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The official organ of the Egyptian Society of Surgeons

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A comparative study of the incidence of postoperative meralgia paraesthetica after open inguinal hernioplasty and after laparoscopic transabdominal preperitoneal approach repair for recurrent inguinal hernia

Basem Sieda, Mohamed Riad, Tamer Alnaimy

Department of General Surgery, Zagazig University Hospitals, Zagazig University, Zagazig, Egypt

Correspondence to Mohamed M. Riad, MD, Department of General Surgery, Zagazig University Hospitals, Zagazig University, Zagazig, Sharkia, Egypt
e-mail: mohamed_riad_dr2006@yahoo.com

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Objective
The aim of this prospective study was to compare the postoperative incidence and the intensity of pain and meralgia paraesthesia in both the laparoscopic transabdominal preperitoneal approach (TAPP) and the open approach for patients with recurrent inguinal hernia.

Patients and methods
A total of 80 patients with recurrent inguinal hernia were selected and operated in the same surgical unit from December 2011 to January 2014. About 40 patients were operated by TAPP and 40 patients with the open surgical technique. We compared the two techniques in terms of the postoperative pain and paraesthesia using the quality of life and the time to return to normal activity. We evaluated postoperative paraesthesia and pain using the visual analog scale.

Results
Our results revealed the superiority of the laparoscopic approach over the open technique in generality, with less incidence of pain and paraesthesia. During the early postoperative period, pain had been abolished completely on the sixth to the seventh day in 37 patients in the laparoscopic (LAP) group, whereas in the open approach (OPEN), it was achieved in only 25 patients. During the late postoperative period, only three patients in the LAP group continued to complain after the first week, whereas in OPEN group, 15 patients continued to complain of pain. In the OPEN group, there were five patients with severe paraesthesia persisting for more than 6 months, whereas in the LAP group, all patients improved before the sixth month.

Conclusion
Postoperative pain and paraesthesia are an important issue in inguinal hernia surgery; hence, long-term follow-up is important. The best approach for recurrent inguinal hernia repair with the least postoperative pain and paraesthesia are the TAPP, with superiority over the open approach.

Keywords:
laparoscopic inguinal hernia, posthernioplasty groin pain, recurrent inguinal hernia

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Introduction

Recurrent inguinal hernia accounted for 10% of hernia repair, in general [1]. The most popular approaches for inguinal hernia repair are the Lichtenstein tension-free repair and it is still popular as a standard for recurrent cases [2]. The laparoscopic approach [transabdominal preperitoneal approach (TAPP)] is described as an ideal approach for recurrent inguinal hernia as the key to repair by the TAPP technique is the familiarity with the intra-abdominal view [3]. Anatomical entities of the inguinal region in the transabdominal approach are approached and hernia repair performed from the interior instead of the classical open external access, thus avoiding postoperative adhesions [4].

Chronic pain is a recognized complication after inguinal hernia repair, but it should subside within an expected time interval of about 2–3 months. For many patients, some degree of pain persists, and some patients develop moderate to severe-intensity pain that can be disabling or may interfere with sexual function [5]. A presumptive diagnosis of postherniorrhaphy neuralgia can be made when the pain persists for more than 3 months after hernia repair and is not related to other causes; the incidence of nerve injury is more common in recurrent cases than in primary cases due to the disturbed anatomy, and the incidence of injury is increasing in recurrent cases compared with primary inguinal hernia due to the disturbed anatomy that makes its injury in open approach more remarkable than laparoscopic approach [6].

The lateral femoral cutaneous nerve (LCNT) originates from L2 and L3 and emerges from the lateral margin of the psoas muscle and crosses the iliacus muscle obliquely towards the anterior superior iliac spine. Medial to the latter, it passes below the iliopubic tract to reach the thigh. The innervated area extends from the

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greater trochanter to the midcalf level. It is extremely vulnerable to injury during mesh fixation at the level of the iliopubic tract. The nerve is frequently injured by the malposition of the staples posterolaterally in the region of the anterior superior iliac spine. Injury leads to meralgia parasthetica and a burning sensation in the lateral area of the thigh [7].

Meralgia paraesthetica (Bernhardt-Roth syndrome) is an Australian spelling and is defined as a benign disturbance of a sensory nature localized to the outer thigh, which at best is annoying, but which may become severely painful and occasionally disabling [8]. It occurs in both men and women, usually of middle age. The disturbance involves the LCNT of the thigh, which is formed immediately before it passes through the tunnel in the inguinal fascia adjacent to the anterior superior spine. It is at this point that angulations may occur, giving rise to symptoms [9]. Meralgia is a mononeuropathy and pain may be acute and radiate into the groin, the thigh, or the knee and may be a chronic neurological disorder also known as lateral femoral cutaneous neuralgia. Meralgia or entrapment of LCNT is a recognized and known complication of laparoscopic hernia repair either due to direct injury or due to entrapment by patient strapping during the procedure, and this is known as position-related meralgia [10].

Patients and methods

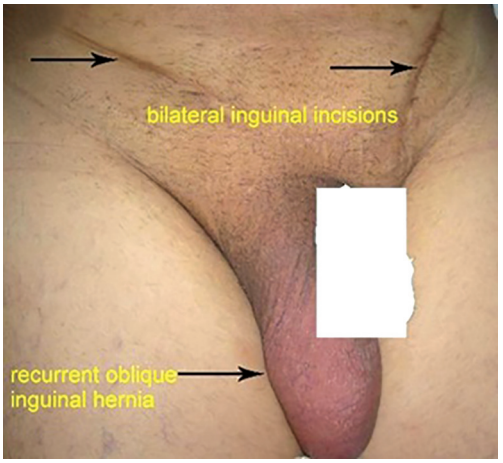
Preoperative assessment

Preoperatively, we obtained the patients' signed consent permitting conversion to open repair if necessary. Patients were informed about the postoperative period. All patients gave their formal consent. The protocol was approved the Ethical committee.

Inclusion criteria included patients with recurrent inguinal hernia (Fig. 1) irrespective of the number of recurrences.

Exclusion criteria were irreducible and incarcerated hernia, diabetes mellitus patients with known peripheral neuritis, all patients with a history of pain and paraesthesia after the previous hernia repair, and patients with any signs of intra-abdominal infection and peritonitis, pregnancy, and organomegaly. The exclusion criteria in general were cardiorespiratory embarrassment, hepatic patients with ascitis, cardiac patients, chronic obstructive pulmonary disease, coagulopathy, obesity with BMI more than 35 and if associated with another sever chronic illness, failure to tolerate general anesthesia, and patient's refusal.

Figure 1



Bilateral recurrent inguinal hernia.

The technique

For both approaches, the patients are strapped to the operating table, especially toward the midthigh, but using an excessive amount of sponge in the strap to avoid compression injury to the lateral cutaneous nerve to avoid postoperative confusion between compression or position-related injury and direct injury during operation.

For the laparoscopic approach

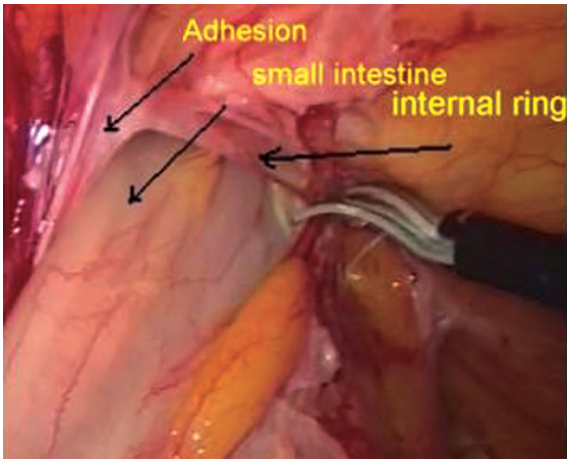
General anesthesia was given, the abdomen was draped and prepared in the ordinary manner, a urinary catheter was always applied and fixed, 0.3 ports were inserted, and the first trocar or the optical trocar was inserted in the umbilicus. The peritoneal cavity was then filled with CO_2 to a maximum pressure of 14 mmHg; the insufflations needle was removed and a 10 mm trocar and a 30° telescope were inserted. The second port was inserted to the right of the rectus sheath (midclavicular) for the surgeon or the assistant. The third port was inserted to the left of the rectus sheath (midclavicular) at the umbilical region. The two operating trocars are 5 mm. The umbilical folds were identified, the defect was seen, visualization of the internal ring was carried out (Fig. 2), and adhesions were lysed (Fig. 3). Then, the sac was mobilized and reduced into the peritoneal cavity. The dissection was started from the internal ring by lifting up a flap of peritoneum, starting by the incision of the peritoneum at or well above the internal inguinal ring by a scissor, medially as far as the median umbilical ligament and laterally toward the anterior superior iliac supine by about 2 or 3 cm from the internal ring to avoid nerve entrapment (Fig. 4). The peritoneal flaps were dissected upward and downward, making the upper flap and the lower flap with sharp and blunt dissection. The cord was dissected. The dissection was continued in the avascular preperitoneal space (Bogros

space) by pushing the peritoneum with its surrounding preperitoneal fibrofatty tissue away from the fascia transversalis and the rectus muscle. The dissection continued to the middle of the symphysis as far as the median umbilical ligament (Fig. 5), creating a large enough space for wrinkle-free placement of the mesh. In the inferior direction, the medial compartment was dissected as far as the triangle of Doom, avoiding the iliac vessels in the floor of the triangle (Figs. 6–8). A large 15 cm × 10 cm mesh (Fig. 9) was inserted and placed sufficiently to overlap all the hernial orifices by at least 3 cm and covered the triangle of Doom. The endotacker (5 mm and 30 staples; Covidien, Tyco Healthcare, Middletown Ave., USA) was prepared and inserted through the 5-mm port. Fixation was carried out by the protack, which fired circular staples (Fig. 10) that have the advantage of reposition; staples were not placed below the level of the iliopubic tract to avoid neuralgia involving the lateral cutaneous nerve of the thigh or the femoral branch of the genitofemoral nerve and they were not placed in the area of the triangle of Doom. After the completion of mesh fixation, the peritoneal flap was closed carefully over the mesh, avoiding buttonholes within the peritoneum that might allow adhesions or herniation of the bowel; this was achieved by stapling and suturing (Fig. 11).

For the open conventional approach

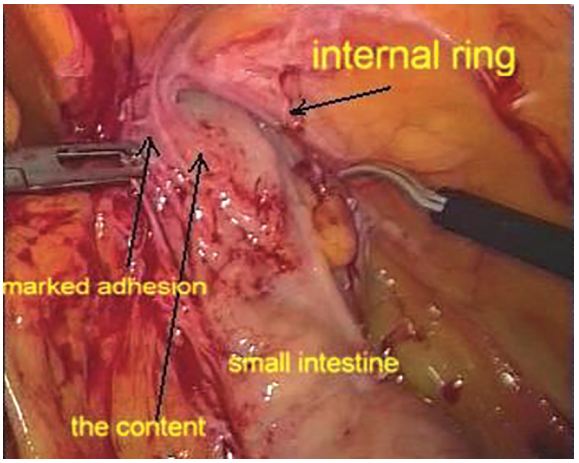
The abdomen was draped and prepped in the ordinary manner, inguinal incision was performed involving the old scar and the plane of the external oblique appeneurosis, and the external ring was identified; the external ring was marked with a silk suture due to adhesions, the sheath was opened, adhesiolysis was performed using sharp and blunt dissection, the cord structure was identified, the sac was identified, skelotinization of the sac was performed, the neck of the sac was identified by the extraperitoneal fat and

Figure 2



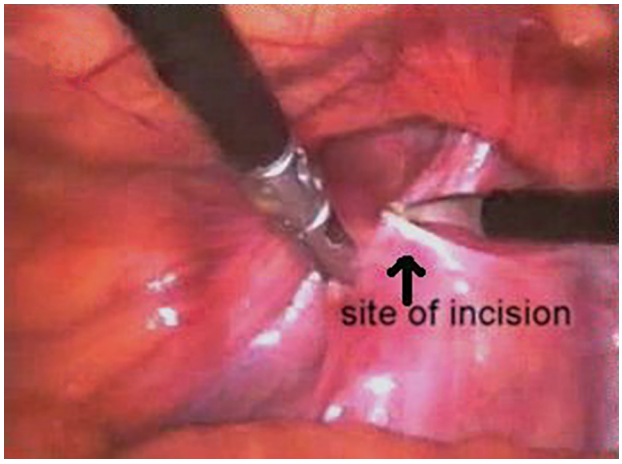
The internal ring: the anatomical landmark.

Figure 3



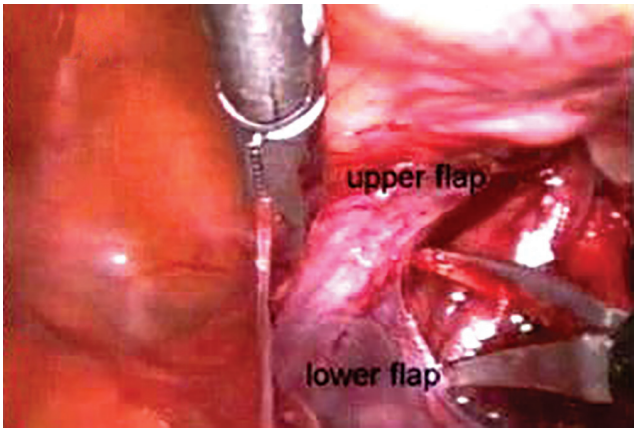
Adhesions from previous hernia repair.

Figure 4



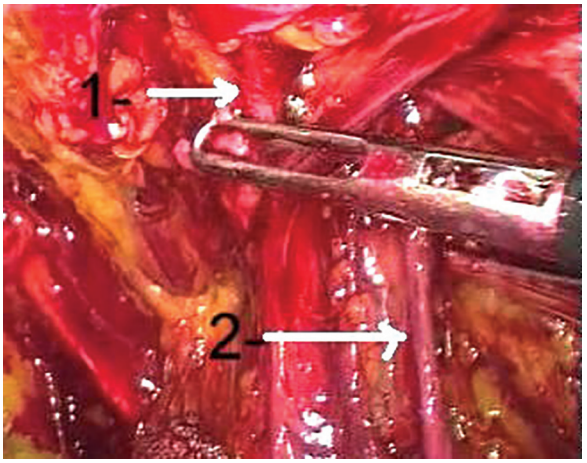
The site of incision to create flaps.

Figure 5



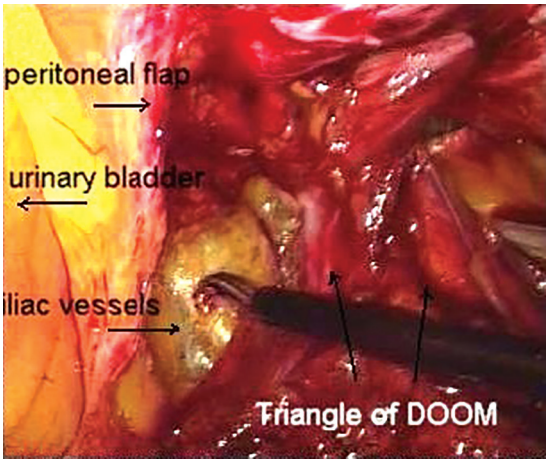
Medial dissection and flaps.

Figure 6



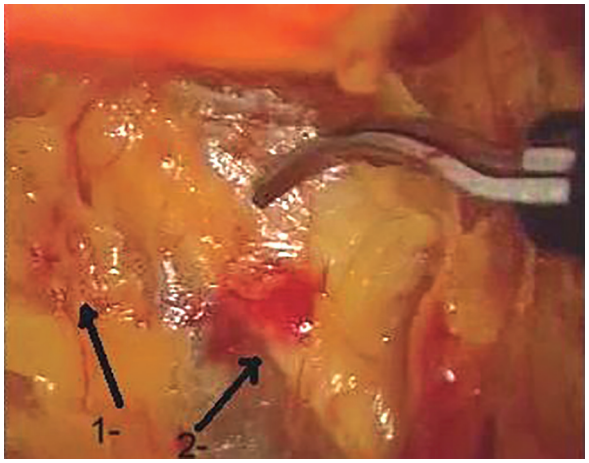
(a) Inferior epigastric and (b) spermatic vessels.

Figure 7



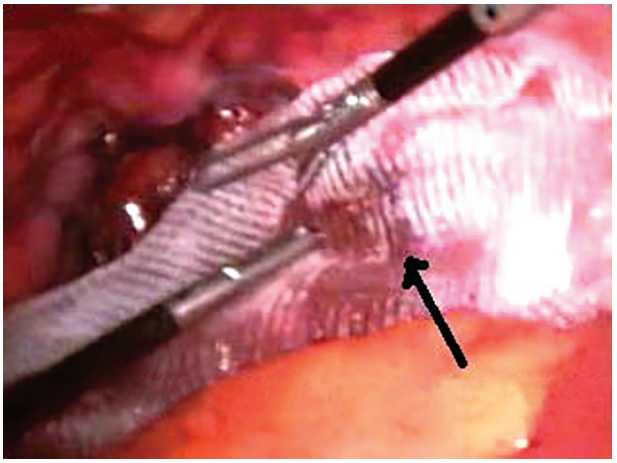
The triangle of Doom and its content.

Figure 8



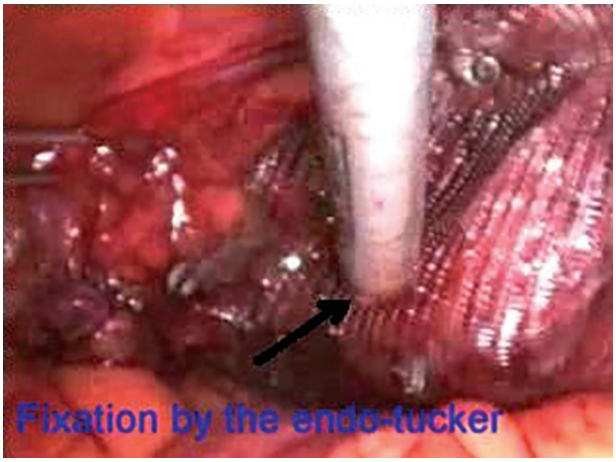
(a) Fibrofatty tissues and (b) External iliac vessels

Figure 9



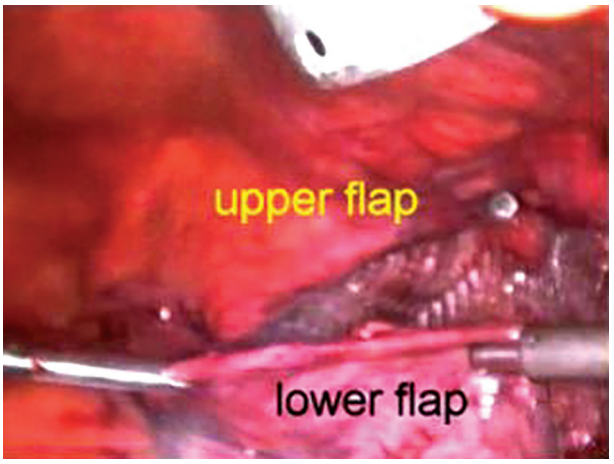
Preparing the mesh for fixation.

Figure 10



Mesh fixation with a tacker.

Figure 11



Closure of flaps.

the inferior epigastric artery, the sac was opened, and then, the content was reduced, and transfixion with a polygalactin suture was performed. In cases with a wide internal ring, narrowing of the ring was performed.

In patients with direct hernia, the sac was identified, dissected, and inverted by a series of sutures.

The polypropylene mesh is fashioned to include the cord, its size ~16 × 8 cm (tailored to the individual patient's requirements). The mesh lies anterior to the posterior wall, overlapping it generously in all directions, including medially over the pubic tubercle, where the mesh was fixed to the periosteum. The mesh was anchored by a tacker using four to five staples, taking care to avoid tacking near the ASIS to preserve the LCNT. The external opening was sutured directly, leaving a new external ring to accommodate the tip of a finger, and lastly, closure was performed without a drain.

Data collection, parameters measured, and follow-up

Standardized data collection was performed on a prospective database; the data were collected by the attending resident and our surgeon team, and each patient was evaluated at the hospital outpatient clinic monthly by a physician.

Before discharge and before giving the patient the sick leave, the patients were requested to return to the outpatient clinic at 1, 4 weeks, 3, and 6 months, and at 1 year for a standardized history taking and physical examination by a resident and, in most cases, by the surgeon team that had performed the surgery.

Information about early postoperative pain and paraesthesia was collected and documented on the day of operation and at the first postoperative visit (at 1 week) using the visual analog scale.

Patients were asked to assess the intensity of pain severity at the site of operation and at the thigh every day for the first week with the help of a 100 mm visual analog scale (scores ranged from 0, for no pain, to 100, for unbearable pain). Oral analgesia, initially ketoprofen, or other NSAIDs were given on request. Chronic pain was defined as pain in the groin, the scrotum, or the medial part of the thigh that was serious enough for the patient to mention at 6 months.

The length of hospitalization, defined as the number of days in the hospital after the day of surgery, was also recorded. Patients were discharged from the hospital if there was no serious infection or bleeding, the patient was able to walk, and only oral analgesic therapy was required to manage pain.

Statistical analysis

Categorical qualitative variables were expressed as absolute frequencies (n) and relative frequencies (%). The percent of categorical variables was compared using the Pearson χ^2-test; also, the trend of change in the distribution of absolute frequencies between ordinal data was compared using the χ^2-test for trend. All tests were two sided; *P* value less than 0.05 was considered significant. All statistics were performed using SPSS, 22.0 for windows (SPSS Inc., Chicago, Illinois, USA) and MedCalc, 13 for windows (MedCalc Software bvba, Ostend, Belgium).

Results

This study included 80 patients with recurrent inguinal hernias, referred to the Department of General Surgery in Zagazig University Hospitals from December 2011 to January 2014 and an extra 1 year of follow-up ended in January 2015.

All the patients were male, with recurrent inguinal hernia: 40 patients were operated by the laparoscopic TAPP and 40 patients with the open approach.

The age of the patients ranged from 25 to 51 years, with a mean age of 33.4 years in the LAP group and a mean age of 35.6 years in the OPEN group. Regarding the type and the size of the hernia, in 80% of the cases in our study, the hernia was not large, and we recorded seven patients (17.5%) with a huge right-sided recurrent inguinal hernia in the OPEN group and no patients with huge hernia in the LAP group. About 80% of the cases had complete (scrotal) hernia in both groups.

In the LAP group, the hernia was bilateral in six patients (15%), and 34 patients (85%) had a unilateral hernia.

Early postoperative pain and paraesthesia in the LAP group revealed that pain and paraesthesia were abolished completely on the sixth to the seventh day in 37 patients. In the LAP group, we recorded mild-intensity pain in most patients on the first (30 patient), the second (29 patients), the third (21 patients), the fourth (16 patients), the fifth (six patients), and on the sixth and the seventh day (three patients). Nine patients developed moderate-intensity pain on the first day, which decreased to one patient on the fourth day. Lastly, only one patient developed severe early postoperative pain up to the third day, which was then abolished completely. In the OPEN group, the results of postoperative pain and paraesthesia were different from that in the LAP group, as we recorded only 25 patients (Table 1).

Follow-up of patients in the outpatient clinic for late pain and parasthesia, revealed that in the LAP

group. After the first week, they described as two separate synonyms as pain persisted in two patients and paraesthesia in one patient, which improved around the third month postoperatively. Of the other two patients with pain, one improved after the first month and the other after the third month. In the OPEN group, 15 patients had persistent pain and paraesthesia after the first week; the nine patients with pain decreased to five patients at the sixth month, and the six patients with paraesthesia decreased to five patients at the sixth month. The five patients with pain continued to complain up to the end of the first year and continued follow-up in the pain clinic; of the five patients with paraesthesia in the OPEN group, only one patient improved spontaneously and the other four patients continued follow-up in the neurology clinic for medical treatment (Table 2).

There was a significant difference between both the studied groups with regard to the postoperative hospital stay, wherein most of the patients (90%) who underwent laparoscopic operation were discharged within 2 days of operation in comparison with 45% in the OPEN group (Table 3).

Discussion

Regarding the evaluation of postoperative pain and meralgia paraesthetica, in the early postoperative period, there was a significant difference between the two groups, in which the LAP group was associated with less early postoperative pain and paraesthesia. This was in accordance with studies of Simons et al. [11] and in contrast to the studies of Tantia et al. [12], who recorded no difference between the two groups, especially in the early postoperative period. In addition, the fact is that in the early postoperative period, both pain and paraesthesia if occurred were described by patients as pain only [13].

However, in the late postoperative period from the first month to the end of the first year, there was still a difference between the two groups in the form of less pain and less paraesthesia in the LAP group, as the number of complaining patients in the OPEN group was more than the number in the LAP group; this matched with other studies [14], especially when the author attributed the lower pain and paraesthesia to the advantage of using a light-weight mesh.

No patients in the LAP group had persistent paraesthesia for more than 6 months, but in the

Table 1: Analysis of early postoperative pain intensity

Day	Lap group				Open group				*P**
	Pain & parathesia				Pain & parathesia				
	No	Mild (%)	Moderate (%)	Severe (%)	No (%)	Mild (%)	Moderate (%)	Severe (%)	
1st day	0 (0)	30 (75)	9 (22.5)	1 (2.5)	0 (0)	36 (90)	2 (5)	2 (5)	0.174
2nd day	8 (20)	29 (72.5)	2 (5)	1 (2.5)	0 (0)	36 (90)	2 (5)	2 (5)	0.041
3rd day	16 (40)	21 (52.5)	2 (5)	1 (2.5)	2 (5)	34 (85)	2 (5)	2 (5)	0.005
4th day	23 (57.5)	16 (40)	1 (2.5)	0 (0)	4 (10)	34 (85)	1 (2.5)	2 (5)	<0.001
5th day	34 (85)	6 (15)	0 (0)	0 (0)	14 (35)	23 (57.5)	1 (2.5)	2 (5)	<0.001
6th & 7th day	37 (92.5)	3 (7.5)	0 (0)	0 (0)	25 (62.5)	13 (32.5)	1 (2.5)	1 (2.5)	0.002
P‡	<0.001				<0.001				

Values are a number (percentage); *Chi-square test for trend; ‡Chi-square test; $P < 0.05$ is significant

Table 2: Late Postoperative pain & meralgia parasthetica follow up

Time after operation	Pain			Meralgia parasthetica		
	Lap group (%)	Open group (%)	*P*‡	Lap group (%)	Open group (%)	*P*‡
After 1 week	2 (5)	9 (22.5)	0.023	1 (2.5)	6 (15)	0.048
After 1 month	1 (2.5)	7 (17.5)	0.025	1 (2.5)	6 (15)	0.048
After 3 month	1 (2.5)	6 (15)	0.048	1 (2.5)	6 (15)	0.048
After 6 month	0 (0)	5 (12.5)	0.021	0 (0)	5 (12.5)	0.021
After 1 year	0 (0)	5 (12.5)	0.021	0 (0)	4 (10)	0.040
P‡	0.467	0.720	—	0.730	0.953	—

Values are a number (percentage); ‡Chi-square test; $P < 0.05$ is significant

Table 3: Postoperative hospital stay

Hospital stay	Lap group (%)	Open group (%)	$P^{\ddagger}$
<2 days	36 (90)	18 (45)	<0.001
2–3 days	2 (5)	16 (40)	<0.001
>3 days	2 (5)	6 (15)	0.263

Values are a number (percentage); ‡Chi-square test; $P < 0.05$ is significant

other group, we recorded five patients with persistent pain and five patients with persistent paraesthesia around the sixth month; this was comparable to other studies, [15,16] but the number of patients was more than the patients included in the study, but the end result is that the OPEN group usually has a number of complaining patients that is significantly higher than the number in the LAP group.

The requirement for analgesia was less in the LAP group. NSAIDs were used and were enough to abolish pain in most of the LAP patients, who recorded a lower number of NSAID tablets than in the OPEN group, This was in accordance with many international multicentre studies [17,18].

We followed our patients for 1 year. With regard to the number of patients in our study and our results of follow-up, this period was enough for our study. Other authors considered it as not enough time to follow the patient, [19] but their study concerned mainly with the treatment of meralgia, and not the incidence.

The results of this study indicate that patients with inguinal hernias recover more rapidly and have fewer recurrences after laparoscopic repair than after open repair [20]. This is completely compatible with our results.

In our study, patients in the LAP group were discharged from the hospital earlier than the OPEN group. This result matched completely with results of the study by Kirshtein et al. [21], who used the TAPP approach for large recurrent and bilateral inguinal hernia, but a smaller number of patients were included in that study.

All the patients included in the study were strapped intraoperatively to the table near the midthigh using excessive sponge in the strap to avoid compression injury or position-related injury to the LCNT; this was comparable to other studies [22] as the maneuver used in many laparoscopic procedures for nerve preservation, but most procedures were for gynecological laparoscopy

Conclusion and recommendations

As postoperative pain and parasthesia are a recognized complication after inguinal hernioplasty in many patients, it is of utmost importance to follow all patients with operated inguinal hernia for a long period regardless of the technique used; a long follow-up is merely a major factor in detecting the incidence of postoperative meralgia parasthetica.

Meralgia parasthetica is a neurological disorder that can be severe enough to disable patient activity and even return to work, and so significant concern for these patients is very important in both selecting the best operation and the follow-up. Entrapment of LCNT can occur due to patient strapping or may be position related; hence, strapping should be performed using excessive sponge.

The TAPP approach is the ideal approach for the repair of recurrent inguinal hernia and the key to TAPP is the familiarity with the intra-abdominal view and away from previous adhesions, which can be dissected easily if present intraperitoneally.

The advantage of laparoscopic TAPP hernia repair for recurrent cases include less postoperative pain, a reduced recovery time, reduced use of analgesics by patients, fewer wound complications, less hematoma, easier operation in recurrent inguinal hernia, a lower incidence of chronic groin symptoms, and identification of additional hernia that might be missed at open surgery.

Acknowledgements

Conflicts of interest

There are no conflicts of interest.

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Evaluation of long superficial femoral artery stenting in a critically ischemic limb

Osama Ismail

Department of Vascular Surgery, Sohag University, Sohag, Egypt

Correspondence to Osama Ismail, Department Vascular Surgery, Sohag University, Sohag, Egypt
Tel: +201005452782;
e-mail: oelnahaas@yahoo.com

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Aim
The aim of the study was to evaluate 1-year efficacy and integrity of long stents implanted in the superficial femoral artery (SFA) in a critically ischemic limb.

Patients and methods
A prospective study was carried out between July 2012 and September 2014 on 25 patients (19 men and six women, mean age 58 years, range 52–65 years) suffering from critical limb ischemia (Rutherford classification 4 or 5) caused by a long SFA lesion who underwent stenting of the targeted segment at the 6th October Insurance Hospital (Dokki, Cairo, Egypt). Patients were scheduled to receive a single stent and were evaluated for 1 year. An overall 60% (15 patients) had occluded segments and 40% (10 patients) had multiple stenotic lesions. Thirteen (52%) patients had three-vessel distal run-off to the foot, seven (28%) patients had two-vessel, and five (20%) patients had single-vessel run-off. The mean lesion length was 13 cm (range 12–18 cm).

Results
Twenty-five stents were implanted in 25 patients. Technical success was achieved in all patients. Primary patency was achieved in 17 (68%) patients, whereas restenosis occurred in eight (32%) cases. Of these eight cases, four patients were treated with angioplasty, one patient was treated with a femoropopliteal bypass, two cases were treated medically, and the last patient developed extensive necrotizing fasciitis that ended in limb amputation.

Conclusion
Management of long SFA lesions with a nitinol stent is effective and safe in patients with critical limb ischemia as there is still the opportunity to receive bypass surgery or endovascular reinterventions.

Keywords:
critically ischemic limb, evaluation, long, stenting, superficial femoral artery

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Introduction

The superficial femoral artery (SFA) and the proximal popliteal artery are the most common diseased segments, being involved in more than 50% of cases of peripheral arterial disease [1]. Trans-Atlantic Inter-Society Consensus (TASC II) identified endovascular treatment as the preferred method for multiple lesions (stenoses or occlusions) measuring 5 cm or less and for single stenoses/occlusions less than or equal to 15 cm not involving the popliteal artery. There is evidence that longer lesions with a mean length of 10 cm treated with stents show improved 12-month freedom from restenosis compared with percutaneous transluminal angioplasty (PTA) [2]. Nitinol self-expanding stents seem to be a good choice for older patients with long SFA occlusions, with acceptable short and midterm results [3]. Soga *et al.* [4] reported the clinical efficacy of nitinol stents in long femoropopliteal lesions. PTA and stenting of SFA become challenging as restenosis is the main drawback, especially in long lesions [5]. Many studies have supported the effectiveness of angioplasty in the treatment of patients with critical limb ischemia (CLI), with lower morbidity and acceptable results, compared with surgical bypass [6]. Scali *et al.* [7] had reported that critically ischemic limb and renal insufficiency were predictors of failure for any intervention, whether bypass or angioplasty, whereas claudication was considered a predictor of success for SFA stenting.

Patients and methods

This prospective study was carried out from July 2012 to September 2014 on 25 patients (19 men and six women, mean age 58 years, range 52–65 years) at the 6th October Insurance Hospital (Dokki, Cairo, Egypt). The inclusion criteria for this study were as follows:

(1) Incidence of CLI caused by a long SFA lesion categorized under Rutherford classification as 4 or 5.
(2) Location of the SFA lesion 1 cm below the origin of the profunda femoral artery and its distal end at least 3 cm above the knee joint.

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(3) Lesion length between 12 and 18 cm, to be covered with a single stent.
(4) Patency of at least one-vessel distal run-off to the foot.

Exclusion criteria were as follows:

(1) Presence of a nonsalvageable limb or life-threatening infection.
(2) Presence of multilevel occlusions.
(3) Total occlusion that cannot be crossed by a wire.
(4) Previous bypass surgery in the same limb.
(5) Requirement of more than one stent to cover the lesion.

All patients were admitted and had to sign a written informed consent form before undergoing treatment. Patients were evaluated by full clinical assessment, including detailed history taking and examination, including history of diabetes mellitus (DM), smoking, hypertension, cardiovascular diseases, cerebrovascular diseases, renal insufficiency, previous endovascular intervention, and bypass surgery. All patients were subjected to thorough physical examination, ankle brachial pressure index (ABI) measurement, and duplex ultrasound imaging. Computed tomography angiography was performed in all cases for diagnosis, for identification of the character of the lesion, and for distal run-off vessels. All patients had undergone full laboratory investigations with special emphasis on renal functions and coagulation profile.

Procedure details

Periprocedural medications included dual antiplatelet therapy in the form of 75 mg salicylates and 300 mg clopidogrel as a loading dose, followed by a daily maintenance dose of 75 mg clopidogrel continued postoperatively for at least 6 months in all cases. The procedure was carried out under local anesthesia in all cases. An ipsilateral antegrade femoral arterial puncture and a 6-F vascular sheath were used in 20 cases, whereas a contralateral approach using an 8-F sheath and a crossover guiding catheter was adopted in the other five cases where the SFA lesion was more proximal to its origin precluding optimum positioning of the sheath ipsilaterally. After sheath insertion, 5000 IU heparin was injected before starting the procedure. Preintervention angiography was performed to assess the lesion: its length, stenosis or occlusion, and distal run-off vessels. A 0.035 Terumo hydrophilic guide-wire (Radifocus, Terumo, Japan) or V-18 control guide-wire (Boston Scientific, USA) was used to cross the lesion either intraluminal or subintimally. After passing the wire, lesions were dilated using 4–5 mm low-profile balloons (Wanda balloon; Boston Scientific) for 1–2 min under nominal pressure. A self-expandable nitinol stent Protégé EverFlex (ev3 Inc., USA) was deployed using the road map technique to cover the whole length of the lesion and extending proximal and distal to the targeted segment. Poststent balloon dilatation was performed along the whole stented segment. Completion angiography was performed while the guide-wire remained in place to assess the technical success of the procedure.

After endovascular intervention, patients with ischemic foot ulcers or gangrene received standard wound care, debridement, and/or minor amputation until wounds were healed.

Follow-up was conducted daily during the period of admission and then in the vascular surgery outpatient clinic at 3, 6, and 12 months with respect to regaining pulse, ABI, disappearance of rest pain, wound healing, and complications. Any decrease in ABI measurement or recurrence of significant manifestations was an indication for duplex imaging to assess patency or stenosis. Restenosis was considered significant if more than 50% on duplex ultrasound, where peak systolic velocity ratio was greater than or equal to 2.4, as reported by Ranke *et al*. [8]. Repeated revascularization was performed on the basis of clinical manifestations, duplex scan, and angiography (Figs. 1 and 2).

