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The diagnostic value of C-reactive protein and white blood cell count in diagnosis of acute appendicitis

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Introduction
Appendectomy is one of the commonest operations performed annually. Despite the advancement in the laboratory tests and radiological tests, still the rate of negative appendectomies is 15–30%. This study was designed to assess the diagnostic value of quantitative C-reactive protein (CRP) and white blood cell count (WCC) in patients suspected to have acute appendicitis.

Patients and methods
Our study is a prospective study that was conducted between December 2012 and March 2013 after approval of the ethical committee.

Inclusion criteria
1. Patients with clinically diagnosed acute appendicitis without generalized peritonitis.

Exclusion criteria
1. Patients with generalized peritonitis

All patients were subjected to the following
1. Clinical examination
2. Routine bloods immediately after decision to admit including full blood count and CRP.
3. Urine test
4. Pregnancy test for all females
5. Ultra sound scan to rule out other causes of abdominal pain

All the patients were operated upon via open approach and the appendix was sent for histopathological analysis and the results were compared with C-Reactive protein (CRP) and the WBC (White blood cell count) and the results were compared using *t*-tests.

Results
Our study recruited 100 patients, 60 males (60%) and 40 females (40%), in the age range 20–55 years. The histopathological analysis showed acute appendicitis in 85 patients (85%), the operative notes showed 60 patients with noncomplicated appendicitis, 25 patients with complicated appendicitis; the WCC alone has a sensitivity of 85%, specificity of 75%, CRP alone has a sensitivity of 93.3% and specificity of 86.6%, WCC alone had positive predictive value of 44% and it improves to 70% when both parameters are combined together, whereas the negative predictive value of the WCC was 100%. In patients with normal appendix the mean CRP level was 10.6 mg/l, the median level was 10.6 mg/l, and the mean WCC was 8×10^9 cells/l, the median WCC 7×10^9 cells/l, whereas in patients with noncomplicated acute appendicitis ($n = 60$) the mean CRP was 40 mg/l, the median was 20 mg/l; in patients with complicated appendicitis ($n = 25$) the mean CRP was 90 mg/l and the median was CRP 60 mg/l.

Conclusion
We suggest that patients experiencing lower abdominal pain, with normal CRP values and normal WCC are unlikely to have acute appendicitis and need further investigations before embarking onto surgery.

Keywords:
acute appendicitis, C-reactive protein, inflammatory markers

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Introduction

Acute appendicitis is one of the most common causes of hospital admission in the emergency settings, and appendectomy is one of the most common surgical procedures all over the world and despite the advancement in the diagnostic and laboratory methods still the rate of negative appendectomy is 15–30% [1].

Health systems nowadays are driven by the cost effectiveness; thus, many studies evolved to find tests that could increase the accuracy of diagnosis and reduce the number of unnecessary operations. C-reactive protein (CRP) and white blood cell count (WCC) are inflammatory markers used in the diagnosis of infection. CRP was first identified in 1930 by Tillet and Francis. It is an acute phase protein produced in the liver. Normal serum concentration is less than 10 mg/l, and it usually increases 8–12 h after infection or trauma. Production of CRP is controlled by interleukin-6. CRP is increased in infections,

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inflammatory arthritis, autoimmune disorders, neoplasia, and pregnancy [2].

The aim of this study was to analyze the role of CRP and WCC values, in the accuracy of diagnosis of acute appendicitis.

Patients and methods

Our study is a prospective study that was conducted between December 2012 and March 2013 after approval of the ethical committee.

Inclusion criteria

Patients with clinically diagnosed acute appendicitis without generalized peritonitis.

Exclusion criteria

Patients with generalized peritonitis.

All patients were subjected to the following:

(1) Clinical examination.
(2) Routine blood tests immediately after decision to admit including full blood count and CRP.
(3) Urine test.
(4) Pregnancy test for all females.
(5) Ultrasound scan to rule out other causes of abdominal pain.

All the patients were operated upon through the open approach and the appendix was sent for histopathological analysis and the results were compared with CRP and the WBC (WCC) and the results were compared using *t*-tests.

Results

Our study recruited 100 patients, males were 60 patients (60%) and females 40 patients (40%), and the age range was 20–55 years.

The histopathological analysis showed acute appendicitis in 85 patients (85%) and normal appendix in 15 patients (15%); the different causes of abdominal pain are shown in Table 1. The operative notes showed 60 patients with noncomplicated appendicitis and 25 patients with complicated appendicitis.

This study showed that WCC alone has a sensitivity of 85% and specificity of 75%, whereas on the other hand raised CRP alone has a sensitivity of 93.3% and specificity of 86.6% and our results showed that WCC alone had a positive predictive value of 44% and it improves to 70% when both parameters are combined together, whereas the negative predictive value of the WCC was 100% and none of the patients with normal levels showed acute appendicitis (Table 2).

In the group of patients with normal appendix the mean CRP level was 10.6 mg/l and the median level was 10.6 mg/l, and the mean WCC was 8×10^9 cells/l, the median WCC was 7×10^9 cells/l. In patients with histopathological proven appendicitis we divided them into two groups, a group that included patients without complicated appendicitis (n = 60) and a group that included patients with complicated appendicitis (n = 25) depending on the intraoperative notes. The mean CRP in the first group was 40 mg/l and the median was 20 mg/l, whereas in the group of complicated appendicitis the mean CRP was 90 mg/l and the median CRP was 60 mg/l (Table 3).

Discussion

Although acute appendicitis is considered as one of the commonest surgical emergencies, still the diagnosis could be difficult and appendectomy for normal appendix usually ranges from 15 to 30% [1].

In our study, the tissue histopathology showed normal appendix in 15% of the patients, which goes with the same results published by Lu and colleagues in 2007,

Table 1 Causes of abdominal pain

Ruptured ovarian cyst	8 patients
Mesenteric adenitis	3 patients
Nonspecific pain	4 patients

Table 2 Sensitivity, specificity, positive predictive value and negative predictive value for white cell count and C-reactive protein

	WCC raised	CRP raised	Both raised	One raised
Sensitivity (%)	85	93.3	50	100
Specificity (%)	75	86.6	90	55
PPV	44	55	70	44
NPV	95	88	88	100

CRP, C-reactive protein; NPV, negative predictive value; PPV, positive predictive value; WCC, white blood cell count.

Table 3 Mean and median white blood cell count and C-reactive protein in patients undergoing appendectomy

	Normal (N = 15)	Without complication (N = 60)	With complication (N = 25)
Mean WCC	8	13.4	16
Median WCC	7	14.6	15
Mean CRP	10.6	40	90
Median CRP	10.6	20	60

CRP, C-reactive protein; WCC, white blood cell count.

which recorded 15% negative appendectomies. And this is considered low number of negative appendectomies in comparison with other studies, as Lee and colleagues in 2014 recorded 30% and March and colleagues in 2014 recorded 21%. However, this could be explained by the lower number of patients recruited in our study in comparison with the number of patients recruited in other studies [3–5].

Our study showed that the specificity and sensitivity of CRP as a diagnostic test in acute appendicitis is 86.6 and 93.3% , respectively, and this goes with the results published by Asfar *et al.* [6] in 2000 and Sammalkorpi *et al.* [7] in 2014. Erkasap *et al*. [8] in 2000 showed a higher specificity and lower sensitivity of the CRP.

Different authors believe that elevated CRP improved the diagnostic accuracy and might help in reducing the use of radiological tests to confirm the diagnosis and specially if combined with Alvarado score as Thirumallai *et al*. [9] in 2013 suggested that further imaging is only required in the absence of elevated CRP level.

Our study showed high levels of CRP in patients with complicated appendicitis and this is in accordance with different studies showing that elevated CRP on admission more than 99 mg/l is associated with increased risk of perforation [7]; based on that the authors suggested proceeding into open appendectomy from the start in patients with CRP more than 150 mg/l [10].

In elderly patients above 60 years, studies showed that CRP more than 100 mg/dl is associated with increased risk of perforation and encouraged to proceed to early laparoscopy and avoid delay but our patients were less than 55 years old [11].

The WCC as a marker for acute appendicitis has been studied extensively and we showed in our study that it has a sensitivity of 85% and specificity of 75%; however, the literature shows different results (Table 4) although our study showed a higher % of sensitivity and specificity but we don't think that elevated WCC alone can be relied on totally to diagnose acute appendicitis but we showed that the negative predictive value of WCC was 100% and this is in accordance with most of the literature and also with the Royal College of Surgeons commissioning guidelines published in 2014, which stated that it is less likely to get an inflamed appendix with a normal WCC so it is less likely to diagnose acute appendicitis in the absence of elevated WCC [12–17]. However, according to the same guide the diagnostic value of the WCC is higher when combined with the CRP level.

Table 4 Sensitivity and specificity of white blood cell count in diagnosis of acute appendicitis

References	Sensitivity	Specificity
Yu *et al.* (2012)	62	75
Yang *et al.* (2006)	86	32
Xharra *et al.* (2012)	85	68
Wu *et al.* (2012)	80	71
Agrawal *et al.* (2008)	79	55
Mentes *et al.* (2012)	72	77

Conclusion

Diagnosis of acute appendicitis is still a clinical diagnosis. We found that elevated serum CRP levels and WCC support the surgeon's clinical diagnosis. We recommend CRP measurement as a routine laboratory test in patients with suspected diagnosis of acute appendicitis. And we suggest that patients with lower abdominal pain and not clinically convincing and in the absence of increased inflammatory markers to undergo further imaging.

Acknowledgements

Conflicts of interest

None declared.

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Clinical outcome after Doppler-guided hemorrhoidal artery ligation and rubber-band ligation for the treatment of primary symptomatic hemorrhoids

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Objective
The aim of this study was to compare the efficacy and clinical outcome after rubber-band ligation (RBL) and Doppler-guided hemorrhoidal artery ligation (DG-HAL) for primary symptomatic (grades II and III) hemorrhoids.

Patients and methods
Fifty patients with symptomatic grade II and grade III uncomplicated internal hemorrhoids were randomly assigned to be treated with either RBL or DG-HAL. Patients were assessed clinically for postoperative complications and recurrence through 6 months after surgery.

Results
Preoperative characteristics were similar between the two groups. The main preoperative complaint was protrusion of piles followed by bleeding. The overall rate of complications was 16% after RBL (9.1% for grade II and 21.4% for grade III) and 4% after DG-HAL (6.7% for grade II and 0% for grade III) ($P = 0.07$). The overall rate of recurrence was 12% after RBL (9.1% for grade II and 14.3% for grade III) and 4% after DG-HAL (0% for grade II and 10% for grade III) ($P = 0.2$). All complications were conservatively controlled with no need for reintervention. At the end of 6 months of follow-up, the overall freedom from symptoms was 88% after RBL (90.9% for grade II and 85.7% for grade III) and 96% after DG-HAL (100% for grade II and 90% for grade III). With regard to grade of hemorrhoids (II or III), there were statistically insignificant differences between the two procedures in terms of recurrence and complications.

Conclusion
DG-HAL is safer and effective compared with RBL in the treatment of grade III hemorrhoids; however, in grade II patients, both procedures had nearly equal rate of complications despite no recurrence with DG-HAL.

Keywords:
Doppler, hemorrhoids, ligation, rubber

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Introduction

Hemorrhoids are normal collections of submucosal, fibrovascular, arteriovenous sinusoids that are a part of the normal anorectum [1]. Approximately 39% had visibly enlarged hemorrhoidal complexes, but only about half of the participants with anatomical abnormalities were symptomatic [2]. Potential causes of symptoms range from weakening of supportive tissues with prolapse of the cushions to abnormal dilatation of arteriovenous anastomoses and hemorrhoidal venous complexes [3].

Numerous modalities and techniques have been developed to treat symptomatic hemorrhoids, ranging from simple dietary measures and bowel habit regulation, through a number of nonoperative procedures, to different techniques of excision of diseased anal cushions [4].

Rubber-band ligation (RBL) is considered the most widely used nonoperative procedure, and it offers the possibility to resolve hemorrhoidal disease without the need for hospitalization or anesthesia, and with lower incidence of complications [5,6].

Doppler-guided hemorrhoidal artery ligation (DG-HAL) is a nonexcisional surgical technique for the treatment of hemorrhoidal disease, consisting of the ligation of the distal branches of the superior rectal artery, resulting in a reduction of blood flow and decongestion of hemorrhoidal plexus resulting in fibrosis. It has been considered as the treatment of choice for second-degree and third-degree hemorrhoids, with minimal postoperative pain and quick recovery [7].

Therefore, the aim of the present study was to compare the safety and clinical efficacy of DG-HAL and RBL in

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terms of intensity of postoperative pain, postoperative complications, and recurrence rate through 6 months after treatment of grade II and III hemorrhoids.

Patients and methods

Selection of patients

Fifty patients with symptomatic hemorrhoids of grade II (prolapsed with spontaneous reduction) and grade III (prolapsed during defecation but are manually reducible) were included in the study, conducted between January 2012 and December 2014, at the Department of General Surgery, Minia University Hospital, and in Alseef Hospital in Kuwait. The patients were selected for the study after exclusion of patients with acute thrombosed hemorrhoids, patients with grade IV hemorrhoids, patients with other concomitant anal diseases, patients with inflammatory bowel disease or hematological disorders, patients on anticoagulants, and patients with a previous history of anorectal surgery. Half of the patients who fulfilled the selection criteria were treated with RBL and the remaining half were treated with DG-HAL.

All patients were subjected to local examination, proctoscopy, sigmoidoscopy, routine baseline laboratory investigations, and ECG. In the RBL and DG-HAL groups, the patients received a short rectal washout 1–2 h before treatment to avoid bowel movements during the first 24 h. Before each procedure, informed consent was obtained from all patients.

Technique of rubber-band ligation

The principle of RBL is to produce submucosal fibrosis. The mucosa 1–2 cm above the dentate line was grasped and pulled into a rubber band applier (the Barron gun). Two black rubber bands were placed for each pile. Only one or two quadrants are banded per visit. No anesthesia was required.

Technique of Doppler-guided ligation

Spinal anesthesia was induced in all patients. The equipment includes a lighted anal retractor with Doppler, needles, and a needle driver. With the patient placed in the lithotomy position, the transanal hemorrhoidal dearterialization device was placed into the anal canal. The Doppler probe was used to identify pulsatile arterial segments. Arteries were suture ligated through the lateral window using absorbable sutures and a long needle-holder. The procedure was duplicated circumferentially until all signals were obliterated. Six to seven separate bites were frequently required. No pack or gauze was used. Stool softeners were used to ensure a more comfortable first bowel movement. Pain was alleviated with non-narcotic analgesics.

Postoperative evaluation and follow-up

The patients were examined with anoscope and evaluated for clinical outcome at 1 week, 1 month, 3 months, and 6 months after each procedure at outpatient clinic. The evaluated postoperative complications include the following: (a) complications including postoperative bleeding within the first 15 days, severe anal pain, urinary retention, poor wound healing (anal fissure or ulceration), abscess or fistula, incontinence or anal stenosis, and (b) recurrence at the end of 6 months of follow-up, which was defined by evidence of intermittent bleeding or prolapsing hemorrhoids.

Statistical analysis

Data were analyzed using SPSS statistical software package for Windows, version 16.0 (SPSS Inc., Chicago, Illinois, USA). Quantitative data were expressed as mean ± SD and were compared using Student's *t*-test, whereas qualitative data were expressed as number and percentage and were compared using the χ^2-test. Cumulative probability of symptom-free patients during the follow-up period was determined using the Kaplan–Meier analysis, and this probability was compared between the two procedures using the log-rank (Mantel–Cox) test. A *P*-value of less than 0.05 was considered to indicate significance.

Results

Preoperative characteristics were similar between the two groups (Table 1). Male sex was predominant in both groups, with a percentage of 60% in the RBL group and 72% in the DG-HAL group. The average

Table 1 Preoperative characteristics of the studied groups

Variables	RBL (*n* = 25)	DG-HAL (*n* = 25)	*P*-value
Age (years)	42.3 ± 13.3	45.4 ± 14.2	0.42
Sex (M/F)	15 (60%)/10 (40%)	18 (72%)/7 (28%)	0.37
Grade (II/III)	11 (44%)/14 (56%)	15 (60%)/10 (40%)	0.25
Duration of complaint (months)	14.2 ± 7.4	13.8 ± 8.5	0.84
Main complaint [*n* (%)]			
Protrusion of piles	25 (100)	25 (100)	1
Bleeding	15 (60)	13 (52)	0.56
Pain	7 (28)	8 (32)	0.75
Constipation	2 (8)	1 (4)	0.55
Itching	1 (4)	3 (12)	0.29

DHAL, Doppler-guided hemorrhoidal artery ligation; RBL, rubber-band ligation.

age was 42.3 ± 13.3 years in the RBL group and 45.4 ± 14.2 years in the DG-HAL group. In the RBL group, 11 (44%) patients had grade II hemorrhoids versus 15 (60%) patients in the DG-HAL group. Grade III was diagnosed in 14 (56%) patients of the RBL group and in 10 (40%) patients of the DG-HAL group. The main preoperative complaint was protrusion of piles in all patients, in addition to bleeding (60% of RBL group patients and 52% of DG-HAL group patients), pain (28% of RBL group patients and 32% of DG-HAL group patients), and constipation (8% of RBL group patients and 4% of DG-HAL group patients).

The overall rate of complications was 16% after RBL and 4% after DG-HAL, whereas the overall rate of recurrence was 12% after RBL and 4% after DG-HAL. There were no statistically significant differences between patients with grade II hemorrhoids regardless of whether they underwent RBL (n = 11) or DG-HAL (n = 15) in terms of postoperative complications and recurrence (Table 2). The overall rate of complications among patients with grade II hemorrhoids was 9.1% in patients who underwent RBL and 6.7% in patients who underwent DG-HAL. In patients with grade II disease who underwent RBL, the complications included severe pain in 9.1%, whereas it included minor bleeding in 6.7% of patients who underwent DG-HAL. The recurrence rate was 9.1% in patients who underwent RBL and 0% in patients underwent DG-HAL.

There were no statistically significant differences between patients with grade III hemorrhoids regardless of whether they underwent RBL (n = 14) or DG-HAL (n = 10) in terms of postoperative complications and recurrence (Table 3). The overall rate of complications among patients with grade III disease was 21.4% in patients who underwent RBL and no complication was seen in patients who underwent DG-HAL. In patients with grade III hemorrhoids who underwent RBL, the complications included bleeding in 7.1% and severe pain in 14.3%. The recurrence rate was 14.3% in patients who underwent RBL and 10% in patients who underwent DG-HAL. All complications after both procedures were mild, treated conservatively, and did not required further intervention.

The four patients with recurrent symptoms at the end 6 months of follow-up (Table 4) had an average age of 50 ± 6.8 years (range = 33–65 years) and most of them were male (three vs. one female). In addition to protrusion of piles, three of those patients had preoperative symptoms of bleeding and one patient had constipation as main complaint at admission. The average duration of complaint was 12.7 ± 2.5 months (range = 10–16 months). Most of the patients with recurrent symptoms had preoperative grade III piles (three of four; 75%) and most of them underwent RBL (three of four; 75%).

The overall percentage of symptom-free patients (Fig. 1) was 88% after RBL and 96% after DG-HAL at the end of 6 months of follow-up, with insignificant difference between the two procedures [Log-rank (Mantel–Cox) test, P = 0.62]. The average symptom-free time was 11.5 months for all patients, 5.1 months for RBL patients, and 5.8 months for DG-HAL patients.

After exclusion of patients with recurrence in the present study, the overall success rate was 88% after RBL and 96% after DG-HAL. RBL procedure had

Table 2 Postoperative complications and recurrence at 6 months in the studied groups with grade II hemorrhoids

Variables	Grade II		*P*-value
	RBL (n = 11) [n (%)]	DG-HAL (n = 15) [n (%)]	
Any complication	1 (9.1)	1 (6.7)	0.73
Minor bleeding	0 (0)	1 (6.7)	0.20
Severe pain	1 (9.1)	0 (0)	0.23
Recurrence	1 (9.1)	0 (0)	0.23

DG-HAL, Doppler-guided hemorrhoidal artery ligation; RBL, rubber-band ligation.

Table 3 Postoperative complications and recurrence at 6 months in the studied groups with grade III hemorrhoids

Variables	Grade III		*P*-value
	RBL (n = 14) [n (%)]	DG-HAL (n = 10) [n (%)]	
Any complication	3 (21.4)	0 (0)	0.11
Minor bleeding	1 (7.1)	0 (0)	0.39
Severe pain	2 (14.3)	0 (0)	0.21
Recurrence	2 (14.3)	1 (10)	0.75

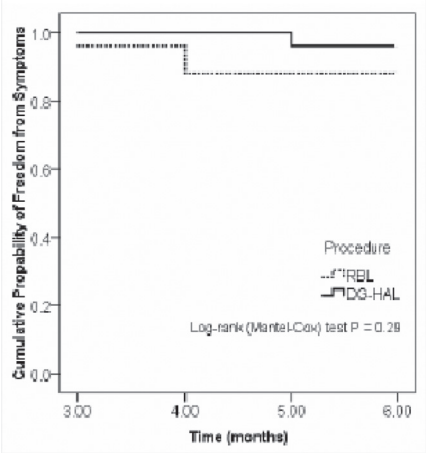
DG-HAL, Doppler-guided hemorrhoidal artery ligation; RBL, rubber-band ligation.

Table 4 Preoperative characteristics of four patients with postoperative recurrence

Number of patients	Procedure	Age (years)	Sex	Main complaint[a]	Duration of complaint (months)	Grade of piles
1	RBL	65	Male	Constipation	10	II
2	RBL	64	Female	Bleeding	13	III
3	RBL	33	Male	Bleeding	16	III
4	DG-HAL	38	Male	Bleeding	12	III

DG-HAL, Doppler-guided hemorrhoidal artery ligation; RBL, rubber-band ligation, [a]All patients had preoperative protrusion of pile.

Figure 1



Cumulative probability of symptom-free patients (no recurrence), as determined using Kaplan–Meier survival analysis, 6 months after rubber-band ligation (RBL) and Doppler-guided hemorrhoidal artery ligation (DG-HAL).

a success rate of 90.9% for grade II and 85.7% for grade III, whereas after DG-HAL the success rate was 100% for grade II and 90% for grade III.

Discussion

Hemorrhoids are a very common anorectal disorder defined as the symptomatic enlargement and abnormally downward displacement of anal cushions associated with degenerative change of supportive tissue within the anal cushions, vascular hyperplasia, and hyperperfusion of hemorrhoidal plexus [8]. When symptoms of hemorrhoidal disease do not respond to medical therapy, procedural intervention is recommended. The conventional surgical procedure includes excision of the external and internal components of the hemorrhoidal tissue, using various techniques, with or without closure of the anorectal mucosa or the anoderm [9].

RBL is the most widely used nonsurgical procedure, and it is reported to be a safe and effective treatment for symptomatic internal hemorrhoids of grades I and II and selective patients with grade III hemorrhoids, with a lower incidence of complications when compared with conventional surgery [5,10,11], and it has been recommended as the first-line treatment for those patients in whom there is contraindication for surgery or anesthesia [12].

In the present study, the postoperative complications after RBL occurred in 16% and included minor bleeding in 4% (1/25) who had grade III disease and severe pain in 12% (3/25) who had grade II (one patient) and grade III (two patients) disease. Although RBL procedure is supposed to be painless, some authors reported severe pain necessitating systemic analgesics, which is believed to be from ischemia induced by the procedure or from application of the bands below the dentate line [13]. Our incidence of postbanding pain is within the recently documented incidences in the literature between 1 and 51% [10,13–15].

Early postoperative bleeding is a significant complication after RBL, which most probably occurred as a result of the fall of the hemorrhoidal nodule and local inflammation [4]. In the present study, minor early postoperative bleeding occurred in 4%, and it was mild and treated conservatively in all cases without further hospitalization or intervention. Forlini *et al.* [10] reported that 2.4% of the patients who underwent RBL experienced rectal bleeding after a week. In the study by El Nakeeb *et al.* [4], complications after RBL were pain, rectal bleeding, and vasovagal symptoms (4.13, 4.13, and 1.33% of patients, respectively).

In the present study, RBL results in an overall freedom from hemorrhoidal symptoms in 88% of patients, which was 90.9% for grade II and 85.7% for grade III hemorrhoids. These findings are confirmed by other findings published in the literature as regards the efficacy of RBL. Recently, Gagloo *et al.* [12] reported freedom from symptoms in 77% of grade II patients and 50% of grade III patients, and concluded that RBL is not as effective as hemorrhoidectomy in grade III.

Early results of RBL in the study by El Nakeeb *et al.* [4] showed overall freedom from symptoms in 86.66% of patients, which was 89.7% in grade II and 76.19% in grade III patients. In the study by Forlini *et al.* [10], no residual symptoms were reported at 1-year follow-up in 90% of the patients with grade II and 75% of patients with grade III hemorrhoids. Bernal *et al.* [16] also reported freedom from rectal symptoms (bleeding and hemorrhoidal prolapse) not requiring further intervention in 86.1% of patients, 90.2% of patients with grade II and 74% of patients with grade III hemorrhoids. Other recent prospective studies reported that an overall freedom from symptoms ranged from 84 to 97.5% after RBL, for all grades of hemorrhoids [5,13,14].

DG-HAL of the terminal branches of the superior hemorrhoidal artery was introduced by Morinaga *et al.* in 1995 [17]. In the literature, DG-HAL has been shown to be associated with potential benefits for symptomatic hemorrhoids (grades II and III) particularly with regard to the perioperative parameters

and 1-year recurrence rate [18–20]. However, some authors have shown that DG-HAL is an effective procedure for treating low-grade hemorrhoid; despite low complication rates with DG-HAL, recurrences are more frequent with this procedure in case of grade III and IV hemorrhoids [21–23].

In the present study, the postoperative complications after DG-HAL occurred in one patient (4%), who had grade II hemorrhoids and suffered from postoperative minor bleeding. This finding relies within the spectrum of postoperative bleeding after DG-HAL reported in other studies, which ranged from 0 to 18.8% [19,23]. Other complications with variable rates were reported after DG-HAL by other authors, including postoperative pain (range = 0–28.6%) [22,23], thrombosis (range = 1.5–6.7%) [24], and anal fissure (range = 1.1–3%) [21,25].

In the present study, after DG-HAL procedure the overall freedom from hemorrhoid symptoms was 96%, which was 100% for grade II and 90% for grade III hemorrhoids. Similarly, the recent study by Yamoul *et al.* [26] reported that after DG-HAL freedom from symptoms was 97% over 1 year (residual rectal bleeding in 3%). Moreover, those authors concluded that DG-HAL is not only effective for stage III and IV hemorrhoids for which the effect is spectacular but also for stage I and II symptoms, which can expand its indications. In a recent systemic review of 28 studies including 2904 patients, the freedom from symptoms ranged from 40 to 97% with a recurrence range between 3 and 60% [25].

Yilmaz *et al.* [7] reported that DG-HAL can be the choice of treatment for grade II and III hemorrhoids with minimal postoperative pain and quick recovery, with complete freedom from symptoms in 88% of patients after 2 years of surgery. Spyridakis *et al.* [25] concluded that DG-HAL seems to be a safe and effective treatment option for all grades of hemorrhoidal disease, and freedom from symptoms was 93.4% with recurrences in six patients (6.6%), two patients with initial grade III and four with grade IV hemorrhoids. The study by Walega *et al.* [27] showed that 92.4% of patients with grade II and 84% of patients with grade III had very good results (patient was free of the disease) or good results (significant symptom relief).

The results by Pol and colleagues showed freedom from symptoms in 67% of patients after DG-HAL, which seems very effective in treating lower-grade hemorrhoids. However, in more advanced disease, recurrence occurs due to persisting mucosal prolapse [22]. Szmulowicz *et al.* [23] stated that recurrences after DG-HAL are more frequent during the learning curve, with freedom from symptoms in 79% of patients (residual hemorrhoids were evident in 21% of patients).

Testa and Torino [28] reported success of DG-HAL in 90% of patients affected by II or III degree hemorrhoids, which suggests the safety, efficacy, and low invasity of DG-HAL in the treatment of II and III degree hemorrhoids, and highlight its use in treating patients with unhealthy conditions, which are a contraindication to the usual surgical treatments. Moreover, those authors suppose the use of HAL Doppler in low-degree hemorrhoids as a therapeutic and also prophylactic rule of advanced degree. Moreover, Conaghan and Farouk [29] reported that DG-HAL reduces the need for conventional hemorrhoid surgery where RBL has been unsuccessful, with freedom from symptoms in 77% of patients (recurrence was 23%); 52 patients with recurrent symptoms after RBL, subsequently underwent DG-HAL.

In the present study, comparison of DG-HAL and RBL in terms of postoperative complications and recurrence revealed statistically insignificant differences; this is in agreement with the results of Pol and colleagues, who retrospectively compared the results of DG-HAL and RBL for the treatment of hemorrhoidal disease, through analysis of 239 DG-HAL patients and 47 RBL patients. Those authors reported an incidence of 67% in the DG-HAL group and 79% in the RBL group as regards improvement in symptoms after one treatment, with statistically insignificant difference [22].

In conclusion, when compared with RBL procedure, DG-HAL results in nearly equal rate of complications in patients with grade II hemorrhoids, but with no recurrence of hemorrhoid symptoms. In grade III patients, DG-HAL results in lower rates of complications and recurrence compared with RBL. All comparisons between the two procedures had statistically insignificant differences. Further comparative, large-scale, and long-term studies are recommended.

Conclusion

DG-HAL is safer and effective compared with RBL in the treatment of grade III hemorrhoids. However, in grade II patients, both procedures had nearly equal rate of complications despite no recurrence with DG-HAL.

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Conflicts of interest

There are no conflicts of interest.

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Management of gastrointestinal stromal tumors: a prospective and retrospective study

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Background
Gastrointestinal stromal tumors (GISTs) are a group of unusual neoplasms arising from the interstitial cells of Cajal. GISTs are the most common mesenchymal tumors of the gastrointestinal (GI) tract. Diagnosis always requires immunohistochemical staining for the expression of c-KIT protein (CD-117).

Purpose
The aim of this study was to present the prospective and retrospective experience of the Gastrointestinal Surgery Department, Alexandria Faculty of Medicine, in the management of GISTs.

Materials and methods
This study was carried out on 102 patients: a prospective study on 22 patients from April 2013 to April 2015 and a retrospective study on 80 patients between January 2009 and March 2013. All patient data, the different clinical presentations, the impact of surgical treatment, complications, follow-up, and survival data were collected and analyzed.

Results
This study included 102 patients (63 men and 39 women) who presented with GISTs on clinical, radiological, and/or endoscopic aspects. Their mean age at diagnosis was 49.18 ± 14.58 years. The most frequent presenting symptom was GI bleeding, seen in 42 patients (41.18%). Twenty-five patients (24.51%) presented with abdominal swelling and pain. Twenty-four patients (23.53%) presented with anemia for investigation. Eight patients (7.84%) presented with repeated attacks of abdominal pain only. The tumors were located in the stomach in 54 patients (52.9%). Upper gastrointestinal endoscopy was performed in 64 patients (62.75%). Upper gastrointestinal endoscopy revealed the presence of a gastric lesion in 46 patients and a duodenal lesion in six patients and was completely free in 12 patients. Complete resection was achieved in 92 patients (92%), whereas eight patients (8%) had incomplete resection.

