The Egyptian Journal of Surgery

The official organ of the Egyptian Society of Surgeons

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EGYPTIAN JOURNAL OF SURGERY

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Last updated September 2014

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Incidence of sliding ovary and fallopian tube in congenital inguinal hernia among female children

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Introduction
Indirect inguinal hernia has incidence of 0.8–4.4%. In female children, the hernia sac contains an ovary in approximately 20–25% of cases, and some also contain a fallopian tube. Different forms of injury to ovaries and fallopian tubes were reported in female children who had herniotomy.
Patients and methods
Prospective study to evaluate incidence and surgical importance of sliding ovary and fallopian tube in congenital inguinal hernia in female children at Menoufia university hospitals between March 2012 and August 2015 included 118 female children with 31 cases with bilateral hernia with total of 149 hernias.
Results
Hernias were bilateral in 31 (26.2%) children, 52 hernias were on the right side (44.1%), and 35(29.7%) were on the left. 18 cases (15.2%) presented with irreducible hernia; 15 of them were sliding hernia and the other 3 reduced spontaneously with induction of anesthesia. Overall sliding hernias with ovary and or fallopian tube were 52 of the 149 hernias (34.8%).
Conclusion
Sliding ovary and fallopian tube is not uncommon finding and it is found in nearly one third of congenital inguinal hernia in female children, so from a clinical point of view, it is of utmost importance to keep in mind this fact while dealing with hernia sac. Hernia sac should be opened in all cases to exclude the presence of sliding ovary and tube; and if present the sliding ovary and tube should be carefully dissected and reduced before ligation of the sac in order to avoid their injuries.

Keywords:
fallopian tube, hernia, ovary, sliding

Egyptian J Surgery 36:1–5

1110-1121

Introduction

Indirect inguinal hernia is one of the most common surgical problems in children with a reported incidence of 0.8–4.4% [1]. In female children, the hernia sac contains an ovary in ~20–35% of the cases, and some also contain a fallopian tube [2]. However, only a few cases contain the uterus and both ovaries in the hernia sac [3–5]. In the female fetus, the peritoneum herniates into the canal of Nuck during the descent of the round ligament of the uterus; this path should be obliterated at birth as its persistence and patency after birth results in indirect inguinal hernia in female children [6]. Unfortunately, hernia repair in female children is often carried out with less care than in male children because of the absence of spermatic cord and its contents in the female inguinal canal. However, some previous studies [7,8] have reported incidences of different forms of injury to ovaries and fallopian tubes in female children who underwent herniotomy. The reason for these injuries to the ovaries and tubes is that more than one-fourth of the inguinal hernias in female children are of the sliding type with ovary and fallopian tube as the main contents and herniotomy, without opening the sac, can easily result in injury to these vital female reproductive organs [9,10].

Patients and methods

The aim of this study was to evaluate the incidence and surgical importance of sliding ovary and fallopian tube in congenital inguinal hernia among female children. The study was carried out at Menoufia University Hospitals between March 2012 and August 2015.

The study included 118 female children diagnosed with congenital inguinal hernia; 31 cases had bilateral hernia, with a total of 149 hernias; the age of the children ranged from 4 weeks to 12 years.

Diagnosis was based on the history from children's parents, which was accomplished by clinical exam-

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ination. Patients with sliding hernia (where the contents of the hernia constitute part of the wall of the hernial sac) were suspected clinically by partial reduction of the hernia. All patients underwent abdominopelvic and groin ultrasound for confirmation of clinical diagnosis, especially in cases with suspected sliding ovary and fallopian tube, and to rule out hernia on the other side.

All patients underwent routine laboratory tests such as complete blood count, bleeding time, and clotting time.

General anesthesia was induced through face/laryngeal mask or the endotracheal tube. The inguinal canal was accessed through a groin-crease incision placed just above and lateral to the pubic tubercle. Inguinal canal was not opened in children below 2 years of age. After delivering the hernia sacs into the wound, dissection of the sac was carried out from the round ligament. Opening of the sac was performed in all cases to assess the presence of sliding ovaries and fallopian tubes. Thereafter the contents were inspected and the findings documented. If there were sliding ovary and/or tubes, they were carefully dissected from the wall of the sac and gently reduced to the pelvis, and the herniotomy was then completed. In case of difficulty in dissecting the ovary from the wall of the hernia, a U-shaped incision including the sliding part of the wall of the hernia that was reduced to the abdomen and a purse string suture were applied at the neck of the hernia sacs and tied under direct vision, following which the sacs were invaginated into the pelvis and the inguinal canal was obliterated by running sutures to decrease the incidence of hernia recurrence; then the wound was closed in layers.

Follow-up period ranged from 6 months to 2 years after operation for the assessment of recurrence.

Ethics statement

Before the inclusion of the children in the study an ethical clearance was sought from the competent authority of Menoufia University Hospitals. Written informed consent was obtained from the children's relatives for publication of this research and any accompanying images.

Statistical analysis

The data obtained were analyzed using SPSS (Statistical Package for Social Science), version 17.0, on an IBM compatible computer (Chicago, Illinois, USA), and presented as count, frequency, percentage, and mean±SD.

Results

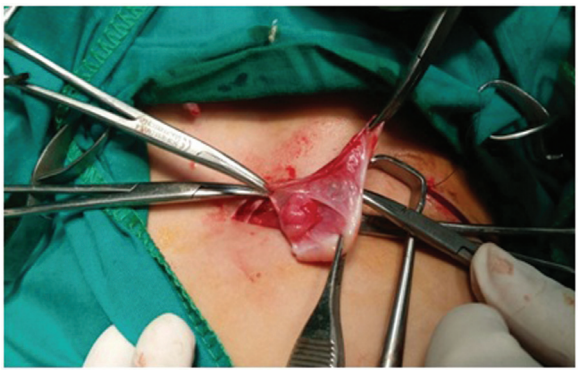
The present study included 118 female children aged between 4 weeks and 12 years (mean=4±2.4 years) who were diagnosed with 149 inguinal hernias (31 case had bilateral hernia) and were treated with hernia repair at Menoufia University Hospitals between March 2012 and August 2015.

As shown in Table 1, 26.2% hernias were bilateral, as diagnosed in 31 children, 52 hernias were on the right side (44.1%), and 35 (29.7%) were on the left side. Eighteen cases (15.2%) presented with irreducible hernia; 15 of them were sliding hernia and the other three reduced spontaneously with induction of anesthesia. Overall, sliding hernias with ovary and or fallopian tube were 52 of the 149 hernias (34.8%), ovary alone in 20 (13.5%) hernias. The ovary and fallopian tube (Fig. 1) were present in 23 (15.4%) hernias, whereas fallopian tube alone was present in eight hernias (5.2%) and sliding ovary, tube, and paraovarian cyst (Fig. 2) were present in one case (0.7%). Four hernias presented with strangulated ovaries, for which the following measures were taken: detorsion of the ovary, and introduction of hot fomites over the ovary, followed by a wait for 10–15 min to see whether the color of the ovary

Table 1

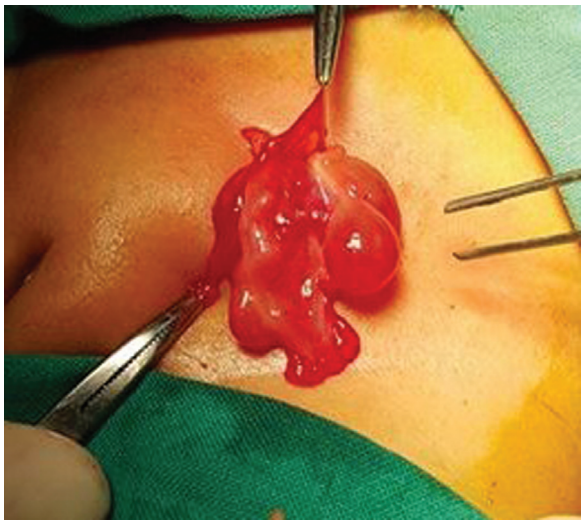
Hernia	Number	Percentage
Bilateral	31	26.2%
Right	52	44.1%
Left	35	29.7%
Irreducible	18	15.2%
Strangulation	4	2.6%
Sliding hernia	52	34.8%
Sliding ovary	20	13.5%
Sliding ovary and tube	23	15.4%
Sliding ovary, tube and paraovarian cyst	1	0.7%
Sliding fallopian tube	8	5.2%

Figure 1



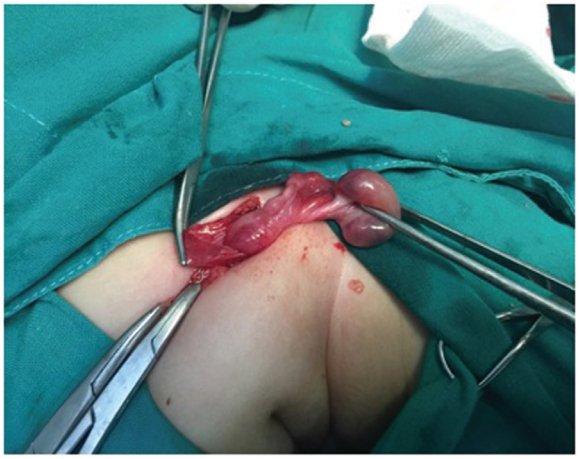
Hernia with sliding ovary and tube.

Figure 2



Opening the hernia sac, sliding ovary, fallopian tube, and paraovarian cyst.

Figure 3

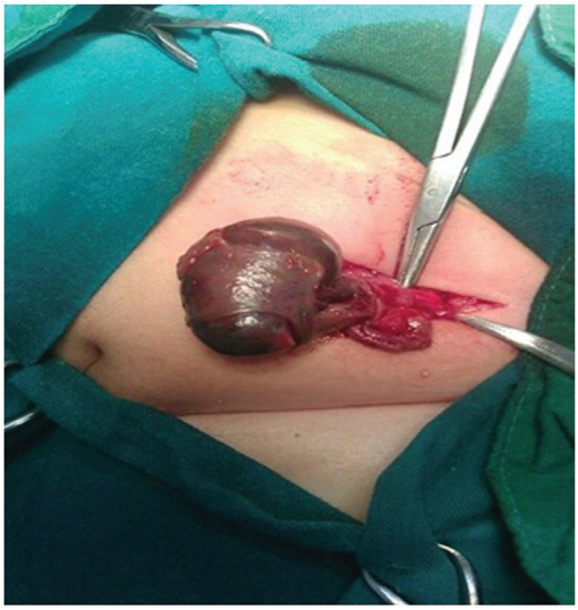


Strangulated ovary that improved and then reduced to the abdomen.

improved or not; if improved, it was preserved, but if not, we made an incision in the ovarian tissue to assess for bleeding, but if no bleeding occurred and necrotic tissue was revealed, gangrenous ovary was verified and oophorectomy was carried out. Two patients with strangulated ovaries improved after the previous measures and reduced to the pelvis (Fig. 3), whereas the other two cases had to undergo oophorectomy due to gangrenous ovary (Fig. 4).

In all cases with sliding ovaries and fallopian tubes, the ovaries and tubes were carefully dissected with combining sharp and blunt dissection and returned to the pelvis. Difficulty in dissecting the ovary from the wall of the hernia was encountered in five cases. A U-shaped incision including the sliding part of the wall of the hernia that was reduced to the pelvis and a purse

Figure 4



Case with strangulated gangrenous ovary that underwent oophorectomy.

string suture were applied at the neck of the hernia sacs and tied under direct vision, following which the sacs were reduced to the pelvis. The postoperative course was uneventful for all children and they were discharged within 24 h of surgery. Follow-up ranged from 6 months to 2 years (mean=12±5.2 months), with no recurrence and no complaints reported from the patients' relatives.

Discussion

The diagnosis of congenital inguinal hernia in children, especially when containing an ovary in female infants, is usually based on the history taking and physical examination [11]. However, when the diagnosis of inguinal hernia is unclear, further diagnostic evaluation is necessary. Because ultrasonography is a relatively straightforward and accessible diagnostic procedure, it is advised to be performed in all cases, especially when an atypical inguinal hernia is suspected in a female child, because unexpected reproductive structures that require prompt surgical intervention may be involved [12].

In general, the standard goal of the repair of congenital inguinal hernias in children is definitive closure of the patent processus vaginalis. However, in female children, ovaries and fallopian tubes are occasionally found as sliding hernias, where they form part of the wall of the hernia sac [8], and injury to the fallopian tube with tubal occlusion has been reported after inguinal hernia repair in female children [13].

The mechanism responsible for the development of inguinal hernias with sliding ovary and tube is regarded as being homologous to the normal descent of the testis in male children [14]. During the development of male fetuses, each testis is anchored to the groin by a well-developed gubernaculum, whereas in female fetuses the gubernacula is attached to the uterus [15].

The caudal part of the gubernaculum in females forms the round ligament, which extends from the uterus through the inguinal canal and to the labia majora, and the cranial part forms the ovarian suspensory ligament. The processus vaginalis descends into the labia majora with the round ligament [14,16].

Associated injury to fallopian tubes and ovaries during herniotomy in young girls is alarming. This has been attributed to the high number of female sliding hernias with vital reproductive organs, particularly ovary and fallopian tube, and in some reports the uterus may be involved in the hernia [5,9]. In this study of the 149 hernias, whose contents were inspected, 52 (34.8%) hernias were found to contain sliding ovary and fallopian tube in different combinations, including one case with paraovarian cyst; therefore, nearly one-third of the hernias contained sliding female reproductive organs, and therefore it was mandatory to open the sac in all cases as some surgeons tend to twist the sac with ligation without opening the sac with the possibility of injuring the ovary or the tube, which results in tubal ligation – as reported in some studies [7]. Osifo and Ovueni [6] reported in their study that, out of 176 hernias, 145 (82.4%) were found to contain ovary and fallopian tube, which is a very high percentage in comparison with that obtained in the present study.

The ovaries and the fallopian tubes are thought to be at an increased risk for injury by unwary surgeons during inguinal hernia repair in female children – at a higher risk than what is expected. Damage to female reproductive structures during herniotomy is an unusual cause of infertility, and there have been only a few case reports in the literature on this [8]. Damage to female reproduction organs during herniotomy is rare, but its actual incidence may be underestimated, and, also, cases of unilateral fallopian tube damage may be underreported, because some of the women may have normal fertility [17].

In this study, four cases presented with strangulated ovaries: two of them were rescued, but the remaining two were resected due to irreversible gangrene. Therefore, surgery should not be delayed and carried out as soon as possible as an elective case under the best circumstances.

Conclusion

The presence of sliding ovary and fallopian tubes is not an uncommon finding: it is found in nearly one-third of congenital inguinal hernia in female children. Therefore, from a clinical point of view, it is of utmost importance to keep this fact in mind while dealing with the hernia sac. Ligation of the sac without opening should be avoided. The hernia sac should be opened in all cases to exclude the presence of sliding ovary and tube, and if present, the sliding ovary and tube should be carefully dissected and reduced to peritoneal cavity before ligation of the sac to avoid their injuries. In addition, it is recommended that surgery should not be delayed to avoid strangulation of the ovary.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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Evaluation of the laparoscopic versus the open approach in patients with complicated appendicitis

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Context
Open appendectomy is the standard procedure for complicated appendicitis and is associated with an increased incidence of postoperative complications. Recently, laparoscopic approach for complicated appendicitis has been gaining ground against the open approach. Some studies still favor the open approach while others advocate the laparoscopic approach.
Aim
The present study aimed to compare the laparoscopic approach with the open approach in the management of patients with complicated appendicitis, and their postoperative complications.
Settings and design
This was a prospective, randomized, comparative study.
Patients and methods
Eighty-eight patients were included in the study and were divided into the laparoscopic group (33 patients) and the open group (55 patients). Each group was further divided into five subgroups according to the operative findings. All patients were monitored for early and late postoperative complications and followed up in the outpatient clinic for 6 months.

The operative time, rate of conversion, drain application, early and late complications, frequency of analgesia, time to start oral feeding, length of hospital stay, and time of returning to normal daily activity were all recorded.
Statistical analysis
Continuous variables were expressed as mean and SD. Categorical variables were expressed as frequencies and percentage.
Results
The open group showed less operative time. Patients in the laparoscopic group needed less analgesia, with early return of the bowel habits and early start of oral feeding. They also had shorter hospital stay and early return to the normal activities. The laparoscopic group had less postoperative complication in comparison with the open group.
Conclusion
The laparoscopic appendectomy was found to be better in comparison with the open approach as it involved less postoperative pain, shorter hospital stay, and fewer postoperative complications in addition to the possibility of exploring the whole abdomen.

Keywords:
laparoscopic appendectomy, open appendectomy, postappendectomy complications

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1110-1121

Introduction

Appendicitis was described for the first time as a disease in the 16th century and was known as perityphlitis [1]. Open appendectomy was the standard procedure; however, laparoscopic appendectomy, which was first reported by Semm [2], has been considered as safe as open appendectomy. Meanwhile, appendicitis complicated by perforation, pus collection, gangrene or abscess formation comprise about 20–30% of the appendicitis cases and is associated with increased incidence of postoperative complications such as surgical site infections and intra-abdominal pus collection [3]. In the recent years, laparoscopic approach for complicated appendicitis has been gaining ground in the face of the open approach but with more complications such as intra-abdominal pus collection [4]. Some studies still favor the open approach [5,6] while others advocate the laparoscopic approach [7,8].

This study aimed to compare the laparoscopic approach with the open approach in the management of patients

with complicated appendicitis, and also their post-operative complications.

Patients and methods

The study was conducted over a period of 30 months from November 2012 to April 2015. It involved the patients presenting at the emergency room who were suspected clinically of having complicated appendicitis, which was later confirmed by using ultrasound or computed tomography scan or both. Patients with noncomplicated appendicitis, generalized peritonitis, history of open abdominal or pelvic operations, and medical conditions that preclude pneumoperitoneum were excluded from the study.

Eighty-eight patients were included in the study and were divided into two groups: group A – the laparoscopic appendectomy group – which included 33 patients; and group B – the open appendectomy group – which included 55 patients. The patients were randomly allocated to the groups based on the fixed admission days. Each group was divided into five subgroups according to the operative findings into the following: subgroup A – appendicular abscess, subgroup B – appendicitis with purulent reaction, subgroup C – gangrenous appendix, subgroup D – appendicular mass, and subgroup E – appendicitis with pelvic abscess.

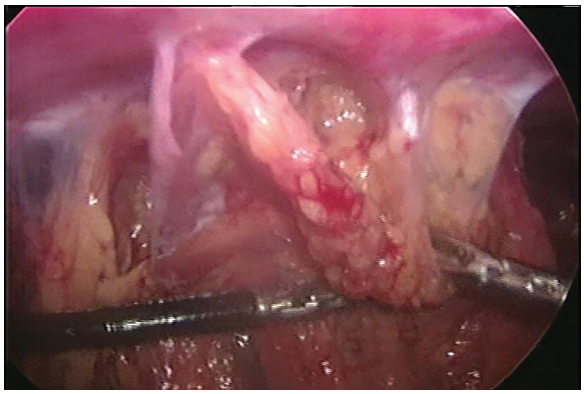
All patients participating in the study signed informed consent, as mandated by the Ethical Committee of the Faculty of Medicine, Ain Shams University.

All patients of both groups received preoperative intravenous third-generation cephalosporins and metronidazole, and, also, Foley's catheter was inserted as needed.

Surgical procedures

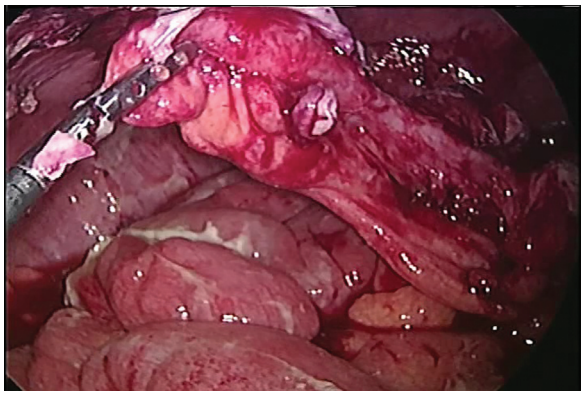
In the laparoscopic group, the pneumoperitoneum was established by using the open technique. Three-port method was carried out where a 10-mm port was inserted at the umbilicus for the 30° camera, a 10-mm port was inserted in the left iliac fossa, and a 5-mm port was inserted in the right subcostal region. An additional 5-mm port might be needed. All patients were supine in Trendelenburg's position, tilted to the left. Any adhesions were dissected to expose the appendix (Figs 1 and 2) and the mesoappendix was secured by ligature, clips (Fig. 3), or bipolar electrocautery, and then the stump of the appendix was secured by a pretied suture loop (Fig. 4) before retrieval of the appendix. The peritoneal cavity was then irrigated by warm saline and aspirated and the process was repeated till the aspirate became clear. A suction drain was left as needed. Open appendectomy was performed my making a McBurney's incision with or without extension or a midline incision. All patients received intravenous third-generation cephalosporins and metronidazole. Analgesics in the form of NSAIDs were administered as required by patients. Intravenous fluids were administered to all patients till return of the

Figure 1



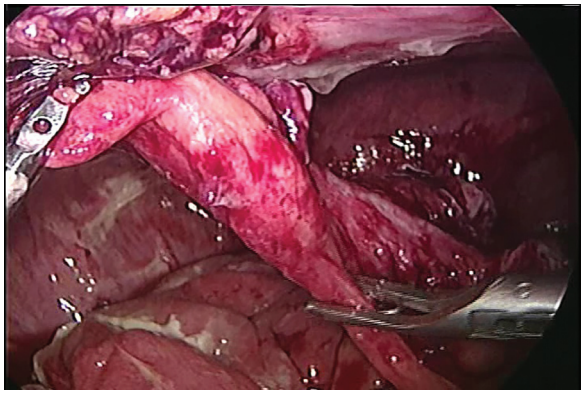
Dissection of adhesions.

Figure 2



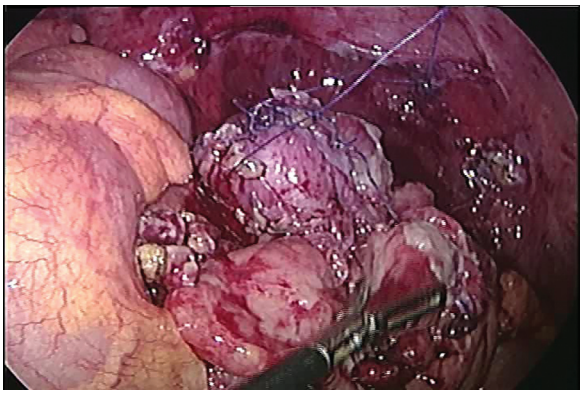
Exposure of the appendix.

Figure 3



Clipping of the mesoappendix.

Figure 4



Appendicular stump after ligation.

bowel function, when oral intake of clear fluids was started. All patients were monitored for early and late postoperative complications and followed up in the outpatient clinic for 6 months.

The operative time, rate of conversion to open approach, drain application, early and late complications, frequency of analgesics administration, time to start oral feeding, length of hospital stay, and time of returning to normal daily activity were all recorded and tabulated for statistical analysis.

Statistical analyses

The collected data were revised, coded, tabulated, and fed into a PC using the statistical package for the social sciences (SPSS 20; SPSS Inc., Chicago, Illinois, USA) software. Data were presented and suitable analyses were carried out according to the type of data obtained for each parameter.

Descriptive statistics

(1) Mean±SD and range for parametric numerical data.
(2) Frequency and percentage of non-numerical data.

Analytical statistics

(1) Student's *T*-test was used to assess the statistical significance of the difference between the mean of the two study groups.
(2) The χ^2-test was used to examine the relationship between two qualitative variables.
(3) Fisher's exact test was used to examine the relationship between two qualitative variables when the expected count was less than 5 in more than 20% of the cells.
(4) ANOVA test was used to assess the statistical significance of the difference between the means of more than two study groups.

Table 1 Sex differences and associated comorbidities among the two groups

	n (%)		χ^2-Test	
	Group A (*n*=33)	Group B (*n*=55)	*P*-value	Significance
Sex				
Male	14 (42.4)	29 (52.7)	0.349	NS
Female	19 (57.6)	26 (47.3)		
Comorbidity	26 (78.8)	40 (72.7)	0.525	NS

The *P*-value for sex difference between the two groups was 0.349, which was statistically nonsignificant. The *P*-value for associated comorbidities between the two groups was 0.525, which was statistically nonsignificant.

(5) Post-hoc test was used for comparisons of all possible pairs of group means.

Results

Patients' demographics

The sex distribution and associated comorbidities are represented in Table 1.

Operative findings

Each group was further subdivided into five subgroups according to the operative findings: subgroup A – appendicular abscess (localized peritonitis), subgroup B – appendicitis with periappendicular pus collection, subgroup C – gangrenous appendix, subgroup D – appendicular mass, and subgroup E – appendicitis with pelvic abscess (diffuse peritonitis with pus collection in the pelvis). The statistical distribution of operative findings among the groups and subgroups is presented in Table 2.

Operative time

The mean operative time for group A was 110.91± 19.50 min (range: 65–160 min), whereas in group B it was 88.09±28.16 min (range: 45–145 min), with a *P*-value of less than 0.001 by *t*-test, which was statistically significant.

The operative times among the subgroups in group A and B are demonstrated in Table 3.

Rate of conversion

The rate of conversion from the laparoscopic approach to open approach was 6% (two cases). One (14.2%) case with appendicular mass was converted to open approach by midline incision due to extensive adhesions, and one (10%) case with gangrenous appendix was converted to open approach by McBurney's incision due to gangrenous base with friable cecum that required trimming of the base with closure by interrupted suture and application of onlay omental patch.

Table 2 Case distribution according to the operative finding among the two groups

	n (%)		Fisher's exact test	
	Group A (*n*=33)	Group B (*n*=55)	*P*-value	Significance
Operative finding				
Appendicular abscess	4 (12.1)	7 (12.7)	0.922	NS
Appendicitis with periappendicular pus collection	2 (6.1)	7 (12.7)		
Gangrenous appendix	10 (30.3)	15 (27.3)		
Appendicular mass	7 (21.2)	11 (20.0)		
Appendicitis with pelvic abscess	10 (30.3)	15 (27.3)		

The *P*-value for the operative finding among the two groups was 0.922 by Fisher's exact test and was considered to be statistically nonsignificant.

Drain application

The rate of drain application was 27.3% (nine cases) in group A, whereas it was higher in group B, reaching 38.2% (21 cases), and yet with a *P*-value of 0.296, which was statistically nonsignificant.

In group A, cases with appendicitis with periappendicular pus collection (subgroup B) and appendicular mass (subgroup D) did not need drain application in comparison with group B where two (28.6%) cases with appendicitis with periappendicular pus collection (subgroup B) and four (36.4) cases with appendicular mass (subgroup D) had drains applied.

The rate of drain application among the subgroups is demonstrated in Table 4.

Use of analgesia

The frequency of the use of analgesia was recorded for both groups. For group A, the mean number for need of analgesia (mean±SD) was 4.09±1.96 times, whereas in group B, it was 5.18±2.03 times. The *P*-value for the use of analgesia was 0.015, which was statistically significant.

The use of analgesia among the subgroups is shown in Table 5.

Oral feeding, hospital stay, and return to normal activity

In group A, the mean time for starting of oral feeding was 21.45±14.22 h, whereas in group B, it was 32.04±20.9 h, with a *P*-value of 0.012, which was statistically significant.

In group A, the mean time for hospital stay was 3.03±2.01 days, whereas in group B, it was 4.69±3.07 days, with a *P*-value of 0.003, which was statistically significant.

Table 3 Operative time (min) among the different subgroups in groups A and B

	Appendicular abscess	Appendicitis with periappendicular pus collection	Gangrenous appendix	Appendicular mass	Appendicitis with pelvic abscess	ANOVA	
						P-value	Significance
Group A (mean±SD)	75±23.8	85±7.07	76.5±20.96	82.86±20.59	71±16.12	0.744	NS
Group B (mean±SD)	99.29±23.88	62.14±26.59	58.67±25.25	90.45±26.59	65.67±23.82	0.002	S

There was no statistically significant difference among the different subgroups in group A as the *P*-value by ANOVA test was 0.744, whereas in group B, *P*-value by ANOVA was 0.002, as there was a statistically significant difference in subgroup A (appendicular abscess) and subgroup C (appendicular mass) against the other subgroups by using the post-hoc test. S, significant.

Table 4 Rate of drain application among the subgroups

	Group A (*n*=33) [*n* (%)]	Group B (*n*=55) [*n* (%)]
Drain application		
Appendicular abscess	4 (100)	7 (100)
Appendicitis with periappendicular pus collection	0 (0)	2 (28.6)
Gangrenous appendix	2 (20)	3 (20)
Appendicular mass	0 (0)	4 (36.4)
Appendicitis with pelvic abscess	3 (30)	5 (33.3)

In group A, the mean time for returning to physical activity was 17.42±8.31 days, whereas in group B, it was 27.95±10.79 days, with a *P*-value of 0.000006, which was statistically significant.

Early and late complications

The incidence of early and late complications is shown in Table 6. In group A, four (12.1%) patients had early postoperative complications and one (3%) patient (that was converted from laparoscopic to open approach due to gangrenous base) had late postoperative complications, whereas in group B, 14 (25.4%) patients had early postoperative complications and five (9%) patients had late postoperative complications. The overall incidence of postoperative complications was five (15.1%) patients in group A and 19 (34.5%) patients in group B. The *P*-values for early complications and for late complications were more than 0.05, which were statistically nonsignificant.

Discussion

Surgeons have recommended the use of laparoscopy for appendectomy; however, the benefit for its use in complicated appendectomy is still controversial [5,9–11]. There has been lack of adequate evidence supporting the use of laparoscopy for the management of complicated appendicitis [12]. Some studies have shown almost equivalent results of the two approaches in respect to morbidity and mortality [13]; many studies clarified significant advantages of the laparoscopic approach, such as less postoperative pain, shorter hospital stay [14–16], chance of exploration of the peritoneal cavity, ease of suction irrigation under vision, and better cosmetic results [17].

In this study, there was no statistical significance between the two groups regarding the sex difference or associated comorbidities. Each group was divided into five subgroups according to the operative findings. The laparoscopic group included 33 patients. Of them, four (12.1%) patients had appendicular abscess, two

Table 5 The use of analgesia among different subgroups

Analgesia (times)	Appendicular abscess	Appendicitis with periappendicular pus collection	Gangrenous appendix	Appendicular mass	Appendicitis with pelvic abscess	ANOVA	
						P-value	Significance
Group A (mean±SD)	5.75±2.06	3±0	3.4±1.43	4.43±3.15	4.1±1.2	0.302	NS
Group B (mean±SD)	7.43±2.07	3.71±0.49	4.27±1.62	6.09±1.76	5.07±1.98	<0.001	S

There was no significant difference among the subgroups in group A as the *P* value by ANOVA test was 0.302, whereas in group B, there was a statistically significant difference in subgroup A (appendicular abscess) against subgroups B, C, and E and in subgroup D (appendicular mass) against subgroup B and C by using the post-hoc test. S, significant.

Table 6 Distribution of early and late complications among the two groups

	Group A [*N* (%)]	Group B [*N* (%)]
Early complication		
Chest infection	2 (6)	0 (0.0)
Intestinal obstruction	0 (0.0)	1 (1.8)
Pelvic collection	0 (0)	1 (1.8)
Prolonged ileus	1 (3)	3 (5.4)
Prolonged ileus+burst	0 (0.0)	1 (1.8)
Surgical site infection	1 (3)	8 (14.5)
Late complication		
Incisional hernia	1 (3)	3 (5.4)
Intestinal obstruction	0 (0.0)	2 (3.6)

(6.1%) patients had acute appendicitis with periappendicular pus collection, 10 (30.3%) patients had gangrenous appendix, seven (21.2%) patients had appendicular mass, and 10 (30.3%) patients had appendicitis with pelvic abscess. The open group included 55 patients. Of them, seven (12.7%) patients had appendicular abscess, seven (12.7%) patients had acute appendicitis with periappendicular pus collection, 15 (27.3%) patients had gangrenous appendix, 11 (20%) patients had appendicular mass, and 15 (27.3%) patients had appendicitis with pelvic abscess. There was no statistical difference between the two groups as regards the operative findings, with a *P*-value of more than 0.05.

The open group involved lesser operative time than did the laparoscopic group, as the mean operative time for the laparoscopic group was 110.91±19.50 min (range: 65–160 min), whereas for the open group, it was 88.09 ±28.16 min (range: 45–145 min), with a *P*-value of less than 0.001 by *t*-test, which was statistically significant. Similar results were obtained by Quezada *et al.* [18] with longer operative time for the laparoscopic group. This may be attributed to the time taken for the peritoneal lavage and securing the appendicular stump [19,20]. The rate of conversion was two out of 33 patients, reaching 6%, which was within the range compared with other studies [3,18]. There was no significant difference between the subgroups of the two groups regarding the need for drain application, except for the patients with appendicitis with periappendicular pus collection and the patients with appendicular mass in the laparoscopic group. This was due to the ability of the laparoscope to explore all parts of the abdominal cavity with easy lavage and suction of the purulent exudates alleviating the need for drain application in these patients.

Patients in the laparoscopic group needed less analgesia [21,22] as the *P*-value was 0.015, with early return of the bowel habits and early start of oral feeding (21.15 vs. 32.04 h, *P*=0.012) in comparison with the patients of the open group. They also had shorter hospital stay [19] (3.03 vs. 4.69 days, *P*=0.003) and early return to the normal activities (17.42 vs. 27.95 days, *P*=0.000006) compared with the patients in the open group.

Regarding the postoperative complications, the laparoscopic group had two patients with chest infection (6%), whereas no patients had chest infections in the open group. This was probably related to the general condition of the patients (as both of them affected in the laparoscopic group were heavy smokers) rather than to the approach carried out. No patients in the laparoscopic group had intestinal obstruction, whereas in the open group, one (1.8%) patient had intestinal obstruction in the early postoperative period due to fibrinous adhesions, and two (3.6%) patients had adhesive intestinal obstruction after 17 and 19 weeks, respectively. This can be attributed to the fact that the laparoscopic approach was more exploratory than the open approach and was able to dissect adhesions made by inflammatory processes compared with the open approach, and also to the fact that the absence of the large abdominal wall wounds prevents the intestine from adhering to the wound scar, which occurred with the open approach [23]. No patients suffered from postoperative collection in the laparoscopic group compared with one (1.8%) patient in the open group, with no statistical significance [24–26]. Only one patient had prolonged ileus more than 48 h in the laparoscopic group, whereas in the open group, three patients had prolonged ileus more than 48 h and one patient had prolonged ileus that remained for four days with distension that was complicated by burst requiring closure by secondary sutures. In the laparoscopic group, one (3%) patient had surgical site infection, whereas in the open group, eight (14.5%) patients had surgical site infection; similar results have been reported in other series [20–22]. In the laparoscopic group, one (3%) patient had incisional hernia after conversion to open approach, whereas in the open group, three (5.4%) patients had incisional hernia. This emphasizes the advantage of the laparoscopic approach in preventing the surgical site infection [27] and incisional hernia in septic operations as in complicated appendicitis.

Conclusion

The laparoscopic appendectomy is considered to be superior in comparison with the open approach as it involves less postoperative pain, shorter hospital stay, and fewer postoperative complications in addition to the possibility of exploring the whole abdomen without the need for midline incision.

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Nil.

Conflicts of interest
There are no conflicts of interest.

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Sacrococcygeal pilonidal sinus: modified sinotomy versus lay-open, limited excision, and primary closure

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Context
Pilonidal sinus PNS is a common condition. Although many methods for treatment are available, there is no consensus on the optimal treatment.
Aim
The aim of this study was to compare the results of a modified sinotomy method with those of lay-open, limited excision, and primary closure with and without a drain in the management of a PNS.
Settings and design
This is a prospective randomized comparative study.
Patients and material
Fifty-eight patients undergoing surgery for primary PNS were enrolled. The patients were randomized into three groups: group A (17 patients) underwent modified sinotomy; group B (22 patients) underwent lay-open, limited excision, and primary closure with a drain; and group C (19 patients) underwent the same procedure as group B but without a drain. Each patient was followed up for 24 months.
Statistical analysis
Continuous variables were expressed as mean±SD. Categorical variables were expressed as frequencies and percentage.
Results
Significantly short operative time was recorded in the modified sinotomy group. Postoperative wound complications occurred in 5.9% of patients in group A, in 31.8% of patients in B, and in 21.1% of patients in group C. Significantly short time was recorded between the completion of the procedure and the patient being able to walk, sit, and sit on a toilet comfortably, as well as be able to return to work, in group A; however, the healing duration was significantly longer. Visual analogue scale score showed significantly less pain in group A. Complete wound healing occurred in all patients in groups B and C, but one patient in group A developed failure of healing. Recurrence rate was a slightly higher in group B but with no statistical significance.
Conclusion
The modified sinotomy technique for treatment of PNS is superior to excision with primary closure either with or without a drain with respect to operative time, hospital stay, comfort in walking, sitting, and sitting on the toilet, return to work, and visual analogue scale scores for pain, although the healing time is longer.

Keywords:
lay-open, pilonidal sinus, primary closure, sacrococcygeal, sinotomy

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Introduction

Sacrococcygeal pilonidal sinus (PNS) is a common condition usually affecting young-to-middle-aged men. Its pathophysiology is uncertain as it has been commonly thought to be embryonic; however, nowadays it is commonly thought to be acquired [1]. PNS is due to hair penetration into the skin of the gluteal cleft that causes a cyst and sinus formation because of reaction to a foreign object, resulting in secondary infections and abscess formation [2]. Risk factors include adiposity, sedentary lifestyle, local irritation-trauma, insufficient body hygiene, excessive hair, and perspiration [3].

Many methods are available for surgical and non-surgical treatment of PNS [4]. PNS is usually treated by wide excision. After excision, the wound may be left open to heal with granulation tissue [5], or may be immediately closed with a midline closure [6] or by using a flap (Z-plasty [7], Karydakis [8], Bascom [9], or Limberg [10] flaps). However, there is not yet a consensus on the optimal treatment. Recurrence after

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any surgical procedure is not uncommon, reaching up to 20% or more [11].

