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Editorial

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I am happy to write this editorial of World Journal of Laparoscopic Surgery issue of January–April 2022, Volume 15, Number 1. As I am writing my first editor's letter of the year 2022, I cannot help but look back and wonder, where did 2021 go? After the short, sharp shock of Omicron, the pandemic phase of COVID-19 looks to be ending for most locations, unless a significant and severe new variant emerges. In this issue Short-term Outcomes after Bariatric Surgery during the COVID-19 Pandemic is an interesting article.

I am thankful that in the past year we published many interesting articles in WJOLS. In this first issue of 2022, we have many interesting articles regarding laparoscopic cholecystectomy. Factors Affecting Conversion of Laparoscopic cholecystectomy to Open Surgery and Study of Difficult Laparoscopic Cholecystectomy and Its Outcome According to Preoperative Scoring System are interesting articles you must go through. For gynecologists, Laparoscopic Management of Uncommon Presentations of Ectopic Pregnancy is an interesting article.

Prospects for the rest of the year and beyond hinge on the questions of whether and when future variants will emerge. We might then expect to see a seasonality-driven wave of disease by next fall of winter, but I am sure that hospitalizations would likely peak well below the level of the wave we just experienced. A new variant may yet trigger another chapter in the COVID-19 pandemic and societies must be prepared to respond if and when that happens. But for now, the pandemic phase looks to be ending.

We should pray for those with the coronavirus, those who care for them, and our doctor friends those who are suffering from anxiety during this stressful time.

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ORIGINAL ARTICLE

Factors Affecting Conversion of Laparoscopic Cholecystectomy to Open Surgery in a Tertiary Healthcare Center in India

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Abstract

Background: Laparoscopic cholecystectomy (LC) is the surgery of choice for patients suffering from gallstone diseases. Open cholecystectomy these days is performed after conversion from laparoscopic surgery due to various reasons. The aim of this study was to assess the factors responsible for conversion of LC to open surgery by identifying preoperative risk factors that could predict conversion and intraoperative technical/surgical difficulties and complications that cause conversion.

Methods: A total of 310 patients were included in this prospective observational study conducted between November 2018 and March 2020.

Results: Out of 310 cases, 38 were converted to open surgery with a conversion rate of 12.2%. Mean age was 10 years more in the converted group. Males had a higher chance of conversion than females (18.6 vs 7%). Conversion rate was significantly higher in patients with body mass index (BMI) >23 kg/m^2 (25%), with features of acute cholecystitis, who underwent interval cholecystectomy (25.8%), who underwent endoscopic retrograde cholangiopancreatography (ERCP) (>40%), with total white blood cell (WBC) counts ≥10,000/mm^3 (25.6%), with serum albumin <3.5 g/dL (43.8%), with imaging findings of acute cholecystitis (25.6%), and with dilated common bile duct (CBD)/choledocholithiasis (33.3%). Conversion rate when LC was performed early after ERCP was 18% and when performed after 4–6 weeks was >50%. The most common causes for conversion were a frozen Calot's triangle due to dense inflammatory adhesions, leading to inadequate visualization of critical structures.

Conclusion: Identifying patients with significant risk factors for conversion could minimize adverse effects of prolonged surgery by limiting duration of trial of laparoscopic dissection. Surgical residents need to identify low-risk patients preoperatively and require proper training before handling difficult cases.

Clinical significance: Early LC should be considered in all patients who are able to withstand surgery, as delayed surgery increases the chances of conversion.

Registration of the study: This prospective study has been registered in the Clinical Trials Registry of India (CTRI). CTRI Registration Number CTRI/2018/11/016338.

Keywords: Acute cholecystitis, Calot's triangle, Complicated gallbladder, Delayed laparoscopic cholecystectomy, Endoscopic retrograde cholangiopancreatography, Laparoscopic cholecystectomy, Open surgery.

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Introduction

The first laparoscopic cholecystectomy (LC) was performed in 1985, and it is the current "gold standard" operation for patients with gallstone disease.[1] The most common indications include symptomatic gallstone disease, acute cholecystitis, and gallstone pancreatitis. Absolute contraindications include an inability to tolerate general anesthesia, patients with severe cardiovascular or pulmonary disease, and patients with gallbladder (GB) cancer. Many conditions previously thought to be contraindications for LC are no longer considered contraindications, e.g., gangrenous GB, empyema of the GB, obesity, pregnancy, previous upper abdominal procedures, and cirrhosis, as there has been a tremendous advancement in the technique and experience of laparoscopic surgeons.