Conclusion
This study concludes that GISTs can occur anywhere in the GI tract but most commonly in the stomach. The prognosis is strictly related to the size of the tumor, number of mitoses, and completeness of surgical resection.

Keywords:
c-KIT protein (CD-117), gastrointestinal stromal tumors, imatinib (Gleevec), surgical resection

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Introduction

Gastrointestinal stromal tumors (GISTs) are a group of neoplasms of mesenchymal origin that develop in the gastrointestinal (GI) system. GISTs are the most common (~80%) mesenchymal tumors of the GI tract, accounting for 1–3% of all GI malignancies [1–4]. These tumors are believed to arise from the interstitial cells of Cajal, a complex cellular network thought to act as pacemaker cells that regulate peristalsis [3–5]. Morphologically, GISTs can be classified into spindle cell type (70%), epithelioid type (20%), and mixed type (10%) [6,7]. Grossly, GISTs are submucosal lesions that appear to arise from the muscularis propria of the bowel wall; intramural in origin, they are often exophytic extraluminal and/or endophytic intraluminal and may have overlying mucosal ulceration. Their size can be extremely variable, from tiny incidental cases to huge masses [8]. Large GISTs nearly always outgrow their vascular supply, leading to extensive areas of necrosis and hemorrhage [9,10].

With the advent of immunohistochemical staining techniques [11–16], Mazur and Clark [11] in 1983 reported that many supposed smooth muscle tumors lacked immunohistochemical or electron microscopic evidence of smooth muscle or neural immunoreactivity, and they suggested that the neutral term ‘stromal tumor’ would be more

appropriate. The discovery of CD-117 expression in many GISTs suggested that they were a specific entity, distinct from smooth muscle tumors [10,13]. This has led to the widely accepted classification of mesenchymal tumors of the GI tract into GISTs, true smooth muscle tumors, and far less frequently into true Schwann cell tumors. However, not all GISTs arise from the interstitial cells of Cajal, as some come from the mesentery or omentum, which lacks interstitial cells of Cajal, suggesting an origin from multipotential mesenchymal stem cells [16].

Most GISTs express the CD-34 antigen (70–78%) and the CD-117 (72–94%) antigen [15]. Other markers that have been used in the evaluation of GISTs include desmin, actin, and S100 (about 20–30% of GISTs express smooth muscle actin, around 10% of GISTs may have positive results for S100, and very rarely about 1–2% express desmin [14,15]).

GISTs can occur anywhere in the GI tract. Approximately 50–70% of GISTs originate in the stomach. The small intestine is the second most common location, with 20–30% of GISTs arising from the jejunum and ileum [7]. They can arise at any age, with a peak around 60 years, and they affect the male and female population equally.

According to guidelines, no GIST can be considered truly benign (about 10–30% of GISTs have malignant behavior) [8], but according to several features they are stratified for risk of malignant behavior. Tumor size, mitotic index, and aneuploidy are negative prognostic factors, as is tumor location (gastric tumors have a better prognosis than those of the small bowel and the rectum). Malignancy is characterized by local invasion and metastases.

The clinical presentations of these tumors are highly variable according to the site and size of the tumor. The most frequent symptoms are iron deficiency anemia, weight loss, GI bleeding, abdominal pain, and mass-related symptoms. Other presentations include nausea, vomiting, and abdominal distension. Other rare presentations include biliary obstruction, dysphagia, intussusception, and hypoglycemia. Patients may present with acute abdomen, obstruction, perforation or rupture, and peritonitis [10–13].

DeMatteo *et al.* [7] reported that metastatic disease is found in nearly half of the patients. The liver is the most common site (65%), followed by the peritoneum (20%), whereas lymph nodes, bone, and lung metastases are rare.

Surgical resection is the 'gold standard' for therapy of GISTs. The primary goal of surgery is complete resection of the disease [8]. However, locally recurrent tumors are usually not amenable to complete resection because of peritoneal implantation, and hence the results of secondary surgery, in the case of recurrent disease, are generally poor [8]. Survival after complete surgical resection ranges from 48 to 80% at 5 years. If resection is not complete, only 9% of patients survive for an average of 12 months [13–15]. The molecular pathogenesis of GISTs is linked to deregulated KIT tyrosine-kinase activity, which has resulted in the successful application of tyrosine-kinase inhibitor [16], imatinib (Gleevec), in the treatment of GIST patients with malignant metastatic or unresectable disease. New evidence-based treatment guidelines recommend imatinib as first-line therapy in cases of marginally resectable GISTs, and postoperative imatinib administration is advised if imatinib response improves resectability [17,18].

The aim of this study was to present the prospective and retrospective experience of the Gastrointestinal Surgery Department, Alexandria Faculty of Medicine, in the management of GISTs.

Materials and methods

This study was carried out on 102 patients:

(1) A prospective study on 22 patients from April 2013 to April 2015.
(2) A retrospective study on 80 patients between January 2009 and March 2013.

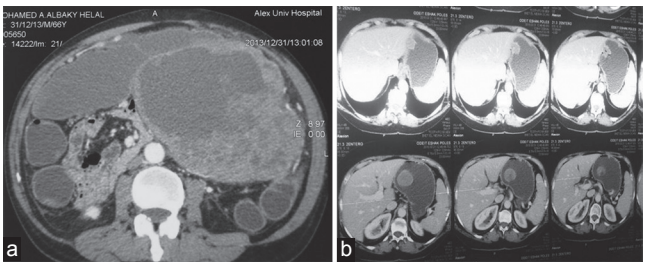
All patient data, the different clinical presentations, value of different investigative tools, histopathological examination and immunohistochemical analysis for c-KIT (CD-117), the impact of surgical treatment, intraoperative and postoperative complications, as well as follow-up and survival data were collected, reviewed, and analyzed.

Computed tomography (CT) scan of the abdomen and pelvis was performed for all patients (Fig. 1). Upper gastrointestinal endoscopy (UGIE) or colonoscopy was done when indicated.

Using the 'risk of aggressive behavior classification' proposed by Fletcher *et al.* [3] (Table 1) we classified GISTs as low, intermediate, and high risk.

Ethical approval was given by Ethical Committee of Alexandria Faculty of Medicine. Informed consent from all patients was taken. In the retrospective study confidentiality of the patients was preserved.

Figure 1



Different computed tomography (CT) images of gastric gastrointestinal stromal tumor (GIST). (a) Large exophytic heterogeneous tumor at the greater curvature of the stomach. (b) Small GIST along the lesser curvature.

Table 1 Proposed approach for defining risk of aggressive behavior in gastrointestinal stromal tumors [3]

Characteristics	Size[a]	Mitotic count
Very low risk	<2 cm	<5/50 HPF
Low risk	2–5 cm	<5/50 HPF
Intermediate risk	<5 cm	6–10/50 HPF
	5–10 cm	<5/50 HPF
High risk	>5 cm	>5/50 HPF
	>10 cm	Any mitotic rate
	Any size	>10/50 HPF

[a]The single largest dimension.

Table 2 Patient characteristics

Characteristics	Number of patients [*n* (%)]
Sex	
Male	63 (61.76)
Female	39 (38.20)
Age (years)	
Mean ± SD	49.18 ± 14.85
Range	23–78
Clinical presentations[a]	
GIT bleeding	42 (41.18)
Abdominal pain and swelling	25 (25)
Anemia	24 (24.51)
Intestinal obstruction	5 (4.90)
Acute abdomen (peritonitis)	8 (7.84)

GIT, gastrointestinal tract; [a]Two patients had more than one presentation.

Data were presented as numbers, percentages, arithmetic mean (*X*), and SD and were analyzed with SPSS (version 10, Chicago: SPSS Inc.) and statistical tests were performed with MedCalc (Version 7.3.0.1, MedCalc Software, Mariakerke, Belgium). Disease-free survival (DFS) curve and overall survival (OS) curve were calculated from the date of trial entry until disease progression, relapse, or death. They were estimated using the Kaplan–Meier method. [19].

Results

This study included 102 patients who presented with GISTs on clinical, radiological, and/or endoscopic aspects. Table 2 summarizes the demographic data and presenting symptoms of cases. The most frequent presenting symptom was GI bleeding in 42 patients (41.18%), of whom 24 patients had hematemesis and melena, 15 patients had melena only, and three patients had severe fresh bleeding per rectum. The tumors were located in the stomach in 54 patients (52.9%), in the duodenum in eight patients (7.8%), in the small intestine in 28 patients (27.5%), in the small intestinal mesentery in five patients (4.9%), in the colon in four patients (3.9%), and in the rectum in three patients (2.9%).

Ninety-one patients (89.22%) presented with primary disease, whereas 11 patients (11%) presented with recurrent disease. Patients with recurrent tumors had their initial tumor located in the small intestine in seven patients and in the stomach in four patients.

UGIE was performed in 64 patients (62.75%). These patients presented with GI bleeding (hematemesis and/or melena), anemia, or abdominal mass, which was suspected to be within the reach of the endoscope. UGIE revealed the presence of a gastric lesion in 46 patients and a duodenal lesion in six patients; no lesion was seen in 12 patients. UGIE located the lesion in the stomach and duodenum correctly but did not show the lesion in the distal third part of the duodenum in two patients, in the small intestine in seven patients, and in the colon in three patients. The three cases of colonic lesion were detected by colonoscopy.

Colonoscopy was performed in six patients: three patients presented with melena (two cases at the ascending colon and one case at the transverse colon); the other three patients presented with severe fresh bleeding per rectum (two cases at the rectum and the other at the sigmoid).

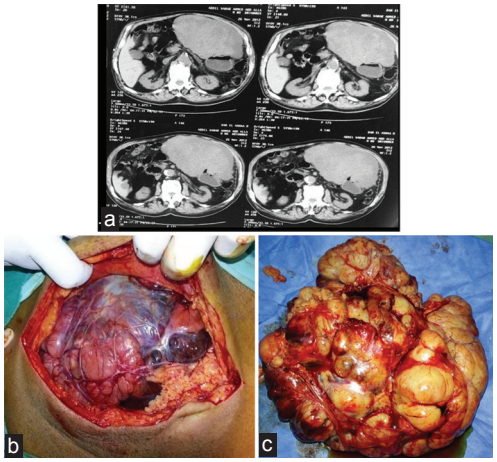
Endoscopic biopsy was performed in 52 patients who showed a lesion on UGIE, and the true pathological nature of the lesions was diagnosed in only 24 of them (46.15%). The pathology report of the other 28 patients showed different forms of chronic gastritis or duodenitis, or was normal as the biopsy was probably taken from the overlying mucosa and the lesions were usually deeply seated.

CT scan was the most commonly performed imaging tool in this study, having been performed on 101 patients (99.02%). CT was able to detect the lesion in all cases, and to locate its site of origin (Figs. 2–6). CT findings were able to suggest the diagnosis of GIST in 78 patients (77.23%) out of 101. It was not possible to perform a

CT scan for a morbidly obese patient who presented with a huge abdominal swelling. He had an abdominal ultrasound examination that showed the presence of a large cystic abdominal swelling (30 cm in diameter), and this was followed by an ultrasound-guided biopsy that was inconclusive, bringing only necrotic tissue. This patient was then operated upon to explore this undefined abdominal swelling.

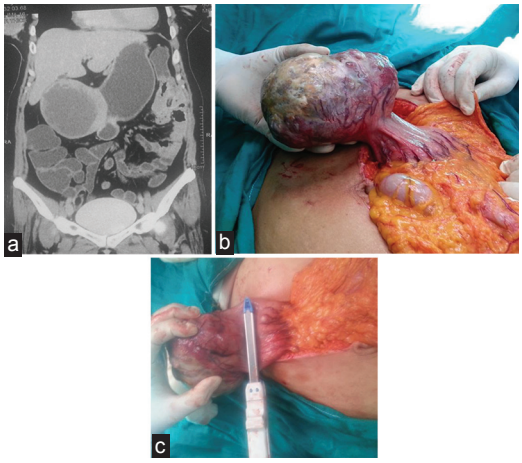
In all, 100 patients were operated upon. All operated patients underwent surgical resection. Table 3 describes the surgical procedures performed in relation to the site of the tumor. Two patients presented with advanced invasive gastric GIST and metastatic invasive duodenal GIST; they did not undergo surgical treatment. These two patients underwent ultrasound-guided biopsies that were conclusive in the two

Figure 2



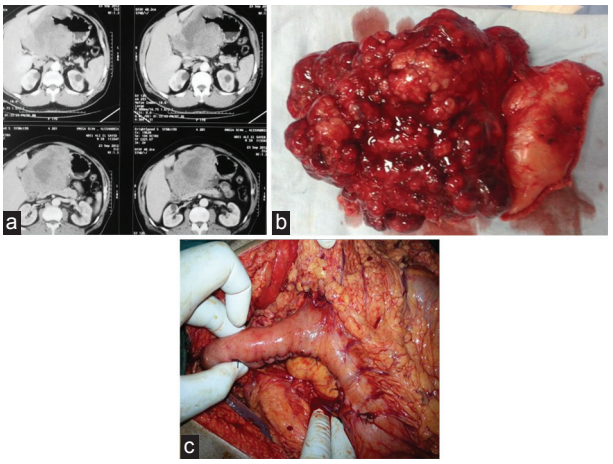
An image of a giant gastric gastrointestinal stromal tumor (GIST). (a) Computed tomography (CT) showing a heterogeneous mass extending to the epigastrium and left hypochondrium. (b) Intraoperative image of the huge mass. (c) The specimen after excision showing hypervascularity and friability.

Figure 4



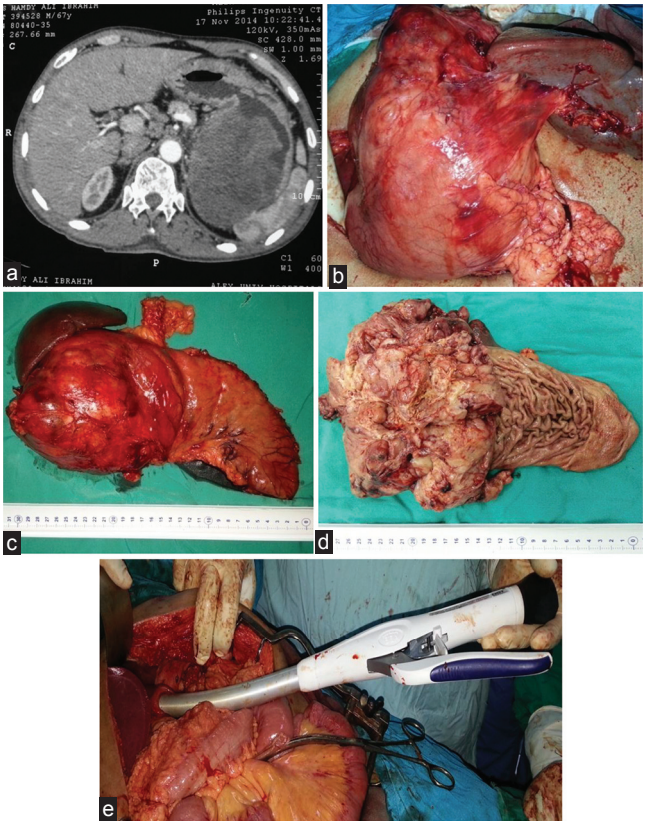
(a) Computed tomography (CT) with IV contrast, an exophytic cystic tumor at the gastric antrum. (b) A huge pedicled tumor at the antrum. (c) Resection using a linear stapler.

Figure 3



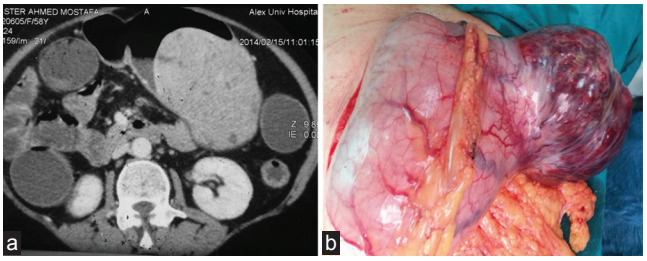
A case of gastric gastrointestinal stromal tumor (GIST). (a) Computed tomography (CT) revealing a large exophytic mass occupying the lesser curvature and distal stomach with marked encroachment on the gastric lumen with central necrosis. (b) The specimen after excision. (c) The lesser curvature was closed after removal with a linear stapler followed by interrupted sutures to invert the staple line.

Figure 5



(a) Computed tomography (CT) images of a giant heterogeneous gastric gastrointestinal stromal tumor (GIST). (b) Intraoperative view of the mass tumor situated in the upper two-third of the stomach. (c) Total gastrectomy specimen. (d) Cut section through the specimen showing friable tissue and central necrosis. (e) Reconstruction by Roux-en Y esophagojejunostomy.

Figure 6



(a) Computed tomography (CT) image of a gastric gastrointestinal stromal tumor (GIST). A sizable exophytic gastric GIST with areas of necrosis. (b) A highly vascular exophytic tumor with a nodular surface (operative view).

Table 3 Different surgical procedures according to tumor anatomical location

Site (*n*)	Surgical procedure	Completeness of resection
Stomach (53)	Localized wedge resection (45)	Complete (53)
	Total gastrectomy (4)	
	Partial gastrectomy (2)	
	Partial gastrectomy+splenectomy and distal pancreatectomy (2)	
Duodenum (6)	Localized wedge resection (5)	Complete (6)
	Partial duodenectomy (1)	
Small intestine (28)	Segmental resection (23)	Complete (23)
	Segmental resection+peritoneal toilet (3)	Incomplete (3)
	Segmental resection + metastasectomy (2)	Incomplete (2)
Small intestinal mesentery (7)	Segmental intestinal resection + tumor excision	Complete (4)
		Incomplete (3)
Colon (4)	Segmental resection (2)	Complete (4)
	Hemicolectomy (2)	
Rectum (2)	Anterior resection (1)	Complete (2)
	Total colectomy and abdominoperineal resection with terminal ileostomy (1)	

cases and allowed for the administration of imatinib (Gleevec) [the standard dosage for the treatment of GISTs is 400–600 mg once daily for 12 weeks (may be extended for another 12 weeks)]. One patient improved dramatically after 6 months of treatment with disappearance of the associated ascites. Surgery was proposed to the patient but he refused and did not attend further follow-up. The other patient was followed up with a CT scan after 1 year of treatment, which showed that the duodenal and hepatic lesions had become less dense. CT-guided biopsy from the hepatic lesions showed evidence of myxomatous degeneration without active tumor cells.

Complete resection was achieved in 92 patients (92%), whereas eight patients (8%) had incomplete resection (Figs. 2–6).

Of the eight patients who underwent incomplete resection, three patients presented with a picture of perforated acute appendicitis, which on exploration was proved to be ruptured tumors with acute peritonitis. The patients presented later with peritoneal deposits and liver metastases. At each surgery, all of the peritoneal deposits were removed. Another two patients presented with recurrent disease. The initial tumors were located in the stomach in one case and in the small intestine in another. Both presented with recurrent tumors in the small intestine and had a history of having undergone two operations for the initial lesion. They also presented with extensive peritoneal and omental deposits, which were removed as much as possible. Anastomotic leakage occurred and the general condition of the patients worsened and they died from multiorgan failure caused by sepsis. The last three patients had huge mesenteric GISTs that underwent incomplete resection as they were fixed to the pancreas and retroperitoneal tissue. All eight patients received postoperative Gleevec therapy.

Histopathological examination of the 100 resected specimens confirmed the diagnosis of GIST in 98 patients only. In the other two patients the diagnosis was a paraganglioma of the small intestinal mesentery in one patient and a duodenal carcinoid tumor in the second. These two patients were subsequently excluded from further analysis. Hence, this study included only 98 patients with the definite diagnosis of GISTs. The GIST originated from the stomach in 53 cases (54%), from the duodenum in seven cases (7%), from the small intestine in 28 cases (28.5%), from the small intestinal mesentery in four cases (4%), from the colon in four cases (4%), and from the rectum in two cases (2%). C-KIT analysis was performed in all patients and proved positive in 91 patients (89.22%).

The mean tumor size was 9.26±5.91 cm (ranged from 2.6 to 30 cm). It was less than 5 cm in 36/98 cases (36.7%), 5–10 cm in 41/98 cases (41.8%), and more than 10 cm in 21/98 cases (21.4%).

The mitotic count was low (2–5/50 HPF) in 60/98 cases (61.3%) and high (>5/50 HPF) in the remaining 38/98 cases (38.7%). None of the patients with low mitotic counts (<5/50 HPF) had recurrence, nor did they die during the 5-year follow-up period, whereas the 5-year OS and the 5-year DFS of patients with high mitotic counts (>5/50 HPF) were 67% (SE = 0.22) and 20% (SE = 0.13), respectively. This difference was statistically significant between the two groups of patients.

Using the 'risk of aggressive behavior' classification, tumors were classified as low risk [53/98 patients (54%)], intermediate risk [5/98 patients (5.1%)],

and high risk [40/98 patients (40.8%)]. Using the 'risk of aggressive behavior classification' for our patients, we found that the 5-year DFS was 100 and 20% for patients with low risk and high risk, respectively. This difference was statistically significant (P = 0.0007). The 5-year OS was 100 and 67% for patients with low risk and high risk, respectively, and this difference was also statistically significant (P = 0.0086). Table 4 shows the anatomic and pathologic GISTs' characteristics.

The perioperative follow-up was smooth in 96 patients, with few minimal complications that were in the form of chest infection (13/98 = 13.2%) and wound infection (12/98, 12.2%), which were treated conservatively. One patient died in the perioperative period from multiorgan failure related to sepsis.

Only 92 patients attended the follow-up visits. The mean duration of follow-up was 56.79 ± 33.46 months (ranged from 6 to 77 months) in the retrospective group and from 2 to 20 months in the prospective group.

Overall, 10 patients (10/98 = 10.2%) developed metastases, or recurrence. One patient who presented initially with a primary large gastric GIST developed liver metastases 13 months after the operative procedure and was subsequently managed by Gleevec therapy. In two patients who presented initially with recurrent gastric GIST, recurrence occurred at 6 and 11 months, respectively, after the operative procedure. Of the remaining seven patients GIST of the small intestine was seen in six cases and mesenteric GIST in one case. Four of the remaining six cases of intestinal GIST presented initially with recurrent disease. Their recurrences occurred at 6, 7, 13, and 15 months respectively. Two presented initially with a primary intestinal GIST and in them recurrence occurred at 12 and 18 months, respectively. All recurrences in these six patients were located in the peritoneum, intestinal mesentery, and serosal surface of the small intestine. One of them died during the follow-up period at 36 months. The last patient with mesenteric GIST underwent incomplete resection initially, with recurrence after 1 month, and received Gleevec therapy.

Table 4 Anatomic and pathologic gastrointestinal stromal tumor characteristics (in the 98 patients with a definite diagnosis of gastrointestinal stromal tumor)

Characteristics	n = 98 [n (%)]
Tumor origin	
Stomach	53 (54)
Duodenum	7 (7)
Small intestine	28 (28.5)
Mesentery	4 (4)
Colon	4 (4)
Rectum	2 (2)
Tumor size (cm)	
<5	36 (36.7)
5–10	41 (41.8)
>10	21 (21.4)
Mitotic count	
Low (2–5/50 HPF)	60 (61.3)
High (>5/50 HPF)	38 (38.7)
Risk class	
Low	53 (54)
Intermediate	5 (5.1)
High	40 (40.8)

The 3- and 5-year OS rates for all patients, using the Kaplan–Meier actuarial curve, were 92.1 and 81.4%, respectively. The 3- and 5-year DFS rates for all patients were 73.2 and 64.5%, respectively.

Discussion

This study included 102 patients (63 men and 39 women) who presented with GISTs. Their mean age at diagnosis was 49.18 ± 14.58 years (ranged from 23 to 78 years).

Cavaliere *et al.* [8] stated that GISTs can arise at any age, with a peak around 60 years, and that they affect the male and female populations equally. Miettinen *et al.* [16,20] stated that GISTs are rare before the age of 40 years and very rare in children. Miettinen *et al.* [20] and DeMatteo [21] reported a slight male predominance; however, other reports showed no sex difference [5]. The results in this study were consistent with most of the series reported in the literature.

In this study, analysis for CD-117 was performed in all patients and was positive in 91 patients (89.22%). Lin *et al.* [9] and El-Zohairy *et al.* [22] reported that CD-117 was positive in 89 and 88.9% of their patients, respectively.

The symptoms associated with primary GISTs are usually vague and nonspecific and depend on the size and location of the lesion [22,23]. Incidental discovery accounts for approximately one-third of cases [23]. The most common symptoms are GI bleeding in 41.1% of patients, abdominal pain in 20–50%, and GI obstruction in 10–30%; 20% of patients may be asymptomatic[18]. The results in this study were consistent with those of other series reported in the literature [1,23,24].

Cavaliere *et al.* [8] and El-Zohairy *et al.* [22] reported that the endoscopic biopsy was diagnostic in 57.14 and 33.3% of their patients, respectively. This was in accordance with the findings in our study. This can be

attributed to the fact that the biopsy was taken from the overlying mucosa and that the lesions are usually more deeply seated.

El-Zohairy *et al.* [22] noted that CT was most useful in terms of demonstrating a mass lesion, determining its size and its relation to the contiguous organs. Daldoul S *et al.* [12] stated that CT is the most common imaging technique used to assess distant metastases from GIST.

In the present study, the stomach was the most common organ from which tumors originated (54%), followed by the small intestine (28.5%). This is in accordance with most of the findings reported by the different series in the literature [3,25].

DeMatteo *et al.* [7] found no correlation between the tumor's site of origin and survival in 200 patients. Contrary results have been reported by Lillemoe and Efron [26] in 133 patients with resected GISTs, in whom survival was related to the tumor's site. In our series, patients with gastric lesions had better prognosis than did patients with lesions in other sites.

Fletcher *et al.* [3] stated that there were more data suggesting that anatomic location was a prognostic factor independent of tumor size, mitotic rate, and patient's age, with a trend for small bowel tumors to have the worst prognosis and esophageal tumors the best, but the basis for these differences remain uncertain [27,28]. Our results coincide with those of Lin *et al.* [9] who found that most of their patients with small intestinal GISTs had lesions larger than 5 cm and a poorer outcome than those with gastric tumors. In our study, three patients who developed recurrence and metastases had their initial tumor originating from the small intestine, and two of them died. Yan *et al.* [28] found that GISTs were four times more likely to recur if the primary site was the intestine compared with the stomach.

The primary goal of surgery was complete en-bloc resection of the disease, with avoidance of tumor rupture as this was considered a poor prognostic factor [13]. This study agreed with the findings of El-Zohairy *et al.* [22] that achieving negative pathologic margins of resection was generally not difficult because GISTs tended to hang from, and not diffusely infiltrate, the organ of origin. Several reviews had reported that small GISTs can be treated adequately by wedge (gastric) or segmental (bowel) resection [29] and more extensive surgery had no better benefit [22]. However, larger GISTs might require more extensive en-bloc resection including adjacent structures or organs if involved [29,30]. GISTs, even with high malignant potential, rarely metastasized to lymph nodes to warrant lymph node dissection [22,31,32]. In our series, the incidence of lymph node involvement was 0%, and no extended lymph node dissection was performed. In this study, complete resection was possible in 92 patients (92%), and resection was considered incomplete in eight cases (8%). Boni *et al.* [33] reported that macroscopically complete resection was possible in 84% of their cases and found that the presence of residual tumor was significantly related to early recurrence and short survival.

The mean tumor size in our series was 9.26 ± 5.91 cm (ranged from 2.6 to 30 cm). Lin *et al.* [9] reported a mean tumor size of 7.5 ± 5.7 cm, whereas Bucher *et al.* [30] reported a median tumor size of 5 cm (ranged from 0.5 to 26). An overall 36.7% of our patients had tumors less than 5 cm and 63.3% had tumors more than 5 cm in diameter.

Boni *et al.* [33] found that patients with GISTs less than 5 cm had a significantly longer survival compared with patients with bigger tumors. In our series, all patients with tumors less than 5 cm were disease free and alive at 5-year follow-up, whereas the 5-year DFS and OS for patients with tumors larger than 5 cm were 33% (SE = 0.16) and 75% (SE = 0.19), respectively. These differences between the two groups of patients were statistically significant. Katharine *et al.* [34] found that tumor size had a significant impact on OS as tumors 5 cm or larger in size had a 28-month median survival, whereas those that were less than 5 cm had a 42-month median survival.

Lin *et al.* [9] reported a 5-year survival of 76% for patients with mitotic counts less than 5/50 HPF, 73% for those with counts between 5 and 10/50 HPF, and 31% for those with counts greater than 10/50 HPF. Boni *et al.* [33] confirmed that low number of mitoses at HPF is related to prognosis with significantly longer survival in the very low-risk and low-risk group compared with the high-risk group.

Bucher *et al.* [30] stated that patient survival after primary surgical resection of GISTs ranges from 48 to 80% at 5 years [7,32]. The overall 5-year survival in our patients was 91.7%, and the overall 5-year DFS was 73.3%, which coincided with the previous findings. For low-risk GIST, the 5-year survival rate (~95%) was similar to the normal population, whereas for high-risk GIST the 5-year survival rate ranged from 0 to 30% [30]. Our results were in accordance with these findings.

In this study Gleevec was used in the incomplete resection cases and in the 10 patients with recurrent metastatic disease to the liver, with locally advanced gastric lesion, small intestine, and its mesentery. We obtained satisfactory results with control of the primary tumor. Some of the liver metastases showed regression in size, whereas some others disappeared. Van den Abbeele *et al.* [35] noted that tumor liquefaction (cystic degeneration) can occur, which may give the appearance of progressive disease, although the tumor is in reality responding.

Conclusion

This study concludes that GISTs can occur anywhere in the GI tract but most commonly in the stomach. GISTs are uncommon and aggressive tumors; their incidence is probably increasing nowadays. The presentation varies according to tumor site with abdominal pain and GI bleeding being most common. The prognosis is strictly related to the size of the tumor, number of mitoses, and completeness of surgical resection. Surgery is still the standard treatment in localized GIST and recurrence of the tumor can occur even after radical surgery. As regards GIST, imatinib therapy (Gleevec) is more effective and considered the first-line therapy for advanced primary GIST, as well as those with recurrent or metastatic GIST. Endoscopy with biopsy is used to identify the tumor, with definitive diagnosis depending on histological and immunohistochemical analysis (CD-117). It is critical that patients be evaluated by a multidisciplinary team with expertise in GISTs to coordinate surgery and therapy and to ensure maximal benefits over the course of the disease. We recommend that all patients with a GIST be regularly followed up and continually evaluated by the surgical team for a possible resectability because we believe that the best strategy is 'surgery when possible' aimed at obtaining an R0 resection when possible.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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Evaluation of Gomco clamp in neonates and early infant male circumcision in a private hospital: a series of 300 cases

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Aim

The aim of this study was to evaluate the impact and safety of neonatal circumcision under a uniform hospital policy using a Gomco clamp and its complication and parents' satisfaction.