The ideal management for PNS should be simple, cause minimal pain, have the best chance for success and the least recurrence rate with a low risk for complications and rapid return to work [12]. The aim of this study was to compare the results of modified sinotomy against those of lay-open, limited excision and primary closure with and without a drain in the management of a PNS.

Patients and methods

This prospective randomized trial was conducted over a period of 48 months from May 2012 to March 2016. Fifty-eight patients undergoing management of their primary PNS were enrolled. They were selected on the basis of age (17–40 years old), BMI (20–29.9 kg/m^2), and number of sinuses (≤5 midline sinuses). If the sinus was not located midline, it was ensured that there was only one sinus and that the sinus was not more than 2 cm away from the midline. Obese patients and those with infected and recurrent PNS were excluded from the study, as well as patients with chronic medical conditions affecting the healing process. The first 24 months of the study was divided into three equal periods (8 months each) at which patients were randomized into three groups: group A (17 patients) underwent modified sinotomy; group B (22 patients) underwent lay-open, limited excision and primary closure with a drain; and group C (19 patients) underwent the same procedure as group B but without a drain. Each patient was followed up for 24 months.

Data extracted for analysis included demographic details, duration of symptoms, operative time, duration of hospital stay, postoperative comfort in walking, sitting and sitting on the toilet, visual analogue scale (VAS) for pain at days 1 and 5, healing time, healing failure, return to work, and recurrence rate.

Surgical techniques

General consideration

After obtaining informed consent from the participating patients, they were prepared preoperatively with intravenous 500 mg metronidazole and 1 g ceftriaxone 20 min before the procedure. Shaving of the operation area and evacuation enema were done a few hours before the procedure. Spinal anesthesia was adopted in most of the cases, according to patient preference, but general or local anesthesia with sedation was also used in some cases. During the operation, the patient was placed in the prone position with the pelvis elevated with a pillow. An adhesive tape was used to strap the buttocks apart for proper exposure of the sinus area, which was disinfected with 10% povidone–iodine.

Group A (modified sinotomy)

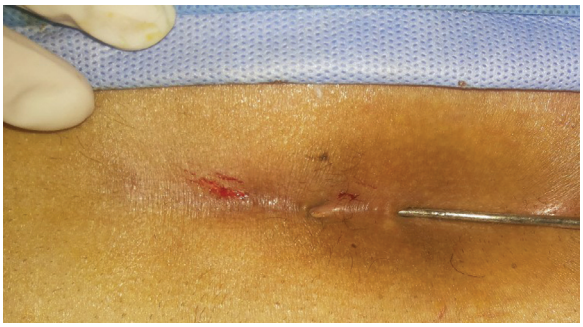
After identification of the main sinus orifice, it was probed (Fig. 1) and the main track was laid open (Fig. 2). Any cysts or hair tufts were removed, followed by curettage of the infected granulation tissue and debris. The modification adopted here is that the skin carrying the sinus openings was excised with partial excision of the lateral wall of the main sinus track (Fig. 3a and b).

Using a magnifying surgical loop and suction instrument, any side track was identified, laid open, and curetted. The whole cavity was then washed with H_2O_2 and 10% povidone–iodine and irrigated with saline (Fig. 4). Meticulous hemostasis and packing with good compression was achieved. The wound was dressed every day for 3 days. Thereafter, healing-promoting local applicants (sitosterol 0.25% as the main active ingredient) were used until complete healing was achieved.

Group B (primary closure with drain)

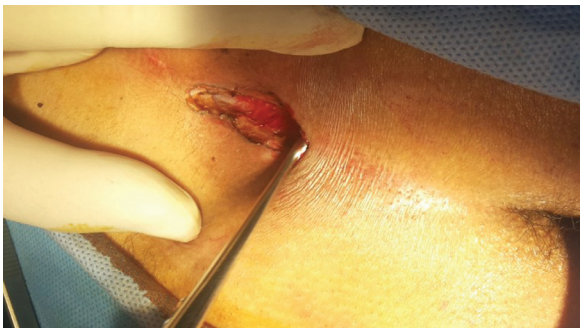
Group B patients underwent the same procedure as those of group A, but after laying open (Fig. 5) the

Figure 1



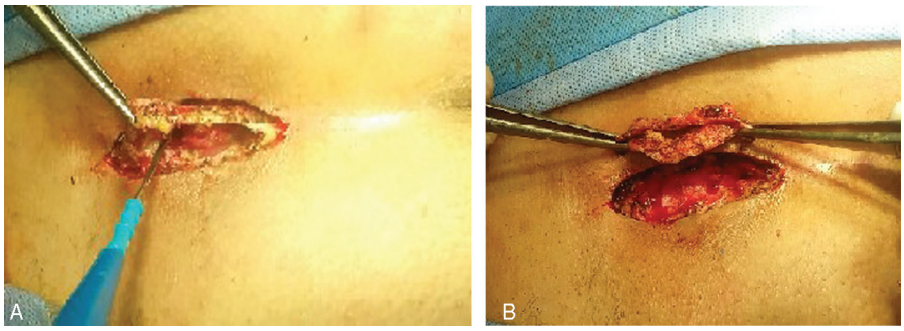
Probing of pilonidal sinus.

Figure 2



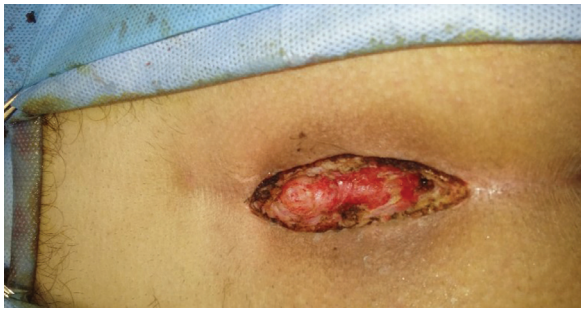
Lay-open and curettage.

Figure 3



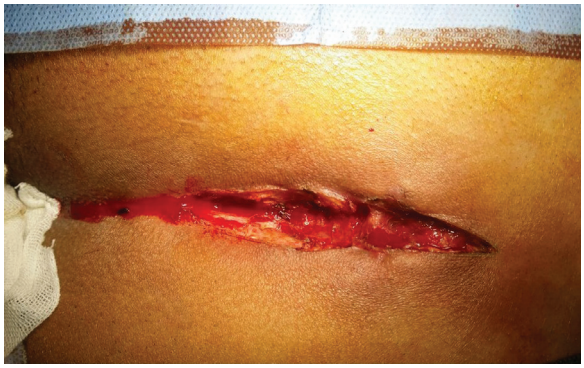
(a, b) Excision of the edge of the wound together with the upper part of the sinus wall.

Figure 4



Sinotomy is completed.

Figure 5



Lay-open.

main and side tracks were excised (Fig. 6a and b) with minimal tissue removal (sinectomy) to achieve a tension-free closure. Thus, there was no need to reach the postsacral fascia.

Closure in layers was achieved starting from the deepest part of the wound using a polyglactin 910 2/0 rounded needle. Then a suction drain 12 was put at the subcutaneous area to be removed within 48–72 h (Fig. 7). Subcutaneous closure with polyglactin 910 2/0 and skin closure was done (Fig. 8) using polypropylene 3/0 followed by compression dressing, which was changed after 48–72 h and then every other day.

Group C (primary closure with no drain)

Group C patients underwent the same procedure as group B patients but subcutaneous and skin closure was accomplished without a drain.

Postoperative

Antibiotics and analgesics were needed for groups B and C postoperatively for 5 days, followed by administration of analgesics on demand, whereas analgesics were used on demand in patients in group A with no need for antibiotics.

All patients were followed up for 24 months postoperatively (at 3, 6, 12, 18, and 24 months) by attendance or by phone. Patients in group A were seen weekly until complete healing of the wound, whereas patients in groups B and C were seen weekly at the first postoperative month. The drain was removed from group B patients within 48–72 h postoperatively to make sure that there were no wound complications. Removal of sutures was done at 2–3 weeks. If there were any wound complications, sutures were removed and the wound was dealt with as the open method until complete healing. If no healing occurred despite careful wound dressing, this was considered as healing failure. Disease recurrence was considered after the disease-free interval following complete healing.

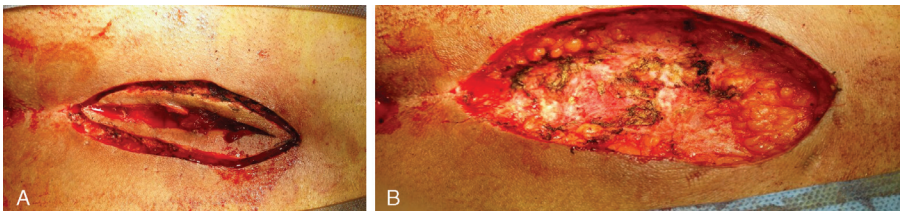
Statistical analysis

Statistical analysis was carried out using SPSS 20 (SPSS Inc., Chicago, Illinois, USA). Mean±SD was used for presenting numerical data. The Fisher exact test, χ^2-test, ANOVA test, and post-hoc test were selectively used according to the data. Statistical significance was considered at P value less than 0.05.

Results

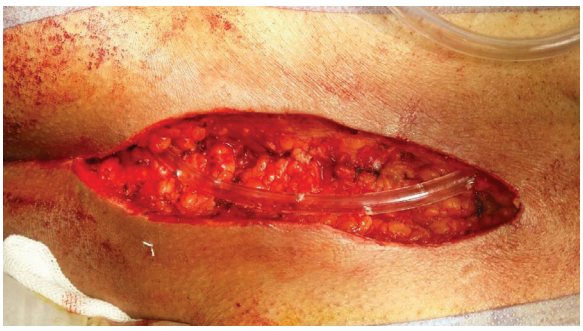
This study included 58 patients who underwent surgical management for their primary PNS at the Department

Figure 6



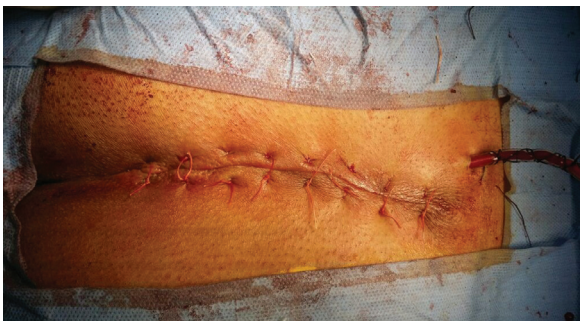
(a, b) Excision of the sinus.

Figure 7



Primary closure with suction drain.

Figure 8



Skin closure.

of General Surgery at Ain Shams University Hospitals over a period of 48 months from May 2012 to March 2016. Thirty-nine (67.2%) patients were male and 19 (32.8%) were female. Their ages ranged from 17 to 40 years with a mean±SD of 25.43±7.02 years. All patients complained of symptoms of PNS (pain and discharge) for 10–30 months, with a mean±SD of 17.66±4.71 months (Table 1).

The mean operative time was 23.12±4.12 min in group A, 34.68±4.12 min in group B, and 35.58±4.69 min in group C, with significantly short operative time in the sinotomy operation group in comparison with the other two groups.

As regards the postoperative complications, one (5.9%) patient in group A developed postoperative bleeding, which needed hemostasis in the operating room with compression, and seven (31.8%) patients in group B developed wound complications in the form of infection in four patients, hematoma in one patient, and discharge in the other two. In group C, four (21.1%) patients showed wound complications in the form of discharge in three patients and infection in one patient. In wound infection, the sutures were removed to open the wound. The wound hematoma that developed in one patient was evacuated in the operating room with hemostasis to be closed again while discharge from the wound was managed conservatively. The hospital stay was significantly shorter among patients in group A in comparison with groups B and C, as shown in Table 2.

There was a significantly short time to comfortable walking, sitting, sitting on the toilet, healing, and time to return to work postoperatively in group A. However, the healing duration was significantly longer in group A when compared with the other two groups. VAS scores for pain on the first and fifth postoperative days showed significantly less pain in group A.

Complete wound healing occurred in all patients in groups B and C, including complicated wounds, whereas one patient in group A developed failure of healing of his wound. The recurrence rate was higher in group B [5.9% (n=1), 18.2% (n=4), and 5.3% (n=1) in groups A, B, and C, respectively].

Discussion

Many techniques have been advocated for the surgical management of PNS. They are classified basically into two groups: total excision of the sinus followed by either leaving the wound open for secondary healing or its primary closure with techniques ranging from simple suturing to the numerous complex methods for coverage. However, recurrence is still an important problem and its optimal management remains controversial [13].

In the present study, there was a remarkable male predominance in the three groups; however, the

Table 1 Demographic data and duration of symptoms of patients in the three groups

	Group A (*N*=17)	Group B (*N*=22)	Group C (*N*=19)	ANOVA test	
				P value	Significance
Age (mean±SD) (years)	26.18±7.03	25.36±7.23	24.84±7.10	0.854	NS
Sex [*n* (%)]					
Male	12 (70.6)	15 (68.2)	12 (63.2)	0.877*	NS
Female	5 (29.4)	7 (31.8)	7 (36.8)		
Symptom duration (mean±SD) (months)	16.74±3.59	17.14±4.94	19.32±5.09	0.158	NS

*χ^2-Test.

Table 2 Postoperative clinical outcomes in the three groups

	Group A (N=17)	Group B (N=22)	Group C (N=19)	Post-hoc test[a]	
				P value	Significance
Operative time (min)	23.12±4.12	34.68±4.12	35.58±4.69	<0.001	S
Hospital stay (days)	0.23±0.08	2.09±1.09	1.50±0.53	<0.001	S
Walking (days)	2.24±0.36	15.23±1.63	15.32±1.60	<0.001	S
Sitting (days)	0.73±0.31	7.82±1.05	7.89±1.10	<0.001	S
Toilet sitting (days)	1.71±0.40	5.82±0.85	5.74±0.93	<0.001	S
Wound healing (days)	30.81±3.12	17.27±4.81	17.74±5.16	<0.001	S
Return to work (days)	4.12±0.52	19.82±3.69	19.68±3.15	<0.001	S
VAS score first day	4.71±1.16	6.86±1.49	6.21±1.18	<0.001	S
VAS score fifth day	2.71±1.16	3.82±1.50	3.79±1.44	<0.001	S

S, significant; VAS, visual analogue scale. [a]Post-hoc test: A versus B (S), A versus C (S) and B versus C (NS).

distribution of sex did not differ significantly between the three groups (70.6, 68.2, and 63.2%, respectively). The duration of symptoms varies between 24 and 50 months in the literature [14,15]. In the present study, the mean duration of symptoms did not differ between the three groups (16.74, 17.14, and 19.32 months for groups A, B, and C, respectively).

Prophylactic antibiotic use in the surgical treatment of PNS is still controversial. Some authors do not recommend antibiotics in view of the fact that preoperative bacterial isolates, usually anaerobes, in chronic PNSs do not affect the complication rate, because bacterial isolates from infected wounds are mostly aerobes [16]. However, others advocate a single dose of metronidazole [17]. Other studies concluded that prophylactic antibiotics seem to be unnecessary in patients undergoing the lay-open technique, while prophylaxis may be helpful to prevent infectious complications during excision with primary closure [18]. In our study, single doses of ceftriaxone and metronidazole were used pre-operatively in all patients in the three groups to achieve standardization, whereas antibiotics were used only in groups B and C (wound closure). No wound infection was observed in patients who underwent modified sinotomy (group A), whereas five patients had wound infection following excision with primary closure (groups B and C), supporting the hypothesis that type of surgical intervention may affect the rate of wound infection more than the use of antibiotic prophylaxis.

The modified sinotomy technique has an advantage of being simple, with short operative time as recorded in our study (23.12 min) compared with closure techniques (34.68 and 35.58 min in groups B and C, respectively).

The spectrum of postoperative wound complications varies according to the type of surgery. Leaving the wound open may result in early bridging or chronic nonhealing, whereas the primary closure technique increases the risks for hematoma, seroma, and infection. In the present study, complications developed in one (5.9%) patient who underwent modified sinotomy compared with 11 (26.8%) patients who underwent primary closure either with or without a drain. We experienced healing failure in one patient in group A. The reported complication rates following excision with primary closure vary markedly. In a randomized study comparing excision and primary suture with excision and open packing in 120 patients, Khaira and Brown [19] showed that the early complication rate was significantly lower in the former technique (27 vs. 38%). In contrast, Perruchoud *et al.* [20] compared excision and open granulation with excision and primary closure and found a primary healing failure rate of 9% following primary closure.

The mean duration of hospital stay in excision and primary closure techniques reported in previous studies was 4–5 days [21,22]. In our study the mean hospital

stay was significantly shorter in group A (0.23 day) compared with groups B and C (2.09 and 1.5 days).

Healing time is generally longer in techniques involving secondary healing than in techniques with primary closure in the absence of wound complications. In the present study, the mean healing time was longer in group A (30.81 days) than in groups B and C (17.27 and 17.74 days), similar to many previous reports [20,23]. The patients undergoing modified sinotomy were encouraged to return to work as early as possible. The mean time before return to work was significantly shorter in this group (4.12 days) compared with the other two groups (19.82 and 19.68 days). Although the healing time is longer following the modified sinotomy technique, the minimal wound care required after the first postoperative week did not undermine the quality of life of the patients [13]. On the other hand, our results seem to be in discordance with those of Perruchoud *et al.* [20], who reported an average healing time of 72 days and an average time before return to work of 38 days in patients who had undergone total excision and open granulation compared with 23 and 21 days, respectively, after excision and primary closure. Similarly, Fuzun *et al.* [24] reported that the time to return to work was significantly shorter following total excision with primary closure compared with that after total excision and secondary healing.

The use of suction drains following excision with primary closure is still controversial. Serour *et al.* [25] recommended routine use of suction drainage with primary closure, whereas Tritapepe and Di Padova [26] used the drain to flush the residual cavity with an antiseptic solution. On the other hand, Erdem *et al.* [27] found no additional benefit from the use of drains. In the present study, the use of suction drainage in patients in group B showed a recurrence rate that was higher (18.2%) compared with that in groups A and C (5.9 and 5.3%, respectively).

In our study, the quality of life of the patients who underwent modified sinotomy (group A) was much better than that of the other two groups in terms of time to comfortable walking, sitting, sitting on the toilet, healing, time to return to work, and VAS score for pain on the first and fifth day postoperatively. This was in accordance with many studies that showed that the sinotomy technique minimized the time away from work, deviation from normal activities, and costs [28,29].

The ideal approach for the management of PNS should be simple, cause minimal pain, have the best chance for success and least recurrence rate with low risk for complications, decrease hospital stay, avoid general anesthesia, require minimal wound care, and ensure minimal inconvenience for the patient with rapid return to normal activity [12].

Conclusion

The modified sinotomy technique for treatment of PNS is superior to the excision with primary closure method either with or without a drain in terms of operative time, hospital stay, comfort in walking, sitting, and sitting on the toilet, return to work, and VAS scores for pain, although the healing time is longer. There was a higher recurrence rate when a drain was inserted in cases of primary closure.

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Conflicts of interest

There are no conflicts of interest.

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Circumareolar concentric excision for Simon's grades 2B and 3 gynecomastia

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Purpose
The aim of this study was to evaluate the surgical outcome of circumareolar concentric skin excision for (grades 2b and 3) gynecomastia and its impact on the quality of life of these patients before and after surgery.
Patients and methods
Thirty male patients with bilateral gynecomastia (grades 2b and 3) were included in this study during the period from January 2012 to December 2014 at Benha University Hospital; all patients were operated upon by performing circumareolar doughnut skin excision for their Simon's (grades 2b and 3) gynecomastia.
Results
There was an acceptable improvement in the shape and contour of the breast with significant patient's satisfaction. No major offending operative or postoperative complications have been reported.
Conclusion
Although there are some possible complications associated with surgery, our case series demonstrates that with shrewd planning and careful patient selection, outcomes of operative correction can be favorable and yield high levels of satisfaction for both the patient and the surgeon.

Keywords:
circumareolar, concentric skin excision, gynecomastia grade (2B and 3)

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Introduction

Gynecomastia is a benign enlargement of the male breast. It is a common condition, with an incidence in young patients as high as 38% [1].

Gynecomastia presents physiologically in two-thirds of normal male at puberty and may persist into adolescence. This transient breast enlargement usually subsides spontaneously, but it may persist during adolescence or adulthood due to a real hypertrophy of breast tissue, fat excess, or a combination of both [2].

Gynecomastia is divided according to Webester into true gynecomastia, which is due to proliferation of ducts and periductal tissues, and pseudogynecomastia, which is due to deposition of adipose tissue and combined cases [3].

Morphologically and according to the degree of skin redundancy, Simon *et al*. [4] classified gynecomastia into three grades:

(1) Grade I: small visible breast enlargement and no skin redundancy.
(2) Grade IIA: moderate breast enlargement without skin redundancy.
(3) Grade IIB: moderate breast enlargement with skin redundancy.
(4) Grade III: severe breast enlargement with marked skin redundancy (pendulous female breast).

On the basis of the different structural components of the breast (skin, the nipple–areola complex, inframammary fold, and glandular tissue) and the relations between these various components and in particular between the inframammary fold and the nipple–areola complex, Adriana and Francesco proposed a new four-grade gynecomastia classification of increasing severity from I to IV as follows. Grade I: increase in male breast diameter and protrusion but still limited to the areolar region. Grade II: hypertrophy of all structural components of the breast beyond the areola region but still the nipple–areola complex is above the inframammary fold. Grade III: hypertrophy of all structural components of the breast with the nipple–areola complex at the same height as or about 1 cm below the inframammary fold. Grade IV: hypertrophy of all structural components of the breast with the nipple–areola complex more than 1 cm below the inframammary fold [5].

True gynecomastia is due to some form of endocrine imbalance [6]. This may be attributable to increased estrogen, decreased androgen, receptor defects, or an altered sensitivity of the breast to estrogen [7].

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The endocrine imbalance may occur first as a physiological condition, which may become evident during various periods of a man's life: neonatal, pubertal, or involutional. It is unlikely that neonatal gynecomastia would be treated surgically. If pubertal gynecomastia is transient, there are no surgical implications. The permanent form is well known. Involutional imbalance is a medical problem, and surgery is rarely indicated. The second endocrine imbalance is endogenous; this condition may result from congenital or acquired hormonal abnormalities such as Klinefelter's syndrome, male hypogonadism, testicular neoplasm, mumps, testicular atrophy, adrenal cortex neoplasm, adrenal cortex hyperplasia, thyrotoxicosis, and pituitary tumor. Finally, the third endocrine imbalance is exogenous; this situation may result from the administration of hormones, drugs whose molecular structure is similar to that of estrogen, or drugs that antagonize androgen [6].

The most common symptom of the patient with gynecomastia is being self-conscious about the appearance of the enlarged breasts, and, occasionally, tenderness or even pain [7].

Most patients request treatment for psychological reasons. The goal in treating these patients is resection of the abnormal tissue that restores the normal male breast contour and minimizes scarring or residual deformity of the breast and the nipple–areola complex [8].

Determination of the site and size of the nipple–areola complex in men according to Beckenstein and colleagues was ~20 cm from the sternal notch and 18 cm from the midclavicular line. The ideal nipple-to-nipple distance is 21 cm. The average areolar diameter is 2.8 cm [9].

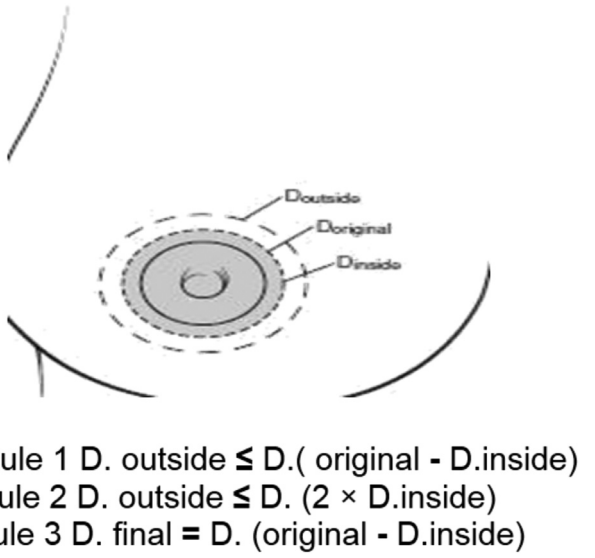
In 1990, Spear *et al*. [10] described three rules to mark the patient having concentric mastopexy that seemed to produce more predictable esthetic results (Fig. 1). The three rules are as follows:

(1) The outer circle diameter must be drawn not to exceed the original areola diameter by more than the difference between the original areola diameter and the inner concentric circle (normal) diameter.
(2) The diameter of the outer circle should never be more than twice the diameter of the inner circle.
(3) The final areola size should be an average of the inner and the outer concentric circle.

Patients and methods

Thirty male patients with bilateral gynecomastia (grades 2b and 3) were included in this study during the period from January 2012 to December 2014 at Benha University Hospital, after approval of the study by the local ethical committee and obtaining written fully informed consent from the patients. The age of the patients ranged between 20 and 44 years with a mean age of 26 years. All patients underwent a routine preoperative evaluation in the form of proper medical history, careful general and local examination, and routine laboratory investigations, especially endocrinal assessment. Cases of secondary gynecomastia due to hormonal imbalance, drugs, or liver diseases and those suffering from morbid obesity were excluded from the study. Only idiopathic cases with average BMI were included in this study. Breast mammography was performed to exclude the presence of breast calcifications.

Figure 1



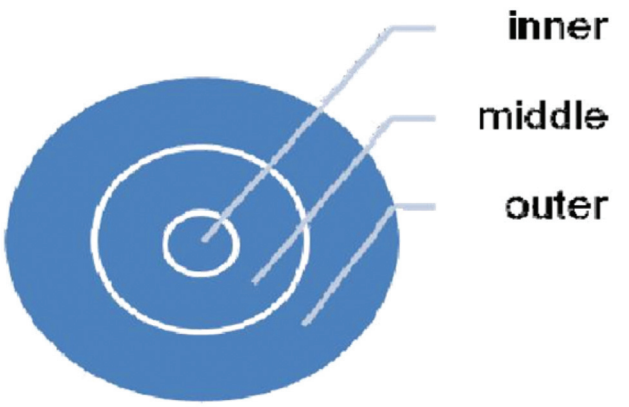
Spear rules. Illustrative markings of the three concentric circles for the spear rules in mastopexy design. D, the diameter of labeled circles. Rule 1: $D_{outside} \leq (D_{original} - D_{inside})$; rule 2: $D_{outside} \leq (D2 \times D_{inside})$; rule 3: $D_{final} = (D_{original} - D_{inside})$.

On the basis of the size of the breast and the degree of skin redundancy in Simon's classification, only the moderate to severe degrees (grades 2b and 3) were included in this study, either true gynecomastia cases (firm, localized, and discoid mass), pseudogynecomastia cases (soft and diffused mass), or mixed cases confirmed by means of mammography.

Surgical technique

Markings were drawn with the patient in upright position and included the midline of the chest, inframammary fold, breast meridian (from the midclavicular point to the nipple normally=18 cm), and then with the patient lying down the concentric circles were drawn in the form of three circles centered at the nipple (Fig. 2).

Figure 2



The three concentric circles.

(1) Original areolar circle in the middle.
(2) Normal-sized areolar circle (about 2.8 cm in diameter) internally.
(3) Circle of the epithelialization outside and its radius were determined by subtraction normal meridian (18 cm) from the actual meridian.

Under general endotracheal anesthesia with the patient in the supine position, the surgical field was prepped and draped, and then infiltration of the subcutaneous tissue with tumescent solution composed of 250–350 ml mixture of normal saline 1000 ml, lidocaine 2% 25 ml, and 1 ml adrenaline 1 : 1000 was carried out. De-epithelialization of the skin area between the inner and the outer circle was meticulously performed so as to not to jeopardize the vascularity of the nipple–areola complex. The dimension of this skin area was carefully tailored to fit the degree of skin redundancy and the size of the breast for each patient. A semicircular incision was made at the lower edge of the large circle through which the gynecomastia structure with a decent amount of breast tissue was dissected from the nipple and areola, leaving 10–15 mm thickness of tissue on the undersurface of the nipple and areola and to the pectoral fascia deeply without insulting it, and then proper hemostasis was carried out and negative suction drain was inserted. The wound was closed with the aid of a purse string proline 4/0 suture through the large circle to become at the size of the small circle. Subsequently, deep dermal interrupted vicryl 4/0 sutures were applied, followed by subcuticular skin closure using vicryl 5/0 sutures. The excised tissue was sent for histopathological examination.

An elastic compression garment was applied for 48 h before exposure of the wound. The patient was discharged the same day from hospital. Broad spectrum antibiotic was prescribed in the form of intravenous second generation cephalosporin every 12 hours for 48 hours, and then maintained on the oral form for 1 week. Sutures were removed after 7–10 days, and the drain was removed once stopped drainage or when the drainage was less than 20 ml per day. The garment was applied for 3 months. Postoperative follow-up visits were scheduled at 2 weeks, 1, 3, and 6 months to allow for close follow-up and photographing.

No validated outcome assessment questionnaire exists specifically for gynecomastia correction. We, therefore, created a three-item questionnaire, which was sent to all patients who underwent surgery to ascertain their satisfaction with the procedure. A similar proforma was used by Ridha *et al.* [11]. The proforma comprised questions that allowed patients to rank their satisfaction levels with their surgery in relation to three factors. The first question was related to patients' comfort with their breast/chest in different settings (intimate, social, and professional). The second question was related to the degree of comfort with their breast/chest appearance. The third question was related to patients ranking as regards the satisfaction level for themselves and their partner/family (1=very dissatisfied; 2=dissatisfied; 3=neither; 4=satisfied; and 5=very satisfied) preoperatively and postoperatively.

To achieve some level of objective assessment, a topographic scale was used to evaluate preoperative and postoperative results. Each patient underwent a photographic assessment before and after surgery at each visit. The photos taken before and after surgery were assessed by three surgeons who were not involved with the patients; surgeon-assessed result was evaluated in a visual analog scale (scale 0–10 wherein 0 is worst outcome and 10 is the best). The visual analog scale considered symmetry, scarring, and natural appearance. Data provided by surgeons were grouped [12].

Results

Thirty patients with grades 2b and 3 gynecomastia were included in the study, 18 (60%) cases of true gynecomastia and 12 (40%) cases of pseudogynecomastia. The age of the patients ranged between 20 and 44 years, with a mean age of 26 years. There were two obese patients, eight overweight patients, five cases of type 2 diabetes mellitus, and one case of hypertension. The remaining 17 cases were free of comorbidity. All patients with bilateral idiopathic gynecomastia were enrolled (Tables 1 and 2).

All patients received general endotracheal anesthesia and local tumescent solution and were operated up on

Table 1 Type of gynecomastia

Total	True gynecomastia	Pseudogynecomastia
30	18 (60%)	12 (40%)

Table 2 Comorbidity with the cases

	n (%)
Obese	2 (6.7)
Overweight	8 (26.7)
Diabetes	2 (6.7)
Hypertension	1 (3.3)
Free	17 (56.6)

by performing circumareolar concentric excision (in the shape of a doughnut), after which the patients were advised to wear elastic garment and were followed up at 2 weeks, 1, 3, and 6 months.

The collected data included the duration of surgery, amount of blood loss, need for blood transfusion, postoperative hospital stay, frequency of complications, and the impact on the patient's quality of life preoperatively and 6 months postoperatively.

Early complications that occurred within the first 2 weeks were hematoma, seroma, skin gangrene, bruises, and infection, and late complications that occurred after 3 months were hypoesthesia, ugly scar, nipple inversion, residual lump, and skin redundancy.

All surgeries were accomplished smoothly without intraoperative complications with a mean operative time of 90±31 min. All patients had an uneventful postoperative course. Complications were classified into two types: early, when occurring within the first 15 days, and late if happening after this period. Early complications were observed in two patients (6.6%), who developed seroma collections after removal of the drains and were treated by means of aspiration.

One patient (3.3%) developed hematoma and was treated medically. Six patients (20%) developed bruises in the surgical field early postoperatively and was managed without trouble. Two patients (6.6%) developed infections in the suture line with partial dehiscence, one patient was managed conservatively and the other required secondary sutures. No cases of skin, nipple, or areola sloughing or gangrene were observed.

As regards late postoperative complications (3 months postoperatively), one (3.3%) patient developed unilateral hyposthenia in the region of the nipple and areola and two (6.6%) patients developed ugly keloid scars and were treated with serial corticosteroid injections. There were no cases of nipple inversion or residual lumps (Tables 3–8).

Table 3 Operative data

Data	Finding
Operative time (min)	90±20
Weight of excised tissue (g/side)	250±30
Hospital stay	All one day

Table 4 Early complications

	n (%)
Hematoma	1 (3.3)
Seroma	2 (6.6)
Skin necrosis	–
Bruises	6 (20)
Infection	2 (6.6)

Table 5 Day of drain removal

Cases	Day of drain removal	Total amount (ml/day)
13	5th	30–80
9	6th	35–85
8	7th	40–110

Table 6 Total amount of seroma on each side before drain removal

Number of cases	Right side (ml)	Left side (ml/day)
13	30	50
9	35	60
8	40	70

Table 7 Seroma after drain removal

	n (%)
Number of cases	2 (6.6)

Table 8 Late complications

	n (%)
Hyposthenia	1 (3.3)
Ugly scar	2 (6.6)
Nipple inversion	–
Residual lump	–
Skin redundancy	–

As regards patient satisfaction preoperatively and postoperatively, all 30 patients were very dissatisfied preoperatively with their images; postoperatively, 20 (66.6%) cases were very satisfied with their images, five (16.7%) cases were satisfied, and five (16.7%) cases were equivocal in their satisfaction with their images.

There were high satisfaction rates among surgeons. In total, 21 patients (70%) had their outcome classified as 'excellent' at their second follow-up appointment, five patients (16.7%) had their outcome classified as 'good',

Table 9 Levels of patients' satisfaction

Postoperative satisfaction	Number of patients [*n* (%)]	*P* value
Very dissatisfied	0 (0)	
Dissatisfied	0 (0)	
Equivocal	5 (16.7)	0.05
Satisfied	5 (16.7)	0.05
Very satisfied	20 (66.6)	0.03

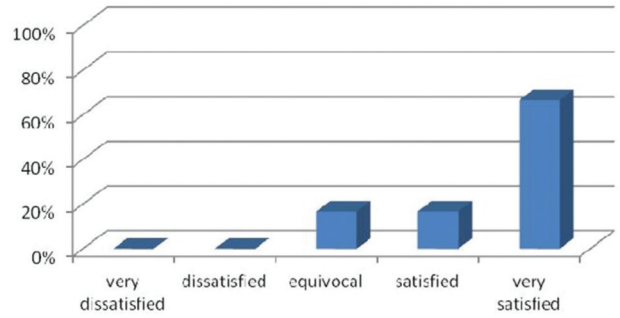
Table 10 Topographic scale

Scales	*n* (%)	*P* value
Excellent	21 (70)	0.01
Good	5 (16.7)	0.05
Satisfactory	4 (13.3)	0.05
Poor	–	

Table 11 Visual analog scale

Data	Score	Finding [*n* (%)]
Scaring	8	9 (30)
	9	21 (70)
Symmetry	7	5 (16.7)
	9	25 (83.3)
Natural appearance	8	10 (33.4)
	9	20 (66.6)

Figure 3



Levels of patient's satisfaction.

and four (13.3%) patients were classified as 'satisfactory' (Tables 9–11 and Figs 3 and 4).

Analysis revealed a general trend showing increased satisfaction rates as time from surgery increased.

Discussion

Numerous esthetic surgical techniques have been described for correction of gynecomastia, but it is a challenge to fulfill the main objectives of the surgical treatment of gynecomastia, which are restoration of the male chest shape with good contour, elimination of the inframammary fold, correction of the position of the nipple–areola complex, removal of redundant skin, and symmetrization between the two sides and the nipple–areola complex [5].

Mild grades of gynecomastia (Simon's 1 and 2) of pseudogynecomastia type are amenable to liposuction, but in severe grades (Simon's 3) open surgery should be performed alone or in combination with liposuction [13].

Surgery is the mainstay of treatment for gynecomastia. Although a wide range of surgical techniques have been described, such as infra-areola excision of breast tissue, concentric mastopexy, formal breast reduction as in female breast reduction with superiorly or inferiorly based pedicled flaps, or breast amputation with free nipple–areola graft, surgeons often find it difficult to choose the technique that will achieve the best results for a given patient [14].

The surgical management of high-grade gynecomastia (Simon's grade III) has remained problematic because both liposuction and conventional subcutaneous mastectomy (without skin excision) have frequently resulted in significant residual skin redundancy, requiring a second operation for skin resection [15].

In an attempt to minimize scarring, Balch [16] introduced the transaxillary approach for glandular excision. The technique is effective in the removal of glandular tissue, but it cannot be used in Simon's grades II and III with much fat and skin excess. However, in the present study, the circumareolar technique helped us to hide the scar around the areola and also helped to widen the range of access to excise all gynecomastia tissues without the aid of liposuction and to excise the redundant skin all around the areola.

