002
Quality of life			
Not satisfied	2 (11.1)	9 (50.0)	
Satisfied	9 (50.0)	8 (44.4)	0.003
Very satisfied	7 (38.9)	1 (5.5)	

Table 4 Follow-up

	Group	Р	
	Laser group (<i>N</i> =18)	Surgery group (<i>N</i> =18)	
Follow-up DUS at 3 mol	nths		
No recurrence	17 (94.4)	17 (94.4)	1.000
Recurrence	1 (5.6)	1 (5.6)	
Follow-up DUS at 6 mor	nths		
No recurrence	17 (94.4)	17 (94.4)	1.000
Recurrence	1 (5.6)	1 (5.6)	
Follow-up DUS at 12 m	onths		
No recurrence or symptoms	16 (88.9)	16 (88.9)	0.261
Recurrence (radiologically)	1 (5.6)	2 (11.1)	

DUS, duplex ultrasonography.

patients consider any wound as a major surgery and they must have longer time for rehabilitation.

In our study, follow-up was done by DUS for 1 year. For the first 6 months, identical results were obtained from both groups. Only one case showed recurrence by duplex examination with mild edema.

On 12-month follow-up, only one patient treated by EVLA has recanalization of the proximal half of GSV. On the contrary, two patients treated with surgical stripping complained of recurrent varicosities demonstrated by DUS with minimal edema and no significant manifestations.

In a prospective, nonrandomized study, Proebstle *et al.* [6] demonstrated that recanalization rate of GSV was less than 10% in cases treated with EVLA. Min *et al.* [7] also showed similar results with recurrence rate less than 7%.

In our study, only 11 patients were not satisfied regarding their limbs, with two of them being treated by laser ablation, and this dissatisfaction was owing to presence of superficial burns which needed longer time for follow-up. Nine patients treated by surgery were not satisfied regarding their results, as some of them were seeking for better cosmetic appearance, and the others did not accept the presence of complications, which led them to more delayed return to their usual activities.

On the contrary, most recent studies have documented that both lines of treatment have similar quality of life postoperatively, with similar satisfactory rates, with minimal privilege toward EVLA owing to better cosmetic appearance [5].

Conclusion

In our study, we found that EVLA has similar results as surgical stripping regarding the efficacy and the recurrence rate, which was our primary outcome. Therefore, we recommend EVLA as the main method for varicose vein treatment, with no scars or cosmetic discomfort.

Postoperative pain and complications are less severe in EVLA than surgical stripping. Moreover, EVLA is associated with shorter time in hospital stay than surgery, allowing patients to return more rapidly to their normal activities.

Although EVLA can be named as the main line of treatment in VV, surgical stripping is still considered a cornerstone in VV treatment owing to many obstacles found during our study, mainly its use in skinny patients as they are more liable to be burnt during thermal ablation.

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Conflicts of interest

There are no conflicts of interest.

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Ligation of intersphincteric fistula tract for high trans-sphincteric fistula-in-ano: our experience

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Background

Fistula is a common perianal pathology. Management of high fistula is challenging, and up till now, there is no sole gold standard surgery for its management. The ideal treatment must eradicate local infection without endangering anal continence. This encouraged us to conduct this study to evaluate the use of one of the newly developed sphincter-saving procedures, which is ligation of intersphincteric fistula (LIFT) technique for management of high trans-sphincteric fistula, regarding fistula healing, anal continence, and recurrence.

Patients and methods

This study was a prospective study. From January 2016 to January 2017, 26 consecutive patients underwent LIFT procedure for high trans-sphincteric fistulaein-ano in Damanhur National Institute Hospital and Medical Research Institute Hospital, Alexandria University.

Results

Success rate of the procedure was 80.8% after a follow-up period of 8 months. No change of continence had occurred in any of patients in this study. Relapse of fistula occurred in 11.5% of patients and nonhealing occurred in 7.7% of patients. The time of fistula healing was 20.0–45.0 days with a median of 26.5 days.

Conclusion

LIFT procedure is a safe procedure for management of high trans-sphincteric fistula with promising short-term results and zero incontinence rate.

Keywords:

fecal incontinence, fistula-in-ano, high trans-sphincteric, ligation of intersphincteric fistula, sphincter-saving procedure

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Introduction

Perianal fistulae are the chronic stages of infections in the anorectal regions and are symptomatized by persistent discharge of pus or recurrent attacks of perianal pain associated with abscess formation, which is relieved by either spontaneous or incisional drainage [1]. Fistula is a common perianal pathology that usually results from obstruction of intersphincteric anal gland ducts with subsequent pus accumulation and abscess formation. Pus is usually drained through an external opening in the perianal skin, resulting in the fistula formation [2]. Fistula-in-ano may be associated with trauma or specific pathologies such as malignancy, inflammatory bowel disease, tuberculosis, and perianal actinomycosis [3,4].

Surgery is the treatment for fistulae-in-ano, aiming to achieve permanent healing without impairment of fecal continence [5–7]. Fistulotomy is the traditional standard surgical modality for treatment of fistulain-ano with a high rate of cure reaching up to 90–97% [4,8]. This high rate of cure is limited by the fact that laying out a high or complex fistulous tract may be associated with a high rate of fecal incontinence [9]; therefore, fistulotomy has been limited to management of simple and low trans-sphincteric fistulae [10,11]. Complex fistulae are treated with various other surgical techniques with the hope to achieve the same cure rate of fistulotomy but without endangering continence. These techniques have a variable degree of success rate and include endoanal (mucosal) advancement flap (MAF), seton use either cutting or draining, debridement, and fibrin glue injection or plug insertion. Recurrence after these procedures is variable reaching up to 63% for MAF, 84% for fibrin glue, and 66% for the plug [12–14]. Incontinence rate following MAF and cutting seton may reach up to 35 and 38%, respectively [15].

Novel sphincter-saving procedures such as ligation of intersphincteric fistula tract (LIFT), video-assisted anal fistula treatment, and fistula-tract laser closure have been recently developed for the treatment of

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fistula-in-ano, with promising early results and minimal risk of incontinence [6,16–18]. Videoassisted anal fistula treatment and fistula-tract laser closure need special instruments and laser fiber which are not available in our institutes. This encouraged us to conduct this study to report our experience in the use of LIFT for treatment of high trans-sphincteric fistulae in terms of fistula healing, intact sphincteric function, and recurrence.

Patients and methods Study design

This study was a prospective experimental study. From January 2016 to January 2017, 26 consecutive patients underwent LIFT procedure for high trans-sphincteric fistulae-in-ano in Damanhur National Institute Hospital and Medical Research Institute Hospital, Alexandria University.

Sample size and study power

On the basis of literature review for success rate of LIFT technique relative to traditional methods considering mainly incontinence rate, a sample of 25 patients will provide a study power of 90% to estimate a clinically acceptable effect size of 0.25 (moderate) with 95% confidence level of 0.1–0.30. The effect size was based on difference at incontinence rate between the LIFT method and what is known about traditional methods of 30% on average with precision of 7 and 10% more sample units to avoid attrition effect [15].

Preoperative course

All patients underwent full history taking with emphasis on their complaints, history of previous perianal abscesses whether relieved spontaneously or by incisional drainage, history of previous surgery for their fistulae, and presence of any type of anal incontinence. Preoperative digital rectal examination, office anoscopy, and endoanal ultrasonography (EUS) were done for each patient in this study. EUS helped in precise localization of the site of the internal opening and determined the volume of the anal sphincter passing beneath the fistulous tract. Trans-sphincteric fistula was considered high if it passed over more than one-third of the external anal sphincter [19,20]. Exclusion criteria included recurrent fistulae, presence of preoperative fecal incontinence, age younger than 18 or older than 75 years, anorectal abscesses or active inflammation, association of the fistula with anorectal malignancy, tuberculosis, HIV, local irradiation, and poorly controlled diabetics. Every patient in this study signed an informed consent, which was approved by ethics committee in our institutes after detailed explanation of the procedure and possible complications.

Surgical technique

An enema was performed for each patient in this study at least 12 h before surgery. All procedures were done under spinal anesthesia. All procedures were done in the lithotomy position. Digital rectal examination and anoscopy were done to exclude any possible associated or underlying pathology. Identification of the internal opening was done by gentle probing of the tract if possible and if not injection of hydrogen peroxide (H_2O_2) was done. Forceful passage of a probe was avoided so as to avoid false passage. A curvilinear incision of 2-3 cm in the intersphincteric space was done opposite to the internal opening. Gentle dissection between internal and external sphincters was done using scissors and bipolar diathermy to identify the fistulous tract. Dissection was facilitated by the use of long narrow blade retractors. A small right-angled clamp hooked the tract after its identification. Double transfixion of the fistulous tract with vicryl 3/0 or 2/0 (Ethicon, Somerville, New Jersey, USA) (according to the size of the tract) was done very close to the internal opening after removal of the probe. Division of the tract distal to the transfixion knots was done. Partial coring out of the external sphincter portion of the divided tract was done followed by ligation or transfixion of the remaining end of the divided tract as far as possible with excision of the intersphincteric portion of the tract and possible infected anal glands. H₂O₂ was injected through the external opening to confirm proper division of the tract. The excised tract was sent for histopathological examination. An ellipse was done around the external opening with aggressive curettage of the external portion of the tract. The internal and external sphincters were reapproximated with vicryl 3/0 (Ethicon). The intersphincteric wound was closed with interrupted loose vicyl 3/0 (Ethicon) sutures and the external opening was left open to heal by secondary intention.

Operative and postoperative course

The following intraoperative data were recorded for each patient: identification of the internal opening (probing or H_2O_2 injection), correlation of preoperative data of EUS with intraoperative findings, and operative time. Postoperatively, all patients were followed up for assessment of fistula healing, continence, and recurrence. Complete fistula healing was considered when complete closure of intersphincteric wound and external opening occurred with absence of purulent discharge or air leak from both wounds. Continence was described according

to clinical staging as: category A: full continence, category B: flatus incontinence but continence of solid and usually fluidly stool, category C: incontinence of fluidly stool and flatus but not of solid stool (intermittent fecal leakage), and category D: complete incontinence (persistent fecal leakage) [21]. Postoperatively, all patients received normal oral diet without any restrictions. Oral ciprofloxacin and metronidazole were given for 2 weeks after the operation. Patients were informed to clean their wound thoroughly with tap water. All patients were discharged on the first postoperative day after assessment of their wounds for possibility of hematomas.

Follow-up

Follow-up was done at the outpatient clinic weekly until complete fistula healing occurred then every 2 months for 8 months. If complete closure of both external opening and intersphincteric wounds did not occur after 10 weeks, this was considered as nonhealing of the fistulous tract. Reopening of the fistula after apparent complete healing, appearance of new external opening, and recurrence of symptoms after complete resolution at any time during the period of follow-up was considered as recurrence of the fistulous tract. None healing and recurrence of the fistulous tract were considered as failure of the procedure. We did not lose any patient during follow-up.

Statistical analysis

Data were fed to the computer and analyzed using IBM SPSS software package, version 20.0 (SPSS, Inc., Chicago, IL, USA). Qualitative data were described using number and percentage, whereas quantitative data were described using minimum–maximum, mean±SD.