Results

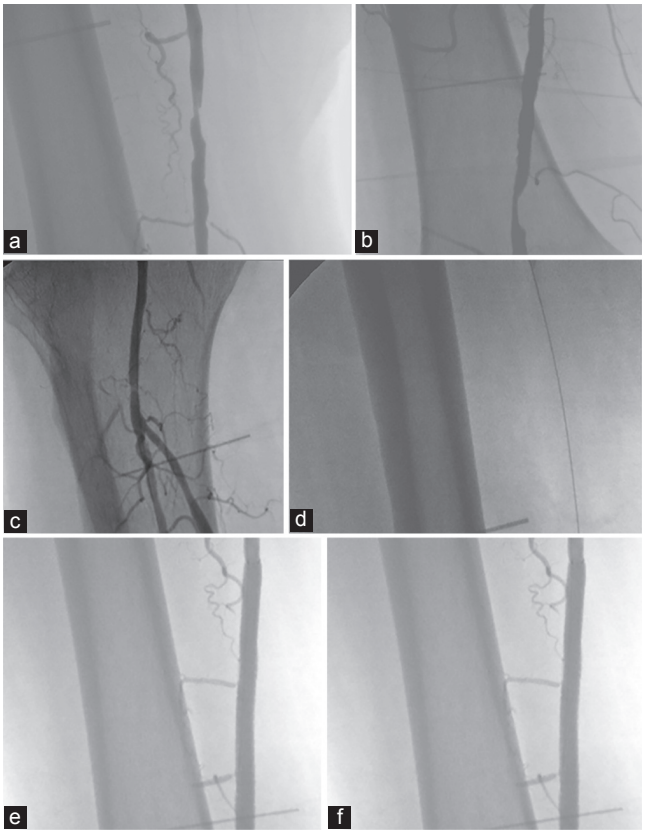
This study was performed on 25 patients with CLI caused by long SFA lesions categorized under Rutherford classification as 4 or 5 with a mean lesion length of 13 cm (range 12–18 cm). All patients received a single self-expandable stent of 15 or 20 cm, of a diameter of 6 mm. Major risk factors were diabetes and smoking, with incidences of 68 and 56%, respectively. All demographic data and patient criteria are summarized in Table 1. The majority of patients were classified as TASC B (16 patients, 64%). Totally occluded segments were observed in 60% (15 patients), whereas multiple stenosis was observed in 40% (10 patients). Nearly half of the patients (52%, 13/25) had three-vessel distal run-off to the foot (Table 2).

Regarding procedural complications, two patients developed groin hematoma, which resolved spontaneously, and one patient developed contrast-induced nephropathy, which was treated medically.

Follow-up results

Technical success was achieved in all patients. Primary patency was achieved in 17 (68%) patients,

Figure 1



(a, b) Multiple stenotic lesions of a long superficial femoral artery SFA segment. (c) Distal run-off based on two vessels. (d) Crossing the lesion with a 0.035 wire. (e) After deployment of a long stent. (f) Completion angiography.

Table 1 Demographic data and patients criteria

	n (%)
Age	58 (52–65)
Males/females	19 (76)/6 (24)
Risk factors	
DM	17 (68)
Smoking	14 (56)
Hypertension	12 (48)
Ischemic heart disease	12 (48)
Stroke	4 (16)
Renal insufficiency	4 (16)
Rutherford classification	
Rutherford category 4	6 (24)
Rutherford category 5	19 (76)

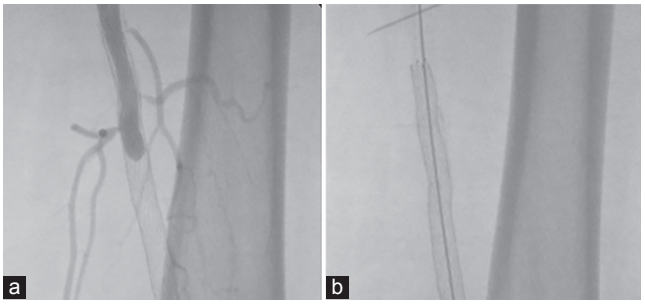
DM, diabetes mellitus.

Table 2 Angiographic criteria

TASC classification	*n* (%)
TASC B	16 (64)
TASC C	9 (36)
Distal run-off vessels	
Three vessels	13 (52)
Two vessels	7 (28)
One vessel	5 (20)

TASC, Trans-Atlantic Inter-Society Consensus.

Figure 2



(a) In-stent stenosis. (b) Crossing the occluded stent with a 0.035 wire. (c) Stent recanalization after balloon dilatation.

whereas restenosis occurred in eight (32%) cases. Six of them occurred within the first 6 months, whereas the other two cases occurred in the 8th and 11th month of follow-up. Four of these eight cases were treated with angioplasty, one patient was treated with a femoropopliteal bypass, and two cases were treated medically as they were claudicants without significant manifestations. The last patient had to undergo limb amputation because of the development of extensive necrotizing fasciitis along with poor general condition. The correlation between restenosis and associated risk factors revealed that DM was the most common risk factor for restenosis, seen in five of eight patients.

Discussion

The femoropopliteal segment was the most common atherosclerotic lesion in the lower extremities [1,9]. Karch *et al.* [10] and Goshima *et al.* [11] confirmed that bypass surgery was the definitive strategy and the recommended procedure for revascularization of long femoropopliteal segment. However, its morbidity and possibility of reoperation are considerable drawbacks, reaching an incidence of ~50%. The main disadvantages of bypass surgery are wound complications, perioperative cardiac complications, and graft failure, with increased reoperation rate. All of these factors have to be considered when comparing surgery and endovascular intervention [11].

Improvement in short-term and midterm patency of SFA stenting has challenged the historical concept of bypass surgery when compared with endovascular therapy [12]. Van der Zaag *et al.* [13] have enumerated the advantages of endovascular therapy in terms of its ability to deal with complex and multilevel lesions, especially in patients with long diseased segments, previous revascularizations, advanced age, and unsuitable veins.

The study on bypass versus angioplasty in severe ischemia of the leg for patients with CLI showed that amputation-free survival and mortality among patients treated with angioplasty were similar to those treated with surgery [14].

The number of patients in this study was relatively small as it was carried out in a single center of an insurance hospital to which patients came from all across the governorate. This made follow up difficult, except for the small number of patients who lived closer to the hospital.

Most patients in this study were men, which matched the observation made by Laird *et al.* [15] that the prevalence of peripheral arterial disease is higher among men and increases with age. Diabetes and smoking were the main risk factors, seen in 68 and 56% of patients, respectively. Nearly similar incidences were observed in other studies [4,16]. Sabeti *et al.* [17] had reported in his series that DM was associated with an approximately four-fold incidence of in-stent stenosis. This could be explained by the influence of DM in hypertrophy of wound healing in areas of vessel wall trauma following stent implantation and then causing neointimal hyperplasia [18]. In contrast, Markose and Bolia [19] reported that endovascular therapy has many advantages among diabetic patients because of less invasiveness, absence of wound-related complications, lack of requirement for venous conduits, facilitation of simultaneous multiple vessel recanalization, and short hospital stay.

Sixteen (64%) patients were TASC B, nine (36%) patients were TASC C, and no patients were TASC A or TASC D. It was observed that primary patency was higher among patients with TASC B lesions compared with those with TASC C lesions. Baril *et al.* [20] published outcomes of endovascular interventions for TASC B and C lesions and found similar patency rates compared with femoropopliteal bypass surgery.

In this series, undersized balloon angioplasty was performed using 4–5 mm low-profile balloons before covering the entire target lesion with a long stent. This allows better deployment of the stent in its optimum position. Hu *et al.* [3] approved stent-supported angioplasty by using a balloon to dilate the whole lesion and then to implant short stents for the residual significant stenoses. Lenti *et al.* [21] commented upon this technique as it decreased the residual stenosis compared with postdilation, but it induced more distal embolization.

Primary stenting remains controversial [22]. Schillinger *et al.* [12] reported that primary stenting was morphologically and clinically superior to balloon angioplasty with optional stenting but was associated with serious problems such as in-stent stenosis and stent fractures. With the development and progress of new-generation nitinol stents, there has been a marked increase in the number of patients treated with this technique [23]. Krankenberg *et al.* [2] and Lofberg *et al.* [24] concluded in their series that SFA stenting is recommended only after technical failure of PTA and for treatment of long lesions measuring more than 10 cm, as balloon angioplasty alone is associated with recurrence rates exceeding 60% at 1 year. Also, Mewissen [25] reported that the 2-year primary patency rates of nitinol stents for symptomatic femoropopliteal disease are superior to PTA.

In this series, SFA stents were preferred over PTA, with optional stenting. This could be attributed to many reasons; first, all patients in this study had CLI and thus our aim was to ensure optimal patency results, adequate restoration of perfusion, and consequently limb salvage. Second, Lumsden *et al.* [26] had stated that the 6-month patency rate for bare nitinol stents was very high but decreased with time, which is sufficient enough for healing of ischemic ulceration in patients with CLI. Third, as reported by Ferreira *et al.* [27], many investigators have concluded that long-term primary patency is not strictly necessary for limb salvage, as some patients with restenosis remain asymptomatic, and in such cases medical treatment is sufficient [28]. Finally, critically ischemic limb commonly occurs in elderly patients suffering from many medical comorbidities, such as coronary artery disease, and the mortality rate among them is ~50–70% at 5 years [29]. Therefore, we believe that long-term patency might not be needed in most cases.

Few studies have been found discussing the results of long stents in the femoropopliteal segment. Sabeti *et al.* [30] reported the effectiveness of a long nitinol stent as an adequate tool to treat variable femoropopliteal lesions. Also, Mewissen [31] had reported that stenting of the entire diseased segment is generally preferred over spot stenting to decrease the possibility of vessel recoil, plaque fracture, and consequent inflammatory reaction between stents. In contrast, deployment of a long stent rather than multiple overlapping stents is risky for stent fracture and for in-stent stenosis [5,31]. Also, Schlager *et al.* [32] had stated that midterm and long-term primary patency was inversely proportional to the length of the treated segment beyond 10 cm.

Bosiers *et al.* [33] published 1-year results of the 200 mm Protégé EverFlex stent to be 64.8%. In this study, the 1-year primary patency rate of nitinol stents (15 and 20 cm) was 68%. The FAST study reported a

similar result (68.3%) with 12 months of freedom from restenosis in the stent arm. Discrepancy in patency rates might be explained by the limited number of cases in this study. Davies *et al.* [34] had reported in his series that long-term patency following PTA varied according to the severity of the treated lesion; claudication versus CLI, stenosis versus occlusion, lesion length, run-off vessels status, and presence or absence of diabetes.

Balloon angioplasty is the traditional method for treating significant intimal growth within a stent with better secondary patency rates [35]. In this study, the same strategy was followed in the treatment of in-stent stenosis in four of eight cases. During reintervention, the lesion could not be crossed by the guide-wire in one patient and was treated by femoropopliteal bypass. There were two patients with restenosis without recurrence of significant manifestations who received conservative treatment. Laird and Yeo [36] reported that femoropopliteal in-stent restenosis was one of the most frustrating problems in endovascular intervention. It is relatively common and occurs in 18–40% of patients within the first year of femoropopliteal artery stenting. Stabile *et al.* [37] treated SFA in-stent restenosis by using a drug-eluting balloon and reported a 100% rate of secondary patency after 1 year; thus, he concluded that a drug-eluting balloon can change the paradigm for treatment of SFA in-stent restenosis.

Machan [38] and Rosenfield *et al.* [39] attributed the main causes of SFA restenosis to complex anatomical factors, as there were multiple mechanical forces acting on SFA during its passage through the adductor canal — for example, repetitive deformity by leg movement and exposure to compression, torsion, and elongation by interaction with the surrounding musculature.

In this series, 13 (52%) patients had three patent vessel distal run-off, seven (28%) patients had two-vessel, and five (20%) patients had only one patent vessel run-off. Norgren *et al.* [5] found that patency rate was affected significantly by poor distal run-off to the foot.

Conclusion

Management of long SFA lesions with a nitinol stent is effective and safe in patients with CLI as there is still the opportunity to receive bypass surgery or endovascular reinterventions.

Acknowledgements

Conflicts of interest

None declared.

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Retrograde transpopliteal access in the supine patient for recanalization of the superficial femoral artery after failed antegrade angioplasty

Ashraf Eweda[a], Wael El Shemy[b], Mohamed Sad[a], Mohamed Hamza[a], Aser Gouda[c], Ahmad Tawfik[b]

[a]Vascular and Endovascular Unites in Al azhar Faculty of medicine, Cairo, [b]Zagazig Faculty of Medicine, Zagazig, [c]Sohag Faculty of Medicine, Sohag, Egypt

Correspondence to Wael El Shemy, MD, Zagazig Faculty of Medicine, Zagazig University, Zagazig, Egypt
Tel: 0552312621; fax: 0552362621
E-mail: wael.elshimy@yahoo.com

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Background
The prevalence of peripheral arterial disease is increasing worldwide due to the increase in life expectancy, obesity, and diabetes. Symptomatic atherosclerosis of the lower extremity arteries commonly involves the superficial femoral artery (SFA) and is characterized by long, diffuse lesions and long total occlusions.

Patients and methods
All patients underwent percutaneous recanalization from a retrograde popliteal access after failure to pass through the antegrade access either by the ipsilateral or by the contralateral femoral approach. All patients were symptomatic with ipsilateral disabling intermittent claudication.

Results
Technical success, defined as puncture of the popliteal artery and recanalization of the SFA, was achieved in all cases. The mean ankle–brachial index increased from 0.5 ± 0.2 preoperatively to 0.7 ± 0.1, with improvement in the walking distance. Primary patency was 80.7% at 6 months and 76.9% at 1 year.

Conclusion
Percutaneous recanalization of femoropopliteal TASC C and D lesions can be increased by the transpopliteal approach. The retrograde popliteal approach with the patient in the supine position can be considered a 'first-choice' method for safe and effective SFA recanalization, especially in occlusions located at the distal and the mid portion SFA and that failed to pass through the femoral antegrade approach. It is an inexpensive and easy-to-learn technique.

Keywords:
angioplasty, recanalization, retrograde, transpopliteal

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Introduction

The prevalence of peripheral arterial disease is increasing worldwide due to the increase in life expectancy, obesity, and diabetes [1]. Symptomatic atherosclerosis of the lower extremity arteries commonly involves the superficial femoral artery (SFA) and is characterized by long, diffuse lesions and long total occlusions [1]. Endovascular therapy has seen major advances in the last decade with the introduction of several new techniques and devices [2]. SFA occlusions are generally managed by an antegrade ipsilateral or retrograde contralateral femoral approach ending in intraluminal or subintimal recanalization of the vessel lumen [3]. In case of failure, a retrograde popliteal access is considered as a valid alternative [4]. This technique, first described years ago by Tonnesen *et al.* [5], has diminished in popularity owing to complications, such as dissections, vessel ruptures, arteriovenous fistulas, pseudoaneurysm, and hematomas, which may all develop at the puncture site [6]. Since Trigaux *et al.* [7] described the relationship between the popliteal artery and vein and the safest technique to puncture the popliteal artery, several guidance methods for popliteal artery puncture have been reported, notably, ultrasound guidance (B-mode or color Doppler or a Doppler-equipped needle that identifies the arterial and the venous flow) [8] and contrast injection under fluoroscopy that creates a roadmap to guide the needle as it is advanced in the popliteal artery. A retrograde approach to chronic total occlusion (CTO) of the SFA through the ipsilateral popliteal artery has been used occasionally if an antegrade approach is not feasible or has failed. The rationale for this increased success rate is that the distal occlusion stump in this vessel, as in others, is usually tapered, thereby increasing the likelihood of intraluminal seating of guidewires. However, the retrograde popliteal approach to SFA occlusions is a relatively new technique and there have been few reports concerning complications with this approach [9].

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Indications for popliteal access (PA) include:

(a) An absent femoral pulse secondary to an iliac or common femoral occlusion, (b) severe calcification,
(c) Combined iliac and femoral lesions,
(d) Occlusion or a high take-off of the origin of the SFA, and
(e) Severe obesity.

PA can also be used to avoid scar tissue and when femoral angioplasty has failed [10]. Traditionally, popliteal artery access is obtained with the patient in the prone or the lateral decubitus position [11]. While retrograde popliteal access offers several advantages that facilitate SFA recanalization [12], the major drawback of this approach is the need for the patient to change position from supine to prone and then back to supine, which produces anxiety and discomfort. Moreover, once the patient is changed to a prone or a decubitus position, the remaining procedures must be performed through the popliteal access [13]. These maneuvers add to the patient's anxiety, make the situation uncomfortable, often prolong the procedure, and complicate the operator's job owing to the difficulty in handling the femoral sheath on which the patient is lying when prone. In addition, this approach is not feasible in patients who are obese, have impaired respiratory function, or have conditions that may interfere with positioning them prone or in the lateral decubitus [14]. To avoid this time-consuming and uncomfortable repositioning, a technique has been developed to access the popliteal artery with the patient in the supine position. With the patient supine, a medial retrograde popliteal access at the infracondylar plane was adopted, without turning the patient. Puncture of the distal PA was guided fluoroscopically and a guidewire was inserted into the true lumen, after which retrograde recanalization proceeded in accordance with the standard protocol [15].

The objective of this article was to report the use of a retrograde popliteal approach performed in a supine patient after failed antegrade angioplasty for CTO in the SFA and to demonstrate that supine retrograde popliteal artery access is a feasible, safe, and effective means to increase the success rate of percutaneous transluminal angioplasty for SFA occlusions after a failed antegrade attempt by means of ipsilateral or contralateral femoral access.

Patients and methods

From November 2012 to November 2014, 26 patients (16 men; mean age 68 ± 6 years) with chronic SFA occlusion (mean length 97.4 ± 3.76 mm) underwent percutaneous recanalization from a retrograde popliteal access. All patients were symptomatic with ipsilateral disabling intermittent claudication (Rutherford grade 3). Risk factors included smoking (n = 18, 75%), hypertension (n = 11, 45%), diabetes (n = 7, 29%), hypercholesterolemia (n = 15, 62%), and coronary heart disease (n = 4, 16%). Each patient underwent a preoperative color Doppler ultrasound scan, assessment of the ankle–brachial index, and multidetector computed tomographic angiography to obtain a complete anatomical overview of the occluded segment and the morphology of the abdominal aorta and peripheral arteries before treatment.

Written informed consent was obtained before each procedure.

The technique

All procedures were performed in the angiosuite under sterile conditions, with the patient in the supine position under local anesthesia (5 ml of 1% lignocaine) with or without intravenous sedation (diazepam 2–10 mg). All surfaces of the patient's affected leg was prepared with betadine wash: thigh to toes, in a thorough surgical manner. The leg was then exteriorized on the table through a hole in the drape. The common femoral artery was punctured with an antegrade (n = 12, 46%) or a retrograde contralateral (n = 14, 53.8%) approach. A 6-Fr, 25-cm-long introducer sheath was used for the antegrade access. Heparin (5000 U) was injected intravenously.

In every case, an initial attempt was made to recanalize the obstructed SFA from the femoral access using a 0.035-inch, 180-cm angle-tipped standard hydrophilic guidewire (Terumo) in combination with a 4-Fr straight catheter. Endoluminal recanalization proved impossible in all these cases owing to the morphological characteristics of the obstructions, and so a retrograde popliteal access was obtained. With the patient still in the supine position, the knee was flexed gently and rotated medially to achieve a good approach to the popliteal artery. The most suitable puncture point was where the popliteal artery was visualized without superimposition of the vein, which is usually proximal and medial to the knee joint and caudal to the semimembranosus muscle. Under fluoroscopic guidance, contrast was injected from the femoral approach to obtain a roadmap to visualize the popliteal artery. The C-arm was brought into a contralateral oblique (30–45 u) position (for the right SFA left oblique and vice versa) to facilitate fluoroscopically guided puncture with a 7-, 9-, or 15-cm-long, 21-G needle chosen to best suit the circumference of the thigh. The needle was used in

a coaxial technique to guarantee stable penetration through the muscle. During needle introduction, the C-arm can be brought into the ipsilateral position, 90 u to the previous projection, to aid in the assessment of the angle of the needle as it approached the artery (optimally,70 u) and to estimate the distance of the needle tip from its target. When the needle tip was visualized inside the popliteal artery lumen, a 0.018- or 0.035-inch, 180-cm angle-tipped standard hydrophilic guidewire (Terumo) was advanced into the distal patent portion of the SFA. The guidewire was inserted through the needle followed by a 4- or 6-Fr, 10-cm sheath. Once retrograde passage of the occlusion was successful (sometimes requiring a 'double-balloon' technique to disrupt the dissection membrane with balloons delivered from access sites), balloon angioplasty and/or stenting could be performed from either directions. A completion angiogram was then performed and the balloon dilatation was repeated for any residual stenosis greater than 30%. Catheters and guidewires were removed and hemostasis was achieved by hand.

Follow-up

All patients received low-molecular-weight heparin (40 mg × 2 days) in association with clopidogrel (75 mg/day) for 4 weeks followed by aspirin (100 mg/day) indefinitely. Clinical examination and duplex ultrasound were performed the day after the procedure and then at 1, 6, and 12 months. Computerized tomographic angiogram (CTA) was preserved for the presence of abnormalities or recurrent symptoms.

Results

Technical success, defined as puncture of the popliteal artery and recanalization of the SFA, was achieved in all cases. The procedure was well tolerated by everyone without any remarkable pain. Retrograde recanalization involved the insertion of a 6-Fr sheath in 11 cases and a 4-Fr sheath in 15 cases. The 'double-balloon' technique was necessary to achieve guidewire passage in 18 cases. In one case, the guidewire from the popliteal approach passed the obstructed segment through the subintimal space and re-entered the SFA lumen proximally. Stenting of the SFA was performed in 10 cases, whereas only balloon dilatation was performed in 16 cases.

The mean time of hospitalization was 2 ± 1 days (similar to patients treated with the transfemoral access only in our experience). Perioperative complications included two distal pseudoaneurysms and one small arteriovenous fistula at the distal puncture site. The mean ankle–brachial index increased from 0.5 ± 0.2 preoperatively to 0.7 ± 0.1, with improvement in the walking distance.

After a mean follow-up of 12.5 ± 4.8 months, 20 (76.9%) SFA arteries were patent. Restenosis occurred in the remaining six (23%) SFAs, but no stent fracture was observed. Three of the restenoses were redilated; the dilated balloon was kept in place for about 2 min. The other three cases were managed conservatively. Primary patency was 80.7% at 6 months and 76.9% at 1 year (Tables 1–6).

Discussion

Retrograde subintimal tracking through the popliteal approach, which utilizes the anatomical characteristics of the femoropopliteal artery, delivers an endovascular solution for unsuccessful antegrade crossing of an occlusive lesion [16]. However, the need for repositioning the patient during the procedure [17] and the potential risk of access site complications appear

Table 1 Age and sex distribution of the studied group

Age	68.6 ± 6
Sex [*n* (%)]	
Male	16 (61.5)
Female	10 (38.5)

Table 2 Risk factors

Smoking	18	75.0
HTN	11	45.0
DM	7	29.0
Hypercholesterolemia	15	62.0
CHD	4	16%
fx1		
fx2		
fx3		

DM, diabetes mellitus; CHD, coronary heart disease; HTN, hypertension.

Table 3 ABI

Test	Pre	Post	Paired *t*-test	*P*
ABI	0.5 ± 0.2	0.7 ± 0.1	7.42	0.00
fx4				

ABI, ankle–brachial index.

Table 4 Follow-up

Patent	20	76.9%
Restenosis	6	23.1%
P	0.00	

Table 5 Primary patency

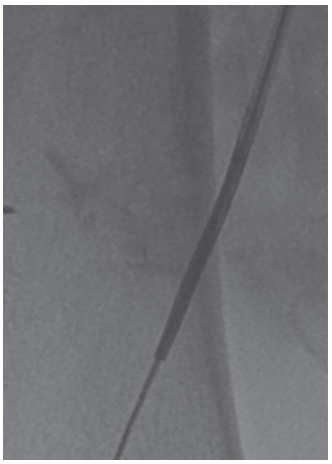
6 months	21	80.7%
1 year	20	76.9%
P	0.76	

to have impeded wider acceptance of the retrograde approach. The proximity of the artery and the vein at the popliteal fossa can carry the potential risk of puncture site complications, including arteriovenous fistula or gross hematoma after the removal of the popliteal sheath [14]. Moreover, once the patient is changed to a prone or a decubitus position, the remaining procedures must be performed through the popliteal access. More recently, this technique was modified to accommodate an entirely supine posture by lifting the heel or flexing and rotating the knee medially [4]. However, as shown in our cases, the patient remains supine during the entire antegrade–retrograde SFA intervention. The technique we used here enables access to the distal SFA and keeps the patient in a supine position, which has a number of advantages. Most importantly, it allows simultaneous manipulation of guidewires and balloon catheters from above and below. The SAFARI technique, which uses both antegrade and retrograde routes simultaneously, is highly successful [12]. There are several limitations in this technique that should be considered. First, a couple of failed attempts of popliteal artery puncture could worsen limb ischemia, with devastating clinical results. Therefore, this technique cannot be a first-line in the endovascular treatment of CTOs in the SFA. Second, patients with extensive occlusion or severe stenosis in the popliteal artery would not be suitable for this approach owing to the high potential of puncture failure and aggravating limb ischemia after sheath placement [18]. Puncture of the distal SFA was performed using fluoroscopy and contrast was injected through the antegrade sheath. This technique was found to be quick and simple to perform; however, ultrasound-guided puncture would be a reasonable alternative. Ultrasound may also minimize the amount of contrast required during the procedure and reduce radiation exposure to the hands of the interventionist and prevent transition of the needle through the accompanying superficial femoral vein, with the risk of arteriovenous fistula [13]. It has been postulated that recanalization may be more successful given the less severely fibrotic/calcified thrombus when approached from the distal end [19]. PA can be performed safely with a high rate of technical success [20]. Zaitoun and colleagues reported an 81% primary angiographic success rate for the popliteal approach, although there was no long-term follow-up. In this study, primary patency was assessed clinically, which is ultimately the most important factor in determining the success of any intervention. Further, it is accepted that objective radiological measurements of patency would have provided further information. Concerns have been highlighted with regard to the incidence of local complications after PA [21]. The formation of arteriovenous fistula has a reported incidence as high as14%; puncture site arterial dissection or thrombosis and peroneal nerve palsy secondary to hematoma have also been described [22]. In our study, the incidence of local puncture site complications was 11.5% (Figs 1, 2).

Conclusion

Percutaneous recanalization of femoropopliteal TASC C and D lesions can be increased by the transpopliteal approach. The retrograde popliteal approach with the patient in the supine position can be considered as a 'first-choice' method for safe and effective SFA

Figure 1



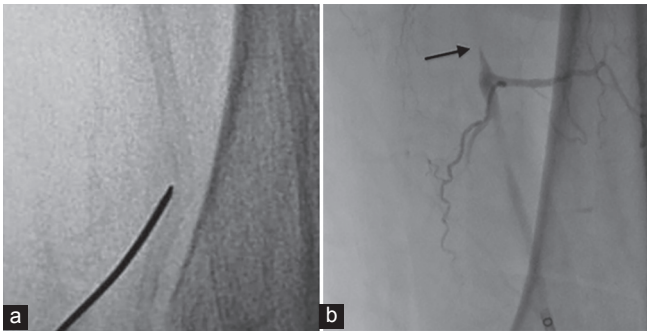
Balloon angioplasty p1.

Table 6 Risk factors for restenosis

Age (mean ± SD)	Restenosis	Patent	*P*	OR (95% CI)
	68.81 ± 4.2	68.45 ± 7.2	0.81	
Sex [*n* (%)]				
Male	4 (66.7)	12 (60.0)	0.76	
Female	2 (33.3)	8 (40.0)		
Smoking	6 (100.0)	12 (60.0)	0.001	10.8 2.3–33.5
HTN	2 (33.3)	9 (45.0)	0.17	
DM	2 (33.3)	5 (25.0)	0.29	
Hypercholesterolemia	5 (83.3)	10 (50.0)	0.004	10.0 1.9–17.5
CHD	1 (17.7)	3 (15.0)	0.63	

DM, diabetes mellitus; CHD, coronary heart disease; CI, confidence interval; HTN, hypertension; OR, odds ratio.

Figure 2



(a, b)The retrograde transpopliteal approach.

recanalization, especially in occlusions located at the distal and the mid portion SFA and that failed to pass through the femoral antegrade approach. It is an inexpensive and easy-to-learn technique.

Acknowledgements

Conflicts of interest

None declared.

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Bascom's cleft lift versus rhomboid flap procedure for the management of primary sacrococcygeal pilonidal sinus

Mohamed Rabea

Department of General Surgery, Faculty of Medicine, El-Minia University, El-Minia, Egypt

Correspondence to Mohamed Rabea, MD, Department of General Surgery, Faculty of Medicine, El-Minia University, El-Minia, Egypt
Tel: 01096670911;
e-mail: mrabea177@gmail.com

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Objective
The aim of this study was to evaluate and compare clinical safety and efficacy after Bascom's cleft lift and rhomboid flap (Limberg) procedures for the treatment of primary sacrococcygeal pilonidal sinus (SCPS).

Patients and methods
This study included 100 adult patients with primary (nonrecurrent) SCPS who were randomized to Bascom's cleft lift procedure (n = 50) or to rhomboid flap procedure (rhomboid-shaped excision and Limberg flap) (n = 50). Through the follow-up period, which ranged from 6 to 12 months, with an average of 9.1 ± 1.7 months, patients were evaluated for wound-related complications and recurrence of symptoms after complete wound healing.

Results
There were insignificant differences in the baseline characteristics between both groups. Compared with Bascom's cleft lift procedure, the rhomboid flap procedure involved a longer duration of operation (61.14 ± 16.36 vs. 40.78 ± 11.96 min; $P < 0.001$). A significant clinical outcome was achieved after the rhomboid flap procedure in terms of less duration to pain relief (12.42 ± 1.59 vs. 17.86 ± 3.10; $P < 0.001$) and less healing time (17.42 ± 4.68 vs. 20.06 ± 5.94; $P < 0.05$). The incidences of postoperative wound-related complications and recurrence were 6 and 2%, respectively, after the Bascom's cleft lift procedure and 4 and 2%, respectively, after the rhomboid flap procedure, with insignificant differences.

Conclusion
Although Bascom's cleft lift operation involves a shorter duration of operation, the rhomboid-shaped excision with the Limberg flap procedure was superior in terms of early wound healing, with similar incidences of wound-related complications and recurrence after treatment of primary SCPS.

Keywords:
Bascom's cleft lift, excision, pilonidal sinus, recurrence, rhomboid flap

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Introduction

Pilonodal disease occurs in ~0.7% of the population, with the peak age of incidence being 16–25 years [1]. There are various theories on the predisposing factors and causes of the disease. It most often results from mechanical stretch, which causes enlargement and rupture of hair follicles in the natal cleft of the sacrococcygeal area [2]. Pilonidal disease may arise in one of three forms: acute abscess, sinus tracts, or complex disease characterized by chronic or recurrent abscesses with extensive branching sinus tracts [3].

There are many different techniques for the treatment of sacrococcygeal pilonidal sinus (SCPS), ranging from open wound fistulotomy and curettage, marsupialization, midline excision and closure, asymmetric/oblique excision, and closure (Karydakis procedure, Bascom's procedure, cleft closure), to flaps (rhomboid, V–Y advancement, Z-plasty, gluteal myocutaneous) [4]. However, no single surgical procedure has been widely accepted as the gold standard for the treatment of SCPS [5].

The importance of avoiding midline incisions and placing any healing wounds off midline to reduce recurrence was recognized by Bascom [6]. Bascom's cleft lift procedure involves only the excision of midline pits and scarred skin, avoiding removal of deep tissues, and places the incision sufficiently to the side so that it can heal well [4,7]. The procedure can be used for primary or recurrent cases of SCPS.

Limberg flap reconstruction following rhomboid excision of the sinus area, involves closing a 60° rhombus-shaped defect with a transposition flap, with sutures away from the midline, giving rise to a tensionless flap of unscarred skin in the midline [8]. In the literature, this procedure has been shown to be superior to primary closure [9] and other flaps [10]. It can be performed for the management of primary or recurrent pilonidal sinus, with a low complication rate, short hospital stay, short time to return to normal activity, and good long-term results [11].

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The aim of the present study was to evaluate and compare the postoperative outcomes of two surgical techniques for the treatment of primary SCPS: Bascom's cleft lift procedure and rhomboid flap operation (rhomboid excision and Limberg flap rotation), particularly in terms of postoperative complications and recurrence rate.

Patients and methods

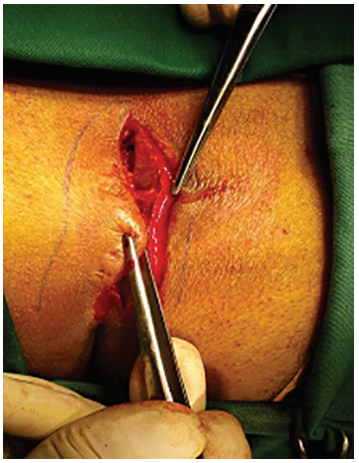
Patients

This prospective study was carried out in the General Surgery Department at Al Jafel Hospital (Riyadh, KSA) from July 2008 to July 2013 after approval of the study protocol by the local ethical committee and obtaining written fully informed consent from the patients. One hundred patients with SCPS were divided randomly into two groups equal in number on the basis of the type of procedure performed: Bascom's procedure or rhomboid flap. The inclusion criteria were adult patients (>18 years old) with primary nonrecurrent SCPS. The exclusion criteria included patients with diabetes mellitus, obesity, acute pilonidal abscess, pregnancy, immunosuppression, dermatological diseases, recurrent SCPS, and patients who had undergone previous flap surgery for pilonidal sinus.

Preoperative preparation

Standard routine tests were carried out. If purulent discharge and infection were present, antibiogramme culture, appropriate antibiotic treatment, and preoperative drainage were performed. The rectum was evacuated through enema on the morning of the operation. Shaving of the operation field was performed on the operating table immediately before the operation. A single dose of 1 g cefazolin antibiotic was administered for prophylaxis.

Figure 1



Bascom's cleft lift procedure before closing the flap.

Surgical techniques

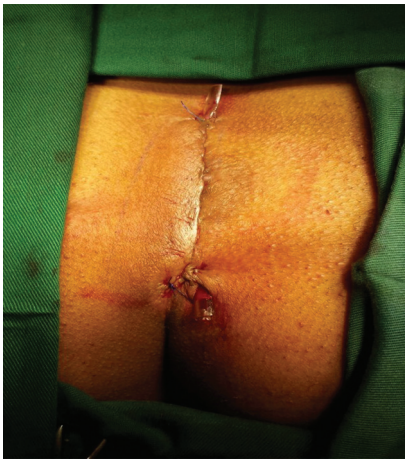
All operations were performed under spinal or general anesthesia. Bascom's cleft lift operation was performed as described previously [7]. With the patient was placed in the prone position, the sinuses and scarred skin were removed. Skin from one side of the natal cleft was excised and skin on the opposite side was freed from the underlying tissue and mobilized out past the edge of the natal cleft on the other side (Fig. 1). The deeper tissues were drawn and sewn together to 'shallow the valley' and to recontour the cleft. The skin flap was then closed and sutured to the side outside the cleft. The new natal cleft was less deep and smoothly transitioned down toward the anus. A temporary drain was placed under the flap of skin and removed in most of the cases within a week (Fig. 2).

The rhomboid flap procedure (rhomboid excision and Limberg flap transposition) was performed as described previously [8]. With the patients were placed in a prone jack-knife position on the operating table with the legs slightly abducted and the buttocks strapped apart by adhesive tapes, a rhomboid-shaped excision containing the sinus orifice with 60 and 120° of internal angles was completed by an incision (Fig. 3). The skin flap's edge lengths, marked as equal to the rhomboid incision, were transposed to the excised field from the right or the left gluteus together with the subcutaneous fat tissue and fascia of gluteus muscle. A suction drain was inserted, and the fascia under flap was sutured to presacral fascia using 2/0 polyglactin. The subcutaneous tissue was closed with two-layer 2/0 polyglactin and the skin was closed with 3/0 polypropylene sutures (Fig. 4).

Postoperative care and follow-up

The administration of intravenous antibiotic and oral metronidazole 500 mg was continued for 3 days after

Figure 2



Bascom's cleft lift procedure after closure. The wound past the midline toward the left side.

surgery. Regular shaving of the operative field and hygienic measures were performed for all cases. Skin sutures were removed on the 10th day after surgery when there were no wound-related complications. Healing time was defined as the time to removal of stitches after surgery or until complete wound healing. Wound-related complications included seroma, hematoma, dehiscence, and infection. Recurrence was defined as recurring symptoms of SCPS after complete wound healing.