Patients and methods

A prospective analysis of 300 consecutive cases of neonatal and infant circumcisions performed with a Gomco clamp at Al Omooma Private Hospital, Kuwait, during the period from March 2012 through March 2015, was carried out. Outcome measures for the study were the number and type of complications in terms of procedure, the adequacy of circumcision, and parents' satisfaction with the final appearance.

Results

An overall 10.6% of cases suffered from intraoperative bleeding, most of which were controlled by means of chemical hemostasis or bipolar diathermy, whereas 2.6% of cases needed vicryl plus 5/0 stitches. All of them were older than 2 weeks. Two cases (0.67%) returned on the same day of discharge with surface oozing; both cases were sutured with vicryl plus 5/0 stitches. The overall percentage of postoperative bleeding that needed sutures was 3.3% (10 cases). All cases of significant bleeding requiring stitches were older than 14 days (mean age, 38 days). Four parents (1.3%) came during the follow-up period complaining of inadequate circumcision; only one of them needed a redo after 6 months of follow-up. 0.67% of cases suffered from frenulum ulcer and only 1% of patients.

Conclusion

Circumcision with a Gomco clamp is a safe and effective technique with satisfactory cosmetic results, provided care is taken in exact marking of the site on the foreskin for excision and selecting a correct size of the clamp. Gomco clamp is a bloodless, sutureless, simple, and safe method of circumcision in the neonatal period and in early infancy. The use of the Gomco clamp for circumcision beyond early infancy (3 months of age) has substantial morbidity.

Keywords:
bloodless sutureles, Gomco clamp, male circumcision, safe circumcision

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Introduction

Male circumcision – that is, partial or complete surgical removal of the foreskin (prepuce) of the penis – is a practice known since antiquity. Ancient Egyptian paintings testify to its long existence. The word 'circumcision' comes from the Latin *circumcidere* (meaning 'to cut around') [1]. Driven by religious, cultural, social, or health-related motives, male circumcision is commonly performed during adolescence or even during infancy. According to the WHO, global estimates suggest that 30% of the male population is circumcised, of whom almost two-third are Muslims [2]. It is a religious commandment in Islam, in which male circumcision is widely practiced [3]. Moreover, it is customary in some Oriental, Orthodox, and other Christian churches of Africa and a routine procedure among the Jews [1,3].

Circumcision is one of the most frequently performed elective surgical procedure on the male population in the USA [4]. The Middle East presently has the highest proportion of circumcised population [5].

Circumcision has been suggested as an effective method of maintaining penile hygiene from the time of the Egyptian Pharaohs. From the middle of the 19th century, circumcision has been performed for medical reasons.

Male circumcision is believed by many to be a defense against a wide range of bacterial and nonbacterial pathogens; however, the precise mechanism of this effect is yet to be defined [6].

Circumcised men are at significantly lower risk for HIV, syphilis, human papillomavirus, and chancroid [7].

Potential benefits of decreased incidence of urinary tract infection and carcinoma of penis has been acknowledged by the American Academy of Pediatrics [8].

Removal of the shaft skin and inner preputial epithelium enough to uncover the glans prevents phimosis and renders the development of paraphimosis impossible.

Throughout the centuries, many methods for performing circumcision have been described.

Besides classical surgical methods, three different circumcision clamps can be used in neonates: Gomco clamp, Plastibell, and Morgen clamps [9,10]. The Gomco clamp is one of the most commonly used instruments for neonatal circumcision in the USA [11]. The procedure with this clamp is bloodless and has proven safe with excellent cosmetic results and minimal postoperative complications [11]. This study was conducted to present our initial experience with circumcision using a Gomco clamp.

Objective

The aim of this study was to evaluate the impact and safety of neonatal circumcision under a uniform hospital policy using a Gomco clamp (C) (Allied Healthcare Products Inc., St Louis, Missouri, USA).

Study design

A prospective analysis of 300 consecutive cases of neonatal and infant circumcisions performed with a Gomco clamp at Al Omooma Private Hospital, Kuwait, during the period from March 2012 through March 2015, was carried out. Outcome measures for the study were as follows:

(a) The number and the type of complication in terms of procedure;
(b) The adequacy of circumcision; and
(c) The parents' satisfaction with the final appearance.

Patients and methods

The procedure started after informed consent was obtained from the parents and the infant was properly examined. Clotting time (CT) and bleeding time (BT) were routinely evaluated for all cases.

After the infant is restrained, the penis, scrotum, and groin area are cleaned with a disinfecting solution and are inspected for anatomic abnormalities. The Gomco clamp is checked to make sure the bell is the right size for the clamp and that there are no defects. A dorsal penile nerve block is administered (1 ml of 1% lignocaine with an insulin needle) at the 2 o'clock and 10 o'clock positions at the base of the penis.

The foreskin is grasped on either side with two hemostats, taking care to avoid the urethral meatus, and a third hemostat is carefully inserted into the preputial ring down to the level of the corona. The instrument should be used to tent the foreskin away from the glans to avoid the urethral meatus. The hemostat is swept around the glans on both the right and left sides, avoiding the ventral frenulum. This separates most of the adhesions between the inner mucosal layer and the glans.

The foreskin is then retracted proximally, exposing the glans. Any remaining adhesions are bluntly divided using a blunt probe or a gauze until the entire coronal sulcus is visible and completely cleared from smegma. The foreskin is then drawn over the glans, and the bell of the Gomco clamp is inserted over the glans. Two mosquito forceps are used to pull the foreskin through the hole of the base plate around the bell. The stem of the bell is then maneuvered through the hole along with the foreskin after the amount of foreskin to be removed has been determined. The amount of remaining shaft skin is evaluated and may be adjusted for length and symmetry.

The top plate of the Gomco clamp is then attached and brought around into the notch of the base plate. The arms of the bell are settled into the yoke, and the nut is tightened, crushing the foreskin between the bell and the base plate. It is kept for 7–10 min (according to BT and CT).

A scalpel is then used to excise the foreskin at the level of the base plate. The nut is then loosened, and the top plate and the base plate are removed from the bell.

The penis should be inspected following the procedure for signs of bleeding, with special attention to the ventral frenulum region. A dressing of antibiotic-soaked gauze should be gently applied over the Surgicel (Surgicel, Absorbable Hemostat, Johnson & Johnson Medical, Inc., USA). The baby should be checked for bleeding after 30 min before the baby is discharged. The parents should be counseled about the healing process.

Exclusion criteria

(1) Infants older than 4 months.
(2) Presence of hypospadias, epispadias, or any congenital anomalies of the urethra or penis.
(3) Short penile shaft.

(4) Abnormally prolonged CT or BT, or high bilirubin level.
(5) Ill or premature baby.

Results

Of the 300 babies (32) (10.6%) who suffered from intraoperative bleeding, 24 were controlled with silver nitrate stick (chemical hemostasis) or bipolar diathermy and eight cases (2.6%) required vicryl plus 5/0 stitches; all of them were older than 2 weeks.

Two cases (0.67%) returned on the same day of discharge with surface oozing; both cases were sutured with vicryl plus 5/0 stitches. The overall percentage of postoperative bleeding that needed sutures was 3.3% (10 cases).

All cases of significant bleeding needing stitches were older than 14 days (mean age, 38 days).

Four parents (1.3%) came during the follow-up period complaining of inadequate circumcision; only one of them needed a redo after 6-month follow-up. Three parents were unsatisfied with the cosmetic result (prolonged edema or crustation). Two cases (0.67%) suffered from frenulum ulcer, which was managed conservatively. Only three patients reported superficial infection, which was treated with local antibiotics (Table 1).

Discussion

In this study, there was an overall incidence of 14% (42 cases) for postoperative bleeding and only (10 cases) 3.3% needed suture, whereas 32 cases (10.6%) were treated conservatively either with chemical, electrocautery, or just compression, to stop oozing or minor bleeding. Only two cases (0.67%) needed to be taken to the operation theater again after discharge. All cases that needed suturing were older than 14 days.

Table 1 Postcircumsicion complications: types, number, and percentage

Complication	*n* (%)
Bleeding	42 (14)
Intraoperative (conservative)	32 (10.6)
Intraoperative (with suture)	8 (2.6)
Postoperative (after discharge)	2 (0.67)
Total number with considerable bleeding	10 (3.3)
Parents unsatisfied (too much/little skin removed)	4 (1.3)
Redo	1 (0.3)
Parents unsatisfied (cosmetic)	3 (1)
Frenulum ulcer	2 (0.67)
Infection	3 (1)

Amir *et al*. [12] reported an overall incidence of 1.9% for complications, with mild-to-moderate bleeding in 31.6% of cases, which settled with further compressive dressing. An overall 21% of complicated cases had superficial sepsis, whereas 10.5% had frenular ulcers that required topical antibiotics. An overall 16% of cases had inadequate circumcisions, whereas only one required a redo operation after 1-year follow-up. Parents were satisfied with the final cosmetic appearance in 99.7% of cases.

Bhat *et al*. [13] reported that 1% of cases required immediate suturing on table after the Gomco clamp was removed, 2.5% were shifted back from the recovery room to minor operation theater for suture repair, and 4% required reinforcement of primary dressing to control the minor ooze. There was no other complication. Cosmesis was satisfactory to both the surgeon as well as the parents.

Horowitz and Gershbein [14] reported that 30% of cases had postoperative bleeding requiring suture repair. All of them were more than 4 weeks of age in agreement with this study.

Although the literature provides a great deal of data on surgical outcome after circumcision, very little is known about parents' satisfaction following the procedure. Clinical experience suggests that the rate of parental dissatisfaction is higher than the rate of reported complication, but the actual rate has not been precisely measured [15].

Rate of parents' dissatisfaction was 1.3% in this study; this is in agreement with that reported in the study by Jennifer *et al*. [16], who reported an unsatisfactory rate of 1.5%.

Conclusion

Circumcision with a Gomco clamp is a safe and effective technique with reproducible results, provided care is taken in exact marking of the site on foreskin for excision and selecting a correct size of the clamp. Each hospital needs to develop its own policy, keeping in view the population for best cosmetic results from circumcision to avoid disappointments and redo operations.

Gomco clamp is a bloodless, sutureless, simple, and safe method of circumcision in the neonatal period and in early infancy. The use of a Gomco clamp for circumcision beyond early infancy (3 months of age) has substantial morbidity. It is cost-effective and can be performed under local anesthesia with excellent cosmetic results (Figs. 1 and 2).

Figure 1

Gomco clamp.

Figure 2

Parts of a Gomco clamp.

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Conflicts of interest
There are no conflicts of interest.

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Does needle-knife precut sphincterotomy and repeated cannulation correlate with post-ERCP pancreatitis in patients with bile duct stone disease?

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Background
Pancreatitis is the most common and serious complication that occurs after endoscopic retrograde cholangiopancreatography (ERCP), resulting in substantial morbidity and occasional mortality. Biliary cannulation is unsuccessful during 5–10% of ERCP procedures. Needle-knife sphincterotomy can improve the success of cannulation but is often used as a last resort.

Aim
The aim of this study was to assess the role of precutting and multiple cannulations in the occurrence of post-ERCP pancreatitis in patients with bile duct stone disease.

Patients and methods
This prospective randomized study was performed at the General Surgery Department of Sohag University Hospital between June 2012 and June 2014. It included 515 patients with bile duct stone disease who were subjected to ERCP. Pancreatitis rate was assessed in relation to the number of cannulation attempts (<10 and ≥10) and precutting.

Results
Cannulation was performed without precutting in 467 cases (90.7%) and with precutting in 48 cases (9.3%). Pancreatitis occurred in 9.21% of patients who had undergone biliary cannulation without precutting and in 18.75% of patients who had undergone biliary cannulation with precutting ($P = 0.006$). Pancreatitis rate was lower in patients with less than 10 attempts than in those with 10 or greater attempts at cannulation ($P < 0.0001$), either without ($P < 0.0001$) or with precutting ($P < 0.01$). Pancreatitis rate did not differ without and with precutting when less than 10 attempts at cannulation were performed, whereas it was lower when precut was performed before 10 attempts than when 10 or more attempts were made without precutting ($P = 0.02$).

Conclusion
Pancreatitis rate was lower when precut was performed with less than 10 attempts than when 10 or greater attempts were made without precutting. In experienced hands, precut biliary sphincterotomy does not seem to be an independent risk factor for post-ERCP pancreatitis in patients undergoing ERCP for bile duct stones.

Keywords:
endoscopic retrograde cholangiopancreatography, precut sphincterotomy, repeated cannulations

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Introduction

Endoscopic retrograde cholangiopancreatography (ERCP) is one of the most complex endoscopic procedures [1]. The reported incidence of ERCP-specific complications ranges from 5 to 15%, depending on the complexity of the procedure, the underlying diagnosis, and patient comorbidities [2,3]. Acute pancreatitis remains the most common and serious complication after ERCP, with reported incidence ranging from 1.3 to 15.1% in most prospective series, resulting in substantial morbidity and occasional mortality [2,4–9]. Post-ERCP pancreatitis (PEP) is defined as acute pancreatitis that has developed *de novo* following ERCP [8,10]. The mechanisms that lead to PEP are complex and not fully understood. Rather than having a single pathogenesis, PEP is believed to be multifactorial, involving a combination of chemical, hydrostatic, enzymatic, mechanical, microbiologic, and thermal factors [11].

Prospective studies have identified specific risk factors, either patient-related or procedure-related, associated with a higher incidence of PEP [8–12]. Repeated attempts at cannulating the papilla and 'needle-knife' precut sphincterotomy are recognized procedure-related risk factors and occur frequently because biliary

cannulation may fail in up to 15% of cases, even in experienced hands; they therefore have a substantial impact on PEP rate. Although multiple cannulations has been widely considered as an independent risk factor for postprocedure pancreatitis, there are still conflicting data on the risk related to needle-knife sphincterotomy. In a recent prospective Italian multicenter study conducted in high-volume and low-volume centers for ERCP procedures, the PEP rate was found significantly increased when 10 or more attempts at cannulation were made [13]. A cutoff of 10 attempts at cannulation for a significantly increased risk for PEP was also found in a previous study that proposed a four-point risk score for the number of cannulations [14].

Since precutting generally follows a number of failed cannulation attempts, it is hard to clarify whether precutting as such or repeated cannulation is the prime culprit in postprocedure pancreatitis. There are few studies comparing the risk for PEP after 'needle-knife' precut sphincterotomy or persistent attempts at biliary cannulation with the standard technique [15–18].

Aim of the work

The aim of this study was to assess the role of precutting and multiple attempts of cannulation of the papilla of Vater, adjusted for the number of attempts at cannulation (<10 and ≥10), in the occurrence of postprocedure pancreatitis, in a prospective evaluation of a consecutive series of patients who had undergone biliary cannulation and sphincterotomy for bile duct stones.

Patients and methods

This prospective study was performed on 515 patients referred to the Gastrointestinal Endoscopy Unit of Surgery Department of Sohag University Hospital, between June 2012 and June 2014.

The inclusion criteria were as follows:

(a) Presence of bile duct stone disease pre-endoscopically evidenced by clinical manifestations, elevated direct serum bilirubin, and abdominal imaging or the presence of bile duct stone disease demonstrated by cholangiography during ERCP, and
(b) Successful biliary cannulation and sphincterotomy.

Patients were excluded for any of the following reasons:

(a) Pregnancy;
(b) Contraindication to ERCP (coagulopathy, history of contrast dye anaphylaxis, severe cardiopulmonary disease, or recent myocardial infarction);
(c) Acute pancreatitis, cholangitis, or hyperamylasemia at the time of the procedure;
(d) Previous biliary sphincterotomy; or
(e) Need for urgent ERCP within 12 h.

Ethical committee approval and informed written consent were taken before conducting the study.

All patients were subjected to complete assessment including proper history, clinical examination, laboratory investigations (complete blood count, serum bilirubin, alanine transaminase, aspartate aminotransferase, alkaline phosphatase, serum albumin, prothrombin time, platelet count, urea and creatinine, blood sugar, and serum amylase), and imaging studies (ultrasound, computed tomography, MRI, or magnetic resonance cholangiopancreatography).

Endoscopic procedure

All ERCP procedures were performed by a high-volume endoscopist using the pentax lateral view endoscope ED-3440T and ED-3485T. Patients were placed in the prone position and sedated with midazolam and propofol in conjunction with a topical anesthetic applied to the posterior oropharynx under the supervision of an anesthesiologist. Deep biliary cannulation was achieved either by direct injection of the contrast agent or by advancing a hydrophilic guide wire, preloaded into the sphincterotome. The decision of whether and when to make the precut was made by the operator. The precut was performed using the freehand technique, starting ~5 mm above the papillary orifice, with a bottom-up cut (fistulotomy). In all cases, a low-osmolality nonionic radiological contrast medium (urografin 76%) was injected for ductal opacification.

All patients were admitted to the hospital at least for 24 h following the procedure to detect early complications. All patients were monitored at least for 6 h after the procedure to detect symptoms and signs of pancreatitis (e.g. abdominal pain, tachycardia, hypotension, fever, and vomiting). Measurement of serum amylase was carried out by sampling of blood at 4 h after ERCP. Abdominal ultrasonography was routinely performed for all patients suffering from pancreatic-like pain lasting at least 24 h. In cases of doubt of developing PEP, abdominal computed tomographic scan was performed. If complications arose, patients stayed in the hospital until they recovered.

Successful cannulation was defined as free and deep instrumentation of the biliary tree. A cannulation

attempt was defined as sustained contact between the cannulating device and the papilla for at least 5 s [19]. Pancreatitis was defined as a postprocedure, new-onset, or increased abdominal pain persisting for at least 24 h, with serum amylase at least three times the upper limit of normal [20]. Amylase values have been found to peak between 90 min and 4 h after ERCP [21]. The serum amylase level measured 4 h after the procedure is the most reliable predictor of PEP [22,23]. We therefore hypothesized and used the 4 h amylase level as the most accurate amylase value for predicting subsequent pancreatitis. Pancreatitis was classified as mild, moderate, or severe according to the criteria of the Atlanta International Symposium of 1992 [24].

Statistical analysis

Data were analyzed using the software package SPSS 15 (SPSS Inc., Chicago, Illinois, USA). Groups were compared using the Mann–Whitney *U*-test and the χ^2-test, as appropriate. Significance was accepted at the 5% level ($P < 0.05$).

Results

This prospective study included 515 patients with bile duct stone disease who fulfilled the inclusion criteria. Attempted biliary cannulation without precut was performed in 467 patients (90.68%). Among these cases, 432 cases (92.51%) required less than 10 attempts, whereas the remaining 35 cases (7.49%) required 10 or more cannulation attempts (Table 1).

'Needle-knife' precut sphincterotomy was required to reach the common bile duct (CBD) in the remaining 48 patients (9.32%). Precutting was associated with fewer than 10 attempts at cannulation in 31 cases (64.58%), and with 10 or more in the other 17 cases (35.42%) (Table 1).

Patients in both groups were matched for age, sex, CBD dilation, serum bilirubin, pancreatic duct opacification, and cannulation technique, with the exception of patients who had undergone precutting, in whom cannulation was attempted mainly with guide wire assistance.

Table 1 Technical details of the procedures

ERCP procedure	Biliary cannulation without precutting		Biliary cannulation with precutting	
Number of attempts	<10	≥10	<10	≥10
Number of procedures	432	35	31	17

Post-ERCP pancreatitis

The overall postprocedure pancreatitis rate was 10.1% (52/515 cases). Pancreatitis occurred in 43 patients (9.21%) in whom precutting was not performed and in nine patients (18.75%) in whom it was performed, independent of the cannulation technique. The incidence of PEP was significantly higher after precutting ($P = 0.006$).

In cases without precutting, the pancreatitis rate was significantly lower ($P < 0.0001$) when fewer than 10 attempts at cannulation were needed than when 10 or more were made. Similarly, after the precut procedure, the pancreatitis rate appeared significantly lower with fewer than 10 attempts than after 10 or more ($P < 0.01$) (Table 2).

Successful biliary cannulation needing 10 or more attempts was associated with four times greater risk for PEP, compared with fewer than 10 attempts. The risk for postprocedure pancreatitis was similar for cases in which the biliary ductal system was cannulated with or without precutting before 10 attempts had been made.

When 10 or more attempts were needed, with or without precutting, the pancreatitis rate was significantly higher. In these cases, precutting did not significantly affect the incidence ($P = 0.45$). However, precutting before 10 attempts at cannulation was significantly less risky compared with 10 or more attempts without precutting.

Discussion

An unsettled question about 'needle-knife' sphincterotomy is whether or not the reported procedure-related high risk for pancreatitis depends on the technique itself or merely reflects the fact that cannulation was difficult, with repeated attempts that may have caused papillary edema, and/or repeated contrast injection into the pancreatic ductal system [25–27].

Table 2 Pancreatitis rates in relation to the number of attempts at cannulation, with and without precutting

Cannulation technique	Cannulation attempts <10 [*n*/*N* (%)]	Cannulation attempts ≥10 [*n*/*N* (%)]	Total [*n*/*N* (%)]	*P* value
Biliary cannulation without precutting	33/432 (7.64)	10/35 (28.57)	43/467 (9.21)	<0.0001
Biliary cannulation with precutting	3/31 (9.68)	6/17 (35.29)	9/48 (18.75)	<0.01
Total	36/463 (7.77)	16/52 (30.77)	52/515 (10.1)	<0.0001

Two studies found that delaying the precut increased the risk for PEP [28,29], whereas four others did not [15,30–32]. Four studies showed that the complication rate of early precut did not exceed that of the standard technique in experienced hands [33–35]. Moreover, Ayoubi *et al.* [36] concluded that, in experienced hands, needle-knife precut sphincterotomy decreases the frequency of PEP.

A recent prospective study stated that the timing of the precut procedure did not influence the complication rate for ERCPs [17]. In contrast, Choudhary *et al.* [37] showed that early precut for CBD cannulation decreases the incidence of PEP.

A meta-analysis of six randomized, controlled trials showed that the precut reduced the risk for pancreatitis compared with conventional technique [38], whereas another recent one suggests that precut sphincterotomy and persistent attempts at cannulation are comparable in terms of overall complication rates. Early precut implementation does not increase PEP complications [39]. Fiocca *et al.* [40] suggested that, in cases of difficult papillary cannulation after five failed attempts, performing precut is safe and is associated with a high success rate of deep biliary cannulation with a low incidence of PEP.

Most of these studies were conducted in high-volume centers by experienced endoscopists and indicated that both precut sphincterotomy and repeated attempts give similar success and complication rates in cases of difficult biliary cannulation. In contrast, in prospective multicenter trials in tertiary referral centers and community-based practices with endoscopists of varying levels of expertise, the precut has been shown to be an independent risk factor for overall complications and pancreatitis, with adjusted odds ratios of 3.61 and 4.34 [4] and relative risk of 1.87 and 2.80, respectively [5].

Our study assessed the PEP rate in relation to a cutoff number of 10 attempts at cannulation and the timing of precutting in a large series of consecutive patients undergoing therapeutic ERCP for documented bile duct stone disease. Repeated attempts at papillary cannulation, independent of pancreatic duct cannulation, were confirmed as a significant risk factor for postprocedure pancreatitis; 10 or more attempts at cannulation increased the rate four-fold, from 7.77 to 30.77%.

Whether the biliary precut was performed before or after 10 attempts at cannulation also significantly changed the postprocedure pancreatitis rate in our study, from 9.68 up to 35.29% – a four-fold difference. The increase was similar to that between less than and more than 10 attempts at cannulation, without precutting (from 7.64 to 28.57%). Adding the precut to persistent cannulation attempts further increased the pancreatitis rate, from 28.57 to 35.29%, although the difference was not statistically significant. These data do not agree with three previous studies [15,17,29] that used the cannulation time instead of the number of attempts and found no difference between delayed precutting and persistence in cannulation.

A biliary precut performed before 10 attempts at cannulation did not significantly raise the pancreatitis risk in comparison with cases in which successful biliary cannulation was achieved with fewer than 10 attempts and without precutting. This confirms that the precut *per se* should not be considered an independent risk factor for postprocedure pancreatitis in experienced hands.

Conclusion

This prospective analysis on a large series of patients undergoing ERCP for bile duct stones showed that a 'needle-knife' precutting to access the biliary ductal system performed before 10 attempts have been made at cannulation did not increase the risk for postprocedure pancreatitis, compared with the standard cannulation technique, and it should be preferred rather than persisting at cannulation when up to nine cannulation attempts have already been made, because the risk for pancreatitis is significantly higher for either repeatedly trying for cannulation or adding a delayed precut.

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Conflicts of interest

There are no conflicts of interest.

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Oral propranolol versus cryotherapy in the management of cutaneous hemangioma in infants and children

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Objective
The aim of the study was to evaluate the efficacy, adverse effects, and success rate of oral propranolol versus liquid nitrogen oxide gas cryotherapy in the management of cutaneous hemangiomas in infants and children.

Patients and methods
A prospective study was conducted between March 2011 and May 2015 on 43 patients with cutaneous hemangioma treated either with oral propranolol (group A, 23 cases) or with liquid nitrogen (cryotherapy) (group B, 20 cases). The outcome of treatment was evaluated clinically and with serial photographs before starting treatment and monthly thereafter as regards the size and color of the lesion. Propranolol was given orally 2 mg/kg per day in two divided doses for 4–6 months. Cryotherapy settings were applied two to four times for a period of 2–6 months under inhalation anesthesia using sevoflurane.

Results
With propranolol, complete involution occurred in 78.2% of cases and good response in 17.3%. Regrowth of the lesion occurred after stopping propranolol in two cases; the parents of the children were instructed to continue the treatment for a further 3 months. With cryotherapy complete involution of the lesions occurred in 65% of cases. No recurrence was observed during the follow-up period. Hypopigmentation at the site of the treated area was evident in eight cases.

Conclusion
Oral propranolol could be considered a safe and effective treatment strategy for cutaneous hemangioma. Although inhalational anesthesia is needed for application of cryotherapy, it is a simple method for treatment of cutaneous hemangioma and has minimal side effects. However, a randomized controlled study on a large number of patients should be conducted.

Keywords:
cryotherapy, cutaneous hemangioma, liquid nitrogen oxide gas, propranolol

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Introduction

Infantile hemangiomas (IHs) are the most common benign tumors of infancy occurring in about 5–10% of newborns and infants, being more common in female children and in premature infants. Occasionally they present at birth and usually appear during the first weeks of life. They usually appear singly, except in 20% of cases, and are commonly located in the skin and subcutaneous tissues of the head and neck [1–3]. Although most of them grow rapidly during the first years of life with spontaneous involution, 10–20% require active intervention because of their aggressive growth, especially those involving the periorbital area, parotid region, airways, and anogenital area [4,5]. Hemangiomas may have great psychological impact on the parents of the affected children; they may feel panic, fear, sadness, guilt, personal shame, and a sense of loneliness [6].

Different treatment modalities have been adopted over the years. However, each of these modalities has its own side effects and sometimes potential serious complications [7–10].

Léauté-Labrèze *et al.* [8] were the first to report in 2008 that there is incidental regression of IH in children treated with propranolol for cardiopulmonary conditions. The relatively small number treated, the lack of long-term follow-up, the difference in behavior of IH, and the variable dose given in different studies make it difficult to assess the actual safety, efficacy, incidence, and cause of recurrence [11–14].

In the present work a comparative study for treatment of cutaneous hemangioma by oral propranolol or by liquid nitrogen (cryotherapy) was conducted to explore

the efficacy, adverse effects, regrowth rate, and feasibility of using either of these two lines for treatment.

Patients and methods

From March 2011 to May 2015 a prospective study was conducted at Assiut University Children's Hospital (a tertiary hospital that serves most of upper Egypt) on 50 cases having cutaneous hemangioma as defined by the international society for the study of vascular anomalies [15]. Children who received any previous form of treatment for their hemangioma or those with deep-seated hemangiomas, cardiac anomalies, heart failure, pulmonary hypertension, or bronchial asthma were excluded from the study. Four patients failed to attend during the follow-up period and three patients' parents refused to participate in this study. Forty-three patients, aged 3–36 months, were enrolled in this study with the following reasons for referral: cosmetic disfigurement in 31 cases, bleeding in seven cases, ulceration in three cases, and pain in two cases. These 43 cases were divided into two groups: group I (23 cases) was treated with propranolol (commercially available preparation inderal) (AstraZeneca plc, London, UK) given orally as a 10 mg tablet crushed and dissolved in 10 ml distilled water (1 mg/ml) starting with a dose of 1 mg/kg per day in two divided doses that was then increased after 1 week to 2 mg/kg per day in two divided doses; group II (20 cases) was treated with liquid nitrogen (cryotherapy) using a Brymill Cro-Ac (Ellington, CT 06029, USA) hand-held liquid nitrogen delivery system producing a temperature of −195.6°C (Fig. 1). Hemangiomas manifested in the 43 patients at 2–6 months of age, except in the case of eight children who were born with hemangiomas (five from group I and three from group II). Before start of either form of treatment a complete clinical and cardiac examination or preanesthetic fitness test was performed to detect any cardiac disease or unfit patients. Written informed consent was taken from the parents of the 43 patients about the line of treatment, and the study protocol was approved by the surgical ethical committee at Assiut University. Patients from both groups were admitted for 24 h after start of treatment and were monitored clinically for bradycardia, hypotension, and symptoms of hypoglycemia (i.e. lethargy, restlessness) or postcryotherapy complications. On discharge, parents of patients from group I were instructed to stop the drug if the child had a serious incidence of cough or dyspnea. Photographs of the hemangioma were taken before start of treatment and during the follow-up period. The clinical assessment during treatment included reduction in size, change in color, complications developed, and any relapse. The treatment period was either until complete involution had occurred or for 6 months at its maximum range for both groups, so as to have uniform results.

Figure 1

Brymill Cro-Ac hand held liquid nitrogen delivery system.

Cryotherapy technique

The procedure was performed in the operating theater without any premedication. Anesthesia was induced with 8% sevoflurane in 100% oxygen under standard monitoring, including ECG, noninvasive arterial pressure monitoring, and pulse oximetry, which were applied during induction and maintenance of anesthesia. After insertion of the intravenous line, children received 15 mg/kg paracetamol intravenously. End-tidal sevoflurane concentration was adjusted according to clinical signs (arterial pressure or heart rate within 20% of baseline). Spontaneous breathing was maintained throughout the procedure.

After disinfecting the target area and covering it with K-Y jelly to ensure better thermoconductivity, the target area was directly sprayed with liquid nitrogen for 20–30 s until an ice ball was formed over the lesion, followed by a thaw period of ~90 s. The freeze–thaw cycle could be repeated according to the size of the lesion. After completion of the procedure the child was sent to a postanesthetic care unit if there was no compromise in airway or hemodynamic instability perioperatively.

The final results of all patients in both groups were determined on the basis of four-point scale modified after Achauer *et al.* [16] based on improvement in volume, color, and texture after treatment. These parameters were rated using the following scales: poor (0 to 25% response rate), fair (26 to 50% response rate), good (51 to 75% response rate), and excellent (76 to 100% response rate).

Follow-up visits were scheduled every 2 weeks for the first month, and then monthly thereafter. During this period all comparative parameters were assessed, along with heart rate, blood pressure, and blood glucose level for patients from group I.