Results

Preoperative and operative data of the studied population were shown in Tables 1 and 2, respectively. Postoperative hematomas occurred in two (7.7%) patients which were mild and managed conservatively. Success rate of the procedure was 80.8% after a follow-up period of 8 months. Postoperative incontinence rate was 0% in this study. Postoperative data of the studied population were shown in Table 3. Figures 1–4, show illustrations of the steps of LIFT procedure for a 39-year-old female patient with high anterior trans-sphincteric fistula.

Discussion

In this study, all procedures were performed in the lithotomy position in accordance to the study by Sileri *et al.* [22]. Most of the authors including Rojanasakul *et al.* [6] who originally described the procedure have used prone Jack knife position [8,23–28], whereas others have used both Jack knife and lithotomy positions [29–31]. In this study, we did not find any difficulty in performing LIFT procedures in the lithotomy position as we were used to performing all anal procedures in this position in our institutes. We thought that operative positioning of patients in various studies was a matter of surgeons' preference.

Table 1	Preoperative	criteria o	f the studied	population (n=26)

	n (%)
Sex	
Male	17 (65.4)
Female	9 (34.6)
Age (years)	
Minimum-maximum	20–60
Mean±SD	36.8±11.0
Clinical presentation	
Discharging sinus	26 (100)
Perianal itching	14 (53.8)
History of perianal abscess	19 (73.1)
Comorbidities	
Hypertension	3 (11.5)
Cardiac	2 (7.7)
Hepatitis C	4 (15.3)

Table 2 Operative data of the studied groups (n=26	Table 2	Operative	data of	the studied	groups	(n=26)
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	n (%)
Operative time (min)	
Minimum-maximum	25–60
Mean±SD	39.8±9.6
Identification of internal opening	
Probing	11 (42.3)
Hydrogen peroxide injection	15 (57.7)
Anatomical location of the fistula	
Anterior	8 (30.8)
Posterior	16 (61.5)
Lateral	2 (7.6)
Accuracy of endoanal ultrasonography	
True	22 (84.6)
False	4 (15.4)

Table 3	Posto	perative	data of	the	studied	groups	(n=26)	
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	n (%)
Complete fistula healing	
Healing	21 (80.8)
Nonhealing	2 (7.7)
Recurrence	3 (11.5)
Incontinence	0 (0)
Hematoma	2 (7.7)
Healing time (days)	
Minimum-maximum	20.0-45.0
Mean±SD	29.3±8.0
Median	26.5

Fig. 1

Anterior trans-sphincteric fistula with probe insertion.





Hooking of the tract by a right angled clamp.

Fig. 4



Closure of intersphincteric wound with widening and curettage of the external opening.

upon naive patients as surgery for recurrent fistulae was expected to be more difficult, and before this study, we did not have a previous experience with the LIFT procedure in our institutes.

We did not perform a preoperative seton for all candidates of this study. Murugesan *et al.* [42] conducted a systematic review for evaluation of efficacy of the LIFT for treatment of perianal fistulae and found 13 studies that evaluated the use of seton before LIFT procedure. No significant changes were found in any of these studies regarding closure of fistulae in a case of use of preoperative seton [22,25,27–31,33,35,40,43–45].

Success rate of LIFT procedure in this study was 80.8% after 8 months of follow-up. Variable success rates of LIFT procedures were reported by previous authors with a wide range from 40 to 90%

Fig. 2



Identification of the tract.

Preoperative EUS was done routinely for all patients in this study, which was similar to several previous studies [22,30–35]. Other authors did not perform routine preoperative ultrasonography and depended only upon the intraoperative evaluation [8,26], and others use it selectively [23,36]. EUS was accurate in localization of internal opening in 84.6% of patients which was close to the results of the study by Tan *et al.* [37]. We thought that it was better to perform preoperative EUS if possible as it had a high accuracy and could help in precise localization of intersphincteric incision for LIFT procedure especially in a case of intraoperative nonidentification of internal opening.

We excluded patients with recurrent fistulae from this study, which was similar to some of the previous studies [38,39]. Most of the authors included patients with recurrent fistulae in their studies [22,25–27,29,30,36,40,41]. We preferred to operate [6,8,22–31,34,36,40,41,45–49]. This wide range may be owing to the differences in inclusion and exclusion criteria of candidates from one study to the other regarding type of the treated fistula, and trials of previous fistula repair. Moreover, differences in the period of postoperative follow-up between various studies may play a role.

The median healing time in this study (26.5 days) was close to that reported by some of the previous studies [6,29,38]. Ooi *et al.* [26] and Sharma *et al.* [41] reported a median healing time of 6 weeks in their studies. Liu *et al.* [40] reported a median healing time of 8 weeks and proposed that healing time after LIFT procedure may be prolonged up to 36 weeks. They thought that patients with persistent symptoms after surgery may be managed conservatively and observed for more than 6 months before taking the decision of reoperation [40]. This difference in healing time between different studies was expected in view of inhomogeneity of candidates of different studies.

In this study, the relapse rate was 11.5%, which was less than the reported by many of the previous studies [40,50,51]. We thought that the low relapse rate in our study was attributed to shorter follow-up (8 months) compared with these studies. Many authors described late recurrence after LIFT which extended to 7–8 months after the initial surgery [24,29]. Liu *et al.* [40] in their study found that recurrence of fistula after LIFT procedure may occur as late as 12 months after surgery and suggested a minimum postoperative follow-up of 1 year to ensure that the patient had complete fistula healing.

In this study, all recurrences presented as intersphincteric fistulae in accordance to several previous studies [26,36,40,50,51]. We thought that medialization of the fistula was beneficial as all these patients were managed by fistulotomy without any compromise of anal continence.

In this study, all patients were admitted to the hospital and discharged on the first postoperative day. Many authors performed LIFT as a same-day surgery [8,22,25,29,31,52,53]. Others admitted patients to the hospitals with 1.25 days as an overall median hospital stay (range: 1–5 days) [6,23,26,27]. We admitted patients overnight to the hospital for fear of postoperative bleeding as a result of intersphincteric dissection, but only two patients developed perianal hematomas, which were mild and managed conservatively. After this study, we thought that LIFT could be performed safely as a same-day surgery, and there was no need for overnight hospital admission to save the additional costs of hospitalization.

Anal continence was evaluated subjectively in the clinic similar to most of the previous studies [6,8,25,30,39,40]. Some authors used various scores for evaluation of anal continence such as the Cleveland Clinic Florida Fecal Incontinence Score [31], Wexner Incontinence Score [26], and Fecal Incontinence Severity Index score [22]. Sirany *et al.* [54] in their systematic review for evaluation of LIFT procedure included 12 studies of classic LIFT, including 352 patients, and described only one patient with postoperative fecal incontinence. In this study, all patients were continent after the procedure similar to most of the previous study.

In terms of high short-term success rate of LIFT procedure with 0% incontinence rate in this study together with the fact that LIFT procedure does not require any special instrument may give LIFT the chance to be an important option for treatment of high trans-sphincteric perianal fistulae in our country as ours is a developing country, and cost of the procedure is very important to us.

The principal limitations of this study were the probable small sample size and the short period of follow-up. The operating surgeons were the same who evaluated the results of the procedure, and this might produce some observational bias.

Conclusion

LIFT is a safe sphincter-saving procedure for management of high trans-sphincteric perianal fistula with reasonable short-term results without endangering anal continence. Further studies with long-term follow-up are required to evaluate LIFT and its modifications for management of various types of complex fistulae-in-ano.

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Conflicts of interest

There are no conflicts of interest.

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Associated maxillofacial bone fractures with zygomatic complex fracture: experience from a tertiary referral hospital in Riyadh, Kingdom of Saudi Arabia

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Background

The zygoma plays a fundamental role because the underlying bony structural design directly influences the facial contour. As a result of the intimate association of the zygomatic complex (ZC) with the rest of the facial skeleton, associated maxillofacial fractures are quite common.

Patients and methods

All cases diagnosed with ZC fracture over a 10-year period starting from December 2002 to December 2012 at Riyadh Dental Center at King Saud Medical City, Riyadh, Saudi Arabia, were studied. Patient's sex, age, etiology, and associated maxillofacial bone fracture were retrieved and recorded. Data were stored and statistically analyzed using SPSS. Results were presented as simple frequencies and percentages.

Results

Overall, 1487 patients presented with maxillofacial trauma and 306 cases were diagnosed with zygomatic bone fractures. There were 271 (88.6%) male patients and 35 (11.4%) female patients, with male : female ratio of 7.7 : 1. Patients in the age range of 21–30 years had the highest number of maxillofacial fracture. Ninetysix (31.4%) patients had associated maxillofacial bone fractures, whereas 231 (69.6%) patients did not have any associated fracture. Road traffic accident was the leading cause of the maxillofacial trauma [221 (72.2%)]. Mandibular fracture had the highest frequency of 35 (11.4%), whereas Le-Fort III and frontal bone fractures had the least number of cases [two (0.7%)].

Conclusion

Associated maxillofacial bone fracture with ZC fracture is quite common. Efforts should be made by the attending surgeon to identify these injuries.

Keywords:

associated fracture, mandibular, maxillofacial, orbital, zygomatic bone

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Introduction

In maintaining facial contour, the zygoma plays a fundamental role because the underlying bony structural design directly influences the facial contour [1]. When this prominent bone fractures and dislocates, it does not only cause aesthetic deficits but also disrupts ocular and mandibular functions. Because of its prominence, it is prone to various traumas; however, its bony architecture is unique as it enables it to resist significant impact without being fractured [2].

Trauma (most of the time road traffic accidents) has been the leading cause of zygomatic bone fracture followed by assault [3–6]. Male preponderance has been reported worldwide [3,4,7]. Third decade of life has been documented as peak age of maxillofacial trauma generally [7,8].

Because of its articulation with four pairs of bone in the caniomaxillofacial region, it is referred to as tetrapod fracture [9]. These bones are the frontal bone of the skull (zygomaticofrontal), the temporal bone of the skull (zygomaticotemporal), the sphenoid bone of the skull (zygomaticosphenoid), and the maxillary bone of the facial skeleton (zygomaticomaxillary) [10].

As a result of the intimate association of the zygomatic complex (ZC) with the rest of the facial skeleton, associated maxillofacial fractures are common. The management of these complex fractures will depend upon thorough evaluation and diagnosis of these associated fractures. The specific aim of the current study therefore is to find out the associated maxillofacial bone fractures with ZC fracture at

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Riyadh Dental Centre, King Saud Medical City, Kingdom of Saudi Arabia.

Patients and methods

All patients with maxillofacial fractures presenting at Riyadh Dental Centre at King Saud Medical City, Riyadh, Saudi Arabia were reviewed retrospectively. All cases diagnosed with ZC fracture were included in this study over a 10-year period starting from December 2002 to December 2012. Patient's sex, age, etiology, and associated maxillofacial bone fracture were retrieved and recorded. The study was approved by the Ethical Committee of King Saud Medical City with protocol number GRP/43236002/38.

Inclusion criteria comprised all patients diagnosed clinically and radiographically with ZC fracture with associated maxillofacial fracture. Exclusions criteria included patients with other maxillofacial injuries or body injuries not associated with zygomatic bone involvement and patients under the care of other speciality such as neurosurgery and orthopedic.