Open cholecystectomy these days is generally performed after conversion from the laparoscopic approach. Factors affecting conversion of LC to open surgery include patient- and disease-related factors, as well as technical difficulties. The two most frequent indications for conversion currently are dense upper abdominal adhesions resulting in a frozen Calot's triangle or a necrotic GB wall that precludes grasping and elevation with a grasper.[2]

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Materials and Methods

A prospective observational study was conducted in the Department of General Surgery, Kasturba Hospital, Manipal, India. A total of 310 patients above the age of 18 years who were planned for LC during the study period of November 2018 till March 2020 were included. Exclusion criteria were (i) gallbladder carcinoma; (ii) laparoscopy done, cholecystectomy not done/procedure abandoned; and (iii) other surgical procedures performed simultaneously.

Preoperatively, relevant history and clinical examination findings of the patients were noted. Laboratory data and radiological findings were accessed through the online database. Intraoperative findings of all cases (irrespective of whether converted or not) were taken from the operative notes. In cases converted to open surgery, the operating surgeon would fill a checklist regarding the reason for conversion.

Statistical Analysis

Chi-square test and unpaired *t*-test were applied. Analysis was done using IBM SPSS® software v 23.

Results

A total of 310 patients planned for LC were included in the study out of which 38 patients underwent conversion to open (CO) surgery. Hence, the conversion rate in this study was 12.2%.

The mean age in the CO group was 58 years, almost 10 more than the mean age of 47 years in the LC group. This was found to be statistically significant with a *p*-value of 0.0001. Patients older than 50 years had a higher conversion rate. The study population had 170 female patients and 140 male patients. Males had a significantly higher conversion rate than females (18.6 vs 7%, $p = 0.001$). Patients who were overweight [body mass index (BMI) >23 kg/m^2] according to the Asian BMI classification had a higher conversion rate, as compared to the patients with a BMI <23 kg/m^2 (25 vs 8.7%, $p = 0.0001$) (Table 1).

As shown in Table 2, patients who presented with symptoms suggestive of acute cholecystitis, i.e., right upper quadrant (RUQ) pain, vomiting, and fever, had a significantly higher rate of conversion. There was no significant difference observed in conversion rate between patients whose duration of symptoms was >1 week and <1 week ($p = 0.120$).

Patients, who had an episode of acute cholecystitis and were managed conservatively, underwent an elective interval cholecystectomy after 4–6 weeks. This also includes those patients who underwent a delayed LC post-endoscopic retrograde cholangiopancreatography (ERCP) with or without stenting. Conversion rate was higher (almost 25%) in patients who underwent an interval cholecystectomy (Table 2).

Comorbid conditions such as diabetes mellitus, cardiovascular disease (ischemic heart disease or hypertension), and respiratory disease (bronchial asthma or chronic obstructive pulmonary disease) had no significant impact on the rate of conversion. Also, a history of abdominal surgery was not found to be significant for conversion (Table 2).

Table 1: Patient characteristics

	Total cases	*Converted cases*	*Conversion rate*	*Chi-square value*	*p value*
Age					
<50	165	9	5.45%	11.816	<0.001
>50	145	29	20%		
Sex					
Male	140	26	18.6%	9.461	0.001
Female	170	12	7%		
BMI					
<23	242	21	8.7%	13.149	<0.001
>23	68	17	25%		

Conversion rate was significantly higher in patients who underwent ERCP with either papillotomy and common bile duct (CBD) stone extraction/clearance of sludge (41.9%) and ERCP with stenting (50%) as compared to those patients who had no ERCP done (2.5%) ($p = 0.0001$) (Table 3).

Patients who had clinical features suggestive of acute cholecystitis—tachycardia (pulse rate >100/m), fever (temperature >99 F), and positive Murphy's sign—had a higher conversion rate. The findings of leukocytosis [total white blood cell (WBC) count >10000/mm^3], obstructive jaundice (total bilirubin >1.2 mg/dL; direct bilirubin >0.3 mg/dL; ALP >130 U/L), pancreatitis (amylase >100 U/L; lipase >60 U/L), and hypoalbuminemia (albumin <3.5 g/dL), preoperatively, had a significant association with conversion rate as shown in Table 2.

All patients (310) underwent ultrasonography (US) of the abdomen. Those who had a contrast-enhanced computed tomography (CT) abdomen (12 patients) or magnetic resonance cholangiopancreatography (5 patients) done were usually in addition to a US abdomen. The imaging findings that were assessed include presence of calculi; pericholecystic fluid collection or fat stranding; a distended GB; sludge; GB perforation; a dilated CBD; or presence of CBD calculi, polyp, or pancreatitis.