Statistical analysis

The data were analyzed using SPSS (version 16; SPSS Inc., Chicago, Illinois, USA). Descriptive statistics were calculated. Cross-tabulation using the χ^2-test for categorical data was presented in the form of frequency and percentage). The difference was considered significant if the *P* value was less than or equal to 0.05.

Results

The demographic and clinical data of all patients are summarized in Table 1. Nineteen cases from group I and 17 from group II had solitary lesions. There was no statistically significant difference between groups regarding the cause of referral, site, size, and type of the lesions (Table 1). The treatment period in group I ranged from 4 to 6 months. By the end of this period 18 cases had excellent response, four had good response, and one had fair response (Figs. 2–5). Nine cases developed bradycardia without any further clinical manifestations. Two cases (one from the good response group and one with fair response) developed regrowth of their lesion after stopping treatment and were instructed to continue the same dose for another 3 months. Thereafter, excellent response was obtained without further recurrence during the follow-up period.

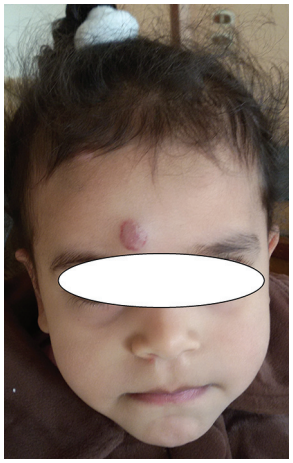
No complications were observed from using sevoflurane as inhalational anesthesia. The number of cryotherapy applications ranged from two to four times at 4–6-week intervals depending on the size and response of hemangioma. Hyperemia, edema, and swelling occurred immediately after cryotherapy in five cases, which improved within 1–2 weeks. Cryonecrosis and formation of dark, dry eschar occurred in four cases. Separation of the eschar commenced and was completed by the end of the first month after cryotherapy, leaving a healthy smooth mobile scar. The main complication due to the use of liquid nitrogen was the hypopigmentation at the site of the lesion in eight cases.

The cryotherapy period ranged from 2 to 6 months by the end of this period 13 cases had excellent response,

Table 1 The demographic data, site, size, and type of the lesion in the 43 patients

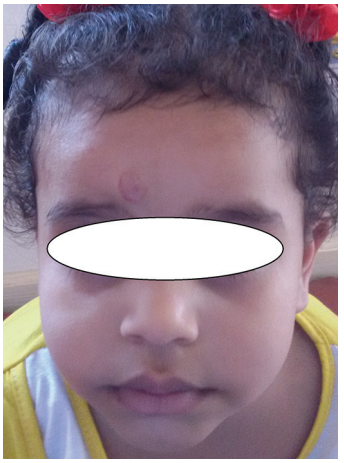
Items	Propranolol (group I) (*N* = 23 cases) [*n* (%)]	Cryotherapy (group II) (*N* = 20 cases) [*n* (%)]
Number of preterm infants	5 (21.7)	3 (15.0)
Age at start of treatment (months)		
<6	9 (39.1)	7 (35.0)
6–12	11 (47.8)	12 (60.0)
13–36	3 (13.1)	1 (5.0)
Sex (female : male)	17 (73.9) : 6 (26.1)	15 (75.0) : 5 (25.0)
Site of lesions		
Head and neck	12 (52.2)	10 (50.0)
Trunk and back	7 (30.4)	6 (30.0)
Limbs	4 (17.4)	3 (15.0)
Genitalia	0 (0.0)	1 (5.0)
Size of lesions (cm)		
<2	4 (17.4)	2 (10.0)
2–5	14 (60.9)	16 (80.0)
>5	5 (21.7)	2 (10.0)
Type of lesion		
Solitary	19 (82.6)	17 (85.0)
Multiple	4 (17.3)	3 (15.0)

Figure 2



Patient before starting propranolol therapy.

Figure 3



Same patient at the end of treatment.

five had good response, and two cases had fair response (Figs. 6 and 7). No cases developed regrowth after cryotherapy. There was no statistically significant difference between the two groups regarding response to treatment or regrowth after treatment (Table 2). The start of response to propranolol therapy was noted from 3 to 4 weeks when the hemangioma started to decrease in size and become softer. This response was noted from the first session in cryotherapy.

All patients were followed up for 1 year, and the main persistent postcryotherapy complication (hypopigmentation) resolved over 3–4 months.

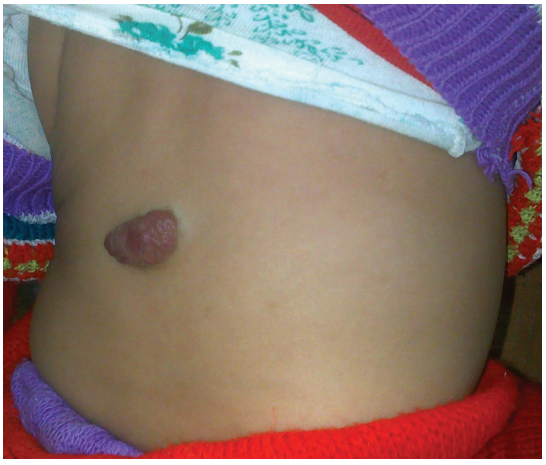
Table 2 Treatment response and regrowth of the lesion in the 43 patients

Item	Propranolol (group I) (*N* = 23 cases) [*n* (%)]	Cryotherapy (group II) (*N* = 20 cases) [*n* (%)]	*P* value
Response to treatment			
Excellent	18 (78.3)	13 (65.0)	0.531
Good	4 (17.4)	5 (25.0)	0.813
Fair	1 (4.3)	2 (10.0)	0.900
Poor	0 (0.0)	0 (0.0)	–
Regrowth of the lesion	2 (8.7)	0 (0.0)	0.532

Discussion

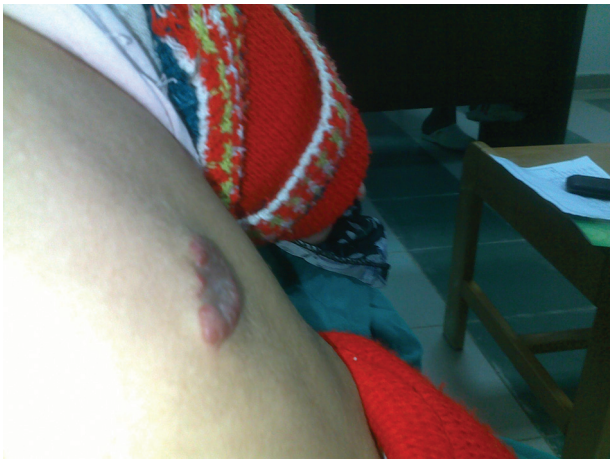
Propranolol is a nonselective beta-adrenergic antagonist that is well absorbed from the gastrointestinal tract and distributed throughout the body, with the highest level in the lungs, kidneys, brain, and heart. Oral propranolol, which markedly improved the medical treatment of Fallot tetralogy and hypertrophic obstructive cardiomyopathy in children, was also considered by many authors to be the first line of treatment for

Figure 4



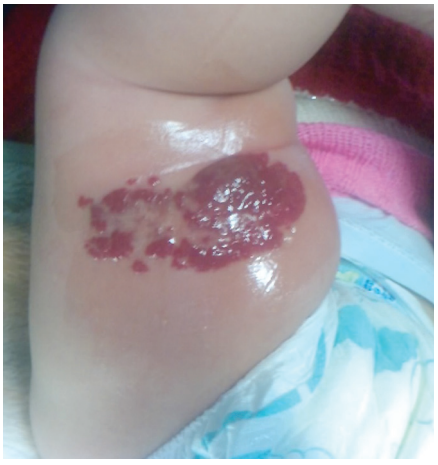
Patient before starting propranolol therapy.

Figure 5



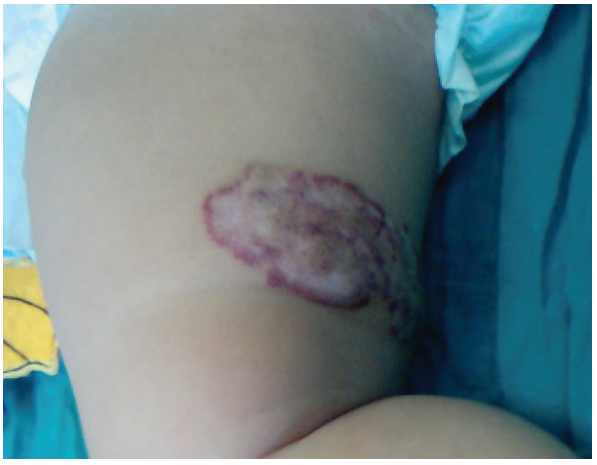
Same patient 2 months after starting treatment.

Figure 6



Male baby before starting cryotherapy.

Figure 7



Same patient at the end of cryotherapy.

IHs [5,17–19]. The mechanism of action of propranolol is not well understood. Potential explanations for the therapeutic effect of propranolol on hemangiomas include vasoconstriction, which is immediately visible as a change in color, associated with a palpable tissue softening. Other proposed mechanisms of action are a downregulation of angiogenetic factors such as vascular endothelial growth factor and basic fibroblast growth factor and an upregulation of apoptosis of capillary endothelial cells [5,8].

Hogeling *et al*. [20] reported that IH significantly dropped in volume, redness, and elevation with a 6-month course of propranolol. Bertrand *et al.* [21] reported good to excellent response to propranolol for the same duration. Hassan and Shreef [22] reported complete resolution after a treatment period of 6–14 months. In this study we had 78.2% excellent response after completing 6 months of treatment with propranolol.

Although a definite reduction or even disappearance of hemangioma is well documented with propranolol [5], some authors have observed that a relative number of these lesions recur after propranolol withdrawal without possible causes [23,24]. The reported recurrence rate after stopping propranolol therapy ranged from 6 to 19% in some studies [5,25]. Sans *et al.* [24] in their series reported 8% recurrence, all of which occurred before the age of 1 year. Hassan and Shreef [22] followed gradual withdrawal of propranolol therapy over 4 weeks and saw a 3.3% regrowth rate. In this study we did not follow the gradual tapering of the dose, and two out of 23 cases (8.6%) had regrowth of their lesion after cessation of propranolol treatment. Both cases were below 6 months of age at the start of treatment. This relatively high rate of regrowth could be related to sudden interruption of treatment and to continuation of the active proliferative phase of hemangioma in these cases. This finding is in agreement with the results obtained by other authors as well [5,26].

Although the safety and efficacy of propranolol as a treatment for hemangioma have been reported in a recent systematic literature review [27], other studies reported severe hypotension and hypoglycemia even when using propranolol in the recommended doses [28]. In this study we did not encounter any significant adverse effects from propranolol apart from bradycardia, which may be related to the adjusted dose given and the good monitoring especially at the beginning of treatment. This is in agreement with the results obtained by other authors [5].

Treatment by cold application has been in use since ancient Egyptian times (3500 BC), where they were using cold application in an attempt to treat various ailments [10]. Many researchers have described the use of cryosurgery in the treatment of lesions in the skin, anorectal region, and eyes, in autolaryngeal lesions, bone, and brain diseases [14,29]. Liquid nitrogen, the most popular and effective cryogen used today, became readily available only after 1945. Use of either closed probes or spraying proved to be the most effective because of its low temperature (–195.6˚C), easy availability from medical and commercial sources, low cost, and safety of use. Also it is not flammable and is inert chemically [30]. The results obtained in 1986 at Assiut University, Egypt [10], on the use of cryotherapy for treatment of cutaneous hemangioma stimulate us to compare its efficacy, adverse effects, advantages, and incidence of recurrence in comparison with oral propranolol.

The mechanism of cell death by cryo is through the formation of intracellular and extracellular ice crystals immediately after cryotherapy. The extracellular ice reduces extracellular water, increasing solute concentration and osmolality, which causes a fluid shift and disrupts the cell membranes. Further damage is produced during the thawing process when intracellular ice damages mitochondria and the endoplasmic reticulum decreases the cell survival. Large ice crystals are more damaging than small ones. Also slow thawing is associated with the recrystallization of ice and is more destructive than rapid thawing [31,32].

In this study 20 cases were treated by cryotherapy using liquid nitrogen. Excellent results with complete involution were obtained in 65%, good results in 25%, and fair results in 10%. These rates are comparable to those reported by other authors [31,33].

There was no regrowth of lesions in any case after cryotherapy during the follow-up period. All of the adverse effects were minor and comparable to those reported by others [31,33]. It was reported that melanocytes are more affected by cold than keratinocytes [10]. This may explain the hypopigmentation in the eight cases as a complication of cryotherapy, but all cases were self-limited and improved during the follow-up period.

Study limitation

The small sample size and lack of randomization of the treatment options are the main limitations of this study.

Conclusion

Oral propranolol is a safe and effective treatment modality for cutaneous hemangioma, provided the optimum dose at the start of treatment is established and proper monitoring of the patient is implemented. Although cryotherapy application needs general anesthesia, it has tolerable side effects, gives rapid response and could be considered a second effective line in the treatment of cutaneous hemangioma.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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Laparoscopic sleeve gastrectomy for morbid obesity: does the size of the bougie matter?

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Background
Laparoscopic sleeve gastrectomy (LSG) is a safe and effective surgical treatment modality for morbid obesity. Variations in surgical technique could affect the results. The optimal size of the bougie remains controversial. The aim of this study was to evaluate the first-year outcome of LSG using two different sizes of bougies.

Patients and methods
Between March 2011 and January 2014, 102 morbidly obese patients underwent LSG. These patients were divided into two groups: group 1 (50 patients) and group 2 (52 patients). In group 1, 32-Fr bougies (orogastric calibration tube) were used, and in group 2 40-Fr bougies were used. Patients completed at least 6 months of follow-up visits.

Results
The excess body weight loss percentage in group 1 was 53.6 ± 10.96% at 6 months and 69.4 ± 15.6% at 1 year postoperatively, whereas in group 2 it was 52.7 ± 11.27% at 6 months and 66.4 ± 13.4% at 1 year postoperatively, with no statistically significant difference between the two groups. There were neither intraoperative complications nor postoperative mortalities. The overall complication rate was 14.7% (15 patients) with no statistically significant difference between the two groups (14% in group 1 vs. 15.4% in group 2). The postoperative hospital stay was 2.3 days in group 1 versus 2.2 days in group 2. There was 58.8% complete resolution of diabetes mellitus, 60% resolution of hypertension, and 87.5% resolution of sleep apnea 6 months after sleeve gastrectomy with no statistically significant difference between the two groups.

Conclusion
LSG is a safe and effective treatment method for morbid obesity. Bougie size does not affect the short-term outcomes.

Keywords:
bariatric surgery, bougie, laparoscopy, morbid obesity, sleeve gastrectomy

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Introduction

The number of laparoscopic sleeve gastrectomies (LSGs) performed worldwide has increased markedly in the past few years and it has earned a place as a primary bariatric surgery. It was initially performed as the first of a two-step surgery, biliopancreatic diversion with a duodenal switch. However, it proved to be effective as a stand-alone procedure for both weight loss and comorbidity resolution [1–4]. LSG produces early satiety by reducing the ability of the residual stomach to distend and resulting in a reduced level of plasma ghrelin. Levels of ghrelin are decreased after the LSG procedure as the predominant part of the ghrelin-producing gastric fundus is resected out, resulting in less stimulation of hunger and greater appetite suppression [5].

The fact that this technique has been considered simple and easy has led to its adoption by a large number of surgeons. Compared with gastric bypass and biliopancreatic diversion, and given that the procedure is performed under laparoscopy; it may seem to involve less risk [6]. Among the advantages of this surgical method is the lack of digestive anastomosis, mesenteric defects that may cause internal hernias and foreign material such as gastric bands [7,8].

The resection of a part of the stomach is done along a calibrating orogastric tube or bougie with diameter from 32 to 60 Fr [9–11]. The success of this restrictive bariatric operation may be limited by dilatation of the remaining gastric tube at longer follow-up, thus diminishing the restrictive effect [12].

This study aimed to evaluate our results of LSG as a single treatment for morbid obesity and to assess the effect of the bougie size on the outcomes.

Patients and methods

This is a prospective randomized study using the closed envelop technique, and includes 102 patients with morbid obesity. These patients underwent LSG

from March 2011 to January 2014. These patients completed at least 1-year follow-up visits. Inclusion criteria were BMI greater than 40 kg/m^2 or BMI greater than 35 kg/m^2 with comorbidity in which surgically induced weight loss is expected to improve the disorder [diabetes mellitus (DM), hypertension (HTN), cardiorespiratory diseases, severe joint disease, …] and failure of a conservative treatment program (diet, exercise, behavior therapy, and drug therapy). Patients with major psychiatric dysfunction or substance abuse, severe inflammation of the esophagus or the stomach, severe organ dysfunction or sweet-eating disorders were excluded.

The patients were divided into two groups: group 1 (50 patients) and group 2. In group 1 32-Fr bougies (orogastric calibration tube) were used, and in group 2 40-Fr bougies were used.

Approval was taken from the Ain Shams ethical committee. The patients were informed in detail about the risk and benefits of the operation. Written consent was obtained from each patient. The patients had a thorough preoperative evaluation that included upper gastrointestinal (GI) endoscopy, ECG, chest radiography, abdominal ultrasonography, echocardiography, pulmonary functional tests, serum cortisol level, thyroid function tests, liver function tests, kidney function tests, complete blood count, prothrombin time, HbA1c level, and fasting blood sugar.

Patients with BMI of at least 50 kg/m^2 were given a low-calorie, high-protein diet for at least 2 weeks before surgery to make the liver pliable at the time of surgery, and this helps in retraction and exposure of the gastroesophageal junction, which is crucial for total fundal mobilization and excision.

Patients with comorbidities were considered cured if all medications for DM, HTN, or dyslipidemia were discontinued, and considered improved with discontinuation or decrease in the dose of one or more drugs but not all. Diabetic patients on insulin were considered improved if they were able to discontinue insulin.

Prophylactic dose of low-molecular-weight heparin was used 12 h preoperatively and then daily for 10 days.

The operative time, postoperative hospital stay, early and late postoperative complications, mortality, effect on comorbidities, and excess body weight loss percentage (EBWL%) were monitored in each group and were compared between the two groups.

Surgical technique

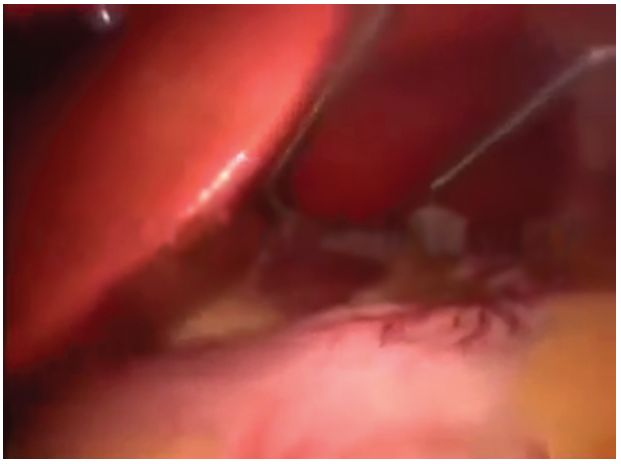
Under general endotracheal anesthesia, the patients were positioned in 30° anti-Trendelenburg position with legs abducted. The lower extremities were supported and secured with a belt and tape. Compression stockings were applied. A nasogastric tube was inserted in all cases.

The monitor was placed at the head end. The surgeon stood between the legs, the camera assistant on the right side, and the second assistant on the left side of the patient. Five trocars were used. An optical port (10 mm) was introduced one and half hand-breadths below the xiphoid just to the left of the midline. Mediflex Nathanson's Liver Retractor (Cook Medical Inc., Bloomington, Indiana, USA) was introduced just below xiphoid and to the left (Fig. 1). The retractor was fixed to the operating theater table. Two 5-mm ports were inserted, one at the left midclavicular line 2 cm below the costal margin and the other at the left anterior axillary line at the level of the optical port. A fifth 15-mm trocar was placed at the right midclavicular line 2 cm above the level of the optical port.

The division of the vascular supply of the gastric greater curvature was started 4 cm from the pylorus and proceeded upward until the angle of His and was performed with radiofrequency (Harmonic Scalpel; Ethicon Endo-Surgery, Cincinnati, Ohio, USA) or with LigaSure 5 mm blunt tip Vessel Sealing (Covidien, Boulder, Colorado, USA) devices (Fig. 2). The upper part of the fundus was mobilized completely from the left crus of the diaphragm (Fig. 3).

Before stapling, the anesthetist passed down a 32- or 40-Fr-sized bougie to guide the gastric division. Using laparoscopic EndoGIA linear staplers (Covidien) the stomach was divided parallel to the gastric calibration

Figure 1



Liver retractor.

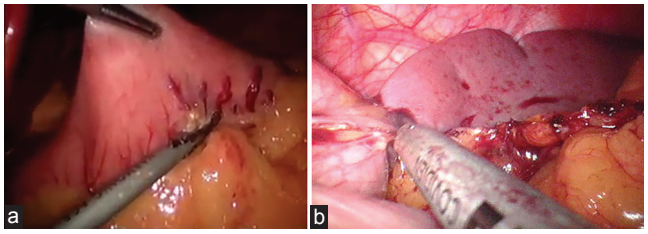
tube along the lesser curvature. The first cartridge was 6 cm long and green (4.8 mm) and the others were 6 cm long and blue (3.5 mm). Care was taken not to create a stricture at the level of the incisura angularis (Figs. 4–6).

The bougie was removed and a nasogastric tube was inserted. A methylene blue test was then carried out. The resected stomach was extracted through the right midclavicular port wound (Fig. 7). A tube drain was placed at the left subdiaphragmatic space under vision.

Postoperative care

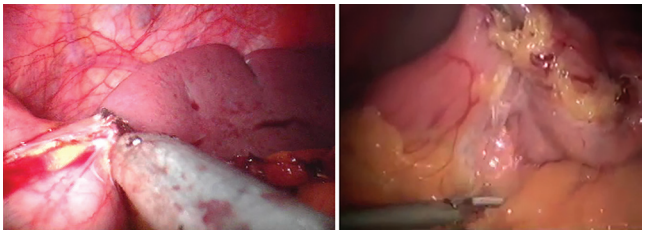
On the first postoperative day, the patients received a clear liquid diet. A gastrografin study was performed

Figure 2



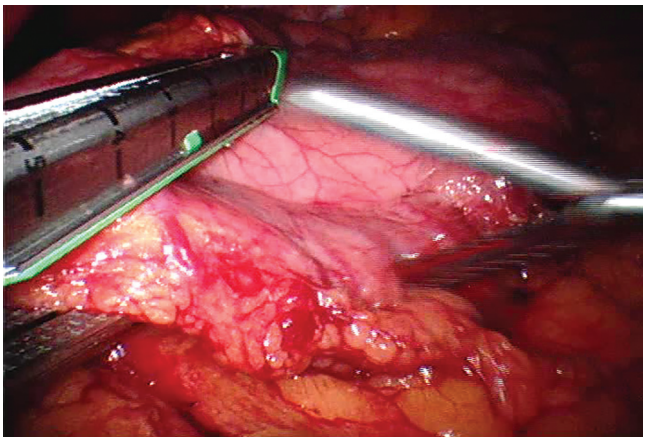
(a) Harmonic Scalpel (Ethicon Endo-Surgery); (b) LigaSure Vessel Sealing (Covidien).

Figure 3



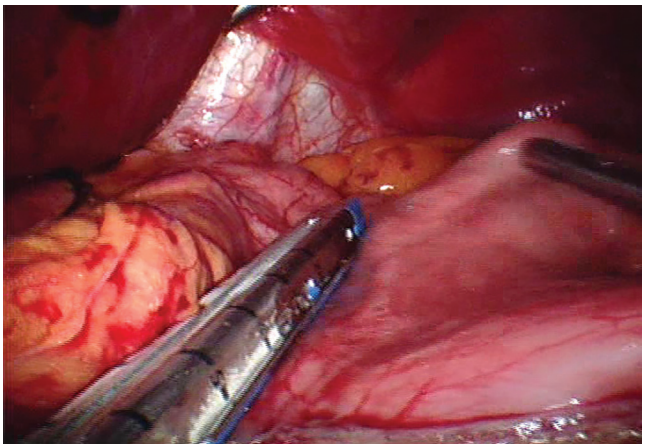
The upper part of the fundus was mobilized completely from the left crus of the diaphragm.

Figure 4



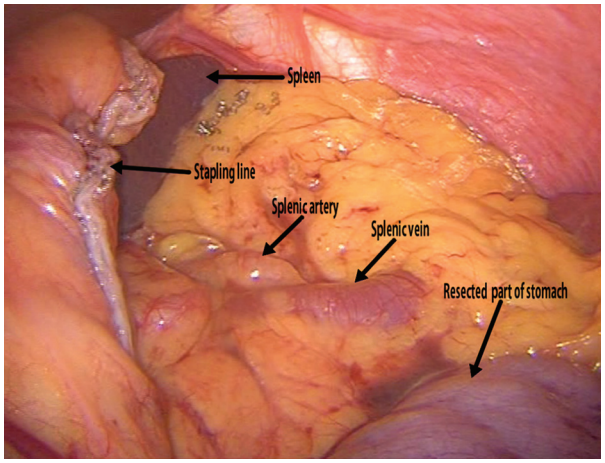
Six-cm-long green cartridge.

Figure 5



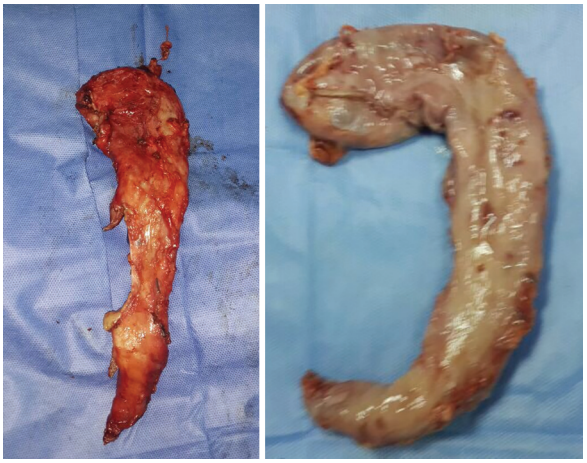
Six-cm-long blue cartridge.

Figure 6



Completion of laparoscopic sleeve gastrectomy (LSG).

Figure 7



Resected stomach.

only if there was suspicion of leakage. The drain was removed on the second postoperative day. The patients were discharged usually by the second postoperative day. The patients received a clear liquid diet for 10 days and then were progressed to a soft diet for 3 weeks.

The patients were seen by the surgeon on day 10 and at 1, 3, 6, 9, and 12 months postoperatively. Proton pump inhibitors were used in all patients for the first 2 months postoperatively. They were encouraged to have a high-protein diet. Vitamin and mineral supplements were prescribed for 1 year after LSG.

Statistical analysis

IBM SPSS software (Statistical Program for Social Science version 22) (2013; IBM Corp., Cairo, Egypt) was used for data analysis. Data were expressed as mean ± SD for quantitative parametric measures, in addition to both number and percentage for categorized data. The Student *t*-test was used to compare two independent mean groups for parametric data. The χ^2-test was used to study the association between two variables or to make a comparison between two independent groups as regards the categorized data. The results were significant (S) with *P* value less than 0.05 and highly significant (HS) with *P* value less than 0.01. *P* values greater than or equal to 0.05 were regarded nonsignificant (NS).

Results

A total of 102 patients [83 women (81.4%) and 19 men (18.6%)] underwent LSG between March 2011 and January 2014. All patients were followed up for 1 year. Patients had a mean age of 32 ± 9.5 years (range 20–59 years). The mean preoperative weight was 135.98 ± 18.5 kg (range 95–184 kg). The mean BMI was 48 ± 5.98 kg/m^2 (range 37.4–65.7 kg/m^2).

Preoperative evaluation showed that 15 patients (14.7%) had HTN, 17 patients (16.6%) had type 2 DM, eight patients (7.8%) had obstructive sleep apnea, and 20 patients (19.6%) had degenerative osteoarthritis.

The mean operative time was 91 ± 20.3 min (range 64–240 min). The mean postoperative hospital stay (2.3 days in group 1 vs. 2.2 days in group 2) was nearly similar between the two groups. None of our patients required conversion to open surgery (Table 1).

Gastroesophageal reflux disease was diagnosed preoperatively in two patients using upper GI endoscopy, esophageal manometry, barium meal in Trendelenburg position, and 24 h pH monitoring. Reduction of sliding hiatus hernia was done, followed by sleeve gastrectomy and crural repair. Postoperatively, symptoms of gastroesophageal reflux disappeared completely. Laparoscopic cholecystectomy was performed at the same session for four patients with asymptomatic gall bladder stones.

There were neither intraoperative complications nor postoperative mortalities. The overall complication rate was 14.7% (15 patients). There were four patients (3.9%) with major complications and 11 patients (10.7%) with minor complications. Table 2 shows complications after sleeve gastrectomy in this study.

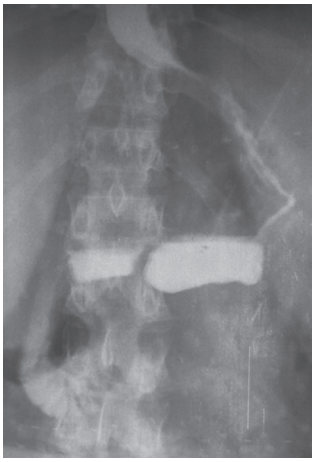
In group 1 (32-Fr bougie) one patient complained of abdominal pain and fever three days after operation. The patient was readmitted; a pelvic-abdominal computed tomography (CT) scan and gastrografin study (Fig. 8)

Table 1 Demographic data

Demographic data	Group 1 (*n* = 50)	Group 2 (*n* = 52)	*P* value
Age			
Mean ± SD	33 ± 10.3	31 ± 8.25	0.280
Range	22–59	20–58	
Sex [*n* (%)]			
Males	8 (16.0)	11 (21.2)	0.678
Females	42 (84.0)	41 (78.8)	
Mean preoperative weight (kg)	135.6 ± 18.4	136.3 ± 18.6	0.86 (NS)
Mean preoperative BMI (kg/m^2)	47.6 ± 6.1	48.4 ± 5.9	0.28 (NS)
Mean operative time (min)	89.5 ± 22.3	94.4 ± 19.5	0.239
Postoperative hospital stay (days)	2.3 ± 0.85	2.2 ± 0.83	0.549
Comorbidities [*n* (%)]			
HTN	9 (18.0)	6 (11.5)	0.521
DM	8 (16.0)	9 (17.3)	0.929
OSA	5 (10.0)	3 (5.8)	0.670

DM, diabetes mellitus; HTN, hypertension; OSA, obstructive sleep apnea.

Figure 8



Normal gastrografin study after sleeve gastrectomy.