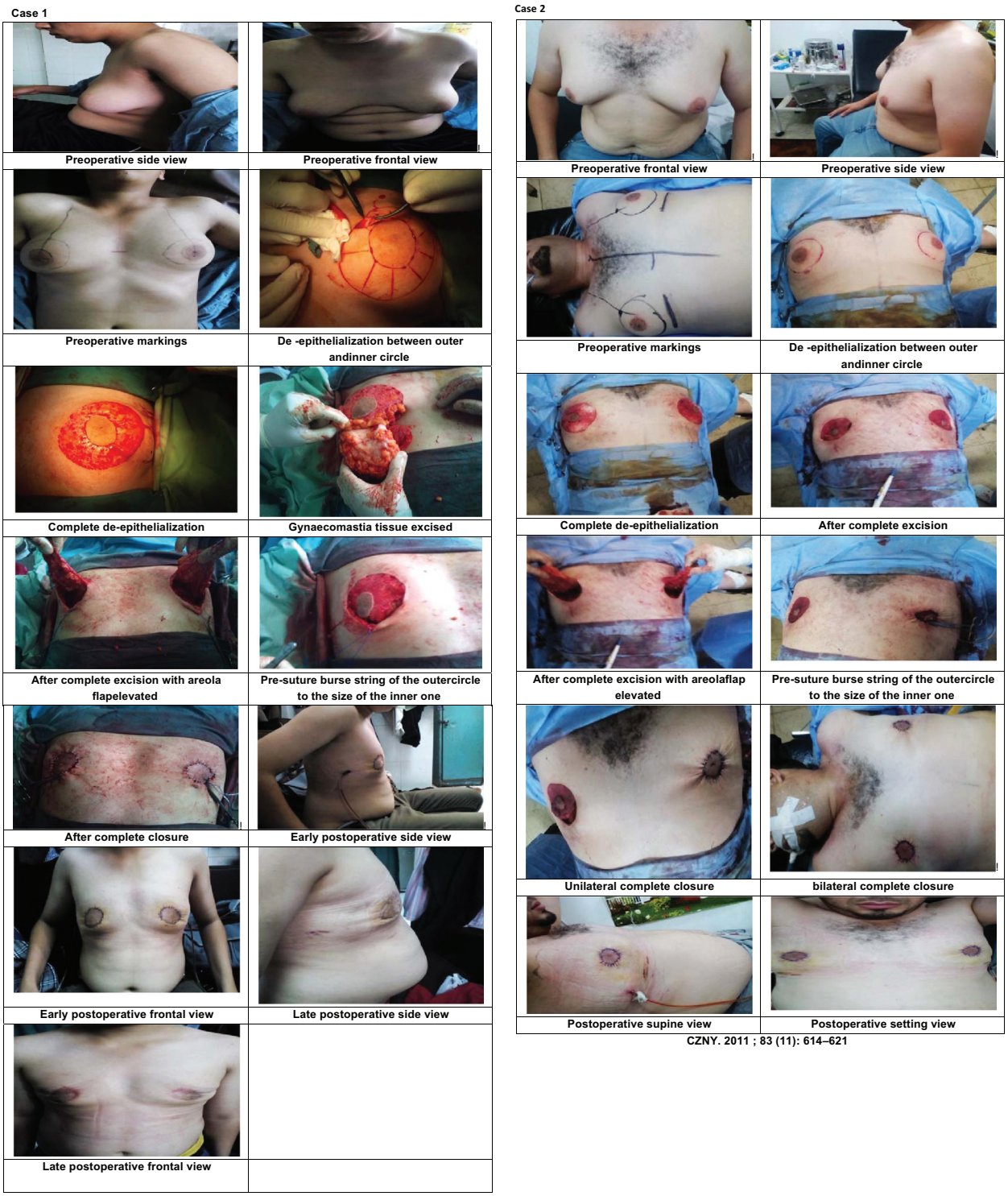
As regards complications, only two patients developed seroma after drain removal and were treated by means of aspiration.

As regards late complications, only two patients developed keloid scar treated with corticosteroid injections, and one patient developed unilateral hypoesthesia in the region of the nipple and the areola.

Celebioglu *et al.* [7] found that the main disadvantage of the free areola nipple graft technique was long transverse scar and loss of sensation in nipple graft. Moreover, in pedicle nipple–areola flap in conventional breast reduction the main disadvantage was the inverted T scar.

The most common complication in the study by Fruhstorfer and Malata [14] was a residual lump in patients treated with conventional liposuction alone, which was often associated with a degree of discomfort.

Figure 4



Topographic scale.

In these cases, some patients were not satisfied with the result, but in our study we excised the redundant skin and the wide circle allowed us a wider plane for fat excision.

Outcome studies of gynecomastia correction have shown varying levels of satisfaction with the results of surgery with Fruhstorfer and Malata [14] showing high levels of satisfaction, whereas the results of Ridha *et al.* [11] showed much lower levels. Our series demonstrated generally high satisfaction rates among both patients and surgeons.

Twenty-one patients (70%) had their outcome classified as 'excellent' (P=0.01) at their second follow-up appointment by the operating surgeon, five patients (16.7%) had it

classified as 'good', and four (13.3%) as 'satisfactory' with no poor outcome among patients and surgeons.

Patients were generally 'satisfied' with their outcome as regards comfort and appearance. Patients who underwent excision were generally very satisfied, obtaining the highest overall scores for satisfaction, chest shape, and self-confidence levels. The periareolar scar was well-accepted and faded with time. This is in accordance with the study by Anna Kasiels and Bogusław Antoszews [17], which revealed that gynecomastia causes considerable emotional discomfort and limitation of everyday activity in young men. Thus, it constitutes a psychosocial problem and surgical treatment of gynecomastia significantly contributes to an increase in social activity and an improvement in social acceptance and emotional comfort, and hence it significantly improves satisfaction from personal life in the men who underwent this intervention.

Conclusion

The reason for adopting this procedure is that it is simple and straightforward procedure that results in flat chest compared with other breast reduction techniques that carry the risk for more complications such as cone-like breast contour, less skin excision with marked skin redundancy, longer time, and ugly scar. Although there are some possible complications associated with surgery, our case series demonstrates that, with careful planning and shrewd patient selection, outcomes of operative correction can be favorable and yield high levels of satisfaction from both patient and surgeon.

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Nil.

Conflicts of interest

No conflict of interest. All procedures done in the best interest of the patients and all patient were delight about their surgical outcome.

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Comparison between the bone cutter with thermal cautery, Gomco, and Plastibell for circumcision in neonates and infants: a prospective randomized trial

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Background
Circumcision is the most common surgical procedure performed for a male newborn. This trial aimed to compare between three commonly used techniques for male circumcision in our institute.
Patients and methods
From January 2014 to January 2015, 150 babies were randomized into three groups according to the circumcision technique: babies circumcised using the bone-cutter forceps with thermal cautery (group I), Gomco clamp (group II), and the Plastibell device (group III). Intraoperative details, postoperative pain and complications, cosmetic outcome, and parent satisfaction were recorded.
Results
Operative time was significantly shorter for group I ($P<0.001$). Postoperative dressing was needed in 50% of infants in group II compared with 12% in group I. Analgesic consumption was significantly lower in group I ($P<0.001$). No significant differences were found between the three groups as regards the peer assessment score for the final cosmetic outcome. Parent satisfaction was significantly higher in groups I and II ($P=0.023$). Infection was reported only in the Plastibell device group, and 10% had device-related complications.
Conclusion
The thermal cautery with bone-cutter technique proved superiority in hemostasis, operative time, and parent satisfaction, with less pain in the postoperative period. All three techniques had comparable final cosmetic outcome.

Keywords:
circumcision techniques, male circumcision, neonatal circumcision

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1110-1121

Introduction

Male circumcision is one of the oldest and most commonly performed surgical procedures in pediatrics worldwide [1]. It was estimated by WHO that 30% of all male individuals above 15 years are circumcised [2]. Circumcision is performed in the majority of infants because of religious, ethnic, and cultural causes, with a minority for medical indications [3]. Despite the current controversy over whether it is ethical for parents to consent for a nontherapeutic neonatal circumcision, it remains a widely practiced procedure in newborn male infants all over the world [4]. Thus, it should be performed properly and safely, with the least probability of complications.

There are many different techniques used for circumcision in neonates and infants, including the Gomco clamp and Mogen clamp, Plastibell device, and dissection technique [5,6]. Although it is not well addressed in recent literature, using bone-cutting forceps is still one of the most commonly used techniques in male circumcision in our country, and using thermal cautery instead of scalpel in cutting the excess skin is preferred by many pediatric surgeons to minimize the risk of bleeding. We aimed from this work to compare between the three commonly performed procedures for male circumcision in our institution.

Patients and methods

This prospective randomized parallel-group clinical trial was conducted from January 2014 to January 2015 at Ain Shams University Hospitals, Pediatric Surgery Department. Male newborns (age ranging from 1 to 90 days old) who presented for routine circumcision were randomized, using sealed envelope technique, and equally allocated into three groups.

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Group I babies were circumcised by bone-cutting forceps using thermal cautery, those in group II were circumcised by Gomco clamp, and those in group III were circumcised using the Plastibell device.

We used a soldering gun as a thermal cautery device. Soldering gun (220 V-50 Hz, 100 W power, soldering gun KL818; China) is composed of a heated metal tip and an insulated handle. Heating is often achieved electrically, by passing an electric current through a resistive heating element. The temperature of the soldering tip is regulated manually by holding the gun button until the tip turns red, indicating that it is ready for cutting, and then releasing the button to get the tip cold again.

Patients with webbed penis, excess suprapubic fat, bleeding tendency, liver disorders, or neurological disorders were excluded from the study. Each circumcision technique was performed by one expert surgeon with more than 5 years' experience in performing the procedure. The study was approved by the ethics committee of Pediatric Surgery Department of Ain Shams University. All parents or guardians of the children involved in the study signed an informed consent.

Surgical procedure

All procedures were performed under local anesthesia with dorsal penile nerve block (DPNB) using lidocaine HCl 2% at a dose of 3 mg/kg, diluted in an equal volume of sodium chloride 0.9%. DPNB was given 5 min before the procedure. The foreskin was completely retracted, freeing the adhesions from the glans, and the smegma was cleaned.

In group I, the skin was held by two hemostats to elevate the foreskin, and then the bone-cutting forceps was applied at the level of the skin to be removed for circumcision. Excess foreskin was cut using the heated thermal cautery (Fig. 1). The skin was retracted proximally after cutting the excess foreskin to expose the glans [7]. Group II infants were circumcised with the Gomco clamp, whereas group III infants were circumcised using the Plastibell device.

Sutures were made only if there was separation between the skin and the mucous membrane, and stitches were made only in the separated part. Postoperative dressing was used only if there was minimal bleeding, and it was removed the next day; otherwise, the penis was left exposed.

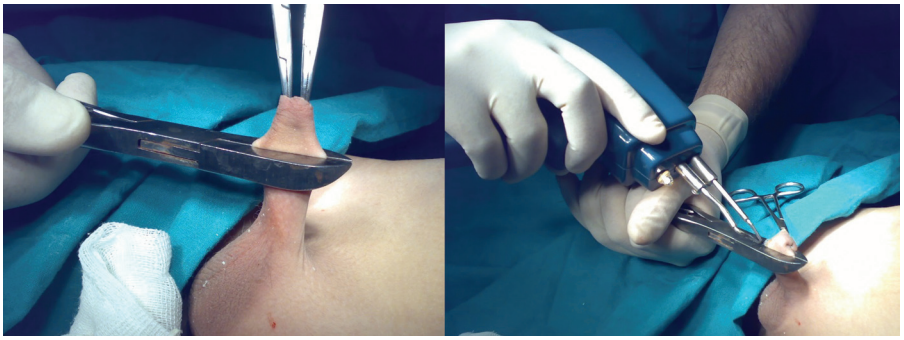
Postoperative analgesia (acetaminophen 15 mg/kg/dose) was prescribed only on demand if the baby was continuously crying and refusing feeds. Topical gentamicin sulfate cream was applied by the parents three times daily for 3 days after the procedure. Follow-up visits in the outpatient clinic were planned at 1 and 4 weeks postoperatively.

Assessment

Initial assessment was carried out at the time of procedure and included the operative time (time needed for the circumcision procedure itself excluding the time for induction of local anesthesia), need for stitches and their number, achievement of target mucosal cuff length (3–5 mm), need for postoperative dressing for minimal bleeding, and the occurrence of complications (significant bleeding – glans injury).

Follow-up visits (1 and 4 weeks) were planned for postoperative assessment as regards postoperative pain (number of required analgesic doses), parental satisfaction, blinded peer assessment, occurrence of complications (adhesions – meatal stenosis), and the demand for second intervention for management of complications.

Figure 1



Circumcision using bone-cutter forceps and thermal cautery.

As regards postoperative pain assessment (primary outcome measure), parents were told to record how many times they gave analgesic each day for the first 3 days separately, and then if there was still need for analgesia after these 3 days until the first postoperative clinic visit. Parental satisfaction about cosmetic appearance was recorded after parent questionnaire in the outpatient clinic 4 weeks postoperatively (giving a score from 0 to 4) (Table 1). Peer assessment was performed by a senior pediatric surgeon who was blinded to the performed method of circumcision (Table 1). The criteria of peer assessment are shown in Table 2.

Statistical analysis

Categorical data were presented as number and percentage, and between-group differences were compared using the Pearson χ^2-test or the χ^2-test for trends for nominal or ordinal data, respectively. Fisher's exact test was used in place of the χ^2-test if more than 20% of cells in any contingency table had an expected count of less than 5. Normality of numerical data distribution was tested using the Shapiro–Wilk test. Non-normally distributed numerical data were presented as median and quartiles. The Kruskal–Wallis test was used for intergroup comparisons with application of the Mann–Whitney *U*-test for post-hoc pairwise comparison whenever a statistically significant difference was detected. All tests were two-sided. This indicated that to maintain a final type I error of 0.05, the significance level should be set at a type I error of 0.017. Otherwise, *P* values less than 0.05 were considered statistically significant. All statistical analyses were performed using SPSS version 21 (IBM© Corp., Armonk, New York, USA).

Table 1 Ranking and interpretation of the scoring systems

Peer assessment score	Parent satisfaction score	Interpretation
0	0	Unacceptable
1	1	Bad
2	2	Fair
3	3	Good
4	4	Excellent

Table 2 Criteria used for peer assessment scoring

Criteria	Score=1	Score=0
Glans injury	Absent	Present
Length of mucosal cuff	3–5 mm	<3 mm or >5 mm
Length of penile shaft skin	Appropriate	Excess or little skin left
Penoscrotal and penopubic angles	Preserved	Not preserved

Results

From January 2014 to January 2015, a total number of 150 male newborns were recruited in this trial. They were randomized into three equal groups. All had the circumcision procedure for nonmedical (religious and cultural) reasons. There was no statistically significant difference between the three groups as regards age and weight (P=0.376 and 0.133, respectively).

In terms of the operative time, group I consumed a median time of 6 min, which was significantly less compared with the other groups (P<0.001). Similarly, the Gomco significantly reduced the operative time when compared with the Plastibell alone, with the median operative time being 9 and 12 min, respectively (P<0.001). As regards the need for stitches, there was no significant difference (P=0.948) between group I (12 patients) and group II (11 patients). On the other hand, none of group III infants required stitching, representing statistical significance (P<0.001).

The target length of the mucosal cuff was not achieved in 10 patients: four patients in group I, two in group II, and four in group III. However, this did not represent a statistical significance (P=0.166). Postoperative dressing was needed in 50% of the infants in group II, and in only 12% of the patients in group I (P<0.001).

In a pairwise comparison, analgesia consumption was significantly less in group I than in groups II and III. On the other hand, when the comparison involved group II versus group III, no statistically significant difference was found (Tables 3 and 4).

As shown in Table 5, postoperative significant bleeding was more common in infants circumcised with the

Table 3 Pairwise comparison of postoperative analgesic consumption in the three study groups

Analgesic consumption	Thermal cautery vs. Gomco (n=50)		Thermal cautery vs. Plastibell (n=50)		Gomco vs. Plastibell (n=50)	
	Mann–Whitney *U*-test	*P* value	Mann–Whitney *U*-test	*P* value	Mann–Whitney *U*-test	*P* value
Day 1	802.0	<0.001	1034.0	0.084	1009.0	0.060
Day 2	928.0	0.013	1074.0	<0.001	1014.0	0.074
Day 3	1225.0	0.317	1175.0	0.080	1200.0	0.310
Cumulative	753.5	<0.001	716.5	<0.001	1173.5	0.574

Table 4 Details of postoperative analgesic consumption in the three study groups through first 3 postoperative days

Analgesic consumption	Thermal cautery (*n*=50) [*N* (%)]	Gomco (*n*=50) [*N* (%)]	Plastibell (*n*=50) [*N* (%)]	*P* value
Day 1				
Nil	34 (68.0)	16 (32.0)	25 (50)	0.132
1 dose	14 (28.0)	30 (60.0)	23 (46.0)	
2 doses	2 (4.0)	4 (8.0)	2 (4.0)	
Day 2				
Nil	32 (64.0)	18 (36.0)	14 (28.0)	<0.001
1 dose	14 (28.0)	28 (56.0)	23 (46.0)	
2 doses	4 (8.0)	4 (8.0)	13 (26.0)	
Day 3				
Nil	50 (100.0)	49 (98.0)	47 (94.0)	0.324
1 dose	0 (0.0)	1 (2.0)	3 (6.0)	
Cumulative				
Nil	25 (50.0)	7 (14.0)	8 (16.0)	<0.001
1 dose	11 (22.0)	17 (34.0)	12 (24.0)	
2 doses	13 (26.0)	21 (42.0)	24 (48.0)	
3 doses	1 (2.0)	4 (8.0)	5 (10.0)	
4 doses	0 (0.0)	1 (2.0)	1 (2.0)	

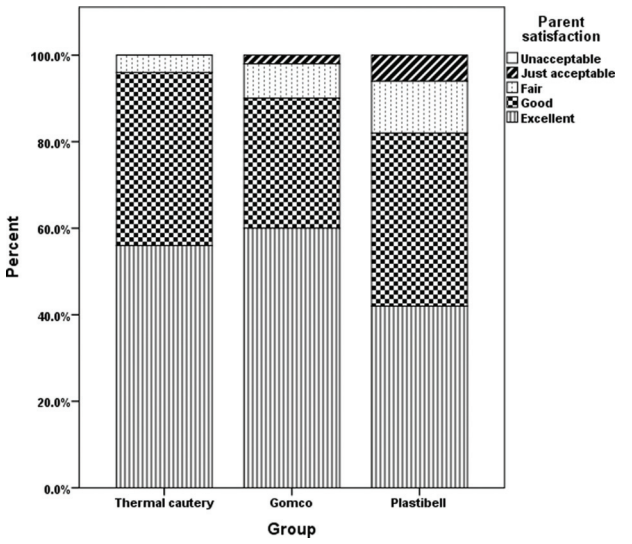
Table 5 Summary of unwanted effects and complications in the three study groups

Unwanted effect or complication	Thermal cautery (*n*=50) [*N* (%)]	Gomco (*n*=50) [*N* (%)]	Plastibell (*n*=50) [*N* (%)]	*P* value
Bleeding	1 (2.0)	3 (6.0)	0 (0.0)	0.324
Excessive skin left	2 (4.0)	1 (2.0)	4 (8.0)	0.504
Little skin left	1 (2.0)	0 (0.0)	0 (0.0)	1.0
Infection	0 (0.0)	0 (0.0)	3 (6.0)	0.107
Retained device			5 (10.0)	NA
Need for reintervention	2 (4.0)	3 (6.0)	6 (12.0)	0.386

Gomco clamp (6%), which was managed by secondary surgical interference for proper hemostasis and suturing afterward. Infection was exclusive among group III and was treated conservatively by local and systemic antibiotics. Five infants (10%) suffered from proximal migration and/or retention of the Plastibell device, and all had second intervention for removal of the device. None of the patients suffered from postcircumcision acute urinary retention, meatal stenosis, phimosis, or paraphimosis.

Infants of group I got the highest parental satisfaction among all other groups. Among group I patients, 96% got a score between 'excellent' and 'good', whereas 90% of those in group II got this score. The Plastibell was beyond them. This difference was statistically significant (*P*=0.023) (Fig. 2). When it came to the peer assessment of the final cosmetic appearance, none of the group I infants got a bad score. Only one patient got a bad score among group II infants, whereas four of group III infants got the worst scores. However, there was no statistically significant difference between the three groups.

Figure 2



Ranking of parental satisfaction in the three study groups.

Discussion

Male circumcision is one of the most commonly performed surgical procedures worldwide, and it is still a subject of considerable debate. In 2012, the American Association of Pediatrics (AAP) released a report stating that the preventive health benefits of elective neonatal circumcision outweigh the risks of the procedure [8]. The choice of circumcision technique depends mostly on the surgeon preference.

Several techniques have been used for safe performance of circumcision. In the USA, the most commonly used devices are the Gomco clamp (67%), the Mogen clamp (10%), and the Plastibell (19%) [9]. In Egypt, using the bone-cutting forceps instead of Mogen clamp is a

preferable technique for many pediatric surgeons. Cutting the prepuce afterward has been done with a scalpel, a bipolar electrocautery, or a thermal cautery [7].

In the present study, we are comparing the bone-cutting technique's outcome against other used techniques: the Gomco and Plastibell. Each group had its procedure performed with a standardized technique by an expert surgeon. The relatively low patient number may be considered a limitation for the trial; however, randomization and the blinded peer assessment made the comparison more accurate and reliable.

In the current study, we had significantly less operative time needed for circumcision using the bone cutter with thermal cautery. This goes hand in hand with what is found in the literature. In a study performed on 121 neonates, the mean operative time was 6 min when the bone cutter was used under general anesthesia [10]. Another study that involved 130 boys claimed that the Gomco needs ~3–5 min to complete its crushing action only [11], and this indicates higher time needed for the procedure as a whole. In a study that compared Plastibell and Mogen methods, it showed the former to consume twice the time needed for the procedure (20 vs. 12 min) [12]. However, in other series, surgical duration for Plastibell is reported to be less with a mean of 3.4 and 5.9 min [13,14]. For the best cosmetic outcome, we targeted the length of the mucosal cuff to be 3–5 mm. Whether it serves a specific function or not is still a debatable issue. Hosseini *et al.* [15] demonstrated that there was no relation between the mucosal cuff length and premature ejaculation in their study group.

Through previous decades, surgeons have been looking for a method to minimize postcircumcision bleeding – for example, bipolar diathermy [16,17], bipolar scissors [18], carbon dioxide laser application [19], ultrasound scalpel [20], skin glue [21], and combined use of bipolar diathermy and tissue glue instead of sutures [22]. Thermal cautery is a method used for hemostasis during circumcision; this technique was used for 20 years at our department for more than 2000 male infants. A main concern with this technique is the hazard of heat transmission through the metal bone cutting to the penile shaft skin. This issue was studied by performing histopathological examination of the skin below the bone-cutting forceps, which revealed that the extent of heat provocation is only 0.1 mm with normal skin afterward [7].

In the current study, the results confirmed superiority of the thermal cautery in terms of hemostasis. There was a statistically significant reduction in the need for postoperative dressing, indicating less postoperative minimal bleeding. Depending on the need for postoperative dressing as reflection of postoperative bleeding is a subjective way of assessment. However, the number of cases that required reintervention because of significant postoperative bleeding was less among group I patients than among group II patients (n=1 vs. 3 respectively), which represented clinical rather than statistical significance.

Pain evaluation always represents a main issue for both the surgeons and the parents. Our institution's standard technique is to use DPNB for infants below 3 months of age. Neonatologists used the physiological responses to pain to create a scale for pain assessment during the procedure. However, no valid scoring system is available for assessment of postoperative pain. In the current study, the mother was strictly instructed to give analgesic dose only when the baby is in pain and to record that in a special sheet. Postoperative pain, reflected by the required number of analgesic doses, was significantly less among group I when compared with group II or group III, but no significant difference was shown between groups II and III. This is consistent with other clinical trials in which the pain was significantly less when using the Mogen clamp (which is similar in action to the bone cutting forceps) as compared with the Gomco during neonatal circumcision in a randomized clinical trial on 48 infants [23]. On the other hand, it is recorded that Plastibell circumcision is less comfortable and requires more analgesic use for extended days after surgery even when compared with the conventional dissection methods [15,24].

The rate of complications and accordingly the demand for reintervention were the least among group I patients. The Plastibell encountered the highest rate of complications and reinterventions because of the retained device or proximally migrated device. One patient was readmitted 12 days later with retained proximally migrated device that caused ischemic ring at the glans, with part of the mucous membrane sloughing off. Similarly, the complication rate of the Plastibell device circumcision was reported in literature to be relatively high, ranging from 3.6 to 7.08% in some studies [14,25]. It is noteworthy that proper selection of the device size is an essential factor to reduce the incidence of Plastibell complication rate.

Parental satisfaction is a cornerstone for performing circumcision especially when performed for nonmedical reasons. Significantly reduced scores among group III were probably because of the device-related complications

that were retained in 10% of patients (P=0.023). To our knowledge, there is no valid postcircumcision parental satisfaction scale in the literature. We tried to strengthen our results by the blinded peer assessment of the final cosmetic appearance, which showed no statistical significance between the three groups. A postcircumcision assessment score needs further evaluation and verification.

Conclusion

In our hands, the use of the thermal cautery with bone-cutting technique proved superiority in hemostasis, operative time, analgesia needs, and was acceptable from the cosmetic point of view. Gomco circumcision is feasible with excellent cosmetic outcome. However, it needs longer operative time, more postoperative analgesia, and it is associated with higher incidence of postoperative bleeding. Circumcision using the Plastibell is the least preferable by parents. It needs good hygiene and cleanliness; otherwise, infection will be a drawback. A multicenter, large-scale clinical trial of infants is justified to generalize our recommendations for best clinical practice.

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Conflicts of interest

There are no conflicts of interest.

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Avoiding ileocolic vessel injury in the second stage of a three-stage ileal pouch anal anastomosis: an observational study

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Ileal pouch anal anastomosis is a commonly performed procedure. The operation can be completed in one stage, two stages, or three stages depending on the general condition of the patient and the local condition of the bowel. The J pouch is the most commonly performed pouch design. After construction, the pouch mesentery can be short, necessitating ligation and division of the superior mesenteric pedicel to allow the pouch reach the anal canal at ease. In this case, the ileocolic pedicle should be intact to give alternative blood supply to the newly constructed pouch. The ileocolic pedicle can be inadvertently injured during dissection to take down the ileostomy in the second stage of a three-stage operation. This can risk the pouch integrity in case the superior mesenteric pedicle needs to be divided. We are describing a method to avoid such inadvertent ileocolic vessel injury. After adopting this method, we did not have a single incident of ileocolic vessel injury in the second stage of a three-stage ileal pouch anal anastomosis.

Keywords:
ileal pouch, ileocolic, J pouch

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Introduction

Ileal pouch anal anastomosis (IPAA) is the standard treatment for many patients suffering from ulcerative colitis (UC) and familial adenomatous polyposis (FAP) [1]. Among the different pouch designs, the J pouch is commonly performed because of the simplicity of its construction and its acceptable long-term function [2]. The operation can be completed in one stage, two stages, or three stages depending on the general condition of the patient and the local condition of the bowel. In the three-stage procedure, colectomy with terminal ileostomy is performed in the first stage; the pouch is constructed and a loop ileostomy is raised in the second stage; and finally the loop ileostomy is closed in the third stage.

After construction, the pouch mesentery can be short, preventing it from reaching the anal canal at ease. Pouch anal anastomosis that is performed under tension can result in anastomotic leak, poor pouch function, and even pouch failure [3,4]. A commonly performed maneuver to lengthen a short pouch is ligation and division of the superior mesenteric pedicel (SMP), in which case the ileocolic pedicle (ICP) should be intact to give alternative blood supply to the newly constructed pouch [5].

In the second stage of a three-stage IPAA, the ICP can be inadvertently injured during dissection to take down the ileostomy, or it can be found inadequate due to prolonged constriction of the terminal ileal mesentery by the contracting edge of the ileostomy wound. This can risk the pouch integrity in case the SMP needs to be divided. Should the terminal ileal mesentery not be brought out in the ileostomy wound at the end of the first stage of the procedure, the two mechanisms of ileocolic vessel injury could possibly be avoided. We are describing a technique that can fulfill this hypothesis.

Surgical technique

In the first stage of three-stage IPAA, standard abdominal exploration and total colectomy is performed with ligation and division of the middle colic, right colic, and left colic vessels. If the cecum is not affected by the original disease, like in case of distal proctosigmoiditis, the ICP is neither dissected nor ligated in this stage and the ileocecal junction is kept intact. The colon is divided few centimeters distal to the ileocecal junction and is brought out as a stoma. In the second stage, the ascending colostomy is taken down, the ICP is carefully dissected and preserved, the residual cecum and ascending colon are resected, and the pouch is constructed as usual (Figs 1 and 2).

If the cecum is affected by the original disease necessitating its resection with the colon in the first

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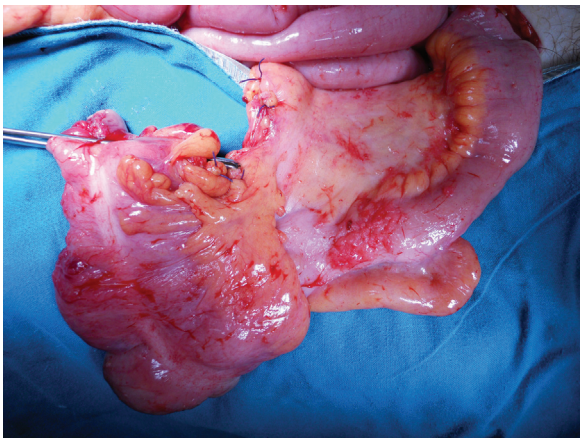
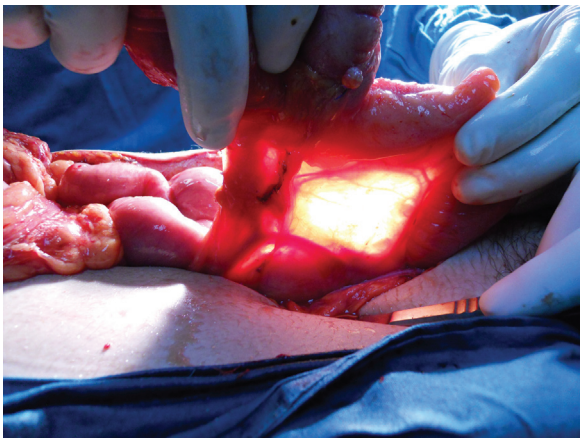
Figure 1



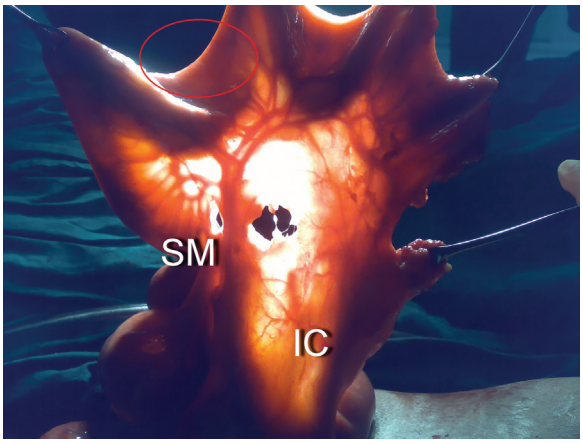
Ascending colon is resected distal to the ileocolic pedicle and ascending colostomy is prepared as a stoma.

Figure 2



Ascending colostomy before fixation as a stoma. Notice the ileocolic pedicle is kept intact with its ileal branches.

Figure 3



Blood supply to the terminal ileum as shown by transillumination during surgery. Notice anastomotic branches between the ileocolic (IC) and superior mesenteric (SM) vessels and mesenteric windows around the SM pedicle preparing it to be ligated and divided. The red mark shows the site of temporary loop ileostomy through which staplers will be introduced to create the J pouch.

stage, careful dissection of the ICP is performed with ligation and division of its colic branch and preservation of its ileal branch. The ileum is carefully divided flush with the cecum with a linear stapler. Instead of fashioning a terminal ileostomy, the ileum is brought out as a loop ileostomy 15–20 cm from its divided end, thus avoiding taking out the edge of the ileal mesentery that contains the ICP in the ileostomy wound. In the second stage, the loop ileostomy is taken down and the opening in the ileum is used to introduce the linear cutter for J-pouch construction, followed by the anvil of the circular stapler for the pouch anal anastomosis (Fig. 3).

Patients and methods

This is an observational before–after study. Patients were recruited from the waiting list for IPAA at the Unit of Colorectal Surgery (6 Surgery), Ain Shams University, during the period between 2010 and 2015. The indications for surgery were UC refractory to medical treatment and FAP. Patients requiring three-stage procedures due to general condition of the patient or local condition of the bowel (patients on high doses of steroids and patients with acute severe colitis, colon perforation, peritonitis, or toxic dilatation) and below 70 years of age were included in the study. All operations were performed at Ain Shams University Surgery Hospitals using the above-described technique modification. All patients were followed up postoperatively for a median of 6 months. Follow-up was scheduled weekly in the first month postoperatively, and then monthly for 6 months. History, abdominal examination, and DRE were carried out at every visit. The primary outcome of the study was successful pouch construction assessed during surgery by constructing a J-pouch 15–20 cm long that is successfully anastomosed to the anal canal with no tension and with complete doughnuts. Secondary outcomes were immediate or delayed pouch complications such as leaks, constriction, or ischemia. The comparison group included patients requiring three-stage IPAA for same indications before the year 2010, the time at which we adopted the modified technique. Data of those patients were acquired by revising the patients' files and the operative records. This study was approved by the local ethical committee.

Results

We adopted the above-described technique since the year 2010. Before that date, we performed 32 IPAA (20 male, median age 25 years, range 13–52 years). Two patients had FAP and 30 patients had UC.

Twenty patients required three-stage procedure and we had five (25%) incidents of inadvertent injury of ICP in the second stage: three were caused by direct injury during dissection to take down the terminal ileostomy, and two were cause by vessel constriction by the ileostomy wound edge. In two patients, pouch anal anastomosis was performed without the need to ligate the SMP; one patient developed Wilkies syndrome on the fifth postoperative day and was treated by means of gastrojejunostomy. In three patients, the SMP or one of its terminal branches needed to be ligated to allow the pouch to reach the anal canal; two patients developed immediate pouch ischemia and required pouch excision, one was treated with delayed redo S pouch, and one is living with a permanent ileostomy. Delayed pouch ischemia occurred in one patient and this was treated with redo J pouch construction.

After the year 2010 we performed 23 IPAA (14 male, median age 32 years, range 12–60 years). Two patients had FAP, one patient had attenuated FAP, and 20 patients had UC. Eleven patients required three-stage procedure. None of those patients had ileocolic vessel injury in the second stage and all had their J pouches constructed safely. The difference in the rate of ileocolic vessel injury before and after adopting this technique was statistically significant ($P<0.05$, z test for comparing percentages).

Discussion

Parks and Nicholls [6] were the first to describe the operation of restorative proctocolectomy or IPAA to treat patients with UC and FAP late in the 20th century. The operation was rapidly accepted by the surgical community because it cured the original disease and at the same time, it ridded the patients from living with a permanent stoma. In the majority of patients the operation can be completed without difficulty. Occasionally, because the terminal ileum is naturally tethered by the SMP, the pouch can be short and needs lengthening to reach the anal canal at ease. Different maneuvers have been described to improve the reach of the pouch to the pelvis. Multiple peritoneal incisions over the major mesenteric blood vessels is a simple maneuver that can add extra 2 cm to the pouch. It is especially useful in case previous laparotomy has resulted in mesenteric fibrosis and shortening [7]. The S pouch can reach lower in the pelvis compared with the J pouch; however, changing the pouch design is rarely resorted to because construction of the S pouch is more complicated and difficulty in its evacuation has been reported [2,3]. Metcalf *et al.* [8] reported a case in which they lengthened an extrashort pouch mesentery using an interposition vein graft to the superior mesenteric. This is obviously a major procedure and the authors recommended it to be used as a last resort.

Ligation and division of selected mesenteric vascular pedicles is the most commonly performed procedure to lengthen a short pouch [7,9,10]. Many vascular ligations have been described to achieve this goal. Burnstein *et al.* [7] recommended the ligation of two or three small ileal mesenteric vessels between the primary and secondary ileal arcades. They claimed this can add extra 2–5 cm length to the pouch [7]. However, this technique can be hazardous, risking segmental necrosis in some areas of the pouch. Goes *et al.* [10] found that the maximum length to the pouch can be achieved by dividing the small marginal vessels between the colon and the marginal artery in the area between the middle colic and the ICPs, the pouch being supplied by the middle colic artery through the marginal artery. The excess length provided by this technique is rarely needed and the marginal artery can be insufficient, especially when the right colic artery is absent [11]. Moreover, radical resection and lymphadenectomy are not performed in this procedure, making it unsuitable for patients with associated right-sided cancer or severe dysplasia.Ligation and division of one of the two major vascular pedicles supplying the terminal ileum – namely, the SMP or the ICP – can give 2–7 cm extra length to the pouch [3,5,9,10]. This is usually all that is needed to make the pouch reach the anal canal at ease [5]. Thirlby [5] found that 48% of their patients needed lengthening of the pouch by ligating the ICP and 29% needed ligation of SMP, the rest of their patients did not need any maneuvers to lengthen the pouch.

By bringing out the ascending colon or the ileum 15–20 cm from the ileocecal junction as a stoma at the end of the first stage in a three-stage procedure, we were able to avoid bringing out the terminal ileal mesentery that contains the ICP at its edge in the stoma wound, and we consequently avoided dissection and possible damage of the ICP during taking down the stoma in the second stage. We also avoided the possible constriction of the ICP by the contracting edge of the stoma wound that inevitably occurs during the waiting period between the first and the second stage. This was reflected in the fact that we did not have any incident of ileocolic vessel injury in the second stage of three-stage IPAA after adopting this technique, as compared with 25% incidence of ileocolic vessel injury, with all its consequences, before adopting this technique.

Conclusion

We are describing a simple modification in the classic technique of the three-stage IPAA that secures the ICP. We recommend using this technique as it might have a significant implication on the rate of successful pouch construction and avoiding a permanent stoma.

Study limitations

The small number of patients and the retrospective nature are evident limitations of the present study.

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Conflicts of interest

There are no conflicts of interest.