Statistical analysis

Statistical analysis was carried out using the SPSS statistical software (version 16.0; SPSS Inc., Chicago, Illinois, USA). The continuous variables were compared using Student's *t*-test and the categorical variables were compared using the χ^2-test or the Fisher exact test. Continuous variables were presented as mean ± SD and categorical variables were presented as number and percent. A *P*-value less than 0.05 was considered statistically significant.

Results

The baseline characteristics were similar between both groups (Table 1). Bascom's procedure was performed in 50 patients (44 men and six women, mean age 30 ± 7 years) and the rhomboid flap procedure was performed in the other 50 patients (41 men and nine women, mean age 29.1 ± 4.9 years). The mean duration of symptoms was 12.5 ± 6.7 months in the Bascom's procedure group and 13.9 ± 6.6 months in the rhomboid flap group. Previous infection had occurred in 31 (62%) patients of the Bascom's procedure group and in 33 (66%) patients of the rhomboid flap group. Previous abscess drainage was performed in 18 (36%) patients of the Bascom's procedure group and 15 (30%) patients of the rhomboid flap group.

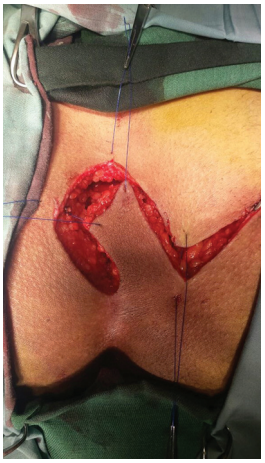
Both groups were comparable in clinical outcome as shown in Table 2. The rhomboid flap procedure involved a longer duration of operation (61.14 ± 16.36 vs. 40.78 ± 11.96 min; $P < 0.001$); however, it resulted in reduced healing time (17.42 ± 4.68 vs. 20.06 ± 5.94; $P < 0.05$). There was an insignificant difference between both procedures in postoperative hospital stay (3.66 ± 1.75 for the rhomboid flap procedure vs. 3.18 ± 1.36 for Bascom's procedure; $P = 0.13$). The follow-up period ranged from 6 to 12 months, with an average of 9.1 ± 1.7 months, which was 9.34 ± 1.80 months after Bascom's procedure and 9.02 ± 1.60 months after the rhomboid flap procedure, with an insignificant difference between both procedures ($P = 0.35$).

There were statistically insignificant differences between both procedures in postoperative complications and recurrence of symptoms during the follow-up period (Table 3). Postoperative wound-related complications (Table 3) occurred in three (6%) after Bascom's procedure and in one (2%) patient underwent the rhomboid flap procedure. After Bascom's procedure,

Table 1 Baseline characteristics

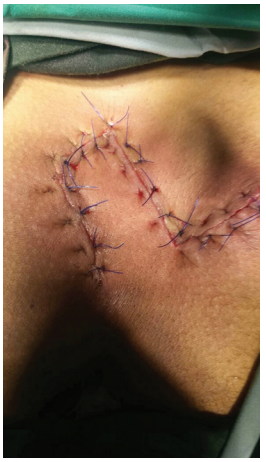
Variables	Bascom's procedure (*n* = 50)	Rhomboid (Limberg) flap (*n* = 50)	*P*-value
Age (years)	30 ± 7	29.1 ± 4.9	0.46
Male/female	44/6	41/9	0.40
Duration of symptoms (months)	12.5 ± 6.7	13.9 ± 6.6	0.27
Previous infection [*n* (%)]	31 (62)	33 (66)	0.68
Previous abscess drainage [*n* (%)]	18 (36)	15 (30)	0.52

Figure 3



The rhomboid flap of limberg before closure.

Figure 4



The rhomboid flap after closure.

Table 2 Clinical outcome

Variables	Bascom's procedure (n = 50)	Rhomboid (Limberg) flap (n = 50)	P-value
Operative time (min)	40.78 ± 11.96	61.14 ± 16.36	0.0001*
Hospital stay (days)	3.18 ± 1.36	3.66 ± 1.75	0.13
Follow-up (months)	9.34 ± 1.80	9.02 ± 1.60	0.35
Healing time (days)	20.06 ± 5.94	17.42 ± 4.68	0.01

**Significant difference.

Table 3 Postoperative complications and recurrence of symptoms

Variables	n (%)		P-value
	Bascom's procedure (n = 50)	Rhomboid (Limberg) flap (n = 50)	
Wound-related complications	3 (6)	1 (2)	0.30
Seroma	1 (2)	0 (0)	0.31
Dehiscence	1 (2)	0 (0)	0.31
Infection	1 (2)	1 (2)	1
Recurrence	2 (4)	1 (2)	0.55

wound-related complications included seroma in one (2%) patient, dehiscence in one (2%) patient, and infection in one (2%) patient, whereas after the rhomboid flap procedure, these complications occurred only in one (2%) patient in the form of wound infection. Of patients subjected to Bascom's procedure, there were two (4%) recurrences, and there was one (2%) recurrence in patients subjected to the rhomboid flap procedure.

Discussion

The ideal treatment for pilonidal sinus remains controversial, with many accepted procedures in current clinical use [12]. Reduction of wound-related complications and recurrence should be the main objectives of any treatment in this respect.

Utilizing the solid concepts of Dr Karydakis' work from the 1970s, Dr John Bascom in Eugene (Oregon, USA) developed a variation of the operation called the cleft lift. Since then, the operation has evolved and improved to its current form. It results in minimal disability and yields good long-term control. In studies of Dr Bascom, the results were satisfactory up to as long as 9 years of follow-up.

With plastic flap surgery, the resulting defective area after wide excision is filled with well-vascularized tissue. Limberg originally introduced his operation (sometimes called Limbegplasty) in 1946, which avoids the suture line tension in addition to flattening of the natal cleft, which most probably are the factors responsible for the low recurrence rates [13,14].

When the rhomboid flap procedure was compared with the Bascom's cleft lift procedure in the present study, the duration of operation was longer for patients who underwent rhomboid-shaped excision with Limberg flap transposition than that for patients who underwent Bascom's procedure. This difference may be attributed to the fact that the Limberg technique required wider tissue from under the postsacral fascia with its fixation to the other side, which takes a longer time for preparation.

In the present study, the incidence of postoperative wound-site complications after Bascom's cleft lift procedure was 6% including seroma, infection, and dehiscence (2% for each). This findings are acceptable as compared with other studies. In the study by Senapati *et al.* [15], there were few postoperative complications, including bleeding in 4% and abscess formation treated by reopening of the incision in 6%. Also, Zorcolo *et al.* [16] reported postoperative complications in 4% of patients who had postoperative bleeding or wound infection.

In the present study, the recurrence rate was 4% after the Bascom's cleft lift procedure during a mean follow-up period of 9.34 ± 1.80 months. Our recurrence rate was comparable with that in the studies in the literature, which varied in relation to the follow-up period. During a mean follow-up of 24 months, Bascom [6] reported a recurrence rate of 8% (four of 50 patients), and then the same author [17] reported a recurrence rate of 16.8% (27 of 161 patients) during a mean follow-up of 42 months. In the study by Mosquera [18], during a mean follow-up of 10.6 months, 7.3% of patients (three of 41 patients) required further surgery for recurrent disease. In the study by Senapati *et al.* [15], during a mean follow-up of 12.1 (range 1–60) months, 10% of patients developed recurrence and needed reoperation. Moreover, Zorcolo *et al.* [16] reported recurrence in 9.2% of patients after Bascom's cleft lift procedure during a mean follow-up of 45 months.

In this study, in the patients subjected to rhomboid-shaped excision with Limberg flap transposition, the rate of postoperative wound-site complications was 2% (only minor wound infection). The reduced incidence of wound-related complications after rhomboid-shaped excision with Limberg flap transposition in this study may be attributed to our protocol of insertion of suction drainage in all patients and the use of prophylactic antibiotics, which help in decreasing the infective complications and seroma formation.

This rate of wound complications is in agreement with other studies in the literature. In a study by Arumugam *et al.* [19], postoperative morbidity involved superficial

wound infection in 13% of patients (seven of 53 patients), which treated with outpatient dressings. Katsoulis *et al.* [20] reported wound complications in 16% (four out of 25 patients) of patients. In the study by Akin *et al.* [14], 2.91% of patients developed a seroma and 3.64% developed wound infection. In 110 patients treated with rhombic excision and Limberg transposition flaps, Aslam *et al.* [21] reported that one (0.9%) patient had minimal necrosis of flap and two (1.8%) had gaping of flap. Minor infection occurred in three (2.7%) patients, but all these complications healed uneventfully. Also, no major wound complications were observed by Müller *et al.* [22], who reported postoperative complications in 25.7% of patients (18 of 70 patients), including superficial infection and partial suture dehiscence. In the study by Osmanoglu and Yetisir [23], the surgical-site infection rate was 4.7%. A lower rate of wound infection of 2% (one of 49 patients) was reported by Okus *et al.* [24].

However, more recent studies showed a wide variation in rates of postoperative wound complications after the classic rhomboid (Limberg) flap procedure, from 1.7% in the study by Khan *et al.* [25] to 17.9% in the study by Karaca *et al.* [26], 19.67% in the study by Guner *et al.* [27], and 20% in the study by Aithal *et al.* [28].

Surprisingly, in contrast to our results and the widely published results of the rhomboid (Limberg) flap, the recent study by Käser *et al.* [29] reported that primary wound closure with a Limberg flap has no advantage over secondary wound healing as it results in a significantly high complication rate of 49%, including seroma (6%), wound dehiscence (45%), skin necrosis (10%), hematoma (6%), infection (4%), and recurrent disease (13%). These authors reported that the main reason for the lack of advantage of the Limberg flap procedure compared with excision only seems to be the rather high complication rate, in addition to several external factors influencing the incapacity for work, such as economic and psychological factors. However, as their study was a randomized-controlled study, Käser *et al.* [29] supposed that it is unlikely that these factors were not evenly distributed in the two groups.

In this study, the recurrence rate was 2% after rhomboid-shaped excision with the Limberg flap during a mean follow-up period of 9.02 ± 1.60 months. This rate is in agreement with that reported in the literature, which ranged from 0% [5,25,28], through 0.9–4% [21–24], up to 7% [19,26].

Patients subjected to rhomboid-shaped excision with Limberg flap transposition in our study showed earlier wound healing than those subjected to Bascom's cleft lift procedure (17.42 ± 4.68 vs. 20.06 ± 5.94 days). This finding indicates that despite being a more extensive procedure, the rhomboid (Limberg) flap technique has the advantage of earlier healing, and this is supported by other findings reported in the literature. The mean healing time reported after Bascom's procedure was 3 weeks in the early studies by Bascom [6,17] and 4 weeks in the study by Senapati *et al.* [15]. However, the mean healing time after the use of the rhomboid (Limberg) flap method was 11.55 (range 10–23) days in the study by Guner *et al.* [27] and 14 days in the study by Arumugam *et al.* [19].

Finally, our results are in agreement with those of Enshaei and Motearefi [30], who compared two methods of primary repair and rotation flap and concluded that each surgeon can select the appropriate method of surgery for chronic pilonidal sinus according to the type and size of the sinuses, occupational status and social class, and the personality and individuality of the patient.

In conclusion, in this study of the treatment of primary SCPS, although Bascom's cleft lift operation was associated with a shorter duration of operation, the use of the rhomboid flap (rhomboid excision and Limberg flap transposition) was associated with early healing time. The incidences of wound related complications and recurrence were similar between both procedures.

Acknowledgements

Conflicts of interest

None declared.

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Evaluation of an enhanced recovery program for elective open colorectal cancer surgery

Mohamed I. Abdel-Aziz[a], Yasser Hatata[a], Maged L. Bolous[b]

Departments of [a]General Surgery, [b]Anesthesia and Pain Management, Fayoum University Hospitals, El Fayoum, Egypt

Correspondence to Mohamed I. Abdel-Aziz, MD, Department of General Surgery, Fayoum Unviersity Hospitals, El Fayoum, Egypt
Tel: +20 100 266 2279; fax: +20846360583;
e-mail: mohamedibrahim555@hotmail.com

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Background
Traditional colorectal surgeries usually require a relatively long hospital stay of around 12 days. Inadequate pain control, intestinal dysfunction, and immobilization are the main factors associated with delay in recovery. Fast track or enhanced recovery colorectal protocols have been used to optimize the perioperative care and to enhance postoperative recovery.

Objectives
This study aimed to determine the outcome of an enhanced recovery program for selected patients with colorectal malignancies subjected to elective surgery.

Methodology
This prospective study was carried out at Fayoum University Hospital from 2008 to 2013 and included 32 patients with colorectal cancer who had undergone elective open colorectal surgeries on the basis of the fast-track protocol. Hospital stay, perioperative morbidity, and mortality data were collected, analyzed, and recorded. All patients were followed up for 24 months.

Results
The mean (±SD) age of the patients was 48.2 ± 5.3 years; 22 patients were men and 10 were women. According to the ASA score, 34.4% of the patients were 1 and 65.6% were 2; 40.6% underwent low anterior resection, 34.4% underwent sigmoidectomy, and 25% underwent right hemicolectomy. The mean (±SD) length of postoperative hospital stay was 3.56 ± 0.24 days. There was no mortality and the overall morbidity rate was 25%; 3.1% of patients developed a wound infection, 3.1% of patients developed abdominal wall dehiscence, 15.6% of patients had persistent vomiting, and one patient (3.1%) required readmission and resurgery to manage anastomotic leakage and peritonitis.

Conclusion
An enhanced recovery program for elective colorectal cancer surgery has a very good impact on postoperative recovery as it shortens the length of hospital stay with high safety and good patient compliance; thus, we strongly recommend the application of such protocols, provided that there is availability of well-trained and adequately experienced personnel in equipped centers.

Keywords:
colorectal, early recovery epidural, enhanced recovery after surgery

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Introduction

Colorectal cancer is one of the most commonly diagnosed cancers in both men and women [1]. Surgery, which is still the first-line treatment, remains a high-risk procedure with clinically significant postoperative stress, complications (8–20%), and a lengthy postoperative hospital stay (average 8–12 days) [2]. This necessitate changes to the management policy of colorectal cancer [3], and hence the idea of fast-track surgery emerged, which is considered, by some authors, the most important innovation after the advent of laparoscopy (by Fowler and White [4] in the 1990s for colorectal surgeries) in the field of colorectal surgery as in other fields of surgery [5]. Fast-track surgery or enhanced recovery after surgery (ERAS) or multimodal surgery is defined as a multimodal pathway aiming to reduce surgical stress through a global package of preoperative, operative, and postoperative techniques, which, in aggregate, result in fewer complications, reduction in and the length of hospital stay, better recovery, and quicker return to work and normal activities [6].

The principles of ERAS were first introduced by Professor Henrik Kehlet [7] in 1997 when he delineated the undesirable sequelae of major surgeries to the surgical stress response and he believed that a multimodal intervention can lead to a major reduction

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in such sequelae with improved recovery and reduction in postoperative morbidity and the overall costs. Four years later, Wilmore and Kehlet [8] was the first to coin the term fast-track surgery, which was originally related primarily to pain and length of hospital stay, and then evolved to mean different things to different parties. In a short period of time, ERAS has rapidly gained popularity worldwide [5]. Kehlet and Wilmore [9] concluded that the key factors that keep a patient in hospital include the need for parenteral analgesia (persistent pain), intravenous fluids (persistent gut dysfunction), and bed rest (persistent lack of mobility). Therefore, he described a clinical pathway based on optimal pain control, stress reduction with regional anesthesia, early enteral nutrition, and early mobilization.

ERAS Program Components include preoperative, intraoperative, and postoperative strategies combined to form a multimodal pathway.

Preoperative

Preadmission care

To optimize comorbidities (such as anemia, hypertension, or diabetes), cessation of smoking and alcohol intake and adequate education of the patient and his/her family are essential [10].

Preoperative measures

No prolonged preoperative fasting was needed, only for 2 hours for fluids and 6 h for solids [11]. Nondiabetic patients received carbohydrate loading on the day before surgery and 2 h before induction of anesthesia [12,13]. No mechanical bowel preparation was required as it could have caused dehydration, and fluid and electrolyte abnormalities [14]. No sedatives were allowed from the day before surgery [15].

Intraoperative

Maintenance of normothermia is mandatory to prevent coagulopathy, adverse cardiac events, and decreased resistance to wound infection [15]. Postoperative ileus was prevented by avoidance of fluid overload and adequate pain control [14,16]. A minimally invasive surgical approach by laparoscopy or transverse incision was used [17]. Fluid restriction is essential with care to avoid hypovolemia [18,19]. A nasogastric tube should be inserted only if ileus develops [20,21]. Drains are avoided as there is no evidence of a beneficial effect in reducing postoperative morbidity [22,23]. The use of epidural anesthesia and analgesia with infiltration of local anesthetics around a surgical incision should be a part of all fast-track protocols [15,24].

Postoperative

Overhydration should be prevented with discontinuation of intravenous fluid therapy as soon as possible with early commencement of enteral feeding [15]. Excellent epidural analgesia is very important with intravenous paracetamol and/or NSAIDs if needed, but opioids should be avoided [25]. Prevention of postoperative nausea and vomiting (PONV) through good perioperative oxygenation, use of prokinetics, antiemetics, β-blockers and dexamethasone, adequate pain control, and no opioids is believed to be effective by some authors in controlling PONV [6,26]. Early oral nutrition should be encouraged as early as possible [25]. Early removal of urinary catheters should be performed as the majority of patients can tolerate its removal on the first postoperative day [26–28]. Postoperative laxatives (oral or rectal) encourage earlier return of bowel function and reduce the incidence of postoperative ileus [29,30]. Early mobilization is the key element of ERAS in colorectal surgery, where a patient should be out of bed for at least 2 h on the day of surgery and 6 h thereafter [31]. Early discharge can be performed when the discharge criteria (e.g. good mobilization, adequate oral intake, no complications) have been fulfilled, followed by a daily telephone call by a well-trained nurse and the first outpatient visit 10–14 days after discharge [15].

Aim of this study

This study aimed to evaluate the outcome of the ERAS program in patients with colorectal cancer who were planned for elective surgeries.

Patients and methods

Study design

This study was designed as a prospective single-center study, which was carried out at the department of general surgery at Fayoum University Hospital during the period from April 2008 to June 2013 and included 32 patients with colorectal cancer who were subjected to surgery on the basis of the ERAS program. The ERAS used in our study was designed by the authors on the basis of published protocols [2,8,9,26]. For all the patients, full assessment of history, detailed clinical examination, and the investigations required were performed; a fully detailed written consent was obtained from every patient individually.

Inclusion criteria: 18 years of age or older, able to understand the requirements of the study, and able to provide adequate informed consent with an adult

responsible caretaker, diagnosed with uncomplicated colorectal cancer for elective surgery without the need for a stoma or any further surgical procedure, and no uncontrolled comorbidity with good general fitness, with an American Society of Anesthesiologists (ASA) score 1 or 2 (Table 1).

Our ERAS program

Preoperative care

All patients were admitted to the hospital 1 day before surgery to ensure that the preoperative measures were adhered to:

(1) Preoperative counseling and education were provided for each patient and his/her caretaker to reduce fear and anxiety, and included complete information on ERAS, its aim, and possible complications divided into four stages; the first stage refers to the period up to the surgery, the second stage refers to the day of surgery, the third stage is the recovery period after surgery up until discharge, and the fourth stage is post-discharge care and follow-up.
(2) Optimization of medical status of the patient by correction of any comorbidity.
(3) No mechanical bowel preparation apart from 120 ml single enema on the night before surgery only for patients with rectal cancer.
(4) No preoperative fasting; intake of clear fluids was allowed 2 h and solids 6 h before induction of anesthesia.
(5) Carbohydrate loading: (except for diabetic patients) 200 ml of fresh apple juice sweetened with three teaspoons of sugar (provides 167 kcal) was provided four to six times on the day before surgery and two times on the morning of the surgery.
(6) Prophylaxis against venous thromboembolism was administered using elastic compression stockings and low-molecular-weight heparin (enoxaparin 1 mg/kg/day subcutaneously) starting from the night before surgery until discharge.
(7) Preanesthetic medications: a β-blocker (50 mg atenolol oral tablet/day) was used; the first dose was administered 24 h before surgery and the second dose was administered on the morning of surgery and continued until discharge. Ultrashort benzodiazepines (midazolam 20 mg/kg intravenously), at a single dose, were administered the night before the surgery.

Table 1 American Society of Anesthesiologists classification [32]

ASA category	Preoperative health status	Examples
ASA 1	Normal healthy patient	No organic, physiologic, or psychiatric disturbance
ASA 2	Patients with mild systemic disease	Controlled hypertension or diabetes without systemic effects
ASA 3	Patients with severe systemic disease	Controlled congestive heart failure
ASA 4	Patients with severe systemic life-threatening disease	Unstable angina or symptomatic congestive heart failure
ASA 5	Patient not expected to survive 24 h without surgery	Multiorgan failure or systemic sepsis with hemodynamic instability
ASA 6	A brain-dead patient	

ASA, American society of anesthesiologists.

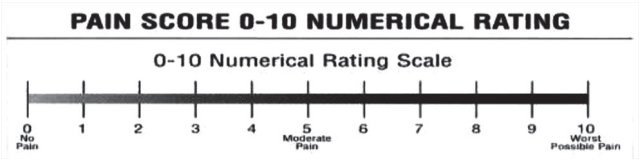
Intraoperative care

(1) Antibiotic prophylaxis was administered by a single dose of third-generation cephalosporins (ceftriaxone 2 g intravenously) at the time of induction of anesthesia together with an intravenous infusion of 1000 mg metronidazole.
(2) Anesthesia: combined thoracic epidural and general anesthesia was administered. Midazolam 1–2 mg intravenous was administered for anxious patients before placing the epidural catheter at T9–T10 or T10–T11 with administration of 6–12 ml of ropivacaine 0.2%; general anesthesia was induced with fentanyl and propofol using atracurium for curarization and sevofluorane in O_2/air to maintain anesthesia. The ventilation was set previously and adjusted during the operation with capnometric monitoring ($PetCO_2$ 32–38 mmHg). Finally, neostigmine was used at the end of the operation to antagonize the curarization.
(3) Transverse abdominal incisions were performed for all patients.
(4) Adequate intraoperative oxygenation was ensured.
(5) Intraoperative normothermia was maintained using an electric heating blanket applied on the thorax and the upper limbs and in the recovery room on the entire body.
(6) Intraoperative restriction of intravenous fluids usually to 1000–2000 ml of lactated Ringer.
(7) Close monitoring of blood sugar was performed, with tight glycemic control in diabetic patients.
(8) No nasogastric tubes were inserted.
(9) No drains were placed, except in patients with rectal cancer, where short-term drains were placed and removed after 24 h.
(10) Urinary catheters were removed at the end of surgery before transfer to the recovery room.
(11) Local anesthetic infiltration of the wound was performed using 20 ml of ropivacaine 0.5% plus 1 mg adrenaline 1 : 1000.

Postoperative care

(1) Postoperative multimodal pain control: Epidural analgesia was administered with morphine 0.5–1 mg and ropivacaine 0.2% in a bolus of 5 ml, followed by maintenance with morphine 0.04 mg/ml as 2 ml/2 h with orbivacaine 0.2% as 3 ml/2 h. The postoperative pain was monitored according to the Numerical Pain Rating Score (NPRS). In case of insufficient analgesia, an intravenous infusion of paracetamol 1 g was administered (up to three doses per day) and/or an intramuscular or an intravenous infusion of NSAIDS (diclofenac sodium 75 mg/3 ml) (up to three doses per day). This multimodal regimen was enough to achieve good pain control in most of our patients. The epidural catheter was removed on the third postoperative day for all patients.
(2) PONV were prevented by administration of ondansetron 8 mg/12 h intravenously, metoclopramide 10 mg intravenously/12 h, and dexamethasone 8 mg intramuscularly/24 days and atenolol 50 mg tablet/24 h. This regimen was followed for all patients starting immediately after surgery for 2–3 days when regular adequate oral nutrition was achieved with comfort.
(3) Postoperative ileus was prevented by ensuring good analgesia, oral laxatives (30 ml bisacodyl syrup) 4 h after surgery and after 12 h, and proper postoperative fluid intake that maintained urine output not less than 0.5 ml/kg/h without subsequent weight gain.
(4) Tight glycemic control was ensured, especially for diabetic patients, to prevent hyperglycemia through continuous monitoring of blood sugar every 2 h, with insulin therapy accordingly.
(5) Early oral nutrition: on the day of surgery and immediately after complete restoration of consciousness, all patients were advised to start chewing gum; 2 h later, all patients started oral intake with 50 ml apple juice every 2 h. If there was no vomiting after two drinks, we continued administration of fluids, average 500–1000 ml per day, and on the first postoperative day, patients started semisolids (jelly, low-fat yoghurt, and pudding) and small amounts of animal protein as small meals every 4 h, with an average fluid intake of 1000–1500 ml per day, and a high-protein diet from the second postoperative day and thereafter as three regular meals, with three snacks in between.
(6) Early mobilization was started 4–8 after surgery for at least 2 h with assistance on the day of surgery and 4–6 h/day independently from the first postoperative day thereafter (Figure 1).

Figure 1



Numerical Pain Rating Score [33].

Discharge and follow-up

Patients with colonic cancer (right colectomy and sigmoidectomy) were discharged on the third postoperative day, whereas patients with rectal and rectosigmoid cancer (low anterior resection) were discharged on the fourth postoperative day, provided that the patient was not in pain, could eat and drink comfortably, could walk freely, had good gastrointestinal motion, had normal urinary function, no wound infection, and no fever. We asked patients how satisfied they were with ERAS. Complete information on possible complications, wound care, maintenance of adequate nutrition, and adequate mobilization was also provided on discharge and this was followed up after the patient returned home through phone calls from the surgical nurse every 48 h for 10 days. The first follow-up visit at the outpatient clinic was scheduled 2 weeks after discharge and the second follow-up after one month, where we asked about pain, complications, fluid and food intake, and daily activities; moreover, a careful clinical examination was performed to detect any possible complications and body weight was measured to assess nutritional status. Then, the follow-up was scheduled every 3 months for 2 years and every 6 months thereafter.

Data on age, sex, diagnosis, surgical procedure, perioperative morbidity and mortality, length of hospital stay, independent mobilization, postoperative pain, sleep quality, and the degree of patient satisfaction were recorded and analyzed as mean ± SD, range, and percentage.

Results

Thirty-two patients were included in this study who initially fulfilled our inclusion criteria. Patient characteristics, tumor locations, and surgical procedures are presented in Table 2. The mean age (±SD) of the patients was 48.2 ± 5.3 years; 22 patients (68.8%) were men and 10 patients (31.2) were women. According to the ASA classification, 34.4% of patients were ASA 1 and 65.6% were ASA 2. All the patients underwent open surgery through a transverse laparotomy incision. 11 patients (34.4%) had carcinoma of the sigmoid

colon, eight patients (25%) had carcinoma of the rectosigmoid junction, eight patients (25%) had carcinoma of the right colon, and five patients (15.6%) had carcinoma of the upper one-third of the rectum. Low anterior resection made up the majority of surgical procedures, performed in 13 patients (40.6%), followed by sigmoidectomy in 11 patients (34.4%) and right hemicolectomy in eight patients (25%). No stomas were performed in any of the patients.

The mean duration of surgery was 142.4 ± 13.6 min, with no intraoperative complications. The mean time spent in the recovery room before transfer to the ward was 159.4 ± 25.4 min; all patients were transferred to the ward and none of them needed intensive care unit admission. The overall morbidity rate was 25% (eight patients), (Table 3); one patient (3.1%) developed a moderate superficial wound infection on the fifth postoperative day (after right hemicolectomy) 2 days after discharge and was treated with repeated dressing and a systemic antibiotic at home, with complete cure after 1 week. Another patient (3.1%) developed partial abdominal wall dehiscence on the fourth postoperative day (after low anterior resection for upper rectal cancer) the day discharge was planned; the patient was reoperated. The wound was closed with secondary tension sutures and systemic antibiotics were administered. The patient was advised to remain at the hospital for 3 more days after the second surgery; persistence of PONV for 24 h was observed in five patients (15.6%) that necessitated cessation of oral intake and use of antiemetic and prokinetic drugs such as ondansetron 16 mg intravenously/12 h and metoclopramide 10 mg intravenously/8 h, dexamethasone 8 mg/12 h, and intravenous fluids (1500 ml lactated ringer and 500 ml dextrose 10%). This regimen was successful for the treatment of PONV after 24 h in four patients (80%) and after 48 h in one patient (20%), with restoration of oral intake and discharge on time in three patients (60%) and 1 day later in two patients (40%) (the last two patients underwent low anterior resection for high rectal cancer). Finally, one patient (3.1%) required readmission and resurgery to manage anastomotic leakage and peritonitis that presented 6 days after surgery (2 days after discharge after low anterior resection for rectosigmoid carcinoma), where the patient underwent peritoneal lavage (which is the usual management in peritonitis) with closure of the rectal stump and left colon colostomy on the anterior abdominal wall. Postoperative management included close monitoring with parenteral antibiotics, intravenous fluid therapy, proton pump inhibitors, and NSAIDs, with nothing per oral for 3 days, after which oral intake was started gradually. Fortunately, this patient was discharged after 1 week in good general health and restoration of gut continuity was performed after 6 months.

In our study, the 30-day readmission rate was 3.1% and no postoperative mortality was encountered.

The mean (±SD) total postoperative hospital stay for all patients including primary admission-related and readmission-related days was 3.78 ± 0.25 days, whereas without readmission days was 3.56 ± 0.24 days. The mean (±SD) POHS in patients who underwent right colectomy and sigmoid colectomy was 3.15 ± 0.21 days, which was significantly shorter than postoperative hospital stay (POHS) in patients who underwent low anterior resection, which was 4.69 ± 0.27, with a *P* value = 0.01 (statistically significant) (Table 4).

The postoperative pain according to the NPRS was 3 in 25 patients (78.2%) and 4 in seven patients (21.8%) on the day of surgery, 3 in 27 patients (83.4%), and 4 in five patients (15.6%) on the first postoperative day, 2 in 23 patients (71.9%), 3 in eight patients (25%), and 4 in one patient (3.1%) on the second postoperative day, 2 in 29 patients (90.6%) and 3 in three patients (9.4%); on the day of discharge, NPRS was 2 in 28 patients (87.5%) and 3 in four patients (12.5%). During the first week after discharge, pain control was satisfactory, with a maximum NPRS of 2 at the first follow-up visit (Table 5).

Table 2 Patient characteristics, tumor locations, and surgical procedures

Variables (*n* = 32)	Value
Age (mean ± SD) (years)	48.2 ± 5.3
Sex [*n* (%)]	
Males	22 (68.8)
Females	10 (31.2)
ASA classification [*n* (%)]	
ASA 1	11 (34.4)
ASA 2	21 (65.6)
Location of the tumor [*n* (%)]	
Upper rectum	5 (15.6)
Rectosigmoid junction	8 (25)
Sigmoid colon	11 (34.4)
Right colon	8 (25)
Surgical procedure [*n* (%)]	
Low anterior resection	13 (40.6)
Sigmoidectomy	11 (34.4)
Right hemicolectomy	8 (25)

ASA, American society of anesthesiologists.

Table 3 Postoperative morbidity and mortality

Complications	Value [*n* (%)]
Mortality	0
Morbidity	8 (25)
Wound infection	1 (3.1)
Abdominal wall dehiscence	1 (3.1)
PONV	5 (15.6)
Anastomotic leakage	1 (3.1)

PONV, postoperative nausea and vomiting.

The first bowel movement occurred after a mean (±SD) of 23.1 ± 4.3 h after surgery. Patient satisfaction was excellent in 13 patients (40.7%), good in 12 patients (37.5%), acceptable in four patients (12.5%), poor in one patient (3.1%), and two patients (6.2%) provided no answer, with an overall rate of patient satisfaction of about 90.7%.

Discussion

The application of ERAS protocols in patients undergoing colorectal surgery, whether open or laparoscopic, positively affects the postoperative outcome [34]. The expanding evidence-based medicine shows that the ERAS program benefits not only all patients but also the health service [15].

The present study is the first application of an ERAS protocol at our hospital and aimed at assessing the possibility of its introduction into our clinical practice as the results presented in our study provide new evidence supporting the feasibility and safety of the ERAS program in the colorectal surgery.

It is worth mentioning that one of the most difficult challenges that we faced in this study is the collision with some deep-seated beliefs in the minds of patients who underwent abdominal surgery especially cancer, and it was extremely difficult to change such beliefs completely (e.g. early mobilization and keeping the patient out of bed shortly after surgery, early oral intake and early discharge), but fortunately we have succeeded to do our mission to a very good extent.

Table 4 Postoperative hospital stay (mean ± SD)

POHS (mean ± SD)	Value (days)
Total POHS with readmission days	3.78 ± 0.25
Total POHS without readmission days	3.56 ± 0.24
POHS in patients underwent colectomy	3.15 ± 0.21
POHS in patients underwent low anterior resection	
Without readmission days	4.15 ± 0.23
With readmission days	4.69 ± 0.27

Table 5 Postoperative pain control

Time	Numerical pain rating scale	Number of patients (%)
Day of surgery	3	25 (78.2)
	4	7 (21.8)
First postoperative day	3	27 (83.4)
	4	5 (15.6)
Second postoperative day	2	23 (71.9)
	3	8 (25)
	4	1 (3.1)
Third postoperative day	2	29 (90.6)
	3	3 (9.4)
On discharge	2	28 (87.5)
	3	4 (12.5)
At the first follow-up visit (1 week after discharge)	1	14 (43.75)
	2	18 (56.25)

Early postoperative mobilization is important in accelerated recovery, to reduce insulin resistance and the risk of thromboembolic complications, undesired muscle loss, and fatigue, and improve pulmonary function and tissue oxygenation [9]. In the present study, early mobilization was started for all patients on the same day of surgery (4–8 h after surgery) with assistance on an average of 2 h/day and for 4–6 h/day independently from the first postoperative day; this rate is slightly lower than that reported by some authors, who recommended earlier mobilization within 2 h or less after surgery and for longer periods (4 h in the day of surgery and 6–8 h/day thereafter) [25,35].

The first oral intake was started 2 h after complete restoration of consciousness and full orientation, which was usually achieved 2–4 h after surgery with about 1000 ml clear fluids (apple juice) divided into 50 ml/30 min on the day of surgery; some studies have reported that patients resumed a liquid diet 2 h after surgery and began to take a protein supplement orally 4 h later [36,37]. On the first postoperative day, we fed patients semisolids and small amounts of animal protein (50 mg) as a small meal every 4 h, with an average fluid intake of 1000–1500 ml per day, and from the second postoperative day, high-protein diets were provided as three regular meals, with three snacks in between. Frontera *et al.* [35] recommended only water for the patients on the first day, a liquid diet on the second day, a half liquid diet on the third day, and a solid diet on the fourth day, whereas some authors recommend a free diet from the first postoperative day [37].

Because fluid restriction is believed to enhance mobilization and recovery and reduce the complication rates [15], the patients in our study group received less intravenous fluid (total fluid intake both oral and intravenous should be around 1500 ml/day).

Our study found a mean postoperative hospital stay of 3.78 days with readmission and 3.56 days without readmission. A total of 18 patients (56.3%) were discharged on the third postoperative day, 11 patients (34.4%) were discharged on the fourth day, two patients (6.2%) were discharged on the fifth day to control PONV, and one patient (3.1%) was discharged 1 week after surgery because of reoperation to repair partial abdominal wall dehiscence. The mean postoperative hospital stay varies markedly in many studies: 2.44 days in the study by Zhuang *et al.* [38], 2.6 days in the study by Jakobsen *et al.* [25], 4 days in the study by Mohn *et al.* [39], 4.57 days in the study by Bona *et al.* [37],

and as high as 6 days in the study by Ramírez *et al.* [36] or even 6.9 days in the study by Frontera *et al.* [35].

Our 30-day readmission rate was 3.1%, which is in agreement with that of many studies that have reported rates ranging from 2.7 to 8.7% [31,36,37], and significantly lower than that reported in the study by Mohn *et al.* [39], in which the rate was 15%. Thus, some believe that the fast-track surgery will not reduce the readmission rate and consider readmission an adverse effect that reflects low medical quality [40,41]; however, others believe that it is because of a low threshold for readmission after accelerated discharge, which is a sign of quality and ensures the safety of patients [39].