Data were stored and statistically analyzed using SPSS (version 16.0; SPSS Inc., Chicago, Illinois, USA). Results were presented as simple frequencies and percentages.

Results

A total of 1487 patients overall presented with maxillofacial trauma and 306 cases were diagnosed with zygomatic bone fractures. There were 271 (88.6%) male patients and 35 (11.4%) female patients, with male : female ratio of 7.7 : 1 (Table 1). The patients with age ranged from 21–30 years had the highest number of maxillofacial fracture (Table 2). Of the 306 cases with zygomatic fractures,

96 (31.4%) had associated maxillofacial bone fractures, whereas 231 (69.6%) did not have any associated fracture. Road traffic accident was the leading cause of the maxillofacial trauma [221 (72.2%)] followed by assault [54 (17.6)]. Mandibular fracture had the highest frequency of 35 (11.4%) closely followed by Le-fort I fracture of the maxilla 20 (6.5%), and then Le-fort II fracture of the maxilla [15 (4.9%)]. Le-Fort III and frontal bone fractures had the least number of cases [two (0.7%)] each (Table 2). Other distribution of associated maxillofacial bone fracture is shown in Table 2 and Figure 1. The most common site of mandibular fracture was parasymphysis fracture which was diagnosed in 13 (4.2%) cases and the least affected site of the mandible was the coronoid process which was diagnosed in only one (0.3%) case (Fig. 2). Orbital fracture was diagnosed in nine (2.9%) cases. Three (1.0%) cases involved the infra-orbital rim, two (0.7%) cases involved the supra-orbital rim, one (0.3%) case affected the medial wall, and three (1.0%)cases were diagnosed with orbital floor fracture (Fig. 3).

Discussion

The incidence of maxillofacial trauma is rising at an alarming rate worldwide. In the UK, it has been

Table 1	Distribution	of sex	and	etiology	of zygomatic
complex	k fracture				

	Frequency	Percentage
Sex of patients		
Male	271	88.6
Female	35	11.4
Total	306	100.0
Etiology of zygomatic f	racture	
RTA	221	72.2
Assault	54	17.6
Camel insult	4	1.3
Fall	17	5.6
Sports	10	3.3
Total	306	100.0

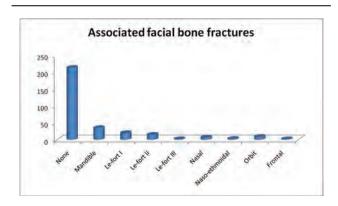
RTA, road traffic accident.

Table 2	Distribution	of associated	fractures wi	ith age group	of patients
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Associated fractures		Total [n (%)]					
	0–10	11–20	21–30	31–40	41–50	>50	
Mandible	0 (0.0)	9 (1.3)	21 (6.9)	4 (1.3)	1 (0.3)	0 (0.0)	35 (11.4)
Le-Fort I	0 (0.0)	4 (1.3)	11 (3.6)	3 (1.0)	0 (0.0)	2 (0.7)	20 (6.5)
Le-Fort II	0 (0.0)	4 (1.3)	5 (1.6)	2 (0.7)	3 (1.0)	1 (0.3)	15 (4.9)
Le-Fort III	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	1 (0.3)	2 (0.7)
Nasal	0 (0.0)	3 (1.0)	3 (1.0)	1 (0.3)	0 (0.0)	0 (0.0)	7 (2.3)
NOE	1 (0.3)	2 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (1.0)
Orbital	1 (0.3)	3 (1.0)	4 (1.3)	0 (0.0)	1 (0.3)	0 (0.0)	9 (2.9)
Frontal	0 (0.0)	2 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (0.7)
None	6 (2.0)	61 (19.9)	88 (28.8)	42 (13.7)	14 (4.6)	2 (0.7)	213 (69.6)
Total	8 (2.6)	88 (28.8)	133 (43.5)	52 (17.0)	19 (6.2)	6 (2.0)	306 (100.0)

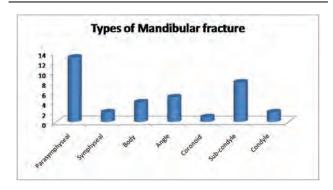
NOE, naso-orbito-ethmoidal.

Figure 1



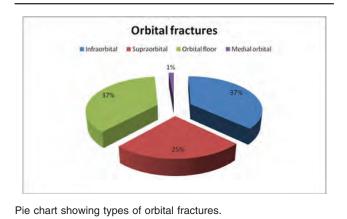
Graph showing associated facial bone fracture with zygomatic bone fracture.

Figure 2



Bar chart depicting types of mandibular fracture.

Figure 3



reported that an increase of 28% was observed in 2011 as compared with 2010 [11]. Males are generally reported to be more predisposed to trauma, and the second to third decades of age was most vulnerable owing to high activities of this age bracket [3,7,8]. Our findings are in support of this position as most of the patients are males and in the second to third decade of life. In developed countries, there has been decrease in motor vehicular crashes owing to strict safety improvements such as airbags and seat belts; however, interpersonal violence continues to rise [12,13]. In Saudi Arabia, UAE, and other African countries, road traffic accidents still remain the main etiology of maxillofacial injuries [6,7,14–17]. This study has buttressed this finding, as 72.2% of the accidents were due to road traffic accident. It is also surprising that in Saudi Arabia, interpersonal violence may be on the increase as 17.6% of the incidents in this study were due to assault.

As a result of the intimate association of the ZC with the rest of the facial skeleton, associated maxillofacial fractures are common. In this study, the mandible was found to be associated with fracture zygoma in 35 (11.4%) patients followed by Le-fort I fracture in 20 (6.5%) cases. This is in agreement with the studies of Afzelius and Rosen [18], Ellis et al. [19], and Obuekwe et al. [7] who reported that mandibular fractures were most often associated with ZC fractures. On the contrary, Trindade et al. [20] reported that Le-fort II fractures were most often associated with zygomatic bone fractures followed by nasal bone fractures. In this study, the mandible was commonly fractured in the parasymphysis and subcondyle area and the least affected site of the mandible was the coronoid process, which was diagnosed in only one case.

The maxilla represents the bridge between the cranial base superiorly and the dental occlusal plane inferiorly. It is closely related to the zygomatic bone at the zygomaticomaxillary suture lines. Therefore, fracture of the zygoma may be associated with fractures of the maxilla to pose a life-threatening as well as disfiguring facial contour [21]. This study has shown Le-Fort I, II, and III are associated with ZC fracture. This was frequently seen with Le-Fort I and II as in 20 (6.5%) and 15 (4.9%) cases, respectively. We opined that because both fractures (Le-Fort I and II) involve the sub-zygomatic region at the buttress, they may be frequently associated with ZC fracture. It has been documented that Le-Fort I fractures caused by a high-velocity impact (i.e. impact from a fall from >1 story or a motor vehicle crash) occur higher on the lateral buttress (zygoma) than do those caused by a low-velocity impact (impact from a fall or an assault with a blunt weapon or closed fist) [22]. Therefore, as most of the causes of ZC fracture from this current study are road traffic crash related, then it sounds to reason why Le-Fort fractures are associated with ZC fractures.

The midface is frequently associated with orbital injuries; therefore, a thorough ophthalmological

examination is compulsory in all suspected ZC fractures [23]. In our study, orbital fracture was diagnosed in nine (2.9%) cases. Three cases involved the infra-orbital rim, two cases involved the supraorbital rim, and one case affected the medial wall, whereas the orbital floor fracture was diagnosed in three cases. Orbital examination should note any lacerations: assess extraoccular motility, visual acuity, visual fields, and the pupillary light reflex. Diplopia, ophthalmoplegia, hypoglobus, enopthalmos, and proptosis must be accessed for all patients. The integrity of the optic nerve must be established even if the eye is closed. An ophthalmological review is essential in the presence of a through-andthrough lid laceration. When there is concomitant naso-orbital-ethmoidal fractures with ZC fracture, then it predict a higher incidence of postoperative deformity [24]. Therefore, associated orbital injuries with ZC fracture should be identified and prompt management instituted to prevent blindness.

Conclusion

Associated maxillofacial bone fracture with ZC fracture is quite common. Efforts should be made by the attending surgeon to identify these injuries especially orbital injury. This will prevent permanent damage to vital structures in the head and neck region and improve the quality of life of patients following maxillofacial injuries.

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Conflicts of interest

There are no conflicts of interest.

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Circumventing the difficulties induced by popliteal artery variation during tibial endovascular intervention

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Aim

The aim was to provide schematic assessments for the popliteal artery variation in order not to misinterpret the vessel of interest as collateral or occluded artery and consequently increase the efficiency of the territorial revascularization.

Materials and methods

This is a prospective observational study conducted over a period of 2 years including 452 patients who underwent popliteal and infrapopliteal endovascular angioplasty.

Results

A total of 437 (98.2%) patients had the usual pattern of popliteal artery branching, which usually correlates with the current published data. There were two (0.44%) patients with type lb, two (0.44%) patients with type lc, one (0.22%) patient with type IIa, one (0.22%) patient with type IIb, six (1.32%) patients with type IIIa pattern, and three (0.66%) patients with type IIIb.

Conclusion

With adequate preoperative assessment and applying the steps of our technique, the incidence to misinterpret the variation and consequently missing a chance for territorial revascularization become very low.

Keywords:

anatomical variants, infrapopliteal angioplasty, peripheral vascular disease

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Introduction

Embryologically, the popliteal artery is formed by union of two arterial systems, the deep popliteal artery derived from the sciatic system and the superficial popliteal artery derived from the femoral system, and during the embryological development, the distal portion of the deep popliteal segment regresses, whereas the superficial popliteal artery fuses with the proximal portion of the deep popliteal segment behind the popliteal muscle eventually forming the truly mature popliteal artery [1].

The anterior and posterior tibial arteries (PTs) are derived from the femoral system. At the lower border of the popliteus muscle, a perforating branch 'ramus communicans' arises from the sciatic system and communicates with the femoral artery and passes anteriorly between the tibia and fibula which later on becomes the anterior tibial artery (AT) [2–5]. The PT is formed through the communication between the distal femoral artery and the popliteal artery [2,6].

Persistent primitive arterial segments, abnormal fusions, segmental hypoplasia, or the absence of these arteries give rise to anatomic variability. This special embryological sequence of events is thought to be the etiological background of popliteal artery variations [7].

Below-the-knee arterial disease is a predominant causative lesion in critical limb ischemia (CLI) especially in diabetic and in renal impairment patients, in whom the disease may be extensive.

An added difficulty of below-knee arterial disease is the wide range of anatomic variation which may adversely affect the revascularization procedures [8].

Because of these variations, underdiagnosis of the infrapopliteal variant may pose a barrier for optimizing the interventional outcome and limb salvage. Hence, knowledge of the anatomical variations of the popliteal artery branching is important. The treating physicians should be aware of these anatomical variations and be ready with different tools and equipment to effectively manage these lesions and improve their outcome [9].

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The anatomical variations have been described by many authors. Kim *et al.* [10] documented a classification of the anatomical variation of the popliteal artery based on the angiographic appearance.