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Retrograde transtibial technique as an alternative to the antegrade approach for the treatment of chronic lower-limb ischemia

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Background
Patients with complete occlusive lesions of the infrainguinal, and more frequently infragenicular, arteries have comorbid diseases that favor the endovascular option for treatment. In those patients the retrograde transtibial approach is suggested when the antegrade approach fails. This study aimed to describe the feasibility and complications of this approach.
Patients and methods
The retrograde transtibial approach was used, after a failed trial with the antegrade approach, in 29 patients suffering from severe chronic lower-limb ischemia. Success in accessing the tibial arteries, crossing the lesion, effectively dilating the occluded lesions, patency up to 6 months, and complication rate were measured.
Results
In all patients one of the tibial arteries was successfully accessed and the lesion was crossed. Postdilatation contrast study confirmed successful dilatation, which was maintained for 6 months, with no significant complications.
Conclusion
The retrograde transtibial approach is a feasible and safe alternative in treating infrainguinal arterial lesions when the antegrade approach fails or cannot be used.

Keywords:
endovascular, retrograde, transtibial

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Introduction

Peripheral vascular disease (PVD) is a widespread problem that has the potential to cause loss of limb or even loss of life [1]. In western countries, the prevalence of PVD in the general population is 12–14%, affecting up to 20% of those over 70 [2]. The incidence of symptomatic PVD increases with age, from about 0.3% per year in men aged 40–55 years to about 1% per year in men aged over 75 years [3]. In the 21st century it became a clear problem in low-income and middle-income countries, which needs to be addressed [4].

PVD manifests as insufficient tissue perfusion initiated by existing atherosclerosis. Risk factors such as diabetes, hypertension, smoking, hyperlipidemia, and lack of exercise contribute to the progress of the disease [2,4]. Patients with PVD commonly suffer from coronary artery disease and visceral and cerebrovascular insufficiency. It is estimated that less than one-third of them will need surgical or radiologic intervention for their limbs. However, data show that patients with symptomatic PVD have at least a 30% risk for death from myocardial infarction or cerebrovascular disease within 5 years. Therefore, PVD is an independent risk factor for cardiovascular death [5].

Patients suffering from chronic lower-limb ischemia due to infrainguinal obstructions are usually high-risk surgical patients because of their many comorbidities [6]. Open vascular revascularization is not suitable for many of them. Fortunately, percutaneous angioplasty offered a suitable treatment option for this group of patients [7]. Furthermore, for patients with tibial occlusive disease, endovascular intervention has became the first option of treatment for these challenging lesions [8].

There are multiple choices for arterial access in angioplasty. The common femoral artery is the most commonly used site, through ipsilateral or contralateral cross-over. If the common femoral artery access is not suitable, alternatively, a retrograde ipsilateral approach can be used through the distal superficial femoral artery (SFA), the popliteal, the tibial, or the dorsalis pedis artery [9]. Another indication for the retrograde approach is the inability to return to the true lumen after subintimal dissection. The suggested re-entry

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devices are expensive and their use is sophisticated. Therefore, they can be replaced by different retrograde approaches [9].

Popliteal artery access has grown in popularity as an alternative to cross SFA occlusions from a retrograde approach [10]. The disadvantage of the need to change the position of the patient is overcome now by performing the procedure in the supine position [11]. However, it is still unsuitable if tibial lesions coexist.

On the other hand, retrograde transtibial access seems to be a potentially effective alternative for endovascular treatment of infrainguinal arterial lesions in patients not amenable to antegrade procedures [12–15].

Aim of the study

This study was conducted to explore the feasibility and complications of this approach in treating infrainguinal lesions when the antegrade approach cannot be used or has failed.

Patients and methods

This is a prospective study conducted over a period of 15 months. Patients with chronic lower-limb ischemia, Rutherford's category 3–6, admitted for intervention at Suez Canal University Hospital, were considered the target population. After obtaining approval from the local ethics committee and consent from the patient before the operation, we started with the antegrade approach, ipsilateral or contralateral. Those patients with infrainguinal lesions fulfilling the following criteria were included in the study.

Inclusion criteria

(1) Antegrade recanalization failure due to the following:
   (a) Inability to recognize the mouth of the occluded artery (flush occlusion).
   (b) Failure to cross the occlusion either through the true lumen or by creating a subintimal plane.
   (c) Failure of re-entry into the true lumen after subintimal dissection.
(2) Has distal run-off (patent distal part of at least one tibial vessel).

Patients who fell under following criteria were excluded from the study.

Exclusion criteria

(1) Refused to be included in the study.
(2) Infection at the site of puncture.
(3) Single tibial vessel run-off, unless the patient had critical limb ischemia.

Information regarding the demographic data, risk factors, associated chronic illnesses, presenting symptoms, clinical signs and examination, lesion Trans-Atlantic Inter-Society Consensus (TASC) classification [16], and results of laboratory tests were obtained for all legible patients.

Technique of the transtibial approach

(1) First, it was ensured that the antegrade femoral approach, either ipsilateral or contralateral, conducted in the operation room under complete aseptic conditions, had failed.
(2) The vertebral catheter used during the antegrade attempt was placed as far as possible, close to the proximal end of the occlusion, to allow contrast injection to guide the tibial puncture.
(3) The tibial arteries were visualized by the contrast injected from above through the vertebral catheter. We looked for a disease-free segment of the artery just above the ankle joint. If the three vessels were suitable for puncturing, and because of the stability of the vessel during puncture, the anterior tibial artery (ATA) was preferred, followed by the peroneal and lastly the posterior tibial artery (PTA).
(4) After skin preparation, the foot was positioned in plantar flexion when accessing the ATA. It was inverted when accessing the distal peroneal artery and was everted and dorsi-flexed when accessing the PTA. The needle was inserted while injecting the contrast from above by the assistant.
(5) After successful vessel puncture, a 0.18′ guidewire was inserted retrograde through the vessel and then through the occlusion and back into the lumen above the lesion. The guidewire was negotiated and entered into the tip of the vertebral, and then through and out of it at the femoral access site. Thereafter, the vertebra was pushed down over the wire beyond the lesion as far as the distal entry of the wire to the vessel. The wire was removed and reinserted with its soft tip through the vertebral catheter from above and advanced distally in the vessel beyond the retrograde puncture site.
(6) Dilatation was performed using an appropriately sized balloon advanced from the femoral site, compressing and sealing the retrograde puncture. Repeated dilatation was performed for any residual stenosis greater than 30% or for flow limiting dissection, for which a bare metal stent was deployed.

Follow-up

The improvements in symptoms, pulses, and ankle brachial pressure index (ABPI) [17] were recorded the next day before discharge, and thereafter at 1 week, 1 month, after 3 months, and after 6 months. An increase in ABPI more than 0.15 mmHg before discharge was considered a success. Arterial duplex was done on a regular basis for all patients at 1, 3, and 6 months. CTA was performed when there was possibility of restenosis or occlusion. Complications, if present, were recorded.

Study endpoint

(1) Failure to access one of the tibial arteries.
(2) Failure to cross the lesion from below.
(3) Restenosis more than 30%, or flow limiting dissection that cannot be corrected.
(4) Arterial thrombosis before discharge or significant restenosis (>50%) at any time during 6 months' follow-up.
(5) Six-month follow-up of the successful cases.

Results

From January 2014 to March 2015, a total of 210 patients underwent endovascular interventions. Out of those, 29 (14%) patients who fulfilled the inclusion and exclusion criteria underwent retrograde transtibial endovascular angioplasty for infrainguinal arterial lesions after failed antegrade access.

The indication for retrograde approach in those patients was inability to pass through the true arterial lumen or subintimally [in (34.5%) 10 patients] and failure of re-entry [in 19 (65.5%) patients].

Those 29 patients consisted of 21 (72.4%) men and eight (27.6%) women. Their ages ranged between 55 and 75 years, with a mean age of 68 years. The risk factors and associated diseases are shown in Table 1.

Regarding the presenting symptoms, five (17.2%) patients presented with severe limiting claudication and 24 (82.8%) patients with ischemic rest pain. In eight (33.3%) out of 24 patients it was associated with gangrene in the toes or unhealed ulcer.

Regarding the distribution of the lesions according to TASC radiological classification, 14 (48.3%) patients had TASC type D1 and D2, eight (27.6%) patients had TASC type D1 and C2, four (13.8%) patients had TASC type C1 and D2, and only three (10.3%) patients had TASC type C1 and C2 (Fig. 1).

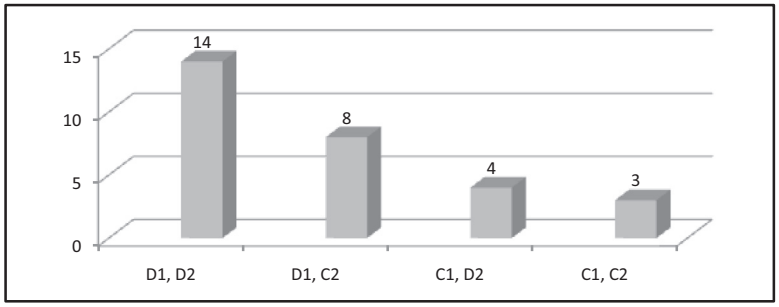
After failure of the antegrade approach, the procedure was completed by accessing the PTA in 15 (51.7%) patients, the ATA in nine (31.0%) patients, and through the peroneal artery in five (17.2%) patients. In all of the 29 patients, one of the tibial arteries was punctured, wired, and lesions were crossed successfully.

Regarding the distribution of the studied population according to the performed technique, balloon angioplasty was performed alone in 24 (82.8%) patients and balloon+stenting in five patients (17.2%).

Table 1 Demographic data and risk factors of the studied population

Variables	*n* (%)
Sex	
Male	21 (72.4)
Female	8 (27.6)
Diabetes	24 (82.8)
Hypertension	22 (75.9)
Ischemic heart disease	19 (65.5)
Smoking	20 (68.9)
Hyperlipidemia	18 (62.1)

Figure 1



Number of patients according to the TASC classification. C1 and D1, femoropopliteal lesions; C2 and D2, infrapopliteal lesions; TASC, Trans-Atlantic Inter-Society Consensus.

Figures 2 and 3 show examples of ATA and PTA access, ballooning, and postangioplasty angiography for the treatment of infragenicular lesions.

The mean ABPI improved from 0.41 before intervention to 0.74 on the first day after intervention. This increased to 0.79 in the first week, to 0.81 in the first month, to 0.83 in the third month, and to 0.85 at 6 months after intervention. This change in mean ABPI was statistically significant (Fig. 4).

By the end of the follow-up period, none of the patients had hematoma, infection, thrombosis, or aneurysm. Few patients had superficial bruises and ecchymosis, which disappeared a few days after the procedure.

Discussion

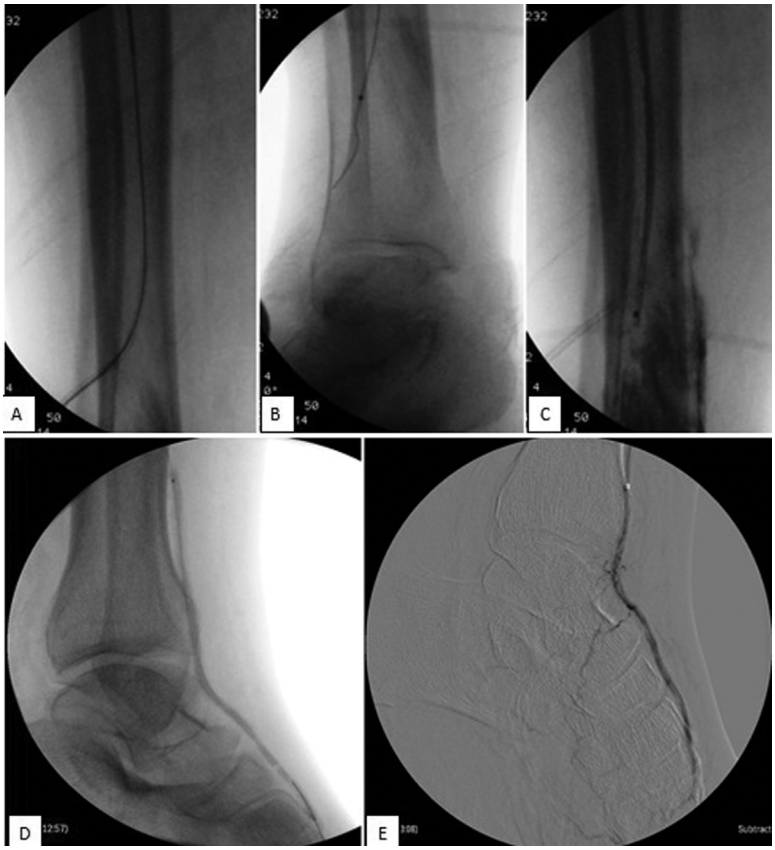
In recent times, endovascular intervention has been considered the first option of treatment for PVD. Efforts have been made to increase the success rate of this modality of treatment by developing new tools and techniques that enable the surgeon to overcome the challenges faced during the procedure. Of these techniques, retrograde tibial artery access is a promising alternative for patients in whom conventional antegrade endovascular techniques failed to achieve recanalization of the lower SFA, popliteal, and/or tibial vessels.

Over a period of 14 months, only 14% of the endovascular interventions performed for PVD in our hospital were through the retrograde transtibial approach. This indicates that the antegrade approach, when feasible, is the preferred one. This was reflected in the sample size, as observed in other studies as well. Botti *et al.* [18] included only six patients and Roger *et al.* [19] included 13 patients. This may suggest a general consensus that revascularization by puncturing the run-off vessel is not justified as the first option, as its failure may jeopardize the antegrade option. However, surgeons skilled in the technique should be available when needed.

The risk factors in the studied group of patients were as expected for the indication for this intervention, as observed in previous studies [9,20].

Most of the patients presented with a severe form of ischemia. In our study 83% of the patients presented with rest pain. This agrees with the observation

Figure 2



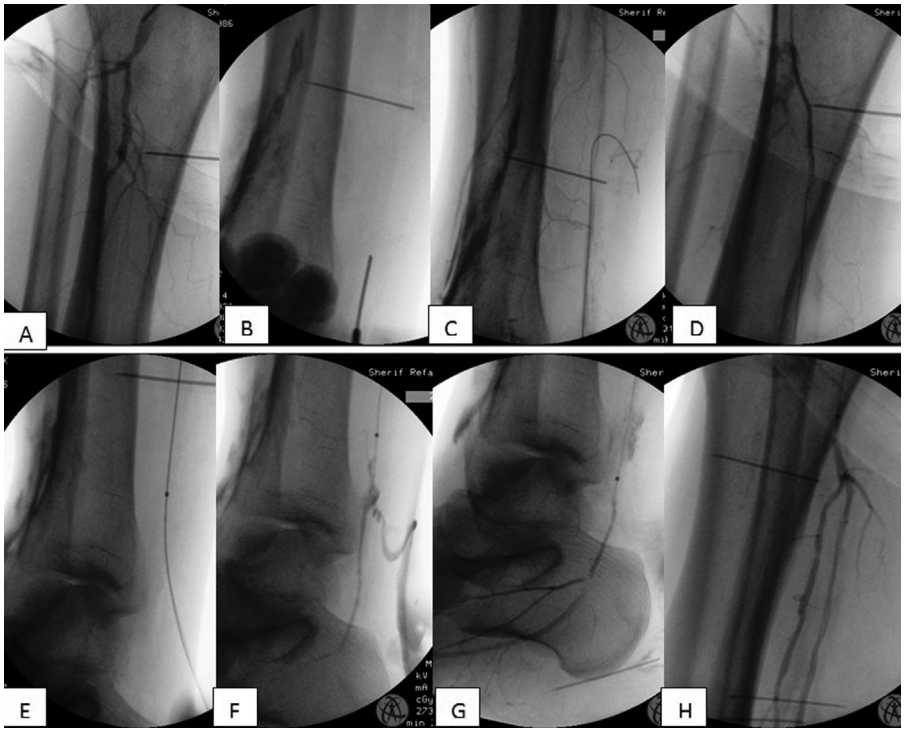
Access through the anterior tibial artery: (a) retrograde wiring; (b) balloon just above the access site; (c) just beyond the access site; (d) ballooning; and (e) postangioplasty angiography.

made in previous studies. All patients included in the study by Botti *et al.* [18] presented with critical limb ischemia. Most of the patients (62%) in the study by Roger *et al.* [19] had critical limb ischemia. The same was found by Montero-Baker *et al.* [9] as 88% of their patients presented with critical limb ischemia . Again, all patients studied by Walker [20] had critical limb ischemia. This severe form of ischemia may explain the recognized severe calcification and the failure to cross the lesion from above, but it is not clear why it is easy to cross the same lesion from below. The shape of the occlusion resulting from the calcium precipitation on the vessel wall, affected by the direction of its build-up overtime, may explain this phenomenon.

Regarding the access site, the PTA was the suitable artery for access in most of the patients (47.8%). This agrees with the observation made in previous studies. It was the access artery in 67% of patients in the study of Botti *et al.* [18] and in 85% in the study of Roger *et al.* [19]. This observation may suggest that the distal part of the PTA is the last segment to be affected by atherosclerosis in chronic ischemia.

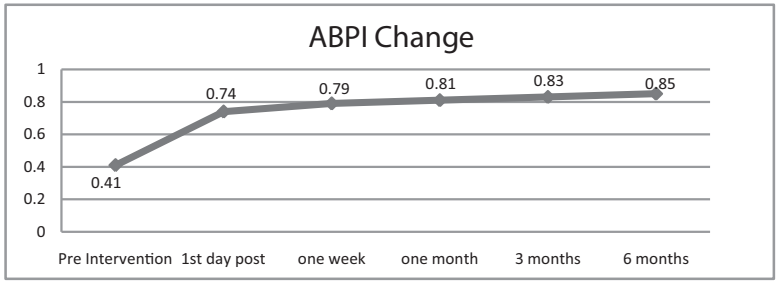
Tibial puncture was successful in all patients and the targeted lesion was successfully treated. This 100% success rate was also recorded by Botti *et al.* [18] and by Hua *et al.* [21]. Such high success rates were also recorded by others such as Montero-Baker and *et al.* [9] (87%) and Roger *et al.* [19] (85%). This high

Figure 3



Access through the posterior tibial artery: (a) vertebral at the popliteal artery; (b) needle in position; (c) wire advanced into the artery; (d) wire going into the vertebra; (e) balloon down near the entry site; (f) contrast through the balloon showing the entry site; (g) balloon below the entry site; (h) postdilatation angiography.

Figure 4



The change in mean ABPI (*N*=29). ABPI, ankle brachial pressure index.

success rate confirms that the transtibial approach is feasible and successful when indicated. This satisfactory result improved the ABPI and maintained it for 6 months.

In our study, minor complications were reported, in the form of nonsignificant subcutaneous hematoma. These complications are also expected during the antegrade transfemoral approach and were not specific to the retrograde approach. No significant complications were recorded for 6 months. We do not expect the incidence of long-term complications to differ depending on whether the lesion is accessed from above or from below. This low rate of complications confirmed the early suggestions regarding the safety of the procedure [9,19–21].

Conclusion

The transtibial approach is feasible, safe, and successful in treating infrainguinal arterial lesions when indicated. This approach should lend support to continue using the endovascular procedure when the antegrade approach fails.

This technique allowed completion of the procedure without the need of a re-entry device, an alternative that would add significant cost to the procedure.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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Laparoscopic drainage of pelvic abscess: evaluation of outcome

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Objective
The aim of this study was to evaluate the outcome of laparoscopic drainage (LD) of pelvic and paracolic abscesses not amenable to percutaneous or transrectal computed tomography-guided or ultrasound-guided drainage.

Patients and methods
Forty patients presented with a picture of acute abdomen. Radiological diagnosis defined 32 primary intra-abdominal abscesses and eight postoperative (PO) abscesses. After laparoscopic exploration, the abscess cavity was entered, and septa were cut down, drained, and irrigated using normal saline. The source of infection was managed if possible and then drains were inserted.

Results
Thirty-six patients underwent successful LD within a mean operative time of 94.3 min. Four patients required conversion to laparotomy for a conversion rate of 10%. Pain scores showed a gradual significant decrease. The mean duration of peritoneal drainage was 3.7±0.9 days and the mean PO hospital stay was 5.6±1.7 days. Three (8.3%) patients developed PO infection; two patients had a surgical wound infection at the umbilical port site and one patient developed recollection that required second-look LD of pelvic recollection. Two patients were died because of flare-up of an already present medical problem.

Conclusion
LD was a feasible, safe, and effective minimally invasive procedure for primary or secondary pelvic abscesses, with a conversion rate of 10%. No surgery-related mortality was encountered.

Keywords:
acute appendicitis, diverticulitis, laparoscopic drainage, pelvic abscess

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1110-1121

Introduction

Intra-abdominal abscesses continue to be a major source of morbidity and mortality in today's surgical practice. The obscure nature of the underlying conditions and the variable clinical course of the disease may result in a delay in diagnosis and management; such delays usually result in deleterious effects on patients' outcome, increased periods of hospitalization, and healthcare costs.

A better understanding of intra-abdominal abscess pathophysiology and a high clinical index of suspicion should enable earlier recognition, definitive treatment, and reduced morbidity and mortality [1].

Localized intra-abdominal abscesses usually tend to form in relation to the affected viscus, for example, appendicular abscess usually formed in the right iliac fossa in relation to a perforated appendix or tubo-ovarian abscess, which is formed in the pelvis in relation to female adnexae; however, remote abscesses may form at remote sites in the intraperitoneal compartments including the pelvis, right and left paracolic gutters, right and left infradiaphragmatic spaces, Morrison's space, and in between small bowel loops.

Omentum, adjacent viscera, and inflammatory adhesions migrate to the site of infection, producing phlegmon, which functions as a barrier against the spread of infection to other peritoneal spaces. Intraperitoneal abscesses, especially those derived from colonic origins, contain a mixture of aerobic and anaerobic bacteria that stimulate inflammatory cellular and immunological responses to fight infection causing pus formation and abscess expansion. The resulting systemic inflammatory response may cause septic syndrome and multiorgan failure if left untreated.

A proper diagnosis and abscess localization is mandatory for prompt treatment. Percutaneous computed tomography (CT)-guided catheter drainage has become the standard treatment of most intra-abdominal abscesses.

In cases where percutaneous drainage is not accessible or not possible because of the presence of multiple

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abscesses, surgical drainage is an option. The surgical approach may be either laparoscopic or open.

Laparoscopic drainage (LD) for a massive intra-abdominal abscess is minimally invasive, enabling exploration of the abdominal cavity without the use of a wide incision; purulent exudates can be aspirated under direct vision [2]. In addition, laparoscopy can serve to remove the cause of sepsis, for example, perforated appendix, and ruptured colonic diverticulum, if the general condition is favorable.

The current prospective study aimed to evaluate the outcome of laparoscopic management of pelvic and paracolic abscesses not amenable to percutaneous or transrectal CT-guided or ultrasound (US)-guided drainage.

Patients and methods

The current study was carried out at the General Surgery Department, Al-Adwani General Hospital (Taif, KSA) and Benha University Hospital, from June 2013 to December 2015. The study protocol was approved by the local ethical committee. All enrolled patients signed written fully informed consents for diagnostic procedures, surgical decisions, and procedures. The study intended to include patients presenting with clinical and radiological manifestations of lower abdominal intraperitoneal abscesses not amenable to/or failed drainage using percutaneous CT-guided or US-guided drainage and irrespective of being primary or postoperative (PO).

All patients underwent a complete assessment of history including age, sex, calculation of BMI, and presence of associated medical diseases, especially diabetes mellitus. Patients were graded according to the international classification of BMI as follows: underweight (BMI$<$ 18.5 kg/m^2); normal weight range (BMI=18.5–24.99 kg/m^2); overweight (BMI=25–29.99 kg/m^2); and obese (BMI$>$30 kg/m^2) [3,4].

Assessment of history also included the presence of pain and its characteristics including site, referral, duration, and severity. The severity of pain was evaluated using a visual analogue scale (VAS) consisted of 10 points, with 0 indicating no pain and 10 indicating the worst intolerable pain [5]. The presence of nausea, vomiting, diarrhea, vaginal bleeding, or discharge was evaluated. Then, patients underwent a complete clinical examination with a special focus on the abdomen; examination per rectum and vagina was also performed. Thereafter, all patients underwent plain radiography in an erect position if possible and abdominal ultrasonography. CT scanning was performed if possible to ensure proper localization of the lesion and underlying pathology.

All patients received preoperative resuscitation in the form of intravenous fluid transfusion consisting of glucose 5% and lactated Ringer's solution in equal amounts for correction of acid–base and electrolyte disturbances, optimization of hemodynamic parameters, nutritional status, and coagulation profile. Diabetic patients received intensive insulin therapy using regular insulin to adjust random blood glucose to a range of 100–110 mg/dl. Thromboprophylaxis was performed whenever indicated.

All surgeries were performed under general inhalational anesthesia with tracheal intubation. Preoperative intravenous antimicrobial therapy in the form of third-generation cephalosporin and metronidazole infusion was administered. Before induction of anesthesia, intravenous ondansetron (4 mg) and dexamethasone (8 mg) was administered to prevent the development of nausea and vomiting.

Surgical treatment and trocar placement sites were planned and individualized according to abscess location, size, suspected pathology, presence of scars of previous surgery, and suspected sites of inflammatory adhesions. The optical port was inserted by an open technique usually in the supraumbilical position. Insufflation was maintained at 14 mmHg and two to four working ports were inserted under vision according to the condition of the abscess and respecting the concept of triangulation and maintaining the ergonomics of working hands.

Laparoscopic management was started by a thorough exploration of the abdominal cavity and breakdown of adhesions. Omentum, and small and large bowel, usually forming an inflammatory barrier around the abscess cavity, were gently swept away by gentle traction, hydrodissection, and a combination of blunt dissection and cold scissors with electrocoagulation of bleeding points. In certain instances, a harmonic scalpel was used in the presence of tough adhesions. The abscess cavity was entered, samples of pus were collected and sent for bacteriological examination and culture and sensitivity tests, and then the abscess was drained. If multiple loculi were found, septa were cut down if possible to create one locus that was drained. The abscess cavity was irrigated using normal saline. The source

of infection was managed if possible, and then drains were inserted. Before theater discharge, patients were catheterized for follow-up of urine output (UOP). Collected intraoperative data included the feasibility of LD and the conversion rate to open exploration, operative time, the need for blood transfusion, and its amount.

Patients were transferred to the postanesthetic care unit and were maintained on fluid therapy according to hemodynamic parameters, central venous pressure, and UOP. Patients were maintained on intravenous antibiotic therapy and metronidazole infusion if indicated. Patients with a hemoglobin concentration of less than 7 g% or with an intraoperative blood loss of more than 500 ml received packed red blood cells. Patients were monitored noninvasively for blood pressure, heart rate, and respiratory rate, and levels of blood gases and blood pH were also determined. UOP was adjusted at a rate of greater than or equal to 0.5 ml/kg/h.

PO pain was scored using the 10-point pain VAS score at admission to postanesthetic care unit and 6-hourly for the next 24-h. PO analgesia was provided in the form of intramuscular meperidine 50 mg on pain VAS score was greater than or equal to four. The occurrence of PO nausea and/or vomiting was recorded and was managed by an intravenous injection of ondansetron (4 mg). Patients were observed for persistent pain despite provision of analgesia, development or persistence of fever, and/or abdominal signs such as distension, local tenderness, guarding, and delayed return of bowel sound. Time until first ambulation and oral fluid intake, development of PO complications, morbidities or mortality, and duration of PO hospital stay were also recorded.

Results

The study included 40 patients, 25 men and 15 women (mean age: 40.8±6.4 years, range: 27–52 years). Details of patients' enrollment data are shown in Table 1.

All patients presented with a picture of acute abdomen with pain as the most prominent complaint. Pain was throbbing in nature and was mostly localized with signs of peritonism. At admission, the mean pain VAS score was 6.9±1 (range: 4–8). Radiological diagnosis defined 32 primary intra-abdominal abscesses and eight PO abscesses. Details of patients' clinical data and outcomes of preoperative investigations are shown in Table 2.

Laparoscopic dissection of tissues away from the abscess cavity seemed to be dangerous in four cases that were converted to laparotomy for open management, for a conversion rate of 10%. The first case was a woman who developed pelvic collection after a vaginal hysterectomy performed since 12 days; the patient looked toxic and required fluid resuscitation and intraoperative fresh blood transfusion. CT imaging showed a multilocular abscess indenting the rectum and urinary bladder and the contents appeared to be thick. Laparoscopic exploration confirmed CT findings, but dissection was difficult. Open laparotomy enabled abscess drainage and there was rectal communication between the abscess cavity and the rectum; proximal diversion was performed (Hartman's procedure). The patient had a smooth PO course and, after 3-min rectal contrast enema, showed complete closure of the fistulous tract and open closure of diversion was performed.

The second patient had missed perforation during transurethral prostatectomy; a pelvic abscess was secondary to leakage starting during the operation and continued postoperatively. The patient was

Table 1 Patients' data

Data	Findings
Age (years)	
Strata	
<30	3 (7.5)
30–39	14 (35)
40–49	19 (47.5)
≥50	4 (10)
Total	40.8±6.4
Sex	
Male	25 (62.5)
Female	15 (37.5)
BMI data	
Weight (kg)	83.2±16.5
Height (cm)	168.4±2.7
BMI (kg/m^2)	
Strata	
Underweight (<18.5)	4 (10)
Average (18.5–24.99)	5 (12.5)
Overweight (25–29.99)	14 (35)
Obese (30–34.99)	12 (30)
Morbid obese (>35)	5 (12.5)
Total	29.3±5.5
Medical comorbidity	
No	29 (72.5)
Yes	
Diabetes mellitus	8 (20)
Hypertension	4 (10)
Cardiac disease	2 (5)
Chronic renal disease	1 (2.5)
Average/patient	1.4

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

catheterized and methylene blue dye was injected into the bladder. Fortunately, the leakage point was identified, the bladder was cautiously dissected, and the fistulous tract communicating the bladder to the abscess cavity was identified and the bladder wall was repaired in two layers. Intestinal loops were found to form a part of the wall of the abscess cavity that was irrigated by saline and drained with peritoneal drainage. On the fifth operative day, ascending cystography was performed to ensure complete closure of the fistula and competent repair. The remaining two patients had acute sigmoid diverticular abscess of Hinchey stages II and III with free perforation and generalized purulent peritonitis. Both patients underwent open drainage and sigmoid resection using Hartmann's procedure.

Table 2 Clinical, laboratory, and radiological data of the patients studied

Data	Findings
Pain VAS scores	
Strata	
4–5	2 (5)
6–7	26 (65)
>7	12 (30)
Mean±SD	6.9±1
GIT manifestations	
Nausea	40 (100)
Vomiting	30 (75)
Diarrhea	15 (37.5)
Constipation	10 (25)
Tenesimus	7 (17.5)
Temperature (°C)	
Strata	
<38	5 (12.5)
38–39	24 (60)
>39	11 (27.5)
Mean±SD	38.8±0.6
Laboratory investigations	
Hemoglobin concentration (g%)	
<8	1 (2.5)
8–10	19 (47.5)
>10–12	17 (42.5)
>12	3 (7.5)
Mean±SD	10.1±1.3
TLC (10^3/ml)	
<15	2 (5)
15–20	11 (27.5)
20–25	15 (37.5)
>25	12 (30)
Mean±SD	22.7±5.4
CRP (mg/dl)	
<24	13 (32.5)
24–36	22 (55)
>36	5 (12.5)
Mean±SD	26.6±7.6
Radiological diagnosis	
Primary	
Appendicular abscess	17 (42.5)
Diverticular abscess	8 (20)
Tubo-ovarian abscess	7 (17.5)
PO	
Appendectomy	3 (7.5)
Hysterectomy	2 (5)
GIT surgery	2 (5)
Urological surgery	1 (2.5)

Data are presented as numbers and mean±SD; percentages are given in parentheses. CRP, C-reactive protein; GIT, gastrointestinal tract; PO, postoperative; TLC, total leukocytic count; VAS, visual analogue scale.

All the rest of the 36 patients underwent successful LD and management (Figs 1–4) within a mean operative time of 94.3±12.1 min (range: 75–120 min). Nineteen patients required an operative time of less than 90 min, but 17 patients required more than 90 min. The mean intraoperative blood loss was 172.5±65.7 ml (range: 100–300 ml). No patient required blood transfusion for intraoperative blood loss, but five patients received a transfusion of freshly donated blood for correction of anemia and to improve their immunity (Table 3).

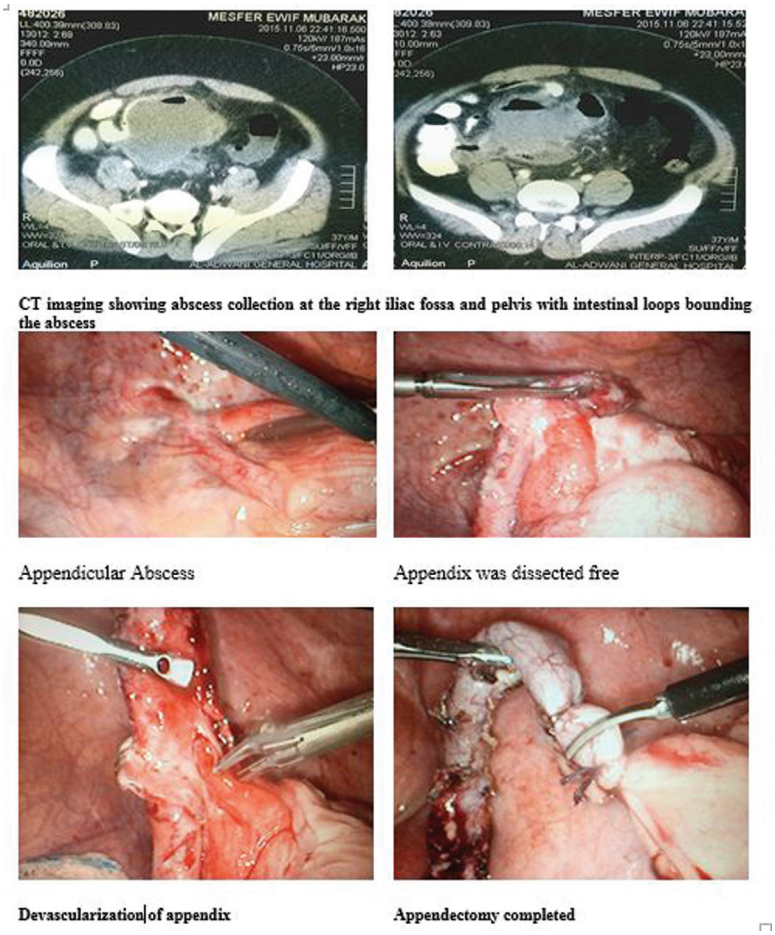
Throughout the immediate PO course, pain VAS scores showed a gradual significant decrease as shown in Fig. 5. All patients tolerated pain during the immediate 6-h PO and no one required rescue analgesia during the first 6-h PO and, thereafter, only 15 patients required rescue analgesia throughout their first 24-h PO. The majority of patients could be mobilized within 4–5-h PO, with a mean duration till first mobilization of 4.3±1 h (range: 3–7 h). The mean time until the first oral intake was 19.4±7.3 h (range: 12–36 h). The mean duration of peritoneal drainage was 8.8±2.7 days (range: 3–14 days), and the mean PO hospital stay was 5.6±1.7 days (range:

Table 3 Operative data for patients who received complete laparoscopic management

Data	Findings
N (%)	36 (90)
Operative time (min)	
Strata	
≤90	19 (52.8)
>90	17 (47.2)
Mean±SD	94.3±12.1
Intraoperative blood loss	
Amount (ml)	
<200	20 (55.6)
>200	16 (44.4)
Mean±SD	172.5±65.7
Need for blood transfusion	
For bleeding	0
Correction of anemia	5 (13.9)
No	31 (86.1)

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

Figure 1



Appendicular abscess secondary to a perforated appendix; abscess was drained and appendectomy was performed successfully. CT, computed tomography.

3–9 days). Details of immediate PO data are shown in Table 4.

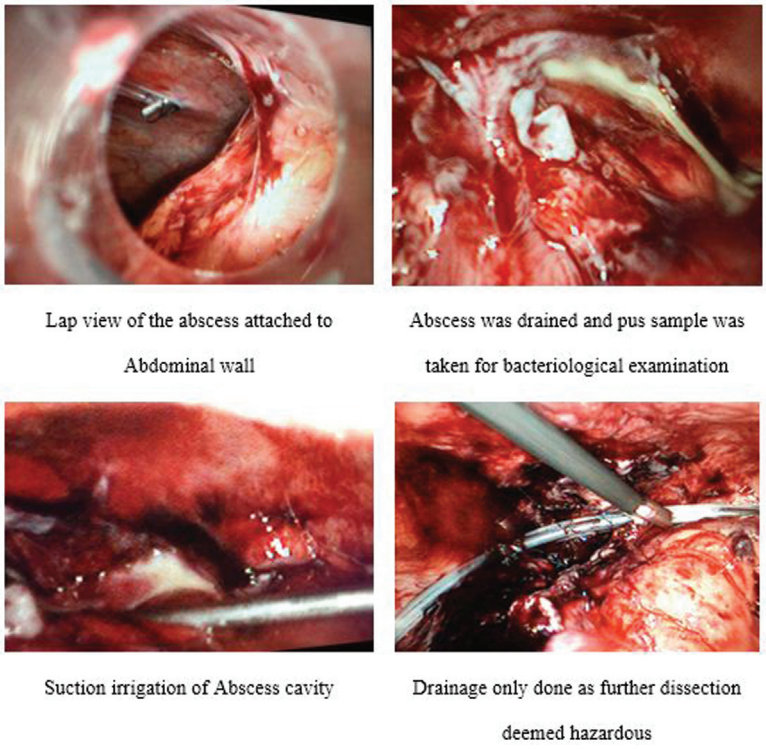
During PO course, three (8.3%) patients developed PO infection; two (5.6%) patients had surgical wound infection at the umbilical port site. Unfortunately, one (2.8%) patient developed recollection that required second-look laparoscopy for drainage of pelvic recollection. Throughout the duration of PO, patients with preoperative medical problems were maintained on their preoperative therapies for strict control, especially for diabetes mellitus. Unfortunately, two patients died during their hospital stay, yielding a mortality rate of 5%. The first patient received laparoscopic management and on the second PO day, developed acute myocardial infarction and required ICU admission, but conservative treatment could not help sustain and the patient died. The second patient underwent laparotomy and developed hyperglycemic hyperosmolar diabetic coma, but unfortunately, did not respond to medical treatment and progressed to acute renal failure and died on the fifth PO day.