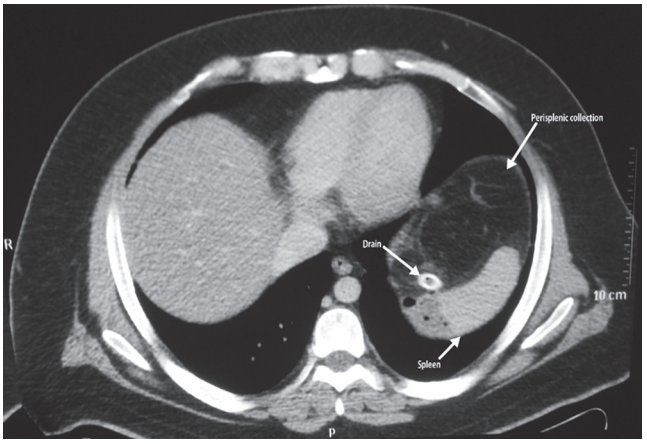
were carried out, which revealed no leakage but only mild left pleural effusion and perisplenic collection in which a CT-guided pigtail drain was placed. On reviewing the video of the operation no problems were seen except for spillage of gastric mucosa intra-abdominally during extraction of the resected stomach. Culture and sensitivity for purulent discharge from the drain was done. The patient received intravenous imipenem and amikin until the result of the culture and sensitivity was available and then she was continued on intravenous antibiotic as per the culture and sensitivity result. After 1 week of readmission, there was neither fever nor abdominal pain and the pelvic-abdominal CT scan was normal; the drain was removed and the patient was discharged.

One patient had postoperative bleeding. Bleeding started on the first postoperative morning as 500 ml blood was noticed in the drain. The patient was vitally stable. The patient received 2 U of blood and 2 U of fresh frozen plasma and managed conservatively.

In group 2 (40-Fr bougie), one patient had postoperative bleeding, which required blood transfusion and abdominal exploration on the first day postoperatively. There was bleeding from short gastric vessels, which was controlled, and the patient recovered smoothly. One patient had high-grade fever (39.2°C) and tachycardia on the third postoperative day. This patient was readmitted and a gastrografin study was conducted, which revealed the presence of gastric leakage. Laparoscopic exploration was performed on the fourth day postoperatively. There were no abnormalities except a small amount of perigastric purulent fluid. Methylene blue was injected into the stomach. There was no leakage of the dye. Aspiration of the purulent fluid was done and a drain was inserted. Gastrografin study was done 3 days after the exploration, which revealed no apparent leakage. The patient was discharged on a clear liquid diet. Two days later, there was continuous pus discharge from the drain. Pelvic-abdominal CT showed large perigastric and perisplenic collection with the tube drain inside (Fig. 9). A self-expandable fully covered metal stent (Mega esophageal stent; Taewoong Medical Co., Pennsylvania, USA) was introduced by upper GI endoscopy. Ten days after stent introduction, the collection resolved and the drain was removed. The stent was removed after 2 months by upper GI endoscopy.

There was port site infection in eight patients (7.8%); of them one patient (group 1) had persistent vomiting and upper abdominal pain that started 5 days after the operation, which improved after drainage of abscess at the site of the 15-mm trocar (at right midclavicular line) where the resected stomach was extracted. Three patients (2.9%) were readmitted after surgery because of persistent severe nausea, vomiting, and dehydration. The gastrografin study was normal. These patients resolved with inpatient medical treatment.

Figure 9



Pelvic-abdominal computed tomography (CT) scan showing large perisplenic collection with the tube drain inside.

Table 2 Complications after sleeve gastrectomy

Complications	Group 1 [*n* (%)]	Group 2 [*n* (%)]	*P* value	Significance
Postoperative bleeding	1 (2)	1 (1.9)	>0.05	NS
Leakage	0	1 (1.9)	>0.05	NS
Stricture (stenosis)	0	0	—	—
Abdominal abscess	1 (2)	0	>0.05	NS
Angioneurotic edema	0	0	—	—
Deep vein thrombosis	0	0	—	—
Pulmonary embolism	0	0	—	—
Postoperative GERD	0	0	—	—
Postoperative vomiting and dehydration	2 (4)	1 (1.9)	>0.05	NS
Port site wound infection	3 (6)	5 (9.6)	>0.05	NS
Total complications	7 (14)	8 (15.4)	>0.05	NS

The overall EBWL% was 53.2 ± 11.1% at 6 months and 67.95 ± 14.5 at 1 year postoperatively. The overall postoperative mean BMI decreased to 35.5 ± 4.5 kg/m^2 at 6 months and to 32.5 ± 5.1 kg/m^2 at 1 year postoperatively. The overall absolute weight loss was 35.6 ± 10.7 kg at 6 months and 46.4 ± 12.2 kg at 1 year postoperatively. Table 3 shows mean preoperative weight, EBWL%, mean preoperative BMI, and BMI and absolute weight loss at 6 months and 1 year after LSG in both groups.

Among 15 patients with preoperative HTN, in group 1 five of nine (55.5%) and in group 2 four of six (66.7%) patients showed complete resolution of HTN with complete discontinuation of medications by 6 months postoperatively. The mean blood pressure decreased from 131.2 mmHg preoperatively to

110.4 mmHg postoperatively. For patients with DM in group 1 four of eight (50.0%) and in group 2 six of nine (66.7%) patients showed complete cessation of medical treatment with normal fasting blood sugar and HbA1c. The mean preoperative fasting blood sugar and HbA1c were 130.3 mg/dl and 7.4%, which decreased to 87 mg/dl and 5.2%, respectively, postoperatively. There was 80.0 and 100% resolution of obstructive sleep apnea in groups 1 and 2, respectively (Table 4).

Discussion

LSG is increasingly being performed as a potentially stand-alone bariatric operation, performed with some ease laparoscopically. In 2009, the American Society for Metabolic and Bariatric Surgery issued an updated statement on sleeve gastrectomy, accepting LSG as an approved bariatric surgical procedure primarily because of its potential value as a first-stage operation for high-risk patients, with the full realization that successful long-term weight reduction in an individual patient after LSG would obviate the need for a second-stage procedure [13].

LSG may have some advantages compared with other established bariatric procedures. In contrast to laparoscopic adjustable gastric band (LAGB), no foreign material is implanted, avoiding complications such as band migration [14,15]. Compared with a Roux-en-Y gastric bypass or biliopancreatic diversion with duodenal switch, the complete upper GI tract remains accessible to endoscopy after LSG. Furthermore, LSG does not alter absorption of orally administered drugs, which may transpire after Roux-en-Y gastric bypass or biliopancreatic diversion with duodenal switch. After vertical band gastroplasty (VBG), a high rate of reoperation of 14–43% has been reported [16].

LSG is followed by less nutritional deficiencies over the long term compared with gastric bypass or malabsorptive operations. Nevertheless, multivitamin, mineral, and adequate protein supplements are necessary [17].

In a study comparing LSG with LAGB, superior EBWL% was found after 6 months (61 vs. 29%). It was theorized that the resection of the fundus after sleeve gastrectomy reduced a large area of ghrelin-producing stomach. Langer and colleagues found decreased levels of ghrelin in sleeve gastrectomy patients after 1 and 6 months and no change after LAGB. The removal of large hormonally active areas of the stomach may account for the superior results seen after sleeve gastrectomy [18].

Most surgeons use a calibration tube of anywhere between 32 and 60 Fr to measure the size of the retained stomach. There is also the issue of where one should put the stapler, snug with the calibration tube or a little away. Regardless of this, it has been reported that there is similar weight loss, at least early postsurgery, with calibration size between 32 and 44 Fr [9]. It is only when the size reaches 60 Fr that differences appear. Most surgeons report the use of a calibration tube of 30–40-Fr size [19]. Table 5 shows the relation of the size of the bougie and EBWL% in different studies.

In this study, the EBWL% for group 1 (32-Fr bougie) was 53.6 ± 10.96% at 6 months and 69.4 ± 15.6% at 1 year postoperatively. The EBWL% for group 2 (40-Fr bougie) was 52.7 ± 11.27% at 6 months and

Table 3 EBWL%, BMI and absolute weight loss at 6 months and 1 year after LSG

EBWL%, BMI and absolute weight loss	Group 1 (32-Fr bougie)	Group 2 (40-Fr bougie)	*P* value
Mean preoperative weight (kg)	135.6 ± 18.4	136.3 ± 18.6	0.86 (NS)
Mean preoperative BMI (kg/m^2)	47.6 ± 6.1	48.4 ± 5.9	0.28 (NS)
EBWL% at 6 months (%)	53.6 ± 10.96	52.7 ± 11.27	0.7 (NS)
EBWL% at 1 year (%)	69.4 ± 15.6	66.4 ± 13.4	0.45 (NS)
Mean BMI at 6 months (kg/m^2)	35.4 ± 4.4	35.7 ± 4.7	0.67 (NS)
Mean BMI at 1 year (kg/m^2)	32.1 ± 5.2	32.9 ± 4.99	0.56 (NS)
Absolute weight loss at 6 months (kg)	36.1 ± 11.1	35.2 ± 10.3	0.69 (NS)
Absolute weight loss at 1 year (kg)	46.1 ± 12.7	46.7 ± 11.8	0.86 (NS)

EBWL%, excess body weight loss percentage; LSH, laparoscopic sleeve gastrectomy.

Table 4 Resolution of comorbidities after sleeve gastrectomy

Comorbidities	Group 1		Group 2		*P* value	Significance
	Patients	Resolved (%)	Patients	Resolved (%)		
HTN	9	5 (55.5)	6	4 (66.7)	>0.05	NS
DM	8	4 (50.0)	9	6 (66.7)	>0.05	NS
OSA	5	4 (80.0)	3	3 (100.0)	>0.05	NS

DM, diabetes mellitus; HTN, hypertension; OSA, obstructive sleep apnea.

Table 5 Relation of the size of bougie and EBWL% in different studies

References	Size of bougie (Fr)	EBWL% at 6 months (%)	EBWL% at 1 year (%)
Lee *et al.* [20]	32	—	59 ± 17
Baltasar *et al.* [21]	32	56	71
Saul *et al.* [22]	34	47	54
Farías *et al.* [23]	36	107 ± 41	116 ± 38
Sammour *et al.* [24]	36	—	63
Chowbey *et al.* [25]	36	52.3	59.13
Nocca *et al.* [26]	36	48.97	59.45
Prasad *et al.* [27]	36	—	67.5 ± 13.0
Skrekas *et al.* [28]	36	53	67
Lee *et al.* [29]	38	56.7	—
Langer *et al.* [12]	48	46	56
Han *et al.* [30]	48	71.6 ± 21.9	83.3 ± 28.3
Roa *et al.* [31]	52	52.8	—

EBWL%, excess body weight loss percentage.

66.4 ± 13.4% at 1 year postoperatively. There was no statistically significant difference between the two groups as regards EBWL% at 6 months and 1 year postoperatively.

The published literature shows a general trend toward smaller diameters of calibration tubes, as evidence suggests that the volume of the resected stomach correlates with long-term weight loss and that dilation of the gastric sleeve may be a cause of weight regain. It is noteworthy that there are concerns regarding stricture formation when smaller diameter bougies are used to calibrate the sleeve segment. Strictures can contribute to gastric leak and fistula after LSG [9].

A recent systematic review and meta-analysis of 9991 patients who underwent LSG showed otherwise: using greater than 40-Fr calibration may decrease leakage without impacting excess weight loss percentage (EWL%) up to 36 months postoperatively compared with smaller bougies (<40 Fr) [32].

Kasalicky and colleagues reported that a 38-Fr bougie leaves the residual gastric sleeve volume of about 100 ml. Such a volume is sufficient to produce excellent weight loss results, and almost eliminates the possibility of narrowing the sleeve diameter too much. However, the diameter of the sleeve created by some authors on a 32-Fr bougie may actually result in the gastric sleeve diameter being narrower than the diameter of the esophagus. This fact could importantly contribute to gradual development of gastric cardia stenosis [33]. In contrast, the stomach sleeve created on a 40-Fr and larger bougie may lead to sleeve dilation within several years after the operation [9,33,34].

Jacobs and colleagues retrospectively reviewed the data on 247 patients who underwent LSG and they found that there is no significant difference between 46-, 40-, and 36-Fr bougies with respect to weight loss, BMI, or EWL%. Likewise, there is no difference between 7- and 4-cm antral pouches [35].

Spivak *et al.* [36] in their study suggested that using a 42- or 32-Fr bougie does not influence first-year weight loss on LSG or resolution of comorbid conditions. Also Cal *et al.* [37] comparing 27- versus 39-Fr calibration bougies found no significant effect on the size of the resected stomach, morbidity, or weight loss at 1 year after LSG, although a trend was seen toward better weight loss with the smaller bougie. Hawasli *et al.* [38] found that the smaller bougie resulted in a longer hospital stay, with a tendency toward increased nausea, more emergency department visits, and readmissions. Long-term weight loss was not affected.

Gumbs *et al.* [33] in their review of the relevant literature found that among the 646 patients having undergone LSG the mortality rate was 0.6%, with a variety of complications, including reoperation (in 4.5%), leak (in 0.9%), stricture (in 0.7%), bleeding (in 0.3%), pulmonary embolism (in 0.3%), delayed gastric emptying (in 0.3%), intra-abdominal abscess (in 0.1%), wound infection (in 0.1%), splenic injury (in 0.1%), and trocar site hernia (in 0.1%).

In a retrospective review and analysis of 185 consecutive LSGs that had completed at least 6 months of follow-up using a 34-Fr calibrating bougie, Chopra *et al.* [39] reported that mean EWL was 44.76, 55.52, 59.22, and 58.92% at 6, 12, 24, and 36 months, respectively. Perioperative complications occurred in 26 patients (14.05%): four staple-line leaks (2.16%), four bleeds (2.16%), four obstructions (2.16%), five cases of vomiting/dehydration (2.70%), six new onsets of gastro oesphagel reflux disease (GERD) symptoms (3.24%), two cases of pneumonia (1.08%), and one case of pulmonary embolism (0.54%).

In a series published by Han *et al.* [30] on the results of 130 patients who underwent LSG using 48 Fr, five patients had complications. Two patients had major complications: one leakage (0.7%) and one delayed bleeding (0.7%). There were two minor complications (1.5%): one patient developed atelectasis, and the other patient experienced nausea and vomiting for 21 days after surgery. One death occurred 3 weeks after surgery (0.7%); according to the autopsy, no leakage or strangulation was found, but primary peritonitis was diagnosed. One patient (0.7%) was converted to laparotomy due to short gastric artery bleeding.

Lee *et al.* [20] reported the results of 216 patients with an average BMI of 49 kg/m^2 who were undergoing

sleeve gastrectomy using a 32-Fr bougie. A perioperative complication rate of 6.3% was seen; leakage occurred in three patients (1.4%) and a reoperation rate of 2.8% was reported.

In this study, there were neither intraoperative complications nor postoperative mortalities. The overall complication rate was 14.7% (15 patients). There were four patients (3.9%) with major complications: two patients (1.96%) developed postoperative bleeding, one patient developed leakage, and one patient had perisplenic collection. Eleven patients (10.7%) had minor complications: eight patients (7.8%) had port site wound infection, and three patients (2.9%) had postoperative vomiting and dehydration.

There was no statistically significant difference between the two groups as regards the incidence of complications (14% in group 1 vs. 15.4% in group 2; $P > 0.05$) and postoperative hospital stay (2.3 days in group 1 vs. 2.2 days in group 2; $P > 0.05$).

Improvement in comorbidities of obesity, such as HTN and DM, has been reported to occur in the majority of patients, with resolution in 60–100% [1,21,40]. Hady *et al.* [41] demonstrated regression of diabetes at 1-year follow-up in 53.66% of patients who underwent LSG and improvement in 43.34% of patients, which confirmed the effectiveness of LSG in the treatment of diabetes in obese patients with metabolic syndrome. In another study, regression of type 2 diabetes after LSG was seen in 27% of patients 2 months after the surgery and in 63% of patients after 6 months [42].

This study shows 58.8% complete resolution of DM, 60% resolution of HTN, and 87.5% resolution of sleep apnea at 6 months postoperatively.

The report from the American College of Surgeons shows a resolution or improvement of 55% for patients with diabetes, 68% for patients with HTN, and 35% resolution for patients with hyperlipidemia after LSG [43,44].

Conclusion

LSG is a safe and effective operation for treatment of morbid obesity and obesity-related comorbidities with significant short-term weight loss and an acceptable complication rate. Bougie size does not affect short-term outcomes. We need to extend our study to determine the effect of the bougie size on the long-term outcomes.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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New approach for subfascial breast augmentation

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Context
Despite many years of experience, there is still an ongoing debate over the potential benefits of incision site, anatomical pocket, and the types of breast implant.
Aim
The aim of this study was to evaluate a new approach for subfascial breast augmentation as regards the site of incision and the plane of placement of the silicone implant.
Patients and methods
Twenty-five female patients suffering from bilateral breast atrophy underwent breast augmentation through an incision made in the pectoral fold along the anterior axillary line, with insertion of the implant in the subfascial plane, deep to the pectoral fascia.
Statistical analysis
Continuous variables were expressed as mean and SD. Categorical variables were expressed as frequencies and percentage.
Results
During the postoperative follow-up period, the breast projection was optimal in all patients with establishment of the superior mammary slope and the inferior pole of the breast, with good reconstruction of inframammary fold and adequate breast volume, and both breasts were symmetrical in all patients.
Conclusion
The subfascial insertion of breast implant through an incision along the anterior axillary line has a low complication rate compared with any other technique and leads to better cosmetic results and high patient satisfaction.

Keywords:
breast augmentation, breast implant, subfascial breast augmentation

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Introduction

Female breast is considered a crucial sign of femininity among women all over the world. Therefore, it is not surprising that women seek cosmetic changes in their breasts for reasons including feelings of inadequacy and lack of confidence in their femininity and desirability, which highlights the great psychological benefits of breast augmentation [1].

Most surgical techniques for breast augmentation are based on the implantation of a silicone implant in the subpectoral or subcutaneous pockets [2]. However, these techniques are not able to predict the final shape of the breast after the intervention, and their success relies entirely on the surgeon's skill [1].

Breast reconstruction aims to replace breast volume with restoration of breast symmetry, establishment of superior mammary slope and inferior pole of the breast, and reconstruction of inframammary fold [3].

In the last 50 years, breast implants have been widely used for breast reconstruction and augmentation [1]. Improvements in the implant design that were achieved over time have led to corresponding improvements in safety and esthetic outcomes of the surgery [1]. However, in a 25-year prospective population-based study [2], capsular contracture and malposition were reported as the first and third most common complications after breast implantation, respectively.

Despite many years of experience, there is still controversy over the potential benefits of the site of incision, the anatomical pocket, and the types of implant (e.g. textured surface, anatomical shape, and gel-fill type) [3–6]. The association between periareolar, axillary, or inframammary surgical incisions and the risk of capsular contracture and wound complications was not well documented in clinical trials [7,8]. However, some reports were published on the benefits of textured surface devices, which showed reduced risk for capsular contracture compared with smooth surface devices when they are placed in the subglandular pocket [9–11]. Nonetheless, it is still unclear whether

subpectoral placement of the implant gives the same results as subglandular placement [9–11].

Aim of the study

This article aims to evaluate a new technique for subfascial breast augmentation with respect to the site of incision and the placement of the silicone implant.

Patients and methods

This study was performed on 25 patients with ages ranging from 18 to 28 years (with a mean age of presentation of 23.3 years) suffering from bilateral breast atrophy. The trial was conducted from January 2014 to June 2015. All statistical procedures were carried out using SPSS version 15 for Windows (SPSS Inc., Chicago, Illinois, USA).

All patients presented with bilateral breast atrophy and normal hormonal profile. Patients with the following criteria were excluded from the study: failure of previous augmentation, presence of breast lump, previous breast surgery, having discharge per nipple, pregnant or lactating women, or refusal to undergo the procedure with its modifications.

Approval of the procedure was obtained from the ethical committee of the Faculty of Medicine at Ain Shams University. Informed written consent was obtained from all patients included in this study.

Preoperatively, all patients were assessed through a detailed history and full clinical examination. Routine preoperative investigations with full hormonal study (estrogen, progesterone, luteinizing hormone, and follicle-stimulating hormone) and radiological examination (breast sonomammography) were performed for all patients.

Before the start of the operation in the operative room, in a standing position, the patients were labeled with several marks on the lateral border of the sternum, anterior axillary crease, the inframammary fold, and the inferior margin of dissection. Round cohesive implant with volume ranging between 175 and 350 ml was used.

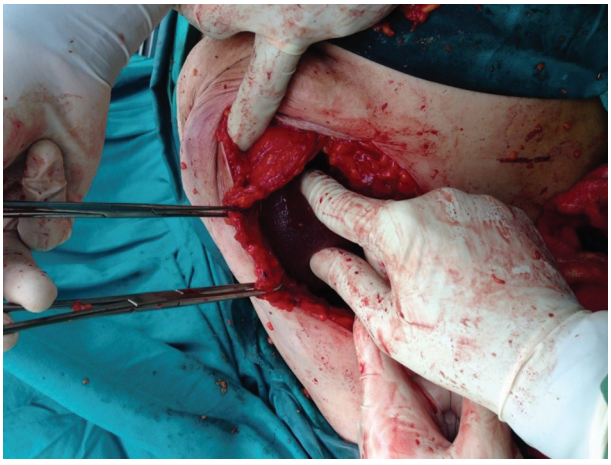
The operation was performed under general anesthesia. All patients were placed in the supine position with both arms fully abducted, and prophylactic antibiotics (100 ml metronidazole and 1.2 g amoxicillin and clavulanic acid) were given to all patients. Sterilization of the target area was performed with povidone iodine.

During the operation, the incision was made in the pectoral fold along the anterior axillary line, instead of inframammary, transaxillary, transverse, or circumareolar incision. Subsequently, the lateral border of the pectorals major muscle was approached by sharp dissection using diathermy (Fig. 1).

The pectoral fascia was identified and elevated from the muscle by means of both sharp and blunt dissection, creating an adequate space underneath the pectoral fascia that precisely fits the implant. Final shaping of the breast was achieved by repeated evaluation and adjustment of the place of the implant (Fig. 2).

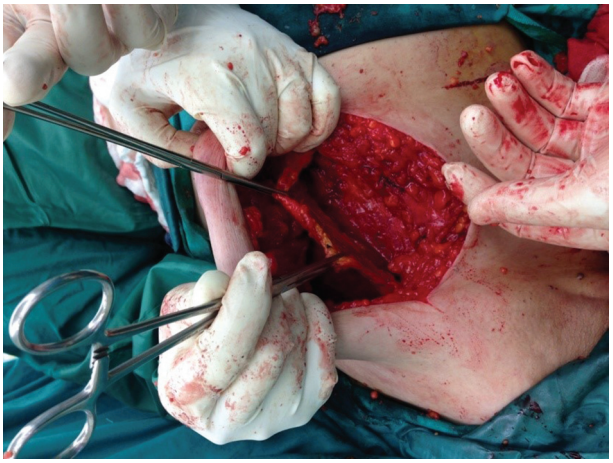
Proper homeostasis that was followed by insertion of vacuum suction drain in the subfascial space was performed before final insertion of the implant. Finally, closure of the lateral border of the pectoral fascia

Figure 1



Combined sharp and blunt dissection along the lateral border of the pectoralis muscle.

Figure 2



Subfascial plane after dissection.

and the subcutaneous tissue and skin was performed (Fig. 3).

At the end of operation, insertion of the implant in the subfascial space with hidden scar along the anterior axillary line was performed (Fig. 4).

Oral intake was only allowed after 3 h following surgery. Treatment was continued with antibiotics and flagyl for 10 days with frequent dressing. Suction drain was removed after delivering less than 20 ml serous fluid.

The follow-up period ranged between 2 and 4 months. Patients visited the outpatient clinic 1 week after surgery and once every month. Postoperative scar, ptosis or misplacement of the implant, skin complication, and overall patient satisfaction were recorded at every hospital visit.

Results

Twenty-five patients suffering from bilateral breast atrophy with a mean age of 23.3 years were enrolled in our study. The intraoperative time ranged from 30 to 75 min, with a mean operative time of 60.2 min. No intraoperative complications occurred and none of the patients needed blood transfusion (Table 1).

The postoperative hospital stay ranged from 1 to 2 days. Suction drain was removed after 7–13 days of surgery (mean time = 9.5 days) when it delivered less than 20 ml serous fluid. No seroma or hematomas were observed after removal of the drain. Stitches were removed after 10–12 days of surgery after complete healing of the wound (Fig. 5).

During the follow-up visits, no ptosis or misplacement of the implant was observed and no skin complications occurred. All wounds healed by primary intention with no early or delayed wound complications. As regards the breast shape, the breast projection was optimal in all patients with the establishment of superior mammary slope and inferior pole of the breast with good reconstruction for inframammary fold. Adequate breast volume and symmetry of both breasts were achieved in all patients. No mortality or morbidity related to the operation was recorded.

Discussion

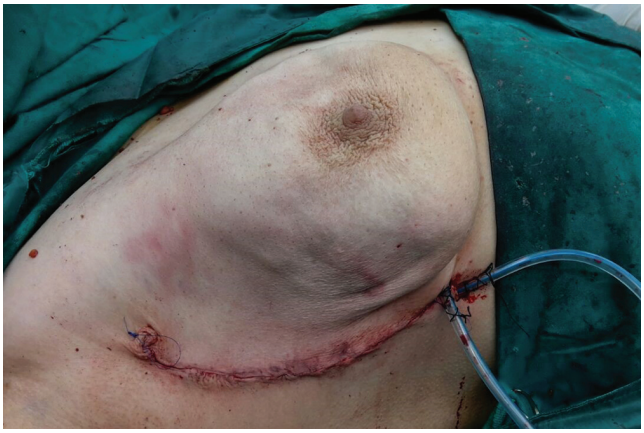
Despite the great advances achieved in surgical techniques and implant design, there is still debate over breast augmentation surgery with respect to the type and size of the implant and the pocket plane of its placement [12]. The anatomical site of the implant plays an important role in the final cosmetic shape of the breast and in the types of complications that may occur [13]. Most of the implants are placed either in the subglandular pocket or in the submuscular pocket, with each one of them having its own advantages and disadvantages. Subfascial insertion of the implant serves as a better alternative that combines the advantages of both position

Table 1 Age, operative time, duration of suction drain insertion, duration of stitches, and postoperative hospital stay

	Mean ± SD	Minimum	Maximum
Age	23.3 ± 4.6	18	28
Operative time (min)	60.2 ± 11.1	30	75
Duration of suction drain insertion (days)	9.5 ± 2.2	7	13
Duration of stitches (days)	10.7 ± 0.8	10	12
Postoperative stay (days)	1.2 ± 0.3	1	2

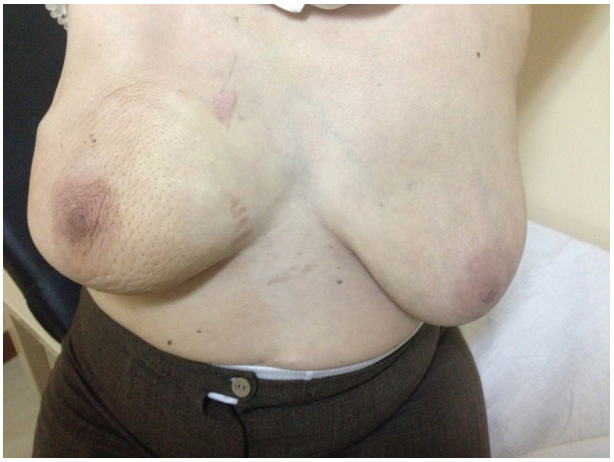
[a]Student's *t*-test.

Figure 3



Final shape of the breast after skin closure.

Figure 4



Shape of the breast after 2 months of the operation.

Figure 5

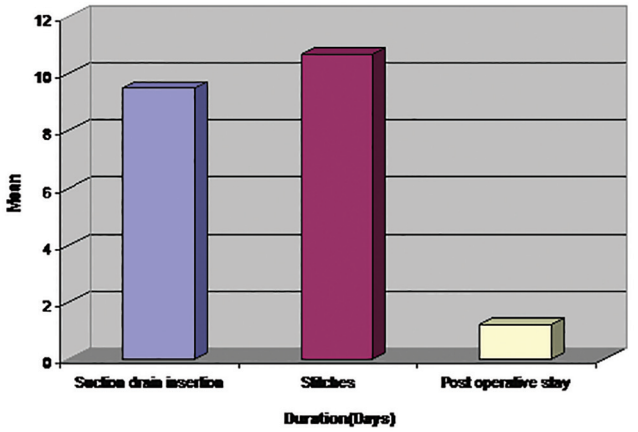


Illustration of postoperative data.

and achieving better cosmetic results with fewer complications [12].

In our study, breast implant was inserted in the subfascial plane (deep to the pectoral fascia only) through the anterior axillary line incision instead of the circumareola, inframammary, and transaxillary incisions. All wounds were healed by primary intention with no early or delayed wound complications. In addition, this incision achieved better cosmetically hidden scar.

In our opinion, the anterior axillary line incision provides a direct approach with maximum visualization of the implant pocket and independent plane of dissection. Moreover, the nipple areola complex was avoided and there was no need for dissection within the breast or axillary tissue. Therefore, this approach allows a more precise atraumatic dissection that minimizes the accumulation of fluid within the peri-implant space and reduces exposure to tissues colonized with bacteria (e.g. mammary glands).

In our experience, there was no seroma or hematoma observed after removal of the drain as previously shown in another study conducted by Ventura and Mrcello [14] in 2005. However, in their study there was dissection to the fascia covering the pectoralis major muscle, the serratus, the lateral oblique, and the rectus anterior muscles. In contrast, in our study the dissection of fascia was minimal and was limited to fit the size of the implant, which minimized the risk for seroma collection.

Another study conducted by Marco *et al.* [15] in 2012 showed that 38 women with small asymmetrical breasts were treated with adjustable implant on the smaller breast side and with fixed volume implant on the other side. The implant pocket was subglandular in 14 cases, subpectoral in 14 cases, and dual plane in 10 cases. They observed delayed wound healing in one case, hematoma in one case, and seroma in another case, which is considered a high rate of complications in comparison with our technique.

In our study, there was no capsular contracture, and breast projection was optimal in all our patients with the establishment of the superior mammary slope and the inferior pole of the breast with good reconstruction of inframammary fold. During the follow-up period, no ptosis or misplacement of the implant was observed. These results are in accordance with another study performed by Ahmed *et al.* [13] in 2011, who stated that, when fascia is dissected from the lateral side without involving its superior or inferior attachment, it provides strong supporting layer for the implant and thus prevents its displacement superiorly or inferiorly, keeping it in place. In addition, their average operating time was 75 min and two patients developed postoperative bleeding, whereas in our study the average operating time was only 60.2 min and there were no postoperative complications.

In another study performed [16], it showed that placing implants in a subpectoral position was associated with a lower risk of developing capsular contracture or moderate and severe malposition. However, they are less visible especially with muscle contraction, which results in less patient satisfaction in contrast to our approach. Therefore, subfascial approach has the advantage of subglandular approach with the benefits of subpectoral approach [13].