In this classification, type I indicates a normal level of popliteal arterial branching, including the usual pattern, trifurcation, and the anterior tibioperoneal trunk. Type II indicates a high division of popliteal artery branching including the AT, PT, and peroneal artery (PR) all arising at or above the knee joint. Type III indicates hypoplastic or aplastic branching with an altered distal supply, including a hypoplastic aplastic PT, AT, or both [10].

The incidence of infrapopliteal artery variations showed type III being the most common variant (1.0-7.6%), followed by type II (1.6-7.5%) [11].

Unfortunately, physical examination is not helpful in anticipation and detection of anatomic variations of the popliteal artery branching pattern [12,13].

Noninvasive imaging of the arterial tree using computed tomography angiography (CTA), magnetic resonance angiography, and duplex scanning could be useful for these situations. However, both CTA and magnetic resonance angiography have their own limitations like the need of a contrast injection, excessive calcification of crural arteries, patients with claustrophobia, cardiac pacemaker and metal-implants, and the need for long examination time [14–16].

The presence of severe calcification does not allow adequate visualization of the crural arteries using duplex ultrasonography [17].

The assessment of infrapopliteal vessel variations with chronic total occlusion (CTO) by these noninvasive modalities does not appear to be a realistic method. Accordingly, invasive angiography including digital subtraction angiography remains the gold standard in the evaluation of severely affected infrapopliteal vessels in the setting of CLI [6,18].

Materials and methods

We performed a prospective observational study to detect the true incidence of variation in popliteal artery branching and to test the efficacy of the proposed protocol of interventional angiography in detecting these variations, as mentioned later on. In this study, over a period of 2 years between August 2015 and September 2017, 452 patients who were candidates for popliteal and infrapopliteal endovascular angioplasty either alone or associated with supragenicular lesions were recruited and analyzed for their branching variations. This protocol has passed the surgical department ethical committee.

Most of the cases required ipsilateral antegrade access; however, contralateral retrograde cross-over access was required in patients with supragenicular lesion according to routine preoperative investigations.

In order not to miss the anatomical variations, we followed a diagnostic angiography protocol which is applied for all patients, and it consists of the following steps.

A 4–5-Fr diagnostic catheter (better with curved tip) is to be placed in the upper popliteal artery. Injection of the contrast material is done, and different views are obtained of the popliteal artery. It is recommended to obtain different views with another injection at the lower popliteal segment and at the foot [9,19].

For better assessment and angiographic evaluation of the arterial branching, ipsilateral oblique view of the upper popliteal segment and contralateral oblique view for the lower popliteal segment are extremely helpful, as they can differentiate between the popliteal genicular branches and the high take-off tibial arteries 'type II variations'. Tracing the course and direction of these arteries around the knee makes their identification much more easier, as the genicular branches can take a lateral direction away from the tibia and fibula and may end up in a cork screw fashion unlike the high take off, the 'type II variation', which will follow their course in the corresponding anatomical leg compartment.

The contralateral view at the lower popliteal segment can provide a better view of the popliteal branches as it widens the space between the origins of the overlapped branches and can be helpful in identification of popliteal variations especially type Ib 'true trifurcation' and type Ic 'anterior tibioperoneal trunk'.

In cases of CTO or ostial lesions of the tibial artery, angiography may not be helpful to allow identification of all variations [9,19].

Angiography of the distal leg segment and the foot should be performed at least in two views, 'anteroposterior and ipsilateral oblique views', as the termination of PR is the clue to identify popliteal variations especially type III. As type III variant being the most predominant, the differentiation between an occluded tibial artery in normal anatomy and hypoplasia/aplasia of tibial artery in type III presents a serious challenge because the distal branching pattern of the dominant vessel could be misinterpreted as a collateral pathway circulation [9,20].

Many angiographic findings may raise the suspicion for anticipating type III arterial pattern. The treating physician should note that the hypertrophied PR may get connected to the dorsalis pedis or paramalleolar PT, and also gradual tapering of the hypoplastic tibial artery, interruption of the aplastic tibial artery, and lack of collateral circulation distally are good diagnostic clues to detect this variation [9,20].

This is a commonly used term describing successful passage of the wire into the target vessel with the aid of road mapping to be achieved using 4-Fr curved tip catheter and careful crossing of the occlusive lesion with either subintimal angioplasty using the 'J loop technique' or transluminal passage with a 0.014–0.018 inch guide wire supported by a 2.5–3 mm over-thewire balloon made along the imaged tract of the occluded segment this is followed by balloon dilatation [19].

Results

Applying the aforementioned protocol proved to be successful in the detection of many anatomical variations. Among 452 patients who underwent popliteal and infrapopliteal endovascular angioplasty, we found the usual branching pattern 'type Ia' in 437 (98.2%) patients, whereas type Ib was found in two (0.44%) patients, and two (0.44%) patients with type Ic, type IIa in one (0.22%) patient, type IIb in one

Table 1	Incidence of	popliteal	branching	pattern
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(0.22%) patient, type IIIa pattern in six (1.32%) patients, and type IIIb in three (0.66%) patients (Table 1).

Although preoperative CTA was helpful in anticipating the anatomical variations in most of the cases, we found that eight patients were diagnosed as an occlusion by CTA, whereas during the intervention and by applying the aforementioned protocol, we unrevealed the variations.

We successfully identified one patient with type IIa 'high take off of AT', which was misdiagnosed as a genicular branch of the upper popliteal segment by applying an ipsilateral projection. We also successfully identified one patient with type Ib and one patient with type Ic, which was not properly visualized in preoperative CTA owing to an overlapped origin giving a false impression of a usual pattern or collateral branch, by applying a contralateral projection at the lower popliteal segment.

According to our protocol, angiographic visualization of the distal leg and the foot with anteroposterior and ipsilateral oblique views, five patients with type III variations were identified, and they was previously misdiagnosed as occluded anterior and PTs.

Discussion

Tibial plateau was used as reference landmark for the classification of popliteal artery branching, whereas in anatomical cadaver studies, the popliteus muscle was used as the reference muscle [11,20–22].

In this study, we followed a predetermined special angiography protocol in order not to miss the anatomical branching variations, and subsequently we can effectively calculate the true incidence of

Types	Angiographic			Cadaveric	This study
	Kim et al. [10]	Kil and Jung [8]	Mavili et al. [2]	Ozgur et al. [11]	
Туре I					
a: Usual pattern	92.2	89.2	82.4	90	98.2
b: Trifurcation	2	1.5	5.4	2.5	0.44
c: Anterior tibioperoneal trunk	1.2	0.1	0.4	NA	0.44
Туре II					
a: AT arise at knee	3.7	1.2	3.9	5	0.22
b: PT arise at knee	0.8	0.4	1.5	2.5	0.22
c: PR arise at knee	0.16	0	NA	NA	NA
Type III					
a: Hypoplastic PT	3.8	5.1	3.7	NA	1.32
b: Hypoplastic AT	1.6	1.7	2.2	NA	0.66
c: Hypoplastic AT and PT	0.2	0.8	0.2	NA	NA

AT, anterior tibial artery; PR, peroneal artery; PT, posterior tibial artery.

these anatomical variations and compare our results with the published data, and also we can detect the missed or the misdiagnosed branching variations of the preinterventional CTA. This eventually will improve the clinical outcome of the endovascular intervention for limb salvage.

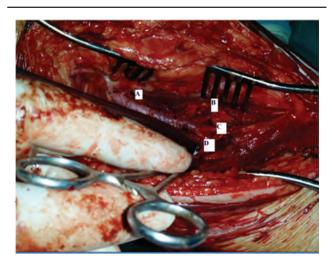
In this study, the usual branching pattern 'type Ia' was found in 98.2% of patients, whereas type Ib was found in 0.44% of patients and type Ic in 0.44% of patients, type IIa in 0.22% of patients, type IIb in 0.22% of patients, type IIIa pattern in 1.32% of patients, and type IIIb 0.66% of patients, which almost correlate with the current published data [2,8,10,23].

The usual popliteal branching pattern ranges between 88 and 96% [4,7,23]. However, Demirtas *et al.* [22] have found in their study many patients with long tibioperoneal trunk, and they consider them as type Id.

Although type IIa and type IIb patterns are relatively uncommon, type IIc pattern is quite rare [3,4,6,7,10,23].

Mavili *et al.* [2] have described type IId, which is a modification of the branching pattern previously described by Kim *et al.* [10], and it involves high division of the popliteal artery with a trifurcation pattern and AT with an initial medial course and a distal lateral course.

Figure 1



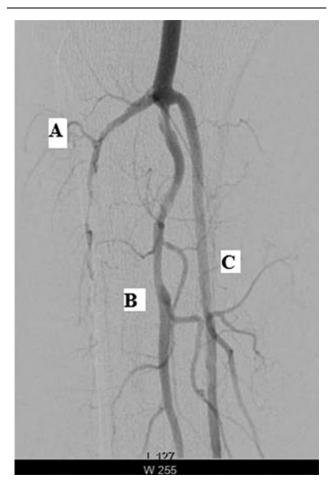
Classification of popliteal artery variations. Adapted from Kawarada et al. [9].

Kim *et al.* [10] have encountered type III variation in 5.6% of limbs, but Day and Orme [23] have reported type III in only 1% of patients. This could be attributed to the difficulty in distinguishing between congenital and acquired arterial abnormalities especially in atherosclerotic vessels.

As shown in Figs 1–6, a hypertrophied PR without transitional tapering at the ankle joint that may be partially or entirely occluded is a particularly important clue suggesting the type III variant.

Moreover, as shown in Figs 7–9, the angiographic appearance that the straight nonundulating course of the distal PR reaches the dorsalis pedis or paramalleolar PT with surrounding collaterals may serve as a hallmark for the presence of the type III variant.

Figure 2



Operative finding of a trifurcation pattern, type lb. (a) Popliteal artery, (b) anterior tibial artery, (c) peroneal artery, (d) posterior tibial artery.

Table 2 Percentage of detected variations by computed tomography angiography

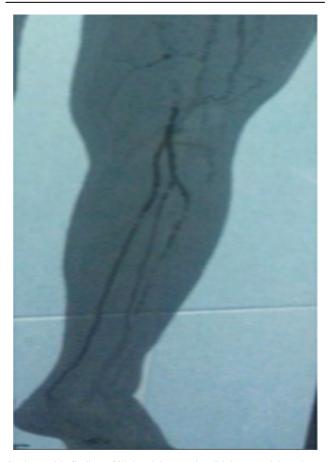
Variations	Type la	Type Ib	Type Ic	Type IIa	Type IIb	Type IIc	Type IIIa	Type IIIb	Type IIIC
Yanik et al. [24]	83.6	0.8	4.4	5.2	2.6	NA	3.4	NA	NA
Calisir et al. [25]	87	4.2	0.2	3.6	1.4	NA	2.7	0.9	NA

Figure 3



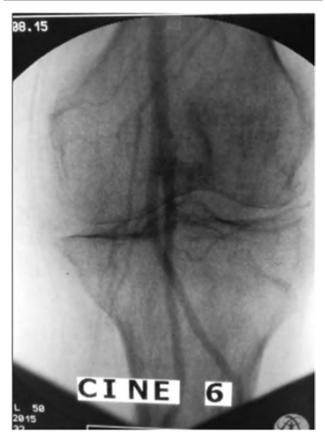
Angiographic finding of a trifurcation pattern, type lb. (a) Anterior tibial artery, (b) peroneal artery, (c) posterior tibial artery.