Conversion rate was significantly higher in patients with features of acute cholecystitis—pericholecystic fluid or fat stranding (43.8 vs 10.5%; $p = 0.0001$), presence of sludge on imaging (32.3 vs 10.0%; $p = 0.0001$), perforated GB (66.7 vs 33.3%; $p = 0.004$), and dilated CBD/CBD calculi (33.3 vs 10.2%; $p = 0.0001$) (Table 2).

GB wall thickness was one of the preoperative imaging findings that the authors wanted to assess, but in the majority of the cases, it was not commented upon. A mention of a thickened GB wall or a wall thickness more than 4 mm was made in a total of 24 patients, out of which 6 were converted (25% conversion rate).

Patients with a preoperative diagnosis of acute cholecystitis, gallstone pancreatitis, and those who underwent a delayed LC after 6 weeks post-ERCP had higher conversion rates of 33, 20, and 52%, respectively.

Reasons for Conversion

Technical Difficulties

In all the 38 cases that were converted to open, the peritoneal cavity was entered, and adequate pneumoperitoneum was created. There were no instances of equipment failure and/or trocar injuries.

Surgical Difficulties Due to Intraoperative Findings

The reasons for conversion in 37 cases due to various surgical difficulties are mentioned in Table 4, with dense inflammatory adhesions leading to a frozen Calot's triangle and inadequate visualization of structures being the most common causes (Fig. 1). Aberrant anatomy was the cause for conversion in four cases (Fig. 2).

Surgical difficulties due to intraoperative complication: One patient had a visceral injury, a transverse colon injury that necessitated CO surgery. In this case, complete dissection of the GB was done laparoscopically.

Postoperative length of stay (LOS) was significantly longer in patients who had converted to open as compared to those patients who had the surgery completed by laparoscopy (8.8 ± 5.9 vs 2.7 ± 1.3; $p = 0.0001$). Most patients who had a prolonged LOS of more than 10–12 days were due to surgical site infection (Table 5).

Table 2: Clinical, laboratory, and imaging findings

		CO (n = 38)	*LC (n = 272)*	*Total cases (N = 310)*	*Chi-square value*	*p value*
Presenting symptoms						
RUQ pain	Present	26 (16.8%)	143 (83.2%)	155 (100%)	5.878	0.015
	Absent	12 (7.7%)	143 (92.3%)	155 (100%)		
Radiation to back	Present	3 (8.1%)	34 (91.9%)	37 (100%)	0.673	0.412
	Absent	35 (12.8%)	238 (87.2%)	273 (100%)		
Fever	Present	6 (27.3%)	16 (72.7%)	22 (100%)	4.964	0.026
	Absent	32 (11.1%)	256 (88.9%)	288 (100%)		
Vomiting	Present	12 (19.7%)	49 (80.3%)	61 (100%)	3.881	0.046
	Absent	26 (10.4%)	223 (89.6%)	249 (100%)		
Jaundice	Present	3 (23.1%)	10 (76.9%)	13 (100%)	1.447	0.224
	Absent	35 (11.8%)	262 (88.2%)	297 (100%)		
Interval cholecystectomy	Yes	35 (32.7%)	72 (67.3%)	107 (100%)	35.069	0.0001
	No	13 (6.4%)	190 (93.6%)	203 (100%)		
Past history						
Cardiovascular disease	Present	14 (17.5%)	66 (82.5%)	80 (100%)	2.755	0.097
	Absent	24 (10.4%)	206 (89.6%)	230 (100%)		
Diabetes	Present	12 (16%)	63 (84%)	75 (100%)	1.288	0.256
	Absent	26 (11.1%)	209 (88.9%)	235 (100%)		
0.825 Respiratory disease	Present	1 (10%)	9 (90%)	10 (100%)	0.049	0.825
	Absent	37 (12.3%)	263 (87.7%)	300 (100%)		
Previous abdominal surgery	Present	2 (4.8%)	40 (95.2%)	42 (100%)	2.538	0.111
	Absent	36 (13.4%)	232 (86.6%)	268 (100%)		
Clinical findings						
Tachycardia	Present	9 (34.6%)	17 (65.4%)	26 (100%)	13.189	<0.001
	Absent	29 (10.2%)	255 (89.8%)	284 (100%)		
Febrile	Present	3 (42.9%)	4 (57.1%)	7 (100%)	6.235	0.013
	Absent	35 (11.6%)	268 (88.4%)	303 (100%)		
RUQ tenderness	Present	22 (13.7%)	139 (86.3%)	161 (100%)	0.616	0.432
	Absent	16 (10.7%)	133 (89.3%)	149 (100%)		
Murphy's sign	Present	6 (40%)	9 (60%)	15 (100%)	11.279	0.001
	Absent	32 (10.8%)	263 (89.2%)	295 (100%)		
Icterus	Present	3 (33.3%)	6 (66.7%)	9 (100%)	3.828	0.043
	Absent	35 (11.6%)	266 (88.4%)	301 (100%)		
Laboratory investigations						
Leukocytosis	Present	10 (25.6%)	29 (74.4%)	39 (100%)	7.429	0.006
	Absent	28 (10.3%)	243 (89.7%)	271 (100%)		
Obstructive jaundice	Present	9 (33.3%)	18 (66.7%)	27 (100%)	12.214	<0.001
	Absent	29 (10.2%)	254 (89.8%)	283 (100%)		
Pancreatitis	Present	4 (57.1%)	3 (42.8%)	7 (100%)	13.415	<0.001
	Absent	34 (11.2%)	269 (88.8%)	303 (100%)		
Low serum albumin	Present	7 (43.8%)	9 (56.3%)	16 (100%)	15.556	<0.001
	Absent	31 (10.5%)	263 (89.5%)	294 (100%)		
Imaging						
Presence of calculi	Present	36 (12.2%)	258 (87.8%)	294 (100%)	0.001	0.976
	Absent	2 (12.5%)	14 (87.5%)	16 (100%)		
Pericholecystic fluid/fat stranding	Present	11 (25.6%)	32 (74.4%)	43 (100%)	8.240	0.004
	Absent	27 (10.1%)	240 (89.9%)	267 (100%)		
Distended GB	Present	23 (15.9%)	122 (84.1%)	145 (100%)	3.290	0.071
	Absent	15 (9.1%)	150 (90.9%)	165 (100%)		