The overall postoperative morbidity rate in the literature shows a wide range from 12.5 to 31% [31,36,38,39]; we recorded an overall complication rate of 25% (eight patients). The most common complication that we encountered was PONV in five patients (15.6%), which resulted in a delayed discharge of two patients (6.2%) 24 h beyond the planned time; this rate of PONA is consistent with that found in many of the studies, ranging from 4.3 to 13.8% [31,35,36,39], whereas currently there is no consensus on the exact regimen to prevent PONV. However, we believe that the use of a multimodal approach with prokinetic and antiemetic drugs (ondansetron 8 mg/12 h and metoclopramide 10 mg/12), β-blockers (atenolol 50 mg/day), excellent pain control, and opioid avoidance are the cornerstones to control PONV. β-Blockers are very effective for controlling transient acute autonomic responses to noxious surgical stimuli [26].

In our study, one patient (3.1%) developed wound infection, one patient (3.1%) had anastomotic leak with peritonitis, and one (3.1%) patient developed abdominal wound dehiscence, which is in agreement with the results reported in many studies [31,35,36].

For our patients, we did not carry out the traditional intestinal preparation because mechanical bowel preparation for colorectal surgeries has recently been the subject of considerable debate [42] as it was found that the use of polyethelyne glycol or sodium phosphate could negatively affect early postoperative healing and recovery [43].

Many recent studies do not recommend preoperative absolute fasting to avoid postoperative nitrogen and protein losses [44,45]; moreover, on providing a clear carbohydrate-rich drink 2 h before surgery, patients can undergo surgery in a metabolically fed state with a reduction in the prevalence of preoperative thirst, hunger, anxiety, and the endocrine catabolic response; it also improves insulin resistance, yielding better surgical results and hastening recovery [9,44]. Therefore, we gave our patients carbohydrate-rich drinks (sweetened apple juice) 1 day before surgery and on the morning of the surgery.

Effective analgesia is a prerequisite to decrease surgical stress response and to enhance mobilization [46]; continuous epidural analgesia has been considered beneficial in major open abdominal procedures not only to control pain but also to decrease catabolism, paralytic ileus, nausea, and vomiting [47].

Epidural analgesia was therefore used in all patients in this study, in addition to paracetamol 1000 mg/8 h for 15 patients (46.89%) on the day of surgery, paracetamol 1000 mg/8 h and NSAID (dicofenac 100 mg/12 h) for 17 patients (53.1%) on the first postoperative day, paracetamol 500 mg/8 h and diclofenac 75 mg/12 h for 10 patients (31.25%) on the second postoperative day, and paracetamol 500/8 h or diclofenac 75 mg/8 h for five patients (15.6%) on the third postoperative day. On discharge, we administered diclofenac 75 mg/12 h alternating with paracetamol 1000 mg/12 h (e.g. diclofenac at 8 a.m. and 8 p.m. and paracetamol at 2 p.m. and 2 a.m.) for 1 week for all patients. Still, we believe that further studies are needed to define optimal procedure-specific analgesia in enhanced recovery after colorectal surgery.

Conclusion

There is now extensive evidence that enhanced recovery programs aid the recovery of colorectal patients, and are also useful for clinicians and healthcare systems. A well-run program reduces the physiological response to the tissue insult from surgery and as a result there is less postoperative pain, fewer complications, a shorter hospital stay, and faster recovery and return to work. The practice of ERAS should be encouraged in both laparoscopic and open surgery. Therefore, we strongly recommend the application of such protocols, provided that these are carried out in well-equipped hospitals with very well-trained and adequately experienced personnel.

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Conflicts of interest

There are no conflicts of interest.

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Three-year experience of laparoscopic greater curvature plication in the treatment of morbid obesity

Mohamed Samir, Yasser Ahmed, Mohamed Ibrahim

Department of Clinical and Experimental Surgery, Medical Research Institute, University of Alexandria, Alexandria, Egypt

Correspondence Mohamed Samir Kamel, MD, MRCS, Surgical Department, Medical Research Institute, Alexandria University, 165 Horreya Street, Ibrahimeya, Alexandria, Egypt
Tel: 034297621, 034282373;
e-mail: mohamedsamir12@yahoo.com

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Background
Laparoscopic greater curvature plication (LGCP) is a new restrictive bariatric procedure. The aim of the present study is to report the outcome of LGCP in 40 morbidly obese patients over a period of 3 years of follow-up.

Patients and methods
All procedures were completed laparoscopically. The mean operative time was 123.5 min (85–200 min) and the mean duration of hospital stay was 1.1 days (1–3 days). No intraoperative complications were reported. The mean excess weight loss was 34.93 ± 19.85% at the end of the study.

Conclusion
LGCP is feasible and safe when applied to morbidly obese patients, but it has an unsustainable effect on weight loss.

Keywords:
gastric placation, laparoscopic, morbid obesity

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Introduction

The prevalence of obesity continues to increase worldwide at an alarming rate. A very high rate of obesity has been reported among Egyptians, especially among hypertensive Egyptian women, with an age-adjusted prevalence rate of 48.8% [1].

Gastric plication is a new restrictive bariatric procedure initially proposed by Tretbar *et al.* [2] and Wilkinson and Peloso [3]. Laparoscopic greater curvature plication (LGCP) was subsequently developed and introduced by Talebpour and Amoli [4].

In LGCP, the gastric wall is infolded to reduce the gastric capacity. It is performed without banding, partitioning, or transection of the gastrointestinal tract; instead, the reconfigured stomach is stabilized with sutures applied in multiple longitudinal rows. LGCP has resulted in minimal anatomic disruption and few complications.

The aim of this study is to report the effectiveness of this new procedure in terms of weight loss and morbidity in 40 morbidly obese patients over a period of 3 years of follow-up.

Patients and methods

All patients gave their formal consent. The protocol was approved the Ethical committee of the Alexandria university.

The patients' inclusion was according to the US National Institute of Health criteria for bariatric surgery [5].

Patients had to understand the risks, benefits, alternatives, necessary lifestyle changes, and expected outcomes.

Patients who did not fulfill the National Institute of Health criteria as well as patients who had undergone previous obesity surgery or extensive abdominal surgery or sweet eater were excluded.

All patients were subjected to the following: complete assessment of history including age of onset of obesity, dietary habits, previous attempts at weight reduction, and history of obesity comorbidity, clinical examination, and laboratory investigations including hormonal profile, and cortisol and thyroid profile.

Operative data of all patients were recorded including duration of the procedure, intraoperative complications, associated procedure, and cause of conversion if any.

Postoperative work-up included the following:

(1) Recording of postoperative complications, in the beginning and at the end of the study.
(2) Effect of operation on weight loss calculated at 1, 2, and at 3 years postoperatively in the form of:
    (a) Percentage of excess BMI loss (%EBMIL) calculated using the formula: (operative BMI–follow-up BMI)×100/(operative BMI–25).

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(b) Percentage of excess weight loss (%EWL) calculated using the formula: [(operative–follow-up weight)/operative excess weight]×100.

Surgical procedure

All surgical procedures took were performed under general anesthesia after administration of epidural analgesia and placement of pressure garments on both lower limbs. Low-molecular-weight heparin was administered 12 h before surgery; the procedure was performed in the French position. Pneumoperitoneum was achieved under vision using a five-trocar port technique. We started dissection of the greater omentum 4–6 cm from the pylorus. Dissection was performed using a harmonic scalpel (Ethicon Endo-Surgery Inc., 4545 Creek Creek Road, Cincinnati, OH 45242, USA) till the angle of His with complete mobilization of the fundus. The next step was to initiate gastric plication by imbricating the greater curvature over a 36 Fr bougie and applying a first row of interrupted stitches of 2-0 Ethibond (Ethicon Inc., Somerville, New Jersey, USA) sutures. This row guided another row created with a running suture line of 2-0 Prolene (Ethicon Inc.) or Ethibond. Intra-abdominal drains and gastrografin meal were performed optionally. In the postoperative period, patients were discharged as soon as they could be on a liquid diet without vomiting and received a prescription of a daily proton-pump inhibitor for 30 days. The postoperative diet was under the supervision of dietitian. Endoscopic evaluation was performed after 1 month in the first 10 cases.

Postoperative work-up included the following:

(1) Recording of postoperative complications in the beginning and at the end of the study.
(2) Effect of operation on weight loss calculated at 6 months and in the first, second, and third year of the study in the form of:
    (a) %EBMIL calculated using the formula: (operative BMI–follow-up BMI)×100/(operative BMI–25).
    (b) %EWL calculated using the formula: [(operative–follow-up weight)/operative excess weight]×100.
(3) Improvement or resolution of comorbidity and effect of operation on quality of life (QoL) was assessed using Moorehead–Ardelt Quality of Life Questionnaire II (MA QoLQII) [6]. Six items were used to measure a patient's subjective impression of QoL in the areas of:
    (a) General self-esteem,
    (b) Physical activity,
    (c) Social contacts,
    (d) Satisfaction in terms of work,
    (e) Pleasure related to sexuality, and
    (f) Eating behavior.

    All patients answered the questionnaire preoperatively and at the end of the study.
(4) Evaluation of gastric plication using 'updated BAROS' [7], which included analysis of weight loss, improvements in obesity comorbidities, and changes in QoL. This scoring system analyzes these three domains, assigning each of three or more points. The final score classifies the results into five outcome groups, from failure to excellent, establishing an objective definition of success (Fig. 1).

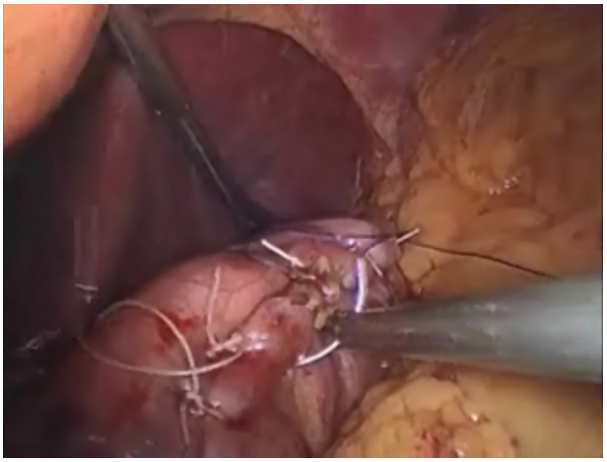
Statistical analysis

Statistical analysis was carried out using IBM SPSS, version 20 (PASW Statistics for windows, Chicago, SPSS Inc. USA).

Quantitative variables such as age, BMI, and weight were summarized by mean and median as measures of central tendency and SD, minimum, and maximum as measures of dispersion, whereas categorical variables were sex and preoperative eating.

Repeated-measure analysis of variance test was used to study whether there was a statistically significant difference in the mean weight, EWL, BMI, and BMI loss preoperatively, and 1, 2, and at 3 years postoperatively. The Mauchly test of sphericity was used to study the homogeneity of variance along different measures and the Greenhouse–Geisser test was also used. Post-hoc tests were used for pairwise comparisons for significant results. A parametric test was used because of the large sample size (>30) in each condition.

Figure 1



Second layer of plication.

All statistical tests were considered at a 0.05 significance level.

Results

Forty patients were included in this study, 34 women (85%) and six men (15%). Their age ranged from 18 to 50 years, with a mean of 34.26 ± 9.38 years. Majority of patients were in the third and fourth decades of life (47.6%). In all, 28 patients (70%) were obese from childhood, whereas 12 patients (30%) developed obesity in adulthood. In all, 26 patients (65%) were married (Table 1). The duration of follow-up ranged from 20 to 36 months, with a mean of 29.74 ± 3.73 months.

No conversion occurred in any of the 40 patients. The total operative time ranged from 85 to 200 min, with a mean of 123.45 ± 33.065 min, and patients' hospital stay ranged from 1 to 3 days, with a mean of 1.1 ± .37 days (Table 2). However, one female patient complained of frequent vomiting and underwent upper gastrointestinal endoscopy 1 week postoperatively; it was found that excess narrowing was present at the level of the gastric cardia and endoscopic relocation of mucosal fold was performed successively. The patient became well.

Intraoperative complications

In two female patients, there was excessive bleeding from the pancreatic surface during dissection of posterior adhesion between the posterior gastric wall and the pancreas, and this was controlled successively. None of the other 40 patients had major intraoperative complications.

Postoperative complications

None of the patients had major early medical complications (e.g. deep vein thrombosis, pneumonia, lung atelecatsis, pulmonary embolism, etc.), but two of our patients had to be reoperated in the first week because of leak from herniated fundus between sutures.

The first patient was a 46-year-old man with a BMI of 41 with controlled hypertension and the other patient was a 38-year-old woman with a BMI of 45 with no comorbidities.

(1) The female patient presented on day 2 with severe upper abdominal pain and fever; computed tomography indicated herniation of the fundus through the cardia with minimal leakage of dye and minimal collection left subphrenic.
(2) The male patient presented 1 week postoperatively with persistent fever, abdominal distension, and tachypnea. Computed tomography indicated supphrenic collection, left pleural effusion, pelvic collection, and leaking dye. Our male patient underwent repair of leak and reinvagination of the fundus. In the other patient, after reduction of the fundus from curra, the fundus was unhealthy and was excised by a stapler and layer reinforcement was performed for the suture line.
(3) Both of them lost weight satisfactorily during the first year; after that, the woman stopped losing weight and her BMI remained at 36. The male patient regained 10 kg of the total 25 kg he had lost during the first year.

However, one or more minor complications were experienced by a few patients (Table 3).

All patients had nausea, vomiting, and epigastric pain with varying degrees of severity and 80% of patients were dissatisfied during the first week because of these symptoms; however, they improved on prokinetics

Table 1 Demographic data of the 40 patients studied

Demographic data	*n* (%)
Age groups (years)	
<35	20 (50)
35–<45	15 (37.5)
45–50	5 (12.5)
Range (years)	18–50
Mean ± SD	34.26 ± 9.38
Sex	
Male	6 (15)
Female	34 (85)
Marital status	
Single	14 (35)
Married	26 (65)
Onset of obesity	
Childhood	28 (70)
Adulthood	12 (30)

Table 2 Technique

Operative details	Description
Operative time (mean ± SD)	123.45 ± 33.065
Conversion	No
Drain number [*n* (%)]	7 (17.5)
Associated procedures	
Laparoscopic cholecystectomy	3
Paraumbilical hernia repair	1

Table 3 Minor postoperative complications

Minor complications	Frequency [*n* (%)]
Surgical complications (minor)	
Wound seroma	1 (2.5)
Trocar site infection	5 (12.5)
Persistent vomiting	4 (10)

and proton-pump inhibitors. One female patient had frequent vomiting after resuming liquids and underwent endoscopic dilatation. Also, one female patient had excessive vomiting and underwent endoscopy on postoperative day 2; mucosal edema was present.

Assessment of weight loss

Preoperative weight of the patients studied ranged from 95 to 160 kg, with a mean of 117.79 ± 15.95 kg. One year postoperatively, the mean weight was 94.35 ± 15.197 kg, at 2 years of follow-up, the mean weight was 92.83 ± 16.272 kg, and at 3 years of follow-up, it was 97.35 ± 18.440 (Table 4), with a statistically significant weight regain during the third year of follow-up in relation to the mean weight at the 1 year follow-up ($P = 0.007$).

The mean %EWL at 1 year postoperatively was 39.48 ± 13.96%, at 2 years postoperatively, the mean was 42.06 ± 17.98%, and at 3 years postoperatively, it was 34.93 ± 19.85% (Table 5). There was a statistically significant difference between (%EWL) at 1 and 3 years of follow-up ($P = 0.013$), indicating significant weight regain.

The mean %EBMIL at 1 year postoperatively was 46.37 ± 17.01%, at 2 years postoperatively, it was 49.45 ± 21.81%, and at 3 years postoperatively, it was 40.81 ± 23.54% (Table 6). There was a statistically significant difference between %EBMIL at 1 and 3 years of follow-up ($P = 0.006$), indicating significant weight regain.

Six of our patients (15%) had completely regained their initial weight by the end of the third year of follow-up; two of them were offered a revision surgery in the form of sleeve gastrectomy and the other four are not considering another operation.

Eight of our patients (20%) regained more than 70% of the lost weight; the remaining patients stopped losing weight and they reported an increase in the amount of food consumption. Only nine (22.5%) patients in our series maintained satisfactory EWL (>50%) after 3 years.

Changes in preoperative comorbidities

Throughout the follow-up during the third year, we found that there was no improvement in the hypertensive and diabetic conditions of our patients (Table 7).

Two of patients who achieved improvement in their respiratory problems returned to the their previous conditions. In all, 50% of osteoarthrotic patients started complaining again from joint pains especially their knees.

Effect on quality of life

All patients were subjected to a diagrammatic questionnaire (MA QoLQII) and were required to answer six questions on the changes that occurred in their QoL postoperatively at the end of the first year. They had already answered the same questionnaire preoperatively. There were significant improvements in all categories of the questionnaire. Also, the overall score of the questionnaire had improved significantly.

The overall result of the operation was assessed at the end of the first year using the updated BAROS. It assessed %EWL or %BMI loss, effect on comorbidities, and QoL using MA QoLQII. Also, it evaluated the occurrence of complications or reoperations. The outcome of the operation was good in 18 patients (46.1%), very good in four patients (10.25%), fair in 12 patients (30.8%), excellent in one patient (2.65%), and failed in four patients (10.25%).

By the end of the third year, almost 40% of patients reported failure of the operation.

Discussion

Bariatric surgery is a promising option for morbidly obese patients with an average loss of two-thirds of excess weight within 1.5 years. Here, we present our experience with the technique of LGCP over a period of 3 years of follow-up in an attempt to explore and develop a low-cost procedure.

The mean %EWL in the present study was 34.93 ± 19.85 at 3 years of follow-up, which is considerably lower than that reported previously in the literature [4,6,8]. In the present study, most of our patients (85%) reported weight regain during the period of follow-up, which reflects the unsustainable effect of weight loss of LGCP.

Table 4 Weight range of the patients studied postoperatively versus preoperatively

	Preoperative weight (kg)	1 year postoperatively	2 years postoperatively	3 years postoperatively
Range	95–160	70–135	68–142	72–155
Mean ± SD	117.79 ± 15.95	94.35 ± 15.19	92.83 ± 16.27	97.35 ± 18.44

Talebpour and Amoli [4] reported a mean %EWL of 21.4% at 1 month, 54% at 6 months, 61% at 12 months, 60% at 24 months, and 57% at 36 months. In the publication of Skrekas *et al.* [8], the mean %EWL was 51.7% at 6 months, 67.1% at 12 months, and 65.2% at 24 months. Ramos *et al.* [6], in their series of 42 cases, reported a mean %EWL of 20% for the first month, 32% at 3 months, 48% at 6 months, 60% at 12 months, and 62% at 18 months.

Our result of %EWL was much lower than the published studies and we believe that this may be because of the lack of a standard technique for the operation or poor compliance of some of our patients to strict adherence of follow-up dietary instructions.

From the technical viewpoint, although we followed the same rules for most of surgeons as reported by Abdelbaki *et al.* [7], the patients who regained weight were divided into two groups after radiological and endoscopic examinations of the stomach.

Overall 70% of patients declared increased amount of food intake, despite the presence intact suture lines which was mainly due to increase size of the remaining stomach. The other group showed failure of the suture line, the fundus was back in its normal position storing food, and slowly emptying into the rest of the stomach; two patients showed complete disruption of the suture line, with the presence of suture material inside the stomach.

LGCP has not been associated with mortality. The minor complication of postoperative nausea and/or vomiting was reported by most of our patients in the current series, and by almost all patients in the previous LGCP studies.

Pujol Gebelli *et al.* [9] reported three patients with persistent vomiting; one patient had severe symptoms that required upper gastrointestinal endoscopy to relocate an invaginated gastric fold and facilitate passage. The other two patients required reoperation because of intractable vomiting and it was found that in one of them, there was a gastrogastric hernia, which required revision to sleeve gastrectomy, whereas the other patient required reversal of plication.

In the study of Talebpour and Amoli, complications included one case with persistent vomiting, which, on reoperation, was found to be caused by a single adhesion causing a kink in the plicated stomach, one case of early postoperative leak attributed to high endogastric pressure because of persistent vomiting, one case of acute prepyloric gastric perforation far from the suture line, and one case of intrahepatic abscess 6 months after the operation caused probably by an intrahepatic hematoma and treated with laparoscopic drainage.

Current evidence on LGCP is scant and has mostly been described in very small series with few patients followed beyond 6 months. Low cost, short hospital stay, absence of prosthetic material, and reversibility make it an attractive option.

Table 5 Percentage of excess weight loss postoperatively

	1 year postoperatively	2 years postoperatively	3 years postoperatively
Range (%)	3.92–63.82	−7.84 to 68.08	−15.83 to 59.57
Mean ± SD	39.48 ± 13.96	42.06 ± 17.98	34.93 ± 19.85

Table 6 Percentage of excess BMI loss at postoperative intervals

	1 year postoperatively	2 years postoperatively	3 years postoperatively
Range (%)	4.54–74.93	−9.8 to 85.85	−17.13 to 71.36
Mean ± SD	46.37 ± 17.01	49.45 ± 21.81	40.81 ± 23.54

Table 7 Changes in preoperative comorbidities after the first year

Comorbidity	*n* (%)	Postoperative			
		Resolved	Improved	Unchanged	Aggravated/new complain
Major					
HTN	6 (14.3)	1	4	1	0
DM	3 (7.1)	1	1	1	0
Dyslipidemia	4 (9.5)	2	2	0	0
Respiratory	10 (23.8)	0	8	2	0
Osteoarthritis	22 (52.4)	3	16	3	0
Infertility	0	0	0	0	0
Minor					
Lower extremity venous stasis disease	10 (23.8)	0	8	2	0
GERD	0	0	0	0	7
Urinary stress incontinence	4 (7.1)	0	4	0	0
Menstrual irregularities	2 (4.8)	2	0	0	0

DM, diabetes mellitus; GERD, gastroesophageal reflux disease; HTN, hypertension.

Further research is required to determine the appropriate indications for LGCP.

The current study found that, over a period of 3 years, LGCP is safe, but it has an unsustainable effect on weight loss.

Acknowledgements

Conflicts of interest

None declared.

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Total extracapsular thyroidectomy versus subtotal thyroidectomy in nonmalignant goiter

AbdelMoniem I. El-Khateeb, Hany A. Ali, Gamal A. Makhlouf, Mohamed A. Rizk

Department of General Surgery, Faculty of Medicine, Assiut University, Assiut, Egypt

Correspondence to Gamal A. Makhlouf, MD, Department of General Surgery, Assiut University Hospital, Faculty of Medicine, Assiut University, Assiut, 71111, Egypt
Tel: +20 882088089; fax: +20 88 2354 130; e-mail: g_makhlouf@yahoo.com

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Introduction
There is still a debate on the management strategies for diffuse benign thyroid diseases mainly between total extracapsular and subtotal thyroidectomy in terms of efficacy and complications.

Aim
To establish the best operative management of benign thyroid diseases and to determine postoperative complications.

Patients and methods
A prospective comparative study was carried out on patients with benign thyroid disease. Two types of surgical procedures were performed: total extracapsular thyroidectomy and subtotal thyroidectomy.

Results
The study included 60 patients operated for benign thyroid disease. Controlled toxic goiter was found in 36 patients (60%), simple multinodular goiter was found in 14 patients (23.3%), primary toxic goiter was found in eight patients (13.3%), and a dominant toxic nodule was found in two patients (3.3%). Thirty patients underwent total extracapsular thyroidectomy and the other 30 patients underwent subtotal thyroidectomy. In this study, one patient (3.3%) from the total thyroidectomy group developed a complication of transient recurrent laryngeal nerve injury compared with no patients (0%) in the subtotal thyroidectomy group. Also, in this study, two patients (6.7%) in the total thyroidectomy group developed complications of hypoparathyroidism and hypocalcemia, but not in patients (0%) in the subtotal thyroidectomy group.

Conclusion
Total extracapsular thyroidectomy is a safe and highly effective procedure, with low postoperative complications.

Keywords:
benign thyroid disease, subtotal thyroidectomy, total extracapsular thyroidectomy

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Introduction

Total thyroidectomy is increasingly being accepted for the management of patients with benign disease when both lobes of the thyroid gland are involved (such as multinodular goiter, thyroiditis, and Graves' disease). This approach can avoid disease recurrence and eliminate any subsequent risk of malignant change and resurgery. Several authors [1–6] have reported that total thyroidectomy can be performed safely for the treatment of bilateral benign thyroid disease, and that a low complication rate can be achieved with a meticulous surgical technique.

Muller *et al.* [7] reported that the rate of complications associated with total thyroidectomy, namely, recurrent nerve palsy, hypocalcemia, wound infection, and secondary hemorrhage, did not differ significantly from that associated with subtotal resections.

Aim of the work

(1) To evaluate the outcome of total thyroidectomy and subtotal thyriodectomy in the management of nonmalignant goiter (simple and toxic goiter).
(2) To determine the postoperative complications.

Patients and methods

This prospective, observational study was carried out in Assiut University Hospital, Department of General Surgery, during a 2-year period (from August 2012 to August 2014). The study was carried out on patients with clinical manifestations of nonmalignant goiter who were candidates for surgical treatment. The patients included were randomly selected to be subjected to either total extracapsular thyroidectomy or bilateral subtotal thyroidectomy.

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Inclusion criteria

(1) Patients with manifestations of hyperthyroidism after failure of medical treatment.
(2) Patients with clinically manifested goiter with a history of thyrotoxicosis.
(3) Patients with simple multinodular goiter.

Exclusion criteria

(1) Patients with clinically evident malignant goiter.
(2) Patients with preoperative biopsy-based evidence of malignant thyroid disease.
(3) Patients who were candidates for medical treatment.
(4) Patients who were unfit for operation.
(5) Cases of thyroiditis.
(6) Cases of recurrent thyroid.

All the included patients were subjected to the following:

(1) Complete assessment of history foucusing on the onset, course, duration of symptoms, predisposing factors, and medical comorbidities.
(2) Thorough clinical examination.
(3) Routine laboratory investigations and thyroid function.
(4) Imaging studies such as neck ultrasonography.
(5) In some patients in whom there was a clinical suspicion for malignancy, a preoperative fine-needle aspiration cytology was performed.

Operative techniques

Patients underwent total extracapsular thyroidectomy

The surgical technique was the same for every operation. After making an incision in the lower anterior neck and after dissecting the subhyoid muscles (without cutting them), the thyroid gland was exposed and the thyroid capsule was dissected and the lobe was delivered into the wound after ligation of the middle thyroid vein.

The superior thyroid vessels were dissected, ligated, and divided in all patients as near as possible to the thyroid gland to preserve the external laryngeal nerve.

The recurrent laryngeal nerves were systematically searched for, an attempt was made to identify and preserve the parathyroid glands on each side of the thyroid lobe to be removed, and to preserve them with intact blood supply.

The inferior thyroid artery was identified on each side and its branches were ligated at the capsule of the thyroid. This is the cephalocaudal technique for thyroidectomy that was used on most patients in this study, but there is also the caudocephalic technique, in which we start by ligating the inferior thyroid pole, followed by ligation of the superior thyroid artery, and this technique was used on a few number of patients in this study.

The parathyroid glands were separated by tying the small blood vessels running between the thyroid and the parathyroid glands, thus allowing the parathyroid glands to be separated in a lateral direction. The parathyroid glands were usually preserved *in situ* on a pedicle supplied by branches of the inferior thyroid artery.

Branches of the inferior thyroid artery supplying the thyroid gland were ligated near the capsule of the thyroid gland with preservation of the main trunk of the inferior thyroid artery.

Patients underwent bilateral subtotal thyroidectomy

Branches of the inferior thyroid artery supplying the thyroid gland were ligated near the capsule of the thyroid gland (or intracapsular ligation) with preservation of the main trunk of the inferior thyroid artery. We only preserved a small slice of posterior gland tissue on each side and sutured the capsule of the remnant of the thyroid gland with the pretracheal fascia to ensure homeostasis.

Ethical consideration

Each patient provided his/her written consent to participate before the surgery and the Faculty of Medicine Ethics Committee approved this study.

Statistical analysis

Statistical analysis was carried out using the statistical package for the social sciences, version 20 (SPSS Inc., Chicago, IL, USA). The results were expressed as mean ± SD or frequency. Proportions were compared using χ^2-tests.

Results

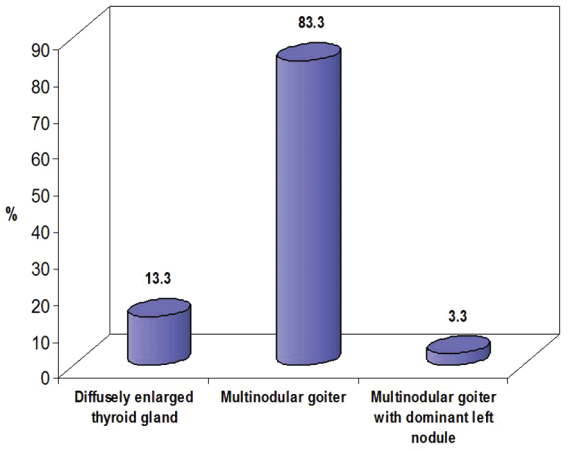
This study included 60 patients with benign goiter disease who were candidates for surgical interference. Thirty patients were subjected to subtotal thyroidectomy and 30 patients were subjected to total thyroidectomy during the period of this study (2 years). The mean age of the patients studied was 37.53 ± 10.48 years (range 20–60 years). Most of the study patients were women, 51 (85%), and there were nine men (15%) (Fig. 1).

Table 1 shows the distribution of the patients studied according to diagnosis.

The relationships between the diagnosis and type of operation are shown in Table 2.

There was no significant difference in the complications reported between the two types of operations as shown in Table 3.

Figure 1



Neck ultrasound findings in the patients studied.

Table 1 Distribution of the patients studied according to diagnosis

Diagnosis	*n* = 60 [*n* (%)]
Controlled secondary toxic goiter	36 (60.0)
Dominant toxic nodule	2 (3.3)
Primary toxic goiter	8 (13.3)
Simple multinodular goiter	14 (23.3)

Table 2 Relation between the diagnosis and type of operation

Diagnosis	Operation [*n* (%)]		*P*-value
	Subtotal thyroidectomy (*n* = 30)	Total extracapsular thyroidectomy (*n* = 30)	
Controlled secondary toxic goiter	9 (30.0)	27 (90.0)	0.000*
Dominant toxic nodule	2 (6.7)	0 (0.0)	0.472
Primary toxic goiter	8 (26.7)	0 (0.0)	0.008*
Simple multinodular goiter	11 (36.7)	3 (10.0)	0.015*

*Means significant.

Table 3 Relation between the type of the operation and the resulting complications

Complications	Operation [*n* (%)]		*P*-value
	Subtotal thyroidectomy (*n* = 30)	Total extracapsular thyroidectomy (*n* = 30)	
Nerve injury	0 (0.0)	1 (3.3)	0.313
Postoperative hypocalcemia	0 (0.0)	2 (6.7)	0.472
Postoperative bleeding	0 (0.0)	1 (3.3)	0.313
Wound complications	1 (3.3)	1 (3.3)	–

Discussion

The extent of thyroidectomy in benign thyroid disease is still a matter of debate and shows a large spectrum of management strategies. The aim of these procedures is to perform the most effective treatment with the less complications, without an incidence of recurrence and without the need for secondary surgical intervention, which will be difficult because of disturbed anatomy and adhesions.

Thirty patients were subjected to total thyroidectomy and the other 30 were subjected to subtotal thyroidectomy as a surgical management for benign goiter disease. Postoperative follow-up for those patients was performed to detect any complications, especially recurrent laryngeal nerve injury and hypoparathyroidism.

In our study, one patient (3.3%) in the total thyroidectomy group developed a complication of recurrent laryngeal nerve injury that was transient compared with no patients (0%) in the subtotal thyroidectomy group.

Also, in our study, two patients (6.7%) in the total thyroidectomy group developed a complication of hypoparathyroidism and hypocalcemia, but not in patients (0%) of the subtotal thyroidectomy group.

Dener [8], in his study on 102 patients to evaluate the safety of total thyroidectomy, reported that total thyroidectomy or lobectomy can be performed with minimal morbidity in cases of benign thyroid disease affecting the entire gland as one (0.9%) temporary superior laryngeal nerve palsy, one (0.9%) temporary recurrent nerve palsy, and one (0.9%) temporary hypoparathyroidism occurred. Wound seroma developed in two patients (1.9%). There were no deaths or permanent complications.

However, Prades *et al.* [9] reported that permanent (>12 months) unilateral recurrent paralysis occurred in four patients (1.4%), permanent (>12 months) hypoparathyroidism in 10 patients (3.7%), and hypertrophic or keloid scar in 14 patients (5.1%).

Their results suggest that total thyroidectomy is a safe surgical procedure for multinodular goiter patients. Low rates of postoperative complications were observed.

However, Muller *et al.* [7] reported that the rate of complications associated with total thyroidectomy, namely, recurrent nerve palsy in 0.9%, hypocalcemia in 0.9%, wound infection in 0.9%, and secondary hemorrhage in 0.6%, did not differ significantly

from that associated with subtotal resections/ hemithyroidectomies. Moreover, 88.3% of the patients who underwent total thyroidectomy were satisfied with the results of surgery. These findings indicate that total thyroidectomy is an acceptable surgical alternative for benign multinodular goiters.

Reoperative surgery for recurrent benign thyroid disease is associated with increased morbidity when preceded by initial subtotal thyroidectomy. Associated high levels of recurrence and increased permanent recurrent laryngeal nerve injury and hypoparathyroidism rates observed in this setting so subtotal thyroidectomy should not be recommende [10].

Conclusion

The study pointed out that subtotal thyroidectomy is safe despite the late complication of recurrence and morbidity of reoperation. There is an obvious decrease in the rate of complications associated with total thyroidectomy, especially with increasing experience and refinement of surgical technique. Total extracapsular thyroidectomy is a safe and highly effective procedure in most patients, with acceptable transient postoperative complications.

Acknowledgements

Conflicts of interest

There are no conflicts of interest.

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Liposuction excision of gynecomastia through an axillary liposuction opening: A novel technique

Hady S. Abou Ashour

Department of General Surgery, Faculty of Medicine, Minoufiya University, Minoufiya, Egypt

Correspondence to Hady Saleh Abou Ashour, MD, Department of General Surgery, Faculty of Medicine, Minoufiya University, Minoufiya, Egypt
Tel: +20 100 063 0111;
e-mail: aboashour_hady@yahoo.com

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Introduction
Gynecomastia has a negative impact on male self-esteem and social health. In the absence of a medically treatable condition, surgery is the only effective treatment. Treatment includes either liposuction, excision of male breast gland, or both. Excision of the breast tissue is usually performed through a circumareolar incision, which could be a site of infection, unsightly scar, nipple, areola inversion, or necrosis.

Aim
This study aimed to evaluate the outcome of liposuction excision of gynecomastia through a small axillary approach.

Patients and methods
One hundred and forty-three patients with gynecomastia, through the period from March 2010 to March 2014, in Minoufiya university hospital and other private hospitals were included in this study; their mean age was 24.3 years. After clinical and laboratory evaluation, liposuction and excision of glandular tissue was performed through the same stab of liposuction at the midaxillary line in the fifth or sixth intercostal spaces under general or local anesthesia; liposuction was first performed using the tumescent technique and then the glandular disc was released from its deep attachments and from subcutaneous and nipple attachments by scissors. Then, drains were inserted through the same liposuction excision opening and pressure bandage and garments were applied.

Results
One hundred and thirty-four (93.7%) patients showed satisfactory results after 6 months and 138 (96.5%) patients were satisfied with the results after 1 year in terms of proper symmetry and sound healing. One hundred and fifteen patients (80.4%) underwent surgery under general anesthesia and 28 patients (19.5%) underwent surgery under tumescent local anesthesia; the mean operative time was 55 min, the mean hospital stay was 9.6 h, and the average period off work was 5 days. Four patients (2.8%) showed unilateral hematoma formation, none of the patients showed saucer dish deformity, areola, nipple necrosis, or inversion, one patient (0.6%) developed a unilateral wound infection, two patients (1.4%) showed seroma formation, and two patients (1.4%) showed skin laxity.

Conclusion
The axillary liposuction excision technique was associated with very good esthetic results for both fibrous and fatty gynecomastia, with little complications.