Conclusion

Subfascial insertion of breast implant through incision along the anterior axillary line is a new approach, which has a low complication rate compared with any other technique, leading to better cosmetic appearance with high patient satisfaction. However, this is a pilot study that needs more time and more patients for evaluating its preliminary results.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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Thyroglossal Cyst and Fistula: Surgical pitfalls and causes of recurrence

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Background: The thyroglossal duct cyst (TDC) results from a failure of complete obliteration of thyroglossal duct. It represents the most common type of developmental cyst seen in the neck region.
Objective: Evaluate our experience in the management of primary and recurrent thyroglossal cyst and fistula and to determine the role of pre- and postoperative infection as an important factor associated with thyroglossal duct recurrence after surgery.
Methods: During the period from January 2013- April 2014, in General and Pediatric Surgery Department, 50 patients with thyroglossal duct cyst (35 patients) and fistulae (15 patients) were diagnosed and treated. All records were reviewed for age and sex, diagnostic methods, surgical management and postoperative infection and recurrences.
Results: The recurrence rate was high in cases with infection occurred preoperative or postoperative.
Conclusion: Infection very important leading factor for recurrence of thyroglossal cyst.

Keywords:
Sistrunk operation, thyroglossal duct cyst, recurrent thyroglossal cyst and fistula

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Introduction

A thyroglossal cyst is the most common congenital anomaly in the neck [1]. The disease is frequently encountered in children and adolescents but may appear in adults as well [2]. It arises from a persistent patent unobliterated portion of the thyroglossal duct that descends from the foramen caecum of the tongue to the neck. It usually presents as a soft cystic midline neck swelling but may present with complications, the most significant being infection. Diagnosis is made mainly by clinical examination and ultrasound examination.

The treatment of thyroglossal cyst is carried out with the Sistrunk operation, which entails removal of the cyst, the track to the foramen caecum and the central portion of the hyoid bone [3]. The recurrence rate of the condition after Sistrunk operation is 5% and rises to 20% if the hyoid bone is not removed [4]. Management of infected thyroglossal duct cysts traditionally included only antibiotics if cellulitis is present, or treated with incision and drainage when an abscess forms [5].

Patients and methods

This was a prospective study of 50 patients with symptoms and signs of thyroglossal cysts and fistulas (Fig. 1), referred to the Department of General and Pediatric Surgery, Zagazig University, during the period between January 2013 and April 2014. All patients underwent Sistrunk operation. Thyroglossal duct cyst was found in 30 cases (60%) and thyroglossal fistula in 20 cases (40%).

Informed consent was obtained from the parents before enrollment in the study. An informed written consent in accordance with the hospital Ethical Committee was also obtained.

The patients in this study were seen, treated, and followed up by a team of general and pediatric surgeons.

Detailed history and medical records of all patients with a diagnosis of thyroglossal cyst disease treated at our department from January 2013 to April 2014 were reviewed.

Preoperative measures included a thorough medical checkup and fitness for general anesthesia, and all patients were investigated by means of routine preoperative investigation; neck ultrasound was the mainstay of imaging for all cases.

Inclusion criteria

The study included all cases with thyroglossal cyst and fistulae.

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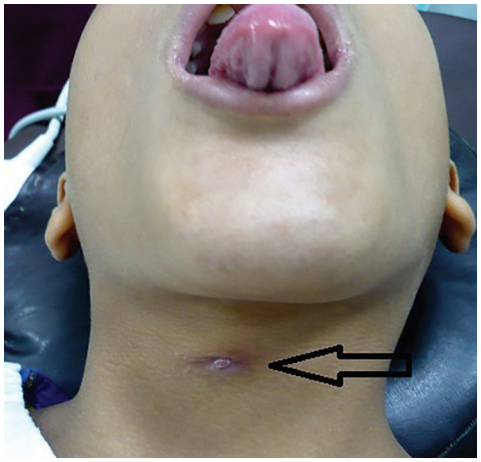
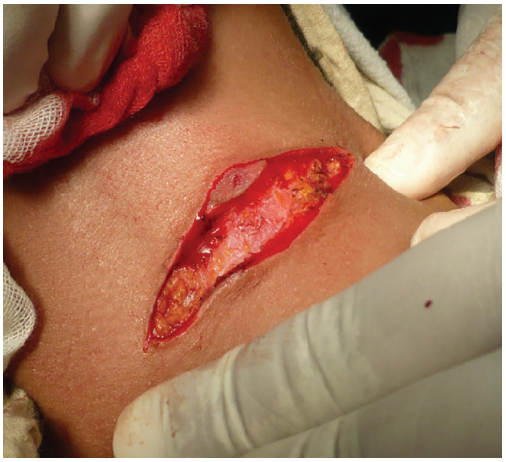
Figure 1



Thyroglossal cyst with fistula.

Figure 2



Transverse elliptical neck incision.

Exclusion criteria

Any case diagnosed intraoperatively with a diagnosis other than cyst or fistula was excluded, in addition to cases unfit for anesthesia. We excluded one case of midline cervical lymph node and one case of dermoid cyst.

Technique

All patients underwent general endotracheal intubation. The patients was made to lie supine with neck extension, and the neck was draped and prepped. Infiltration of the skin was carried out with lignocaine and adrenaline (1 : 200 000) and then the track of the fistula was delineated with methylene blue, followed by transverse elliptical skin incision in case of fistula (Fig. 2) or curved transverse incision in case of cyst. The subplatysmal space was reached and flaps were elevated (Fig. 3). The track was dissected with the removal of the central portion of the hyoid bone and V-shaped excision of the tongue was performed (Figs. 4 and 5). Proper hemostasis with a closure of the wound in layers was performed and the drain was inserted. The sutures were removed 1 week later and the patients were followed up from 6 months up to 1 year.

Parameters and data collection postoperatively

Standardized data collection was performed by the attending resident and our surgeon team, and each patient was evaluated by the main surgeon twice per day according to the hospital stay, and then the patients were followed up at the hospital outpatient clinic monthly for 6 to 12 months.

Follow-up data included patient age, sex, and clinical presentation, the presence of preoperative infection and postoperative infection, and recurrence.

Statistical analysis

Continuous variables were checked for normality using the Shapiro–Wilk test. Continuous variables were expressed as mean ± SD and median (range), and the categorical variables were expressed as number (percentage). Percentages of categorical variables were compared using the χ^2-test. All tests were two sided, with *P*-value less than 0.05 being considered statistically significant (S), *P*-value less than 0.01 considered highly statistically significant (HS), and *P*-value greater than 0.05 considered nonstatistically significant (NS). All data were analyzed using SPSS 22.0 for Windows (SPSS Inc., Chicago, Illinois, USA).

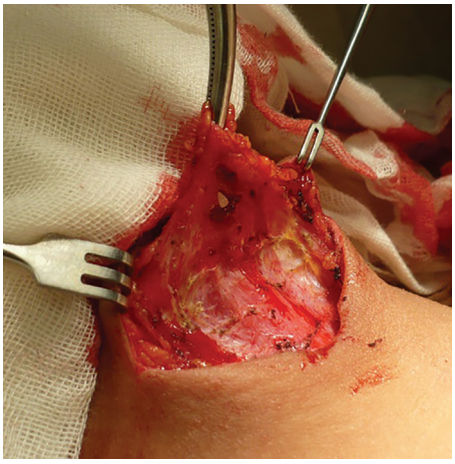
Results

One of the thyroglossal duct cysts was discovered histologically to be dermoid cyst and two cases were of prelaryngeal lymph nodes; the three cases were excluded from the study. A total of 35 patients had thyroglossal duct cyst preoperatively. The study group comprised 35 boys and 15 girls, with a sex ratio of 2.3 : 1. In the age group 3–7 years there were 25 patients (50%), in the age group 7–10 years there were 20 patients (40%), and the rest of patients were above 10 years of age, with a mean age of 8.1 years (Table 1).

The most common presenting complaints were a mass alone without infection (25 of 35 cases), mass with abscess or cellulitis (10 of 35 cases), and thyroglossal fistula without infection (15 of 50 cases). Most thyroglossal duct cysts were found in the classic midline infrahyoid position. However, four patients were noted to have their thyroglossal duct cysts in atypical locations: two were suprahyoid, one was infrahyoid and to the left, and one was infrahyoid and to the right (Table 2).

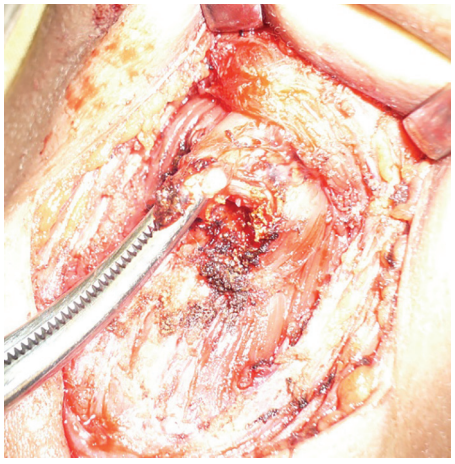
Data were analyzed in two ways. First, of the 35 patients who presented with thyroglossal duct cyst and underwent surgical intervention, there was no evidence of preoperative infection in 25 patients. In this group without preoperative infection, two patients had a recurrence of their disease, whereas 23 recovered uneventfully.

Figure 3



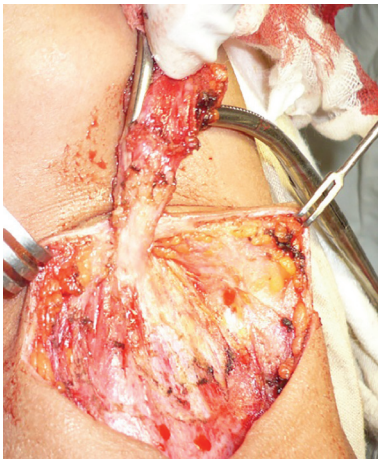
Subplatysmal dissection.

Figure 4



Excision of the central portion of the hyoid.

Figure 5



Removal of the central portion of the hyoid bone.

Of the 10 thyroglossal duct cyst patients who had a preoperative infection, three presented initially with an abscess and seven presented with cellulitis. In the three patients with preoperative abscess formation, drainage of the abscess was accomplished in patients (one incision and drainage and two spontaneously drained). In this group of preoperative abscess patients, two patients had recurrent disease. Of the seven patients who presented initially with cellulitis and underwent preoperative antibiotic therapy, two patients had recurrent disease.

There was a statistical difference with regard to recurrence between those patients who presented with infection (four of 10) and those who did not present with infection (two of 25) (Table 3).

The second way in which these data were analyzed was by comparing postoperative infection with the development of a recurrent disease. Postoperative infection developed in 10 patients of the 50 patients. In three patients, there was no evidence of recurrent disease, and only seven of these 50 (14%) patients had a postoperative recurrence, four of whom had a preoperative infection. Each of these seven patients with recurrent disease underwent reoperation with

Table 1 Demographic data

Demographic data	*n* (%)
Age (years)	
Mean ± SD	8.1 ± 2.2
Median (range)	8 (3–13)
3–7 years	25 (50)
>7–10 years	20 (40)
>10 years	5 (10)
Sex	
Male	35 (70)
Female	15 (30)

Table 2 Complaint and site of cyst or fistula

Complaint and site of cyst or fistula	*n* (%)
Complaint	
Thyroglossal duct cyst	35 (70)
Without infection	25 (50)
With infection	10 (20)
Thyroglossal fistula	15 (30)
Site of cyst or fistula	
Infrahyoid midline	46 (92)
Infrahyoid to right	1 (2)
Infrahyoid to left	1 (2)
Suprahyoid	2 (4)

wide excision of the area and re-excision of the hyoid bone (Table 4).

Discussion

Thyroglossal cyst disease is the most common developmental neck lesion in the pediatric group. There is a slight male predominance. These lesions usually present as a midline mass, but can present initially as a draining sinus or abscess [6,7]. Most thyroglossal duct cysts present during the first 5 years of life, although the lesion has been repeatedly described during adulthood [8]. Associated ectopic thyroid tissue was found in one case only in our specimen, but thyroid gland was in normal place. An author studied the recurrence rate after Sistrunk operation and reported a case with an intrathyroidal thyroglossal cyst [9].

In this study, preoperative infection was detected in 10 cases: seven cases were of cellulitis and three cases were of abscess, which was treated with incision and drainage. Another study [10] stated that only one patient in their study (5%) had a history of infection and the culture showed Homophiles influenza.

In this study, there were seven recurrent cases and most of them were due to postoperative infection. Infection may cause rupture of the cyst and implantation of the epithelium of the cyst into the surrounding tissue and is responsible for recurrence. Recurrence rate of thyroglossal cyst after complete excision using the Sistrunk procedure is reported to be 2.6–5%, whereas simple excision of the cyst can result in recurrence rates as high as 38–70%. Other authors [11,12] have reported a recurrence in two cases in a series of 62 patients. Ein *et al*. [13] reported a recurrence rate of 10% in a series of 270 patients, with most recurrences occurring when the middle third of the hyoid was left intact.

Authors [14,15] have reported a recurrence rate of 3.4% in their series of 29 patients who underwent the Sistrunk procedure. Recurrence rates ranging from 1 to 30% have been reported in a few other series [16,17]. The most common cause of recurrence is rupture of the cyst intraoperatively or leaving a part of the wall behind.

Histological analysis of the specimens showed that there were three cases misdiagnosed preoperatively as thyroglossal cyst, but histopathological examination postoperatively showed two cases of lymph nodes and one case of dermoid cyst. Athow *et al*. [18] stated that dermoid cysts, second in incidence to thyroglossal duct cyst, are reported to sometimes occur simultaneously with thyroglossal duct cyst.

Table 3 Preoperative infection and recurrence

Preoperative infection and recurrence	*n* (%)
Preoperative infection	10 (20)
Abscess	3 (6)
Cellulitis	7 (14)
Recurrence	6 (12)
Presence of preoperative infection	4 (8)
Absence of preoperative infection	2 (4)
Test[a]	5.149
P-value	0.023

[a]The value is calculated using the χ^2-test; $P < 0.05$, significant.

Table 4 Postoperative infection and recurrence

Postoperative infection and recurrence	*n* (%)
Postoperative infection	10 (20)
Recurrence	7 (14)
Presence of preoperative infection	4 (8)
Absence of preoperative infection	3 (6)

Conclusion

To prevent recurrence of thyroglossal cyst and fistula, complete excision of the track and central portion of the hyoid bone should be performed.

Infection is a very important factor preoperatively and postoperatively that increases the risk of recurrence of thyroglossal fistula.

Postoperative infection is associated with a higher rate of recurrence compared with preoperative infection.

Recommendation

Sistrunk operation is performed as an ideal surgery for the treatment of thyroglossal cyst and fistula.

Every effort is taken to prevent postoperative infection as it is the important factor causing recurrence of the disease.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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Laparoscopic common bile duct exploration for choledocholithiasis: Theodor Bilharz Research Institute preliminary experience

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Background
Laparoscopic common bile duct stones exploration (LCBDE) is a potential option for the management of stones within the biliary tree at the same time as laparoscopic cholecystectomy.
Materials and methods
All data on LCBDE were prospectively collected from April 2014 to June 2015; 36 consecutive patients diagnosed with cholelithiasis and common bile duct stones were enrolled in this study. There were 10 men and 26 women, median age 57 years (range 43–71 years). Our inclusion criteria were as follows: patients with obstructive jaundice because of stones, patients who had not undergone upper abdominal surgery, surgically fit patients with concomitant gallstones and common bile duct (CBD) stones (de-novo cases), patients in whom endoscopic retrograde cholangiopancreatectomy retrieval had failed previously mainly because of instrumentation failure; large or multiple CBD stones requiring extraction and drainage with remaining stent; LCBDE that could be approached either through the cystic duct or directly through a choledochotomy incision.
Results
All patients survived the operation. Successful LCBDE and stone clearance were achieved in 34 of 36 patients, whereas treatment failure occurred in the other two patients. The reasons for failure were due to instruments issues e.g. balloon rupture and broken basket. No incidences of bile leakage, hemobilia, abdominal bleeding, or pancreatitis occurred in the patients in our series. Transient colic pain occurred in two patients and was treated conservatively. A transient increase in the liver function tests (aspartate aminotransferase and alanine aminotransferase) was observed in three patients and returned to normal on postoperative day 3 without any treatment. The external drainage tube was removed 48 h postoperatively.
Conclusion
LCBDE can be performed after proper training and with the availability of adequate equipment and laparoscopic facilities. LCBDE is a safe and cost-effective treatment option for gall bladder and CBD stones in the short term.

Keywords:
choledochotomy, common bile duct, exploration, laparoscopic, transcystic

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Introduction

CBD stones are encountered in about 9–16% of cases during laparoscopic cholecystectomy. It has been reported that endoscopic sphincterotomy may cause recurrent ductal stones, stenosis of the papilla with cholangitis, and late development of bile duct cancer, which is a cause of concern especially in younger patients. Laparoscopic common bile duct stones exploration (LCBDE) is a potential option for the management of stones within the biliary tree at the same time as laparoscopic cholecystectomy [1–4].

Materials and methods

(1) All data on LCBDE were collected prospectively from April 2014 to June 2015; 36 consecutive patients diagnosed with cholelithiasis and CBD stones were enrolled in this study.
(2) There were 10 men and 26 women, median age 57 years (range 43–71 years).
(3) The diagnosis of CBD stones was made by ultrasonography and/or magnetic resonance cholangiopancreatectomy.
(4) The inclusion criteria were as follows:
    (a) stones gall bladder (multiple or single), CBD measuring greater than 6 mm, no intrahepatic duct stones, number of stones (single up to three), with or without jaundice, and

those who had failed endoscopic retrograde cholangiopancreatectomy (ERCP) stone extraction with or without stent.

(5) All the patients had been fully informed about the study, the characteristics of the procedure, and its advantages over conventional choledochotomy exploration and their consent was obtained.
   (a) This study was approved by the local IRP.
   (b) Before induction of general anesthesia, the patient received prophylactic antibiotics and low molecular weight heparin (LMWH).
   (c) The procedure was performed with the patient in the supine position and the operating bed was positioned such that a fluoroscopic C-arm could be positioned for imaging in the patient's right upper quadrant.
   (d) The procedure was carried out using a four-trocar laparoscopic cholecystectomy technique. After dissection of the Calot's triangle, the cystic artery and cystic duct came into view. Once the cystic artery was transected, the cystic duct was left intact, connecting to the CBD.

Cholangiogram and common bile duct exploration

We used two different approaches to perform LCBDE: the transcystic duct or a choledochotomy approach (Fig. 1).

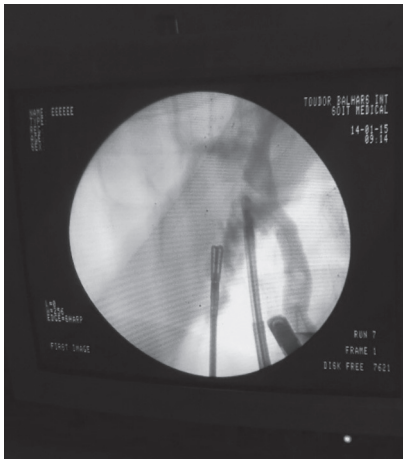
Transcystic approach (seven patients)

(1) A clear cystic duct identification with its junction to the CBD was the main and first objective.
(2) Then, the CBD was flushed with 30 ml of saline through the catheter. Small stones may be flushed and fluoroscopic-guided basket retrieval can be performed or a 4-Fr Fogarty balloon can be inserted through the cystic duct in an attempt to first dilate it after inflation and then withdraw to pull stones into the intra-abdominal cavity for retrieval.
(3) Clear Cystic duct identification with its junction to the CBD was the main and first objective.
Then common bile duct was flushed with 30 cc of saline via the catheter. Small stones may be flushed and fluoroscopic-guided basket retrieval can be performed, or a 4 French Fogarty balloon can be inserted through the cystic duct trying first to dilate it after inflation, and then withdrawn to pull stones into the intra-abdominal cavity to be retrieved (Fig. 2).

Choledochotomy approach (29 patients)

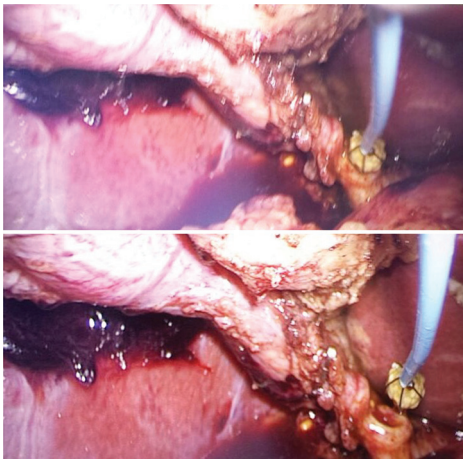
(1) Alternatively, this method was performed through a choledochotomy.
(2) The CBD was exposed and a vertical ductotomy was performed on the anterior surface of the duct distal to the cystic–CBD junction.
(3) The techniques for stone clearance are identical to the transcystic approach, that is, Fogarty balloon dilatation and then withdrawal of stones into the intra-abdominal cavity for retrieval.
(4) Through the choledochoscope, pressurized saline through a side working port of the scope facilitates clearance of small stones and particulate matter and to ensure that all stones were removed.
(5) The choledochotomy was managed with a T-tube in 20 of 29 cases and primary closure in other cases, where it was sutured in place with absorbable suture, primary closure over a stent (for later removal by ERCP) in five of 29 cases, and primary closure alone in the remaining four of 29 cases.
(6) External tube drains were used only when we used the choledochotomy technique and not in the transcystic technique (Figs. 3 and 4).

Figure 1



Intraoperative cholangiogram.

Figure 2



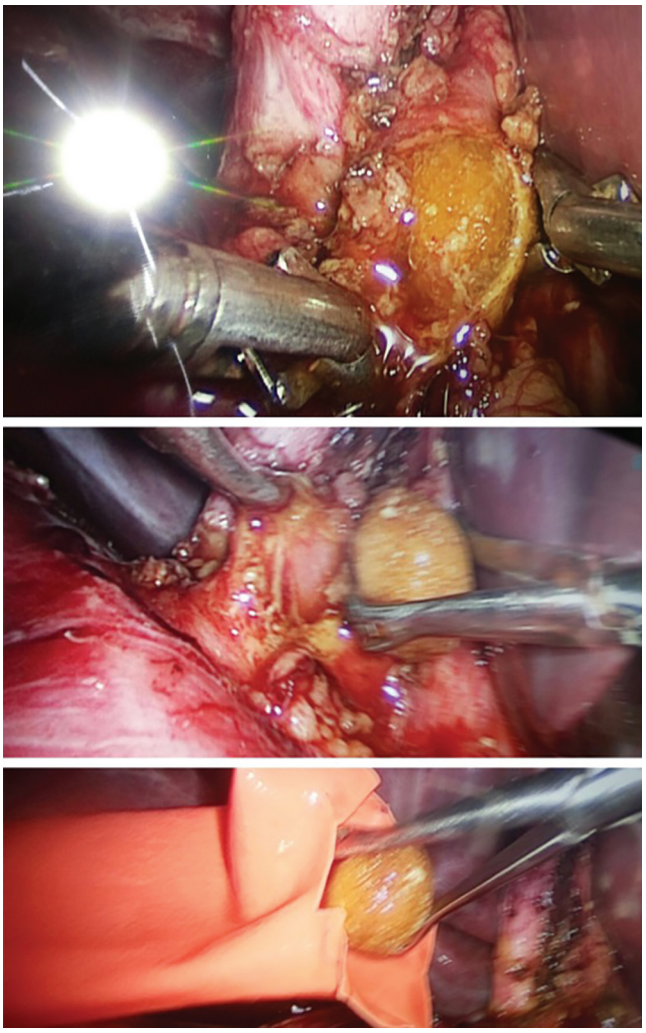
Transcystic stone extraction by the Dormia basket.

Results

(1) All patients survived the operation. Successful LCBDE and stone clearance was achieved in 34 of 36 patients, whereas treatment failure occurred in the other two patients because of instrument failure – balloon ruptured and basket broken.
(2) The duration of the operation in the 34 of 36 patients with successful laparoscopic CBD stone clearance was 126 min (range 102–140 min), and was similar in both transcystic and choledochotomy techniques.
(3) Open CBD exploration was performed successfully in the two of 36 patients in whom failure occurred in the same session.
(4) No bile leakage, hemobilia, abdominal bleeding, or pancreatitis occurred in our series. Transient colic pain occurred in two patients and was treated conservatively. A transient increase in the liver function tests (aspartate aminotransferase and alanine aminotransferase) was observed in three patients and returned to normal on postoperative day 3 without any treatment. The external drainage tube was removed 48 h postoperatively.
(5) Finally, when the transcystic approach was used, the patients were discharged home on day 3–4 postoperatively once we completely ensured that the operation was successful and no complications had occurred.
(6) In the choledochotomy approach, the T-tube was left in place for 7–10 days; a cholangiogram was performed through the T-tube first to ensure adequate clearance of the ductal system.

Short-term follow-up (median 5 months; range 1–11 months) showed no recurrence of CBD stones by clinical, laboratory, and imaging studies.

Figure 3



Choledochotomy technique and extraction of a large common bile duct (CBD) stone.

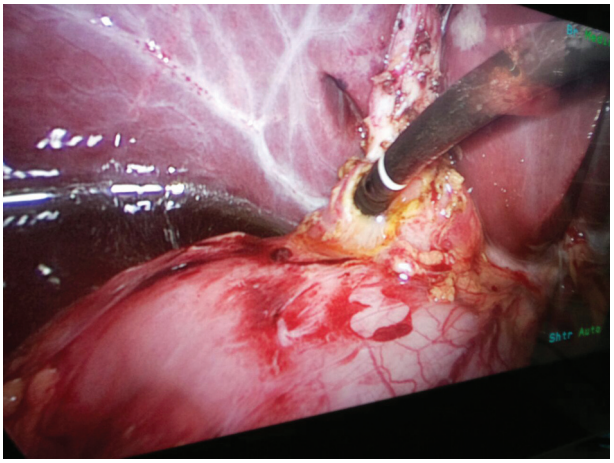
Discussion

The introduction of LCBDE has made it possible to avoid the drawbacks of both a two-stage procedure (preoperative ERCP+laparoscopic cholecystectomy) and the open CBD exploration [5–8].

In this study, we present our preliminary experiences at the Theodore Bilharz Research Institute (TBRI), with a success rate of 92.5% (34/36), which are comparable with the results of ERCP and open CBD exploration with less morbidity and mortality; it is hoped that the success rate will increase with increasing experience.

The transcystic approach is technically easer, but it has its limitations and indications, for example, dilated cystic duct, small stones (preferably single stone), and there should be no stent in the CBD [9–12]. In TBRI, as a tertiary center, we rarely encounter such cases.

Figure 4



Intraoperative transcystic choledocoscope.

The choledochotomy approach is technically demanding and needs advanced laparoscopic and biliary experience [4,13,14]. In our series, most of the cases were referred to us after the ERCP has failed to retrieve the stone from the CBD due to impacted big stone, that's why we decided to use the choledochotomy technique in these cases from the begining without trying to retrieve the stone by the transcystic technique.

In our study, we routinely used an intraoperative cholangiogram before and after stone extraction to confirm the presence of stones and later to confirm complete clearance of the CBD.

A choledochoscope is a very useful tool in CBD exploration both for direct visualization of the intraluminal stones and for their removal using the Dormia basket or Fogarty's vascular catheter [7,15–17]. In our study, we used the choledochoscope in most of our cases to confirm the complete clearance of the CBD and to inject saline and wash out stone fragments and debris.

In our study, we closed the choledochotomy over the T-tube in 20 of 36 cases (55%); when there was concern in terms of retained fragments or tiny stones, we used primary closure over a stent in five of 36 cases (15%) and primary closure without a stent in four of 36 cases (12.5%). There was no bile leakage in our cases and also no intra-abdominal collections.

Whereas the length of stay for the laparoscopic cholecystectomy is generally short (from 1–3 days), it is longer for LCBDE, 1–7 days, in most of studies [11,17–19]. In our study, the length of stay depended on the technique used. In the transcystic technique, it was 1–3 days and in the choledochotomy technique, it was longer, 2–7 days, especially when we used the T-tube to close the choledochotomy.

In most studies, the mortality of LCBDE is 0–1% in the hands of experienced biliary surgeons. This rate is similar to the incidence found in open CBD exploration [5,20–23]. In our study, there was no mortality, which may be attributed to improved preoperative preparation, and improved anesthesia and selection of patients.

Conclusion

LCBDE is an effective single-stage procedure for the treatment of gall bladder and CBD stone in one session, with the benefits of a minimally invasive approach and avoiding the drawbacks of both the ERCP and the open CBD approach.

LCBDE can be performed after proper training, and with the availability of adequate equipment and laparoscopic facilities.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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Balloon angioplasty versus stenting of sequential tandem lesions in superficial femoral and popliteal arteries

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Objective: To compare Efficacy and durability immediately, after one, 6 months results of balloon angioplasty alone versus balloon angioplasty and stenting of multiple tandem lesions in superficial femoral artery (SFA).
Methods: percutaneous transluminal angioplasty (PTA) with dilatation was done for 20 cases (group I) and PTA and stenting was done for 20 cases (group II) with (stenosis or occlusion).
Results: On stratifying our cases according to TASC II classification, cases showed that in group I: 11(55%), 9 (45%) TASC B and C respectively, group II: 9 (45%), 11(55%) TASC B and were C lesions of the SFA. At one month, six month follow up, group I: 3occluded cases, no more occluded cases while in group II: all cases were successful, 9 cases occluded respectively.
Conclusion: Although primary stenting of SFA provide excellent results in patients with TASC B& C lesions (short term). It doesn't provide Superior (Mid-term) to results to angioplasty alone. (Leave no Metal behind Policy).

Keywords:
angioplasty, stenting, tandem, Trans-Atlantic Inter-Society Consensus

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Introduction

Egypt will have at least 8.6 million adults with diabetes and will have the 10th largest population of diabetic patients in the world by 2030 [1]. Many studies have shown an association between diabetes mellitus and the development of peripheral artery disease (PAD). Overall, intermittent claudications (IC) is about twice as common among diabetic patients than among nondiabetic patients. In patients with diabetes, for every 1% increase in hemoglobin A1c, there is a corresponding 26% increased risk for PAD [2].

Occlusion of the superficial femoral artery (SFA) can lead to claudication and can contribute to chronic critical ischemia. For patients with claudication, aggressive risk factor modification and exercise programs are recommended, and interventions are reserved for failures of this therapy. For critical ischemia, revascularization, if possible, is the standard of care. During the last few years, the treatment of SFA occlusive disease has undergone a shift in management within these paradigms to include more aggressive endoluminal therapy [3].

The SFA extending to the proximal popliteal artery (PA) segment is the most commonly diseased vasculature. More than 50% of all PAD cases involve the SFA and PA. Femoropopliteal disease is often characterized by long, diffuse lesions, long occlusions (as opposed to mild focal stenoses). The unique slow-flow and high resistance environment in the femoropopliteal region creates a milieu that seems to increase the prevalence of de-novo disease [4].

The technical and clinical success rates of the endovascular therapy for the stenotic and occlusive lesions in the femoropopliteal artery have reached over 95% due to the improvements in new generation devices, but long-term patency, however, remains an unsolved issue [5].