Figure 5



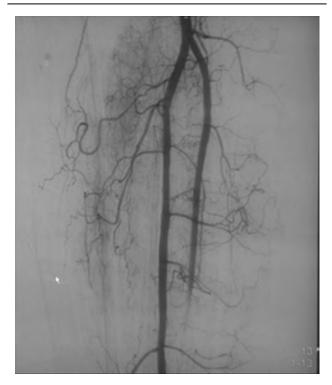
Angiographic finding of high-origin anterior tibial artery rising above the knee, type IIa.

Figure 4



Angiographic finding of anterior tibioperoneal trunk pattern, type Ic. (a) anterior tibial artery, (b) peroneal artery, (c) posterior tibial artery.

Figure 6



Computed tomography angiography showing high-origin posterior tibial artery rising above the knee, type IIb.



Angiographic finding of hypoplastic posterior tibial artery, type IIIa.

Demirtas *et al.* [22] have found PR hypoplasia that was occluded shortly after its origin and not considered this to be an artifact of stenosis. However, they have assigned this observation as type IIId [22].

Using 64-section MDCT angiography as a preoperative assessment, Yanık *et al.* [24] did not observe type IIb, IIc, or IIIc patterns, whereas Calisir *et al.* [25] reported that they did not found any type IIc or IIIc patterns (Table 2).

In this study, we found that eight patients were misdiagnosed as an occlusion by preinterventional CTA, but by applying the aforementioned protocol, we successfully identified the branching variations. There was one patient with type IIa 'high take off of AT', which was misdiagnosed as a genicular branch of the upper popliteal segment, but the variation was identified by obtaining an ipsilateral oblique projection. Moreover, there was one patient with type Ib and one patient with type Ic, which was not Figure 8



Angiographic finding of a hypoplastic anterior tibial artery, type IIIb. From Kawarada *et al.* [9].

properly visualized in preoperative CTA owing to an overlapped origins, giving rise to a false impression of a usual pattern or collateral branch; however, by obtaining a contralateral oblique projection at the lower popliteal segment, the variation was clearly identified. There were five patients previously misdiagnosed as occluded AT and PT, but by obtaining an anteroposterior and ipsilateral oblique views at the distal leg and foot, we successfully detect type III variation.

These differences between the preoperative CTA and the diagnostic angiography could be explained by the presence of an ostial lesion or the CTO of the tibial arteries, which add an extra difficulty to the real diagnosis. Moreover, it is worth mentioning that CTA may not be obtained in the ideal views for proper evaluation of the branching pattern.

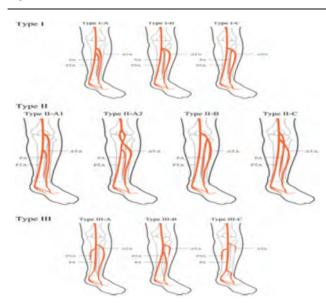
According to Kil and Jung [8], when infrapopliteal variation is noted in one limb, there is a 28–50% probability the other side will likely be a variant pattern. This finding would be of importance in the setting of bilateral CLI as shown in Fig. 10 [7,8,11,26].

Figure 9



Angiographic finding of hypoplastic both anterior and posterior tibial arteries, type IIIC. From Kawarada et al. [9].

Figure 10



Computed tomography angiography showing bilateral popliteal anomaly; on the right side, there is high-origin posterior tibial artery, type IIb, whereas on the left side, there is anterior tibioperoneal trunk, type Ic.

If a patient shows a type III pattern, it might be necessary to change the extremity angioplasty technique in balloon catheter angioplasty. Moreover, adequate planning is required when considering fibular free flap in patients showing type III pattern [18,21,22,27]. Patients with a high-origin AT located behind the popliteus muscle are more vulnerable to injuries particularly during orthopedic procedures [5,6].

Conclusion

With adequate preoperative assessment and applying the steps of our technique, the incidence to misinterpret the variation and consequently missing a chance for territorial revascularization becomes very low.

Keeping the infrapopliteal variant vessels in mind is the key to a successful and optimal tibial intervention. Similarly, increased experience in performing femoropopliteal intervention will offer much experience with infrapopliteal variant.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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Evaluation of the round block technique in early breast cancer Sherif M. Akram^a, Ahmed F. El Kased^b, Hossam A.E. Kader El Fol^b, Mahmoud G. Hagag^a

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Introduction

Conservative surgery has become a well-established alternative to mastectomy in the treatment of breast cancer. However, in case of larger lesions or small-sized breasts, the removal of adequate volumes of breast tissue to achieve tumor-free margins and reducing the risk of local relapse may compromise the cosmetic outcome, causing unpleasant results. To address this issue, surgical techniques, the so-called oncoplastic techniques, have been introduced in recent years to optimize the efficacy of conservative surgery in terms of both local control and cosmetic results. Patients and methods

A Clinical Interventional descriptive single arm randomized prospective study, conducted on twenty female patients presenting with operable breast cancer stages 1 and 2 located at the Upper or Central breast. Ages ranging 25 to 75 years to be treated using the "round block" technique.

Results

Cosmetic results were found to be excellent in three cases, good in eight cases, fair in five cases, and poor in two cases. In this study, the cosmetic results were unacceptable (fair and poor) in patients who underwent 25% resection or in whom the resected area was part of the lower portion of the breast.

Conclusion

These techniques are useful for performing breast-conserving surgery in the upper portion of the breast. However, if the excision volume is greater than 20% or excision of part of the lower portion of the breast is required, other procedures should be considered.

This article discusses the indications, advantages, and limitations of the round block breast-conserving oncoplastic techniques and its results in terms of feasibility, maintaining breast esthetics, limitations, and early complications.

Keywords:

breast cancer, conservative surgery, oncoplastic techniques

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Introduction

Breast-conserving surgery (BCS) is the standard procedure used to treat breast cancer. The primary goal of BCS is to control cancer as effectively as mastectomy, with the additional goal of achieving cosmetic results that are acceptable to patients. achieving good cosmetic results is However, sometimes difficult. The important factors considered to influence cosmetic results include excision volume, tumor location, and glandular density. Oncoplastic techniques can allow for good cosmesis even after large excisions of breast volume, and many oncoplastic volume-displacement techniques for partial mastectomy have been reported [1,2].

The round block technique (RBT) [1,3,4] is a mastopexy technique. It is also known as doughnut mastopexy or periareolar mastopexy, which is another oncoplastic volume-displacement technique used in BCS. Patients with small-sized to-medium-sized breasts without any major ptosis and who may not require contralateral breast surgery for symmetrization are considered to be most appropriate to undergo this procedure. The procedure begins by making two concentric periareolar incisions, resulting in a periareolar scar only. The nipple-areola complex (NAC) can be moved using this technique, depending on the distance of the outer incision from the new areola incision. As a result, this technique is thought to be highly appropriate for Egyptian patients.

Patients and methods

In the period from May 2014 to June 2015, a prospective study of 20 females patients presented with stage I or II breast cancer was conducted, and they were treated using the round block reduction

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mammoplasty technique as an oncoplastic tool for tumoral exision in Menoufiya University hospitals. The ages ranged from 25 to 75 years old. Diagnosis of breast cancer was by full history and clinical examination, preoperative investigations including routine preoperative investigations, investigations for exclusion and/or detection of distant metastasis, and investigations that confirm or exclude diagnosis. All patients were subjected to frozen section during surgery primarily for diagnosis of malignancy if not already diagnosed and document free margins around the excised mass. The Ethics Committee Approval is among my Papers in Menoufiya University as I am using this topic for the Defence of my thesis. Kindly Kontakt Mme. Samah the secretary of the Department of surgery at Menoufiya University as I am in Germany for the Time being.

All patients received full course of radiotherapy postoperatively for local control of the disease.

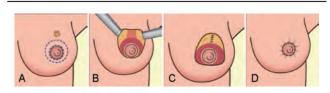
Patients with hormonal receptors positive received hormonal therapy in the form of tamoxifen.

In addition, high-risk group patients with positive lymph nodes received adjuvant chemotherapy where we used a nontaxane chemotherapy regimen for the systemic control of breast carcinoma in the form of cyclophosphamide, methotrexate, and 5-fluorouracil for six cycles. However, updates in chemotherapy modalities showed a statistically significant overall survival and disease-free survival for the taxane-containing regimens compared with the nontaxane regimens [5].

Surgical procedure

While the patient is sitting, two circular skin markings are made (Fig. 1a) on her breasts. The inner marking is made on the areolar border, and the external marking border varies based on the tumor size and location, nipple position, and the degree of ptosis. An external incision is made further away from the inner incision with increasing degrees of ptosis and tumor size. After the incisions are made, the tissue between the two incisions is de-epithelialized. Care must be taken to

Figure 1



The round block technique. (a) Periareolar incision and nipple-areola complex preservation; (b) tumor dissection and flap preparation; (c) postoperative result.

prevent injury to the dermis to preserve blood supply to the NAC (Fig. 1b).

After separation of the skin around the tumor, lumpectomy is performed including the tumor and normal breast tissue. The surrounding breast tissue undergoes undermining and approximation for glandular reshaping (Fig. 1c), and the two periareolar skin incisions are closed using a running suture technique while checking for symmetry of the two breasts (Fig. 1d). If necessary, as in severe ptosis, the opposite NAC may be repositioned using the same method to result in a symmetric and ideal position as well as appearance of the NAC. After the surgery, the cosmetic results are satisfactory because there are only perimamillary scars without any additional scars.

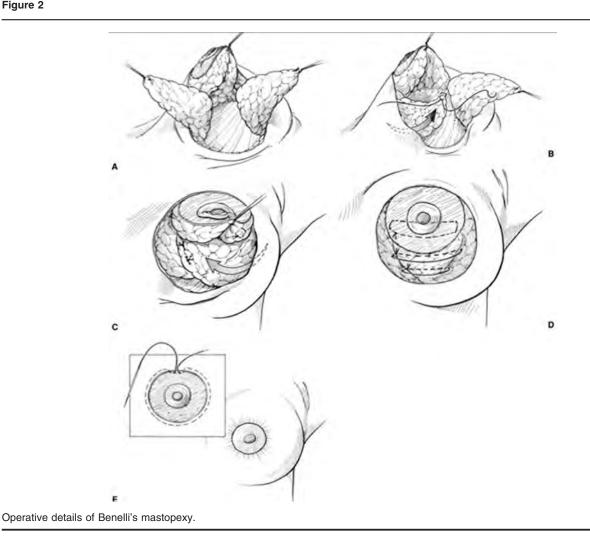
Results

The mean age in this study was 47 years, tumor stages were IA (2.326%), IIA (30.233%), IIB (55.814%), and IIIA (11.628%) with a mean tumor size of 3.2 \pm 1.1912 cm, least resected margins of 0.7–3.8 cm, and mean operative time of 48–124 min (average: 96.5 min). The mean hospital length of stay was 3.25 \pm 1.02 days. The results were found to be excellent in three (15%) cases, good in 10 (50%) cases, fair in four (20%) cases, and poor in three (15%) cases. Unacceptable outcomes (either fair or poor) were observed in seven (35%) cases. However, of the three patients with poor cosmetic results, two required additional excision owing to having a positive margin. None of the patients wished to undergo contralateral breast surgery for symmetrization.