(*Contd...*)

Table 2: *(Contd...)*

		CO (n = 38)	*LC (n = 272)*	*Total cases (N = 310)*	*Chi-square value*	*p value*
Sludge	Present	10 (32.3%)	21 (67.7%)	31 (100%)	12.810	<0.001
	Absent	28 (10%)	251 (90%)	279 (100%)		
Perforated GB	Present	2 (66.7%)	1 (33.3%)	3 (100%)	8.338	0.004
	Absent	36 (11.7%)	271 (88.3%)	307 (100%)		
Dilated CBD/CBD calculi	Present	9 (33.3%)	18 (66.7%)	27 (100%)	12.214	<0.001
	Absent	29 (10.2%)	254 (89.8%)	283 (100%)		

Table 3: Association with ERCP

	CO (n = 38)	*LC (n = 272)*	*Total cases (N = 310)*	*p value*
ERCP				
Not done	6 (2.5%)	233 (97.4%)	239 (100%)	0.0001
ERCP alone	18 (41.9%)	25 (58.1%)	43 (100%)	
ERCP + stenting	14 (50%)	14 (50%)	28 (100%)	
Duration post-ERCP				
Late (>6 weeks)	26 (53%)	23 (47%)	49 (100%)	0.0059
Early (within 48 hours)	4 (18%)	18 (82%)	22 (100%)	

Table 4: Reasons for conversion

Reason for conversion	*Number*
Dense adhesions due to severe tissue inflammation/ frozen Calot's triangle	27 (71%)
Aberrant anatomy • Aberrant vessel noted in posterior wall of GB (2) • Abnormal insertion of cystic duct (1) • Double GB (1)	4 (10.5%)
Inadequate visualization of structures	19 (50%)
Buried/intrahepatic GB	6 (15.7%)
Perforated GB	4 (10.5%)
Thickened GB wall	6 (15.7%)
Stones in CBD	1 (2.63%)
Pyocele/empyema/gangrenous GB	3 (7.89%)

Discussion

LC is one of the most commonly performed surgical procedures. In a retrospective review by Livingston et al., it was found that 25% of all cholecystectomies were open cholecystectomies, and the remaining 75% were laparoscopic cholecystectomies, which had a 5–10% conversion rate. The major risk factors for conversion included male sex, obesity, and cholecystitis. Conditions such as concurrent choledocholithiasis, cholelithiasis, and cholecystitis had a higher conversion rate of 25%.[2]

The conversion rate varies from 5 to 20% in various studies as shown in Table 6. In a study by Jang et al., the conversion rate was found to be 19%, which is more than that found in this study.[3] In a retrospective study of 1,802 patients by Simopoulos et al., the conversion rate was 5.2%.[4]