The Trans-Atlantic Inter-Society Consensus (TASC) II B lesions of SFA were defined as multiple lesions (stenoses or occlusions) measuring 5 cm or less, single stenosis or occlusion of 15 cm or less not involving the infrageniculate PA, single or multiple lesions in the absence of continuous tibial vessels to improve inflow for a distal bypass, heavily calcified occlusions of 5 cm in length, or a single popliteal stenosis [5].

The TASC II C lesions were defined as multiple stenoses or occlusions totaling more than 15 cm with or without heavy calcification, or recurrent stenoses or occlusions that need treatment after two endovascular interventions [5].

Nitinol stents have been used for long time, which have demonstrated superior primary patency to balloon angioplasty alone. Catheter-based interventions serve as a first-line intervention for many patients with

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infrainguinal occlusive disease. Angioplasty with or without stenting offers the advantage of low morbidity, decreased convalescence, and high patient acceptance. However, longevity and cost-effectiveness remain a concern [6].

Technological advances continue to occur at an ever increasing pace with the intent of increasing the durability of infrainguinal endovascular procedures. Some have suggested that primary nitinol stenting of the SFAs and PAs can provide results that are superior to angioplasty and selective stenting alone and extend the anatomic indications for endovascular intervention. However, stents add considerable cost to any percutaneous intervention and should demonstrate clear benefit before their routine use can be advocated or current treatment recommendations changed [6].

Previous studies have shown that angioplasty alone or with selective stenting have yielded acceptable rates of primary patency in the treatment of short-segment TASC A and B lesions [6].

Patients and methods

This prospective study was conducted on 40 patients presenting mainly to the Vascular and Endovascular Department in Kasr Al Ainy Hospital, Cairo University, between October 2011 and February 2013. All patients presenting with femoropopliteal occlusive disease with multiple tandem SFA and PA lesions (stenosis and/or occlusion) were included in the study. Percutaneous transluminal angioplasty with dilatation only was performed for 20 cases and percutaneous transluminal angioplasty with dilatation and stenting was performed for 20 cases. All patients admitted had to sign a written informed consent form before undergoing treatment.

Patient sex, demographics, presence of comorbidities, history of smoking, indication for intervention, and the use of anticoagulation therapy were recorded. The procedure, possible complications, benefits, risks, and other alternative interventions were all explained to the patients and informed consent was obtained.

Methodology

Clinical assessment

History taking and clinical examination was carried out for all patients, which included the following:

(1) Age and sex.
(2) Major risk factors for atherosclerosis, such as diabetes mellitus, smoking, hypertension, hyperlipidemia, and ischemic heart disease.
(3) Clinical assessment of the patient, degree of ischemia, claudication distance, tissue loss, gangrene, motor power, capillary circulation, color changes, and pulsations (most palpable distal pulse).

Preprocedural investigations

(1) Routine laboratory tests, including complete blood picture, kidney and liver function tests, coagulation profile and blood glucose level, and lipid profile, were carried out.
(2) Patients were scheduled for duplex scanning before intervention with ankle brachial index (ABI) and peak systolic velocities; duplex scanning was performed for all cases.
(3) Computerized topographic angiography (CTA) was resorted to only if duplex was not conclusive.
(4) Echocardiography was performed.

Selection criteria for the study

Inclusion criteria:

(1) Having critical limb ischemia (rest pain, gangrene) with multiple sequential short stenoses or occlusions of the SFA and PA.
    (a) TASC II B: Multiple lesions (stenoses or occlusions), each measuring 5 cm or less, or single stenosis or occlusion of 15 cm or less not involving the infrageniculate PA.
    (b) TASC II C: Multiple stenoses or occlusions totaling more than 15 cm.

Exclusion criteria:

(1) Having iliac artery lesions (stenoses or occlusions).
(2) Having orificial occlusion of the SFA.
(3) Having long lesions of the SFA and/or PA.

All endovascular procedures were performed in the angiosuite under local anesthesia.

For every patient, the following data were recorded:

(1) The location and length of the arterial lesion.
(2) Size of the balloon (diameter and length).
(3) Size of the stent (diameter and length) and type.
(4) Quality of distal runoff.
(5) Complications and their management.

Procedural data

(1) Access site:

The ipsilateral femoral approach was used in 16/20 (80%) limbs in group I and in 14/20 (70%) limbs in group II. The contralateral (crossover) approach was

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used in 4/20 (20%) limbs in group I and in 6/20 (30%) limbs in group II.

(2) Sheath size:
In 35 cases, the 6-Fr sheath was used, whereas in five cases the 8-Fr sheath was used.

(3) Wires:
In this study, Terumo 0.035 inch was the principle wire of angioplasty; 0.014 inch was used in one case.

(4) Passage of wire:
Intraluminal passage of the wire was the main technique used in 25 cases (62.5%), whereas subintimal route was used in 15 cases (37.5%).

(5) Balloon angioplasty (group I):
Balloon angioplasty was performed in all cases (20 limbs). The balloon diameter ranged from 5 to 6 mm and balloon length ranged between 40 and 80 mm. Inflation pressure ranged between 8 and 12 ATM. Inflation time ranged between 60 and 120 s.

(6) Stent deployment (group II):
Stenting (self-expandable nitinol) with one stent was carried out with predilatation in 17 of 20 (85%) cases, stenting with two stents was carried out in two of 20 (10%) cases, and stenting with three stents was carried out in one of 20 (5%) cases. In all patients, the diameter was 6 mm and stent length ranged between 60 and 150 mm.

Procedural outcome

Initial procedural technical success was considered to have occurred when, angiographically, less than 30% residual stenosis measured at the narrowest point of arterial lumen was obtained.

Clinical success was considered to have occurred in the form of regaining of pulse, revascularization warmth, disappearance of rest pain, good capillary circulation, or good healing of ulcer or minor amputation.

Most patients were discharged on the second day following the procedure after receiving instructions on risk factors, control measures, and treatment, which included aspirin 150 mg/day for life, clopidogrel 75 mg/day for at least 1 month, and atorvastatin according to the presence or absence of dyslipidemia.

Follow-up

Patients were followed up immediately after the procedure for the following:

(1) Palpable pulses (popliteal and pedal).
(2) Femoral hematoma and retroperitoneal hemorrhage.
(3) Acute thrombosis (acute ischemia).
(4) Blood transfusions.
(5) Acute renal failure.
(6) Prolonged hospitalization.
(7) The need for minor or major amputation [major amputation was defined as loss of a sufficiently functional foot remnant (to allow standing and walking) and necessitating the fitting of prosthesis – that is, above and below knee amputations for the purposes of this study. Minor amputation constituted Ray and forefoot amputations [7]].
Subsequently, 1 and 6 months later the patients were followed up for the following:
(8) Tissue loss (healing of ulcers and dry gangrene).
(9) Restenosis and reocclusion.
(10) Operative intervention (open surgery).

Results

Table 1.

Detection of the patency and survival of the angioplasty/angioplasty and stent after 1 month and after 6 months

At 1-month follow-up, three occlusions were seen in group I (dilatation) (success rate was 85%), whereas in group II all cases were patent (success rate was 100%). The successful cases fulfilled the criteria of angiographic and clinical success mentioned above.

At 6-month follow-up, no occlusions were detected in group I (dilatation), whereas in group II occlusions were detected in nine cases (primary patency was 55%).

Follow-up

Group I: Follow-up in group I was smooth, except for two cases with forefoot amputations.

Group II: Three cases needed forefoot amputations and two cases needed above-knee amputation. In addition, two cases had puncture site hematoma (Figs 1 and 2).

Discussion

The present study was conducted on 40 patients; 20 cases were managed with PTA without stenting and 20 cases were managed with PTA with stenting for femoropopliteal occlusive disease that fulfilled the selection criteria. According to the TASC classification, we had all cases (40) with TASC II type B and C lesions.

Table 1 Demographic features, clinical presentation, and clinical examination of patients

Item	Patients treated with dilatation only (group I) [*n* (%)]	Patients treated with dilatation and stent (group II) [*n* (%)]	
Demographic features			
Age groups (years)			
40–50	4 (20)	4 (20)	
51–60	3 (15)	3 (15)	
61–70	11 (55)	2 (20)	
71–80	2 (10)	11 (55)	
Sex (%)			
Male	55		
Female	45		
Risk factors			
Diabetes	20 (100)	20 (100)	
Hypertension	18 (90)	16 (80)	
Hyperlipidemia	10 (50)	10 (50)	
Cardiac abnormality	9 (45)	7 (35)	
COPD	0 (0)	1 (5)	
Smoking	12 (60)	11 (55)	
Renal failure	0 (0)	0 (0)	
Stroke	3 (15)	4 (20)	
History			
Previous amputation	0 (0)	1 (5)	
Previous angioplasty	2 (10)	0 (0)	
Previous arterial bypass	0 (0)	0 (0)	
Previous coronary bypass	0 (0)	2 (10)	
Clinical presentation			
Rest pain	5 (25)	7 (35)	
Tissue loss	15 (75)	13 (65)	
Lesion description			
TASC classification			
TASC-B	11 (55)	9 (45)	$P = 0.378$
TASC-C	9 (45)	9 (45)	
Sites of occlusions and stenoses			
Stenosis only			
SFA	8 (40)	11 (55)	$P > 0.004$
SFA and pop	9 (45)	3 (15)	
Pop and PTA	1 (5)	0 (0)	
Pop and ATA	0 (0)	0 (0)	
Occlusions only			
SFA	0 (0)	3 (15)	$P > 0.008$
SFA and pop	0 (0)	1 (5)	
Stenosis and occlusion sites			
SFA	2 (10)	0 (0)	$P > 0.005$
SFA and pop	0 (0)	4 (20)	

SFA, superficial femoral artery; TASC, Trans-Atlantic Inter-Society Consensus; ATA, anterior tibial artery; COPD, chronic obstructive pulmonary disease.

This study was undertaken to determine whether the addition of primary stenting to angioplasty of the SFA and PA would improve the durability of these interventions in tandem lesions. The risk factors were examined as predictors of success, including age, sex, diabetes, hypertension, smoking history, and coronary artery disease (Table 2). The ages of the patients ranged from 41 to 75 years, with a mean age of 61.85 ± 9.79 years. The proportion of male patients was 55%, whereas the proportion of female patients was 45%. All patients (100%) had diabetes, 34 patients (85%) had hypertension (mean blood pressure: 152.60 ± 21.57 mmHg), 16 patients (40%) had cardiac abnormality, and 20 patients (50%) had hyperlipidemia. These factors did not affect patency rate within a relative 6 months of follow-up.

Conrad *et al.* [8] cited that hypertension, diabetes mellitus, renal failure, congestive heart failure, and long lesion length were associated with lower patency rates following angioplasty and stenting of femoropopliteal occlusive lesions in 12-month follow-up [8].

The higher incidence in male population was mentioned by Faglia *et al.* [7], Cull *et al.* [9], and Iida *et al.* [10], who reported that it ranged from 54 to 76%. However, in a study by Chisci *et al.* [11], the incidence in male sex was equal to that in female sex.

The higher incidence in male population may be attributed to the prevalence of predisposing factors (smoking, hyperlipidemia, stress of life, and hypertension).

Although hypercholesterolemia has not previously been directly correlated with worse outcomes for lower extremity vascular interventions, there is some evidence that lipid-lowering agents may help in controlling atherosclerotic disease in the lower extremities [12].

Endovascular treatment in diabetic patients with end-stage renal disease remains a challenge, mainly due to the presence of heavy calcification and the involvement of more than one vascular segment. Diabetic patients with critical ischemia and end-stage renal disease should be treated at an early stage, ideally before tissue loss appears [13].

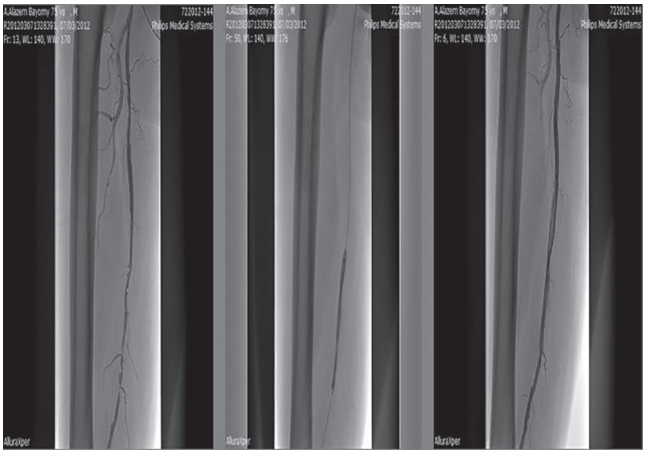
In our study, of patients treated with dilatation, five patients (25%) presented with rest pain and 15 patients (75%) presented with tissue loss (forefoot gangrene and toe and heel ulcers). However, among patients treated with dilation and stent, seven patients (35%) presented with rest pain and 13 patients (65%) presented with tissue loss.

According to Chisci *et al.* (2012) [11], of the 480 patients, 19.3% presented with rest pain, 37.4% presented with major tissue loss, and 43.3% presented with minor tissue loss. It is commonly recognized that a more severe state of the limb, especially Rutherford 6 ulcer/gangrene, more likely results in a higher major

Table 2 Risk factors in group I (dilatation only) and group II (dilatation and stent)

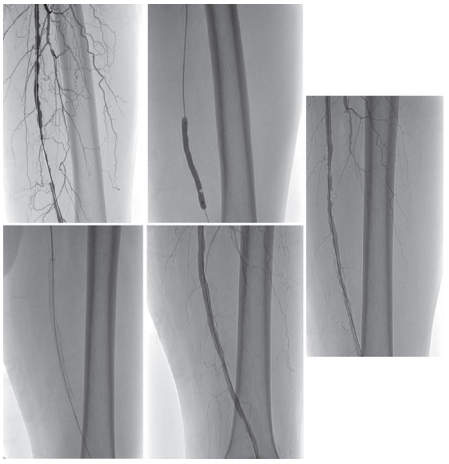
Risk factors	Group I (dilatation only)		Group II (dilatation and stent)	
	Patent at 6 months (*N* = 17) [*N* (%)]	Occluded at 6 months (*N* = 3) [*N* (%)]	Occluded at 6 months (*N* = 11) [*N* (%)]	Patent at 6 months (*N* = 9) [*N* (%)]
Diabetes mellitus	17 (100)	3 (100)	11 (100)	9 (100)
Hypertension	15 (88)	3 (100)	11 (100)	5 (55.5)
Hyperlipidemia	8 (47)	2 (67)	5 (45.5)	5 (55.5)
Cardiac abnormality	7 (41)	2 (67)	3 (27.3)	4 (44.4)
Renal	0 (0)	0 (0)	0 (0)	0 (0)
Smoking	9 (53)	3 (100)	6 (54.5)	5 (55.5)

Figure 1



Selected case from group I (dilatation only). Angiographic picture showing multiple stenoses of right superficial femoral artery (SFA), balloon dilatation of right SFA, and good filling of right SFA after balloon dilatation (no flow limiting dissection).

Figure 2



Selected case from group II (dilatation and stenting). Angiographic pictures showing multiple lesions and stent deployment in superficial femoral artery (SFA).

amputation rate. The need for major amputation is two-fold higher in patients with ulcers or gangrene than in patients with only rest pain [10].

In this study, total lesion length less than 5 cm was found in four patients (20%) in group I and in six patients (30%) in group II. Lesions measuring between 5 and 10 cm were found in four patients (20%) in group I and in three patients (15%) in group II. However, lesions measuring more than 10 cm were found in 12 patients (60%) in group I and in 11 patients (55%) in group II.

Schillinger *et al.* [14] reported an average lesion length of the treated segments in the stenting and PTA groups between 132 ± 71 and 127 ± 55 mm, respectively. Krankenberg *et al.* [15] reported a mean SFA lesion length between 4 and 5 cm in both groups.

It is logical that the results of angioplasty should be influenced by the type and severity of the occlusive lesion. This has been confirmed by several studies of femoropopliteal stenting [16]; the patency at 2 years was significantly better for single stenosis (71.7%) than for multiple stenoses (26.7%). It was mentioned by Setaccia *et al.* [17] that short SFA lesions (<5 cm) are preferably treated with angioplasty. Stenting of short lesions should only be performed when suboptimal results are obtained with PTA alone (level 1a; grade B). The preferred treatment of intermediate SFA lesions (5–15 cm) is PTA with primary bare nitinol stenting (level 1b; grade B).

The endovascular treatment of multilevel disease is thought to result in worse outcomes compared with the treatment of single-level disease of the femoropopliteal or aortoiliac vasculature, because each lesion has its own failure rate that results in an additive effect. In addition, patients with multilevel disease are frequently older, have more comorbidities, and have lower baseline ankle-brachial indexes than patients with single-level disease [18].

Schnieder [19] found that patients with stenosis had a more favorable outcome compared with those with occlusion, with a better patency and lower probability for technical failure at 1 year (7 vs. 18%) and lower complication rate (7 vs. 22%).

In the present study, stenting (self-expandable nitinol) with one stent was carried out with predilatation in 17/20 (85%) cases, stenting with two stents was carried out in 2/20 (10%) cases, and stenting with three stents was carried out in 1/20 (5%) cases. In all patients, the diameter was 6 mm and stent length ranged between 60 and 150 mm. Jerry *et al*. [20] reported that the correct diameter and length of the stent is critical in treating SFA disease. For self-expanding uncovered stents, slight oversizing of the stent (typically by ~10%) is appropriate.

Although stents have been increasingly used in the femoropopliteal segment, no convincing data exist to show that primary stenting dramatically improves outcome. SFA is subjected to many external forces (torsion, compression, flexion, extension, and contraction) that make stenting unpopular. However, after suboptimal balloon dilatation (dissection, residual stenosis, or recoil occurs), stenting can improve the outcome [17]. Data from multiple prospective trials and meta-analyses have been inconclusive with regard to patency and the routine use of stent implantation following angioplasty of femoropopliteal occlusive lesions [21].

In this study, at 1-month follow-up, three cases were occluded in group I (dilatation only) (eight 5% patency), whereas in group II (dilatation and stenting) all cases were successful (100% patency). At 6-month follow-up, it was found that group I had no more occluded cases (primary patency was 85%), whereas in group II nine cases were occluded (primary patency was 55%).

In a study by Baril *et al* [22], freedom from restenosis/occlusion was 58.9% at 12 months in cases that underwent PTA, whereas Cvetanovski *et al.* [16] reported a patency of 75% after stenting in 6 months, and Krankenberg *et al*. [15] reported patency rates in the stenting and PTA groups of 68 and 61%, respectively, after 12 months.

It is now recognized that the patency of revascularization is not as important as limb salvage, and actually there is a population of asymptomatic patients with subclinical lower extremity ischemia and very low perfusion pressures. These patients become symptomatic only when they develop incidental foot ulceration and do not have the circulatory reserve to heal. A boost in arterial perfusion, even transiently, usually allows healing of the ulcer. Once the ulcer is healed, maintenance of enhanced perfusion is not critical, and recurrent ischemia is usually well tolerated as the patient resumes the subclinical ischemic state [23].

Baril *et al.* [22] reported a major complication rate of 2% and no intervention-associated mortalities. Furthermore, the majority of patients treated were discharged home the same day or after one-night hospital stay, whereas in our study major complications of 5% were present in the form of above-knee amputation and minor complications of 5% in the form of groin hematoma.

Krankenberg *et al*. [15] concluded that balloon angioplasty in short femoropopliteal lesions (less than 5 cm in length) can result in similar clinical efficacy compared with primary stenting with respect to restenosis prevention, whereas Schillinger and colleagues concluded that primary stenting improved morphological and clinical outcomes in these patients, with a median SFA lesion length of 10 cm compared with PTA treatment.

We agree with the study by Setaccia *et al.* [17]. and disagree with the study by Krankenberg *et al*. [15] that despite the short period of follow-up, the results of balloon angioplasty in multiple short femoropopliteal lesions (each less than 5 cm in length) are far better compared with primary stenting.

Conclusion

Endovascular treatment of TASC II B and C lesions may be performed safely with minimal morbidity. Low preoperative ABIs, hypercholesterolemia, and longer lesions appear to be associated with higher rates of restenosis. Short SFA lesions (<5 cm) are preferably treated with angioplasty. Stenting of short lesions should only be performed when suboptimal results are obtained with PTA alone (e.g. flow limiting dissection, residual stenosis >25%, post-PTA stenosis). Primary stenting cannot be recommended in patients with multiple stenoses, located at the level of the femoropopliteal junction and upper PA, or for patients with TASC B lesions. Primary stenting of the SFAs and PAs can provide short durable results in patients with TASC B and TASC C lesions and may be an effective treatment strategy, but long-term results are far behind with balloon angioplasty alone.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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Impact of laparoscopic greater curvature plication on weight loss and some metabolic comorbidities, plus important recommendations

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Background
Laparoscopic greater curvature plication (LGCP) is a new bariatric procedure that until now has not found universal acceptance and is practiced by a limited number of surgeons with both promising and disappointing results.

Objectives
The aim of the study was to investigate the impact of LGCP on weight loss and associated metabolic diseases and evaluate its safety.

Patients and methods
A total of 120 morbidly obese patients, 50 hypertensive patients, 48 dyslipidemic patients, and 32 type II diabetic patients underwent LGCP and were followed up for 1 year.

Results
This study comprised 64 women and 56 men. Their mean age was 35.4 ± 11.8 years. Their mean preoperative BMI was 43.7 ± 7.6 kg/m^2, the mean procedural duration was 73 ± 19.7 min, the mean length of hospital stay was 42.3 ± 4.5 h, and the average BMI at 12 months was 27.7 ± 3.6 kg/m^2 ($P < 0.001$). Of 32 type II diabetes mellitus patients, 23 (71.8%) became normoglycemic, 37 (77%) of 48 patients experienced disappearance of dyslipidemia, and 36 (72%) of 50 hypertensive patients became normotensive at the sixth and 12th month. Three patients (2.5%) had gastric stenosis, and three patients (2.5%) had gastric leak. One patient (0.8%) had partial disruption during the first week at the upper end. One patient had prolapse of the intragastric fold causing gastroduodenal intussusception and obstructive jaundice after 8 months.

Conclusion
LGCP has a positive impact on weight loss and associated metabolic comorbidities but has potential specific complications.

Keywords:
bariatric surgery, laparoscopic greater curvature plication, metabolic comorbidities

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Background

Many types of restrictive procedures have been performed to achieve weight loss [1]. Most of them have been abandoned because of poor long-term weight loss, food intolerance, and severe gastroesophageal reflux. Vertical banded gastroplasty in particular has resulted in poor long-term outcomes, and a high percentage of vertical banded gastroplasty patients have required revision to Roux-en-Y gastric bypass (RYGB) to alleviate intolerable reflux symptoms and dysphagia [2].

Some authors believed that irreversible resection of gastric tissue in gastric sleeve surgery and the reported complications such as leak and hemorrhage along the staple line have affected patient and physician acceptance of this procedure [3]. Adjustable banding has some drawbacks such as erosion and migration, proved by endoscopic surveillance after lap band ligation [4–6]. Despite malabsorptive methods having a longer effect on weight loss, the risk of late complications due to vitamin deficiency and anemia is noticeable [7]. Laparoscopic greater curvature plication (LGCP) was initially proposed by Wilkinson and Peloso [8] in 1981 and was introduced in 2006 by Talebpour and Amoli [3] in Iran. LGCP was thought to offer an alternative surgical option to patients willing to undergo a more invasive bariatric procedure, such as RYGB or sleeve gastrectomy [3,9]. Some authors reported that the mean excess weight loss (EWL) in different restrictive methods is almost the same [10,11]. Others reported that the EWL% after LGCP is comparable to the EWL% after sleeve gastrectomy [3,9]. Kourkoulos *et al.* [9] and Talebpour *et al.* [12] in 2012 believed that

laparoscopic gastric plication (LGP) is less invasive and more conservative, with reversible potency and lower risk for complications such as leakage compared with stapler resection procedures.

The aim of the present study was to evaluate the impact of LGCP on weight loss and metabolic comorbidities including type II diabetes, hypertension, and dyslipidemia, and evaluate its safety.

Patients and methods

This prospective study was performed in Minoufiya University Hospitals in Egypt and in other private hospitals in Kuwait (Al Seef Hospital, Hadi Hospital and Tibia Hospital) from September 2009 to March 2014).

Patients were screened and recruited for enrollment from the outpatient population. Their consent was obtained and the procedure was offered in addition to other standard bariatric procedures. Patients who expressed interest in the gastric plication procedure participated in an initial screening process. Those who met the criteria for the present study were evaluated, the details of the procedure were discussed, and it was clearly stated to the patient that this procedure was still under trial. Early findings and complications were discussed with the patients in detail, along with previous successful management options. Patients who agreed to participate in the present study signed an informed consent document and underwent a second level of screening, including laboratory tests, a routine preoperative evaluation, upper gastrointestinal endoscopy when indicated, respiratory function tests, and evaluations by psychologists and nutritionists.

Inclusion criteria

The participants were considered appropriate candidates for the present study if they were willing to give consent and comply with the evaluation and treatment schedule, including the International Fedration of the Surgery of Obesity and metabolic disorders (IFSO), and had a BMI greater than 40 kg/m^2; a BMI of 35–40 kg/m^2 was allowed, with at patients should have no psychopathological illness to be able to understand and tolerate the operation.

Exclusion criteria

The exclusion criteria included pregnancy or lactation at the time of screening for surgery, history of drug and/or alcohol abuse within 2 years of the screening visit, psychological disturbances, previous malabsorptive or restrictive procedures performed for the treatment of obesity, hypothyroidism or Cushing's disease, inflammatory diseases of the gastrointestinal tract within the previous 10 years, or other serious organic disease making the participant a high-risk surgical candidate. Additional exclusion criteria included chronic or acute upper gastrointestinal bleeding, hiatal hernia, previous surgery of the foregut (i.e. hiatal hernia repair or previous gastric surgery), pancreatitis, an immunocompromised status or autoimmune connective tissue disease, and the use of prescriptions or over-the-counter weight reduction medications or supplements within 30 days of the screening visit.

Study endpoint

Weight loss

The main primary study objective was to assess the weight loss. Assessments included absolute change in weight, change in BMI, and EWL%.

Weight was measured at the initial visit, on the day of surgery, and 1, 3, 6, and 12 months after surgery.

Other secondary study endpoints

Adverse events

Surgical safety and the occurrence of adverse events were carefully monitored throughout the entire study period and recorded on the day of surgery, during the first week after surgery, and at 1, 3, 6, and 12 months postoperatively.

Effect on metabolic disease

The effect on type II diabetes, hypertension, and dyslipidemia, and effects on serum albumin, gamma glutamyl transferase (GGT), and blood hemoglobin at 3, 6, and 12 months after surgery were evaluated.

Durability of the plication

We performed postoperative endoscopy in the outpatient setting at 6 and 12 months postoperatively to assess plication durability. Preoperative and postoperative upper gastrointestinal contrast studies were sometimes performed.

Patients underwent upper gastrointestinal endoscopy, blood tests, and abdominal ultrasound preoperatively. Anticoagulants were given, and prophylaxis with antibiotics was given on induction of anesthesia.

Surgical procedures

According to experience gained through the study, the first 40 patients were classified as phase 1 and the remaining patients (80 patients) were classified as phase 2.

The short gastric vessels were divided starting 5 cm from the pylorus and continuing up to the left crus of the diaphragm (Fig. 1).

The fundus and body were completely mobilized (Fig. 2), and a calibration tube of 36 Fr was introduced into the stomach. The stomach was deflated to facilitate the plication, and then the greater curvature was folded inward with two rows of continuous 2-0 polypropylene sutures over a round needle to create a linear intraluminal fold, reducing the stomach capacity (Figs. 3–5). The fold was started 1 cm from the gastroesophageal junction and continued distally to 5 cm above the pylorus. The second row of sutures was applied parallel to the first one (Fig. 4). Initially, the distance of the needle bite of the second row of sutures was 2 cm away from the lesser curve, but in subsequent cases we noticed that the stomach dimensions were not the same along its whole length. Thus we tended to be more flexible when performing the second row of sutures to avoid tension, stenosis, or intragastric fold plug. The bite sites were later adjusted in phase 2 to 2.5–3 cm from the lesser curve on either side because of reported stenosis in phase 1. In phase 1 we stopped plication 3 cm above the pylorus and then at 5 cm in subsequent cases in phase 2 to keep the pylorus empty (Fig. 6).

This modification was made because of the occurrence of gastroduodenal intussusception in one case in our study. In all cases, sutures were approximately not more than 1 cm spaced to avoid gastrogastric hernia. Routine intraoperative methylene blue test was used in phase 2 because of the occurrence of leak in phase 1.

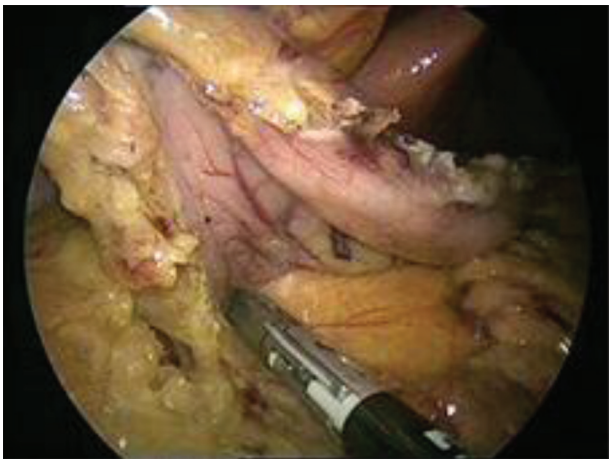
Postoperative care

Pain was assessed by the visual analogue scale and controlled by both pethidine and paracetamol infusion. Low-molecular-weight heparin was administrated

Figure 1

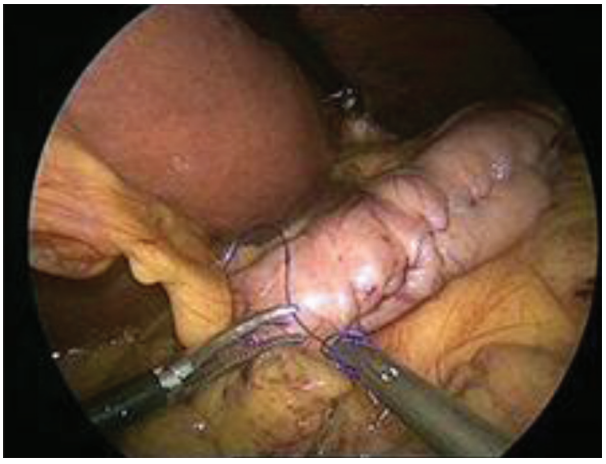
Sealing of the short gastric vessels.

Figure 2



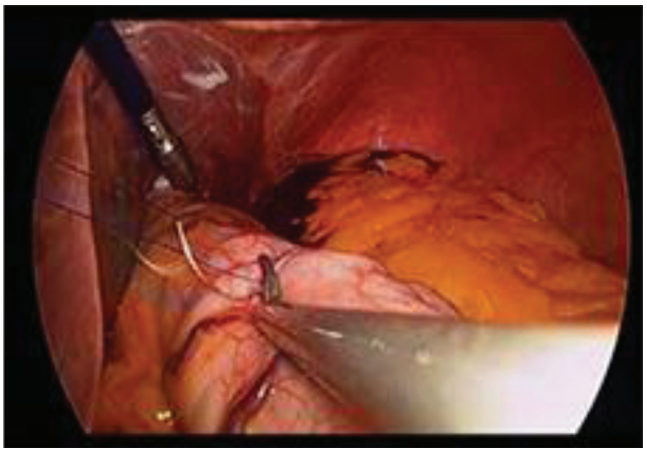
Mobilization of the body and fundus.