Discussion

The results obtained showed the feasibility of LD of pelvic abscess not amenable to US-guided or CT-guided needle drainage with a conversion rate of 10% not only for difficult dissection but also for patients' condition. Moreover, LD was feasible for both primary and PO abscesses; thus, laparotomy was not performed for such cases, especially PO abscesses, because of the presence of intraperitoneal adhesions, and for cases with an appendicular abscess or mass that required only drainage and another setting for management.

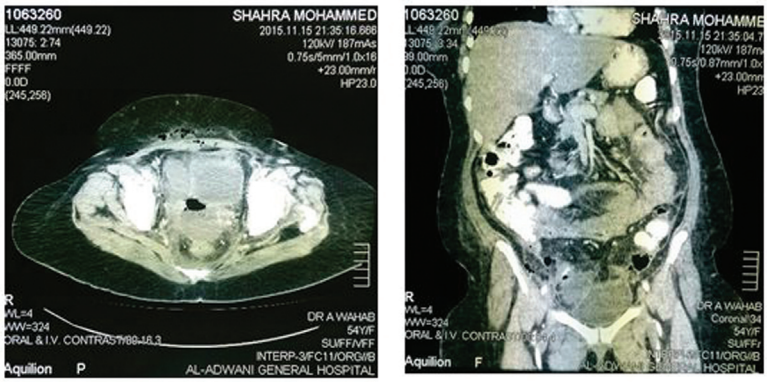
In support of the feasibility and safety of laparoscopic management for patients with complicated appendicitis (CA), Gosemann *et al.* [6] reported a conversion rate of 1.2% and found that laparoscopic compared with open surgery was associated with lower readmission rates for surgical complications in both uncomplicated appendicitis and CA. As another support for the feasibility of laparoscopic management of CA, Kang *et al.* [7] compared conventional versus single-port laparoscopy, and found no difference between both groups in the

Figure 2



Appendicular abscess secondary to a perforated appendix; abscess was drained and appendectomy was postponed.

Figure 3

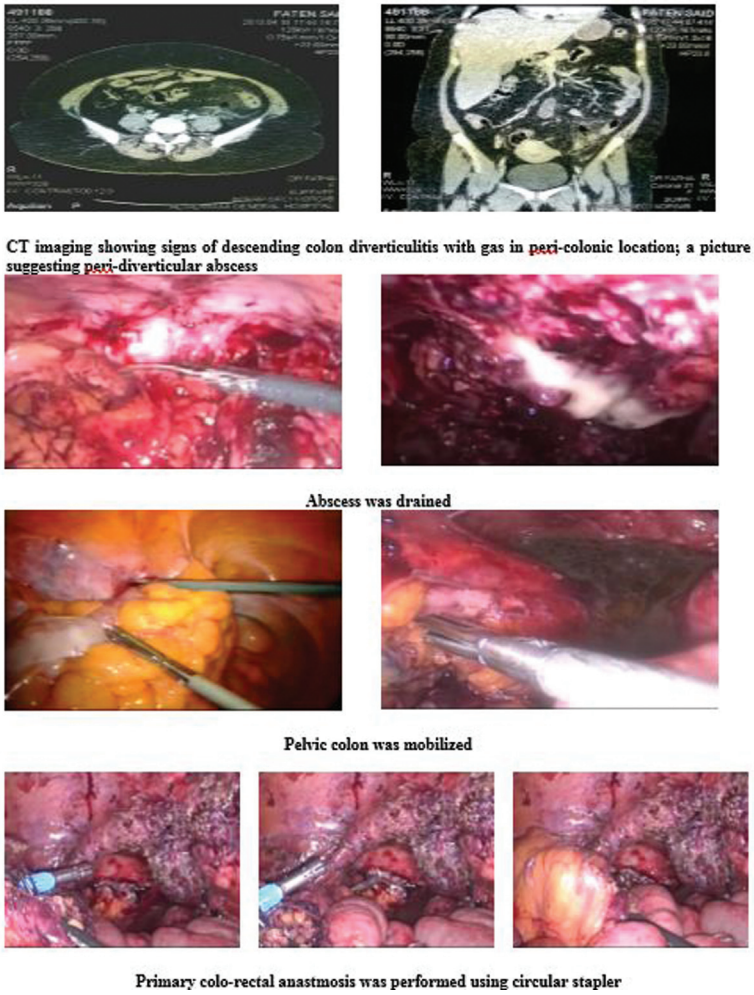


Computed tomography imaging showing posthysterectomy multiple pelvic abscesses, of which one large abscess was located on the right side of the urinary bladder and another large one behind the bladder.

operation time, PO hospital stay, readmission rate, and rate of PO complications, but more patients with CA needed conversion to open surgery with single-port laparoscopy. In contrast, Taguchi *et al.* [8] found that the rate of PO complications, including incisional or organ/space infection and stump leakage, did not differ significantly between open and laparoscopic appendectomy.

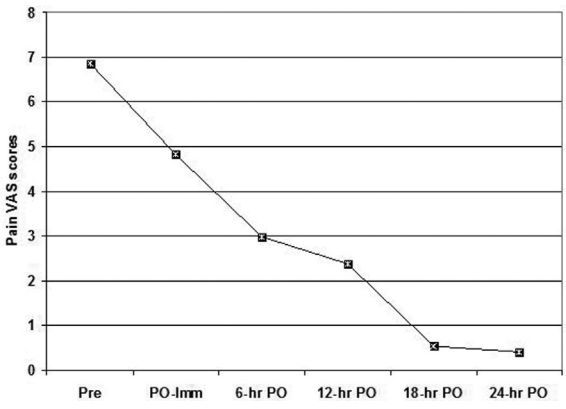
LD provided the studied patients with the routine advantages of laparoscopic surgeries, namely, low PO pain scores and requirement for rescue analgesia, early PO ambulation, and oral intake, with subsequent early return home. In line with these data, Gosemann *et al.* [6] found that laparoscopic compared with open surgery was associated with a shorter length of hospital stay. Also, Çiftçi [9] reported that the VAS of pain was significantly higher in the open appendectomy group at the 1st, 6th, and 12th hour PO, with a significantly higher need for analgesic medication compared with the laparoscopic group, but with no differences between the two groups in terms of morbidity and total complication rates. In contrast, Taguchi *et al.* [8] found no significant

Figure 4



Peridiverticular abscess; abscess was drained and colorectal anastomosis was performed successfully. CT, computed tomography.

Figure 5



Mean pain VAS scores determined throughout 24-h postoperatively compared with the preoperative scores. PO, postoperative; VAS, visual analogue scale.

differences between open and laparoscopic appendectomy in hospital stay, duration of drainage, analgesic use, or parameters for PO recovery, except days required for mobilization.

In terms of diverticular disease, the study included eight patients with complicated acute diverticulitis (AD); six cases were managed laparoscopically and two cases required conversion to open surgery, but all cases were managed uneventfully. These data indicated the safe applicability of laparoscopic management of AD despite the still present controversy on the applicability of LD and/or definitive management for complicated AD, where Royds *et al.* [10] documented that laparoscopic surgery for both complicated and uncomplicated diverticular disease is associated with low rates of PO morbidity and relatively low conversion rates and could thus be considered as the standard of care for diverticular disease. Also, Köckerling [11] reported that LD can be performed safely and act effectively for pericolic and pelvic abscesses (Hinchey stages I and II) and purulent and feculent peritonitis (Hinchey stages III and IV) and Hidaka *et al.* [12] documented that laparoscopic sigmoidectomy and fistulectomy could be performed for

Table 4 Postoperative data for patients (*n*=36) who received complete laparoscopic management

Data	Findings
Pain data	
VAS score	
Preoperative	6.9±1
Immediate PO	4.8±0.7
6-h PO	3±0.8
12-h PO	2.4±1.5
18-h PO	0.5±1
24-h PO	0.4±0.6
Request of rescue analgesia	
Yes	15 (41.7)
No	21 (58.3)
Duration of analgesia (h)	
6	11 (30.6)
12	4 (11.1)
≥18	21 (58.3)
Time till first mobilization (h)	
Strata	
2–3	8 (22.2)
4–5	24 (66.7)
>6	4 (11.1)
Total	4.3±1
Time till first oral intake (h)	
Strata	
12–18	22 (61.1)
>18–24	9 (25)
>24	5 (13.9)
Total	19.4±7.3
Duration of abdominal drainage (days)	
Strata	
3–6	3 (8.3)
7–10	22 (61.1)
>10	11 (30.6)
Total	8.8±2.7
Duration of hospital stay (days)	
Strata	
3–4	11 (30.6)
5–7	18 (50)
8–9	7 (19.4)
Total	5.6±1.7

Data are presented as numbers and mean±SD; percentages are given in parentheses. PO, postoperative; VAS, visual analogue scale.

sigmoidocutaneous fistula with an uneventful PO course.

In contrast, Schultz *et al.* [13] and Vennix *et al.* [14] documented that among patients with perforated diverticulitis and undergoing emergency surgery, the use of laparoscopic lavage versus primary resection did not reduce severe PO complications and led to worse outcomes in secondary end points.

However, recently, in 2016, Rotholtz *et al.* [15] documented that the laparoscopic approach in any kind of complicated diverticular disease can be performed with low morbidity and acceptable conversion rates compared with patients undergoing laparoscopic surgery for recurrent diverticulitis. Also, Bhakta *et al.* [16] reported that in patients with complicated diverticulitis, the overall conversion rate was 12.8%; patients who had conversion to an open procedure had a significantly higher rate of PO complications and concluded that the laparoscopic approach to sigmoid colectomy is safe and preferable in experienced hands.

During PO course, three (8.3%) patients developed PO infection; two (5.6%) patients had surgical wound infection at the umbilical port site and one (2.8%) patient developed recollection that required second-look laparoscopy for drainage. Similarly, Agrawal *et al.* [17], in their series of laparoscopic management of cases of appendicular mass, reported PO complications in 7.69% of patients, of whom 5.76% had a minor wound infection at the umbilical port site and 1.92% had PO pelvic abscess, which was managed with percutaneous aspiration.

Conclusion

LD was a feasible, safe, and effective therapeutic modality for primary or secondary pelvic abscesses. LD is a minimally invasive procedure with low PO morbidities. Laparoscopic definitive surgery could be performed with a conversion rate of 10%. No surgery-related mortality was encountered.

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Conflicts of interest

There are no conflicts of interest.

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Comparison between the validity of the 'Modified Alvarado' and 'Raja Isteri Pengiran Anak Saleha' scores for the diagnosis of acute appendicitis

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Background
Clinical scores were designed to improve the diagnostic accuracy (DA) of acute appendicitis. However, their results vary when applied in different populations. This study aimed to compare the validity of the Modified Alvarado Score (MAS) with the Raja Isteri Pengiran Anak Saleha (RIPASA) score for diagnosing acute appendicitis in adult Saudi population.

Materials and methods
This study followed a prospective study design. It was carried out in Aseer Central Hospital, Abha, Saudi Arabia, during the period from November 2014 to May 2015. The study included 60 (aged >13 years) patients who were admitted in the Emergency Department and were clinically diagnosed as having acute appendicitis. Both the MAS and the RIPASA score were applied. A cutoff value for positive MAS was more than or equal to 7, and it was of at least 7.5 for positive RIPASA score. Surgical team members were blinded to the results of both scores. Operative findings describing the appendix, postoperative complications, hospital stay, and final diagnosis by histopathology were recorded.

Results
The study included 60 patients. There were 17 (28.3%) male and 43 (71.7%) female patients, with a mean age of 23.3±9.7 years. Negative appendectomy rate was 13.3%. The mean duration of hospital stay was 2.39±1.67 days. The MAS showed poor sensitivity (59.6%), poor DA (63.3%), and good specificity (87.5%). Compared with the MAS, the RIPASA score showed better sensitivity (96.2%) and DA (85.0%) when applied to our patients.

Conclusion
Neither the RIPASA score nor the MAS seems ideal for the accurate diagnosis of acute appendicitis when applied to patients in the southern region of Saudi Arabia.

Keywords:
acute appendicitis, appendectomy, diagnostic techniques, Modified Alvarado Score, Raja Isteri Pengiran Anak Saleha

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Introduction

Acute appendicitis is the most common cause of acute abdomen in young adults. Appendicitis is sufficiently common and appendectomy is the most frequently performed abdominal operation [1]. The incidence of appendicitis is 1.5–1.9/1000, and it is ~1.4 times greater in men than in women [2]. Accurate identification of patients who require immediate surgery as opposed to those who will benefit from active observation is not always easy [3].

The definitive diagnosis of acute appendicitis is only possible with histopathology results after appendectomy. However, the decision to perform surgery is based solely on clinical evaluation supported by laboratory data. Therefore, diagnostic errors are common, resulting in a median incidence of perforation of 20% and a negative laparotomy rate ranging from 2 to 30% [4]. Ultrasonography and computed tomography (CT) scan are used nowadays to decrease the incidence of negative laparotomies. Nevertheless, ultrasonography cannot replace clinical evaluation, as false-negative rates of up to 24% have been reported [5]. In addition, nonavailability of ultrasonography or CT scan in many medical institutes constitutes a main obstacle that forces many surgeons to depend on clinical evaluation even in difficult cases.

In order to reduce the negative appendectomy rates, various scoring systems have been developed for supporting the diagnosis of acute appendicitis [6].

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The Alvarado scoring system is one of them and is purely based on history, clinical examination, and laboratory tests [7]. The classic Alvarado score included left shift of neutrophil maturation yielding a total score of 10. However, in 1994, Kalan *et al.* [8] omitted this parameter and produced a modified score. The Modified Alvarado Score (MAS) has comparable sensitivity and specificity to the classic Alvarado score and is easier to apply [9]. Differences in sensitivities and specificities were observed if the scores were applied to various populations and clinical settings, usually with worse yield when applied outside the population in which they were originally created [3].

In 2010, a group in Raja Isteri Pengiran Anak Saleha (RIPASA) Hospital, in Brunei, developed a new scoring system called the RIPASA score [10] and claimed that it was more suitable for Asian and Middle Eastern populations compared with the classic Alvarado and the MAS system that were created for European population.

Therefore, the aim of our study was to compare the validity of the MAS with the RIPASA score for diagnosing acute appendicitis in adult Saudi population in Aseer region (southwestern part of Saudi Arabia) in terms of sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and diagnostic accuracy (DA).

Patients and methods

This study followed a prospective study design that was carried out in Aseer Central Hospital, a tertiary care hospital in Abha, Saudi Arabia, during the period from November 2014 to May 2015. The study included patients above 13 years of age admitted in the Emergency Department with complains of acute abdomen who were clinically diagnosed as having acute appendicitis. Patients below 13 years of age were treated by the pediatrics' team according to the policy of our hospital and were excluded from the study.

The sample size was calculated according to Dahiru *et al.* [11] to be 60 patients (with Z_α=1.96, expected prevalence of correctly diagnosed cases of appendicitis is 85%, and accepted error of 0.09).

Diagnosis and decision to operate were made by general surgical team members who were not involved in this research and their decision was based totally on clinical judgment supported by investigations. The research team met the patients and recorded the data required once clinical diagnosis of appendicitis was made. If a patient was placed under observation, the scores were recorded on admission and every 6 h, and only cases that eventually underwent appendectomy were included in the study and their last recorded data were used.

Preoperative workup

All patients included in the study were subjected to history taking and clinical examination. Investigations were reported. Informed consent for the operation and for participation in the research was obtained from all patients. Both the MAS and RIPASA scores were applied by the research team (Tables 1 and 2). A cutoff value for positive MAS was at least 7 [9], whereas the cutoff for positive RIPASA score was at least 7.5 [10]. The surgical team members were blinded to both scores to avoid influencing their clinical decision.

Table 1 Modified Alvarado Score

Items	Score
Symptoms	
Migration of pain to the right lower quadrant	1
Anorexia	1
Nausea/vomiting	1
Signs	
Tenderness in the right iliac fossa	2
Rebound tenderness in the right iliac fossa	1
Elevated temperature (>37.3°C)	1
Investigations (leukocytosis) (>10 000/ml)	2

Table 2 Raja Isteri Pengiran Anak Saleha scores

Items	Score
Demographic data	
Male	1.0
Female	0.5
Age <39.9 years	1.0
Age ≥40 years	0.5
Symptoms	
RIF pain	0.5
Migration of RQP	0.5
Anorexia	1.0
Nausea/vomiting	1.0
Duration of symptoms <48 h	1.0
Duration of symptoms >48 h	0.5
Signs	
RIF tenderness	1.0
RIF guarging	2.0
Rebound tenderness	1.0
Rovsing's sign	2.0
Fever >37–<39	1.0
Investigations	
Raised WBCs	1.0
Negative urinalysis	1.0
Additional scores	
Foreign ID	1.0

RQP, right quadrant pain; RIF, right iliac fossa; WBCs, white blood cells.

Operative workup

The operative findings describing the appendix were recorded (normal, inflamed, or perforated).

Postoperative workup

Postoperative complications (if any) in addition to hospital stay and final diagnosis by histopathology were recorded by the researchers.

Outcomes

Primary endpoint

The primary endpoint was the comparison between the validity (sensitivity, specificity, PPV, NPV, and DA) of the MAS and the RIPASA score in accurately diagnosing acute appendicitis.

Secondary endpoint

The secondary endpoint was determination of the effect of patients' age and sex on the validity parameters for the MAS and the RIPASA score in accurately diagnosing acute appendicitis.

The statistical analysis of the data was performed to determine the validity of both the MAS and the RIPASA score using the statistical package for the social sciences (SPSS, version 22). To test significance of differences, the independent sample *t*-test was applied for quantitative data, whereas the χ^2-test was applied for qualitative data (the Fisher exact test was used when appropriate). A statistically significant *P*-value was considered at *P* less than 0.05.

Number of trial registry ACTRN12614001043628 (http://www.ANZCTR.org.au/ACTRN12614001043628.aspx).

Results

The study included 60 [17 (28.3%) male and 43 (71.7%) female] patients who underwent appendectomy. The mean age of the patients was 23.3±9.7 (range: 14–62 years) years. Fifty-two (86.7%) patients were diagnosed immediately after clinical examination with or without radiological investigation. However, eight (13.3%) patients were placed under observation and the decision of operation was taken after a mean time of 17.43 h. Two of the eight patients who were placed under active observation were found by means of postoperative histopathology to have normal appendices. However, the MAS and the RIPASA score indicated false-positive results for both of them.

Postoperative histopathology was carried out for all 60 patients and revealed that 52 (86.7%) patients had acute appendicitis with variable degrees of inflammation, whereas eight (13.3%) patients did not have acute appendicitis. Details of histopathological findings are shown in Table 3.

The mean duration of hospital stay was 2.39±1.67 (range: 1–12 days) days. Four (6.7%) patients developed superficial wound infection in the form of erythema and serous discharge and were treated successfully with conservative measures. One (1.7%) patient developed localized pelvic collection and required ultrasound-guided drainage. One (1.7%) patient developed adhesive intestinal obstruction 5 months after surgery. Conservative measures were not successful to relieve his condition and laparoscopic adhesiolysis was performed.

Sensitivity, specificity, PPV, NPV, and DA were calculated [12] for the MAS and the RIPASA score for all patients (Table 4). Moreover, the same were calculated for young (≤30 years), old (>30 years), male, and female patients separately to determine the effect of age and sex on the accuracy of diagnosis of both scores (Table 4).

Analysis of the components of each score was performed to determine the possible positive or negative influences of each component on the corresponding score (Table 5).

Discussion

Although acute appendicitis is the most common emergency condition that requires surgical intervention [1], accurate diagnosis of acute appendicitis is a challenge all over the world. Accurate diagnosis of acute appendicitis is important to avoid missing cases of acute appendicitis resulting in further complications such as perforated appendix that may lead to an avoidable poor outcome. In addition, accurate diagnosis prevents operating negative cases, during which a patient is subjected unnecessarily to 10% risk for morbidity and mortality in addition to exhaustion of the resources of healthcare [13]. Until now, neither clinical nor laboratory investigations could provide 100% accuracy in

Table 3 Histopathology of excised appendices (*n*=60)

Findings	*n* (%)
Inflamed appendix	52 (86.7)
Acute uncomplicated appendicitis	31 (51.7)
Acute gangrenous appendicitis	16 (26.7)
Perforated appendix	5 (8.3)
Noninflamed	8 (13.3)
Carcinoid	1 (1.7)
Normal (ovarian cyst detected intraoperatively)	3 (5.0)
Normal	4 (6.7)

Table 4 Validity of the Modified Alvarado Score and the Raja Isteri Pengiran Anak Saleha score

	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Diagnostic accuracy (%)
Modified Alvarado Score (all patients) (*n*=60)	59.6	87.5	96.9	25.0	63.3
RIPASA (all patients) (*n*=60)	96.2	12.5	87.7	33.3	85.0
Modified Alvarado Score					
Young (≤30 years) (*n*=52)	54.4	83.3	96.2	19.2	57.7
Old (>30 years) (*n*=8)	100.0	100.0	100.0	100.0	100.0
RIPASA					
Young (≤30 years) (*n*=52)	95.7	16.7	89.8	33.3	86.6
Old (>30 years) (*n*=8)	100.0	0.0	75.0	–	75
Modified Alvarado Score					
Male (*n*=17)	58.8	–	100	0	58.8
Female (*n*=43)	60.0	87.5	95.5	33.3	65.1
RIPASA					
Male (*n*=17)	100.0	–	100.0	–	100.0
Female (*n*=43)	94.3	12.5	82.5	33.3	79.1

RIPASA, Raja Isteri Pengiran Anak Saleha.

Table 5 Analysis of the components of both scores

Item	Negative component		Positive component		*P* value
	Nonappendicitis	Appendicitis	Nonappendicitis	Appendicitis	
MAS					
Migration of pain	7 (11.7)	15 (25.0)	1 (1.7)	37 (61.7)	0.001*
Anorexia	1 (1.7)	5 (8.3)	7 (11.7)	47 (78.3)	0.800
Nausea and vomiting	0 (0)	5 (8.3)	8 (13.3)	47 (78.3)	0.360
Tenderness RIF	0 (0)	0 (0)	8 (13.3)	52 (86.7)	–
Rebound tenderness RIF	1 (1.7)	2 (3.3)	7 (11.7)	50 (83.3)	0.296
Elevated temperature (>37.3°C)	5 (8.3)	7 (11.7)	3 (5.0)	45 (75.0)	0.006*
Leukocytosis	6 (10.0)	10 (16.7)	2 (3.3)	42 (70.0)	0.003*
RIPASA					
Sex					
Male	0	0	0	17	0.193
Female	1	2	7	33	
Age	18.0±0.0	22.0±0.0	24.7±6.4	23.3±10.4	0.928
Right IF pain	0 (0)	0 (0)	8 (13.3)	52 (86.7)	–
Migration of pain	7 (11.7)	15 (25.0)	1 (1.7)	37 (61.7)	0.001*
Anorexia	1 (1.7)	5 (8.3)	7 (11.7)	47 (78.3)	0.800
Nausea and vomiting	0 (0)	5 (8.3)	8 (13.3)	47 (78.3)	0.360
Duration of symptoms	0	26	8	26	0.008*
RIF tenderness	0 (0)	0 (0)	8 (13.3)	52 (86.7)	–
RIF guarding	6 (10.0)	33 (55.0)	2 (3.3)	19 (31.7)	0.524
Rebound tenderness	1 (1.7)	2 (3.3)	7 (11.7)	50 (83.3)	0.296
Rovsing's sign	5 (8.3)	30 (50.0)	3 (5.0)	22 (36.7)	0.797
Fever 37–39	4 (6.7)	5 (8.3)	3 (5.0)	47 (78.3)	0.008*
Leukocytosis	6 (10.0)	10 (16.7)	2 (3.3)	42 (70.0)	0.003*
Negative urinalysis	3 (5.0)	11 (18.3)	5 (8.3)	41 (68.3)	0.309
Foreign ID	7 (11.7)	49 (81.7)	1 (1.7)	3 (5.0)	0.477

Values are presented as mean±SD and *n* (%). IF, iliac fossa; MAS, Modified Alvarado Score; RIF, right iliac fossa; RIPASA, Raja Isteri Pengiran Anak Saleha. *Significant.

diagnosis. However, trials have been made to improve the DA in many centers of the world [6,7,10].

In our study, we had a negative appendectomy rate of 13.3%. Similar results were reported in the literature, with a negative appendectomy rate of 21% [14], 15.6% [15], and 15% [3]. It was proved in some studies that radiological modalities such as CT imaging further aid in making a definite diagnosis and have been reported to have high sensitivity (94%) and specificity (95%) for diagnosing acute appendicitis [16]. However, such practice could not be standardized because of nonavailability of the CT facility in many medical institutes. It is also very costly and could not be implemented in poor countries. Furthermore, arrangement for CT scan may delay emergency

appendectomy. In addition, recent reports have suggested that the indiscriminate use of CT scan may lead to the detection of early low-grade appendicitis and these patients may then be subjected to unnecessary appendectomy, in a condition that would otherwise have resolved spontaneously with antibiotic therapy [17]. A population-based study in the USA indicated that there was essentially no change in the frequency of negative appendicectomy using CT scan for all patients with query appendicitis [18]. In our hospital, a selective approach is applied by requesting CT scan for doubtful cases only and not for all patients. The effect of CT scan in improving the DA is beyond the scope of our study.

Diagnosis of acute appendicitis with nonclassic presentations represents a real challenge even for expert doctors. Junior doctors are the first ones to encounter patients of acute appendicitis in emergency departments; therefore, the idea of creating scoring systems to aid in the accurate diagnosis of acute appendicitis was good and theoretically helpful. The MAS system has been applied since 1994 to aid the clinical decision-making process in achieving an accurate diagnosis of acute appendicitis both efficiently and effectively [8]. However, the MAS was originally developed among western populations, and when applied in different communities, such as the Middle East and Asia, the sensitivity and specificity levels achieved were very low [15,19]. Accordingly, a new scoring system called the RIPASA score was developed and proved to be more extensive and avoided the theoretical mistakes of the MAS by considering demographic data such as age and sex in its components [19]. In a retrospective study, the RIPASA score has been shown to achieve better sensitivity (88%) and specificity (67%) compared with the Alvarado score (sensitivity 59% and specificity 23%) in an Asian population [10].

We agree with Horzić *et al.* [3] that any rigid scoring system that does not respect different significances of defined signs and symptoms within different subpopulations and geographical settings will not be as effective when applied to the entire population in the emergency department. In the literature, no studies were found to determine as to which of the most common scores, the MAS and the RIPASA score, will have a better DA when applied to our population in the southern region of Saudi Arabia. Therefore, in this study, we applied both scores to all patients who were subjected to appendectomy to determine their DA compared with the absolute evidence of accurate diagnosis, by histopathology. We followed a cutoff value for positive MAS to be more than or equal to 7, whereas a cutoff for positive RIPASA score to be more than or equal to 7.5, as most of the studies showed better diagnostic parameters on these cutoff values [9,10,20]. When applied to our patients, the MAS showed poor sensitivity, poor DA, and good specificity (with a sensitivity of 59.6%, specificity of 87.5%, PPV of 96.9%, NPV of 25.0%, and DA of 63.3%). Similar poor results of the MAS were found in other studies that applied the score for non-European populations [10,15,19,21]. However, the RIPASA score showed better sensitivity and DA when applied to our patients compared with the MAS (with a sensitivity of 96.2%, specificity of 12.5%, PPV of 87.7%, NPV of 33.3%, and DA of 85.0%) but with evident very poor specificity. Both scores had good positive and bad NPV s. Our study showed female predominance, with 71.7% of female patients compared with 28.3% of male patients. A similar finding was reported by some authors in the middle east [22]. This is in disagreement with other studies in Africa that showed male predominance [23,24]. This may highlight the importance of considering the racial differences that affect presentation of different diseases. Both the MAS and the RIPASA score showed excellent PPV for diagnosing male patients compared with female patients. However, this may be influenced by the fact that all male patients included in the study showed positive histopathology results for appendicitis. The RIPASA score showed better DA compared with the MAS for both male and female patients, but with outstanding DA for male patients (100.0%). This may be attributed to the fact that female patients with right iliac fossa pain have a wide range of differential diagnosis, as a result of which acute appendicitis may be overdiagnosed. On analyzing the effect of age on both scores, the RIPASA score showed better sensitivity and DA for young people ($\leq$30 years). However, the MAS showed 100% DA for older patients (>30 years) compared with 75% in the RIPASA score. From the previous results, we can find that the MAS is better for diagnosing patients older than 30 years, whereas the RIPASA score is better in diagnosing male patients.

Analysis of components of both scores showed that elevated temperature and leukocytosis have a significant positive influence. Ignoring demographic data of patients may have a negative influence on the MAS as described above. Surprisingly, migration of pain was found to have a significant negative influence in both scores. Moreover, duration of symptoms was found to have a significant negative influence on the

RIPASA score. This may be related to the patients' ability to describe their symptoms, which may necessitate the correlation of these negative results to the level of education of these patients.

Conclusion

We can conclude that neither the RIPASA score nor the MAS seems ideal for accurate diagnosis of acute appendicitis when applied to patients in the southern region of Saudi Arabia. If we consider that operating a negative appendicitis is less harmful compared with missing a positive one, the RIPASA score would be more suitable for our patients compared with the MAS. However, a future larger detailed study for all demographic and clinical data investigations, in addition to level of education may be required to determine factors that correlate significantly with the accurate diagnosis of our population.

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Conflicts of interest

There are no conflicts of interest.

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The use of tourniquet versus bipolar cautery as hemostatic aid in distal hypospadias repair in children: a multicentric study

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Background/purpose
Hypospadias is a congenital penile defect in which the urethra opens into the ventral part of the penis, scrotum, or perineum. Hypospadias surgery is performed in children where losses of even minimal amounts of blood are of concern. The two commonly used methods to achieve hemostasis are vasoconstrictive agents and the bipolar and application of a penile tourniquet. *The aim of this study* is to compare the outcome of using vasoconstrictors and bipolar diathermy without tourniquet versus the use of tourniquet and bipolar diathermy to obtain hemostasis during hypospadias repair in children.

Patients and methods
This prospective study was carried out at 4 different pediatric surgery units, during the period from April 2012 to September 2014. The study included 60 uncircumcised boys with mid penile, distal penile or coronal hypospadias with ages ranging between 6 months and three years. Recurrent hypospadias, proximal penile hypospadias and patient had sickle cell disease or sickle cell trait was excluded from this study. Standardized proformas were used to allot patients to two treatment groups. ***Group A***, included 30 patients in whom the tourniquet, *rolled rubber glove*, was applied around the base of the penis during operations to control bleeding. **Group B**, included 30 cases, in whom the operation was performed without tourniquet and hemostasis was obtained by preoperative infiltration of the incision site with adrenaline and bipolar cautery throughout the procedure.

Results
The operative time ranged from 66–85 minutes (mean 76.66 ± 21.50) in **group A**, while in **group B** it was 79–95 minutes (mean 88.50 ± 29.40). The difference between the two groups was statistically significant. Early Postoperative hematomas occurred in 13.3% of group A and 6.6% of group B patients respectively. The rate of fistula formation was higher in group B patients than group A (10% and 6.6% respectively). One patient developed urethral stricture in group A and two cases in group B. Metal stenosis was higher in group A than group B, (6.6% and 3.3% respectively). However, there was no significant statistical difference between both groups as regard the post-operative complications.

Conclusion
Use of tourniquets as hemostatic technique is a good option in hypospadias surgery. It facilitates the surgical technique and gives clear field to the surgeon so reduces the operating time.

Keywords:
bipolar, hemostasis, hypospadias, tourniquets, vasoconstrictors

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Introduction

Hypospadias is a congenital penile defect in which the urethra opens into the ventral part of the penis, scrotum, or perineum. It is the result of incomplete development of the urethra, which occurs in 0.3–0.8% of male newborns. About 70% of hypospadias are distal, 10% midshaft, and 20% proximal (penoscrotal, scrotal, perineal) [1].

Hypospadias surgery is performed in children where loss of even minimal amounts of blood is of concern [2,3]. Maintaining a bloodless field during the repair facilitates safe dissection and accurate placement of sutures [1]. The two commonly used methods to achieve hemostasis are the use of vasoconstrictive agents and a bipolar tourniquet, or application of a penile tourniquet [4].

Tourniquets can be maintained by applying various devices – for example, a rubber band, an elastic vascular loop, a Penrose drain, or a cylinder cut from the finger of a glove and rolled to the base of the penis (technique of Barnett) [1,3].

The systemic effects of penile tourniquet use are unlikely to be of any major significance because of the relatively minor changes in blood volume that would occur following penile tourniquet application. It is the local effects of tourniquet application that are of concern when following a hemostatic approach in penile surgery [3]. The usual methods of hemostasis – for example, cauterization and ligation – can cause tissue damage in children [2].

The aim of this study was to compare the outcome of using vasoconstrictors and bipolar diathermy without tourniquet versus the use of tourniquet and bipolar diathermy to obtain hemostasis during hypospadias repair in children.

Materials and methods

This prospective study was carried out at the Pediatric Surgery Unit, Surgical Department, Zagazig University Hospital, Egypt, Assir Central Hospital and King Saud Hospital, Qassem, KSA, and Soba University, Sudan, from April 2012 to September 2014. Standardized proformas were used to allot patients to two treatment groups. The study included 60 uncircumcised boys with midpenile, distal penile, or coronal hypospadias with ages ranging between 6 months and 3 years. Patients with recurrent hypospadias, proximal penile hypospadias, or sickle cell disease or sickle cell trait were excluded from this study. The study was granted approval by our institutional Ethical Committee.

The enrolled patients were divided into two groups:

Group A included 30 patients in whom the tourniquet, rolled rubber glove, was applied around the base of the penis during operations to control bleeding. The maximum application time was 40 min; if the operation lasted longer than 40 min the tourniquet was released for 10 min.

Group B included 30 patients in whom the operation was performed without using a tourniquet and hemostasis was obtained by preoperative infiltration of the incision site with adrenaline (1/20 000) and bipolar cautery throughout the procedure.

The patients received an injection of cefuroxime perioperatively and for 7 days postoperatively. All patients were operated upon by senior surgeons of comparable experience. Snodgrass technique was used for hypospadias repair. Urethral catheters were left for 1 week. Dressing was done with petroleum jelly-impregnated gauze (bactigras wrapped with gauze and plaster). The dressing was changed on the third day after the operation.

The following observations were made:

(1) Time taken for the operation.
(2) The need for changing the dressing because of bleeding in the early postoperative period.
(3) Presence or absence of hematomas.
(4) Infection.
(5) Appearance or absence of diffuse penile edema.
(6) Postoperative appearance of fistula, meatal stenosis, or stricture in the late postoperative period and during clinic visits.

The data were collected, organized, and tabulated with particular reference to age, site of hypospadias opening, operative time, and postoperative complications. The collected data were statistically analyzed using Statistical package for social science (SPSS) software, version 13; IBM, Armonk, New York, USA. Data comparison between the two groups was made using the χ^2-test. Correlation between variables (age, site of opening, operative time, and complications) was evaluated. Significance was adopted at P value less than 0.05 for interpretation of results of tests of significance.

Results

The age of our patients ranged from 6 to 38 months (average=1.8 years). The hypospadias opening was coronal in 18 patients (30%), distal penile in 27 patients (45%), and midpenile in 15 patients (25%) (Table 1).

The operative time ranged from 66 to 85 min (mean=76.66±21.50) in group A, whereas in group B it was 79–95 min (mean=88.50±29.40). The difference between the two groups was statistically significant (Table 2).

Early postoperative hematomas occurred in 13.3% of group A and 6.6% of group B patients. Diffuse penile edema appeared in 23.3% of group A and 10% of group B patients. Postoperative bleeding occurred in 6.6% of group A and 3.3% of group B patients. One patient in group A developed wound infection. However, there was no significant statistical difference between the two groups with regard to early postoperative complications (Table 3).

The rate of fistula formation was higher in group B patients than in group A patients (10 and 6.6%), respectively. One patient developed urethral stricture in group A, compared with two patients in group B. However, meatal stenosis was higher in group A than in group B (6.6 and 3.3%), respectively. This difference was not statistically significant (Table 4).

Table 1 Clinical data

Variables	Group A	Group B	Total numbers of patients [*n* (%)]
Age (months)	6–38	8–35	
Site of opening			
Coronal	9	9	18 (30)
Distal penile	14	13	27 (45)
Midpenile	7	8	15 (25)

Table 2 Operative time

	Group A	Group B	*P* value
Operative time (min)	66–85	79–95	
Mean±SD	76.66±21.50	88.50±29.40	<0.05

Table 3 Early postoperative complications

Complications	Group A [*n* (%)]	Group B [*n* (%)]	Total numbers of patients [*n* (%)]	*P* value
Wound hematoma	4 (13.3)	2 (6.6)	6 (10)	>0.05
Diffuse penile edema	7 (23.3)	3 (10)	10 (16.6)	>0.05
Postoperative bleeding	2 (6.6)	1 (3.3)	3 (5)	>0.05
Wound infection	1 (3.3)	0 (0)	1 (1.6)	>0.05

Table 4 Late postoperative complications

Complications	Group A [*n* (%)]	Group B [*n* (%)]	Total numbers of patients [*n* (%)]	*P* value
Meatal stenosis	2 (6.6)	1 (3.3)	3 (5)	>0.05
Urethrocutaneous fistula	2 (6.6)	3 (10)	5 (8.3)	>0.05
Urethral stricture	1 (3.3)	2 (6.6)	3 (5)	>0.05

Discussion

Meticulous hemostasis is an important requisite for any form of surgery. It reduces blood loss and ensures good operating conditions. During hypospadias repair, the best option for maintenance of effective hemostasis without permanent tissue injury has not been determined. However, it is generally accepted that the use of hemostasis methods should be kept to a minimum to avoid ischemic injuries [3,5].

We set out to compare two different methods for obtaining hemostasis during hypospadias surgery – vasoconstrictors and bipolar diathermy versus tourniquet only.