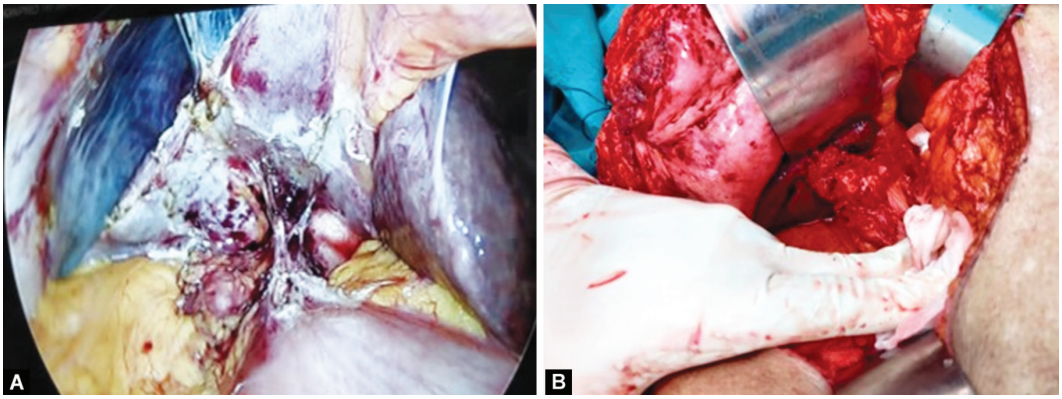
Causes for Conversion

Obesity has been identified as a significant risk factor for conversion in various studies. Most studies have considered a BMI >30 kg/m^2 as the cutoff for obesity.[3,5] But considering this study population being only Indians, the cutoff for obesity is based on the Asian BMI criteria, with >23 kg/m^2 classified as overweight and >25 kg/m^2 considered obese.[6] In this study, BMI of more than 23 kg/m^2, i.e., being overweight, was found to be a significant predisposing factor for conversion. This could be due to the higher prevalence of diabetes in these patients, leading to the possibility of recurrent and severe attacks of cholecystitis, causing dense inflammation and adhesions. However, diabetes alone was not found to be associated with a higher conversion rate in this study. Also, obese individuals have a higher visceral fat content obscuring vision during dissection, and the bulky omentum and transverse colon make manipulation tricky.

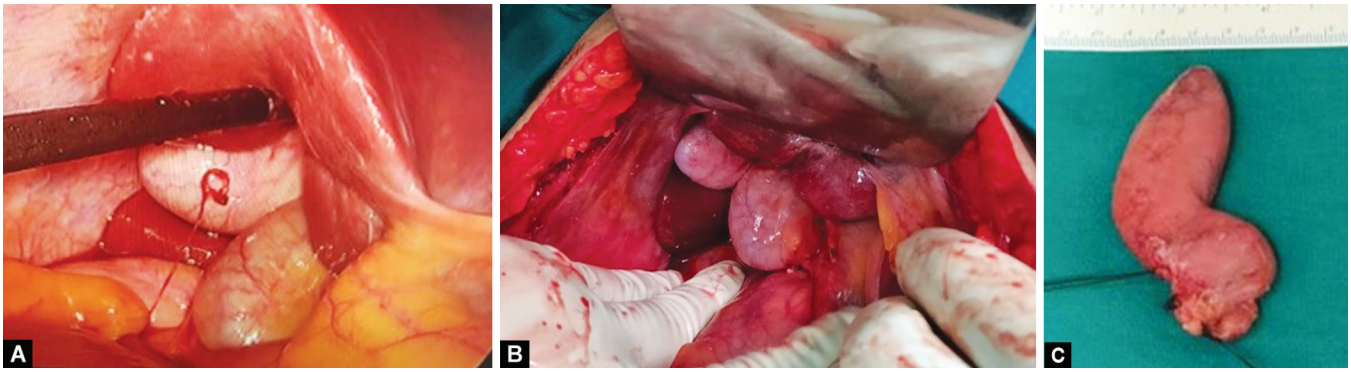
Various studies have shown that the conversion rate is higher in male patients, compared to female patients.[4,7,8] Several series have reported that advanced age is associated with a higher conversion rate. In the study by Livingston et al., very little correlation was found between age and the need for conversion.[2] Both male sex and advanced age having been identified as significant risk factors for conversion in this study, the authors emphasized the fact that a laparoscopic procedure should be offered to these patients with a high likelihood of conversion explained clearly. Male patients tend to ignore initial mild symptoms of upper abdominal pain, leading to a delayed presentation or presentation after recurrent episodes of cholecystitis, which could lead to chronic cholecystitis and a fibrotic GB, making the procedure difficult.