Discussion

The 'round block' enables the use of the periareolar approach to be extended to numerous types of breast surgery, giving easy access to all the glandular areas by extending the incision in an ellipse of depithelialized periareolar skin. By performing a mastopexy, the main goal is to obtain an attractive breast shape with a lasting result, leaving the most inconspicuous scar. The shortest scar is confined to the periareolar circle, avoiding a vertical infra-areolar scar and a horizontal submammary scar. After Benelli introduced RBT, this approach became one of the most popular methods. The characteristics of RBT are periareolar approach, superiorly based dermoglandular pedicle, criss-cross mastopexy, and round block suture.

Benelli was one of the first to note that to create an excellent long-lasting breast shape, the surgery on the gland must be separated from the surgery on the breast skin. Similar to older procedures that sutured the breast



parenchyma to create better breast contour. Benelli shaped the breast parenchyma by creating multiple flaps within the breast gland that were then crisscrossed and sutured together to create a conical breast shape (Fig. 2a-c). The breast was then 'laced' with a permanent suture (Fig. 2d). The round block permanent periareolar suture (Fig. 2e) was placed in the dermis of the skin and then tied down so that the size of the cutaneous areola matched the size of the actual areola. The breast was sometimes sutured to the chest wall to maintain its shape and location. The skin was allowed to re-drape over the newly shaped breast. The best patient for this technique had moderately sized breasts with some hypertrophy. Patients with very loose or very large ptotic breasts were difficult to treat. Patients with tubular breast deformity were also considered good candidates for round block mastopexy [6] (Fig. 3).

The advantage of RBT is that the position of the NAC is correctable, and a very good view is acquired. These advantages are greatest for treating breast cancer in the upper inner portion of the breast. However, it is not the

Figure 3



The round block technique. (a) Incision and nipple-areola complex preservation; (b) tumor dissection and flap preparation; (c) postoperative result.

volume of the defect that compensates for these techniques. If the resection volume exceeds 20% of the total breast volume or the tumor position makes it difficult to obtain an adequate volume by mobilizing the surrounding tissue, the cosmetic results will be poor. These techniques are considered in cases of breast cancer whose excision volume is up to 20% in the upper portion. However, because small-tomoderate-sized dense glandular breasts can be mobilized easily by advancing the breast tissue into the excision cavity without the risk of creating fat necrosis, the cosmetic results may be relatively good

if the excision volume is greater than 20%. By contrast, moderate-to-large-sized breasts tend to exhibit poor outcomes owing to asymmetrical breast size caused by a shrinking volume if the excision volume is greater than 20%. However, when the form of the breast is kept beautiful even though the sizes of the left and right breasts differ considerably, patient satisfaction can be high. Therefore, patients with moderate-to-large-sized breasts may also be indicated for these techniques. In this study, cosmetic results were unacceptable in patients who underwent 25% resection. Other oncoplastic techniques should also be considered in such cases. In addition, because excision of the breast tissue just under the NAC is required in RBT, four patients in this study exhibited blood flow insufficiency in a portion of the NAC. Although this condition was improved with conservative treatment in all cases, careful attention must be paid during and after surgery. Based on the results of the present study, in our opinion, RBT is a useful procedure for performing BCS in the upper portion of the breast. However, if the excision volume is 25%, or part of the region in the lower portion requires excision, RBT should be considered in combination with other techniques or procedures. Oncoplastic procedures are less technically demanding and time consuming than major reconstructive operations and usually require limited training to be properly performed by surgeons experienced in routine breast surgery. These procedures are usually performed in a single surgical access, and the patient leaves the operating room without major residual asymmetry or deformity. Avoidance of poor cosmetic appearance after wide excision by simple oncoplastic methods will increase the number of women who can be treated with BCS by allowing larger breast excisions with improved cosmetic results that achieve widened surgical margins around the cancer.

Conclusion

Many patients, especially with increasing public perception of the incidence of cancer breast, are extremely worried about developing a cancer in their breasts. This has led to a great interest in prophylactic mastectomies. The round block mastopexy with an ontable reconstruction of the contralateral breast if needed offers them the possibility of having an esthetic breast while removing all the breast tissue liable to develop a malignancy. Volume-displacement techniques are time and cost effective, avoiding distal donor site morbidities and also well accepted by both patients and surgeons. However, postoperative breast radiotherapy associated with its possible complications may lead to compromising the esthetic results.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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Outcome after preservation of Scarpa's fascia in abdominoplasty Mahmoud A. Shahin, Mahmoud G. Hagag, Mohamed H. El-Meligy

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Background

Postoperative seroma formation remains the most frequent complication following abdominoplasty. The exact pathogenesis of postabdominoplasty seroma remains unclear. Both the process of flap elevation and redundant skin resection disrupt lymphatic drainage in the immediate postoperative period. Preservation of the Scarpa's fascia in abdominoplasty leads to preservation of deep lymphatic vessels. **Patients and methods**

Thirty-eight patients underwent abdominoplasty (18 of them with Scarpa's fascia preservation) in the General Surgery Department of Menoufia University Hospital in the period between April 2015 and May 2017. Comparison was done between classic technique and Scarpa's fascia preservation regarding early outcomes and postoperative complications.

Results

With Scarpa's fascia preservation, the mean total drain output $(171.5\pm72.18 \text{ ml})$ was much lesser than classic abdominoplasty $(702\pm136.7 \text{ ml})$; moreover, drains were removed earlier with Scarpa's fascia preservation (*P*=0.001 and 0.002, respectively). All patients passed without seroma formation in Scarpa's fascia preservation group; however, in the group of classic abdominoplasty, seroma was detected in three (15%) patients. In Scarpa's fascia preservation group, minor wound dehiscence occurred in two (11%) patients and asymmetry in two (11%) other patients, whereas in the other group, two (10%) patients presented with minor wound dehiscence and two (10%) patients developed wound infection.

Conclusion

Preservation of Scarpa fascia during abdominoplasty has a beneficial effect on patient recovery, reducing total drain output, time to drain removal, and hospital stay.

Keywords:

abdominoplasty, classic abdominoplasty, Scarpa's fascia preservation

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Introduction

Abdominoplasty is a very popular body-contouring procedure, especially for women who have lost a considerable amount of weight, or who have had multiple pregnancies. It ranks fifth among the most common surgical cosmetic procedures from the American Society of Plastic Surgeons [1].

Such a major increase in popularity is owing to a recent increase in bariatric surgery, which precedes the popularity of cosmetic surgery, and very good results obtained with this technique, with a positive effect on the patient's self-image and quality of life [2].

Postoperative seroma formation remains the most frequent complication following abdominoplasty. Seroma alone is still reported with frequencies as high as 30 percent [3,4].

The exact pathogenesis of postabdominoplasty seroma remains unclear. Elevation of the skin flap necessarily results in a large elevated surface area that produces serous fluid secondary to the inflammatory stimulus of injury. Both the process of flap elevation and redundant skin resection also disrupt lymphatic vessels, resulting in a compromised state of lymphatic drainage in the immediate postoperative period [5].

Preservation of the Scarpa's fascia in abdominoplasty is not new. Its benefits are as follows: less bleeding owing to preservation of the inferior perforating vessels, good adherence between the flap and the deep layers, and less seroma formation owing to preservation of deep lymphatic vessels [6].

Patients and methods

This study was conducted on patients who presented to the outpatient clinic of the General Surgery

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Department and Plastic and Reconstructive Surgery Unit of Menoufia University Hospital with anterior abdominal wall laxity of different causes. The study was performed in the period between April 2015 and May 2017.

Inclusion criteria

Patients presented with anterior abdominal wall deformities including excess abdominal skin and/or adipose tissue with or without muscle laxity.

Exclusion criteria

Patients with pregnancy within the previous year, increased intra-abdominal pressure owing to ascites or organomegally, morbid obesity with BMI more than 40 and with previous liposuction or other abdominal surgeries rather than cesarean sections were excluded.

Patients included in the study were divided into two groups: A (18 patients) and B (20 patients).

Patients in group A were subjected to Scarpa's fascia preservation during abdominoplasty and patients in group B were subjected to the classic abdominoplasty.

All patients were subjected to the following:

- Preoperative workup, explanation and an informed consent before admission (informed about the location of the incision and placement of drains), full history taking, general examination, local examination, and investigations.
- (2) Operative workup:
 - (a) Preoperative marking and photographing was done in standing position with relaxed skin tension.
 - (b) Anesthesia and patient positioning: the procedure was performed under general anesthesia. The patient was positioned on the operating room table in supine position, with upper body raised 30°.
 - (c) Operative technique.

Following the individually marked incision line, a sharp incision was done as far as the Scarpa's fascia in group A and rectus fascia in group B. After identification of the abdominal fascia, the flap was dissected cranially along the selected fascia. In group A, the abdominal flap was dissected in two different planes: presuperficial fascia (pre-Scarpa's fascia) in infraumbilical region and preaponeurotic (premuscular) in the supraumbilical region. In group B, the abdominal flap was classically dissected in the preaponeurotic plane.

A circular incision was done around the umbilicus. The dermo-fat flap was then mobilized away from the umbilicus while ensuring that the umbilical stalk would be sufficiently thick and that a wide base would be created during the dissection to prevent later perfusion disorders of the umbilicus.

Plication of the fascia longitudinally was routinely carried out with continuous nonabsorbable thread.

In group A, a small central strip of Scarpa's fascia (few centimeters from the midline) was removed with the underlying deep fat to expose the muscular fascia plane to simplify fascial placation (Fig. 1). The entire dermo-fat flap was then pulled down under traction with the upper body flexed 30° to define the boundaries for later resection. The umbilicus was then positioned outwardly and fitted into the correct new position in the external cutaneous incision without tension.

An 18-Fr suction drain was placed through a separate stab incision. The wound was then closed in three planes. The wound was then covered by placing a simple sterile dressing over the scar. Compressive garment was then used.

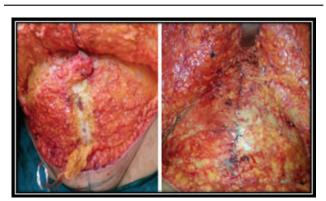
Postoperative follow-up

Patients were subjected to early postoperative followup and late follow-up after 1 and 3 months via serial scheduled follow-up visits at outpatient clinic.

Parenteral antibiotic therapy was prescribed during hospitalization period that was replaced with oral tablets as out-patient treatment, as well as antiinflammatory agents and analgesic agents.

The drains were evacuated daily and removed once the output was less than 30 ml/24 h. The first dressing was

Figure 1



Strip of Scarpa's fascia was removed (left side) with the underlying deep fat to expose the muscular fascia plane to simplify fascial placation (right side).

scheduled on the fifth postoperative day, with the objective of verifying the surgical incision, local hygiene, and presence of hematomas, dehiscence, or seromas.