The average duration of surgery in group A was 76.66 versus 88.50 min in group B.

The duration of surgery was significantly different in the two groups ($P<0.05$). The shorter times in group A may be attributed to the clearer operative field consequent to tourniquet application.

In our results, the incidence of postoperative diffuse penile edema, hematoma, bleeding, and stenosis was higher in group A when compared with group B. These results are in accordance with other studies [6,7].

The percentage of urethrocutaneous fistulae and urethral stricture in group A was lower than that in group B. Nevertheless, in our study these differences were statistically nonsignificant. These results are in agreement with the results of Orhan and colleagues, in whose study the rate of meatal stenosis was higher with the application of tourniquets. In their study fistulae occurred more frequently with the use of bipolar cautery (11.1 vs. 9.3%) [6]. We observed urethral fistulae and strictures to be more common in group B. This has been attributed to impaired healing caused by diathermy use [8]. Pfistermuller *et al.* [9], however, observed more fistulae (5.7%) and urethral strictures (1.3%). Snodgrass believes that meatal stenosis is due to insufficiently deep incision of the urethral plate or continuing the urethral plate tubularization too far distally into the glans. Correcting these errors has been reported to significantly reduce complications [10].

Conclusion

Our study concluded that the use of tourniquets as a hemostatic technique is a good option in hypospadias surgery. It facilitates the surgical technique and gives a clear field, thus reducing the operating time significantly. However, as regards the early and late postoperative complications our results were statistically nonsignificant and need to be interpreted with caution as the surgeons' experience and preferences can be considered as confounding variables. In addition we think that a larger population and longer follow-up are needed.

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Conflicts of interest

There are no conflicts of interest.

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Sutureless thyroidectomy for controlled toxic goiter: a single-institute experience

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Background
Total thyroidectomy for controlled toxic goiter is usually associated with more bleeding because of high vascularity of the toxic gland. Several new instruments were developed as hemostatic tools (harmonic scalpel; LigaSure) during total thyroidectomy as an alternative to conventional hemostatic methods. This study aimed to compare the use of Harmonic Focus Scalpel to conventional hemostatic technique (classic suture ligation with standard bipolar diathermy forceps) in patients with controlled toxic goiter undergoing total thyroidectomy regarding operative time, intraoperative complications, postoperative complications, postoperative hospital stay, and return to normal daily activities.

Patients and methods
The present study included 50 patients with a diagnosis of controlled toxic goiter who underwent total thyroidectomy at the Department of Surgery, Medical Research Institute Hospital, Alexandria University. Candidates were randomized into two groups: group A, in which patients underwent total thyroidectomy using Harmonic Focus Scalpel, and group B, in which patients underwent total thyroidectomy using classic suture ligation and standard reusable bipolar diathermy.

Results
There was no significant difference between both groups regarding preoperative data (age, sex, comorbidities, and type of thyrotoxicosis). The operative time was significantly shorter in group A patients compared with group B patients ($P<0.001$). Both groups were comparable to each other with regard to intraoperative blood loss, postoperative transient and permanent vocal cord paresis, transient and permanent hypocalcemia, postoperative hematomas and bleeding requiring surgery, hospital stay, timing of drain removal, and return to normal daily activities.

Conclusion
Harmonic Focus Scalpel can be used safely and effectively as a hemostatic tool instead of conventional hemostatic techniques in total thyroidectomy for controlled toxic goiter.

Keywords:
harmonic scalpel, hypocalcemia, sutureless thyroidectomy, toxic goiter, vocal cord paresis

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Introduction

Total thyroidectomy is the most commonly performed operation in the field of endocrine gland surgery. It is the optimum treatment for many thyroid disorders [1,2]. Thyroidectomy in thyrotoxic patients has a special difficulty because of high vascularity of the thyroid gland with an increased risk of intraoperative and postoperative bleeding [3,4]. During thyroid surgery, traditional hemostasis is performed through suture ligation with clamp-and-tie technique with or without electrocoagulation. Clamp-and-tie technique is time-consuming; moreover, slippage of ligature may occur. Electrocoagulation is associated with heat dispersion and increased risk of injury to important nearby structures [5,6]. The introduction of harmonic scalpel (HS) in the early 1990s was a great technical advance [7]. It coagulates and cuts vessels and tissues at the same time without the need for classic suture ligation [8]. The mechanism of action depends on the use of ultrasound vibration of a blade at 55 Hz over a distance of 80 μm. In the present study, we compared the use of Harmonic Focus Scalpel with conventional hemostatic technique (classic suture ligation with standard bipolar diathermy forceps) in total thyroidectomy for patients with controlled toxic goiter regarding operative time, intraoperative complications, postoperative complications, postoperative hospital stay, and return to normal daily activities.

Study design

This was a prospective randomized controlled study. The present study included 50 patients with a diagnosis of controlled toxic goiter who underwent total thyroidectomy

at the Department of Surgery, Medical Research Institute Hospital, Alexandria University. Patients were considered eligible for the study after thorough history taking, clinical examination, laboratory investigations (routine tests, thyroid function tests, and plasma calcium level) and radiologic evaluation (neck ultrasonography). All patients received antithyroid drugs, and were euthyroid and normocalcemic before surgery. Preoperative indirect laryngoscopy was performed for each patient in the study before surgery for assessment of vocal cord mobility. Patients were divided into two groups: group A (25 patients who underwent total thyroidectomy using Harmonic Focus Scalpel) and group B (25 patients who underwent total thyroidectomy using classic suture ligation and standard reusable bipolar diathermy for hemostasis). Patients with recurrent toxic goiter, preoperative hypocalcemia, vocal cord disorders, and those with uncontrolled thyrotoxicosis were excluded from the study.

Ethics

All patients signed an informed consent before inclusion in the study. This consent was approved by our institution's ethics committee and included thorough information about the surgery and the possible complications.

Endpoints

Primary endpoints

The primary end points were postoperative bleeding, permanent recurrent laryngeal nerve injury permanent hypocalcemia in the two groups of patients.

Secondary endpoints

Secondary endpoints included (i) operative and postoperative parameters (operative time, intraoperative blood loss, and postoperative complications), (ii) duration of hospital stay, (iii) and timing of return to normal daily activities.

Randomization method

Eligible candidates were randomized into two groups: group A (underwent total thyroidectomy using Harmonic Focus Scalpel) and group B (underwent total thyroidectomy using classic suturing and standard reusable bipolar diathermy). Randomization was done using computer-generated random numbers contained in sealed opaque envelopes. Randomization was performed during preoperative assessment (10 days before surgery).

Surgical techniques

All patients underwent total thyroidectomy under general anesthesia with endotracheal intubation. All patients were placed in supine position with neck extension. Neck extension was optimized through placement of a pillow behind the shoulders and a head ring for head support. A standard Kocher's incision, 5–8 cm in length, was used. Subplatysmal flaps were developed with separation of strap muscles in the midline using monopolar diathermy to expose the thyroid gland. In group A, Ultracision Harmonic Focus Scalpel (Ethicon EndoSurgery, Cincinnati, Ohio, USA) was used for simultaneous coagulation and cutting. In the present study, power level 2 was used when dividing larger vessels such as superior, inferior thyroid arteries and veins, whereas level 5 was used with smaller vessels such as capsular veins. No sutures were used in this group of patients. Superior thyroid vessels were divided in branches close to the gland to avoid damage to the external laryngeal nerve. In group B, hemostasis was performed using suture ligation with Vicryl 3/0 (polyglactin 910 suture, violet braided; Ethicon EndoSurgery) and reusable standard bipolar diathermy forceps with tips 1 mm in diameter, using the Force FX Electrosurgical Generator (Valleylab, Boulder, Colorado, USA) at a power setting of 10 W. Large vessels such as superior thyroid vessels, inferior thyroid vessels, and middle thyroid veins were ligated with Vicryl 3/0 (Ethicon EndoSurgery) and cut. All other vessels were cauterized using bipolar diathermy. Structures were lifted away from laryngeal nerves by spreading arteries underneath before cauterization to limit heat transmission to nerves; this technique was also used before the use of HS in group A patients. Closed negative suction drains [PRI-LOW-VAC (two XDrain/one xTrocar), 500 ml, number 12; Primed, Halberstadt, Medizintechnik, Germany] were used routinely for all patients in the study (only one limb of the drain was used), strap muscles were approximated using Vicryl 3/0 (Ethicon EndoSurgery) and platysma muscle was repaired using Vicryl 3/0. The skin was closed with subcuticular sutures using Monocryl 4/0 (poliglecaprone 25 suture, undyed monofilament; Ethicon EndoSurgery).

Postoperative course

Operative data of each patient were recorded with stressing upon operative time, intraoperative blood loss and intraoperative complications. The used gauzes were weighted before and after use to estimate the amount of intraoperative blood loss (1 g was considered to be equal to 1 ml of blood). Furthermore, if suction was used, the amount of suctioned blood was also recorded. Postoperative data recording included assessment of postoperative complications, time of drain removal, hospital stay, and time of return to normal daily activities. All patients underwent vocal cord examination using

indirect laryngoscopy on the night of the same operative day. Follow-up of patients with vocal cord injury was performed every month for detection of return of vocal cord mobility. Persistence of vocal cord injury for more than 6 months was defined as permanent vocal cord injury [9]. In the current study, calcium infusion was given routinely in the first postoperative day followed by prophylactic oral calcium plus vitamin D for 2 weeks [10–12]. Postoperative serum calcium was measured only if the patient developed hypocalcemic symptoms. Patients with hypocalcemia were followed up with serum calcium monthly for 6 months for possibility of return of normal serum calcium level after which the patient was considered to have permanent hypocalcemia. Hypocalcemia was defined as serum calcium less than 8.5 mg/dl (lower limit of our institutional reference range) [13] with development of hypocalcemic symptoms [14–16]. Permanent hypocalcemia was defined as persistence of hypocalcemia with need for calcium sup plementation lasting for 6 months or more [13]. Bleeding and hematomas were detected clinically. Drains were removed when the amount of discharge is 15 ml or less and the color is mainly serous, and patients were discharged from the hospital after removal of their drains.

Follow-up

All patients were followed up at 7 days, 1 month, and 6 months after the operation at the outpatient clinic for assessment of complications and return to normal daily activities. Patients with hypocalcemia or vocal cord dysfunction were followed up every month for better assessment.

Results

There was no significant difference between both groups regarding preoperative data, as shown in Table 1. The operative time was significantly shorter in group A patients compared with group B patients, as shown in Table 2 ($P<0.001$). No statistically significant difference was found between both groups regarding intraoperative blood loss, number of identified parathyroid glands, and weight of thyroid glands, as shown in Table 2. There were no intraoperative major vascular (carotid artery or internal jugular vein) or visceral injury (esophagus and trachea) in either group. There was no significant difference between both groups regarding postoperative complications (transient and permanent vocal cord paresis, transient and permanent hypocalcemia, and postoperative hematomas), timing of drain removal, postoperative hospital stay, and return to normal daily activities, as shown in Table 3. In group A, two (8%) patients developed postoperative hematomas, which were mild and resolved with conservative treatment [hot fomentation, Extrauma Forte Gel (topical r-hirudin 420 IU) and oral antibiotic]. In group B, postoperative hematomas occurred in three (12%) patients: two (8%) patients developed mild hematomas after removal of their drains and were managed conservatively and one (4%) patient presented with suffocation, cyanosis, and large hematoma about 6 h after operation; this patient was reoperated urgently for control of bleeding and to secure the patent airway – the source of bleeding was slippage of ligature from the anterior branch of the superior thyroid artery. Figure 1 shows Harmonic Focus Scalpel shear and its use in total thyroidectomy for a patient with controlled multinodular toxic goiter in the present study.

Table 1 Preoperative assessment of both groups

	Group A (n=25)	Group B (n=25)	Test of significance	P
Age (years)				
Minimum–maximum	21–57	25–55	t=0.205	0.839
Mean±SD	39.6±10.8	39±11.3		
Sex				
Male	3 (12)	4 (16)	χ^2=0.166	^{FE}P=1.000
Female	22 (88)	21 (84)		
Type of thyrotoxicosis				
Graves' disease	15 (60)	15 (60)	χ^2=0.162	^{MC}P=1.000
Toxic multinodular goiter	8 (32)	8 (32)		
Solitary toxic goiter	2 (8)	2 (8)		
Normocalcemia	25 (100)	25 (100)	–	–
Euthyroid	25 (100)	25 (100)	–	–
Comorbidities				
Hypertension	3 (12)	4 (16)	χ^2=0.166	^{FE}P=1.000
DM	3 (12)	2 (8)	χ^2=0.222	^{FE}P=1.000
Cardiac	1 (4)	0 (0)	χ^2=1.020	^{FE}P=1.000

Qualitative data were described as n (%) and was compared using χ^2, Monte–Carlo, or Fisher's exact test. Normally quantitative data were expressed as mean±SD and compared using Student's t-test. DM, diabetes mellitus; FE, Fisher's exact test.

Table 2 Operative data of both groups

	Group A (*n*=25)	Group B (*n*=25)	Test of significance	*P*
Operative time (min)				
Minimum–maximum	60–120	45–140	*t*=3.797*	<0.001*
Mean±SD	76.9±15.1	97.3±22.1		
Operative bleeding (ml)				
Median (minimum–maximum)	90 (40–220)	80 (40–250)	*Z*=0.146	0.884
Mean±SD	103.1±52.3	102.3±54.6		
Number of identified parathyroid glands				
Median (minimum–maximum)	3 (2–5)	4 (2–5)	*Z*=0.609	0.543
Mean±SD	3.4±0.9	3.5±0.8		
Weight of thyroid glands (g)				
Median (minimum–maximum)	60 (20–120)	50 (20–120)	*Z*=0.243	0.808
Mean±SD	61.6±26.9	60.4±29.5		

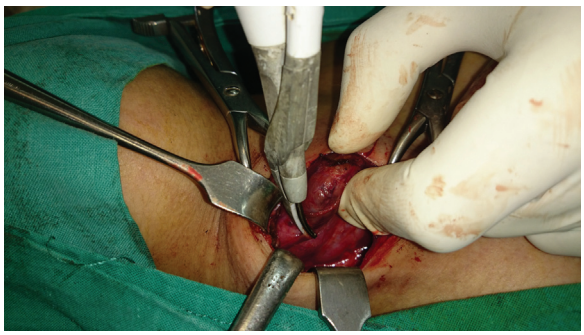
Normally quantitative data were expressed as mean±SD and compared using Student's *t*-test, whereas abnormally distributed data were expressed using median (minimum–maximum) and were compared using Mann–Whitney test. *Statistically significant at $P \leq 0.05$.

Table 3 Postoperative data of both groups

	Group A (*n*=25)	Group B (*n*=25)	Test of significance	*P*
Postoperative complications				
Recurrent laryngeal nerve injury				
Transient	1 (4)	1 (4)	χ^2=0.000	^{FE}P=1.000
Permanent	1 (4)	0 (0)	χ^2=1.020	^{FE}P=1.000
Hypocalcemia				
Transient	4 (16)	3 (12)	χ^2=0.166	^{FE}P=1.000
Permanent	1 (4)	1 (4)	χ^2=0.000	^{FE}P=1.000
Hematoma	2 (8)	3 (12)	χ^2=0.222	^{FE}P=1.000
Drain removal (h)				
Median (minimum–maximum)	48 (24–72)	48 (24–72)	*Z*=0.951	0.342
Mean±SD	42.3±14.3	38.4±13.9		
Hospital stay (days)				
Median (minimum–maximum)	2 (1–3)	2 (1–3)	*Z*=0.951	0.342
Mean±SD	1.8±0.60	1.6±0.6		
Return to normal daily activities (days)				
Median (minimum–maximum)	10 (7–21)	9 (7–21)	*Z*=1.326	0.185
Mean±SD	11.4±3.7	10.6±3.9		

Qualitative data were described as *n* (%) and were compared using χ^2 or Fisher's exact test. Abnormally distributed data were expressed using median (minimum–maximum) and were compared using Mann–Whitney test. FE, Fisher's exact test.

Figure 1



A 45-year-old female patient with controlled multinodular toxic goiter during total thyroidectomy using Harmonic Focus Scalpel.

Discussion

In the present study, the use of Harmonic Focus Scalpel significantly reduced operative time compared with conventional hemostatic tools ($P<0.001$), which was also reported by Hallgrimsson *et al.* [17]. In the study by Hallgrimsson *et al.* [17], all patients had a diagnosis of Graves' disease, were euthyroid before surgery and underwent total thyroidectomy. This study included 27 patients in the HS group and 24 patients in the conventional group. The two groups were comparable to each other regarding recorded preoperative variables. The operating time was shorter in the HS group (median: 121 min; range: 84–213 min) compared with the conventional group (median: 172 min; range: 66–268 min; P=0.011). Contin *et al.* [18], in a meta-analysis of 35 studies, discovered that operating time for thyroidectomy using harmonic devices was significantly shorter compared with conventional techniques. Significant faster operative time with the use of HS was also confirmed by

others [19,20]. Faster operative time with the use of Harmonic Focus Scalpel is expected, as it can be used for dissection, coagulation, and cutting so that it decreases the use, change of surgical instruments, and saves time of suturing, clipping, and cutting as in conventional thyroidectomy. In the present study, there was no significant difference between both groups regarding intraoperative blood loss. The same results were recorded by Hallgrimsson *et al.* [17] in their study as they found no difference in operative bleeding between both groups; blood loss in the HS group ranged between 16 and 279 ml, with a median of 69 ml, whereas in conventional thyroidectomy it ranged between 20 and 290 ml, with a median of 79 ml (P=0.42). Cheng *et al.* [21] conducted a meta-analysis of 14 randomized controlled studies comparing Harmonic Focus Scalpel with conventional hemostatic techniques in thyroidectomy; intraoperative blood loss was reported in six studies [22–27], mean intraoperative blood loss was 75.34 ml in the conventional technique compared with 29.84 ml in the Harmonic Focus Scalpel technique and mean intraoperative blood loss was statistically significantly reduced by 45.54 ml, a 60.4% decrease with the use of Harmonic Focus Scalpel compared with conventional hemostatic techniques in total thyroidectomy. Results of this meta-analysis were different from our results, and the mean intraoperative blood loss was significantly less regarding both HS and conventional hemostatic groups. Our explanation is that meta-analysis included different types of goiters (benign, malignant, toxic) and the percentage of toxic goiters is not declared in the study. It is well known that toxic thyroid is more vascular than the nontoxic gland, and thyroidectomy for toxic goiter is associated with more bleeding; moreover, this meta-analysis did not declare whether completely sutureless technique was used in the HS group or not, as hemostatic techniques using HS differ from one author to another. Some authors use ligatures or clips close to recurrent laryngeal nerve and parathyroid glands, and others use ligatures for ligation of upper pole and others use HS as the sole hemostatic tool without any ligatures or clips (completely sutureless technique). In our opinion, to avoid any bias the population of the study has to be homogeneous, and the technique of hemostasis and the indication for thyroidectomy have to be standardized. In the present study, there was no significant difference between both groups regarding transient and permanent vocal cord paresis. The same results were reported by other several studies [22–33]. The use of HS close to recurrent laryngeal nerve had been evaluated by several studies, which reported that the effect of harmonic use on the nerve is similar to the use of scalpel when used up to 2 mm away from the nerve [34]. Other studies reported that the use of HS was associated with an increased risk of transient vocal cord paresis compared with conventional techniques [17,35], but no difference regarding permanent vocal cord paresis was reported. This may be attributed to the lack of experience and familiarity of operating surgeons with the use of HS or improper dissection of recurrent laryngeal nerves. In the current study, there was no significant difference between both groups regarding transient and permanent hypocalcemia. Several authors [26,29,31–33] reported a lower rate of transient hypocalcemia associated with the use of HS compared with conventional techniques, with no significant difference between both groups regarding permanent hypocalcemia. Lower rate of transient hypocalcemia in these studies may be attributed to more shorter operative time, as hypocalcemia does not only result from unintended damage to the parathyroid glands or their blood supply but also as a systemic response to longer and more involved surgical procedures. Results of the present study regarding transient hypocalcemia were reported by other studies [20,22,24,27,30]. Hallgrimsson *et al.* [17] in their study reported a higher rate of transient hypocalcemia in the HS group compared with the conventional group, with no difference between both groups regarding persistent hypocalcemia. In our opinion, different results from one study to another regarding transient hypocalcemia may be attributed to experience of the surgeon and familiarity with the use of HS; moreover, the majority of the studies comparing HS with conventional hemostatic techniques in total thyroidectomy include a heterogeneous group of patients with different indications for total thyroidectomy, which may influence ease of the procedure, extent of surgical dissection, manipulations, and therefore influence transient hypocalcemia; moreover, certain thyroid pathologies such as toxic goiters may be associated with a higher incidence of hypocalcemia because of development of bone hunger syndrome [36–38]. Conventional hemostatic techniques used in different studies close to parathyroid glands vary greatly to include clamp-and-tie technique and electrocauterization (either bipolar or monopolar diathermy), and others use vascular clips; we believe that this difference may influence the incidence of transient hypocalcemia, as electrocauterization may be associated with heat transmission to parathyroid glands if not used cautiously. In the present study, there was no significant difference between both groups regarding incidence of postoperative hematomas or bleeding requiring surgery. The same results were reported by several studies [20,22,26,29–31,33]. In the current study, both groups were comparable to each other regarding postoperative hospital stay; the same results

were reported by other studies [20,23]. Several authors [24–26,32] reported a significant reduction in the length of postoperative hospital stay in the HS group compared with the conventional hemostatic technique group. These different results regarding postoperative hospital stay may be attributed to different results regarding overall operative and postoperative complications from one author to another.

Conclusion and recommendations

Meticulous hemostasis and proper dissection during total thyroidectomy is of utmost significance so as to avoid injury to important nearby structures and thus decrease morbidity of the procedure. Harmonic Focus Scalpel can be used safely and effectively as a hemostatic tool instead of conventional hemostatic techniques in total thyroidectomy for controlled toxic goiter with a significant reduction in operating time and without increase in overall operative and postoperative complications. Further studies with a larger number of patients are required to study the use of HS in patients with controlled toxic goiter and to calculate overall costs of the procedures when performed with HS.

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Conflicts of interest

There are no conflicts of interest.

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Ventral hernias meshplasty: does mesh-implantation site affect the outcome?

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Background
Although meshplasty has been established as the gold standard for ventral hernia repair, there is debate on the mesh-placement site. This study tried to compare onlay mesh placement with sublay meshplasty in terms of outcome.
Patients and methods
This is a prospective cross-armed study including 65 patients suffering from ventral hernias who were electively admitted to Sohag University Hospital between October 2013 and November 2014. Patients were randomly allocated to two groups: group A included 32 patients who underwent onlay meshplasty and group B included 33 patients who underwent sublay meshplasty. Patients were evaluated with respect to the outcome of both techniques and statistically analyzed after 2 years of follow-up.
Results
Regarding the operative and postoperative outcomes, the operative time was longer in group B, which was highly significant ($P \leq 0.001$). Postoperative wound pain was less in group B, which was significant ($P=0.018$). Regarding early postoperative complications, postoperative superficial infection ($P=0.050$) and hematoma formation ($P=0.033$) were significantly less in group B. Seroma formation was also significantly less in group B ($P=0.050$). The mean duration of postoperative hospital stay was shorter in group B and this was highly significant ($P<0.001$). During follow-up, recurrence was seen in group A, which was statistically significant ($P=0.015$).
Conclusion
Sublay meshplasty, when feasible, is superior to onlay mesh placement for open ventral hernia repair.

Keywords:
abdominal wall hernia, mesh repair, onlay, sublay

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1110-1121

Introduction

Ventral hernias occur through defects in the midline or in the lateral abdominal wall, including epigastric, umbilical, paraumbilical, incisional, and rare Spigelian hernias [1]. They should be repaired unless the patient's general condition contraindicates surgery or when complications are rare [2]. The use of a prosthetic mesh has become the gold standard treatment for all hernias as it has minimal or no tension and has lower recurrence rate as well as rapid recovery with minimal pain [1]. However, many studies show an increased risk for wound complications with mesh implantation, including infections, seromas, and mesh erosions [3].

There is debate regarding the best site for mesh placement – whether onlay (anterior to the aponeurosis and the defect), sublay/retrorectus, or inlay [4,5]. To choose the best site for mesh implantation, a number of conditions should be considered: mesh–tissue integration will decrease long-term recurrence [6]; wound complications increase the risk for recurrence [7]; the ideal mesh placement should have tissue coverage to minimize exposure to superficial infections as well as to the intraperitoneal bowel; finally, technical ease and risks for postoperative complications will encourage the surgeon's choice of technique [5].

Aim of the work

Onlay and sublay meshplasties are the two most frequently adopted techniques in open ventral hernia repair. Our aim was to compare the outcome of each to identify the best site for mesh implantation in open ventral hernia repair.

Patients and methods

This was a prospective uncontrolled randomized study comparing onlay with sublay meshplasty for

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open ventral hernia repair at the General Surgery Department, Sohag University Hospital, from October 2013 to November 2014. Patients were admitted electively through the outpatient clinic. Institutional Ethical Committee approval was taken before commencement of the study. Written and informed consent was taken from all patients after explaining the details of the operative procedures.

The included patients were divided randomly by the closed envelop method into two groups: group A (onlay meshplasty) and group B (sublay meshplasty).

The study included all patients with ventral hernias between 30 and 70 years of age without sex discrimination with a defect size of 4–15 cm. We excluded patients with chronic obstructive pulmonary disease, patients with abdominal malignancy and cirrhosis with end-stage liver disease, patients with previous loss of the abdominal wall and large scarred area of the abdominal skin, those with hernia size larger than 15 cm, patients with more than one hernia, patients with prior meshplasty, pregnant women or women planning future pregnancies, and those with active skin infection.

Operative techniques

In group A (onlay) herniotomy was performed in the usual way and the defect was closed with nonabsorbable suture. Then after an onlay mesh was fixed to the aponeurosis in the subcutaneous prefascial space using nonabsorbable suture without tension covering a distance of 5 cm in all directions from the suture line, with multiple interrupted stitches after fixing the four edges of the mesh, and then closure over one or two suction drains.

In group B (sublay) after herniotomy a retrorectus space was created for mesh placement. Thereafter the posterior rectus sheath and peritoneum were closed. A prolene mesh tailored to the size of this space was placed. Two drains were placed: one above the mesh and the other above the anterior sheath after its closure in the subcutaneous tissue (Fig. 1). Drains were removed when drainage was less than 20 ml in 24 h. The period of drainage ranged from 3 to 8 days.

Postoperative care

All patients received ceftriaxone for 3–5 days and later on oral quinolones (ciprofloxacin/levofloxacin) until removal of the drains for a further 3–9 days. Patients stayed in hospital following their surgery until they were ambulatory and had regained their bladder and bowel functions.

Follow-up visits were arranged on the seventh, 15th, and 30th day after discharge, and then every 3 months for 2 years.

Statistical study

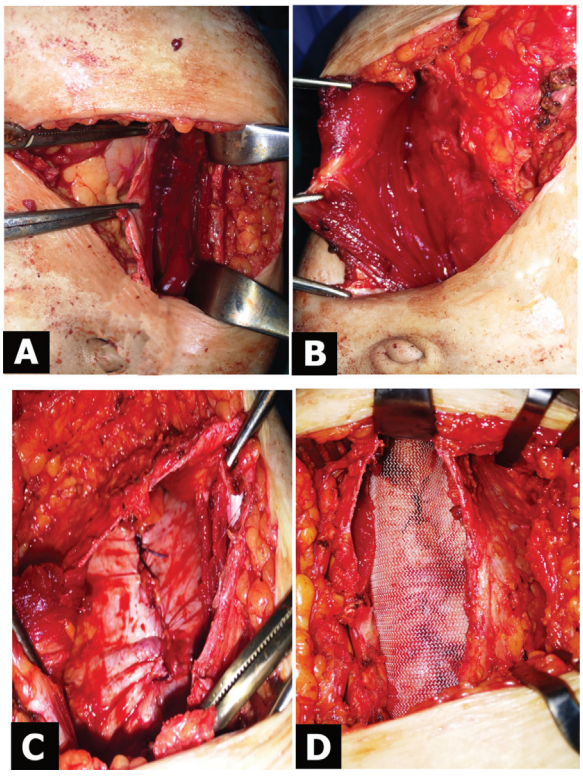
Parameters to be analyzed

Epidemiological data analyzed included age and sex, clinical features, smoking history, presence of diabetes mellitus, BMI, and glucocorticoid use. The primary outcome measure was the recurrence rate after at least 1 year of follow-up. The secondary outcomes included operative time (min), length of hospital stay (days), patient satisfaction, wound complications such as acute and chronic infections (sinus and mesh infection), seroma or hematoma formations, enterocutaneous fistula, and wound pain.

Statistical analysis

Statistical analysis was performed using SPSS (IBM-SPSS version 22 program for Windows (SPSS Inc, Chicago, IL)). Qualitative data were expressed as number and percentages, and quantitative data were

Figure 1



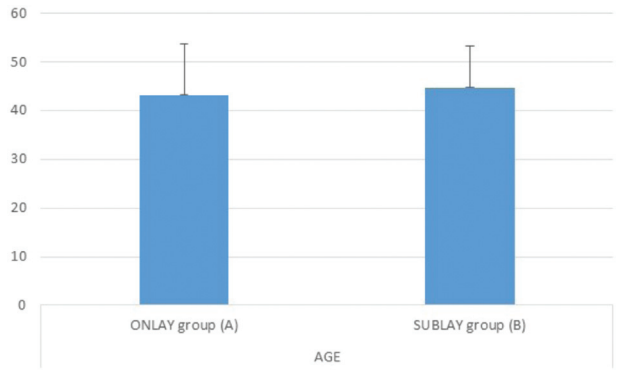
Sublay meshplasty technique: (a) and (b) Retrorectus dissection. (c) Closure of the posterior rectus sheath. (d) Placement of the mesh in retromuscular or preperitoneal position.

expressed as mean and SD. For comparison of percentages in qualitative variables, a χ^2-test was used for parametric (normally distributed) data and Fisher's exact test was used for nonparametric (non-normally distributed) data. For comparison of means in quantitative variables, a Student *t*-test was used. For all of these tests, the *P* value was considered significant if less than 0.05 and highly significant if less than 0.001.

Results

This study included 65 patients suffering from various types of ventral hernias who underwent meshplasty during the first year of the study, after exclusion of 12 patients who were lost to follow-up. Patients were classified into two groups: group A (onlay) included 32 patients and group B (sublay) included 33 patients. Patient demographics are listed in Table 1 and Fig. 2.

Figure 2



Age of the study groups.

Table 1 Demographic criteria and clinical presentation

	Total [*n* (%)]	Group A (onlay mesh) (*n*=32) [*n* (%)]	Group B (sublay mesh) (*n*=33) [*n* (%)]	χ^2-Test/Fisher test	*P* value
Age					
3rd decade	4 (6.2)	3 (9.4)	1 (3.0)	6.519[b]	0.164
4th decade	20 (30.8)	9 (28)	11 (33.3)		
5th decade	27 (41.5)	15 (46.9)	12 (36.4)		
6th decade	12 (18.5)	3 (9.4)	9 (27.3)		
7th decade	2 (3)	2 (6.3)	0 (0.0)		
Mean age	–	43.16	44.76	0.667[b]	0.506
SD	–	10.62	8.58		
SEM	–	1.88	1.49		
Sex					
Male	26 (40)	12 (37.5)	14 (42.4)	0.164[a]	0.685 (NS)
Female	39 (60)	20 (62.5)	19 (56.6)		
Diabetes mellitus	10 (15)	8 (25)	2 (6)	4.057[b]	0.044 (S)
Smoking history					
Current smoker	18 (28)	12 (37.5)	6 (17)	4.018[b]	0.038 (S)
Nonsmoker	47 (72)	20 (62.5)	29 (83)		
Glucocorticoid use	2 (3)	2 (6.3)	0	2.128[b]	0.145 (NS)
BMI>30	10 (15)	3 (9.4)	1(3.0)	6.519[b]	0.164
Clinical presentation					
Abdominal swelling					
Reducible	55 (85)	24 (75)	31 (94)	4.447[b]	0.034 (S)
Irreducible	10 (15)	8 (25)	2 (6)	4.057[b]	0.044 (S)
Dragging pain	23 (35.4)	18 (56.3)	5 (15)	12.002[a]	<0.001 (HS)
Cough impulse					
Positive	55 (85)	24 (75)	31 (94)	4.447[b]	0.034 (S)
Weak	10 (15)	8 (25)	2 (6)	4.057[b]	0.044 (S)
Abdominal intertrigo	2 (3)	2 (6.3)	0	2.128[b]	0.145 (NS)
Type of ventral hernia					
Incisional	33 (51)	16 (50)	17 (52)	0.015[a]	0.903 (NS)
Spontaneous	32 (49)	16 (50)	16 (48)	0.015[a]	0.903 (NS)
PU		12 (37.5)	12 (36)	0.000[b]	1.000 (NS)
Epigastric		4 (12.5)	4 (12)	0.000[b]	1.000 (NS)
Size of the defect (cm)					
From 5–10 cm	28 (43)	18 (56)	10 (30)	4.461[a]	0.035 (S)
>10 cm	37 (57)	14 (44)	23 (70)	4.461[a]	0.035 (S)

Fisher's exact test was performed for some statistical data instead of the χ^2-test because of non-normality of distribution. PU, paraumbilical hernia. [a]The values were calculated using the χ^2-test. [b]The values were calculated using the Fisher test.

Regarding clinical presentation, all patients had a common presentation: an abdominal swelling, which was reducible in 84.6% of cases (44% in group A and 56% in group B) and irreducible in 15.4% of cases (80% in group A and 20% in group B). This was followed by dragging pain at the site of swelling in 35.4% of cases (78% in group A and 22% in group B). On examination the swelling was found to have positive cough impulse in 84.6% of cases (44% in group A and 56% in group B) and diminished in 15.4% (80% in group A and 20% in group B). Lastly there was abdominal intertrigo in relation to the swelling in 6% of patients in group A.

The most common type of ventral hernias dealt with was incisional hernia (51%), followed by spontaneous hernia (49%); this difference was nonsignificant (P=0.897). All incisional hernias were through midline scar and the majority through lower midline or lower part of full midline scar. Nature of previous surgery included cesarean section, hysterectomy, and laparotomy for appendix or gut perforation. Spontaneous hernias were distributed as paraumbilical hernia (75%; 50% in group A and 50% in group B) and epigastric hernia (25%; 50% in group A and 50% in group B). This difference was nonsignificant (P=0.993).

Regarding the defect size, 43% had a defect size measuring 4–10 cm, distributed as 64% in group A and 36% in group B, whereas the remaining 57% had defect size greater than 10 cm, distributed as 37.8% in group A and 62.2% in group B. Accordingly group B had more patients with a defect size greater than 10 cm and this was statistically significant (P=0.035) (Table 1).

Regarding the operative and postoperative outcomes, the operative time was longer in the sublay group; this difference was highly significant ($P \leq 0.001$) (Fig. 3). With respect to postoperative wound pain 27% of the sublay group had no wound pain, in comparison with 3% in the onlay group; this was reflected as a higher need for analgesics (NSAIDs and narcotics) among onlay group patients. This difference was significant (χ^2=7.277 and P=0.018).

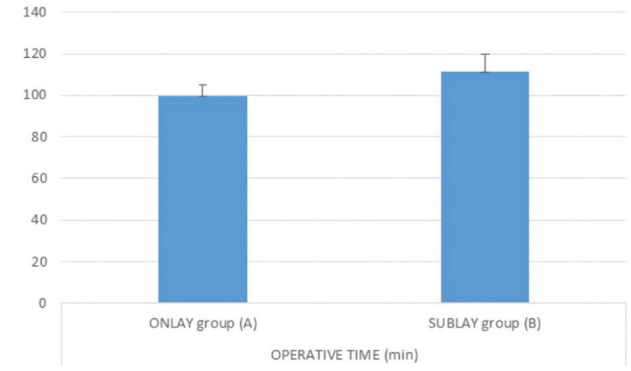
Regarding early postoperative complications, postoperative superficial infection was significantly lower in the sublay group (3%) compared with the onlay group (22%) (χ^2=5.908 and P=0.050).

Hematoma formation was seen only in 3% of patients in the sublay group compared with 19% in the onlay group; this was a significant difference (χ^2=4.569 and P=0.033). It responded well to conservative management; just needed delayed drainage.

Postoperative seroma formation was seen in 3% of patients in the sublay group compared with 22% in the onlay group and it responded well to conservative measures. This difference was statistically significant (χ^2=5.346 and P=0.050). Postoperative sinus formation with chronic seroma formation occurred in 3% of patients of the onlay group and in none in the sublay group; the difference was nonsignificant (χ^2=1.047 and P=1).

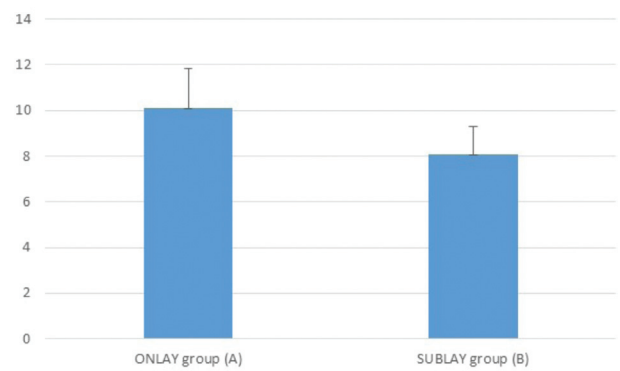
Although wound dehiscence was not seen in any of the patients in the sublay group compared with 6% of patients in the onlay group, the difference was nonsignificant (χ^2=2.128 and P=0.459). Although mesh infection was not seen in any of the patients in the sublay group compared with 6% of the onlay group, the difference was nonsignificant (χ^2=2.128 and P=0.459). Meanwhile, enterocutaneous fistula occurred in 3% of patients in the sublay group and in none in the onlay group; the difference was nonsignificant (χ^2=0.985 and P=1). The reason for this nonsignificance may be the limited number of these complications.

Figure 3



Operative time in groups.