In this study, the conversion rates in patients with features of cholecystitis were significantly higher. Clinical findings of a positive Murphy's sign and a fever (temperature >37.5) were found to be significant in this study. This is similar to the results from studies by Simopoulos et al., Rosen et al., and Chauhan et al.[4,5,7] Preoperative laboratory investigations and radiological findings suggestive of acute cholecystitis include elevated total WBC count of more than 10,000/mm^3, and features of pericholecystic fluid collection and fat stranding were found to be significant factors that could predict CO surgery. Simopoulos et al. found that a WBC count >9,000/mL and total bilirubin >1.2 mg/dL doubled the likelihood of conversion.[4] Jang et al. found that CT findings of the absence of GB wall enhancement, presence of a gallstone in the infundibulum, and inflammation of the hepatic pedicle were significantly associated with conversion.[3]

Patients with acute cholecystitis have varying degrees of inflammatory changes involving Calot's triangle, and it is of utmost importance that the critical view of safety is visualized, and the safety steps as recommended by the Tokyo Guidelines 2018 are followed.[9] The severity of cholecystitis must be gauged promptly preoperatively, and there should be no delay in performing a LC in a patient who can withstand surgery, as there is a higher chance of a difficult surgery and CO if there is a delay in the surgery, or if performed as an interval surgery, as shown in this study as well.



Figs 1A and B: (A) Pyocele of GB with dense adhesions between omentum, colon, and GB—seen laparoscopically; (B) On conversion to open



Figs 2A to C: (A) Bilobed GB visualized laparoscopically; (B) On conversion to open; (C) Cholecystectomy was done, infundibulum of GB was found to be enlarged and folded over the body of the GB giving an impression of a bilobed GB

Table 5: Length of stay

	CO (n = 38) (Mean ± SD)	*LC (n = 272) (Mean ± SD)*	*Total (N = 310) (Mean ± SD)*
LOS (days)	8.8 ± 5.9	2.7 ± 1.3	3.5 ± 3.1

Early vs Delayed Surgery Following ERCP

In a systematic review of 14 studies including 1,930 patients, it was found that early LC post-ERCP was associated with a lower conversion rate.[10]

The indications for ERCP in most studies including this study are choledocholithiasis or dilated CBD on imaging and clinical and laboratory evidence of obstructive jaundice or cholangitis. In this study, the conversion rate when LC was performed early after ERCP was 18% and when performed after 4–6 weeks was 53%. The higher conversion rate in delayed LC after ERCP can be attributed to the fact that ERCP creates an inflammation of the hepatoduodenal ligament, leading to difficulty in delineating the anatomy and dissection of Calot's triangle in the following LC; in addition, it can lead to the formation of additional stones in the CBD, thereby increasing the risk of conversion.[11,12]

The current study has shown that patients with preoperative low-serum albumin value (<3.5 g/dL) had a higher conversion rate, compared to the patients with a normal serum albumin value (43.8 vs 10.5%; $p = 0.0001$). A similar association was found in a study by Ishizuka et al., in which they have stated that serum albumin of <3.8 g/dL was an independent risk factor for conversion from LC to open surgery.[13]

Limitations of the Study

The surgeons' experience could not be studied as a factor for conversion as all difficult surgeries were performed by experienced surgeons only, or they had taken over as the operating surgeon during the surgery.

Conclusion

The preoperative factors that were found to be significantly associated with a higher conversion rate in this study are male gender, BMI >23 kg/m^2, clinical, laboratory, and imaging findings suggestive of acute cholecystitis, interval surgery after 4–6 weeks, and surgery post-ERCP. The intraoperative findings that were commonly found prior to conversion are dense adhesions or severe tissue inflammation leading to a frozen Calot's triangle with inadequate visualization of structures.

The decision to convert to open surgery must be made before a complication occurs. This reflects sound surgical judgment and should not be viewed as a failure or complication of the laparoscopic approach. There are quite a few advantages of open surgery over laparoscopy, especially in trying situations, as manual pressure can be applied, tactile feedback is better experienced, exposure and movements are better, and there is less restriction on the number of instruments.