Keywords:
excision, gynecomastia, liposuction

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Introduction

Gynecomastia is defined as a benign enlargement of the male breast. It is a common condition, with a prevalence in young patients as high as 38% [1,2]. Gynecomastia is the most common disorder of male breast, accounting for nearly 60% of all male breast disorders. It also accounts for 85% of male breast masses [3]. Gynecomastia has a trimodal peak of incidence and commonly presents in newborns, adolescents, and men older than 50 years of age; it causes considerable emotional discomfort and limitations in everyday activity in young men, and this is why it represents a psychosocial problem of social acceptance and emotional comfort [4]. In adolescents, surgery should be discussed after a period of 2 years as most cases of adolescent gynecomastia resolve within 6 months to 2 years [5]. Pseudogynecomastia is enlargement of the male breast, which can also result from obesity and fat deposition [6]. Gynecomastia was classified by Webster in the 1930s into the following three categories:

Type one was glandular, type two was 'fatty glandular', and type three was 'simple fatty'. Simon *et al.* [7] classified

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gynecomastia in 1973 according to morphology and volume into four different groups:

(1) I: minor breast enlargement without skin redundancy.
(2) IIa: moderate breast enlargement without skin redundancy.
(3) IIb: moderate breast enlargement with minor skin redundancy.
(4) III: gross breast enlargement with skin redundancy that mimics female breast ptosis.

Bannayan and Hajdu [8] have described three histological types of gynecomastia: florid, fibrous, and intermediate. In the majority of cases, if the duration of gynecomastia is greater than 1 year, the fibrous type is more prevalent and irreversible, which may limit the success of medical treatments. In the absence of medically treatable conditions, surgery is the main line of treatment. Surgical approaches to the treatment of gynecomastia include subcutaneous mastectomy, liposuction-assisted mastectomy, laser-assisted liposuction, and laser lipolysis without liposuction. Complications of mastectomy may include hematoma, surgical wound infection, breast asymmetry, changes in sensation in the breast, necrosis of the areola or nipple, seroma, noticeable or painful scars, keloid formation of the scar, and contour deformities [9–11]. The first description of surgical treatment for gynecomastia was provided by Paulus Aegineta (635–690 AD), a Byzantine Greek physician who described breast reduction mammoplasty using a semilunar inframammary incision [12]. Several treatments for gynecomastia have been described in the literature since the 19th century. Subcutaneous mastectomy as a treatment for gynecomastia was described by Webster [13] in 1946, and was the treatment of choice up to the 1980s. The introduction of suction-assisted lipectomy by Illouz [14] in the late 1970s improved the treatment of gynecomastia because it enabled the contouring of diffusely enlarged breasts, resulting in only small scars. In the late 1980s, Zocchi [15] developed ultrasound-assisted liposuction (UAL), a technique that allows selective destruction of adipose tissue. In the last decades, more attention has been paid to esthetically acceptable and minimally invasive approaches in the management of gynecomastia. Teimourian and Perlman [3] described liposuction-assisted excision in the 1995s; UAL was introduced successfully in 87% of cases with various grades of gynecomastia [16]. Endoscopic techniques were used by Eaves *et al.* [17] in 1995 in an attempt to avoid violation of the nipple areola complex, whereas Ramon *et al.* [18] in 2005 linked the power-assisted liposuction (PAL), PAL technique with endoscopic-assisted pull-through excision. Then, Lista and Ahmad [19] in 2008 reported the use of the pullthrough technique in combination with PAL. In 2010, Qutob *et al.* [20] reported a case series of 36 patients who underwent vacuum mammotome resection of gynecomastia through one opening and another opening for liposuction. The utility of pathologic examination of breast tissue removed from male adolescent gynecomastia patients has recently been questioned because of the rarity of breast cancer in this population [21].

In this study, our objectives were to evaluate the applicability and safety of conventional liposuction plus excision of gynecomastia through a single midaxillary liposuction stab and to report any complications.

Patients and methods

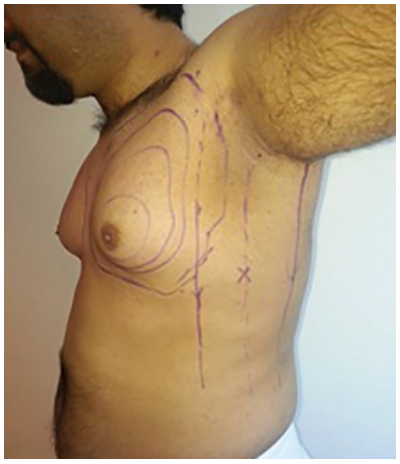
Through the period from March 2010 to March 2014 in Minoufiya University Hospital and other private hospitals, 143 patients with gynecomastia were included in this prospective study. Their age ranged from 16 to 53 years, with a mean age of 24.3 years. Patients with all grades of gynecomastia were included in this study, except Simons grade III. The assessment of disease history, and clinical and laboratory evaluation were performed to exclude any medical cause of gynecomastia, for example, drugs, hormonal, or adolescent gynecomastia of less than 2 years' duration. Informed consent was obtained and patients were clearly informed of the possibility that a periareolar incision may have to be performed if excess bleeding occurred that required definitive hemostasis. This was followed by marking of the topography of the outlines of breast tissue and areas of fat excess and the most prominent areas under the areola and nipple. The anterior, mid, and posterior axillary lines were marked and the liposuction stab points were marked bilaterally at the level of the fifth or sixth intercostal spaces (Fig. 1). All patients were treated on a day-case basis. Skin preparation was performed and wetting fluid was used (1000 ml normal saline, 20 ml lidocaine 2%, and 1 mg epinephrine) for local anesthesia. Only epinephrine was added and no local anesthetic was added to the normal saline if general anesthesia was administered. After a period of 15 min, a 4 mm or a 5 mm round-tip Mercedes cannula was used for the initial suction using the palm down and pinch techniques. The final contouring was performed and changes were constantly monitored by direct observation. The periphery of the breast was feathered to produce a smooth transition to avoid saucer dish deformity (Fig. 4). It was found that parts of the soft lobular tissue could be suctioned in certain cases. Continuous suction attempts were made in an attempt to reduce the firm retroareolar glandular disc to the

least compact size. The remaining glandular tissue was separated from its deep attachments from the pectoralis major muscle and fascia by scissors. Then, the breast tissue was separated from its cutaneous attachment using scissors and better using sinus scissors through the same liposuction opening without the need to make another incision (Figs 2 and 3). On a few occasions, we had to extend the stab wound to 8–10 mm to excise and deliver larger glandular tissue. Careful leaving a substantial disc of ductal tissue attached to the areola will enable healing in a convex and natural manner (Fig. 4). A Kocher forceps was introduced through the liposuction opening to deliver the glandular tissue step by step as one mass or pieces and scissors were used to release any attachment (Figs 2 and 3); then, the cavity was milked to evacuate any free remnants through the liposuction opening. Hemostasis was checked by excluding excess bleeding for few minutes while performing the other side, then a 16 or better 18 Fr suction drain was lifted into the cavity through the same liposuction stab on both sides. Then, elastic bandage was immediately applied for 24 h and use of a pressure garment was continued for 2–6 weeks. A specimen was sent to the pathologist for examination. Postoperative antibiotic and analgesics were prescribed for 5 days. All patients were re-evaluated in the first 24 h after surgery to rule out hematoma formation. Evacuation of any hematomas at the earliest possible interval is of key importance in the postoperative management. Patients were followed up over a period of 12 months at 2-month intervals after frequent visits in the first 2 months. The patients were informed that skin irregularity is common during the first 2 months postoperatively, and generally with skilled surgery, the breasts ultimately appear smooth and acceptable. Also, they were informed that slight areola distortion could occur and this often improves over 8 months to 1 year.

Results

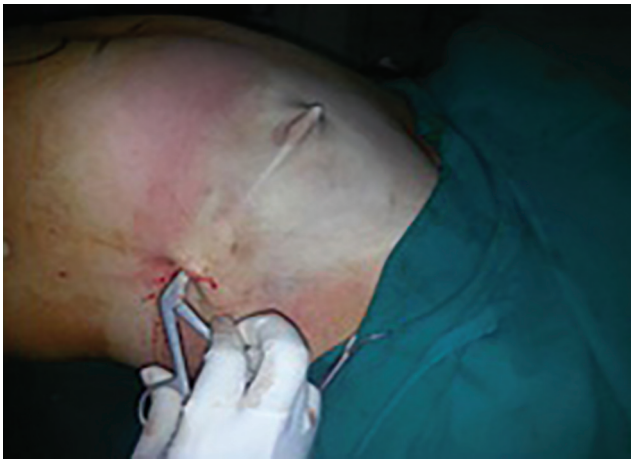
A total of 143 patients were included in this study; 134 (93.7%) patients showed satisfactory results after 6 months and 138 (96.5) patients were satisfied with the results after 1 year. One hundred and fifteen patients underwent surgery under general anesthesia and 28 patients (19.5%) underwent surgery under tumescent anesthesia. Their age ranged from 16 to 53 years, with a mean of 23.4 years. The operative time ranged from 45 to 92 min, with a mean of 55 min. The volume of fat suctioned from both breasts ranged from 150 to 1350 ml, with a mean of 520 ml; the mean weight of excised tissue bilaterally ranged from 80 to 260 g, with a mean of 135 g. The hospital stay ranged from 6 to 13 h, with a mean of 9.6 h. The average time off work was 5 days, ranging from 2 to 7 days. Two patients showed seroma formation and were managed by frequent percutaneous aspiration. Four patients 2.8% showed unilateral hematoma formation: two patients had moderate hematoma of 100 and 180 ml, respectively, and two patients had minor hematoma of about 50–90 ml, respectively. Patients with hematoma were managed at the outpatient clinic where the obstructed drain was removed, the clotted blood was evacuated and irrigation by warm saline through the liposuction opening. A new drain was re-inserted through the primary incision and was left for a few days along with application of tight bandage for 3 days. No asymmetry appeared in the follow-up period and no saucer dish deformity occurred. Despite some early irregularity of the contour of the areola and nipple, a smooth contour began to develop at 4–6 weeks postoperatively. No areola or nipple necrosis or inversion occurred in any of the cases throughout the follow-up period. One patient (0.6%) developed unilateral wound infection, which was treated conservatively. Seventy-six patients showed skin laxity that resolved over 5–7 months,

Figure 1



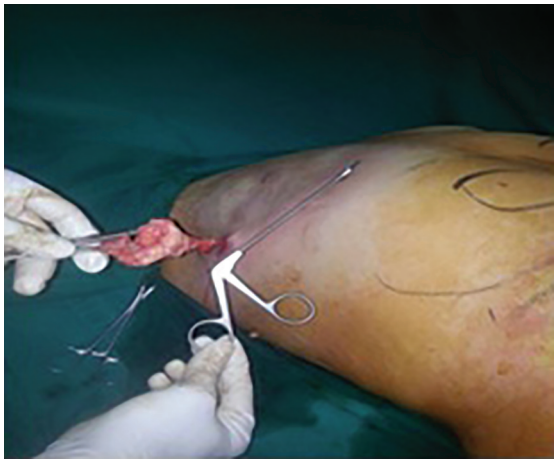
Topography of the breast and incision.

Figure 2



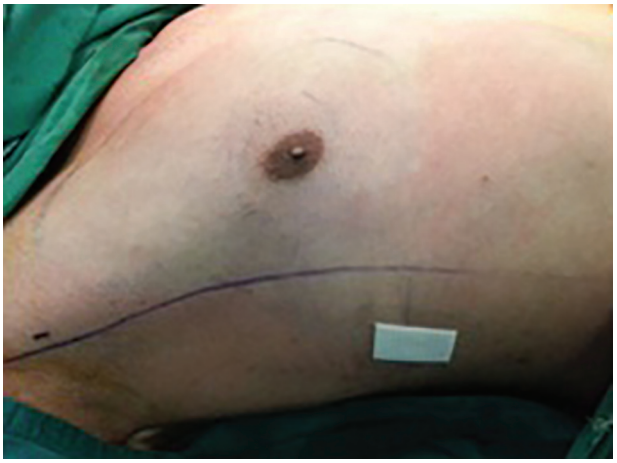
Use of scissors to release the glandular disk.

Figure 3



Delivery of the gland from the liposuction wound.

Figure 4



Smooth transition of breast and unviolated areola.

but two patients (1.4%) showed mild skin laxity and irregularity that continued after 1 year of follow-up; patients did not request revision surgery as the size of the breast was of primary concern to him. Areola and nipple sensation was lost early in 52 patients (36.3%); 36 (69.2%) of the 52 patients gradually recovered their sensation over 7 months and a total of 41 patients (78.8%) recovered their sensation after 1 year. Only 11 patients had altered nipple and areola sensation after 1 year. There was no reported cancer in any of the pathological specimens. The technique was easier with the use of sinus scissors, which facilitated sharp dissection of the far medial breast tissue and the peripheries (Fig. 2).

The results are presented in Tables 1–3 and Figs 4–7.

Table 1 Demography and result parameters

Result parameters	Range	Mean
Age (years)	16–53	23.4
Operative time (min)	45–92	55
Hospital stay (h)	6–13	9.6
Amount of aspirated fat (ml)	150–1350	520
Weight of excised glandular tissue (bilaterally) (g)	80–260	135
Time off work (days)	2–7	5

Table 2 Anesthesia and patient satisfaction

Result parameters	Number of patients (%)
Type of anesthesia	
General	115 (80.4)
Local	28 (19.5)
Pseudogynecomastia	24 (16.7)
Patient satisfaction after 3 months	134 (93.7)
Patient satisfaction after 12 months	138 (96.5)

Table 3 Complications

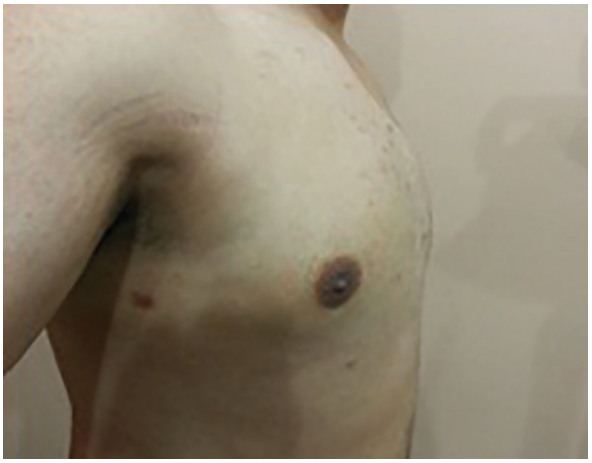
Complications	Number of patients (%)
Hematoma	
Small	2 (1.3)
Medium	2 (1.3)
Seroma	2 (1.3)
Nipple	
Inversion	0
Necrosis	0
Infection	2 (1.3)
Hypertrophic scars	0
Keloid	0
Asymmetry	0
Loss of sensation	
Temporary	52 (6.3)
After 1year	11 (7.6)
Saucer dish deformity	0
Skin laxity after 1 year	2 (1.3)
Breast cancer in biopsies	0

Discussion

Gynecomastia has a negative impact on male self-esteem and social health, and to date, surgery has been the mainstay of treatment. The ideal goal is to remove the excess breast tissue together with achievement of symmetry with minimal scarring. Conventionally, liposuction in gynecomastia is performed by one or two small incisions on each side of the chest [22,23]. The gland is excised through a periareolar incision [13,24]. The scars of the periareolar incision, the liposuction openings, and that of the drains still have a negative impact on the esthetic results [25].

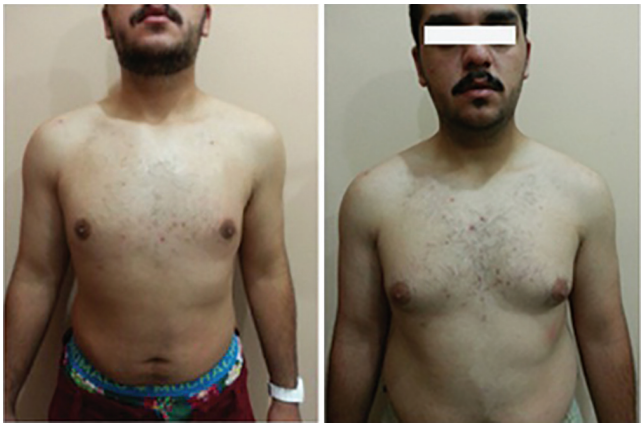
Subcutaneous mastectomy through a periareolar incision is the most commonly used technique. Its combination with liposuction and feathering of the breast periphery result in better cosmosis and avoidance of crater deformity. As a periareolar incision is performed, it leads to the risk of development of wound-healing complications, especially keloid formation, tethering of the areola and nipple to the pectoralis muscle,

Figure 5



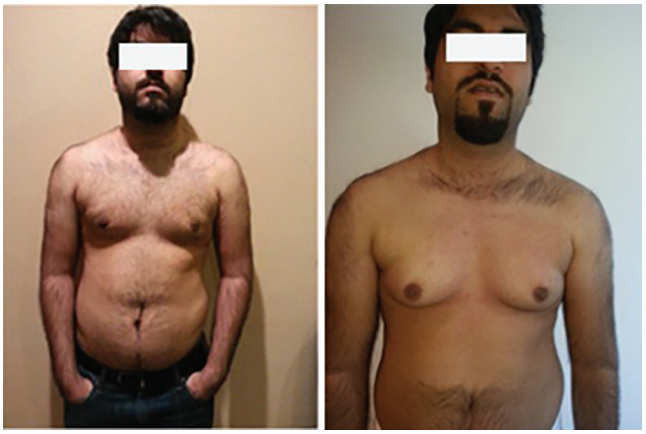
Scar away from the pectoral esthetic unit.

Figure 6



Preoperative and postoperative photo.

Figure 7



Preoperative and postoperative photo.

nipple and areola necrosis, and altered periareolar sensation [10,11]. Although the combined periareolar incision and liposuction can successfully remove the glandular and fatty element of the condition, the risk of development of potential complications because of the use of an open procedure mentioned above still remains. UAL has yielded good results in terms of fat suction; unfortunately, it has no effect on the firm glandular retroareolar tissue and thus excision remains a mainstay of treatment for this condition. Another disadvantage of (UAL) is the need for continuous cooling to prevent skin burns from the thermal contact generated at the point of entry [9,23,26,27]. Another disadvantage is the risk of demyelination-type injury of nerves, which can result in variable degrees of nerve damage [25,27–29]. Other surgeons have used the pullthrough technique successfully with UAL [23] or PAL [19]. Eaves *et al.* [17], in 1995, described an endoscopic-assisted excision for surgery without violation of the areola and nipple, where three incisions were used, and this technique did not completely eliminate the potential complication of a scar on a visible part of the chest; in this technique, three incisions were used. Bracaglia *et al.* [31], in 2004, combined suction-assisted lipectomy and the pullthrough technique using an inframammary crease incision and an incision overlying the sternum. Mentz *et al.* [31], in 2007, described another effective technique: correction of gynecomastia through a single puncture incision at the 6-o'clock position of the areola combined with a separate incision for liposuction at the anterior axillary fold.

In 2010, Petty *et al.* [33] reported their experience with UAL and the arthroscopic shaver to resect the subareolar fibrous component. Morselli and Morellin *et al*. [34], in 2012, reported their 15 years' experience with the use of the pullthrough technique, with satisfactory results, but again they used two incisions: one in the inframammary fold and the other behind the anterior axillary line. The above procedures place the incision in a prominent position, either over the sternum or the inframammary line or behind the anterior axillary fold, and may be visible either on the front or the sides of the patient's chest and may be unsightly if hypertrophy of the scar occurs. The above procedures also involve another incision for liposuction compared with our approach (Figs 4 and 5). Jarrar *et al.* [35], in 2011, used a single large incision in the anterior axillary fold 18 mm in size using endoscopic assessment after excision; again, the incision was more noticeable than the smaller and more posterior incision and not all cases required direct hemostasis.

The far midaxillary point of liposuction represents another advantage, especially if we use the sixth intercostal space level; thus, the fat lateral to the breast and below the arm bit can be suctioned in up, down, medial, and posterior directions from the same stab.

Another advantage of our single far approach is that some enlarged male breasts cannot be accurately judged clinically to be either true or pseudogynecomastia; this was encountered in about 24 patients (16.78%). Therefore, only liposuction was sufficient for such cases, with no further need for any other incisions. This means that an incision at the periareolar region is not useful in case of pseudogynecomastia and can result in another unwanted scar, with potential wound complications.

Together with application of tight elastic bandage, the use of epinephrine containing tumescent fluid minimized the operative and postoperative bleeding. In this study, hematoma occurred in four patients: two patients had minor hematoma and the other two patients had moderate hematoma. Early hematoma evacuation and irrigation by normal saline was the mainstay of treatment. Evacuation was performed in the outpatient clinic under local anesthesia, with no further complications. Temporary skin laxity and occasional asymmetry were present during the first 3 months, but no asymmetry persisted over 3 months. Skin laxity was encountered and the patients were reassured that this is a normal outcome following such surgery and will resolve over a few months after skin shrinkage. In this study, use of the transaxillary approach yielded very good esthetic results; the stab of liposuction remained concealed in the midaxillary region. The technique is applicable and the scar is hidden (Figs 1, 4 and 5). One more advantage that liposuction of the fatty areas lateral to the breast can be suctioned from the same stab, and any potentially unwanted complications, especially hyperpigmentation, hypopigmentation, keloid, hypertrophic scars, and tethering, will be away from the pectoral esthetic unit Figs 4 and 5.

Conclusion

The axillary liposuction excision technique was safe and associated with good esthetic results. The technique is suitable for those who stress to appear unoperated.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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Evaluation of pre-emptive mastectomy flap infiltration with bupivacaine adrenaline

Ashraf Khater[a], Mohamed Adel[c], Mohamed Awad[b], Amr Yassin[c], Hosam Ghazy[d], Mona Gad[c], Maha Abozed[c]

Departments of [a]Surgical Oncology, [b]Medical Oncology, Mansoura Oncology Center (OCMU), [c]Anesthesia Department, [d]General Surgery Department, Mansoura University Hospital, Faculty of Medicine, Mansoura University, Mansoura, Egypt

Correspondence to Ashraf Khater, PhD, Department of Surgical Oncology, Mansoura Oncology Center, Faculty of Medicine, Mansoura University, 60 Gomhoria Street, Mansoura 35511, Egypt
Tel: +20 50 235 8021;
e-mail: dr.ashrafkhater@yahoo.com

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Objective
Postmastectomy pain is responsible for distress with subsequent organ dysfunction. Systemic analgesics such as opioids are not free of complications. The idea of preincisional mastectomy flap infiltration with bupivacaine and adrenaline was shown by many reports to decrease the postmastectomy pain and analgesic requirements. The aim of this study was to prove this with the assessment of the stress-response changes.

Patients and methods
A total of 120 females who were candidates for mastectomy were randomized into an equal two groups using computer-generated random numbers; first was the study group in which the mastectomy flap was infiltrated before skin incision with bupivacaine and adrenaline, whereas the second was a control. Assessment of patient and operative data was done.

Results
There was no statistical difference between both groups regarding the demographic data, the tumor pathological data, hospital stay, and overall complications. The mean operative time was significantly longer in the study group ($P = 0.01$). The mean blood loss was significantly less in the study group ($P = 0.001$). The mean postoperative arterial blood pressure and pulse were significantly less in the study group ($P = 0.004$ and 0.04, respectively). The mean intraoperative fentanyl and mean postoperative nalbuphine requirements were significantly less in the study group ($P = 0.007$ and 0.002, respectively). Visual analogue scale was significantly less in the study group ($P = 0.01$).

Conclusion
Pre-emptive mastectomy flap infiltration with bupivacaine adrenaline solution is a safe and effective method for reduction of postmastectomy pain and stress response with a significant reduction of the analgesic requirements.

Keywords:
adrenaline, bupivacaine, mastectomy, pain

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Introduction

Postoperative pain is responsible for the afferent stimuli that precipitate abnormal reflexes and result in stress response with subsequent organs dysfunction. Blockade of these stimuli is proposed to decrease the postoperative organs' dysfunctions [1]. The control of postoperative pain is a major concern to achieving a smooth postoperative recovery and to alleviating the stress response especially in patients with associated comorbidities and the elder group [2]. The noxious stimuli that are caused by the surgical incision are transmitted from the cutaneous nociceptors to the brain through the lateral spinothalamic tract in the spinal cord. Opioids can alleviate the incision pain through a central mechanism [3]. Their use is not free of complications, especially those related to the central nervous system depression and vomiting [4]. Local anesthetic techniques were found to be superior to systemic therapy whatever the type of operation or the method of delivery [5,6]. Although regional anesthesia and nerve block techniques are widely used in many situations, many anesthetists are still minded by the simplest way – the wound infiltration [2]. It is very important to mention that wound infiltration with long-standing local anesthetics decreases the anesthetic and analgesic doses during surgery. Moreover, it decreases the need for postoperative opioid-containing analgesics with subsequent decrease of the opioid hazards (opioid-sparing effects) [7]. Moreover, a comparison of different modes of delivery showed equal results of analgesia; for example, creams, patches, topical instillation, local wound infiltration, or regional block [8,9]. There was a debate: either to apply the anesthesia at the end of the procedure or at the start (pre-emptive anesthesia). The second one is more desirable as it was found to decrease both the intraoperative anesthetic requirement and opioid consumption [2,10]. The rate of wound infection was not increased using these techniques [10]. The main concern was the systemic toxicity of the local anesthesia, which was not recorded in a large number

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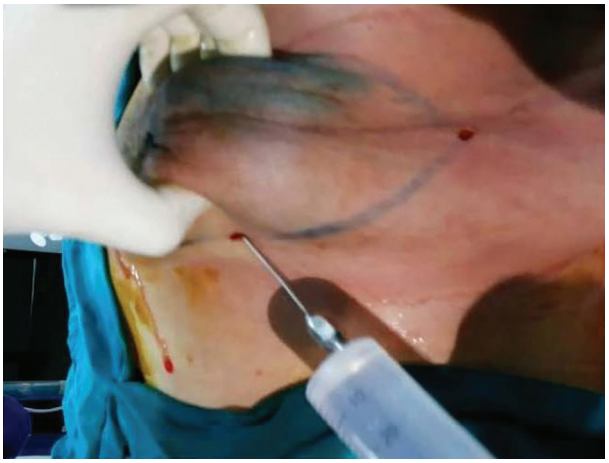
of studies [11]. The addition of adrenaline to the local anesthetic prolongs its duration of action; moreover, it decreases its systemic absorption, thus decreasing its toxicity [12]. This study aimed at evaluating the effects of pre-emptive mastectomy flaps infiltration with a cocktail including bupivacaine hydrochloride and adrenaline 1/200 000 over the postoperative stress response, pain score, and the opioid requirement.

Patients and methods

This study was conducted during the period from January 2014 to December 2014. It included 120 operable female patients who were candidates for total mastectomy and axillary clearance for breast carcinoma. A written consent was obtained from all patients prior to enrollment. Patients with a history of prior chemotherapy or breast irradiation, those with a history of previous breast surgery, those with morbid obesity, those with collagen disease, those with ASA (the American Society of Anesthesiologists) score poorer than 3, and those with a history of hypersensitivity for local anesthesia were excluded from this study. After obtaining an approval from the institutional review board, patients were randomized into an equal two groups using computer-generated random numbers. In all cases, induction of the general anesthesia was done using a standard technique including 1 μg/kg of fentanyl, 2.5 mg/kg of propofol, and 0.5 mg/kg of atracurium. Maintenance with isoflurane inhalational anesthesia (MAC 1.2) and atracurium at a dose of 0.1 mg/kg every 20 min was carried out. Intraoperative standard monitors were recorded as ECG, pulse oximeter, blood pressure, capnogram, and core body temperature. All these measures were recorded as baseline at skin incision and then every 15 min till the end of surgery. Intraoperative bolus of fentanyl at a dose of 1 μg/kg was administered if the pulse was more than 90/min or blood pressure was higher than 25% of baseline. In the first (study) group (n = 60), mastectomy was done with pre-emptive local infiltration with a cocktail of 120 ml of bupivacaine hydrochloride (0.125% concentration) and adrenaline 1/200 000. For infiltration, mastectomy was done using the classic horizontal Meyer's incision and this line was marked preoperatively, then while the patient was under the induction with propofol, four skin snips were made over angles of the diamond through which a 5-mm liposuction cannula was used to inject the cocktail (Fig. 1), whereas in the second (control) group (n = 60), mastectomy was done in the routine way without local infiltration. All patients received a postoperative 30 mg of intramuscular ketorolac and 1 mg of acetaminophen infusion.

Figure 1



Skin incision marking and method of infiltration.

Patients follow-up

All patients were monitored for pulse, blood pressure, respiratory rate, and pain score [using the visual analogue score (VAS)] every 2 h. Any patient expressing a VAS score more than 4 was offered a bolus of 5 mg intravenous nalbuphine. The amount of drainage of the wound was recorded during the first 12 h as well.

Statistical analysis

Data were presented as frequencies and percentages for categorical data and mean, SD, and range for continuous data. The association between categorical variables was examined using χ^2-test. The difference in mean values of continuous data was examined using independent-samples t-test. All P values were two-tailed. P value less than 0.05 was considered as significant. SPSS software (release 15.0; SPSS Inc., Chicago, Illinois, USA) was used for statistical analyses.

Results

Patients' demographic data are shown in Table 1 with no significant differences among both groups. Table 2 shows the operative data and postoperative outcome. There was no significant difference in between the two groups as regard the tumor size, the nodal status, the incidence of flap necrosis, hematoma, and seroma. There was a significantly longer mean operative time in the study group (127 ± 10.5 min with a range of 90–160 min vs. 105 ± 7.5 min with a range of 80–139 min with P = 0.01). On the other hand the mean blood loss was significantly less in the study group (290 ± 75 ml with a range of 210–370 ml vs. 370 ± 105 ml with a range of 250–480 ml). Meanwhile, the tumor sizes, the nodal status, the hospital stay, the incidence of hematoma, seroma, and flap necrosis

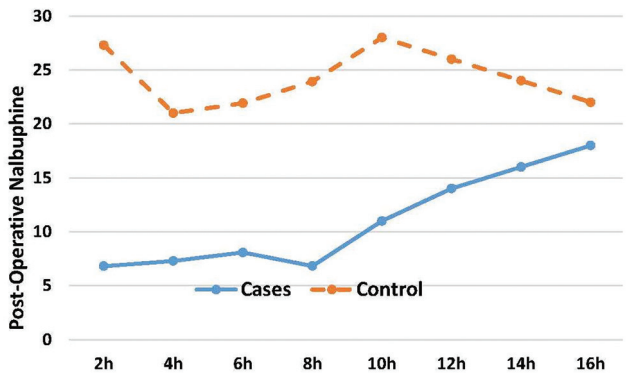
were not statistically different between the two groups (Table 2). By comparing the mean intraoperative fentanyl requirement between both groups, it was significantly less in the study group (1.4 ± 0.7 μg/kg with a range of 1–3 μg/kg vs. 3.4 ± 1.2 μg/kg with a range of 2–5 μg/kg with $P = 0.007$). By comparing the mean postoperative nalbuphine requirement between both groups, it was significantly less in the study group (9 ± 4 mg with a range 5–14 mg vs. 26 ± 7 mg with a range 16–35 mg with $P = 0.002$) (Fig 2). The mean postoperative arterial blood pressure in the study group was 75 ± 4 mmHg with a range of 70–80 mmHg, whereas in the control group it was 81 ± 5 mmHg with a range of 78–90 mmHg with a P value of 0.004 (highly significant). The same was found for the mean postoperative pulse (in beats/min). In the study group it was 82 ± 5 with a range of 74–88 versus 91 ± 7 with a range of 80–100 with a P value of 0.04 (significant). The mean postoperative VAS in the study group was 4 ± 2.6 with a range of 4–7 versus 7 ± 6.9 with a range of 5–8 in the control group with a significant P value of 0.01 (Fig 3).

Discussion

The concept of pre-emptive analgesia is the application of local anesthetic drug by regional nerve blockade, infiltration of the surgical wound, or by topical instillation into the operative bed before tissue trauma, thus preventing the noxious stimuli that result from the tissue damage [3,13].

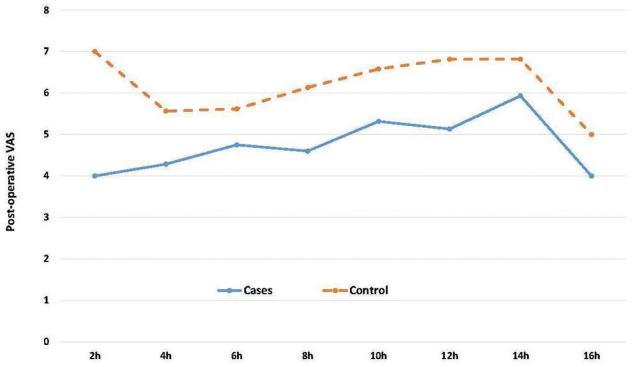
Some studies reported that the preincisional infiltration is more superior to the postincisional one [14]. This was documented by many reports including several

Figure 2



Postoperative mean nalbuphine requirement for cases and control groups.

Figure 3



Postoperative mean visual analogue scale among cases and control groups.

Table 1 Demographic data of the two study groups

Parameter	Study group (n = 60)	Control group (n = 60)	P value
Mean ± SD age (range) (years)	42 ± 7 (28–66)	44 ± 8 (37–66)	0.12
Mean ± SD BMI (range)	29.4 ± 1.8 (22–36)	30.1 ± 1.6 (21–35)	0.39
Mean ± SD BSA (range)	1.7 ± 0.7 (1.55–2.3)	1.65 ± 0.6 (1.51–2.2)	0.9
Hypertension [n (%)]	7 (11.7)	8 (13.3)	1
DM [n (%)]	7 (11.7)	9 (15)	0.82

BSA, Body surface area, DM, diabetes mellitus.

Table 2 Operative data and postoperative outcome

Parameter	Study group (n = 60)	Control group (n = 60)	P value
Mean ± SD operative time (range) (min)	127 ± 10.5 (90–160)	105 ± 7.5 (80–139)	0.01
Mean ± SD blood loss (range) (ml)	290 ± 75 (210–370)	370 ± 105 (250–480)	0.001
Mean ± SD hospital stay (range) (days)	2.1 ± 1.4 (1–4)	2.5 ± 1.1 (1–5)	0.09
Postoperative seroma [n (%)]	22 (36.7)	23 (38.3)	0.32
Postoperative hematoma [n (%)]	9 (15)	8 (13.3)	0.80
Partial flap necrosis [n (%)]	2 (3.3)	1 (1.7)	1.00
Tumor size (mm) ± SD (range)	36 ± 6 (23–69)	34 ± 8 (24–69)	0.51
Total number of lymph node ± SD (range)	11 ± 3 (8–23)	15 ± 3 (9–26)	0.12
Number of positive lymph node ± SD (range)	3.3 ± 1.5 (0–9)	3.6 ± 1.6 (0–10)	0.30

Table 3 Intraoperative and postoperative pain and stress response records

Parameter	Study group (n = 60)	Control group (n = 60)	P value
Mean ± SD intraoperative fentanyl (range)	1.4 ± 0.7 (1–3)	3.4 ± 1.2 (2–5)	0.007
Mean ± SD postoperative nalbuphine (range)	9 ± 4 (5–14)	26 ± 7 (16–35)	0.002
Mean ± SD postoperative ABP (range)	75 ± 4 (70–80)	81 ± 5 (78–90)	0.004
Mean ± SD postoperative pulse (range)	82 ± 5 (74–88)	91 ± 7 (80–100)	0.04
Mean ± SD postoperative VAS (range)	4 ± 2.6 (4–7)	7 ± 6.9 (5–8)	0.01

ABP, arterial blood pressure; VAS, visual analogue scale.

operative tasks [15]. In an important recent systematic review for 10 trials entailing the use of pre-emptive wound infiltration with bupivacaine adrenaline solution, three for mastectomy, four for segmental mastectomy, and three for reduction mammoplasty or excision of benign masses, six of them demonstrated a statistically significant reduction of postoperative pain score and four demonstrated a reduction of postoperative opioid use [16]. A recent trial demonstrated a significant reduction of the opioid requirement in mastectomy after local bupivacaine infiltration [17]. However, the intraoperative and postoperative assessment of the stress response in the form of pulse, blood pressure, and respiratory rate changes is an important issue to be investigated in any painful surgical maneuver. A significant reduction of the VAS and opioids consumption was reported by several studies [18]. A significant reduction of the postoperative pain score and postoperative opioid requirements was also reported with preincisional bupivacaine infiltration in cases of reduction mammoplasty [19]. Our work demonstrated that the postoperative VAS was significantly reduced in the study group. All stigmata of the stress response were reduced in the study group with a highly significant P value. The same was noticed in the doses of intraoperative fentanyl and postoperative nalbuphine. This copes with most of that recorded by the other studies [16]. This valuable benefit was at the cost of increased operative time (Table 2). An interesting finding in our results is the significant reduction of the mean blood loss and this is mostly due to the use of epinephrine in our cocktail (Table 3).