After 15 days, abdominal ultrasound was prescribed to evaluate presence of seroma. Compression garments were used for at least 6 weeks after surgery. Patients were instructed to avoid strenuous activity for 8 weeks postoperatively.

Results

The results included comparison between the two groups in their preoperative data, intraoperative steps, and postoperative follow-up.

Group A included 16 (89%) women and two (11%) men, whereas group B included 20 (100%) women. Mean age of groups A and B was 35.2±9.07 and 35.5±9.57 years, respectively, and there was no significant difference statistically between the two studied groups.

The mean±SD BMI of group A patients was 33.81 ±4.3, ranging from 23.66 minimally to 37.46 maximally. However, mean±SD BMI of group B patients was 34.47±5.47, ranging from 24.68 to 40.

There was no statistically significant difference in both groups regarding operative time and total resection weight. The average operative time in hours in group A was 2:27 h ranging from 2:00 to 3:00 h, whereas that of group B patients was 2:09 h, ranging

from 1:30 to 3:00 h. The average total resection weight in group A was 2390 g, ranging from 800 to 3500 g, whereas that of group B was 3220 g, ranging from 1500 to 4500 g, with statistically significant difference between the groups (P=0.002) (Table 1).

In group A, the mean total drain output was 171.5 ± 72.18 ml, which was much lesser than group B, where it was 702 ± 136.7 ml. Moreover, drains in group A were removed earlier on the third day (range: 2–4 days), whereas in group B were removed on the sixth day (range: 3–12 days). There is a significant statistical difference between the two studied groups regarding the total drain output and time of drain removal (*P*=0.001 and 0.002, respectively) (Table 2).

Seroma formation was evaluated postoperatively either clinically or via abdominal ultrasound. In group A, all patients passed without seroma formation. However, in group B, seroma was detected in three (15%) patients. Other complications were recorded in eight (21%) patients among the 38 patients included in this study. In group A, minor wound dehiscence occurred in two (11%) patients and asymmetry in two (11%) other patients. In group B, two (10%) patients presented postoperatively with minor wound dehiscence, two (10%) patients developed wound infection, whereas three (15%) patients developed seroma formation.

Discussion

Postoperative seroma formation remains the most frequent complication following an abdominoplasty procedure. A number of investigators have reviewed

 Table 1 Comparison between both groups regarding patients' characteristics and operative parameters

Patient characteristics	Group A (mean±SD)	Group B (mean±SD)	<i>t</i> -Test	P-value
Age (years)	35.20±9.07	35.50±9.57		0.944
BMI	33.81±4.28	34.47±+5.47	0.092	0.765
Operative time (min)	147±22	129±25	2.945	0.103
Resection weight (g)	2390±834.5	3220±1123.2	3.518	0.002*

*Statistically significant.

Table 2 Comparison between both groups regarding drain output, its removal and seroma formation

	Group A	Group B	t-Test	P-value
Total drain output (ml)				
Range	70–260	180–1600	14.649	0.001*
Mean±SD	171.5±72.18	702±136.7		
Drain removal (days)				
Range	2–4	3–12	13.750	0.002*
Mean±SD	2.90±0.73	6±2.53		
Seroma formation				
Yes	0	3 (15)	1.546 (χ^2)	0.102
No	100	17 (85)		

*Statistically significant.

the frequency of postoperative seromas over the past 30 years, reporting incidences between 5 and 50% [7].

Multiple surgical strategies have been described to lower the incidence of seroma formation, such as internal fixation techniques, and avoidance of electrocautery, progressive tension sutures, use of pressure dressings, and use of fibrin glue. Seroma alone is still reported with frequencies as high as 30% [1].

In the unresected abdomen, the supraumbilical flap drains its lymphatic superiorly in the axilla and the infraumbilical flap drains into the inguinal region. After flap resection, the only remaining tissue is the supraumbilical flap, which still drains in the axilla. At this point, the lymphatic vessels of the subscarpal fat are disconnected from the tissues they originally drained, the infraumbilical resected flap, and thus are not likely to contribute to the drainage of the resected tissues. It is possible that these potentially intact subscarpal lymphatic would simply pick up any free fluid produced in the wound, thus reducing the risk of seroma [8].

According to our results, there is mild decrease of the mean operative time in classic abdominoplasty (group B) compared with suprascarpal plane of dissection (group A), as technically it is the easiest plane to find and to be dissected. Moreover, patients of classic abdominoplasty have significantly higher mean duration till drain removal of \sim 6 days as compared with suprascarpal group of \sim 3 days.

Costa-Ferreira *et al.* [1] performed 208 abdominoplasty, including 65 patients who underwent abdominoplasty with preservation of Scarpa's fascia in infraumbilical region. There was no statistically significant difference between groups with respect to BMI, previous abdominal operations, or comorbid medical conditions. The group with preservation of the Scarpa fascia had an average reduction of the total amount of drain output of more than 50%. This group also had an average reduction of 2.0 days until the time to drain removal and average of 1.9 days of the hospital stay.

In our work, we found group B with preservation of scarpus fascia had reduction of total amount in drain of \sim 50% and reduction of time of drain removal of \sim 2 days.

Fang *et al.* [9] have reviewed consecutive abdominoplasties with 99 procedures performed using a standard suprafascial dissection (group I) and 103 procedures using a modified plane of flap elevation that preserves the thin areolar tissue along the abdominal wall (group II). Patient characteristics did not differ significantly, with the mean age and BMI being almost similar. Perioperative complications included seven seromas in group I and two seromas in group II. The drains for patients in group II met the criteria for removal 3 days earlier than those for group I. On average, patients in group II had drains removed at postoperative days 4–5.

Koller and Hintringer [10] performed a study that enrolled 50 patients who underwent a full abdominoplasty with umbilicus transposition. The patients were alternated to the Scarpa group or the rectus group. In the rectus group, the average drain output collected until removal was 157 ml in the rectus group and 93 ml in the Scarpa group. Drains were removed between postoperative days 2 and 5. Symptomatic seroma formation took place in four patients in the rectus group, with no reported case of seroma in the Scarpa group.

In our work, we found that patients with low BMI are better candidate for the preservation of Scarpa's fascia during abdominoplasty. Scarpa fascia preservation on the infraumbilical area better respects the physiology of the abdominal wall, as it also implies the preservation of the deep fatty layer along with its connective tissue, lymphatic vessels, arteries, and veins [11].

Preservation of the Scarpa fascia in the infraumbilical region leads to apposition of fat to fat when the flap is approximated in position and that this decreases seroma; rapid reconstruction of the lymphatic vessels results in rapid reconstruction of the lymphatic drainage than in traditional abdominoplasty where the superficial lymphatic vessels are cut completely. Moreover, it can be conjectured that a fat-to-fat interface leads to less shear movement and/or more 'stickiness' between the opposing surfaces [3].

Conclusion

Preservation of Scarpa fascia during abdominoplasty has a beneficial effect on patient recovery, reducing total drain output, time to drain removal and hospital stay.

Financial support and sponsorship $\ensuremath{\operatorname{Nil}}$.

Conflicts of interest

There are no conflicts of interest.

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Volumetric pouch study after laparoscopic sleeve gastrectomy Ahmed A. Sabry^a, Doaa Emara^b

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Background

Laparoscopic sleeve gastrectomy (LSG) is frequently performed as a definitive bariatric procedure today. The aim of this study is to evaluate the volumetric changes of gastric reservoir 1 year after LSG using multislice spiral computed tomography (MSCT) and to analyze their relationship with weight loss.

Patients and methods

This is a prospective study of 50 morbidly obese patients submitted to LSG in the Upper Gastrointestinal Surgery Unit, Alexandria Main University Hospital. All patients were referred for abdominal MSCT with volumetric assessment of gastric pouch 1 month and 1 year after surgery.

Results

A significant increase in total gastric reservoir volume $(111.90\pm41.56 \text{ and } 144.14\pm42.87 \text{ ml} \text{ at } 1 \text{ and } 12 \text{ months}$, respectively) was observed. The percentage of excess weight loss was not significantly correlated with reservoir volume after 1 year of LSG.

Conclusion

MSCT allows for a comprehensive and quantitative evaluation of the gastric pouch volume. Gastric dilatation seems to be a normal behavior after LSG, yet it is not correlated with insufficient weight loss or weight regain after 1 year of LSG. A long-term follow-up is mandatory to confirm this conclusion.

Keywords:

bariatric surgery, gastric reservoir, multislice computed tomography, sleeve gastrectomy, volumetric assessment

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Introduction

Laparoscopic sleeve gastrectomy (LSG) was introduced for the management of obese patients as a first step before other techniques such as gastric bypass and duodenal switch. Yet in the last years after satisfactory results of LSG in weight reduction, it has been used as a single surgical technique for obese patients [1,2].

LSG is usually classified as a restrictive procedure, yet several hormonal changes have been described to account for the results of LSG. The gastric pouch volume is not the only key to success and so there is no specific volume that has been decided for the gastric reservoir; however, the suggested volumes range from 50 to 120 ml [1].

During the routine follow-up after LSG, usually there is dilatation of the gastric pouch; however, it is unclear whether there is a physiological process or a cause of weight regain and insufficient weight loss [3].

Radiology nowadays plays an important patients after LSG, either to measure the volume of gastric reservoir, and correlate it with the clinical outcome, or to diagnose the presence of complications [1,3,4].

Aim

The aim of this work was to study the relation between the gastric pouch volume after sleeve gastrectomy and weight loss using MDCT volumetry study.

Patients and methods Patients

The study was carried out on 50 patients with morbid obesity admitted to the Upper Gastrointestinal Surgery Unit, Alexandria Main University Hospital. The inclusion criteria were: age ranging from 18 to 60 years, BMI of more than 40 or 35 kg/m² with comorbidities, obesity for more than 5 years, failure of supervised conservative management for obesity for at least 2 years, and willingness for prolonged follow-up with the surgeon and the nutritionist. The exclusion criteria were: BMI of more than 60 kg/m², endocrinal disorders, active peptic ulcer disease, general contraindication for laparoscopy, active alcohol abuse, major psychiatric disorders, and mental retardation.

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Methods

Surgical technique

After establishing a capnoperitoneum, dissection began on the greater curvature ~ 5 cm from the pylorus. The greater curvature of the stomach was separated from the omentum and dissection continued until the left crus of the diaphragm was well visualized. A 36-Fr gastric tube was subsequently advanced into the stomach. Starting 5–6 cm lateral from the pylorus, a series of linear staples was applied toward the left of the lesser curvature vessels until reaching the gastric tube and then up to the angle of His. The resected stomach specimen was removed, and possible leakage was excluded by methylene blue testing.

All patients were scheduled for follow-up at 3, 6 months, and 1-year postoperatively. It included: weight loss data, laboratory investigations, amelioration of comorbidities, long-term complications, quality of life, and gastric volumetry using MDCT at 1 and 12 months after surgery.

Computed tomography technique

The patient was instructed to drink negative oral contrast immediately before scanning in order to distend the gastric pouch, directly afterward the patient laid down on the scanner table in the supine position. All examinations were performed on multislice spiral computed tomography (MSCT) scanners (64 slices) with dedicated workstation for postprocessing volumetric assessment of the gastric pouch. All acquisitions were performed during breath-hold. No intravenous contrast agent was administered.