Figure 3



First row plication.

Figure 4



Second row plication.

for 15 days postoperatively. The postoperative diet was prescribed in consultation with a dietitian and was based on clear liquids for the first week and semiliquids as tolerated for 3 weeks. Solid food was allowed 4 weeks postoperatively. Follow-up visits for the assessment were scheduled postoperatively at 1 week, 2 weeks, 1 month, 3 months, 6 months, and 12 months. Statistics were recorded at 1, 6, and 12 months.

Results

A total of 120 patients (56 men and 64 women) were enrolled in the present study. Their mean age was 35.4 ± 11.8 years (range 18–63 years), and the average preoperative BMI was 43.7 ± 7.6 kg/m^2 (range 36.5–69.3 kg/m^2).

The procedure duration ranged from 57 to 155 min, with a mean of 73 ± 19.7 min. The mean hospital length of stay was 42.3 ± 4.5 h and ranged from 24 h to 26 days.

The visual analogue scale assessments were performed before discharge, and the average pain score was 2.5, ranging from 2 to 4 (Table 1).

Weight loss

The mean preoperative BMI was 43.7 ± 4.6 kg/m^2.

The mean BMI at 12 months was 27.7 ± 3.6 kg/m^2.

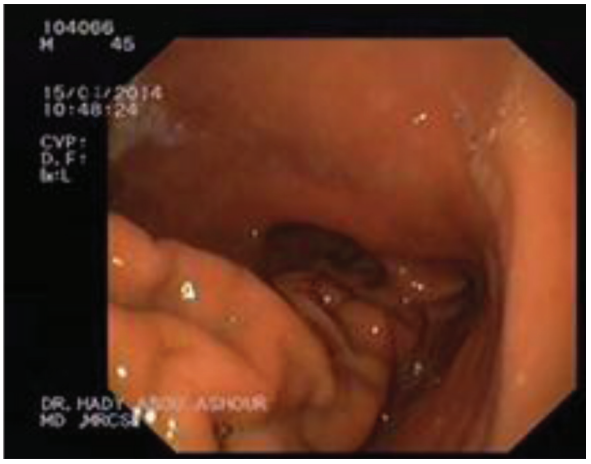
The EWL% for the patients at 3, 6, and 12 months was 29.3 ± 9.3, 42 ± 6.3, and 61.3 ± 3.7%, respectively. The difference in weight loss for patients enrolled in this study was statistically significant ($P < 0.001$) at the 12-month visit (Table 2).

The mean BMI decreased from 43.7 ± 4.6 to 27.7 ± 3.6 kg/m^2, a mean of 36.6% change in BMI at 1 year with an average decrease in BMI of 16 points. The EWL% showed better results during the follow-up periods for patients with BMI less than 45. In our study we had 21 patients with BMI over 45 kg/m^2 and their mean EWL% was 52.4 ± 9.6% over 12 months.

Effects on metabolic comorbidities

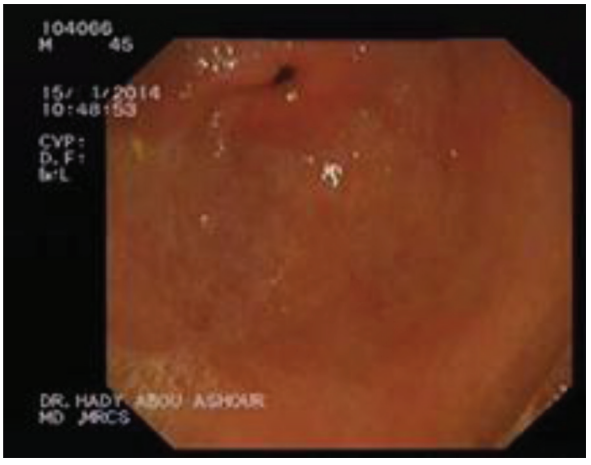
Thirty-two diabetic patients were encountered in our study; 15 of them were receiving insulin only, 12 were controlled with oral hypoglycemic medications only, and five diabetic patients were uncontrolled and did not receive any treatment for diabetes. Of the 15 patients receiving insulin, 10 showed a return to normal glucose level without any medication at 6 and 12 months after surgery. Of the 12 patients receiving oral medications, 10 became normoglycemic without medications. Of the five patients who were on no treatment, four returned to normoglycemic levels. Oral glucose tolerance test was performed for the normoglycemic patients after 12 months postoperatively and was negative except in the case of two patients. Thus, 23 out of 32 type II diabetes mellitus patients (71.8%) had normal blood glucose

Figure 5



Durable intragastric fold (endoscopy).

Figure 6



Empty pyloric region.

Table 1 Pre-op. BMI ,pain score and hospital stay

	Age	Pre op. BMI	Procedure Duration	Hospital stay	Pain score
Mean	35.4 ± 11.8 ys	(43.7 ± 7.6) kg/m^2	73± 19.7 min	42.3 ± 4.5 hrs	2.5
Range	18-63ys	36.5-65.3	57-155 min	24hrs-26 days	2-4

level without any medications, and the rest of the diabetic patients showed better glycemic control at the 6- and 12-month visits ($P < 0.001$).

Of the 50 hypertensive patients, 36 (72%) returned to normal blood pressure levels and the rest of them showed better control; 40 out of 50 patients (80%) showed improvement in the ejection fraction and reduction in the left ventricular size ($P < 0.001$).

Of 48 dyslipidemic patients, 37 (77%) showed improvement in dyslipidemia and returned to normal level by the end of the sixth and 12th month visits ($P < 0.001$) (Table 3).

None of the patients had abnormality in serum albumin or GGT, or appearance of anemia at the third, sixth, and 12th month of follow-up.

Follow-up endoscopy

Thirty-four patients did not complete the 12-month follow-up endoscopic evaluation after the sixth month. The other 86 patients (71.6%) who had completed the 6- and 12-month endoscopic evaluations had durable intragastric fold (Fig. 5) except one patient who had a partially disrupted fold that occurred during the first week at the upper end. This was confirmed by gastrografin contrast imaging without weight regain.

The disruption area was less than one inch and appeared as a small proximal pouch with a wide base and the patient refused intervention and had no further complications throughout the follow-up period.

Complications (Table 4).

Table 2 EWL % in follow up:

Months (%)	3rd (%)	6th (%)	12th (%)	*P* value
Over all mean EWL	29.3 ± 9.3	42 ± 6.3	64.6 ± 7.3	<0.001
Mean EWL for BMI >(45)	—	—	52.4 ± 9.6	< 0.05

Intraoperative complications

Two patients had small subcapsular hematoma in the left lobe of the liver.

Mild intraoperative bleeding from the short gastric vessels to the splenic side was seen in three cases and was dealt with by proper sealing.

The following complications also arose:

(1) Nausea in 44 patients (36.6%) and sialorrhea in 25 patients (20.8%) occurred during the first 30 h; seven patients (5.8%) had persistent vomiting and four of them resolved within a few days.
(2) Three patients (2.5%) showed manifestations of gastric stenosis; one responded to conservative treatment. The other two patients underwent laparoscopic plication undo after failure of conservative treatment and laparoscopic sleeve gastrectomy was performed. The barium study and the endoscopic view proved that the stenosed areas in each case were single and were:
    (a) Subesophageal.
    (b) Midgastric (because of the presence of voluminous intragastric fold, as this is the largest folded area of the stomach) (Fig. 7).
    (c) Prepyloric.
(3) Three patients (2.5%) had manifestations of gastric leak, where perforations were multiple in two of them and were located in both the anterior and posterior wall of the stomach (Figs. 8 and 9). These perforations occurred at the site of the second suture row (highest tension). As the application of endoscopic stents was not suitable

Table 3 Impact on metabolic comorbidities

Metabolic parameter	No. of patients	Impact of LGCP after 12th month	*P* value
Hypertension	50	36 patients (72%) became normotensives	<0.001
Type II diabetes	32	23 patients (71.8 %) returned to normal blood sugar and Glycated Hg returned to normal	<0.001
Dyslipidemia	48	37 patients (77%) returned to normal lipid profile	<0.001

Table 4 Complications

Intraoperative complications	Early intraoperative complications	Late intraoperative complications	Reoperation rate
Small sub capsular haematoma 2 patients (1.6%) Intraoperative (bleeding 2 patients (2.5%), not with ligasure.	Nausea 44 patients patients (36%) Sialorrhea 25 patients (20.8%) Gas bloating 45 (37.5%) Proximal disruption of gastric fold (0.83%) Gastric Leak (2.5%) (phase I) Gastric stenosis ,3 patients (2.5%) (phase I) Wound infection 2 patients (1.6%) Chest infection 3 pateints (2.5%)	Gastrodudenal one patient intussusception (0.83%)	6 patients (5%) all in phase 1 cases

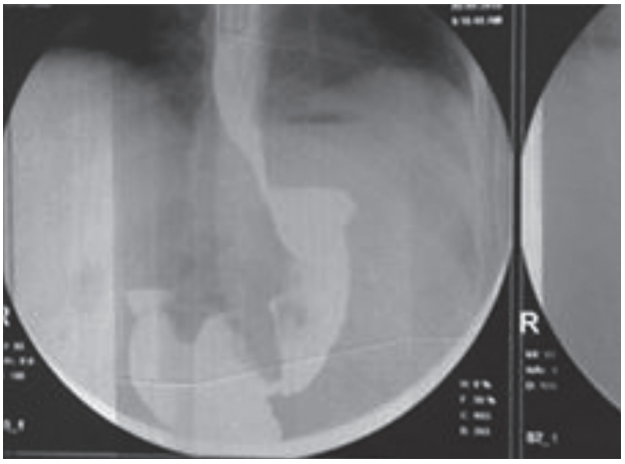
because of large intragastric fold, the tears were managed early by laparoscopic exploration, peritoneal wash, plication undo, identification of tears, trimming of their edges, suture repair, and liberal drainage. Omental flap was used to plug the defects in the stomach with tie over sutures in two cases of leak (Fig. 10). The fistula closed in 26, 24, and 23 days, respectively, with an average of 24.3 days, and the hospital stay was 26, 20, and 17 days, respectively, with an average of 21 days. Omental flap plug was used in two cases where defects were large and the margins were not firm enough to hold secure sutures; moreover, there was not enough distance from the lesser curve to the holes to ensure immediate safe sleeve gastrectomy. Patients received jejunostomy feeding, first at the hospital and then at home, before complete closure of the fistulae, whenever the condition was stable and the leak was minimal, controlled, together with normal passage of stool and no abdominal signs of peritonitis.

(4) One patient showed limited proximal fold disruption in the first week with no weight gain.
(5) Gas bloating appeared during the first postoperative week in 45 patients (37.5%) and disappeared after a few days.
(6) Two patients (1.6%) showed port site wound infection and were managed in a few days.
(7) Three patients (2.5%) had chest infection and responded to conservative treatment.

Late complications

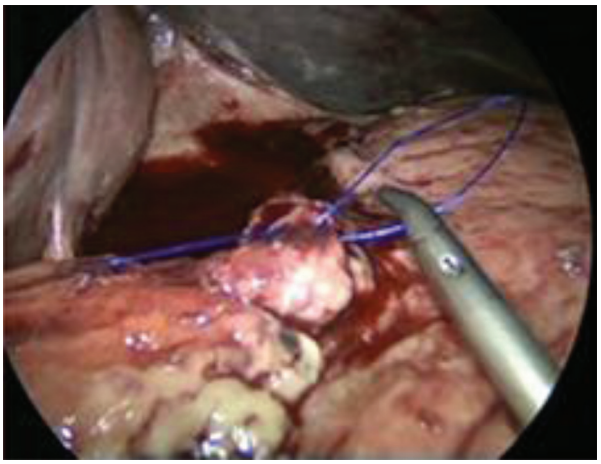
After 8 months one patient showed prolapse of the distal fold through the pylorus and duodenum and presented with vomiting and obstructive jaundice. Laparoscopic exploration was performed in the form of laparoscopic plication undo and withdrawal of the gastroduodenal intussusceptum; then laparoscopic reux-en y gastric bypass (LRYGP) was performed

Figure 7



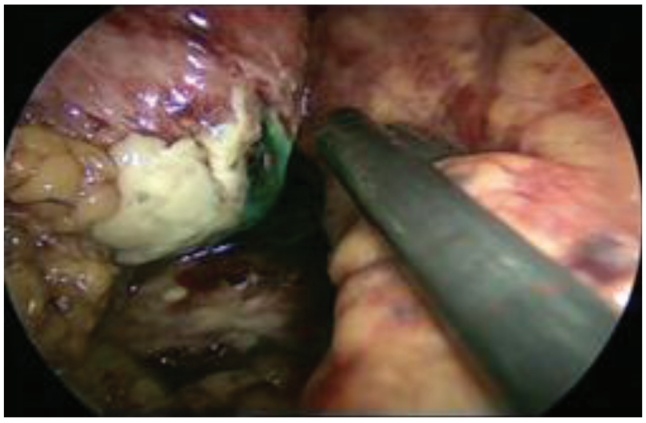
Midgastric stenosis (contrast image).

Figure 8



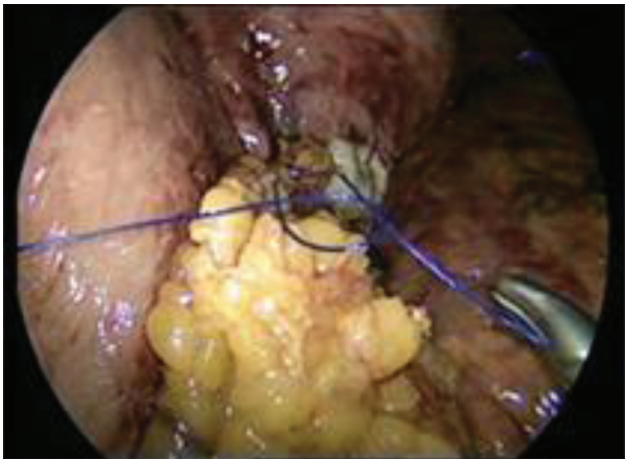
Suturing of perforation in the anterior wall.

Figure 9



Perforation in the posterior wall.

Figure 10



Omental flap plug with tie over suturing.

after 3 months. The overall reoperation rate was 5%, three cases for leak, two for gastric stenosis, and one for fold prolapse with gastroduodenal intussusceptions (Table 4).

Discussion

As the number of bariatric procedures is growing every year, the demand for a cost-effective procedure is gaining prominence. Talebpour and Amoli (2007) [3], Ramos *et al.* (2010) [9], and Brethauer *et al.* (2010) [13] reported that LGCP provided effective surgical weight loss at 12 months that, on average, was greater than 50% EWL. In our study, weight loss was significant over 1-year follow-up as EWL% was 29.3 ± 9.3, 42 ± 6.3, and 61.3 ± 3.7% at the third, sixth, and 12th month, respectively. These results were comparable to those of other standard bariatric procedures such as sleeve gastrectomy and gastric bypass. Our results showed that the EWL% was only 52.4 ± 5.63% for patients with BMI greater than 45 at the 12th month. Thus, LGCP was not the proper surgery for those with BMI greater than 45 kg/m^2.

LGCP can be reversed to other bariatric procedures, as in our study two patients underwent sleeve gastrectomy and one patient underwent RYGB after plication undo. After the occurrence of complications, we changed LGCP to other procedures, similarly to Kourkoulos *et al.* (2012) [10], Brethauer *et al.* (2011) [13,14], Pujol Gebelli *et al.* (2011) [15], Coskun *et al.* (2013) [16], and Ahnfeldt *et al.* (2013) [17], who occasionally changed LGCP to other bariatric procedures in certain instances with no recorded complication. Gastric leak was higher than we expected in this series (2.5%). This is because of the lack of accurate seromuscular needle bite, which could not be addressed especially in thin stomachs, and can cause concealed gastric perforations, which can widen and cause acid exposure and leak.

Talebpour and Amoli (2007) [3], Skrekas *et al.* (2011) [18], Menchaca *et al.* (2011) [19], Andraos *et al.* (2011) [20], and Kourkoulos *et al.* (2012) [10] reported an incidence of leak in their studies, although they reported that plication must be submucosal. This confirms that the leak sometimes could not be avoided even with strong attempts. This indicates that LGCP carries a comparable rate of leakage to sleeve gastrectomy and has not shown superiority with respect to leak. In subsequent cases (phase 2), considerable attempts were made for frequent aspiration of air and fluid using the gastric tube from the lower two-thirds of the stomach, avoiding tight plication or pulling of the continuous suture under tension in partially distended stomach. Because of these precautionary measures we had no recorded leak as in phase 1.

Vomiting due to fold edema and early gastric spasm responded to conservative treatment in a few days. Gastric fold prolapse to the duodenum was reported in one case after 8 months, which was complicated with gastroduodenal intussusception and obstructive jaundice. After this complication we modified the technique described by Talebpour and Amoli (2007) [3] to 5 cm instead of 3 cm above the pylorus to avoid prolapse. Our study was in agreement with that of Shen *et al.* (2013) [21], who reported that the total cost of LSG was $7826 ± 537 compared with LGCP ($3358 ± 264). The overall hospital cost was less when compared with laparoscopic sleeve gastrectomy or RYGB. In the present study the mean cost of LGCP was $3500 ± 312 in our country and was lower than sleeve and gastric bypass cost ($P < 0.05$).

Highly superficial plication disrupted early in this study because of increased intragastric pressure during vomiting in one case. Very deep plication carried the risk of acute gastric perforation and higher risk of leak; moreover, seromuscular suture could not be ensured in thin-walled stomach. Because of the experience gained in phase 1, we encountered neither gastric stenosis nor gastric leak in phase 2; however, this needs to be researched further. In this study, LGCP showed significant impact on metabolic comorbidities as 71.8% of type II diabetes mellitus patients experienced a return to normal blood glucose levels and negative oral glucose tolerance test; the remaining diabetic patients had better glycemic control; 72% of hypertensive patients demonstrated a return to normal blood pressure and the rest of them showed better control; 77% of dyslipidemic patients experienced an improvement of dyslipidemia, which returned to its normal level. This indicated beneficial effects on metabolic syndrome and supports the theory that type II diabetes is a curable surgical disease in obese patients.

No nutritional deficiencies or anemia was reported in this study. LGCP provided effective surgical weight loss at 12 months, especially in those with BMI less than 45 with an overall average greater than 61% EWL. From this study, it can be concluded that LGCP is an alternative restrictive weight loss surgical technique with specific potential serious complications that needs further validation for universal applicability and acceptance.

Important technical pitfalls and recommendations gained from this study

(1) Plication should be done on a completely empty stomach, gas free and fluid free, to avoid thinning of its wall and to reduce its volume to avoid acute gastric perforation during suturing.
(2) Gastric stenosis occurred in three cases in this study. Stenosis was also seen in some studies [16,17]. Therefore, the second row of sutures should not be less than 3 cm from the lesser curve.
(3) Plication should stop 5 cm above the pylorus to avoid fold prolapse.
(4) The second row of sutures should not be more than 1 cm spaced or loose to avoid gastrogastric hernia, which was a reported complication in some studies [15].
(5) Very superficial needle bites cause fold disruption, and very deep bites cause gastric perforation.
(6) The stomach size and thickness in patients were not similar. Some were thick walled, contracted, and easily plicated; others were thin walled, redundant, and difficult to be plicated.
(7) Intraoperative methylene blue test should be used in all cases (gastric plication can cause leakage).

Conclusion

LGCP has a positive impact on weight loss and associated metabolic comorbidities but has potential specific complications.

Acknowledgements

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Informed consent: Informed consent was obtained from all participants included in this study.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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A large posterior perforation of gastric ulcer: a rare surgical emergency

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A 65-year-old woman was admitted with a complaint of a constant dull aching pain in the epigastrium for 4 days, with subsequent worsening and generalization of the pain. Clinically the abdomen was tender all over with board-like rigidity. Chest radiography revealed pneumoperitoneum and a decision was made to explore the patient. During laparotomy we found mild peritoneal collection with no perforation in the anterior surface of the stomach, duodenum, or the entire gastrointestinal tract. After opening the gastrocolic omentum, we found a large perforation of the posterior wall of the stomach. After direct repair with an omental patch, the patient recovered and was discharged after 14 days, with only wound infection. Posterior perforation of a gastric ulcer is a very rare condition.

Keywords:
gastric ulcer, posterior perforation, surgical emergency

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1110-1121

Introduction

Every year peptic ulcer affects four million people globally [1]. Complications are encountered in 10–20% of these patients and 2–14% of the ulcers perforate [2,3]. Perforated peptic ulcer is relatively rare, and occurs usually in the anterior aspect of the duodenum [4].

Posterior perforation of gastric ulcer is a unique category of peptic ulcer perforation with a distinct clinical presentation [5]. Despite its rareness, awareness of this surgical emergency is very important, because it is usually associated with high morbidity and mortality especially if the diagnosis is missed.

Here we report a case of a large posterior perforation of a gastric ulcer and a review of the literature.

Case report

A 65-year-old woman was admitted with a complaint of a constant dull aching pain in the epigastrium for 4 days, which progressively worsened and generalized. She had a history of diabetes mellitus and ischemic heart disease.

The patient was febrile on admission and her vital signs were stable. The abdomen was tender all over with board-like rigidity. Chest radiography demonstrated pneumoperitoneum and the patient was diagnosed with generalized peritonitis due to perforated hollow viscus.

An emergency laparotomy was therefore performed. During the laparotomy, mild collection of pus was found, with no perforation in the anterior surface of the stomach or duodenum; the rest of the gastrointestinal tract was normal.

The gastrocolic omentum was opened and pus was drained out from the lesser sac. A 3-cm perforation of the posterior gastric wall of the body of the stomach was noted (Figs 1 and 2). We took a biopsy from the ulcer margins, and then closed the perforation with an omental patch. The biopsy was insignificant. The patient recovered and was discharged after 14 days, with wound infection.

Discussion

Posterior perforation of a gastric ulcer is a rare condition. There are fewer than 30 cases reported in the literature. Wong and colleagues (2003) reviewed nine patients with posterior perforations, who were treated from January 1990 to June 2002. Their findings were sealed perforation, localized retroperitoneal abscess, and generalized peritoneal contamination of the lesser sac and peritoneal cavity [5].

In a series of 125 consecutive perforated peptic ulcer patients operated upon by Hamilton Bailey, there was only one case of perforation on the posterior surface of the stomach [6].

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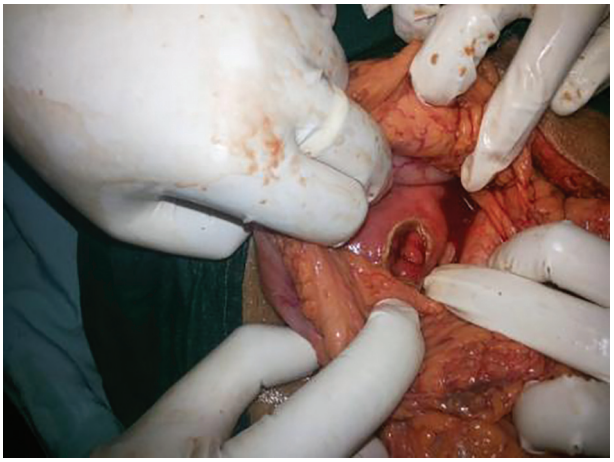
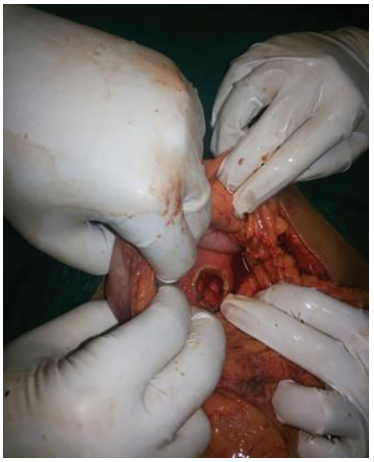
Figure 1



Posterior perforation of the gastric ulcer.

Figure 2



Posterior perforation of the gastric ulcer.

The great majority of benign gastric ulcers lie along the lesser curvature of the stomach. However, ~5–8% of ulcers lie in the posterior wall of the body of the stomach [7].

When posterior gastric ulcer perforates, it usually penetrates into the lesser sac behind the stomach (for gastric ulcers in the fundus or body of the stomach). The lesser sac is a potential space and is less effective in sealing off the perforation; thus, the gastric content and pus will accumulate in the lesser sac, forming abscess, and through the foramen of Winslow this fluid will pass into the peritoneal cavity, leading to generalized peritonitis [5].

That is why the clinical presentation of posterior gastric perforation is less dramatic than that of the more common anterior perforations and is characterized by late presentation. And because of the late presentation and missed diagnosis at laparotomy, posterior perforation is usually associated with high mortality [5,8].

In the case of posterior perforation of pyloric or duodenal ulcers, these ulcers penetrate into the retroperitoneal space, which results in either retroperitoneal abscess formation, or the perforation will be sealed off by the local inflammatory reaction and fibrosis of the surrounding adherent retroperitoneal tissue [5].

Computed tomography (CT) scanning has an important role, particularly multidetector CT, in the diagnosis of perforated peptic ulcer and in the determination of the site of perforation. There are particular findings in CT scanning that suggest gastric posterior wall perforation, such as retrogastric air and/or fluid collection [9].

Conclusion

Posterior perforation of a gastric ulcer is a rare condition and should be suspected when there is collection of pus or gastric content intraperitoneally with no perforation in the whole gastrointestinal tract on exploration of the abdomen. It usually presents late and is associated with a high mortality rate. Operative findings depend on the location of the perforation with either a lesser sac abscess associated with generalized peritonitis or retroperitoneal abscess. An unexplained retroperitoneal abscess should always draw attention to the possibility of the presence of a posteriorly perforated peptic ulcer. CT scanning plays an important role in the diagnosis of the site of the perforated peptic ulcer.

Acknowledgements

The author thanks Professor Dr. Ahmed Shawky and Professor Dr. Alaa Hussein for their support and help in treating this case.

Consent: Written, informed consent was taken from the patient for reporting this case.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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The Question: Liposuction excision of gynecomastia through an axillary liposuction opening: a novel technique: poor control of bleeding?

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We read the article 'Liposuction excision of gynecomastia through an axillary liposuction opening: a novel technique' [1] published in your reputed journal with interest. We must congratulate the author for a commendable and innovative approach. However, we have few reservations and comments to make with regard to the approach.

First, the author excludes Simon's [2] grade III from this approach and he does not mention its management. Moreover, he does not justify the exclusion, which becomes a major limitation of the technique. How were the patients with grade III gynecomastia managed? Second, the author's apprehension about the chances of hematoma and the need for a direct approach (periareolar incision) for hemostasis is evident at the level of obtaining patient's consent. Previously published data [3] suggest that routine closed-suction drainage after gynecomastia surgery is unnecessary, and it may be appropriate to omit drains after gynecomastia surgery; however, the author uses 16- or 18-Fr drain routinely, which suggests that the control of bleeding in this indirect excision technique is poor. Third, the author waits for natural hemostasis to occur when operating on the opposite breast, but does not have any means of controlling active bleeding. Hematoma ranging from 50 to 180 ml in four patients despite the use of large suction drains (16–18 Fr) clearly suggests poor control of bleeding. Finally, as this technique is blind, indirect, and utilizes a distant approach from the operative site, there is definite chance of residual gland being left in the cavity, resulting in contour abnormality; this is evident in the postoperative picture (i.e. Fig. 1).

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The Answer from Dr. Hady Abou Ashour:

Dear Sir, thank you for your interest in the article; I graciously accept your congratulation. It gives me immense pleasure to interpret your queries. Although most of them were clearly covered throughout the paper discussion, I would like to quote from the text in the article (in italic) to answer some questions and write answers for the rest of your queries.

The first query: the exclusion of Simon's grade III in the study.

Patient and methods: All grades of gynecomastia were included in this study except those of Simon's grade III.

Simon's grade III of course has a separate entity of treatment due to the redundancy, which does not yield to the normal skin recoil after breast stroma excision. This means that reduction mammoplasty techniques are required to remove concomitant skin excess (look references below).

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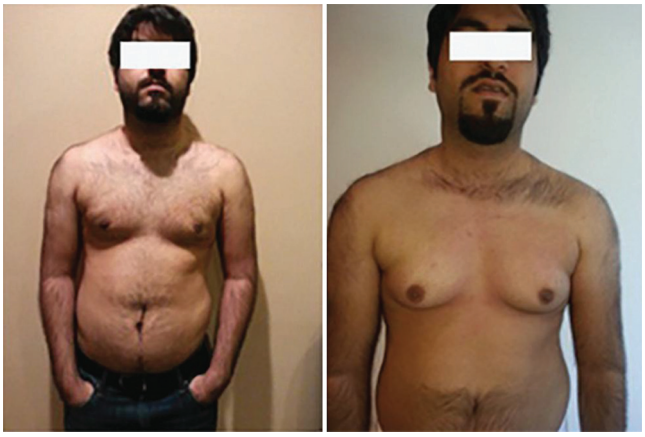
Figure 1



Preoperative and postoperative photo.

One more benefit of our single far approach is that some enlarged male breasts could not be accurately judged clinically to be either true or pseudogynecomastia. This situation was encountered in about 24 patients (16.78%). Therefore, liposuction only was sufficient for such cases, with no further need for any other incisions. This means that incision at the periareolar region is of no benefit in case of pseudogynecomastia and can cost the patient another unwanted scar with potential unexpected wound complications.

The second and third question: Most of the patients do not bleed after proper liposuction; we also excised the connecting terminal trabecula and unnamed vessels, which collapsed due to excess liposuction, and managed bleeding with the use of epinephrine with subsequent bandage. Inserting of drains is a conservative mean to drain acceptable amount of blood.

(Paper text) Together with application of tight elastic bandage, the use of epinephrine-containing tumescent fluid minimized the operative and postoperative bleeding.

The fourth question: Any irregularity in Simon's grade I and II is temporary and the skin recoils over time. By proper palpation of the breast, one can pick and excise any glandular remnant using both liposuction and scissors. The healing and recoil correct the contour over time.

NB: The following authors did not use direct hemostasis during their excision techniques; some of them used two openings unlike us, we used single opening. This means that gynecomastia bleeding is lesser in correct excision plane (look at the paper text).

(Introduction) Lista and Ahmad (19) (2008) referred to the use of the pull-through technique in association with PAL.

(Introduction) In 2010, Petty *et al*. (35) reported their experience with UAL and the arthroscopic shaver to resect the subareolar fibrous component.

(Introduction) In 2010, O Qutob (20) reported a case series of 36 patients undergoing vacuum mammotome resection of gynecomastia through one opening and liposuction through the other opening.

(Introduction) Paolo Morselli *et al*. (2012) (36) reported their 15 years of experience in the pull-through technique, with satisfying results, but again they used two incisions – one in the inframammary fold and the other one behind the anterior axillary line.

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Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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