Conclusion

Pre-emptive mastectomy flap infiltration with bupivacaine adrenaline solution is a safe and effective method for reduction of postmastectomy pain and stress response with a significant reduction of the analgesic requirements.

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Conflicts of interest

There are no conflicts of interest.

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Single-port sleeve gastrectomy, a valuable procedure in the treatment of morbidly obese patients

Ali El Anwar, Mohamed El Shinawi, Mostafa Abdo

Department of General Surgery, Faculty of Medicine, Ain Shams University, Cairo, Egypt

Correspondence to Ali El Anwar, MD, 13 St., Mohamed Hussein Heikal, Nasr City, Cairo, 11371, Egypt
Tel: 01000069690; fax: 0224019879; e-mail: alianwar1973@yahoo.com

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Background
Laparoscopic sleeve gastrectomy has recently been proposed as a sole bariatric procedure because of the considerable weight loss that is achieved in morbidly obese patients. Single-incision laparoscopic sleeve gastrectomy has recently gained acceptance in bariatric surgery as the procedure has possible benefits. The aim of our study was to evaluate the feasibility and safety of a laparoscopic single-incision sleeve gastrectomy for morbid obesity.

Patients and methods
From January 2011 to March 2014, single-port laparoscopic sleeve gastrectomy through a special single-port silicon device that is flexible and reusable with a novel method for liver retraction was performed on 30 consecutive morbidly obese patients enrolled from Ain Shams University hospitals. The patients were 22 women (73.3%) and eight men (26.7%), mean age 31 years (range: 23–45) years. The patients recruited in this study had a mean BMI of 41.3 kg/m^2 (range: 35–45) kg/m^2. The operative technique, operative time, postoperative hospital stay, and early and late postoperative complications were monitored, and the percentage of excess weight loss (%EWL), which was measured at 3, 6, and 12 months, respectively, was determined.

Results
A total of 30 single-incision laparoscopic sleeve gastrectomies were performed. The procedure was performed successfully in 27 patients (90%), with three conversions (10%) to traditional laparoscopic sleeve gastrectomy. The mean operative time was 92 min (range: 80–135) min, whereas the mean hospital stay was 2.4 days (range: 2–4) days. In terms of morbidities, there were six cases of vomiting (20%), one case of wound infection (3.3%), and two cases of incisional hernia (6.6%). The %EWL was 26, 38.3, and 61.43 at 3, 6, and 12 months, respectively. There were no mortalities in our study.

Conclusion
Laparoscopic single-incision sleeve gastrectomy seems to be safe, technically feasible, and reproducible. Our technique for liver retraction provides adequate exposure. However, additional work must be carried out before these techniques achieve the level of standardization. More flexible articulating instruments, high-illumination, high-magnification, flexible endoscopes, and free-standing insertable retractors need to be developed.

Keywords:
primary outcome, secondary outcome, single port, sleeve gastrectomy

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Introduction

Obesity is now considered an epidemic; projections of the WHO indicate that, in 2006, at least 400 million adults were obese [1].

Bariatric surgery has proved to be the most effective treatment for morbid obesity, resulting in excellent weight loss and correcting the associated comorbidities, with a marked survival advantage [2].

Worldwide, the most widely used surgical procedures are the Roux-en-Y gastric bypass and gastric banding. Sleeve gastrectomy has recently been identified as an attractive procedure for the surgical management of obesity [3].

The recent American Society for Metabolic and Bariatric Surgery position statement on the sleeve gastrectomy has also confirmed its use as a sole bariatric operation [4].

Laparoscopic sleeve gastrectomy has gained popularity in the surgical armamentarium for treatment of obesity because it does not require gastrointestinal anastomosis or intestinal bypass. Furthermore, there is no dumping because preservation of the pylorus and resection of the stomach minimizes the risk of gastric ulcer and cancer. It also yields, in addition to the restrictive effect, hormonal regulation of appetite, because of reduced levels of ghrelin, a hormone produced by cells in the gastric fundus that stimulates hunger [5]. This technique is typically performed laparoscopically, which reduces access morbidity and recovery time; it requires five to seven ports [6].

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Over the past 20 years, minimally invasive surgery has progressed from surgery with minimal incisions, which includes laparoscopic surgery to transorifice surgery, with no skin incisions, using natural orifices such as the mouth, vagina, and rectum as ports of entry. However, this technique is highly demanding from a technical point of view. Besides, the proper technology has to be available in the operating room and the learning curve is slow. Moreover, this technique has the significant disadvantage of going through healthy organs to gain access to the peritoneal cavity; because of this disadvantage, transorifice surgery is still in its initial stages and will probably require a long time to become acceptable [7].

Transumbilical surgery has emerged as an intermediate procedure in the evolution of surgery as it allows abdominal surgery to be performed with only one port at the umbilicus, which is almost invisible, most likely with less trauma to the abdominal wall, faster recovery, and a decrease in the use of analgesics [8].

The first single-incision laparoscopic sleeve gastrectomy was described in 2008 by Saber *et al.* [9]. This new approach minimized scars and was considered minimally invasive. Today, single-port surgery can be performed with existing technology using refinements of traditional laparoscopic instruments [10].

A series of prospective studies of single-incision laparoscopic sleeve gastrectomy were carried out in 2013 by Pourcher *et al*. [10] that confirmed the efficacy and feasibility of this technique. Single-port surgery is acceptable now as a result of advances in equipment, laparoscopic skills, and a positive evolution of conventional laparoscopic surgery [10].

This is a prospective study that aimed to evaluate laparoscopic single-port sleeve gastrectomy in the treatment of morbidly obese patients in terms of the choice of the type of patients, intraoperative challenges, postoperative outcomes, advantages, and disadvantages.

Patients and methods

This is a prospective study that includes 30 morbidly obese patients. Surgical procedures and follow-up were performed at Ain Shams University hospitals. An approval from the surgical ethical committee was obtained and validated to carry out this study. Written informed consent was signed by each patient participating in this study.

From January 2011 to March 2014, single-port laparoscopic sleeve gastrectomy through a special single-port silicon device that is flexible and reusable with a novel method for liver retraction was performed on 30 consecutive morbidly obese patients enrolled from Ain Shams University hospitals. The patients were 22 women (73.3%) and eight men (26.7%), mean age 31 years (range: 23–45) years. The patients recruited in this study had a mean BMI of 41.3 kg/m^2 (range: 35–45) kg/m^2. Patients with major cardiac, respiratory, renal, or hepatic comorbidities interfering with anesthesia or laparoscopy were excluded as were patients younger than 18 years of age and older than 60 years of age. The operative technique, operative time, postoperative hospital stay, and early and late postoperative complications were monitored, and the percentage of excess weight loss (%EWL), which was measured at 3, 6, and 12 months, respectively, was also determined.

Preoperative evaluation

(1) Full assessment of history and examination.
(2) Accurate measurement of the BMI and waist contour.
(3) Questionnaire for the psychological assessment of the patient.
(4) Routine laboratory studies.
(5) Pulmonary function test.
(6) Pelvi-abdominal ultrasound.

Operative details

Positioning

All procedures were performed under general anesthesia in the supine antitrendelenburg position with the legs apart after the patient was positioned on the table with a belt and application of compression bandage around both legs up to the mid thigh. The main surgeon stood between the patient's legs, with assistants standing on both sides. A monitor was located at the head of the patient.

Single-port application

A 2.5 cm transumbilical incision was performed to introduce the multichannel port using a Kocher clamp. We used a special single-port silicon device that had two 5 mm and one 12 mm trocars in addition to two insufflation channels. The port was flexible and reusable (Fig. 1).

Once pneumoperitonium was achieved with carbon dioxide, we used a 5 mm angled scope to visualize the peritoneal cavity.

In all patients, we used a laparoscopic Babcock, which was introduced through a 5 mm port in the epigastrium for liver retraction.

Procedure

The operative steps were similar to those of a conventional laparoscopic sleeve gastrectomy. However, we used a group of long, straight, and curved articulating instruments in this procedure to improve ergonomics and overcome the swording and overcrowding of instruments during surgery (Fig. 2).

Traction on the greater curvature of the stomach was achieved using a 5 mm articulated clamp, and then the stomach was mobilized at 3–4 cm proximal to the pylorus using a vessel sealing device, 5 mm (Harmonic scalpel (Ethicon, Cincinnati, Ohio, USA), Ligasure TM Vessel SealingSystem (Vallylab, Boulder Co, USA), Kocher clamp is a surgical tool which can be made anywhere Sonicision (Vallylab, Boulder Co, USA)). The lesser sac was entered, and remaining close to the wall of the stomach, the greater curvature ligaments (gastrosplenic and gastrocolic) were divided all the way up to the angle of His. It is important to identify and mobilize the angle of His with exposure of the left crus of the diaphragm to delineate the gastroesophageal junction and to facilitate complete resection of the gastric fundus. Retrogastric adhesions were taken down to allow complete mobilization of the stomach (Fig. 3).

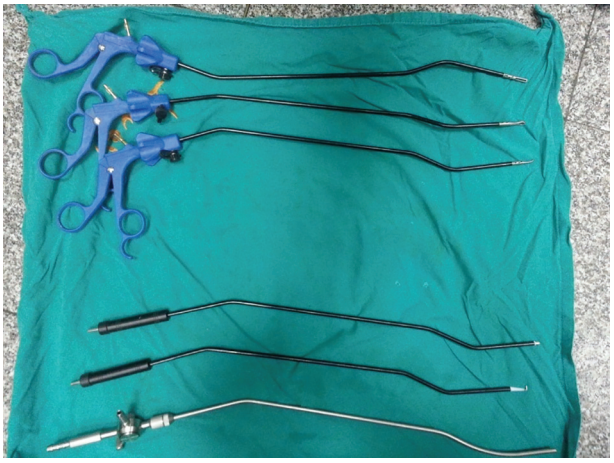
Once the stomach had been completely mobilized, a 36 Fr bougie was introduced into the stomach by the anesthetist and directed medially along the lesser curvature into the distal stomach. Gastric transaction was then started at a point 3–4 cm proximal to the pylorus using an articulating long laparoscopic stapler with 60 mm loads. The first stapling fire was performed by green load, followed by sequential fires by blue loads along the length of the bougie till complete separation of the stomach. The staple line was then carefully inspected for bleeding and the methylene blue test was performed to exclude leakage (Fig. 4).

Then, an intra-abdominal drain was inserted along the staple line and the stomach remnant was exteriorized

Figure 1

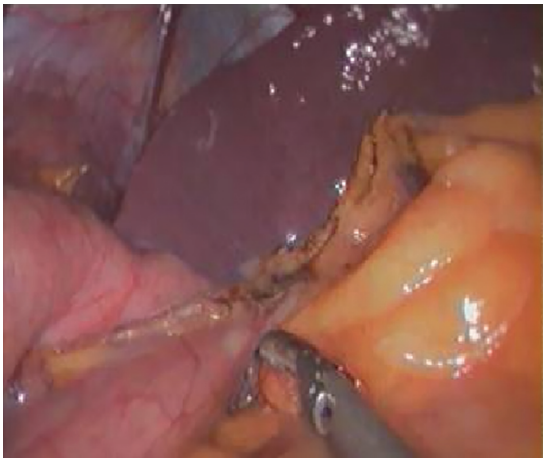
The reusable multichannel port.

Figure 2



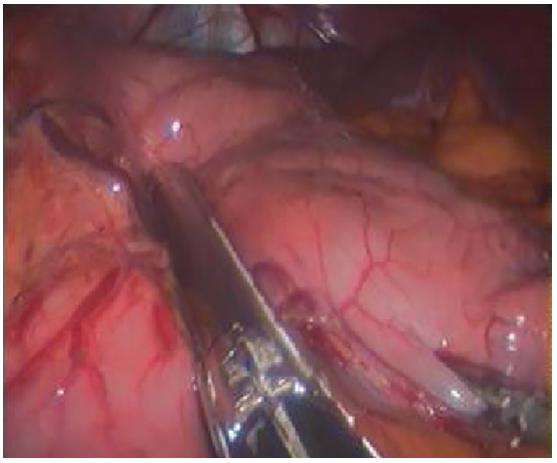
Curved instruments for the single-port procedure.

Figure 3



Division of the short gastric vessels near the spleen to free the fundus.

Figure 4



Laparoscopic stapling of the stomach.

from the same fascial incision. The defect was then carefully closed with a nonabsorbable one suture to prevent incisional hernia (Figs 5 and 6).

Patients' care and follow-up

Routine postoperative care was performed for all patients, with the initiation of a prophylactic dose intravenous anticoagulant on the night of the operation. Patients were monitored for short-term complications (hemorrhage, leakage, infection, deep venous thrombosis, infection, vomiting). Patients were discharged home after they demonstrated that they were ambulatory, could tolerate a liquid diet, and had achieved pain control with oral narcotics. Patients were followed up 2 weeks after surgery and subsequently at 3, 6, and 12 months.

Outcome measures

Primary outcome measures

The primary endpoint was the intraoperative assessment of the procedure in terms of technical challenges, operative time, incidence of bleeding, quality of the instruments used, and the rate of conversion either to conventional laparoscopy or open surgery.

Secondary outcome measures

The secondary endpoint was the assessment of postoperative sequelae of the procedure performed such as postoperative pain, cosmoses, psychological impression of the patient, length of hospital stay, incidence of complications, and mean %EWL after 3, 6, and 12 months. The percentage of EWL was calculated as the ratio between postoperative weight loss and excess weight over the ideal body weight, which was calculated according to a BMI of 25 kg/m^2.

Statistical analysis

Demographic, clinical, morbidity, and weight loss data were collected, recorded, and stored in a secure prospective bariatric surgery database. The data were collected, coded, revised, and entered into the statistical package for social science, version 20 (IBM, Armonk, New York, USA). The data were presented as number and percentages for the qualitative data and mean with ranges for the quantitative data.

Results

Demographic data

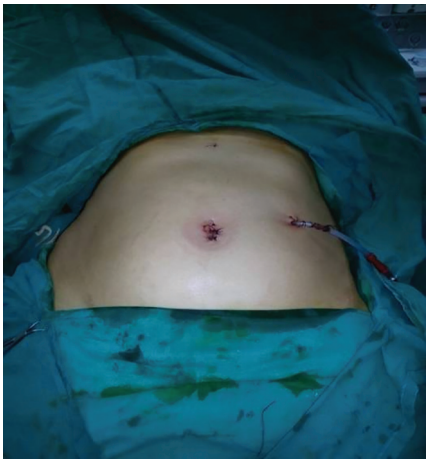
Thirty patients were included in the study, 22 women (73.3%) and eight men (26.7%), mean age 31 years (range: 23–45) years. The patients recruited in this study had a mean BMI of 41.3 kg/m^2 (range: 35–45) kg/m^2. Their mean preoperative body weight was 109 kg (range: 99–150) kg (Fig. 7).

Conversion to multiport laparoscopy occurred in three cases (10%): in two cases, to control bleeding at the gastrosplenic area and one because of technical difficulties in the dissection and endostapler. However, no conversion to open surgery was observed. Otherwise, no other intraoperative complications occurred.

The mean operative time was 92 min (range: 80–135 min) (Fig. 8). In the initial 15 cases, the mean time was 110 min (range: 96–135) min, whereas in the last 15 cases, the mean time was 85 min (range: 80–100) min.

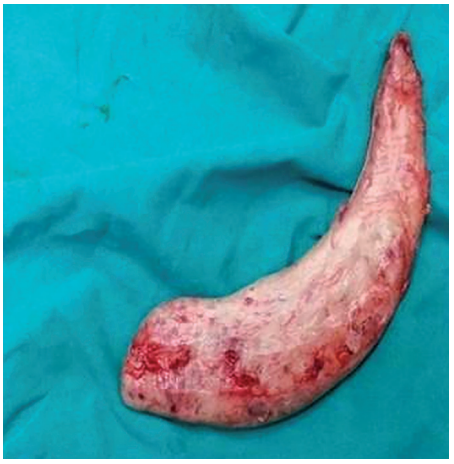
The mean hospital stay was 2.4 days (range: 2–4) days. All the patients reported mild postoperative pain, which was controlled by intravenous analgesics, and improved markedly upon discharge of the patients from the hospital.

Figure 5



Final shape after wound closure and intra-abdominal drain.

Figure 6



Stomach remnant.

Early postoperative complications included six cases of vomiting (20%) starting on day 1, which was controlled by medications and antiemetic drugs and improved in all patients maximum by the third day. There was one case of wound infection, which was managed by oral antibiotics and resolved.

Otherwise, there were no other early morbidities such as leakage or hemorrhage. The mortality rate was 0%.

Late complications occurred in two cases that developed incisional hernia at the umbilical scar after 9 and 11 months and needed surgical repair with mesh. There was no evidence of late stenosis, psychological disturbance, or nutritional deficiencies in any patient (Table 1).

The mean %EWL was measured at 3, 6, and 12 months. At 3 months, %EWL was 26%, whereas at 6 months, %EWL was 38.3%, reaching 61.43% by the end of the 12th month (Fig. 9).

Discussion

Laparoscopic sleeve gastrectomy is a comparatively new technique that is safe and effective especially in superobese patients. It involves resection of two-thirds of the stomach, including the fundus, whereas the remaining part from the gastroesophageal junction to the pylorus along the great curvature is used to form a 'sleeve'. This procedure decreases the volume of the stomach to about 100 ml, which is easier to fill and thus leads to lower food intake [11].

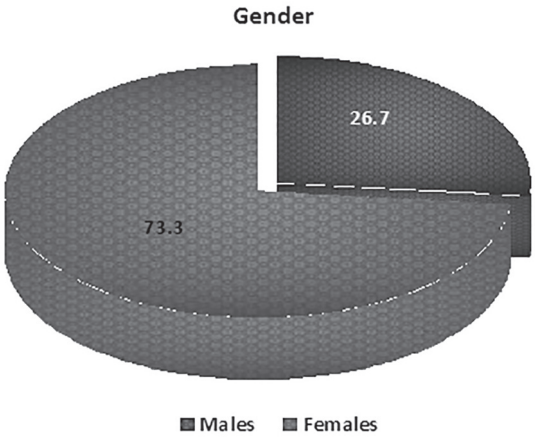
The last decade witnessed some of the most spectacular innovations in the field of surgery. The aim has been to deliver more through less. The basic idea behind every new development has been reduction of pain, better cosmetic results, and reduction in the hospital stay, with comparable results and complication rates as the conventionally accepted procedures [12].

Table 1 Summary of postoperative complications

Complications	SILS Sleeve
Early	
Leakage	0
Hemorrhage	0
Vomiting	6
Wound infection	1
DVT	0
Late	
Stricture	0
GERD	0
Nutritional Deficiency	0
Incisional Hernia	2
Psychological	0

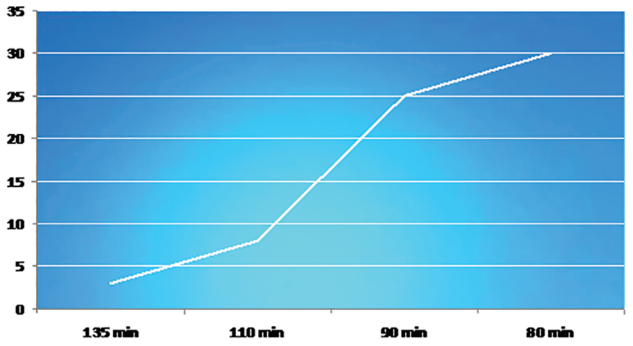
Whenever a new technology is put forward, questions on its feasibility, safety, efficacy, and reproducibility are raised. The risk versus benefit ratio of any new procedure must be weighed before it can be promoted as a standard procedure that can stand the test of time [12].

Figure 7



Sex distribution among the studied sample.

Figure 8



Mean operative time.

Figure 9

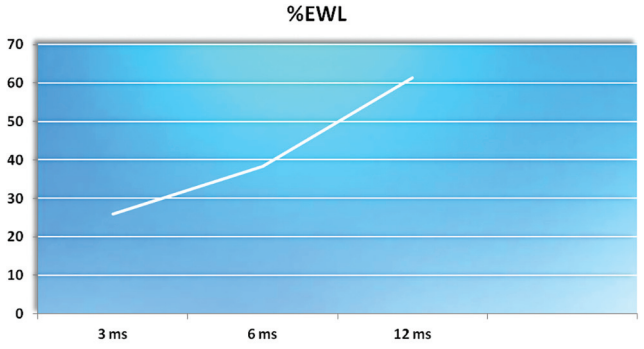


Chart showing the percentage of excess weight loss over 1 year.

Ever since laparoscopic surgery has been considered the new standard in abdominal surgery, a permanent question has remained on further reduction in the number of ports for abdominal access routes. The search has mainly occurred in two directions: surgery through natural orifices and exclusive access using the transumbilical route [13].

Morbid obesity was initially considered a disadvantage in single-incision surgery. Increasing BMI with very high intra-abdominal fat content and large fatty livers, in addition to the inherent difficulty of single-incision surgery, proved to be hurdles for the application of this technique to bariatric surgery. Thus, case selection is of paramount importance, especially in the first few cases [12].

In this study, we report our initial experience with laparoscopic single-port sleeve gastrectomy. This is not a novel approach as it has been described by other authors and discussed the challenges of the technique and their impression about it.

In our study, we recruited 30 obese patients for the procedure; their mean BMI 41.3 ranged from 35 to 45 kg/m^2. In our opinion, the choice of patients was very important, especially considering that this was our initial experience with this technique. We decided to use this technique on patients with a relatively low BMI particularly in the first few cases. The patients had undergone no previous abdominal operations and we excluded patients with extremes of age as well as patients with major cardiac, respiratory, renal, or hepatic comorbidities that could interfere with anesthesia or laparoscopy. This was to minimize the risks during operation until we established a safety protocol for single-incision surgery. This is in agreement with the study carried out by Delgado *et al.* [3], in which the mean BMI of the patients in their initial series was 40.1 kg/m^2 (35.6–55.6 kg/m^2), lower than that reported by Saber *et al.* [9] and the same as that published recently by Huang *et al.* [14].

We believe that in obese patients, enlarged fatty liver poses a major difficulty for laparoscopic bariatric surgery and single-port surgery; it is a true technical challenge. For this reason, we used a 5 mm port in the epigastric region to introduce a laparoscopic Babcock for liver retraction. Using this technique, we observed marked improvement in the visualization of the operative anatomy, especially at the region of the gastroesophageal junction and short gastric vessels.

In one of the first case reports, Raevis *et al.* [15] successfully performed a single-incision surgery on a 54-year-old male patient with a BMI of 38 kg/m^2. They suggested that without any kind of liver retraction, the use of single-incision surgery in bariatric surgery will be limited only to patients with lower BMI. In the same year, Saber *et al.* [16] reported a series of seven single-access laparoscopic sleeve gastrectomy patients. They used an additional Nathanson's liver retractor through a small subxiphoid incision in all patients. In 2010, Saber *et al.* [16] extended the use of this technique to include super obese patients and performed single-incision surgery in four super obese with a mean BMI of 62.5 kg/m^2. Huang *et al.* [14] described the placement of a band for liver suspension, prepared personally by the authors, with a double puncture to the liver using the end of a Jackson–Pratt drain.

Muffazal *et al.* [12] carried out a similar study on 50 patients. In that series, they retracted the liver using monofilament sutures on straight needles with a pledget to retract the liver to the anterior abdominal wall. Delgado *et al.* [3] also reported on a series of 20 patients and they used a small 2–3 mm port in the epigastric region for liver retraction.

In the study carried out by Pourcher *et al.* [10], 13 patients (21.6%) had a large left lateral lobe requiring the use of an additional trocar, probably corresponding to the use of a fourth trocar in the three-port laparoscopic technique. The use of an additional trocar facilitated the adaptation of the LESS surgical technique without the need to extend the operating time or convert to open surgery.

The main principle of single-incision laparoscopic surgery is to perform the entire procedure through a single approach in the skin through a multiport device. In our series, we used this technique and introduced the multiport through the umbilicus. The distance between the umbilicus and the xiphisternum was another operative challenge particularly in tall patients, in whom long instruments had to be used to reach and manipulate the operative field.

Compared with conventional laparoscopic surgery, single-incision surgery defies the standard surgical principles of traction and counter-traction. The shortcomings of the siljgle insicion sleeve gasterctomy (SISG) compared with laparoscopic sleeve gasterctomy (LSG) are as follows:

(a) Clashing of instruments,
(b) Crossing of hands during surgery,
(c) Difficulty in repairing the hiatal defects, and
(d) The fact that oversewing of the staple line, if needed, is technically very demanding.

The lack of triangulation and parallel vision of the scope are additional hurdles [12].

Coordination between the surgeon and the camera person and switching the 5 mm instrument between

the laparoscopic ports are essential to optimize the instruments' range of motion for better ergonomics and to avoid clashing of the instruments and the laparoscope during the procedure. Confident, multiport laparoscopic skills are critical to safely introduce this new technique without added complications. This approach has a unique learning curve, principally to overcome the technical challenges of navigating instruments within a limited range of motion [9].

In our study, three cases were converted to conventional laparoscopic surgery. All these conversions occurred in the first 15 patients. Two of these cases were to control bleeding from the short gastric vessels; these patients had a large liver and needed proper counter-traction with additional ports. The other case was converted because of technical difficulties in the use of instruments and stapler. However, in the last 15 cases, the procedure was smooth and technical challenges were nearly eliminated. There was no conversion to open surgery in our series. In the series reported by Delgado *et al.* [3], one case was converted (5%)(N = 1/20 patients) because of technical problems with the length of the endostapler and a large liver steatosis, rendering sleeve gastrectomy technically impossible; however, Maluenda *et al.* [13] and Gentileschi *et al.* [2] reported no conversions to open or conventional laparoscopic surgery.

In our study, we used a group of long, straight, and curved laparoscopic instruments in addition to a rigid 5 mm 45° scope. It took some time in the first few cases to achieve the best harmony between the instruments used and standardize a technique for the procedure. This was reflected on the operative time, which was 110 min on average for the first 15 cases and reduced to 85 min on average in the last 15 patients. Our overall mean operative time was 92 min. Saber *et al.* [9] reported a mean surgical duration of 125 min in their series of seven cases of sleeve gastrectomy performed through a single transumbilical incision. The operating time reported by Gentileschi *et al.* [2] was 128 min (range 84–140 min), whereas Delgado *et al.* [3] reported 79.2 min (range 50–130 min), Pourcher *et al.* [10] reported 86 min (range 52–205 min), and finally Maluenda *et al.* [13] reported an average operative time of 127 min (range 90–170 min). We believe that with increased experience, the operative time would decrease proportionally.

No other intraoperative complications were reported.

Our observation was that the patients had less pain after the first 8 h postoperatively and did not require regular analgesics during hospital stay and upon discharge, and none of them developed significant pain after 7 days. Maluenda *et al.* [13] reported that patients who had undergone single-port sleeve gastrectomy had considerably less pain from the eighth hour after surgery, resulting in a decrease in the use of analgesics. In the study carried out by Lakdawala *et al.* [15], single port sleeve gasterctomy (SPSG) and conventional laparoscopic sleeve gastrectomy were compared in 50 patients per group, and similar results were found. They also confirmed the results of pain reduction and better cosmesis. The pain reduction probably resulted from the use of single-site incision, with effect on the abdominal wall.

The mean hospital stay was 2.4 days (range 2–4 days), which is comparable with the other case series reported by other centers. Pourcher *et al.* [10] reported a median length of hospital stay of 4 days (range 3–9), whereas Gentileschi *et al.* [2] reported a median hospital stay of 2.4 days (range 1–3 days).

In our study, we divided the postoperative complications into early and late.

(1) Early: leakage, hemorrhage, infections, vomiting, and deep venous thrombosis (DVT).
(2) Late: stricture, gastro esophageal reflux disease (GERD), incisional hernia, nutritional deficiency, and psychological disturbance.

There was one case of wound infection at the umbilical scar that appeared on the fourth postoperative day and this was managed by oral antibiotics without readmission to the hospital.

Another early complication was vomiting, which occurred in six patients (20%) within the first 72 h. This was resolved by the administration of intravenous antiemetics and proton pump inhibitors during hospital stay, and all these patients showed an improvement and were discharged; none of them complained of significant vomiting after discharge.

In terms of late complications, two patients developed incisional hernia at the umbilical scar. They developed the hernia at 9 and 11 months, respectively. One patient already had a weak abdominal wall at the time of the operation and the other patient developed wound infection. Both patients underwent repair of the hernia with mesh.

No other complications were encountered. There were no cases of mortality in our study.

There was no morbidity or mortality up to 30 postoperative days in the study carried out by Maluenda *et al.* [13], whereas Pourcher *et al.* [10] reported a complication rate of (3.3%) (N = 2/60 patients). The first was a leak on the upper gastric zone,

which was treated by a covered endoscopic prosthesis. The second was hand parasaethesia because of cubital nerve compression, which disappeared spontaneously 6 h after surgery. They did not observe any incisional hernia during the follow-up period. Also, no death occurred in the postoperative period.

Delgado *et al*. [3] reported a complication rate of 10% (two cases) in the form of postoperative hemoperitoneum, which required early reoperation 1 day after surgery. There was no operative wound infection, evidence of late stenosis, or other complications during follow-up. The 30-day mortality was 0%.

Gentileschi *et al*. [2] reported only one postoperative complication (n = 1/8, 12.5%) of wound infection, which was treated with drainage and antibiotic therapy. No postoperative trocar site hernia development was encountered in this study as well as in the study carried out by Pourcher *et al.* [10].

Efficacy is a very important aspect of any new procedure. It must be implemented only if the results of the conventional procedure can be duplicated or improved. The most important factor for assessment of the efficacy of our procedure is the %EWL, which was measured at 3, 6, and 12 months.

At 3 months, %EWL was 26% whereas at 6 months %EWL was 38.3%, reaching 61.43% by the end of the 12th month. Maluenda *et al*. [13] reported that a mean EWL at 6, 12, and 24 months after surgery of 99, 118, and 114% respectively. Pourcher *et al.* [10] reported a mean reduction in excess weight of 65.8%, with all 60 patients losing more than 50.0% of their excess weight. Delgado *et al*. [3] and Muffazal *et al.* [12] published in their series of patients who underwent single-port sleeve gastrectomy a mean %EWL of 52% and 64.38% at 6 months, respectively. Our results were also comparable with other studies on conventional laparoscopic sleeve gastrectomy. Baltasar *et al.* [17] have reported a mean percent EWL of 56.1% from 4 to 27 months after surgery. Lakdawala *et al*. [15] also reported a mean percent EWL of 50.8% at the end of 6 months.

All the patients were satisfied with the cosmetic results of the operation in the sequential follow-up visits as, using the single-access approach, we could combine all of the standard laparoscopic entry points into one port of entry, that is, the umbilicus, thus decreasing the number of incisions required for laparoscopic sleeve gastrectomy from six or seven incisions to two incisions. Fewer incisions ultimately result in minimal discomfort, fast recovery time, and a hidden scar [9].

The limitations of this study were that these were short-term results in a small patient pool. We acknowledge that this is a pilot study, and the aim was to establish the feasibility and safety of this new single-incision technique after determining the weight loss results and complication rates. Another limitation of our study was that the feeling of satisfaction related to the superior cosmetic scar after surgery was a purely subjective feeling expressed in the opinion of most of our patients. We hope to record this on a validated patient outcome questionnaire in our future series. The limitations of the technique are the benefits of this procedure may not extend to patients who are super obese or have a scarred abdomen. In addition, a larger randomized study on larger numbers of patients with a long-term follow-up of 5 years is recommended to determine its applicability in comparison with conventional laparoscopy and to detect any additional complications.

Additional work must be carried out before these techniques can be standardized. More flexible articulating instruments, high-illumination, high-magnification, flexible endoscopes, and free-standing insertable retractors need to be developed. Introduction of robotically controlled flexible instruments through the single port might be the ultimate solution to improve technical performance.

Acknowledgements

Conflicts of interest

None declared.

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Management of concomitant gall bladder and common bile duct stones, single stages laparoscopic versus endo-laparoscopic: A center experience

Wael Mansy[a], Morsi Mohamed[a], Wael Mahmmoud[b], Mohammed Lofty[a], Ossama Gharib[c]

[a]General Surgery Consultant, [b]Endoscopist Consultant, [c]Assistant Professor, General Surgery Department, Zagazig University, Zagazig, Egypt

Correspondence to Wael Mansy, MD, General Surgery Consultant, Zagazig University, Hepato–Pancreatico–Biliary Specialist, Villal Gamaa, Villa Nesma, Zagazig, Egypt
Tel: 01221607587; fax: 055-2307-830;
e-mail: drwaelmansy@hotmail.com

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Background
One-stage laparoscopic cholecystectomy and endoscopic retrograde cholangiopancreaticography (ERCP-LC) was compared with one-stage laparoscopic cholecystectomy and laparoscopic exploration of common bile duct (LC-LCBDE) in patients with choledocholithiasis in an attempt to find the best mini-invasive treatment for choledocholithiasis.

Patients and methods
For this study, 46 patients with cholelithiasis and choledocholithiasis diagnosed with preoperative ultrasonography and other diagnostic studies were divided randomly into an ERCP-LC group (group A) (23 cases) and an LC-LCBDE group (group B) (23 cases).
The surgical time, surgical success rate, postoperative complications, retained common bile duct stones, postoperative length of stay, and hospital charges for operative procedures were compared prospectively.

Results
There were no statistically significant differences between the two groups in terms of surgical time, surgical success rate, postoperative complications, retained common bile duct stones, and postoperative length of stay, but there was a big difference in hospital charges for operative procedures.

Conclusion
Finally, we can conclude that there was no statistically significant difference between the two groups in terms of surgical time, surgical success rate, postoperative complications, mortality rates, retained common bile duct stones, and postoperative length of stay. However, patients in group A were more vulnerable than patients in group B to developing low-grade cholangitis because of sphincterotomy performed during stone extraction.

Keywords:
choledocholithiasis, laparoscopic cholecystectomy and endoscopic retrograde cholangiopancreaticography, laparoscopic cholecystectomy and laparoscopic exploration of common bile duct

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Introduction

Worldwide, there is large variability in the incidence and prevalence of choledocholithiasis. In most patients in western countries, choledocholithiasis is secondary to cholelithiasis. In contrast, higher rates of primary choledocholithiasis have been reported from Asian countries [1].

Ten percent of the female population and 6% of the male population is affected by cholelithiasis. About 10–20% of them are associated with common bile duct (CBD) stones, with the percentage of association between 8 and 15% in patients under the age of 60 and between 15 and 60% in patients over the age of 60 [2].

Choledocholithiasis is often suspected in patients who have elevated liver enzymes, jaundice, pancreatitis, radiologic signs of dilated intrahepatic or extrahepatic ducts, or evidence of CBD stones either on transabdominal ultrasound, computed tomography, MRI, endoscopic ultrasonography, or cholangiography [3].

Recently, laparoscopic common bile duct exploration (LCBDE) emerged as a safe and effective therapy for CBD stones. Many stones can be quickly and simply cleared by transcystic means or through the CBD, providing patients with a single-stage procedure [4].

ERCP with sphincterotomy has become the gold standard nonoperative modality for the removal of CBD stones. Morbidity is 2–10%, and mortality is less than 2%. Immediate complications include bleeding, duodenal perforation, cholangitis, and pancreatitis, but many of these can be prevented by using various tools, including an alternating coagulation and cutting diathermy, routine biliary stenting, frequent

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use of guidewire to avoid precutting, and mechanical lithotripsy [5].

Patients and methods

This study was carried out on 46 patients who presented with choledocholithiasis at the General Surgery department of Zagazig University Hospitals between January 2013 and January 2015. The patients were divided into two treatment groups: The first group (23 patients) (group A) comprised patients who underwent one-stage laparoscopic cholecystectomy and endoscopic retrograde cholangiopancreaticography (ERCP-LC). The second group (23 patients) (group B) comprised patients who underwent one-stage laparoscopic cholecystectomy and laparoscopic exploration of the common bile duct (LC-LCBDE).

All patients were subjected to routine history taking, physical examination, and routine laboratory investigations in the form of complete blood count, liver and kidney function tests, and evaluation of PT and INR, lipase, amylase, and CA19-9.

All patients underwent imaging studies in the form of transabdominal ultrasonography to assess the gall bladder, CBD dilatation, or stones, and to assess the liver for diseases such as cirrhosis, fibrosis, and dilated intrahepatic radicals. Magnetic resonance cholangiopancreaticography (MRCP) in patients with a positive history suggestive of biliary stone disease and ultrasonography did not reveal stones in a dilated CBD.

A preoperative broad-spectrum antibiotic was given to all patients and preoperative intramuscular injection of vitamin K was given for 3 days to patients with prolonged PT to correct the coagulopathy.