Postprocessing volumetric study and image analysis

Thin-sliced images were reconstructed with a slice thickness of 1 mm with a soft tissue convolution kernel and were transferred to a dedicated workstation. Volumerendering images were generated, and the total stomach volume was automatically calculated by the software. Furthermore, two curved planar reformats were manually generated with the image axis following the centerline of the stomach itself and the course of the staple lines.

Results

This was a prospective study which included 50 patients, 42 (84.0%) women and eight (16.0%) men. Their age ranged from 20 to 45 years with a mean age of 33.50±7.43 years (Table 1).

Preoperative anthropometric measures

Preoperative anthropometric measures are summarized in Table 2. Preoperative weight ranged from 110 to 175 kg with a mean of 134.40 \pm 18.27 kg. Height ranged from 150 to 175 cm with a mean of 162.65 \pm 6.47 cm. Preoperative BMI ranged from 42.20 to 57.0 kg/m² with a mean of 49.89 \pm 5.08 kg/m².

Early postoperative morbidity

Early (<30 days) postoperative surgical complications are summarized in Table 3. It was divided into major and minor complications. The major complications include leakage, wound dehiscence, incisional hernia, and deep vein thrombosis (DVT). No major complications happened in the studied patients.

Minor complications include wound infection and persistent vomiting. Two patients had trocar site infection which was treated by antibiotics and dressing. One patient suffered from persistent vomiting after resuming soft diet. The patient stopped soft diet, returned to fluids for a while, and treated by proton-pump inhibitors and prokinetic drugs until vomiting stopped.

Mortality rate

There was no mortality in the studied patients.

Follow-up

The patients were scheduled for follow-up at 3, 6 months, and 1 year postoperatively. This was done for all patients through regular visits at the outpatient clinic.

Table 1 Demographic profile of patients

Sex	n (%)
Female	42 (84.0)
Male	8 (16.0)
Age (years)	
<30	13 (26.0)
30 to <40	27 (54.0)
40	10 (20.0)
Minimum-maximum	20.0-45.0
Mean±SD	33.50±7.43
Median	33.50

Table 2	Preoperative	anthropometric	measures
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	Minimum-maximum	Mean±SD	Median
Weight (kg)	110.0-175.0	134.40±18.27	131.0
Height (cm)	150.0–175.0	162.65±6.47	162.50
BMI (kg/m ²)	42.20-57.0	49.89±5.08	50.0

Table 3 Early postoperative complications

Early complications	n (%)
Major	0 (0.0)
Minor	3 (6.0)
Persistent vomiting	1 (2.0)
Trocar site infection	2 (4.0)

Table 4 Preoperative and postoperative patients' weight

Weight (kg)	Preoperative	3 months postoperatively	6 months postoperatively	1 year postoperatively	F	Р
Minimum-maximum	110.0–175.0	96.20-152.70	82.50-126.80	70.70-104.60		
Mean±SD	134.40±18.27	115.63±15.59	98.60±12.04	83.95±9.19	1297.166*	< 0.001*
Median	131.0	114.75	98.45	83.70		
<i>P</i> ₁		>0.001*	>0.001*	>0.001*		

F: *F* test (analysis of variance) with repeated measures. P_1 : *P* value for adjusted Bonferroni for comparing between pre and each other period. **P*=0.05, statistically significant.

Table 5 Percentage of excess weight loss in the follow-up period

Percentage of excess weight loss	3 months	6 months	1 year	F	Р
Minimum-maximum	20.0-30.50	40.0–55.0	54.80-73.60	754.898*	<0.001*
Mean±SD	24.79±3.16	47.0±4.90	66.14±5.64		
Median	24.85	46.20	67.50		
<i>P</i> ₁		<0.001*	<0.001*		

F: *F* test (analysis of variance) with repeated measures. P_1 : *P* value for adjusted Bonferroni for comparing between pre and each other period. **P*=0.05, statistically significant.

Table 6 Long-term complications

Long-term complications	n (%)
Gastroesophageal reflux disease	1 (2.0)
Peripheral neuropathy	1 (2.0)

Weight loss data

Table 4 summarizes the patients' weight throughout the follow-up period. Starting from 3 months postoperatively, there was a statistically significant decrease of weight than initial weight and this significance increased with time during the followup period (P=0.05).

Table 5 summarizes the patients' percentage of excess weight loss (PEWL) throughout the follow-up period. The mean PEWL after 3 months was 24.79±3.16%, at 6 months it was 47.0±4.90%, and finally at 1 year it was 66.14±5.64.

Long-term complications

Symptoms of gastroesophageal reflux disease occurred in one patient. The patient was treated by protonpump inhibitors until the end of the follow-up period (Table 6).

One patient developed peripheral neuropathy due to folic acid and vitamin B_{12} deficiency. The patient was treated by vitamin B_{12} injection.

Gastric computed tomography volumetry

All patients were referred for abdominal MSCT with volumetric assessment of gastric pouch within 1 month of surgery and 1 year postoperatively. Gastric volume within 1 month of surgery ranged from 60.0 to 210.0 ml with a mean of 110.6±40.52 ml, while the gastric volume 1 year postoperatively ranged from 91.0 to 250.0 ml with a mean of 142.1±39.63 ml. There was

Table 7 Comparison between gastric reservoir volume at 1 and 12 months after laparoscopic sleeve gastrectomy

Gastric volume (ml)	After 1 month (<i>n</i> =50)	After 12 months (<i>n</i> =50)	t	Р
Minimum-maximum Mean±SD	60.0–211.0 110.6 ±40.52	91.0–250.0 142.1 ±39.63	17.051*	<0.001*
Median	103.50	136.0		
Percentage of change	32.64			

P: *P* value for paired *t*-test for comparing between early and late gastric volume. *P=0.05, statistically significant.

a statistically significant increase of gastric volume after 1 year (P=0.05) (Table 7 and Figs 1 and 2).

There was a nonstatistically significant weak negative correlation (r=-0.267, P=0.255) between PEWL and increase of gastric reservoir volume after 1 year of surgery (Table 8).

Discussion

It is essential to measure the gastric pouch volume and correlate it with our aim which is weight reduction. Recently, newly developed imaging techniques have been used to assess the volume of gastric pouch; MDCT with postprocessing volumetry study is considered an accurate method to measure the gastric pouch volume [4–6].

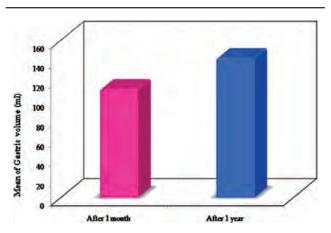
In our study, there was a statistically significant increase of gastric volume after 1 year of surgery which is consistent with other studies [3,7].

Braghetto *et al.* [3] reported a significant increase in residual gastric capacity after 2 years of surgery. They found that the early (3 days) postoperative gastric

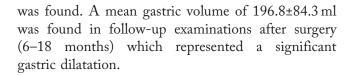
volume was 116.2±78.24 ml assessed with MSCT and it was increased to 254±56.8 ml after 2 years of surgery.

Baumann et al. [7] also observed a significant correlation between time after surgery and gastric volume with results similar to our study. In their study, MSCT was conducted early after surgery (1-2 months) and a mean gastric volume of 105.3±30.2 ml





Comparison between gastric reservoir volume at 1 and 12 months after laparoscopic sleeve gastrectomy (Alexandria, Egypt). Copyright Alexandria, Egypt. All permission requests for this image should be made to the copyright holder.



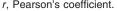
Several factors affect the gastric pouch volume such as the bougie size used during surgery, eating habits of the patient, the distance from the pylorus to the LSG suture line, and complete fundus resection [1].

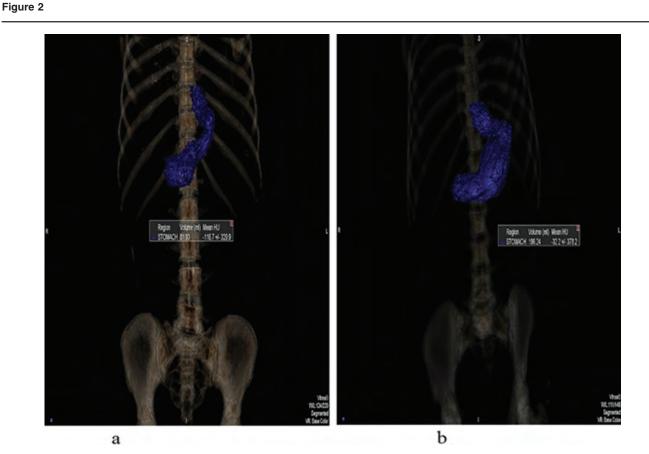
In the current study, we found that there is a nonstatistically significant weak negative correlation (r=-0.267, P=0.255) between the EWL and the increase of gastric reservoir volume after 1 year of surgery.

Braghetto et al. [3] reported that the increase in residual gastric volume after 2 years of LSG assessed with MSCT did not mean regain of weight until the end of their study.

Table 8 Correlation between percentage of excess weight loss and gastric volume after 1 year percentage of excess weight loss after 1 year

	r	Р
Gastric volume after 1 year	-0.267	0.255
r Deersen's coefficient		





Three-dimensional multislice computed tomography image of gastric reservoir: (a) 1 month after laparoscopic sleeve gastrectomy (volume=81.9 ml) and (b) 1 year after laparoscopic sleeve gastrectomy (volume=196.2 ml).

Baumann *et al.* [7] concluded that gastric dilatation appears to be a normal finding after LSG and with no correlation with inadequate weight loss or weight regain. They found that PEWL 12 months after surgery showed no significant correlation with gastric volume measured by MSCT. However, if the initial size of the sleeve was already large at the operative time, mild weight regain has been found after 3 years of follow-up. We should consider that data from longer follow-up are necessary before a correlation between secondary dilatation of the pouch and weight regain can be excluded.

On the other hand, Vidal *et al.* [1] found that there was a 50% increase in gastric reservoir volume 1 year after LSG and a direct relationship between the increase in gastric sleeve volume and a lower weight loss 1 year postoperatively. However, they used a new radiological volumetric method to measure the residual gastric pouch volume. Gastric pouch volume was measured based on a simple defragmentation of the radiological image (obtained after an upper gastrointestinal series) into two well-known geometrical shapes: a cylinder (gastric body) and a truncated cone (antrum). Adding these two partial volumes, the total gastric sleeve volume can be measured. Therefore, we cannot compare our results with this publication.

Weight loss after LSG is not only determined by residual gastric volume, but also other factors are involved, such as postoperative neurohormonal mechanisms associated with ghrelin, PYY, GLP-1, and rapid gastric emptying [1].

Conclusion

LSG has proven more early weight loss during the first 2 years regardless of the sleeve volume, but it was

associated with a weight gain after several years depending on the initial gastric pouch volume and postoperative neurohormonal mechanisms. The diameter of the residual gastric sleeve is important for later dilatation; a sleeve with a wide diameter will dilate earlier than a tighter one. Gastric dilatation seems to be the normal behavior after LSG.

Gastric dilatation was not correlated with insufficient weight loss or weight regain after 1 year after LSG. A long-term follow-up is mandatory to confirm this conclusion.

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Conflicts of interest

There are no conflicts of interest.

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