Figure 4



Postoperative stay.

The mean duration of postoperative hospital stay was 10.994±1.766 days in the onlay group and 8.061±1.223 days in the sublay group; this difference was highly significant ($P<0.001$) (Fig. 4).

During follow-up, although more patients in the sublay group were satisfied compared with the onlay group, this was nonsignificant ($\chi^2=2.424$ and $P=0.238$). Neuralgia was not seen in any of the patients in group B compared with 6% of patients in group A; this difference was nonsignificant ($\chi^2=2.128$ and $P=0.459$). The reason for this nonsignificance may be the limited number of patients with neuralgia. Recurrence was seen in 12.5% of group A patients and in none of the group B patients. This was statistically significant ($\chi^2=4.395$ and $P=0.015$) (Table 2).

Discussion

Open ventral hernia repair with a mesh has improved long-term outcomes [3], although there is debate on the best site for mesh placement [5].

In our study, the incidence of ventral hernia was highest (72%) in the fourth and fifth decades of life, with a female to male ratio of 1.5 : 1. This difference was nonsignificant ($P=0.69$). The difference in age group and higher female incidence was due to the higher number of lower midline incisions among women for obstetric and gynecological surgeries, which result in incisional hernia, which was the most common type of ventral hernia (51%) dealt with; all incisional hernias were through the lower midline or lower part of the full midline scar. This is in line with other literature [8].

Sublay meshplasty is technically more difficult than onlay meshplasty, thus making the operative time longer in the sublay group. This difference was highly significant ($P\leq0.001$). However, sublay meshplasty is limited in patients with damaged posterior rectus sheath or damaged rectus abdominis muscle, which will render this space difficult to create, limited in size, or nonexistent, in addition to the risks of damaging the blood supply, muscle, or lateral penetrating nerves. Furthermore, the semilunar lines limit the lateral extent of the sublay repair and potentially limit the amount of mesh overlap. Also this technique is not applicable for offmidline incisions [5].

Many studies showed an increased risk for wound complications with meshplasty, including infections, seromas, and mesh erosions, which are influenced by the mesh site [9]. Of the common postoperative complications encountered in our study was transient seroma formation in 22% of the onlay meshplasty patients; this difference was statistically significant ($\chi^2=5.346$ and $P=0.050$). The previously reported rates of seroma occurrence with different types of mesh

Table 2 Operative and postoperative outcomes

	Group A (onlay mesh) ($n=32$)	Group B (sublay mesh) ($n=33$)	*t*-Test[a]/Fisher test[b]	*P* value
Operative time (min)	99.53±5.29	111.36±8.41	6.764[a]	<0.001 (HS)
SEM	0.94	1.46		
Wound pain				
No postoperative analgesia	1	9		
NSAIDs ($n=44$)	23	21	7.277[b]	0.018 (S)
Narcotics ($n=11$)	8	3		
Postoperative superficial infection	7	1	5.346[b]	0.050 (S)
Hematoma formation ($n=7$)	6	1	4.569[b]	0.033 (S)
Postoperative seroma formation	7	1	5.346[b]	0.050 (S)
Postoperative sinus formation	1	0	1.047[b]	1 (NS)
Wound dehiscence	2	0	2.128[b]	0.459 (NS)
Postoperative mesh infection	2	0	2.128[b]	0.459 (NS)
Enterocutaneous fistula	0	1	0.985[b]	1 (NS)
Postoperative hospital stay				
Mean±SD	10.094±1.776	8.061±1.223	5.380[a]	<0.001 (HS)
SEM	0.312	0.213		
Patient satisfaction				
Satisfied ($n=57$)	26	31	2.424[b]	0.238 (NS)
Nonsatisfied ($n=8$)	6	2		
Neuralgia	2	0	2.128[b]	0.459 (NS)
Recurrence	4	0	4.395[b]	0.015 (S)

Fisher's exact test was performed instead of the χ^2-test because of non-normality of distribution. HS, highly significant; S, significant. [a]The values were calculated using the *t*-test. [b]The values were calculated using the Fisher-test.

range from 4 to 8% with polypropylene grafts [10]. The reasons for this are not known; however, implantation of a foreign body increases the risk for seroma formation and infection [11]. Moreover, direct contact between mesh and subcutaneous fat contributes to seroma formation and purulent complications that result in hernia recurrence [12]. In our study postoperative superficial infection occurred in 22% of onlay meshplasty patients and was significantly lower in the sublay group (χ^2=5.908 and P=0.050). Also postoperative sinus formation with chronic seroma formation occurred in 3% of patients in the onlay group; the difference was nonsignificant (χ^2=1.047 and P=1). This can be explained by insufficient biocompatibility of the used mesh [13].

Add to this, hematoma formation was seen in 19% of patients in the onlay group, and was significantly less in the sublay group (χ^2=4.569 and P=0.033), and although wound dehiscence was not an annoying complication it occurred only in two patients of the onlay group with a nonsignificant difference (χ^2=2.128 and P=0.459). This can be because of the extensive undermining of subcutaneous tissue while placing the onlay mesh leading to disruption of skin perforators and impairment of healing [14].

Enterocutaneous fistula occurred in only one patient of the sublay group, with a nonsignificant difference (χ^2=0.985 and P=1). This may be due to the deep placement of the mesh leading to erosion into the bowel and fistula formation [15].

There is a higher rate of postoperative wound pain with the use of nonabsorable suture material due to permanent mechanical tissue irritation [16]. Add to this the lateral attachment of the mesh to the anterior rectus sheath leading to reduced flexibility of the abdominal wall [17]. This is reflected in the incidence of postoperative wound pain, which showed a significant difference (χ^2=7.277 and P=0.018), being less in sublay meshplasty.

The mean duration of postoperative hospital stay, which is an indicator of postoperative outcome, was quite longer in the onlay meshplasty group, and this difference was highly significant between the two groups (P<0.001). This is in line with other studies [18].

During follow-up onlay meshplasty group had higher recurrence (12.5%), which was statistically significant (χ^2=4.395 and P=0.113). These results are in line with the results of other studies [19,20]. This is due to the anatomical position of the mesh. Intra-abdominal pressure leads to lateral detachment of the mesh in onlay meshplasty, resulting in its higher recurrence rates, while it keeps the mesh in place in case of sublay meshplasty (Pascal's principle) [21].

On the basis of our results we believe that sublay meshplasty when feasible is superior to onlay meshplasty because of the lower recurrence rates and lower complication rates.

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Nil.

Conflicts of interest
There are no conflicts of interest.

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Common bile duct clearance of stones by open surgery, laparoscopic surgery, and endoscopic approaches (comparative study)

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Background and aim of the work
Around 10–18% of patients undergoing cholecystectomy for gallstones have common bile duct (CBD) stones. Treatment can be provided as open cholecystectomy plus open CBD exploration, laparoscopic cholecystectomy plus laparoscopic common bile duct exploration (LC+LCBDE), or precholecystectomy or postcholecystectomy endoscopic retrograde cholangio-pancreatography (ERCP) in two stages for CBD clearance. The aim of this study is to compare the CBD clearance rate by each procedure in a well-equipped tertiary center.
Patients and methods
A total of 250 patients with choledocholithiasis were included from the General Surgery Department, Sohag and Assiut University Hospitals, and managed randomly by either conventional surgery, endoscopic, or laparoscopic procedures.
Results
The ages of our patients ranged from 20 to 60 years (mean=40 years), with a slight female predominance (1.6 : 1); most of them presented with calcular obstruction (54.3%). However, there were also other presentations such as colic, cholangitis, or accidental discovery in 14.3, 10, and 21.5%, respectively. Patients were categorized randomly into three groups: group I included 100 patients (40%) who were treated by open choledocholithotomy and T-tube insertion; the operative time was 90 (60–180) min, with the success rate of the attempted procedures reaching 100%, and CBD clearance of stones was achieved in 95% of cases (five cases of missed stones). Hospital stay was 8 (5–12) days, with no mortality, and morbidity rate reached 15% in the form of wound infection, bile leak, and missed stone. The patient could return to work after 2 weeks (12–20 days). Group II included 100 patients (40%) treated by endoscopic sphincterotomy; basket extraction was performed in 45%, balloon in 25%, the combined maneuver in 15%, and mechanical lithotripsy in 13%, with failure of the technique in two cases (2%); the duration of the procedure was about 30 (20–45) min, with a success rate of attempted procedures of 98%, and CBD clearance of stones was achieved by 100%, with no mortality; the morbidity rate was 9% in the form of cholangitis (3%) and mild pancreatitis with hyperamylasemia (6%). The period of hospital stay was 1 (1–2) days and the patient returned to work after 3 (2–5) days. Group III included 50 patients (20%) treated by laparoscopic approaches: transcystic approaches in five cases and transcholedochotomy approaches in 45 cases. Choledochoscopic exploration was performed in almost all cases (45 cases) to detect, extract the stones, and test CBD clearance, and there was conversion to open techniques in one case. The time needed for this procedure was 123 (70–292) min, with CBD clearance of stones in 96% (two cases of missed stone), with no mortality, and a morbidity rate of about 10% in the form of mild hyperamylasemia, fever, and missed stone. The period of hospital stay was 3.2 (2–4) days, with return to work after 7 (5–10) days.
Conclusion
Both ERCP/LC and LCBDE were highly effective in CBD clearance, and equal in terms of the overall cost and patient acceptance. However, the overall duration of hospitalization was shorter for LCBDE with elimination of the potential risks of ERCP-associated pancreatitis, further procedures, and anesthesia risks. It is feasible, cost-effective, and ultimately should be available for most patients in each specialized center.

Keywords:
choledocholithotomy, ERCP, laparoscopic common bile duct exploration, sphincterotomy

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Introduction and aim of the work

Around 10–18% of patients undergoing cholecystectomy for gallstones have common bile duct (CBD) stones [1]. Symptoms caused by CBD stones consist of colic or may

result from complications such as jaundice, cholangitis, or pancreatitis [2]. In case of symptomatic CBD stones, decompression of the CBD and removal of ductal stones is warranted. Decompression may be achieved using endoscopic methods such as endoscopic sphincterotomy, papillary dilatation, and nasal-biliary drainage [2].

Treatment of the bile duct stones can be performed as open cholecystectomy plus open CBD exploration, laparoscopic cholecystectomy plus laparoscopic common bile duct exploration (LC+LCBDE), or precholecystectomy or postcholecystectomy ERCP in two stages usually combined with either sphincterotomy (commonest) or sphincteroplasty (papillary dilatation) for CBD clearance [1].

LCBDE was postulated through the transcystic approach in small-sized stones or by choledochotomy, which allows a more selective approach for the removal of CBD stones, thus avoiding unnecessary preoperative ERCP. It has the advantage of combining two procedures into a single minimally invasive operation [3].

The majority of secondary biliary stones can be diagnosed at the time of cholecystectomy and cleared transcystically; otherwise, the choledochotomy approach or postoperative ERCP is needed, but choledochotomy should be avoided in ducts less than 7 mm in size at the time of operative cholangiogram, and also in severely inflamed friable tissues with difficult dissection. Choledochotomy is advocated as a good choice for patients after gastrectomy, failed ERCP access, or absence of medical service for ERCP [4]. The intraoperative ERCP approach for CBD stones during LC also benefits the patient by reducing the treatment from a two-step procedure to a single-step procedure under general anesthesia. It minimizes the risk of pancreatitis and avoids exploration of the CBD [3].

Both ERCP/LC and LCBDE were highly effective in detecting and removing CBD stones and were equivalent in overall cost and patient acceptance. However, the overall duration of hospitalization was shorter for LCBDE; moreover, LCBDE eliminates the potential risks of ERCP-associated pancreatitis and the need for another procedure and the associated risks of anesthesia. It is feasible, cost-effective, and ultimately should be available for most patients [5].

As surgical skill with LCBDE increases, the need for routine preoperative ERCP will likely decrease, except in unique high-risk situations. Therefore, a single surgical procedure for CBD stone is needed [5].

All randomized clinical trials that compared the results from open surgery versus endoscopic clearance and laparoscopic surgery versus endoscopic clearance for CBD stones showed no significant difference in the mortality and morbidity between laparoscopic and endoscopic CBD clearance. Also, there was no significant reduction in the number of retained stones and failure rates in the laparoscopy groups compared with the preoperative and intraoperative ERCP groups. Moreover, there was no significant difference in the mortality, morbidity, retained stones, and failure rates between the single-stage laparoscopic bile duct clearance and two-stage endoscopic management [2].

Patients and methods

Study design

This prospective observational study included all consecutive patients who were referred for the management of choledocholithiasis to the Surgery Department, Assiut and Sohag University Hospitals. The study protocol was approved by the local ethical committee of our hospitals. Also, a written informed consent was obtained from all patients' before recruitment into the study.

Patients

From June 2014 to July 2016, patients with symptomatic choledocholithiasis at the General Surgery Department, Assiut and Sohag University Hospitals, were enrolled in this study. The inclusion criteria were patients with a preoperative diagnosis of symptomatic CBD stones aged from 20 to 60 years, American Society of Anesthesiologists (ASA) grade I, II or III, and agreement to complete the study requirement. Exclusion criteria were patients with contraindication to laparoscopy, or endoscopy, suspected Mirizzi syndrome, malignancy, previous upper abdominal surgery, previous mesh repair of an umbilical hernia, long-term anticoagulant treatment, pregnant women, and diagnosis of intrahepatic stones in preoperative ultrasonography. In all, 250 patients who fulfilled all the criteria of the study were enrolled in the study protocols and thoroughly investigated and studied.

Randomization

This was done with the permuted block method using blocks of 10. Envelopes were drawn and opened by an operating room nurse who was not involved in the study. Randomization was performed just before the procedure. Only operating surgeons and operating room staff were aware of the procedure performed. Records of the procedure were kept in a sealed envelope during the patient's hospital stay to keep the patient and ward personnel blinded to the procedure used.

Management protocols

The proposed treatment option was assigned randomly by one of the three procedures of either conventional surgery, endoscopic, or laparoscopic approaches as group I, group II, and group III, respectively.

Operative techniques

All surgeries were performed by the same experienced surgical team, under general anesthesia, with standardized techniques.

The conventional surgical approach includes open cholecystectomy plus choledocholithotomy and a T-tube drain through the choledochotomy incision with a subhepatic drain in all cases (Figs 1 and 2).

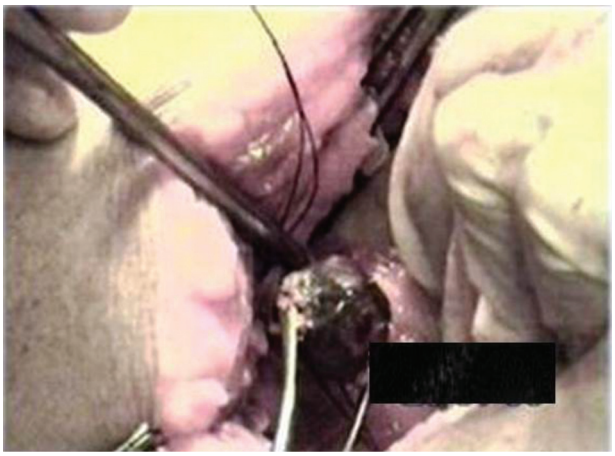
Endoscopic treatment was performed by precholecystectomy or postcholecystectomy ERCP, with sphincterotomy or sphincteroplasty to clear CBD from stones by either basket, balloon extraction, basket extraction with balloon sweeping, or mechanical manual internal or external lithotripsy (Figs 3–8).

LCBDE was performed by the transcystic or the transcholedochotomy route. Intraoperative cholangiogram was used in most of the cases, and a choledochoscope was used in choledochotomy patients to detect, extract, and assess CBD clearance. T-tube drain application was performed; however, direct CBD primary closure was also performed in some cases, with a subhepatic drain in all cases (Figs 9–22).

Statistical analysis

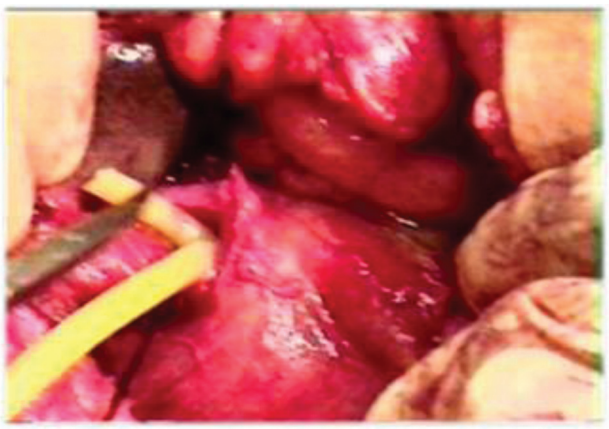
Descriptive data were expressed as mean and standard error of the mean, or as median and ranges for continuous variables and proportions for categorical variables. Statistical analysis was carried out using Fisher's and χ^2-tests. A P value less than 0.05 was considered statistically significant.

Figure 1



Open choledocholithotomy.

Figure 2



T-tube application after choledocholithotomy.

Results

The ages of our patients ranged from 20 to 60 years (mean=40 years), with a slight female predominance (female to male=1.6 : 1). The main presentation of our cases was calcular obstructive jaundice in 54.3%, biliary colic in 14.3%, cholangitis in 10%, or accidental discovery in 21.5%. Patients were categorized randomly into three groups according to stone treatment as follows:

Group I

Group I included 100 patients (40%) treated by open choledocholithotomy and T-tube insertion; the operative time was 90 (60–180) min, with a success rate of attempted procedures reaching 100%, and CBD clearance of stones was achieved in 93% of cases (seven cases of missed stones). Hospital stay was 8 (5–12) days, with no mortality, and morbidity rate reached 13% (Table 1). The patient could return to work 2 weeks (12–20 days) postoperatively.

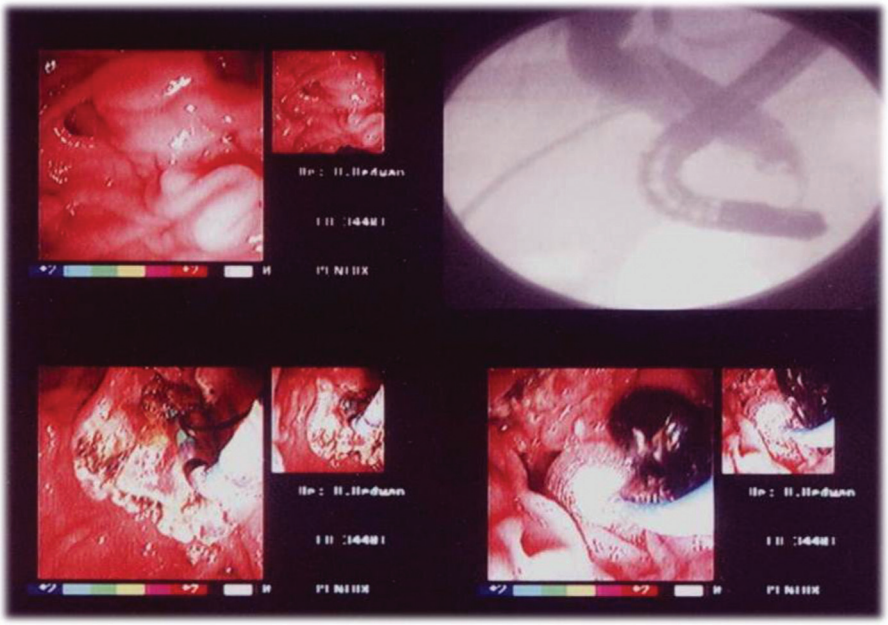
Group II

Group II included 100 cases (40%) treated by endoscopic sphincterotomy and stone(s) extraction using variable techniques (Table 2), with failure of the technique in two cases (2%); the procedure time was about 30 (20–45) min, with a success rate of attempted procedures of 98%, and CBD clearance of stones was achieved by 100%, with no mortality, and a morbidity rate of 7% (Table 3). The period of hospital stay was 1 (1–2) days and the patient returned to work after 3 (2–5) days.

Group III

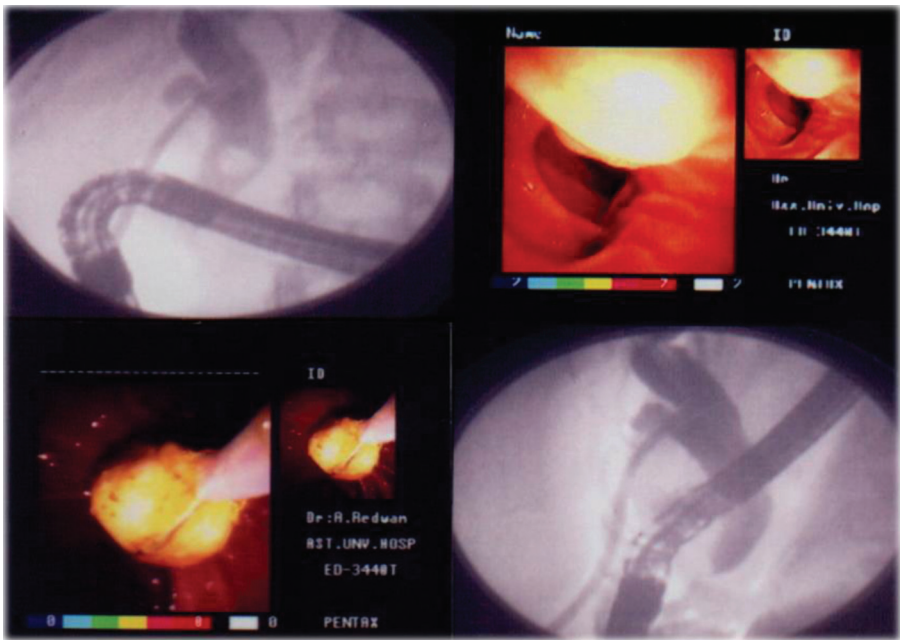
Group III included 50 cases (20%) treated by LCBDE: transcystic in five cases and transcholedochotomy in 45

Figure 3



Sphincterotomy and balloon extraction of common bile duct (CBD) stone.

Figure 4



Basket extraction of common bile duct (CBD) stone.

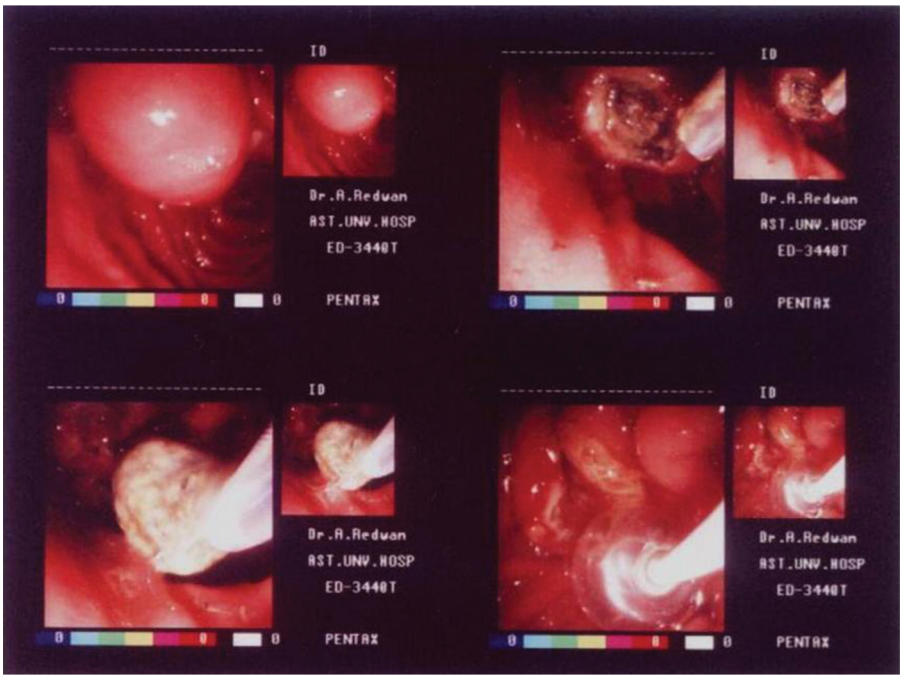
cases (Table 4). Choledochoscopy was performed in almost all cases (45 cases), with conversion to open techniques in one case. The time needed for this procedure was 123 (70–292) min, with CBD clearance of stones in 96% (two case of missed stone), with no mortality, and the morbidity rate was about 20% (Table 5). The period of hospital stay was 3.2 (2–4) days, with return to work after 7 (5–10) days.

Data of all patients were collected and categorized in each group to evaluate and compare these techniques of CBD stone clearance (Table 6).

Discussion

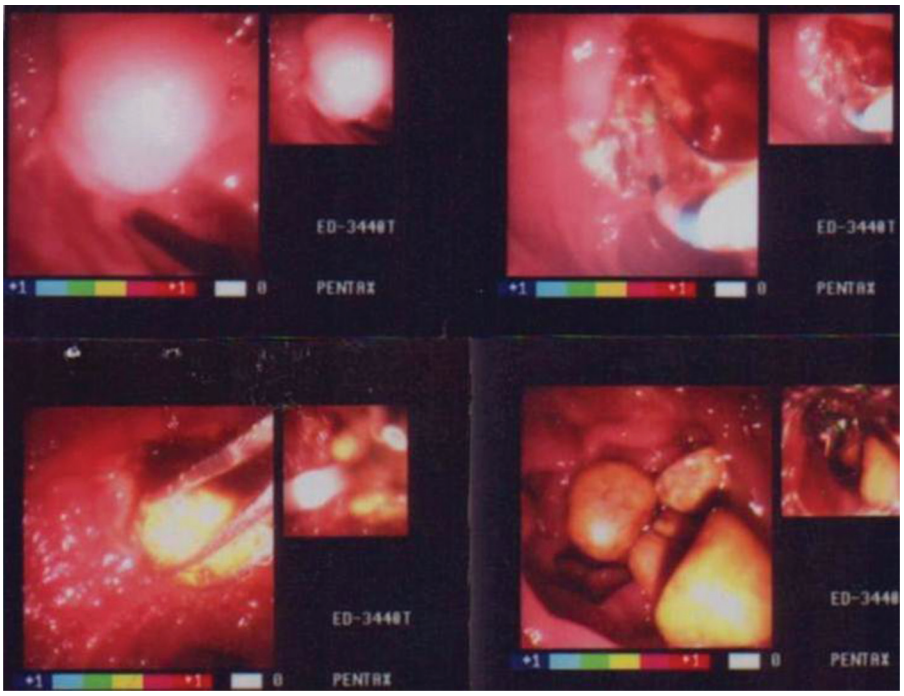
Symptomatic gallstone disease is a very common indication for abdominal surgery [6]. Before the laparoscopic era, cholecystectomy and CBD stones

Figure 5



Basket stone extraction and balloon sweeping of common bile duct (CBD).

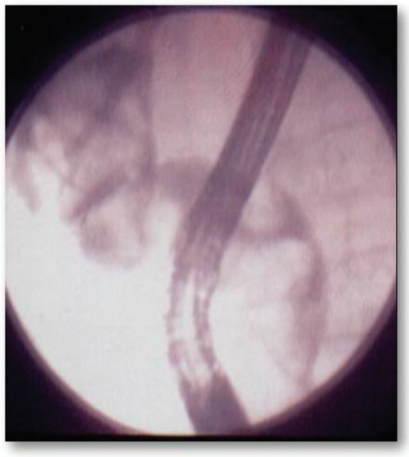
Figure 6



Basket extraction of multiple common bile duct (CBD) stone.

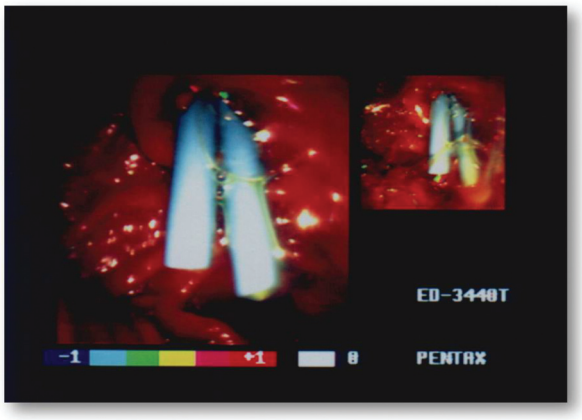
were removed during a single procedure. This approach has been effective, with morbidity below 15% and mortality below 1% in patients up to 65 years of age [7]. In the era of minimally invasive procedures, open laparotomy for CBD exploration may still be the choice in some hospitals in developing countries; thus, therapeutic decision-making is based on the local availability of expertise [8], and hence concomitant gallstones and CBD stones were managed by preoperative or postoperative ERCP [9]. Although this approach is effective and safe, it has several drawbacks as it requires two periods of anesthesia and two hospital admissions, which increase expenses. Furthermore, if patients still have CBDS detected intraoperatively, surgeons will face

Figure 7



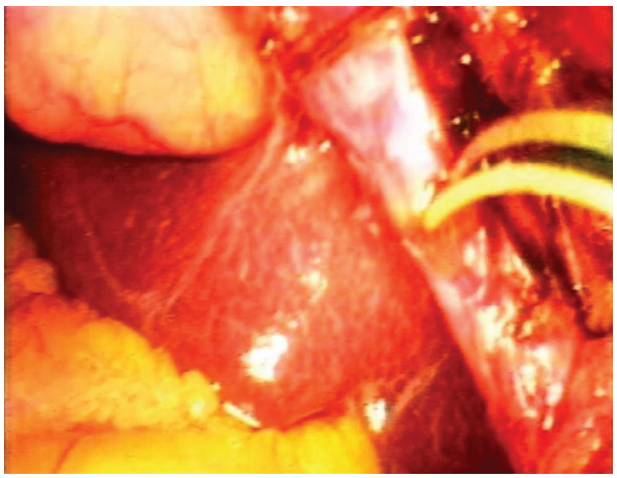
Radiologic view showing multiple common bile duct (CBD) stones casting whole CBD.

Figure 8



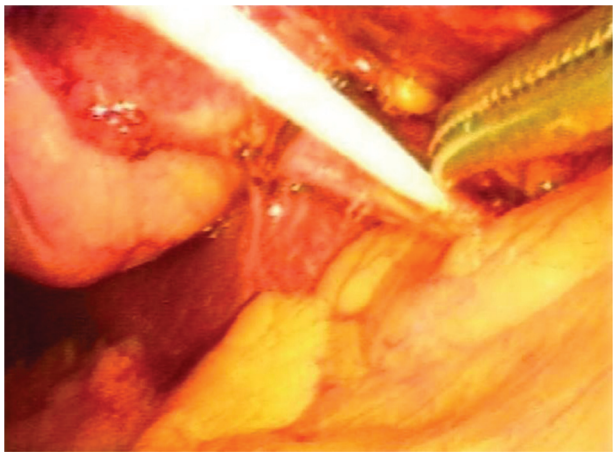
Endoscopic stenting for multiple common bile duct (CBD) stones before surgery.

Figure 9



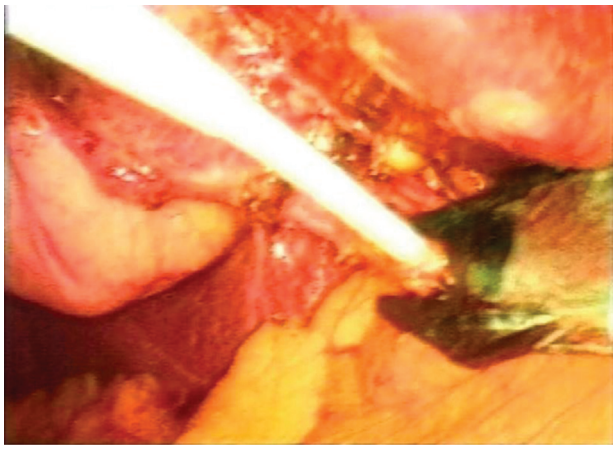
Laparoscopic cut in cystic duct prior intraoperative cholangiogram.

Figure 10



Ureteric catheter in the cystic duct for intraoperative cholangiogram.

Figure 11

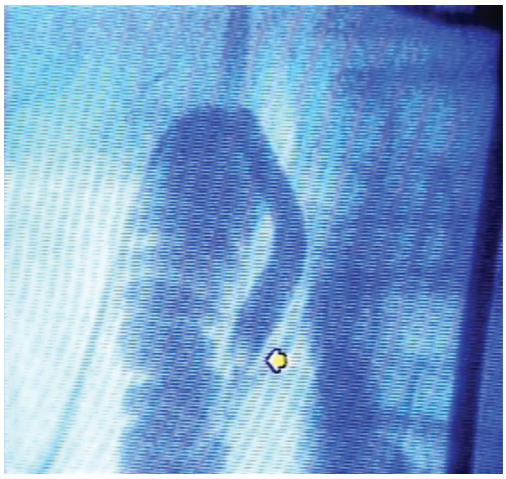


Light clipping of cystic duct over the catheter prior cholangiogram.

the dilemma of depending on LCBDE, postoperative ERCP, or traditional open choledochotomy [10]. Most importantly, even in those patients with clinical, biochemical, and imaging risk factors for CBDS, preoperative ERCP can produce false-negative results, leading to the possibility of increasing the morbidity and mortality [3]. Although with postoperative ERCP the risk of preoperative ERCP in patients without CBDS can indeed be avoided, it necessitates another surgical procedure when it fails to remove the CBDS [11]. Both preoperative and postoperative ERCP are likely to lead to some short-term and long-term complications [10].

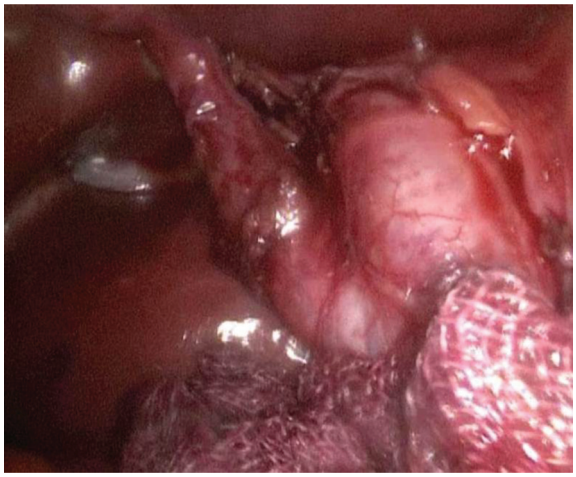
With the improvement in laparoscopic equipment and skills, LCBDE has increasingly been used to remove the CBDS [12–19]. Moreover, the use of single incision laparoscopic surgery in CBDE was introduced by many centers [20–25]. Although LCBDE has a crucial advantage in that it simultaneously treats cholelithiasis and choledocholithiasis, thereby shortening hospital

Figure 12



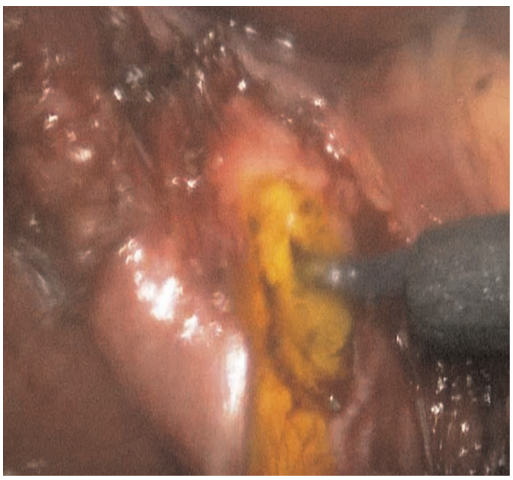
Intraoperative cholangiogram view showing common bile duct (CBD) stone.

Figure 13



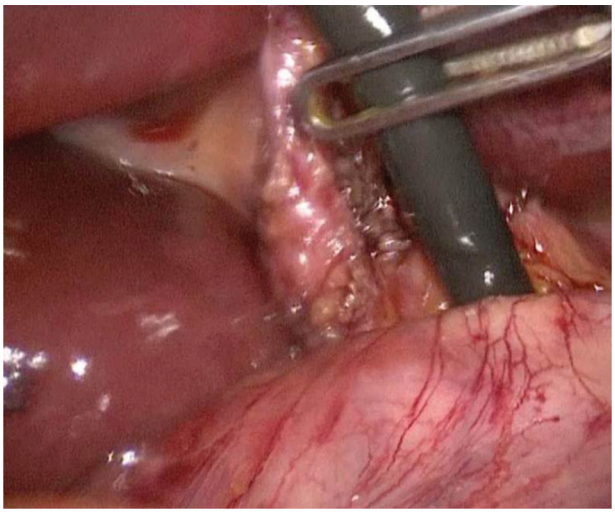
Laparoscopic skeletonization of the anterior surface of common bile duct (CBD) before choledochotomy.

Figure 14



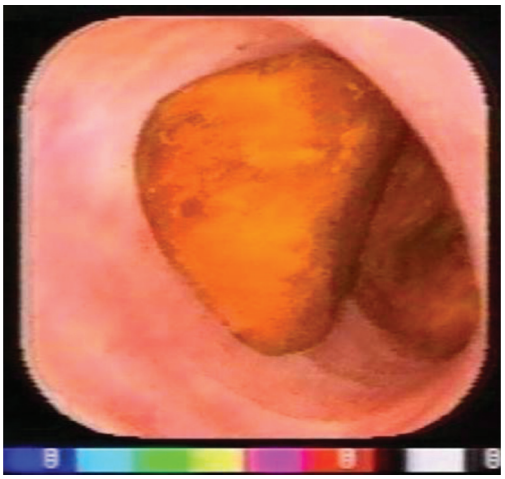
Choledochotomy in the anterolateral aspect of common bile duct (CBD).

Figure 15



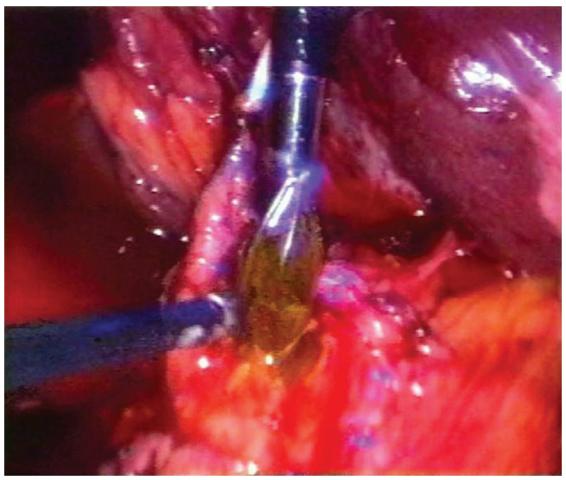
Choledochoscope introduction through choledochotomy.