The operative interventions for group A

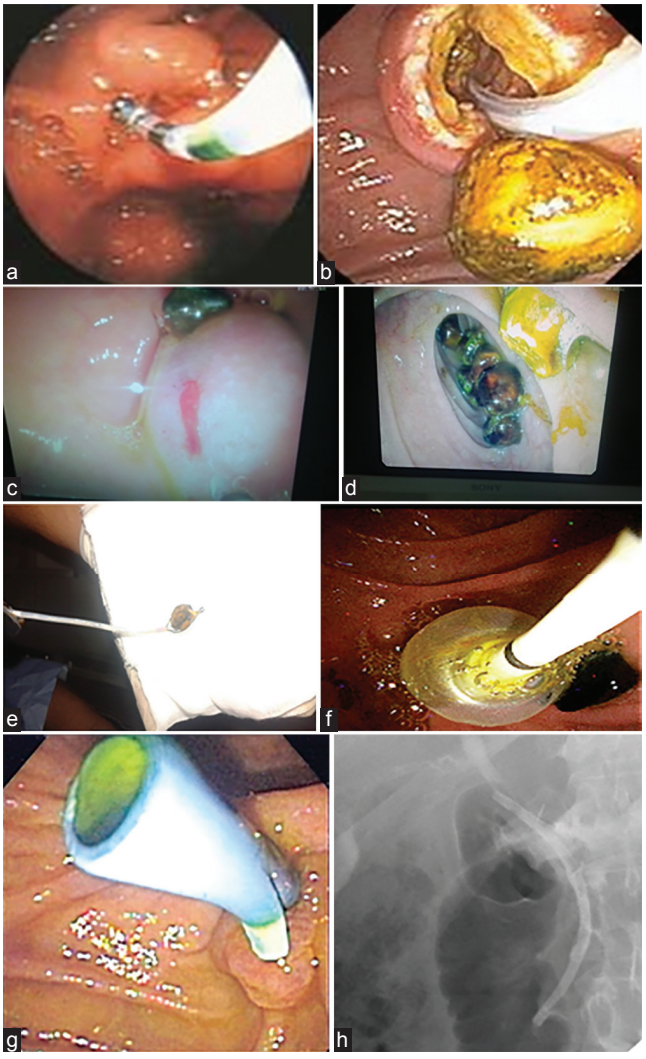
Patients randomized to group A (ERCP/S + LC group) were scheduled to undergo the endoscopic procedure using fluoroscopy before intended laparoscopy.

The endoscopic retrograde cholangiopancreaticography technique

The endoscope was passed gently down the esophagus into the stomach and then advanced toward the pylorus. Gentle rotation and pressure was used to pass the endoscope through the pylorus into the proximal duodenum. Selective cannulation of the CBD was performed. Thereafter, we injected 1–2 ml of 50% Hypaque dye gently to delineate the biliary tree (to determine the presence or absence of intrahepatic and extrahepatic biliary dilatation and stones in CBD). A wire-guided sphincterotomy was performed with the sphincterotome over the guidewire. Further procedures were then performed, either stone extraction using balloons (for stones that were <1 cm in diameter) or a Dormia basket (for larger stones) with stenting using plastic stents of 7-Fr diameter and 10 cm long (Fig. 1).

Patients were subjected to laparscopic cholecystectomy at the same setting after complete suction of air introduced into the gut during endoscopy. Liver function tests for pancreatic enzymes were conducted for all patients before hospital discharge. The patients in this group were readmitted to the hospital 1 month after discharge as 1-day surgical cases for plastic stent removal by ERCP.

Figure 1



(a) Cannulation of common bile duct (CBD). (b) Completed sphincterotomy. (c) Stone bulging from papilla. (d) Multiple extracted CBD stones. (e) Basket stone extraction. (f) Balloon stone extraction. (g) Endoscopic view of the biliary stent. (h) Radiographic view of the biliary stent.

The operative interventions for group B

Intraoperative cholangiogram

After clipping the cystic duct at or near its termination on the gallbladder and before dividing it, a small transverse incision was made about 1 cm from its insertion into the common hepatic duct. Then a 3-Fr cholangiocatheter was introduced through a gray cannula sheath inserted in the right hypochondrium. This catheter was connected to a 20-ml syringe filled with urografin 76% diluted with warm normal saline (1 : 1). The catheter was advanced 1–2 cm into the dochotomy in gradual motion and was secured in place by a clip on the cystic duct (Fig. 2).

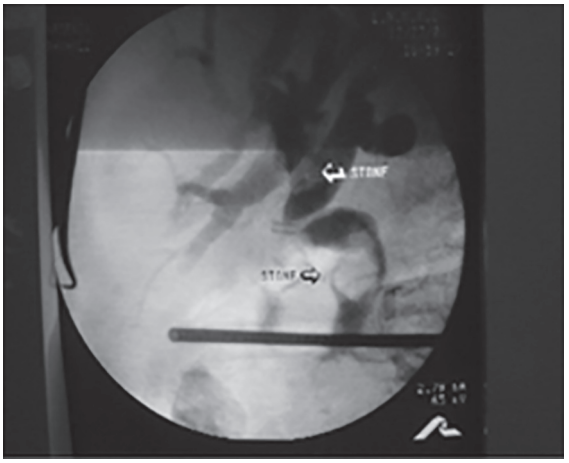
After confirmation of the presence of CBD stones, we proceeded toward a transcystic approach or a choledochotomy approach (Fig. 3).

Transcystic approach

The transcystic approach was applied in seven patients. The catheter was removed and a balloon dilatation catheter was inserted over a guidewire into the cystic duct, and dilatation of the cystic duct to 5–7 mm in diameter was carried out in 3 min. Thereafter, stone extraction through transcystic common bile duct exploration (TCBDE) was performed using a three-wire soft Dormia basket with three different approaches:

(1) By blunt introduction of the instrument into the CBD through the cystic duct (in one patient).
(2) Under fluoroscopic guidance (safer for ensuring stone capture and avoiding instrumental CBD injury) (in four patients).
(3) Under visual cholangioscopic guidance (for small stones) (in two patients).

Figure 2



Intraoperative cholangiogram showing two stones in the common bile duct.

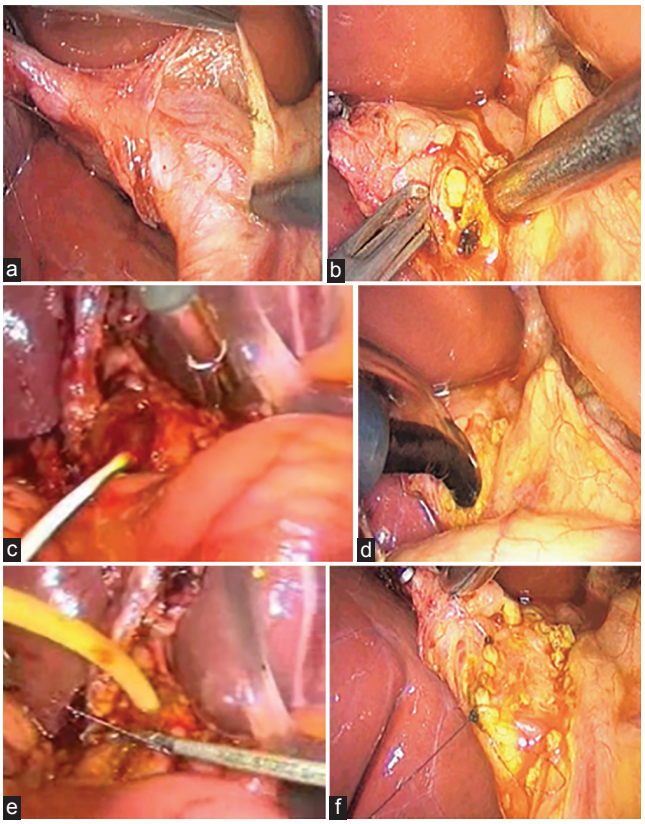
We did not use a balloon catheter during TCBDE to avoid stone migration to the upper part of the CBD. Stone clearance assessment was performed in two different ways, by control cholangiography or by using a flexible choledochoscope. When doubt existed about the completeness of stone clearance, the CBD was drained by means of a transcystic duct drain.

Choledochotomy approach

The choledochotomy approach was performed in 14 patients. A longitudinal incision was made in the CBD. Stone extraction was carried out as per the transcystic approach, but the balloon could be used. Thereafter, stone clearance assessment was made as in the transcystic approach. Suture of the choledochotomy was done by primary CBD closure or by external biliary drainage using a T-tube exteriorized through the site of the most lateral trocar. Closure of the choledochotomy was performed with interrupted or continuous suture with vicryl 4-0 stitches. After finishing CBD exploration, laparoscopic cholecystectomy was performed as in group A.

Postoperative assessment was made clinically, by means of liver function tests, assessment of pancreatic

Figure 3



(a) Exposure of common bile duct (CBD). (b) Stone extraction. (c) Balloon stone extraction. (d) Cholangioscope. (e) Closure of CBD by means of a T-tube. (f) Primary closure of CBD.

enzymes, checking of biliary drains, and through control cholangiography on postoperative days 2–3 (before hospital discharge) if a T-tube drain is in place, to exclude a residual CBD stone or a biliary leak.

All patients were followed up after 1, 2 weeks, 1, 2, and 6 months on outpatient basis with repeated assessment of patients' symptomatic status, physical exam, liver function tests, and abdominal ultrasonography.

Results

This study included 46 patients with cholelithiasis and choledocholithiasis; half of them (50%) were in the age group of 41–60 years (mean age 42.5 ± 15.7 years). The majority were female (67.4%). Some patients were found to have comorbid medical problems: five patients were hypertensive, one was diabetic, and two were found to have ischemic heart disease (Table 1).

Most of our patients (39, 84.8%) complained of right upper-quadrant pain (RUQP).

There was disturbance in liver functions in most of the cases. Elevated serum bilirubin level was detected in 38 patients (82.6%), elevated γ-glutamyl transeferase levels were found in 45 patients (97.8%), and elevated serum glutamic oxaloacetic transaminase and serum glutamic pyruvic transaminase levels were found in 42 patients (91.3%); in 31 of them, elevated enzymes were up to two-fold of normal, and in 11 patients the elevated enzymes were more than two-fold of normal. Normal laboratory results were found in four patients.

Abdominal ultrasonography was performed on all patients. It revealed chronic calcular cholecystitis in 46 patients. Dilatation of CBD with stones inside was detectable in 37 patients (80.4%) only (dilated >1 cm in 34 cases and dilated >2 cm in three cases). The remaining nine cases showed equivocal results and were subjected to MRCP to ensure the diagnosis of calcular obstructive jaundice.

The operative procedures in group B were completed in 20 cases (86.9%). The transcystic approach was applied in seven cases and the choledochotomy approach in 14 cases, of which four cases were closed by means of a T-tube, nine cases were closed primarily, and one case failed because of a large impacted stone in the distal part of the CBD.

Group A

The procedures were completed in 21 cases (91.3%) in group A, with two cases converted to open surgery (8.7%). The conversion included one case in whom CBD clearance could not be achieved because of an impacted large stone in its lower part with failed CBD cannulation and one case because of the presence of the papilla in the floor of the large duodenal diverticulum. The diameters of the stones removed ranged between 5 and 15 mm. The procedure time ranged from 145 to 180 min with a mean of 160 ± (10.4) min. The duration of the procedure was longer in the early cases than in the late cases. Our procedure's mean operative time was 160 min. Efficacy of CBD clearance was 86.9% (two cases that failed ERCP were converted to open surgery and one patient had retained CBD stones postoperatively in this group).

Group B

The procedures were completed in 20 cases (86.9%) in group B; three cases were converted to open surgery (13%): two because of severe adhesions in Calot's triangle and one because of impacted large stones measuring 2 cm with no available lithotripsy. The diameters of the stones removed ranged between 8 and 24 mm. The procedure time ranged from 160 to 190 min with a mean of 176.4 min. The efficacy of CBD clearance was 82.6% (three cases were converted to open surgery and one patient had retained CBD stones postoperatively in this group) (Table 2).

As regards group A, postoperative complications occurred in three patients (13%): minor complications in the form of mild pancreatitis with elevation of serum amylase in two patients, which was managed conservatively, and pneumonia in one patient. As regards group B, postoperative complications occurred in four patients (17.4%): minor complications in the form of minimal biliary leakage in the subhepatic drain in two patients, which was managed conservatively, pneumonia in one patient, and T-tube infection in one patient.

The postoperative length of hospital stay in group A ranged from 2 to 5 days (mean 3 days). In group B, the postoperative length of hospital stay ranged from 2 to 7 days (mean 3.5 days). Mortality was zero in both groups.

Comparison of the surgical cost in noncomplicated cases as regards the operative charges only in Zagazig university hospitals revealed that the mean cost in group A (2542.5 ± 64.4 EP) was significantly higher than that in group B (720.6 ± 40.1 EP) (Table 3).

Table 3 shows that of 41 patients who had undergone successful procedures (21 patients in group A and 20 patients in group B) 37 patients (90.2%) were followed up until the time of submission of this study and four cases (9.8%) were lost to follow up after 2 months. One

Table 1: Age and sex distribution among the studied group

Items	No. (46) (%)
Age (years)	
0–20	4 (8.7)
21–40	15 (32.6)
41–60	23 (50)
61–80	4 (8.7)
Sex	
Male	15 (32.6)
Female	31 (67.4)

Table 2: Surgical results among groups (A) and (B)

	Group (A)		Group (B)		*P* value
	No.	%	No.	%	
Success rate	21	91.3	20	86.9	0.029*
Conversion to open surgery	2	8.7	3	13	0.029*
Efficacy of CBD clearance	20	87	19	82.6	0.029*
Mean Surgical time in minutes ± (SD)	160 ± (10.4)		176.4 ± (10.1)		0.061**
Stones diameter range (mm)	5-15		8-24		

**P* value of chi square test, ***P* value of student *t* test.

Table 3: Long term follow up data among successful cases

	Group A (No. = 21)		Group B (No. = 20)	
	No.	%	No.	%
Incomplete follow up	2	9.5	2	10
Completed follow up				
Cholangitis	2	9.5	0	0.0
Retained CBD	1	4.8	1	5
Uncomplicated	8	76.2	17	85

patient in group A suffered from repeated attacks of cholangitis, which responded to conservative treatment, and one patient had retained CBD stones, which were removed after 1 month during removal of the stent. One patient in group B suffered from retained CBD stones, which required readmission and endoscopic sphincterotomy.

Discussion

Approximately 20 years ago, there were not many options for management of patients with CBD stones; surgery was the only possible solution, and open cholecystectomy with choledocholithotomy was the treatment of choice [6–8].

The current options available for the management of choledocholithisis at the time of LC include preoperative ERCP and endoscopic sphincterotomy, intraoperative ERCP, postoperative ERCP, laparoscopic transcystic common bile duct exploration, laparoscopic choledochotomy and LCBDE, and open bile duct exploration [9]. The obvious goal of therapy in choledocholithiasis is to achieve ductal clearance with the fewest interventions, at the lowest cost, and with least morbidity [9].

Since the advent and progress of endoscopic surgery in biliary diseases, various procedures have been suggested for the management of CBD condition, including endoscopic sphincterotomy before or after laparoscopic cholecystectomy [7].

This novel discovery of minimally invasive surgery has also extended to LCBDE, but its progress is somewhat retarded by the introduction of ERCP. In addition, LCBDE has its limitation. It is more technically demanding and requires an experienced laparoscopic surgeon equipped with advanced laparoscopic skills. The operating time is also prolonged in LCBDE, and this makes it a relative contraindication in patients with poor anesthetic risk [10].

Our study was carried out on 46 patients with CBD stones and gallbladder stones. Our study revealed that cholecysto-choledocholithiasis is more common in the female population (67.4%). In our study it was more common in the fourth and sixth decades of life (50% of our patients; mean age 42.5 ± 15.7 years). This was in agreement with the results of Desai and Shokouhi *et al.* and Reshetnyak and colleagues [9,11,12].

The most common complaint in our patients was RUQP (84.8%), followed by jaundice (82.6%). These findings were in some agreement with those of Rajendra *et al.* and Reshetnyak *et al.* [12], who reported that the most common complaints were RUQP (81%), jaundice(74%), epigastric pain, and nausea [9,11,12].

Abdominal ultrasonography revealed gallstones in all patients. Dilatation of CBD with stones inside was detected in 37 patients only. This denotes that ultrasonography is highly accurate for detection of gallstones (100%), but less accurate for detection of CBD stones (80.4%). These finding were also reported by Majid *et al.* [13] and Costi *et al.* [14], as they stated that the sensitivity of ultrasonography for detection of gallstones and CBD stones was 80–100 and 70–90%, respectively.

MRCP was used successfully to diagnose CBD stones in nine patients who had equivocal results on transabdominal ultrasonography with a sensitivity near 100%. These findings were also reported by Mandelia *et al.* [15] and Wong *et al.* [16], as they stated that MRCP has an excellent overall sensitivity of 95% and

a specificity of 97% for demonstrating CBD stones.

Intraoperative cholangiography was found to be an accurate method for detecting CBD stones and it helped us greatly in avoiding injury to the bile ducts. It was performed in 21 patients of group B before LCBDE and it revealed stones in all patients (100% sensitivity). These findings were similar to the findings of Griniatsos and Karvounis [17], who denoted that IOC (intraoperative cholangiography) has a sensitivity of 98% and specificity of 94% for detection of CBD stones.

In our study, the procedures were completed in 21 patients (91.3%) of group A; two cases were converted to open surgery (8.7%). The conversion included one case in whom CBD clearance could not be achieved because of an impacted large stone in its lower part with failed CBD cannulation, and one case with absent papilla in the floor of the large duodenal diverticulum.

There was one patient with retained CBD stones in group A, which was removed during stent removal; efficacy of CBD clearance was 87% (two cases that failed ERCP were converted to open surgery and one patient had retained CBD stones postoperatively). This was in contrast to the study carried out by Dasari *et al.* [18] who reported retained CBD stones in 21/85 (25%) patients.

Postoperative complications occurred in three patients (13%): minor complications in the form of mild pancreatitis with elevation of serum amylase in two patients and pneumonia in one patient; mortality was zero, nearly in agreement with several studies that reported morbidity and mortality rates of 5–11 and 8–12%, respectively, with this method [19].

In group B, the procedures were completed in 20 cases (87%); three cases were converted to open surgery (13%): two due to severe adhesions in Calot's triangle and one due to impacted large stones measuring 2 cm with no available lithotripsy. A similar study carried out by Alexakis and Connor [20] denoted a success rate of 80–91%. In another study by Lu *et al.* [19], success rates of 89–95% were reported.

The transcystic approach was applied in seven cases and choledochotomy was performed in 14 cases, of which four cases were closed using a T-tube, nine cases were closed primarily, and one failed because of impacted large stone.

In this study we used the choledochoscope in 11 patients (in two undergoing the transcystic approach and in nine undergoing choledochotomy), but in these cases the operating time was slightly longer. In the other nine cases we used fluoroscopic guidance and confirmatory IOC. This was in agreement with the results of Alexakis and Connor [20] but different from those of Topal *et al.* [21], who reported that the use of a flexible choledochoscope is preferable to fluoroscopic guidance.

Fourteen patients were subjected to choledochotomy, and the procedure was completed in 13 cases. CBD was closed primarily in nine cases and the other four cases were drained by means of a T-tube. Biliary leakage occurred postoperatively in two patients (one of them was drained with a T-tube and in the other one the CBD closed primarily). Many studies comparing primary closure with T-tube drainage suggest similar rates of complications, with shorter operating times and a trend toward shorter hospital stay with primary closure. But some authors believe that for the safety of the patient bile duct decompression must be achieved. Despite its advantages, the T-tube has significant complications such as postoperative bacteremia, stone formation around the tube, skin excoriations at the exit site, prolonged biliary fistula, retention of a fragment of the tube, late bile duct stricture, and dislodgement of the tube with subsequent bile peritonitis and sepsis leading to mortality [22].

The efficacy of CBD clearance was 82.6% (three cases were converted to open surgery and one patient had retained CBD stones postoperatively). This was in contrast to the study carried out by Dasari *et al.* [18], who reported retained CBD stones in 9/81 (9%) patients.

Postoperative complications occurred in four patients (20%): minor complications in the form of minimal biliary leakage in the subhepatic drain managed conservatively in two patients, pneumonia in one patient, and t-tube infection in one patient; all of these complications were managed conservatively, and mortality was zero. This was in agreement with several studies that reported a morbidity rate of 8–19% and a mortality rate of around 0–1% [20]. This was in contrast to the study carried out by Shojaiefard *et al.* [23], who reported 5.55% morbidity but 0% mortality.

Conclusion

Finally we can conclude that there was no statistically significant difference between the two groups in terms of surgical time, surgical success rate, postoperative complications, mortality rates, retained CBD stones, and postoperative length of stay. However, patients belonging to group A were more vulnerable than

patients belonging to group B to developing low-grade cholangitis because of sphincterotomy performed during stone extraction.

Regarding indications, ERCP is more preferable for the management of CBD stones when the CBD is smaller than 10 mm in diameter, when there is cholangitis, biliary pancreatitis, and suspected malignancy, whereas LCBDE is more prefereable in case of multiple large calculi in CBD larger than 10 mm in diameter, in young patients, and when there is doubt about the presence of CBD stones.

Finally, further studies should be carried out to reveal the long-term hazards in sphincterotomized patients.

Acknowledgements

Conflicts of interest

None declared.

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Autologous saphenous vein graft as a urethral substitute for recurrent and proximal hypospadias

Khaled Elalfy[a], Ibrahim Awad[a], Ahmed Khalil[b], Hosam Ghazy[c]

[a]Departments of Vascular Surgery, [b]Plastic Surgery, [c]General Surgery, Mansoura University, Mansoura, Egypt

Correspondence to Khaled Elalfy, MD, Mansoura University Hospitals, Elgomhoria Street, Mansoura, Dakahlia Governorate, 355116, Egypt
Tel: +20 100 108 7757; fax: 0200502267017; e-mail: khaledalfy@gmail.com

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Introduction
Hypospadias is a congenital anomaly occurring in 0.3–5% of newly born males. Techniques for reconstructions of the urethra are: operations using local tissue flaps especially the prepuce or operations using distant flaps such as: skin, oral mucosa, bladder mucosa, intestinal mucosa, and tunica vaginalis or vein graft.

The aim
The aim of this study is to evaluate the efficacy of autologous saphenous vein graft as a urethral substitute in recurrent and proximal hypospadias.

Study design
This is a case series study which involved 11 patients (4–15) years old with recurrent or proximal hypospadias who presented to Mansoura university hospital during the period from January 2013 to September 2014. All patients underwent a vein graft as a urethral substitute.

Results
The follow-up range: (6–19 months), with a median of 10.3 months. Complications developed in 4/11(36%). 1 case suffered from early postoperative penile hematoma, another patient developed early fistula and 2 cases developed meatal stenosis.

Discussion
There are various urethral replacement by extra genital tissue which may be needed especially in circumcised infants and those with proximal or recurrent hypospadias. Veins used as urethral substitute usually are: saphenous, external jugular or the internal jugular because of their accessibility, available length and good caliber when compared with the urethral diameter. Although the study has the limitations of small number of cases and short follow up period we believe that it can pave the way for large multicenter studies which may give a new tool adding to our armamentarium in our struggle for the optimum cure for hypospadias especially recurrent and proximal case.

Conclusion
autologous saphenous vein urethroplasty is a simple, safe, and effective procedure for hypospadias.

Keywords:
autologous vein, hypospadias, urethral substitute

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Introduction

Hypospadias is a rather common congenital anomaly occurring in 0.3–5% of new-born boy babies [1]. It is due to incomplete formation of the urethra usually during the 10th–14th week of gestation [2].

There is a family incidence of 12–14% in first-degree relatives, which may suggest genetic predisposition in some cases [3]. Usually, hypospadias occurs as an isolated anomaly, despite being described as a part of more than 200 different congenital anomaly syndromes [4]. Hypospadias has a large psychological impact on the parents of the child as regards its disfigurement and its future impact on the patient's sexual ability [1]. There are many factors that can affect the time of surgery, such as patient environment, anesthetic risks, and the parents' expectations for the genital surgery [5]. After 6 months of age, provided there are specialist anesthetists and a dedicated pediatric facility, usually there is not much added risk compared with older children [6].

Many studies have attempted to define the optimum time for surgical intervention in hypospadias and have reported varying results, ranging from 2 to 11 months [7], before 15 months [8], and before 18 months of age [9]. American Academy of Pediatrics, in 1996, suggested that the optimal age for surgical intervention in hypospadias is between 6 and 12 months of age [10]. Administration of testosterone hormone may be beneficial in small-size penis [11].

First successful repair was reported in 1874 by Anger [12]. Since then, many different techniques have emerged and may reach up to more than 200 different distinct techniques [1].

At these early times, it was rather a standard to perform the surgery in a staged manner, such as CECIL three-

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staged approach for complicated hypospadias cripple, which was introduced in 1940 [13].

In 1959, Devine and Horton [14] suggested one-stage repair for hypospadias, and nowadays the trend is to perform the surgery even in proximal or complicated cases in single repair to decrease the incidence of complications.

The techniques for reconstructions of the urethra can be classified into two main categories: the first involves operations using local tissue flaps, especially the prepuce; and the second involves operations that entail the use of distant flaps such as skin, oral mucosa, bladder mucosa, intestinal mucosa, and tunica vaginalis [15].

Obviously, the prepuce is the most convenient substitute for urethra as it is from the same locality, with no skin appendages; thus, we do not have the problem of subsequent hair growth, and this will decrease the incidence of stone formation. Moreover, it has good elastic properties and so will cope well with the erectile function. However, it may be deficient in circumcised infants and in re-do cases; in addition, it may not give the desired length in proximal cases [15].

Therefore, the search continues for the ideal urethral substitute that would provide enough length in proximal types and good elasticity to cope with erection without curvature. It also should be pretubularized to avoid a longitudinal suture line, thus decreasing the possibility of fistula formation [1].

The aim of this study was to evaluate the efficacy of autologous saphenous vein graft as a urethral substitute in hypospadias cases, especially recurrent and proximal cases.

Patients and methods

This study included 11 patients between 4 and 15 years of age, with a mean of 7 years, with recurrent or proximal hypospadias, who presented to Mansoura University Hospital during the period from January 2013 to September 2014 (Table 1). All patients underwent vein grafts for urethral substitute. Preoperative history taking, general and local examination, and routine investigations, including duplex assessment of great saphenous vein diameter and patency, were carried out. Those with anterior penile hypospadias or vein diameter less than 3 mm were not chosen for this technique. Informed written consent was obtained from the parents. The study was approved by the local ethical committee of Mansoura university hospitals.

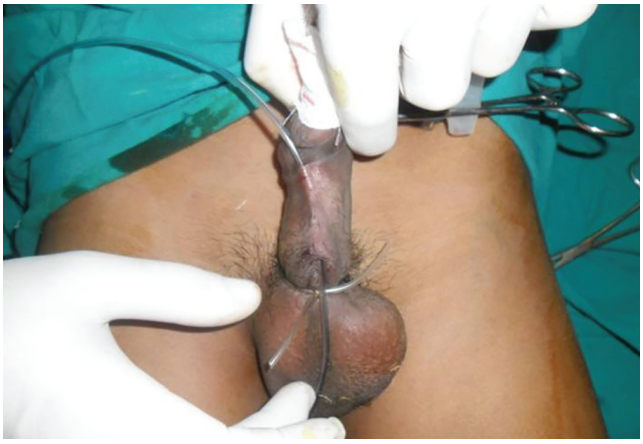
Procedure

All cases were performed under general anesthesia in a supine position. A nelaton catheter of 8–10 Fr was inserted into the urethra and sutured to the glans. The urethral opening is mobilized with freshening of the edge. A tunnel for the neourethra was created in the ventral skin (Fig. 1) from the location of the proximal urethra to the distal, along the penile length. A longitudinal midline deep incision on the glans was made to avoid the narrowing of neourethra. The saphenous vein was exposed and harvested as a double length of the stretched urethra to be reconstructed to counteract the possibility of graft contracture and morning erection (Fig. 2). Ligation of the vein branches and marking of the caudal end of

Table 1 Types of hypospadias

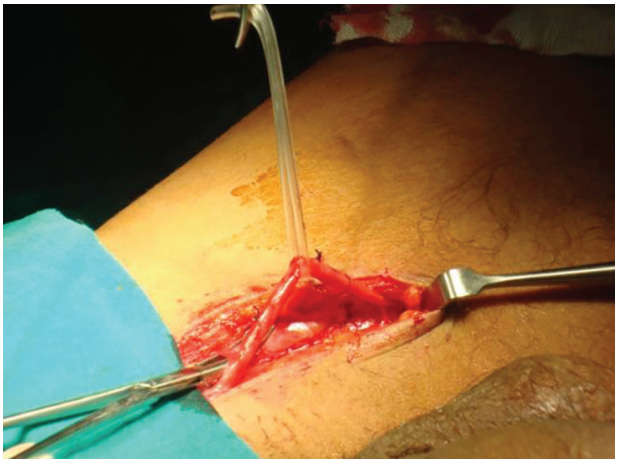
Types of hypospadias	Number of cases
Proximal penile	4
Penoscrotal	2
Recurrent	5

Figure 1



Creation of the tunnel.

Figure 2



Great saphenous vein harvest.

harvested vein were carried out. Then the vein was dilated by occluding one end with bulldog clamp and injecting heparinized saline from the other end with checking for any leaks from side branches that was managed by either ligature with 4/o absorbable (vicryl) suture if there is enough length of the cut stump or sutured with 6/0 non-absorbable (prolene) in case of short or no stump (Fig. 3). The catheter was passed through the tunnel from distal to proximal; the harvested vein was inserted into the catheter from its cranial end; and the catheter tip was inserted into proximal urethra to the bladder. Thereafter, suturing the caudal end of the harvested vein with the proximal urethra in oblique manner ,with continuous nonabsorbable 7/0 under loupe magnification, and the cranial end with the skin at the tip of the glans were performed (Figs. 4 and 5). Two wings of the glans were closed with 5/0 absorbable sutures. The urethral catheter was removed after 3 weeks.

Results

None of the patients showed familial incidence or gave history of maternal risk factors. Only one patient showed right undescended testis as an association.

The follow-up period ranged between 6 and 19 months, with a median of 10.3 months. Complications developed in 4/11 (36%) cases. One case suffered from early postoperative penile hematoma, which was clinically insignificant and resolved spontaneously. Another patient developed early fistula, which requires re-exploration and repair. Two cases developed meatal stenosis after 5 and 6 months of follow-up, which was treated with application of urethral catheter for another 2 weeks. No early postoperative infection was noted. The parents were satisfied with this repair and reported normal urination with good healing.

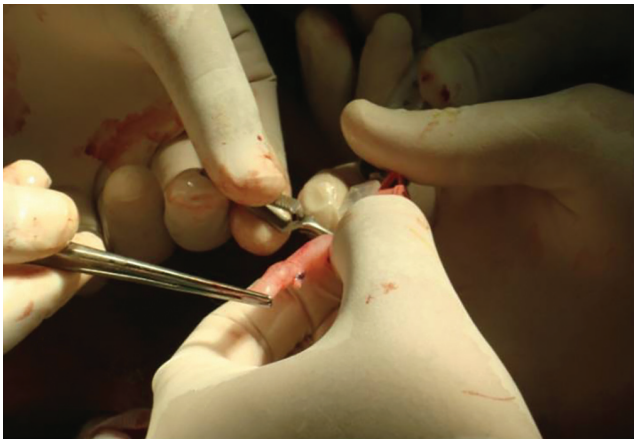
Discussion

There are various urethral replacement with extragenital tissue that may be needed as we have mentioned earlier, especially in circumcised infants and those with proximal or recurrent hypospadias.

The extragenital replacing tissue may be ureter [16], vermiformappendix[17],skingraft[18],oralmucosa[19], bladder mucosa [20], tunica vaginalis [21], intestinal, and colonic mucosa [22,23].

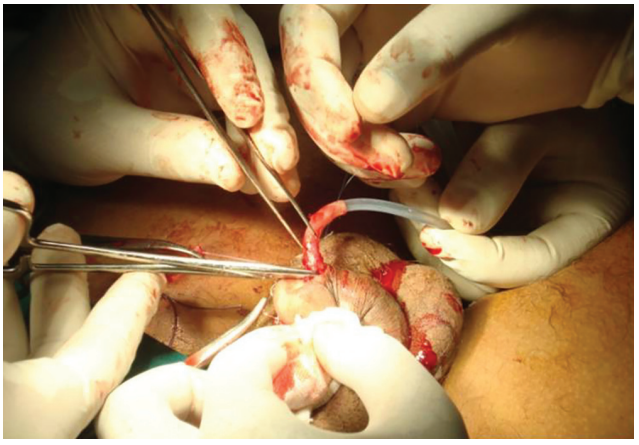
Tissue-engineered grafts and porcine acellular matrix are two new promising techniques that may have a major impact on the future of urethral replacement surgeries [24–26].

Figure 3



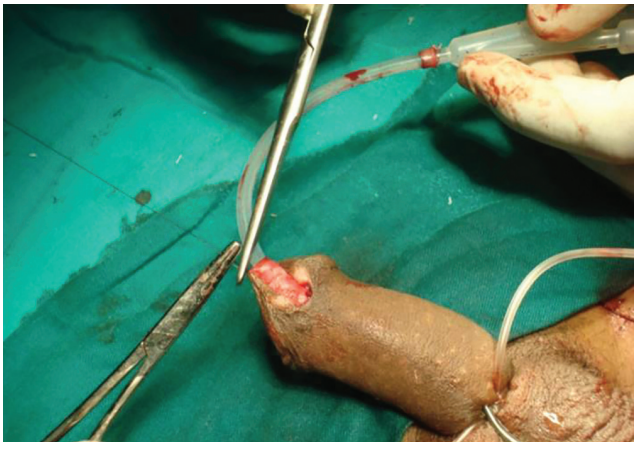
Great saphenous vein dilatation.

Figure 4



Proximal anastomosis.

Figure 5



Distal anastomosis.

The vermiform appendix, together with the ureter, as a urethral substitute is a rather historical method with

no recent trials, and has been surpassed by other less invasive methods with less complications.

Skin grafts have low elasticity and may not cope well with the erectile properties needed for the ideal urethral substitute, liable for contracture and hair growth even if harvested from nonhairy areas, which may lead to stone formation [27].

Oral and bladder mucosa are relatively thin so they are more prone to ballooning and they may not provide enough length needed for repair especially in proximal types and this may also may occur with tunica vaginalis. All three substitutes have the disadvantage of not being tabularized, which mandates a longitudinal suture line, thus increasing the incidence of fistula formation [1,15].

Oral mucosal graft can be harvested from buccal, abial, or lingual mucosa [28–31].

The use of autologous vein graft outside the vascular system has been attempted both experimentally and clinically in bile duct replacement [32,33], ureter replacement [34–36], and urethra in both hypospadias and urethral stricture.

Veins used as urethral substitute usually are saphenous, external jugular, or the internal jugular because of their accessibility, available length, and good caliber as compared with the urethral diameter [37].

The internal jugular vein has the advantages of being valveless and of good diameter [38], but the great saphenous vein can provide more length and can be harvested endoscopically unlike the internal jugular vein [39].

Vein graft urethroplasty was described more than a 100 years ago by Tanton and colleagues [40–43].

The results obtained by those pioneer innovative researchers were poor due to lack of magnification and the limited resources in instruments, sutures, and medications.

In the 1970s, Kjaer *et al.* [44] and Breitenecker *et al.* [45] used lypholized vein grafts in urethra and vascular system and they both reported more satisfactory results as regards neoepithelialization, but they had a drawback of crypts and polyps at their anastomotic sites.

Frang *et al.* [46], tried vein graft in a canine model but he reported poor results that were attributed to persistence of valves.

Later, Hubner *et al.* [47] and Foroutan *et al.* [38] tried using everted vein graft, whereas Kim *et al.* [48] incised the vein longitudinally and performed excision of the valves, and Kahveci *et al.* [49] used the vein as urethral substitute. All of them reported good results with low incidence of fistulae and strictures, and some also proved histological changes of vein endothelium into uroepithelium.

In 2006, Shaeer and El-Sadat [15] reported their first experience with vein graft in an 8-year-old child with hypospadias, which showed good results after 1 year, with forward stream, no fistula, and no curvature on morning erection. This motivated Keshk *et al.* [1] 3 years later, in 2009, to publish their report on vein graft in hypospadias in eight patients with promising results, with only two fistula and one meatal stenosis case.