If we can identify patients with these significant risk factors for conversion, we could refine preoperative counseling in such selected patients and emphasize the higher conversion rate of around 12% as found in this study. We can also reduce the adverse effects of prolonged surgery by limiting the duration of the trial

Table 6: Comparing other studies

Study	*Type of study*	*Sample size*	*Conversion rate*	*Most significant factors*
Jang et al.[2] (2020)	Retrospective	581	19%	Obesity Previous abdominal surgery Prolonged PT Absence of GB wall enhancement on CT Gallstone at infundibulum
Chauhan et al.[6] (2019)	Retrospective	764	4.3%	Age >60 Male gender Prior ERCP Dense adhesions Frozen Calot's triangle
Thyagarajan et al.[7] (2017)	Prospective	500	10%	Male gender Diabetes Previous upper abdominal surgery Obesity Acute cholecystitis
Simopoulos et al.[3] (2005)	Retrospective	1,804	5.2%	Male gender Age >60 years Previous upper abdominal surgery Diabetes Severity of inflammation
Rosen et al.[4] (2002)	Retrospective	1,347	5.3%	BMI >30 ASA >2 WBC count >9,000 GB wall thickness >4 mm
Current study	Prospective	310	12.2%	Male gender, BMI >23, Age >50, WBC >10,000/mm^3, post-ERCP Imaging features of acute cholecystitis Dense adhesions, frozen Calot's triangle, and perforated GB

of laparoscopic dissection and can consider operating low-risk patients safely in day care surgery facilities.

Identifying low-risk patients is crucial when surgical residents are operating and appropriate training under supervision can also be planned for residents requiring training in high-risk cases or in open surgery.

Compliance with Ethical Standards

Ethics Approval

This study has been approved by the institutional ethics committee.

Informed Consent

Informed consent was obtained from all individual participants included in the study.

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ORIGINAL ARTICLE

Comparative Study of Management of Hemorrhoids: Stapler vs Open Hemorrhoidectomy

Keyur Surati[1], Jatin Modi[2], Sourabh Damani[3], Kushal Prajapati[4], Aneri Shah[5]

Abstract

Aims and objective: To study postoperative pain, time taken for procedure, postoperative complications, return to normal activity, and recurrence between stapler and open hemorrhoidectomy.

Materials and methods: For this study, 40 patients of second- and third-degree hemorrhoids were operated for stapler or open method of hemorrhoidectomy. Follow-up of all patients was taken at first week, third week, and 1 year postoperatively.

Results: On the postoperative days one to four in stapler hemorrhoidectomy, there was decreased postoperative pain according to visual analog score, significantly reduced operating time and early gain of work (3 vs 20.5 days; $p = 0.001$). No difference in complications of both the method of surgeries was found. No recurrence was found in either of surgeries, while impaired wound healing was found more in open hemorrhoidectomy. After 1 year, there were no any complications such as recurrence, rectal stenosis, or perianal fistulas in stapler group.

Conclusions: Stapler hemorrhoidectomy was found to have decreased postoperative pain, earlier return to work, earlier recovery time, and zero recurrence in comparison with the open technique up to 1 year.

Clinical significance: Stapler hemorrhoidectomy can be a good option as compared to open hemorrhoidectomy in the form of less postoperative pain, hospital stay, and early return to work in second- and third-degree hemorrhoids without significant postoperative complications.

Keywords: Open hemorrhoidectomy, Recurrence of hemorrhoids, Stapler hemorrhoidectomy.

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Introduction

Pathological changes in cushion of vascular tissue in the anus leads to internal hemorrhoid development. Anal continence is maintained by these cushions as they help internal sphincter in complete closure of the anal canal. Hemorrhoids are presented with bleeding, mucus discharge, itching, pain, and something coming out per rectum which might be symptomatic or asymptomatic. Hemorrhoid is present in 4–34% of population.

Theories behind the development of hemorrhoids are rise in abdominal pressure, portal hypertension, straining during defecation, connective tissue abnormalities, and tissue metaplasia.[1] There is different grading of hemorrhoids according to their prolapse. First- and second-degree hemorrhoids are treated by band ligation and sclerotherapy or by conservative method. Surgical intervention is required for the third- and fourth-degree hemorrhoids. Anal mucosa is sensitive, so in the patient of open hemorrhoidectomy, removal of the hemorrhoid with anal mucosa and perianal skin causes pain. Also, patients have to get done cleaning and dressing of the wound and have to take care of hygiene especially from fecal contamination. Infection may occur which can prolong wound healing. Stapler hemorrhoidectomy also known as stapler rectal mucosectomy,[2] has emerged as a painless alternative. In this method, interruption of the blood supply of hemorrhoid reduces the size of the hemorrhoid and reduces the available rectal mucosa by which it decreases the rectal mucosal prolapse.[3]

This study compares stapler and open hemorrhoidectomy in terms of postoperative pain, hospital stay, and early return to work with or without complications for second- and third-grade hemorrhoids.