Figure 16



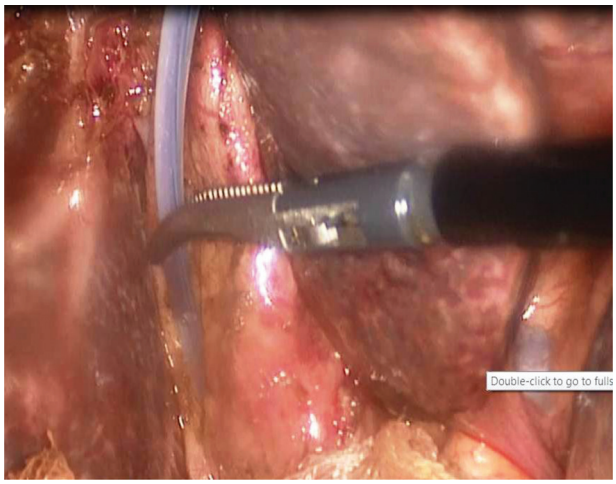
Choledochoscopic view showing common bile duct (CBD) stones.

Figure 17



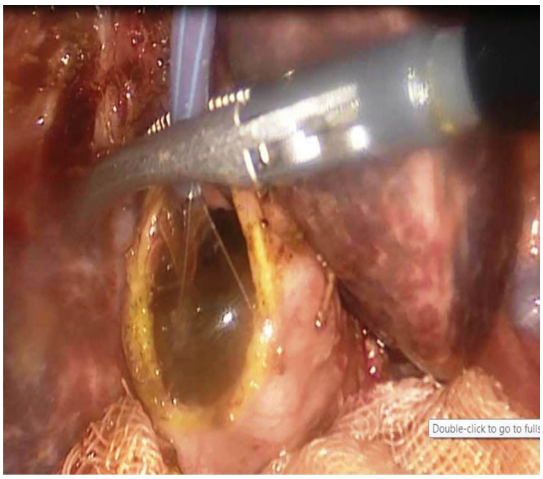
Choledochoscopic extraction of common bile duct (CBD) stones using basket.

Figure 18



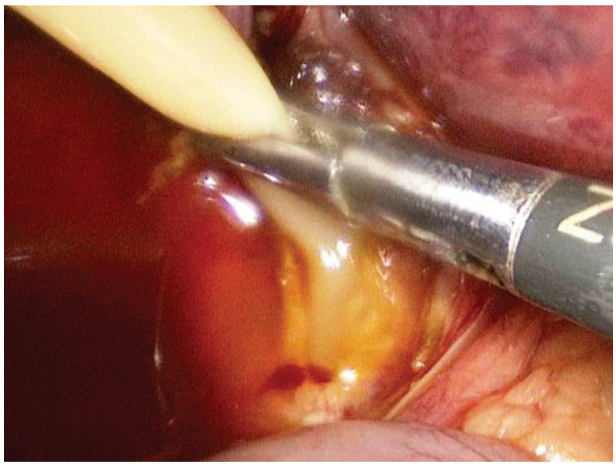
Direct introduction of the ERCP basket through choledochotomy.

Figure 19



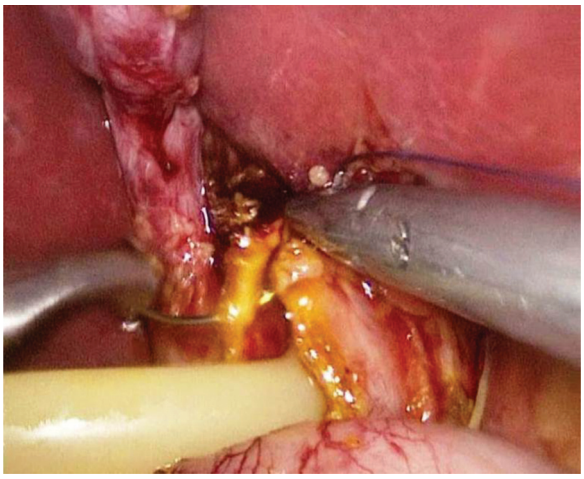
Direct extraction of the stone by ERCP basket through choledochotomy.

Figure 20



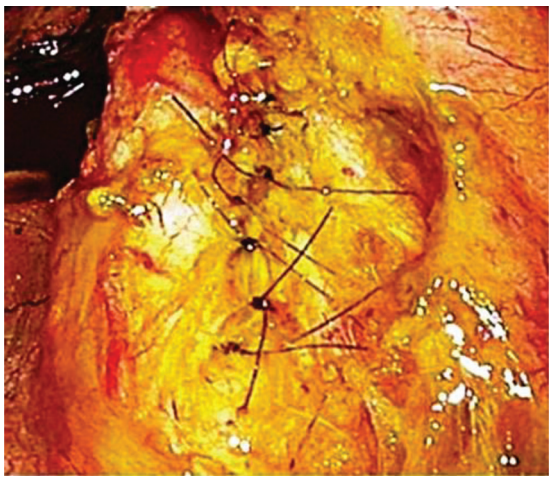
T-tube drain through choledochotomy incision to drain common bile duct (CBD).

Figure 21



Laparoscopic stitching of common bile duct (CBD) over the T-tube drain.

Figure 22



Laparoscopic primary closure of common bile duct (CBD) after choledocholithotomy.

Table 1 Complications of surgical common bile duct clearance

Complications	*n* (%)
Wound infection	3 (3)
Bile leakage	4 (4)
Missed stone(s)	7 (7)
Jaundice (CBD stricture)	1 (1)
Total	15 (15)

CBD, common bile duct.

stays and reducing hospital costs, only surgeons with advanced laparoscopic skills can perform LCBDE because the procedure requires very specialized laparoscopic techniques and equipment [26,27]. Moreover, it is difficult to use laparoscopic techniques (especially during primary closure of the CBD) in conventional LCBDE for patients whose CBD is less

than 1 cm because of the difficulty of laparoscopic manipulation and concerns of postoperative ductal stricture after suturing [27,28].

Table 2 Endoscopic procedure to clear common bile duct

Procedures	*n* (%)
Basket extraction	45 (45)
Balloon extraction	25 (25)
Combined basket and balloon sweeping	15 (15)
Mechanical manual lithotripsy	13 (13)
Stenting of CBD with failure of the attempt	2 (2)
Total	100 (100)

CBD, common bile duct.

Table 3 Complications of endoscopic common bile duct clearance

Complications	*n* (%)
Cholangitis	3 (3)
Mild pancreatitis with hyperamylasemia	6 (6)
Total	9 (9)

Table 4 Methods of laparoscopic common bile duct clearance

Items	*n* (%)
Transcystic approach	5 (10)
Transcholedochotomy approach	45 (90)
Choledochoscopic technique	45 (90)
Converted to open technique (failed attempt)	1 (2)
Total cases	50 (100)

Table 5 Complications of laparoscopic common bile duct clearance

Complications	*n* (%)
Postoperative hypothermia	2 (4)
Postoperative fever and hyperamylasemia	1 (2)
Missed stone	2 (4)
Total	5 (10)

LCBDE is a safe, efficient, and cost-effective treatment, and associated with a high stone clearance rate ranging from 84 to 97%, a postoperative morbidity rate of 4–16%, and a mortality rate of ~0–0.8% [29]. However, to decompress the bile duct and decrease biliary complications, T-tube drainage is routinely used after choledochotomy, which is inevitable with complications including bile leakage, bile infection, and wound infection. Furthermore, it lasted several weeks before removal, causing great discomfort and delaying return to work [30,31].

In our study, the T-tube drain was used in most of the laparoscopically treated patients by LCBDE (30 patients about 60%); however, primary CBD closure was also performed in 20 patients (40% of cases) after retrieval of the stones and choledochorrhaphy was performed by either interrupted or continuous sutures as many reports supported its use, with favorable long-term outcomes [26,32,33]. Although continuous suturing may initially result in increased operative time, with practice, it may actually decrease the total operative time.

CBD repair is one of the most challenging steps during LCBDE and has been performed with various techniques [34,35]. The degree of difficulty is particularly increased when the T-tube is inserted into the CBD; however, meta-analysis data have provided evidence that primary closure instead of T-tube drainage is superior in terms of operative time, overall postoperative complications, and postoperative hospital stay [36,37]. No statistically evident complications occurred in patients treated with primary CBD closure, probably explained by the use of choledochoscopy only without probing for the lower end of the CBD. These measures reduced the risk of

Table 6 Comparison between methods of common bile duct clearance

Items	Group I (surgery)	Group II (endoscopy)	Group III (laparoscopy)	*P* value
Invasiveness	Invasive	Minimally invasive	Minimally invasive	
Operative time (min)	60–180	20–45	70–292	0.000
Mean±SD	90.81±21.45	30.24±8.72	123.72±41.5	Highly significant
Success rate of the attempted procedures	100%	98%	70%	0.245
Failed cases	–	2	1	Not significant
CBD clearance	93%	100%	98%	–
Missed stone(s)	7	–	2	
Procedural mortality	–	–	–	–
Postprocedural morbidity	15%	9%	10%	0.425Not significant
Hospital stay (days)	5–12	1–2	2–4	0.002
Mean±SD	8.3±3.84	1.21±0.27	3.2±1.18	Significant
Return to work (days)	12–20	2–5	5–10	0.030
Mean±SD	14.3±3.71	3.2±1.86	12.61±3.9	Significant
Difficulty	Easy	Difficult	Difficult	–
Feasibility	Feasible	Not feasible	Not feasible	–

CBD, common bile duct.

postoperative biliary leakage, with a significant decrease in postoperative hospital admission and the total cost of treatment; moreover, the primary closure group were not burdened by a T-tube with the additional cost of postoperative cholangiography [7,30].

Comparison between the three groups in this study showed that the operative time was considerably reduced in the endoscopic group (20–45 min), and the open surgery group (60–180 min) versus the laparoscopic group (70–292 min); this was highly significant. These results were supported by previous data.

In terms of CBD clearance from stones in our study, it was 93% in the surgery group, with seven cases of missed stones postoperatively, and 100% in the endoscopic group, versus 98% in the laparoscopic group, with two cases of missed stones postoperatively. Several studies have been reported on the safety and efficiency of CBD clearance of stones whether by ERCP and/or by LCBDE. ERCP with sphincterotomy has been available in most major medical centers worldwide for nearly 30 years, and is currently routinely used in conjunction with LC, rather than open surgery, to treat choledocholithiasis. The overall success rate of ERCP in experienced hands is well established at about 95%. However, the minimum number of ERCP procedures necessary for competency has been suggested to be between 102 and 185 procedures to achieve a success rate of 85–90%. LCBDE has been developed over the past two decades as a means of dealing with CBD stones discovered incidentally during the course of LC with an overall success rate of LCBDE of 94.6% [9].

Some studies showed that LCBDE is equal in terms of efficacy and safety to preoperative ERCP+LC for patients with 'likely' CBD stones. However, stones were more frequently reported during ERCP+LC than during LCBDE; this is likely because ERCP by technique allows fluoroscopic and endoscopic identification of small stones and sludge that would otherwise be immediately pushed clear when contrast is first injected during the antegrade cholangiography phase of LCBDE [9]. Furthermore, ERCP with retrograde passage of occlusion balloons enables better detection and removal of proximal ductal stones. Meta-analysis also showed that single-stage (LC+LCBDE) management was as effective as two-stage (LC+ERCP) management, but one trial [38] was more strongly in favor of the single-stage (LC+ LCBDE) management than any other included studies. One possible reason could be that they abandoned ERCP at an earlier stage when they detected multiple and large stones in the CBD, and they favored a transductal approach if the bile duct diameter was large or if the stones were large and multiple. Another reason might be the use of an intention-to-treat analysis [10].

The difference in our results between laparoscopic and endoscopic clearance rate, which was comparable in many studies, may be explained by the use of choledochoscope techniques alone for detection, extraction of CBD stones and assessment of CBD clearance during laparoscopy versus cholangiogram that is used during ERCP. Therefore, intraoperative cholangiogram is very crucial in LCBDE and must be available for the detection of CBD stones and assurance of CBD clearance during the procedure to guard against these pitfalls.

Hospital stay in days was significantly reduced in endoscopic and laparoscopic-treated cases versus surgery-treated cases (1–2 days for endoscopy, and 2–4 days for laparoscopy versus 5–12 days for surgery), with a P value of 0.002. Consequently, return to work was also significantly reduced in endoscopic and laparoscopic-treated cases versus surgery-treated cases (2–5 days for endoscopy and 5–10 days for laparoscopy versus 12–20 days for surgery), with a P value of 0.030. However, meta-analysis showed that the difference in the length of hospital stay between the two groups was not statistically significant, but two of the included trials reported that the length of hospital stay was shorter for the single-stage (LC+LCBDE) approach with a statistically significant difference compared with the two-stage (LC+ERCP) management [9]. Other data also suggested that single-stage management had the potential advantage of a shorter hospital stay [39]. One probable reason was that the definitions of hospital stay varied, which had an impact on the validity of the data. Some trials defined it as the duration from the last finished procedure to discharge, whereas other trials defined it as the entire duration from hospital admission to discharge [9,10].

The postoperative morbidity and mortality in our study were comparable and not statistically significant; however, the operative time was statistically highly significant between groups (20–45 min for endoscopy, 60–180 min for open surgery vs. 70–292 min for LCBDE), with P value of 0.000, in contrast to previous data showing that total operation durations were similar between two-stage (LC+ERCP) and single-stage (LC+LCBDE) management, with no

statistically significant difference in this meta-analysis. When considering preoperative ERCP+LC versus LC+ LCBDE and postoperative ERCP+LC versus LC+ LCBDE separately in the subgroup analysis, the outcomes, as stated, remained consistent [10,40].

Conclusion

It is important to realize that open CBDE has enjoyed a long and successful history as the benchmark against which all other treatment modalities for choledocholithiasis are compared; furthermore, open surgery enables direct manual palpation and instrumentation of bile ducts using a variety of instruments. However, it has its drawbacks such as long maneuver time, invasiveness, increased mortality and morbidity, long hospital stay, and delayed return to work.

In contrast, endoscopic management of choledocholithiasis has the advantage of minimally invasive maneuvers, that fact that it can be performed in the outpatient clinic, lower duration of procedure, less hospital stay, very low if no mortality and morbidity, and rapid return of the patients to work, but the cost effectiveness and feasibility are still a problem. Moreover, LCBDE is a feasible minimally invasive procedure, with low morbidity and mortality, but it requires excellent laparoscopic surgical skills, a long learning curve, and up-to-date complete equipment including intraoperative cholangiogram facilities, and a good selection of patients.

The minimally invasive techniques (endoscopy and laparoscopy) have a comparable efficiency, safety, and CBD stone clearance rate; this must be kept in mind during decision-making for the treatment of choledocholithiasis in all tertiary centers.

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Conflicts of interest

There are no conflicts of interest.

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Efficacy and safety assessment of α-chymotrypsin injection in postoperative and post-traumatic edema: a prospective, open-label, multicenter observational registry study in Egypt

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Background
Edema occurs because of trauma to tissues from an injury or a surgical procedure and is bothersome to both patients and treating physicians. The presence of edema is an initial component of the inflammatory response to tissue trauma. Chymotrypsin possesses potent anti-inflammatory properties that accelerate the reabsorption of inflammatory edemas as well as postoperative and post-traumatic hematomas and edemas. This study is a pioneer research to evaluate the efficacy and safety of α-chemotrypsin injection in postoperative and post-traumatic edema.
Patients and methods
A total of 529 patients with postoperative and postfracture edemas were recruited from three centers in Egypt (Orthopedic, Gynecology, and Surgery). Edema grades during visit 1 (V1) and visit 2 (V2) were evaluated and given scores from 1 to 4; their mean values were obtained and compared using the paired *t*-test for the overall sample, for each center, and by nature of edema (postoperative and post-traumatic).
Results
Of the 529 patients, 523 (98.9%) cases improved, six (1.1%) cases did not change, and the condition of no patient worsened. The mean edema grade score in V1 in the overall sample was 2.75, which decreased to 1.53 in V2 ($P<0.001$), with a percent change of –61%. There was a statistically significant difference in edema grade between V1 and V2. No adverse events or serious adverse events were reported during the study.
Conclusion
α-Chymotrypsin ampoules from Amoun are effective in lowering the edema grade and in managing patients with postoperative edema and postfracture edema as well.

Keywords:
α-Chymotrypsin, chymotrypsin, edema, fractures, inflammation, surgery, trauma

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1110-1121

Background

Edema occurs because of trauma to tissues from an injury or a surgical procedure, which is bothersome to both patients and treating physicians. Trauma to tissues causes increased capillary permeability or capillary rupture, which burdens a healthy lymphatic system as fluids and protein leak into tissue spaces. Temporary block or damage to the neighboring lymphatic tissue reduces protein and fluid uptake, causing a disruption in Starling's equilibrium as well as swelling [1,2]. Presence of edema is the primary element in the tissue trauma inflammatory response [3–5]. Edematous fluid causes further complications in soft tissue and joint structures if persistent beyond the typical healing period. The manifestation of lengthy edema after surgery or trauma is clinically significant as it can compromise recovery as it delays wound healing and stimulates pain receptors by pressuring neuroreceptors causing pain [5–9]. Finding the most suitable treatment to prevent persistent edema is challenging. There are many traditional treatment methods for edema resolution, such as physiotherapy, chemical modalities suchas NSAIDs, and enzyme preparations [10,11]. Chymotrypsin has potent anti-inflammatory properties that accelerate the reabsorption of inflammatory edemas as well as of postoperative and post-traumatic hematomas and edemas. Moreover, chymotrypsin has proteolytic activity that enables the destruction of the fibrinous formations resulting from subacute or chronic inflammatory processes [12].This study is to confirm the efficacy and safety of α-chymotrypsin in patients with

post-traumatic edema, arthritis, and postoperative edema. In this study we wanted to primarily assess edema grade score improvement and rate of change after treatment with α-chymotrypsin Ampoules in patients aged 18–65 years.

Patients and methods

This is an open-label, noninterventional, multicenter survey conducted on patients having edema due to either operation or trauma. Approval from the ethics committee of the three centers and from the Ethics Committee of the Ministry of Health was obtained before the study. A total of 529 patients from three centers in Egypt were enrolled in this study from 28 August 2014 to 30 November 2015 (Table 1).

At initial visit (visit 1), patients underwent a history and physical examination, including complete examination of the edema; they had to mention whether it was postoperative or post-traumatic. Grade of edema was calculated (Tables 1 and 2 and Fig. 1).

An informed consent form was signed and the patient underwent investigations. The treatment regimen consisted of α-chymotrypsin 5 mg ampoules manufactured by Amoun Pharmaceuticals (Amoun Pharmaceutical Company, Obour city, Industrial zone (1), Cairo, Egypt) once a day for 1 week or as per the investigator's advice. α-chymotrypsin injection is packed as a box of three ampoules of 5 mg crystallized and lyophilized chymotrypsin (450 EA units)+three ampoules of 3 ml apyrogenic saline.

All patients were seen in the outpatient clinic by the investigators who assessed edema grade after 1 week from initial visit (visit 2). The patients were asked to return 30 days after initial study enrollment if needed for post-trauma or adverse events (visit 3). Most of the patients did not need be followed up with visit 3.

Table 1 Centers and number of patients

Centers	Site	Description	Number of enrolled patients
Surgery Center (Center 1)	Ain Shams University Hospital	Operations were performed in the abdomen and pelvis, neck, breast and upper and lower limbs	244
Obstetric Center (Center 2)	Al-Galaa Hospital	Operations were cesarean section, hysterectomy, laparotomy, and ovarian cystectomy	85
Orthopedic Center (Center 3)	Om Al-Masryin Hospital	Operations: open reduction and internal fixation procedures. These operations were performed in the upper limb and in the pelvis (101 patients)Traumas: open and closed fractures (99 patients)	200

Table 2 Edema grade score

Grades of edema	Description	Score
0	No edema	0
1+	2 mm or less: slight pitting, no visible distortion, disappears rapidly	1
2+	2–4 mm indent: somewhat deeper pit, no readably detectable distortion, disappears in 10–25 s	2
3+	4–6 mm: pit is noticeably deep. May last more than a minute. Dependent extremity looks swollen and fuller	3
4+	6–8 mm: pit is very deep. Lasts for 2–5 min. Dependent extremity is grossly distorted	4

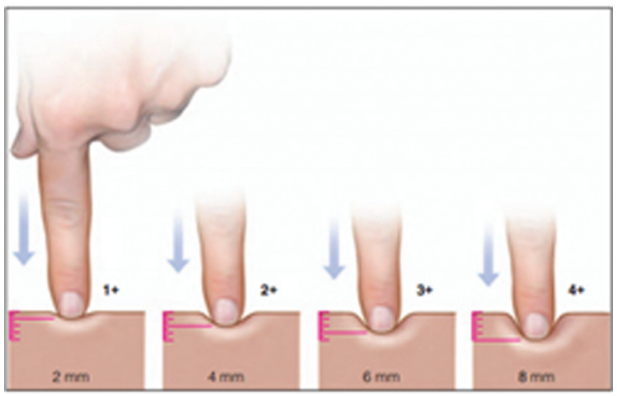
Statistical analysis

Data of 529 patients were analyzed in this study, which gives a margin error of ±4.8% at 95% confidence level and with expected number of patients with improving edema of 50%. Categorical data were presented as number and percentage and the χ^2-test (or its subsidiaries) was used to obtain *P*-values to test the significance of differences between centers and sample subsets. Descriptive statistics (mean±SD) presented the numerical data and the Student *t*-test (or its subsidiaries) was used to obtain *P*-values to test the significance of differences between centers and sample subsets. The calculation of statistics and proportions did not include the missing data.

Demography

The mean age of the participants was 42.38±12 years; 61.5% of patients in center 1, 41% of patients in site 3, and all patients of center 2 were female (Table 3).

Figure 1



Grading method: dent depth and duration.

Results

Of the 529 patients, 523 (98.9%) cases improved, six (1.1%) cases did not change, and none worsened. The mean edema grade score in visit 1 (V1) in the overall sample was 2.75, which decreased to 1.53 in visit 2 (V2), with a percentage change of −61%. The difference was very highly significant ($P<0.001$).

In the surgical center the mean edema grade score in V1 was 2.16, which decreased to 1.04 in V2, with a percentage change of 52%. In the Gynecology Center the mean edema grade score in V1 was 1.55, which decreased to 0.14 in V2, with a percentage change of −91. In the Orthopedic Center the mean edema grade score in V1 was 3.34, which decreased to 1.29 in V2, with a percentage change of −61%. The difference was very highly significant ($P<0.001$) in all centers.

As for edema indication, postoperative mean edema grade score in V1 was 2.29, which decreased to 0.92 in V2, with a percentage change of 60%. In post-traumatic edema, the mean edema score was 3.44 in V1, which decreased to 1.29 in V2, with a percentage change of −63%. The difference was very highly significant ($P<0.001$) for both indications.

No adverse events or serious adverse events were reported during the study time from V1 to V2 and for 30 days after the last dose of α-chymotrypsin had been received.

Discussion

The scope of this study was to evaluate the efficacy and safety of α-chymotrypsin in the management of postoperative and post-traumatic edema in patients aged 18–65 years. The patients were not suffering from any severe liver or kidney disease, nor were they allergic to chemotrypsin. The study enrolled 529 patients; no patients terminated their participation in the study, nor were any lost to follow-up. Among the 529 patients 523 (98.9%) cases improved, six (1.1%) cases did not change, and no cases worsened. Our study is a pioneer investigation into the efficacy of α-chemotrypsin injection, as we could not find any similar studies conducted to assess the efficacy of α-chymotrypsin intramuscularly. Edema grade score dropped from 2.75 in V1 to 1.53 in V2 in the overall sample and the difference is very highly significant ($P<0.001$). There was 61% improvement in edema grade score and a change in edema grade in the overall sample as well.

α-Chymotrypsin showed significant improvement in edema grade scores and percentage change in edema score in all centers. Edema grade score improved by 52, 91, and 61% in center 1 (General Surgery),center 2 (Gynecology), and center 3 (Orthopedic), respectively (Fig. 2).

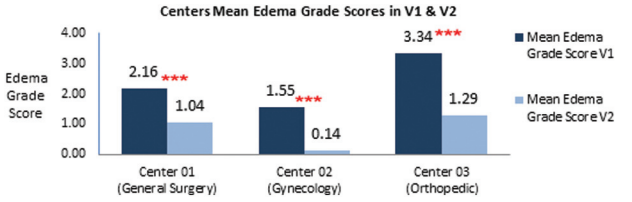
α-Chymotrypsin showed significant improvement in edema grade scores in both postoperative and postfracture groups, with the score improving by 60 and 63%, respectively (Fig. 3).

No adverse events or serious adverse events were reported for α-chymotrypsin in the study.

Table 3 Demography of patients in the three centers

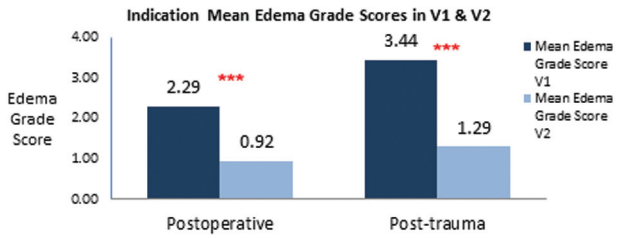
	Center 1	Center 2	Center 3
Sex [*n* (%)]			
Male	94 (38.5)	0 (0)	118 (59)
Female	150 (61.5)	85 (100)	82 (41)
Age (years) [*n* (%)]			
Mean±SD	45±10.564	36±11.1	29±7.696
<36	60 (24.6)	52 (61.2)	74 (37)
36–50	103 (42.2)	24 (28.2)	68 (34)
>50	81 (33.2)	9 (10.6)	58 (29)
BMI [*n* (%)]			
Mean±SD	29.1±5.4	28±46	20±46
Normal	64 (26.2)	12 (14.1)	23 (11.5)
Overweight	111 (45.5)	24 (28.2)	135 (67.5)
Obese	69 (28.3)	49 (57.6)	42 (21)

Figure 2



Percentage change in edema grade score by center. V1, visit 1; V2, visit 2.

Figure 3



Mean edema grade scores by indication in V1 and V2. V1, visit 1; V2, visit 2.

Limitation

This study was an observational rather than an interventional study, and therefore suffered from a number of limitations. We tried to consider most of the variables that may affect the endpoint; however, there were many variables that were not counted, such as differences in clinical practice between study investigators, lifestyle, diet-style factors, and socioeconomic status. Furthermore, the proportion of patients' sample subsets was not ascertained. Center 2 enrolled 85 patients (20% of total sample).

As there were no similar studies assessing the same objective, we were not able to compare our study results with previous study findings.

Conclusion

α-Chymotrypsin ampoules of Amoun are safe and effective in lowering edema grade and in managing patients with postoperative edema and postfracture edema as well.

Acknowledgements

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Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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Subserosal cecal lipoma: a rare cause of ileocolic intussusception in adults

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Intussusception is a rare cause of intestinal obstruction in adults and is usually secondary to malignant neoplasms as the pathologic leading point. We present a case of ileocolic intussusception in an adult caused by a large pedunculated cecal lipoma and mobile cecum. The patient was a 45-year-old woman with 3 weeks' history of colicky abdominal pain, hematochezia, and alternating bowel habits. Computed tomography of the abdomen revealed ileocolic intussusception with 7×5 cm low-density mass in the cecum. Right hemicolectomy was performed, and histopathological examination of the specimen confirmed the diagnosis of a subserosal cecal lipoma.

Keywords:
cecal lipoma, ileocolic intussusception, intestinal obstruction

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1110-1121

Introduction

Intussusception in adults is less common than that in pediatric population and is usually caused by malignant neoplasms in up to half of the cases [1]. The presentation of intussusception in adults is variable and nonspecific; the patient may present with chronic intermittent abdominal pain, obstruction, and/or bleeding [2].

Colonic lipomas are rare mesenchymal tumors and their incidence ranges from 0.2 to 4.4% [3]. They occur usually in elderly women and are located mainly in the cecum and ascending colon [4].

The majority of colonic lipomas are small in size and asymptomatic and discovered incidentally during surgery or endoscopy. Only 30% of them reach a diameter of 2 cm or larger, and the patients may present with anemia, constipation, bleeding, diarrhea, abdominal pain, or intussusception [4,5].

We present a case of ileocolic intussusception secondary to a large pedunculated subserosal cecal lipoma and review of the literature.

Case report

A 45-year-old female patient complained of intermittent central colicky abdominal pain since 3 weeks associated with alternating bowel habits, hematochezia, and vomiting. Clinically, a mobile mass was felt in the right side of the abdomen, with mild tenderness over it. Written informed consent was obtained from our patient for publication of this case report and any accompanying images.

The laboratory investigations showed leukocytosis, hypoalbuminemia, and hypokalemia. Contrast-enhanced computed tomography (CT) of the abdomen revealed ileocolic intussusception reaching the ascending colon and a low-density mass about 7×5 cm in the cecum (Fig. 1,2).

Exploratory laparotomy was performed, and we found ileocolic intussusception that was easily reduced. A mass in the cecum was felt. In addition, the cecum and a part of the ascending colon were mobile, and hence right hemicolectomy was performed due to the possibility of being malignant neoplasm (Fig. 3). Histopathological examination of the specimen revealed pedunculated subserosal cecal lipoma as the leading point of intussusception with evidence of traumatic fat necrosis (Fig. 4).

Discussion

Colonic lipomas are rare nonepithelial neoplasms and they were first described by Bauer in 1757 [6]. However, they are the most common mesenchymal tumors of the colon and the third common benign tumor after the adenomatous and hyperplastic polyps [7].

In the majority of cases, they arise from the submucosa and appear as sessile polypoid masses, and rarely they arise from the subserosa and/or appear as pedunculated polypoid masses. They are usually solitary lesions in the

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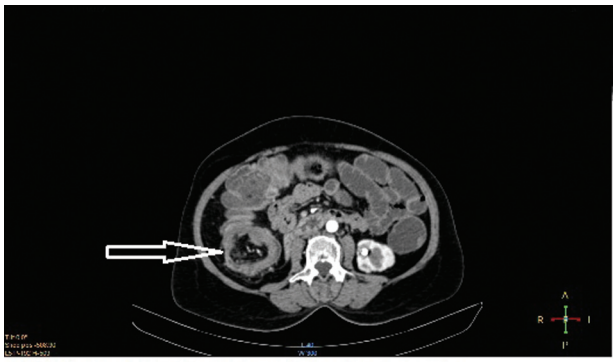
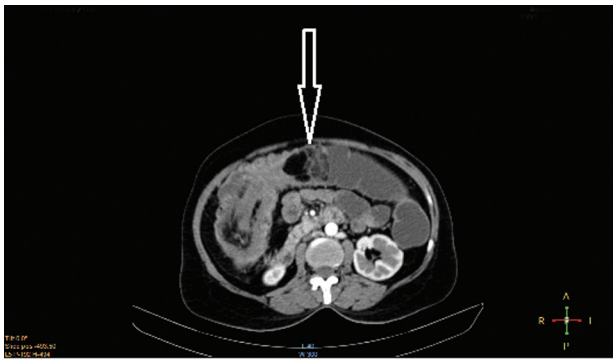
Figure 1



CT Abdomen showing the target sign of ileo-colic intussusception

Computed tomography of the abdomen showing the target sign of ileocolic intussusceptions.

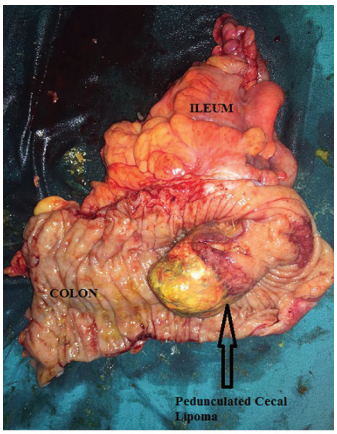
Figure 2



CT Abdomen showing intraluminal fatty mass as the leading point

Computed tomography of the abdomen showing intraluminal fatty mass as the leading point.

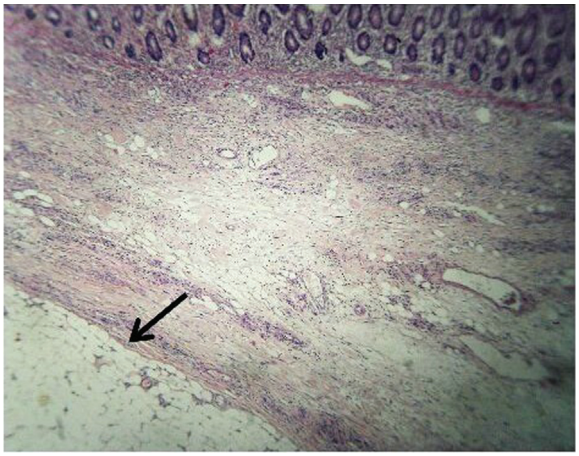
Figure 3



Resected segment of colon showing subserosal cecal lipoma

Resected segment of the colon showing subserosal cecal lipoma.

Figure 4



Subserous mass formed of lobules of mature fat cells x40.

colon and only in 10–25% of cases are multiple lesions [5,8–10].

Paškauskas *et al.* [11] found 37 cases of colonic lipoma causing intussusception after reviewing the English language publications, and we found only four cases of ileocolic intussusception caused by submucosal cecal lipoma and no similar cases of subserosal cecal lipoma causing intussusception after reviewing the English literature using PubMed [12–15].

Abdominal CT is a noninvasive imaging modality that helps in the diagnosis of intussusception caused by cecal lipoma. The radiological features of colonic lipoma are spherical or ovoid mass with sharp margins and low absorption densities of −40 to −120 Hounsfield units [5,16].

Colonic lipoma can be resected by means of either endoscopy or surgery. Endoscopic polypectomy is recommended for small lipomas (<2 cm), whereas colonic lipomas exceeding 2 cm should be surgically removed [11,17].

Surgical options include segmental resection, colostomy with local excision, hemicolectomy, or subtotal colectomy according to the size, location of the tumor, and presence of definite preoperative diagnosis [12].

Conclusion

Intussusception in adults is rare and is usually caused by malignant neoplasms. However, colonic lipoma should be considered in the differential diagnosis. CT of the abdomen is the investigation of choice in the diagnosis of intussusception secondary to colonic lipoma. Surgical approach remains the treatment of choice for large colonic lipoma, and the type of procedure depends on the size, site of tumor, and presence of definite preoperative diagnosis.

Financial support and sponsorship
Nil.

Conflicts of interest
There are no conflicts of interest.

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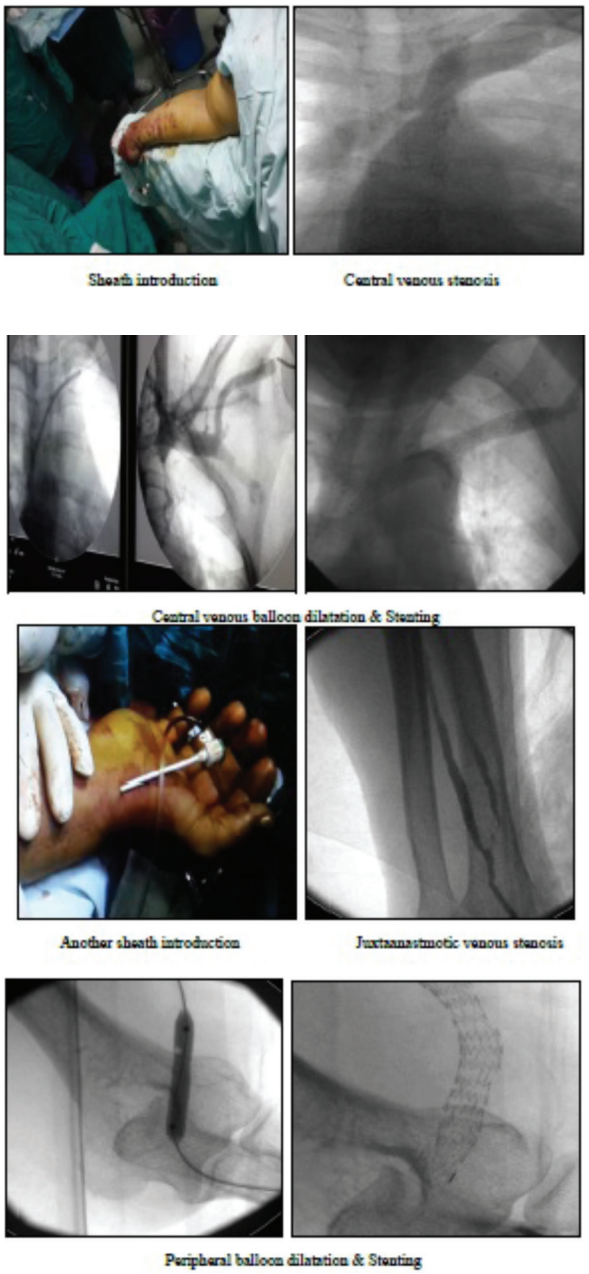
Erratum: Sometimes endovascular salvage of failing hemodialysis access is indispensable as you may not get another

In the article titled, "Sometimes endovascular salvage of failing hemodialysis access is indispensable as you may not get another" published in pages 384–390, issue 4, vol. 35 of The Egyptian Journal of Surgery[1], Figure 6 is missing. Figure 6 should be cited under the section "Statistical analysis". The figure and the legend of the figure is mentioned below.

Figure 6



This figure show two cases of central & peripheral balloon dilatation & Stenting.

Reference

1 Ahmed H, Abd El-Mabood ESA, Salama RS. Sometimes endovascular salvage of failing hemodialysis access is indispensable as you may not get another. Egypt J Surg 2016; 35:384–390.

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