Therefore, we present this study as a next step in searching for the best urethral substitute, especially in recurrent or re-do case, hoping it can pave the way for larger multicenter studies with longer follow-up periods.

In our study, we did not remove the adventitia of the vein and this was also reported in the study by Keshk and colleagues but Shaeer and El-Sadat in their study removed the adventitia of the vein. We believe that the multilayer normal anatomy of the vein is rather an advantage in securing the anastomosis, thereby acting as an additional supporting layer similar to covering urethral repairs with the dartos [50], external spermatic fascia [51], or tunica vaginalis flaps [52]. Moreover, circumferential stenosis can be prevented by spatulation of both the urethral opening and the vein.

On comparing our results with the available two clinical nonexperimental studies, they were found to be promising with only one case of fistula and one case of meatal stenosis, which needed dilatation.

Study limitations

We acknowledge these potential limitations of our study:

(1) Small number of cases.
(2) Short follow-up period.

Conclusion

Autologous saphenous vein urethroplasty is a simple, safe, and effective procedure for hypospadias with acceptable results, especially for proximal type, which needs a long neourethra, and a: for recurrent o or circumcised cases without enough healthy local tissue for repair.

Acknowledgements

Conflicts of interest

None declared.

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Dome down approach for difficult laparoscopic cholecystectomy

Mohamed I. Kassem, Maher M. Elzeiny, Hany M. El-haddad, Adel A. AbuNasr

Department of Surgery, Gastrointestinal Surgery Unit, Faculty of Medicine, Alexandria University, Alexandria, Egypt

Correspondence to Mohamed I. Kassem, MD, Department of Surgery, Faculty of Medicine, Alexandria University, Alexandria, Egypt
Tel: +201001224750; fax: +2/03/5920956
e-mail: dr_m_kassem@yahoo.com

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Background
Visualization of anatomical structures during laparoscopic cholecystectomy may be impaired by difficulties including severe inflammation in Calot's triangle, a short cystic duct, tenting of the ductal structures, or Mirizzi's syndrome.

Purpose
To evaluate the feasibility, safety, and outcome of dome-down laparoscopic cholecystectomy in difficult cholecystectomy.

Patients and methods
A total of 60 patients with difficult laparoscopic cholecystectomy as decided intraoperatively were enrolled. The dome-down technique was used after a trial of the conventional procedure.

Results
There were 33 women (55%) and 27 (45%) men. Their age ranged from 18 to 68 years. Preoperative prediction of difficulty of the operation was anticipated in 37 cases (61.7%). The mean operative time was 102.84 (92–150) min. The conversion rate was 8.3%. The mean hospital stay was 2.5 (2–5) days.

Conclusion
Dome-down laparoscopic cholecystectomy is a feasible and applicable procedure during difficult cholecystectomy, and yet it needs a learning curve for optimum results.

Keywords:
dome down, laparoscopic cholecystectomy, difficult cholecystectomy

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Introduction

During laparoscopic cholecystectomy (LC), the surgeon may encounter difficult situations in which the procedure fails to progress, with a major risk of injuring the major biliary passages because of loss of anatomical details particularly in the triangle of Calot.

LC is known to have a slightly higher complication rate than open cholecystectomy, with the most common complication being injury to the common bile duct (CBD) (0.1–1.4%) [1–3], followed by vascular injury, bowel/hollow viscous injury, pneumoperitoneum-related complication, wound infection, and trocar site herniation [1,4].

Dissection in LC usually starts from the triangle of Calot upward to the fundus of the gall bladder. Initial dissection in the triangle of Calot carries an operative risk for the surgeon because of the probability for misidentification of major bile ducts, increasing the risk of bile duct injury.

Visualization of anatomical structures may be markedly impaired by many factors, including difficult anatomy secondary to severe inflammation or scar tissue, a short cystic duct, tenting of the ductal structures, anomalous right hepatic artery or duct, or Mirizzi's syndrome [5].

One technique to reduce the risk for surgical complications in LC has been the development of an alternative gall bladder dissection sequence. Removal of the gall bladder from the gall bladder bed first (dome-down) is a technique used frequently during open cholecystectomy before the advent of LC and is used commonly when surgeons now convert to the open technique. Dissecting the gall bladder from the gall bladder bed first, and subsequently following the gall bladder to the cystic duct, enables utilization of the preferred surgical principle of dissecting from known anatomy (gall bladder wall) to unknown anatomy (potentially difficult anatomy in the triangle of Calot) [5].

Although described under different names as retrograde or fundus first cholecystectomy, several studies [5] have

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emphasized the feasibility of dome-down LC. All had a high success rate and a low rate of conversion to the open technique.

The aim of this study was to evaluate the feasibility, safety, and outcome of the technique of dome-down LC in difficult cholecystitis.

Patients and methods

This was a prospective study carried out on 60 patients admitted to the upper gastrointestinal surgery unit, Alexandria Main University Hospital, over a period of 24 months from March 2013 to March 2015.

Inclusion criteria included all cases with difficult LC as decided intraoperatively after a trial of the conventional procedure. This included the presence of dense adhesions in Calot's triangle, acute cholecystitis, and mirizzi syndrome. We excluded patients with CBD stones and gall bladder cancer. After obtaining the approval of our ethics committee, all patients enrolled in this study were informed about the procedure of conventional LC and they signed a written consent.

All patients were subjected preoperatively to the following: complete assessment of history, thorough general and local abdominal examination, routine laboratory work-up, liver function tests and liver enzymes, abdominal ultrasonography, computed tomography, and magnetic resonance cholangiopancreatography if CBD stones were suspected.

Preoperative prediction of difficulty was judged on the basis of the following: the presence of contracted thick wall gall bladder on preoperative ultrasound or computed tomography, presence of collection in the pericholecystic or the subhepatic space, clinical diagnosis of empyema by severe right hypochondrial pain and tenderness together with fever and leukocytosis, palpable gall bladder, longstanding cases with a history of more than 2 years of gall bladder stones, and suspicion of mirizzi syndrome.

Operative procedure

All patients received general anesthesia; third-generation cephalosporins (ceftriaxone) and metronidazole (to prevent anaerobic infection in case of stone spillage) were administered on induction. The patient was prepped and draped, exposing the upper right part of the abdomen. Pneumoperitoneum was created by a Veress needle and the pressure was set at 14 mmHg. A zero degree scope was entered through a 10 mm supraumbilical port. The patient was repositioned in a 30° reverse Trendelenburg position with a 10° tilt to the left. The procedure was then continued using the American four-port technique as a conventional LC (two 10 mm trocar in the supraumbilical and epigastric regions and two 5 mm trocars in the right midclavicular and anterior axillary lines).

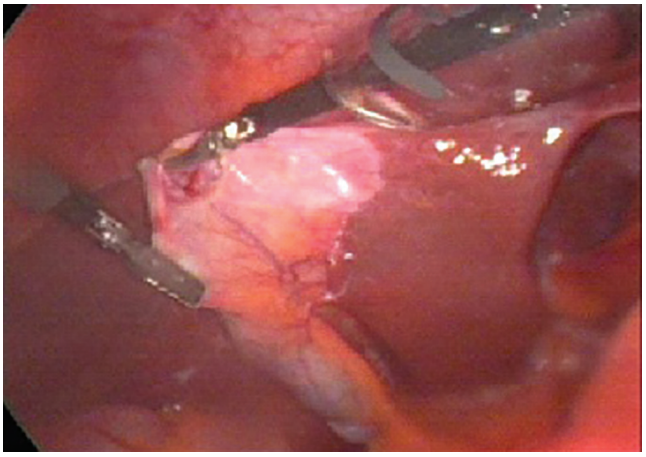
After general laparoscopic exploration, adhesions between the gall bladder with the omentum or the duodenum were detached by blunt or sharp dissection. If the gall bladder was distended, it was aspirated by a needle connected to a suction machine. The Hartman pouch was grasped and retracted laterally to open the triangle of Calot (Fig. 1).

If, after careful dissection of the Calot triangle, the operation was found to be difficult on the basis of the inclusion criteria, the decision of converting to the dome-down technique was made instead of conversion to open cholecystectomy as we believe that if the procedure is laparoscopically difficult, it will also be difficult by the open method.

For the dome-down technique, dissection of the gall bladder was started from the fundus (Fig. 2). This was accomplished using either monopolar diathermy (on a curved maryland forceps or hook) or a 5 mm ultrasonic vessel sealing device (Harmonic scalpel Shears with curved blades; Ethicon EndoSurgery Inc., ACE 36, West Somerville, NJ, USA).

The dissecting instrument was placed in the epigastric 10 mm port. A grasper was inserted by the assistant through the right axillary 5 mm port to retract the fundus of the gall bladder downwards and laterally. Another grasper was introduced through a 5 mm right clavicular port that was used to retract the liver upwards and medially, creating a space between the liver and the fundus of the gall bladder.

Figure 1



Lateral retraction on the Hartman pouch.

By traction–counter traction, keeping close to the wall of the gall bladder, we were able to keep the body of the gall bladder apart from the gall bladder bed (Fig. 3). Hemostasis by electrocautery or ultrasonic energy was performed as needed to keep the field as dry as possible.

The cystic artery was usually identified before the cystic duct and was divided between two clips or by the harmonic scalpel. Dissection around the cystic duct was then carried out so that the cystic duct was the only structure attaching the gall bladder with the CBD (Fig. 4).

Intraoperative cholangiography (IOC) was possible at this stage and the procedure was performed selectively to confirm the safety of the dissection and to exclude any bile duct injury. The cystic duct was then divided between three clips: two clips on the stump and one on the proximal part.

The gall bladder was removed from the epigastric trocar. In all cases, we left a tube drain in the subhepatic space. Conversion to open cholecystectomy was planned at any time if there was failure of progress in dissection with the dome-down technique.

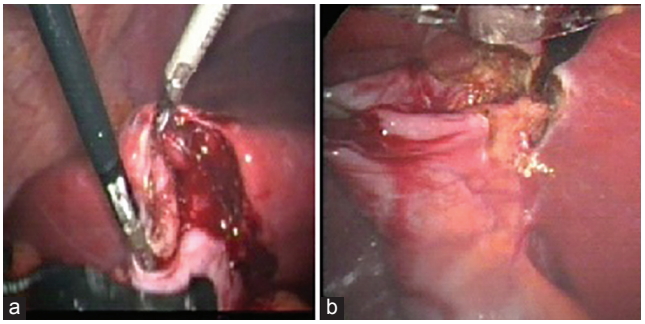
Results

This study was carried out on 60 patients who had difficult LC in the gastrointestinal surgical unit, Faculty of Medicine, Alexandria University, during a 2-year period from March 2013 to March 2015. All patients signed consent for LC. Cholecystectomy by the dome-down technique was subsequently performed after failure of the conventional technique.

Among these patients, there were 33 women (55%) and 27 (45%) men, with a female to male ratio of 1.22. The age ranged from 18 to 68 years, with a mean age of 53.3 years (Table 1).

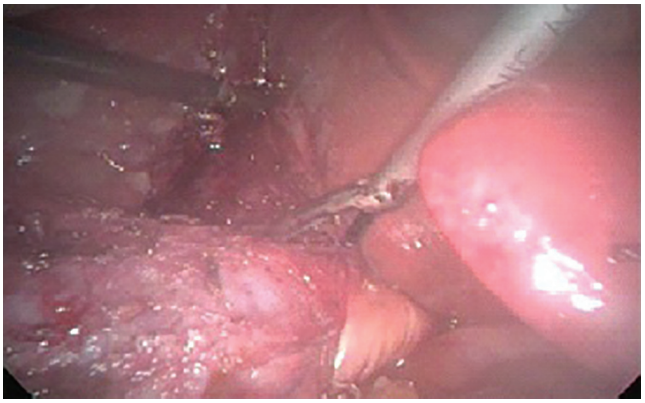
In terms of the mode of admission, 37 patients (61.6%) were admitted on an elective basis, 13 (21.6%) were operated in an emergency because of an attack of acute cholecystitis, five patients (8.3%) after extraction of CBD stones by endoscopic retrograde cholangiopancreatography, and five patients (8.3%) were operated by interval cholecystectomy. Interval cholecystectomy was performed in four cases after resolution of an attack of acute mild biliary pancreatitis and in one case, 3 months after resolution of an attack of acute cholecystitis that was managed conservatively in another hospital. These patients were operated within 72 h of admission after improvement of the attack of pancreatitis on the basis of clinical examination (disappearance of pain, fever, and epigastric tenderness) and a decrease in amylase level.

Figure 2



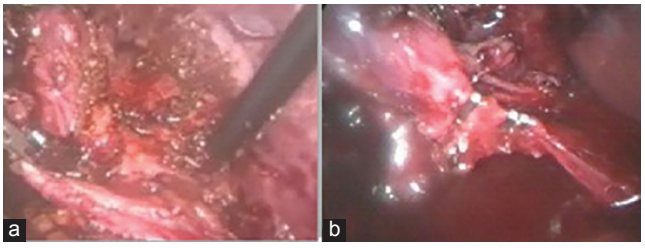
(a) Dissection at the fundus with ultrasonic dissection shears, (b) traction–counter traction at the fundus.

Figure 3



Dissection close to the wall of the gall bladder.

Figure 4



(a, b) Cystic duct (arrow) is the only attachment to the common bile duct.

Preoperative prediction of difficulty of the operation was anticipated in 37 cases (61.7%).

Nine patients had undergone a previous abdominal surgery; six patients had undergone an appendectomy and three women had pfanensteil scar tissue.

Thirty-eight patients had associated comorbid diseases in our cases; 16 patients were hypertensive, 27 patients were diabetic, 19 patients had ischemic heart disease, three patients had renal impairment, four patients had

chronic obstructive pulmonary disease, five patients had hepatomegaly, and three patients had liver cirrhosis.

According to the American Association of Anesthesiology (ASA) classification, 42 patients were class II, 13 patients were class I, and five patients were class III (Table 2).

On laparoscopic exploration, adhesions attached to the gall bladder were found in 43 patients, severe chronic inflammation in 45 patients, empyema of the gall bladder in 18 patients, a recent attack of acute pancreatitis in five patients, a short cystic duct in three patients, cirrhosis in eight patients, and hepatomegaly in four patients.

The gall bladder was dissected from its bed using monopolar diathermy in 36 cases and by ultrasonic energy (harmonic scalpel) in 24 cases. The amount of blood loss as aspirated by suction machine ranged from 10 to 200 ml.

IOC was performed in 13 patients because of undefined anatomy in eight patients and for preoperative elevated liver enzymes with suspicion of CBD stones in five patients. No filling defect was detected intraoperatively and assurance of safety of major bile duct confirmed.

In terms of intraoperative complications, gall bladder perforation with bile spillage occurred in 15 patients. No bile duct or visceral injury was recorded. The mean operative time was 102.84 (92–150) min. The learning curve improved with time. The mean operative time of the first 10 patients was 2.5 h, which decreased to a mean of 1 h in later patients. The procedure was aborted in five cases and converted to open cholecystectomy because of failure of proper identification of anatomical details in the Calot triangle; the conversion rate was 8.3%. The details of these patients are shown in Tables 3 and 4.

Early postoperative complications were encountered in 13 patients: eight with chest infection, three with port site infection, and two with a small subhepatic collection that was drained percutaneously. The mean hospital stay was 2.5 (2–5) days until the drain was removed. No early postoperative mortality occurred. The pathology results were as follows: acute cholecystitis in 35 patients, gangrene of the gall bladder in 18 patients, and empyema in seven patients (Table 5).

Table 1 Patients' characteristics

Variables	Number (%)
Total number of patients	60 (100)
Age [mean (range)] (years)	53.3 (18–68)
Sex	
Males	27 (45)
Females	33 (55)
Female to male ratio	1.22
Mode of admission	
Elective	37 (61.7)
Emergency	13 (21.7)
Preoperative ERCP	5 (8.3)
Interval cholecystectomy	5 (8.3)
Preoperative prediction of difficulty	37 (61.7)

ERCP, endoscopic retrograde cholangiopancreatography.

Table 2 Preoperative state in our patients

Variables	Number (*n*) (%)
Comorbid disease	38 (63.3)
Hypertension	16 (26.6)
DM	27 (45)
Ischemic heart disease	19 (31.6)
Renal impairment	3 (5)
COPD	4 (6.6)
Hepatomegaly	5 (8.3)
Cirrhosis	3 (5)
ASA classification	
Class I	13 (21.6)
Class II	42 (70)
Class III	5 (8.3)

ASA, American Association of Anesthesiology; COPD, chronic obstructive pulmonary disease; DM, diabetes mellitus.

Table 3 Operative findings in our patients

Variables	Number (*n*) (%)
Difficulties	
Attachment of adhesions	43 (71.6)
Severe chronic cholecystitis	45 (75)
Empyema	18 (30)
Recent acute pancreatitis	5 (8.3)
Short cystic duct	3 (5)
Cirrhosis	8 (13.3)
Hepatomegaly	4 (6.6)
Method of dissection	
Monopolar diathermy	36 (60)
Ultrasonic energy	24 (40)
Blood loss [mean (range)]	(10–200) ml
Intraoperative cholangiography	
Done	13 (21.6)
Not done	47 (78.3)
Operative time [mean (range)]	102.84 (92–150) min
Conversion rate	5 (8.3)
Gall bladder perforation	15 (25)

Discussion

The aim of this study was to assess the feasibility of a different mode of dissection of the gall bladder and whether this technique is safe in terms of a risk of bile duct injury in difficult situations. This study describes our first experience with this technique at the department of upper gastrointestinal surgery, faculty of medicine, Alexandria University, Egypt. In the past, difficult cholecystectomies were converted immediately to an open approach, but 55 cases were saved from the morbidity of big incision thanks to the dome-down approach.

Table 4 Patients' conversion to open cholecystectomy

Patients (n = 5)	Cholecystitis	Reasons for conversion
1	Severe chronic	Short cystic duct, uncontrolled bleeding, liver cirrhosis
2	Acute gangrenous	Undefined anatomy, common bile duct not seen
3	Severe chronic	Mirizzi syndrome
4	Severe chronic	Mirizzi syndrome
5	Acute	Dense adhesions at Calot triangle

Table 5 Postoperative course in our patients

Variables	Number (n) (%)
Postoperative complications	13 (21.6)
Chest infection	8 (13.3)
Port site infection	3 (5)
Subhepatic collection	2 (3.3)
Hospital stay [mean (range)]	2.5 (2–5) days
Mortality	0
Pathology results	
Acute cholecystitis	35 (58.3)
Gall bladder gangrene	18 (30)
Empyema	7 (11.6)

In the experience described here, dome down laparoscopic cholecystectomy (DDLC) was not performed routinely, but was used only in difficult cases when we failed with the standard technique to achieve adequate exposure or to perform a safe dissection. The selective use of this technique was also recommended by Kelly [6] in 1.1% of all laparoscopic cholecystectomies. A few investigators have recommended that the technique should be used routinely in all laparoscopic cholecystectomies. Cengiz *et al.* [7] found the DDLC with ultrasonic dissection to have a shorter operative time compared with the standard technique and also patients complained of less postoperative pain and nausea. Neri *et al.* [8] also suggested the DDLC to be the technique of choice as they found it more simple to perform with a shorter operative time.

Most studies on DDLC concluded that the technique is safe and feasible, with a low risk of biliary injury and decreased rate of open conversion.

The main advantage of the DDLC technique is the ability to visualize and identify anatomy as the dissection proceeds from an anatomically identified area (fundus of the gall bladder) in a step-by-step manner to a densely hidden area. Mahmud and colleagues found the procedure safe and feasible, and prevented conversion in difficult LC from 5.2 to 1.2%.

Although gallstones are more common in women, 27 patients (45%) were men. This increased incidence of difficult cholecystectomy in Egyptian men may be because of delayed presentation, especially the elderly with comorbid diseases such as diabetes mellitus. This observation was also reported by Wang *et al.* [9] and Mahmud *et al.* [10].

Thirty-eight patients (63.3%) had associated risk factors such as old age and comorbid diseases which is a high incidence. Moreover, 47 patients were ASA II or III. We believe that the dome-down technique is usually performed in such high-risk patients; thus, surgeons performing LC in these cases should be skilled in this technique.

Fundus first LC was performed in the study of Wang *et al.* [9] in 36 elderly patients (older than 65 years of age) with acute cholecystitis; conversion to open cholecystectomy was necessary only in one patient (2.7%).

Gupta *et al.* [11] compared conventional LC with DDLC and observed that the mean operative time was 15 min less in the DDLC group than the conventional group in difficult cholecystectomies (89.8 + 14.05 vs. 104.8 + 18.6 min). A randomized clinical trial [7] that compared ultrasonic fundus first dissection versus electrocautery dissection at the triangle of Calot postulated that the former technique had a shorter operative time and hospital stay, and resulted in a lower postoperative pain score and less nausea.

A malleable laparoscopic liver retractor was necessary in nine of 11 cases published by Kelly [6]. Their opinion was that only liver retraction solved the problem as it improved the view and made the dissection easier. They found that the use of a grasper to directly push the liver was safe only in two cases. Mahmud *et al.* [10] used the thick peritoneal rim at the edge of the liver for liver retraction and did not use a liver retractor.

IOC was performed only in 13 cases. Introduction of the cholangiogram catheter was technically challenging as the cystic duct was difficult to find initially with distorted anatomy because of dense adhesions. In some cases, after complete separation of the gall bladder from the gall bladder bed, the cystic duct–CBD junction was evident and the possibility of bile duct injury was remote. No IOC was performed by Kato *et al.* [12] as the anatomy was clear as this technique obviated the risk of bile duct injury. In another report, Tuveri *et al.*[13] performed IOC routinely in 50 patients done with DDLC and achieved a success rate of 74%. Kelly [6] reported that IOC was desirable for disclosure of ambiguous anatomy and impossible in difficult cases. Mahmud *et al.* [10] were obliged to perform IOC in 68.5% of their patients as they also included patients with CBD stones in their study, but this failed in 24% and did not attempt it in one patient because

of a very short cystic duct. We excluded patients with CBD stones from our study and this made us indolent to prolong the operative time in these difficult cases.

The mean hospital stay was 2.5 (2–5) days, which is longer than that in previous reports. This was because the majority of patients had uncontrolled diseases and 37 patients had been operated in an emergency, because of which we had to extend the period of postoperative observation and ensure stabilization before discharge.

Control of bleeding from the bed of the gall bladder was possible by either source of energy. It stopped by gentle application of an electrically charged hook or spatula or between the shears of a harmonic scalpel. The cystic artery was usually double clipped and cut when encountered. The amount of blood loss as aspirated by suction ranged from 10 to 200 ml, indicating efficiency of hemostasis. Bleeding were encountered in three cirrhotic patients (with coagulopathy) in whom the liver bled horribly on touch that forced us to convert in one case.

On the basis of our experience with the technique, we found that it was not easy to perform in cases of dense adhesion and needed time to learn. Liver retraction was difficult to apply and resulted in troublesome bleeding from pressure. Control of the position of the gall bladder was difficult and the gall bladder wall was friable. On the basis of a questionnaire, Alley *et al.* [14] found that the mean number of patients who needed during the learning curve was 14.7 and recommended that the DDLC technique be incorporated into residency teaching programs to deal with difficult cholecystectomies. In agreement, Tuveri *et al.* [13] confirmed that the procedure was laborious and it was hard for them to apply traction in the correct plane.

However, although technically challenging, with patience, we could divide all attachments safely between the gall bladder and the liver so that at the end of dissection, only the cystic duct anchored the gall bladder to the major bile ducts.

We found no significant difference in the method of dissection between ultrasonic energy and monopolar diathermy. The theoretical risk of lateral spread of electrocautery did not cause any bile duct injury in our cases. In four patients, gall bladder perforation with bile spillage occurred because of the close application of the jaws of the harmonic scalpel to the wall of the gall bladder. One case of bile duct injury and bile peritonitis occurred in the study of Alley *et al.* [14], which was attributed to stray current of electrocautery that forced them to change their method of dissection to ultrasonic energy for safety. Fullum *et al.* [5] and Rosenberg and Leinskold [15] recommended the use of ultrasonic energy with DDLC for safety and reported that it facilitated the dissection by a cavitation effect on tissue planes [5]. However, no case of bile duct injury was reported in the study of Gupta *et al.* [11] and Mahmud *et al.* [10], who used solely monopolar electrocautery in cases in which the DDLC was used. To avoid diathermy injury, Tuveri *et al.* [13] halted their electrocautery dissection at the level of the infundibilum of the gall bladder.

In terms of the condition of the liver at the time of surgery, the technique was beneficial in five patients with hepatomegaly that would otherwise have made the dissection difficult and tedious. On the three cases with cirrhosis, two were completed with difficulty and in the third case, excessive bleeding from a major hepatic sinus forced us to convert to open surgery. Kelly [6] warned against the use of this technique in six cirrhotic patients in their series.

The operation was converted to open cholecystectomy in five cases. Two of them were because of the presence of mirizzi syndrome. The close proximity of the cystic duct and Hartman's pouch to the CBD made further dissection dangerous and the procedure was converted to open to deal with the defect in CBD. The decision was made and the defect in the CBD was repaired over a T-tube. Fullum *et al.* [5] treated two cases successfully with DDLC, which allowed safe and precise identification of the anatomy. In the study of Kelly [6], the technique conferred them with a technical advantage in mobilization of the gall bladder before Calot triangle dissection. Mahmud *et al.* [10] reported that mirizzi syndrome was one of the reasons for conversion to open surgery.

Gall bladder perforation and bile spillage occurred in 15 cases (25%). They were managed by repeated saline irrigation and suction till the aspirate became clear with an intraoperative extra dose of antibiotic and metronidazole injection. Gupta *et al.* [11] reported the misshape of a duodenal perforation that was converted to open surgery and 28 gall bladder perforations and bile spillage that neither prolonged the hospital stay nor led to postoperative complications.

Fifty-five difficult cholecystectomies were performed by the DDLC in this analysis, with a success rate of 91.6%. Multiple reports [10,11,16] emphasized that DDLC saved a considerable proportion of patients from the morbidity of open cholecystectomy.

Conclusion

Dome-down LC is a feasible and applicable procedure during difficult cholecystectomies, and yet it needs a learning curve for optimum results.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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Alleviating perineal tightness following abdominoperineal rectal resection

Alaa A. Alseesi, Ayman A. Albatanony, Tarek M. Rageh

Department of General Surgery, Menoufia Faculty of Medicine, Menoufia University, Shibin Alkom, Egypt

Correspondence to Ayman A. Albatanony, MD, MRCS, 12 Sabry Abu Alam Street, Shibin Alkom 32114, Egypt
Tel: +00201024341333;
e-mail: aymanalbatanony@hotmail.com

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Background
Perineal wound complications after abdominoperineal rectal resection (APR) are both frequent and clinically relevant for their impact on length of hospitalization, overall costs, patients' quality of life and oncological results. A close follow-up of these patients even when primary healing was complete revealed that most of them still had a sense of perineal tightness and discomfort during daily activities such as walking, sitting, and riding.

Aim of the work
The aim of this work was to study the use of a simple perineal L-shaped flap in alleviating the sense of perineal tightness and discomfort following APR, as well as for improving wound-healing rates.

Patients and methods
The study included 28 patients indicated for APR. After APR was carried out (conventional or extralevator), an L-shaped fasciocutaneous flap was designed on one side of the perineum and was used to close the perineal wound. Wound complications and sense of perineal tightness were recorded.

Results
An overall 75% of perineal wounds following APR healed without complications. The remaining had minor complications. A total of 23 patients (82.1%) stated that they had no sense of perineal tightness.

Conclusion
The simple L-shaped fasciocutaneous flap not only improves perineal wound healing but also improves the patients' quality of life by alleviating the sense of tightness, especially during sitting.

Keywords:
fasciocutaneous, flap, neoadjuvant, perineal wound

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Introduction

Perineal wound complications after abdominoperineal rectal resection (APR) are both frequent and clinically relevant for their impact on length of hospitalization, overall costs, patient quality of life, and oncological results. With the increasing use of preoperative radiotherapy and the gradual shift of extralevator approach, the perineal wound morbidity rates are increasing [1,2].

Primary closure is frequently under tension and is a significant factor in wound breakdown [3]. The adverse effects of radiotherapy on wound healing are directly related to the progressive occlusive vasculitis and the consequent fibrosis of the perineal skin [4].

Thus, the radiation-induced fibrosis is likely to limit the ability to close the perineum due to loss of normal tissue elasticity, especially if the closure is under tension. Bullard *et al.* [1] found that preoperative radiotherapy increases the wound complication rate from 23% to 47%; similar results were reported by Artioukh *et al.* [5].

A close follow-up of these patients even when primary healing was complete revealed that most of them still had a sense of tightness and discomfort in the perineum when performing daily activities such as walking, sitting, and riding. Therefore, we present this work to improve both perineal wound healing rates and the sense of perineal tightness after complete healing.

Aim of the work

The aim of this work was to study the use of a simple perineal L-shaped flap in improving wound healing rates, as well as for alleviating the sense of perineal tightness and discomfort following APR.

Patients and methods

This study was carried out between December 2010 and December 2014 in the Department of Surgery, Menoufia University Hospital, Shibin Alkom, Egypt. All patients were indicated for APR following

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neoadjuvant therapy. We excluded from this study any patient suffering from severe systemic disease affecting wound healing (e.g. collagen disease). The study was approved by the ethical committee of the hospital. Each patient signed informed consent. This was a prospective study.

Surgical technique

After APR was carried out (conventional or extralevator), an L-shaped fasciocutaneous flap was designed on one side of the perineum and was used to close the perineal wound (Fig. 1). Full mobilization of the flap incorporating the deep fascia was carried out, and the flap was transposed medially to cover the defect without tension over a suction drain (Figs. 2–4). The subcutaneous fascioadipose tissue was approximated using interrupted 0-vicyl sutures. The skin was closed using interrupted 2/0 poly propylene sutures.

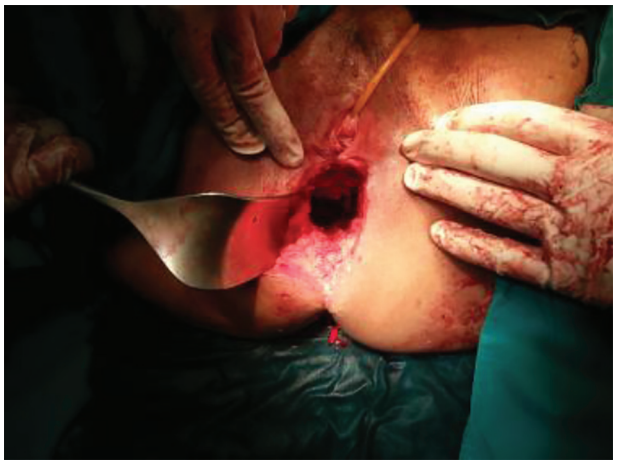
Postoperative follow-up

Patients were asked to avoid sitting for 2 weeks. Drains were removed once the daily output was less than 50 ml/day. First dressing was applied on the third postoperative day with the objectives of verifying the viability of the flap, local hygiene, dehiscence, and seromas. Sutures were removed in 2 weeks. Patients were followed up for 3 months, by the end of which each patient was asked to state whether or not there was a sense of perineal tightness (Fig. 5).

Results

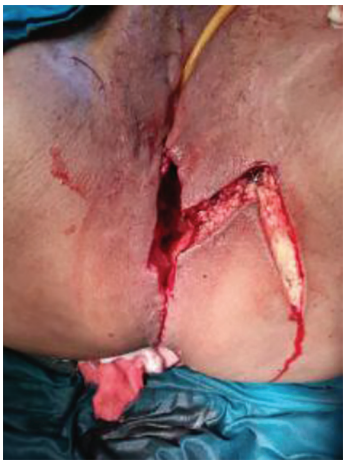
The study included 28 patients, 16 male (57.1%) and 12 female (42.9%). Their ages ranged between 26 and 67 years. Table 1 represents the wound complications. Table 2 represents the sense of tightness in the perineum.

Figure 1



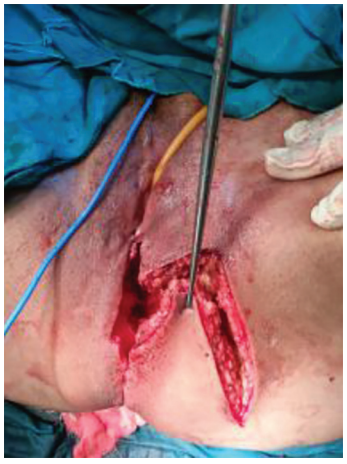
The defect.

Figure 2



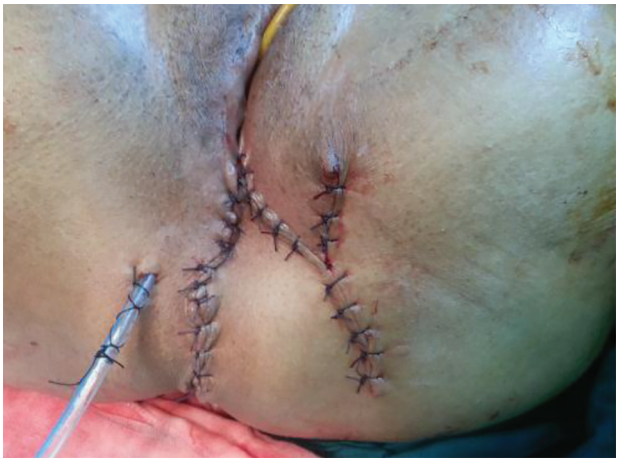
Design of the flap.

Figure 3



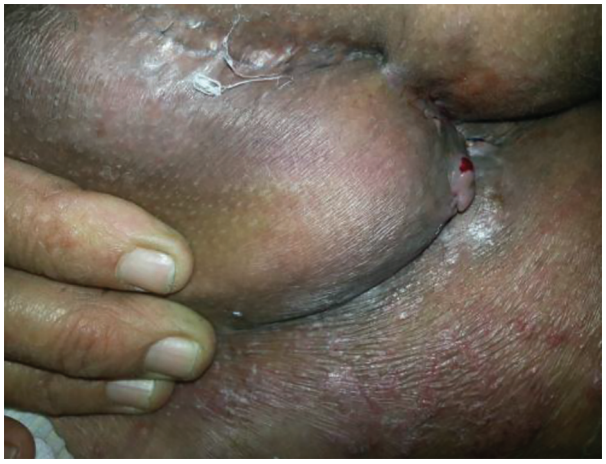
Mobilization.

Figure 4



Flap completed.

Figure 5



After healing.

Table 1 Wound complications

Type of complication	*N* (%)
No complication	21 (75)
Partial flap necrosis	1 (3.6)
Wound infection	2 (7.1)
Wound dehiscence	1 (3.6)
Seroma	3 (10.7)

Table 2 Sense of tightness and/or discomfort after 3-month follow-up

Degree of tightness	*N* (%)
None	23 (82.1)
Mild	4 (14.3)
Moderate	1 (3.6)
Severe	0 (0)

Discussion

Impaired perineal wound healing is a significant clinical problem being associated with increased hospital stay, reoperation and intensive wound care for several weeks. The increasing use of neoadjuvant radiotherapy significantly increases perineal wound healing problems. It has been reported that tissue transfer of well-vascularized nonirradiated tissue to the postirradiation pelvic defect results in improved perineal wound healing [6]; even with these techniques, wound complications are reported to range from 0–30% [7].

Performing muscle and myocutaneous flaps to transfer nonirradiated tissues to the perineum usually requires the expertise of a plastic surgeon, increases the operative time by about 2 h and has donor site morbidity [8,9].

Our study represents a simple procedure that can be performed in short time, needs no special expertise and involves no major tissue transfer. This simple L-shaped fasciocutaneous flap lead to sound wound healing in 75% of cases, with minor complications in 25% of cases. These figures are better compared with that reported in other studies [1–3].

Patients' quality of life may be impaired due to tightness and discomfort felt in the perineum, which may interfere with some simple daily activities such as sitting, walking, and riding. The natural design of the perineum allows both buttocks to spread apart during sitting, making use of the cleft between buttocks. This cleft is excised during APR, depriving the perineum from its ability to widen during sitting.

Another value of this technique is the marked improvement in the sense of tightness and discomfort often felt in the perineum by patients after APR. In our study, more than 82% of patients were free of this consequence. This allowed the patients to sit and walk freely and to enjoy bicycling. In one case (3.6%) moderate tightness was reported by the patient and was related to increased transverse diameter of the excised skin following squamous anal carcinoma with perineal extension.

Conclusion

This simple L-shaped fasciocutaneous flap not only improves perineal wound healing but also improves the patients' quality of life by alleviating the sense of tightness, especially during sitting.

Acknowledgements

Conflicts of interest

None declared.

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