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Materials and Methods

Patients for this clinical study were selected who have internal hemorrhoids with the following inclusion and exclusion criteria. The study was comparing open hemorrhoidectomy and stapler hemorrhoidectomy for the management of grade-II bleeding hemorrhoids and grade-III hemorrhoids. Twenty cases of open hemorrhoidectomy and 20 cases of stapler hemorrhoidectomy were studied.

Inclusion Criteria

Patients coming to tertiary care center with grade-II bleeding hemorrhoids and grade-III hemorrhoids, who were willing for surgical management in hospital, were included in the study.

Exclusion Criteria

Patients who were not fit for the surgery, patients not willing to be a part of this study, patients having comorbid conditions and

associated gastrointestinal diseases, patients with gangrenous thrombosed piles, and patients with internal + external hemorrhoids were excluded.

In our study, we used 33-mm-diameter two-row staple line stapler.

Result

Nineteen patients of second-degree hemorrhoids and 21 of third-degree hemorrhoids were selected (according to the Milles classification).[4] Age, sex, and degree of hemorrhoid in all the patients were comparable. The findings of the patients in each groups are as follows (Table 1).

The mean operating time was 34 minutes with minimum of 20 and maximum of 50 minutes in the stapler group and mean of 40 minutes with minimum of 20 minutes and maximum of 60 minutes in the open group which was comparable to the Khalil study.[5]

Mean pain scores were 2.4 by using the visual analog scale (Fig. 1) on the first postoperative day and 0.3 on the fourth postoperative day in the stapler hemorrhoidectomy, while in the open hemorrhoidectomy, the values were 5.9 and 2.6, respectively. The average amount of pain in the stapler group was significantly lower than in the open group ($p = 0.001$). In Mehigan study,[6] mean pain scores were 2.7 and 0.5 on day 1 and day 4 in the stapler group, while in the open group, the respective values were 6.3 and 4.8 which is comparable to our study. More pain in the open hemorrhoidectomy is due to formation of raw area as compared to stapler hemorrhoidectomy which was performed without formation of raw area.

Table 1: Comparison of study groups

Characteristics	*Stapler group*	*Open group*
Total no. of patients	20	20
Degree of hemorrhoids:		
Second-degree	10	9
Third-degree	10	11
Mean age (range)	48.4 (28–73)	45.8 (30–71)
Male/female ratio	16:4	15:5

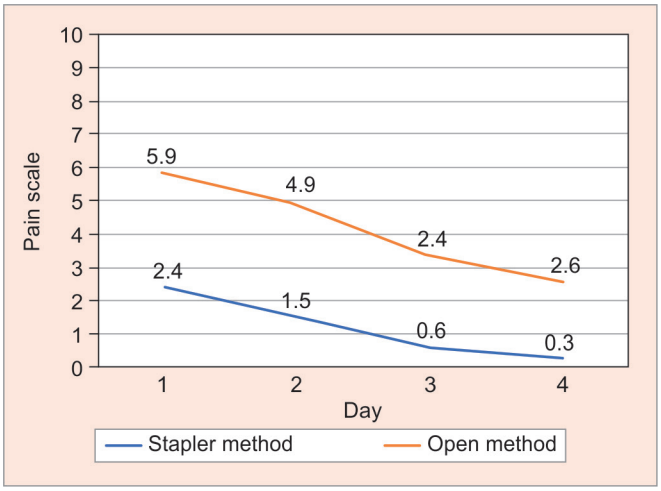


Fig. 1: Postoperative pain evaluated by the visual analog scale

The mean length of the hospital stay after stapler hemorrhoidectomy was 1.5 days, whereas it was 2.4 days in the open hemorrhoidectomy. Return to work by patients was an average of 3 days (range: 2–8 days) in the stapler hemorrhoidectomy and 20.5 days (range: 6–46 days) in the open hemorrhoidectomy ($p = 0.001$).

Postoperative complications observed included bleeding in one patient of stapler hemorrhoidectomy which was minor from the stapler line while urinary retention in one patient in the open group (Table 2). Bleeding complications occurred intraoperatively and managed by suturing with Vicryl (4'0) interrupted suture technique. Retention in open hemorrhoidectomy required K-90 catheterization.

Patients were followed up at 3 and 12 weeks, and impaired wound healing was found in 3 of the 40 patients, all in the open group, while none were found in stapler hemorrhoidectomy group. None of the patients had complaint of incontinence.

There were no recurrence, rectal stenosis, or perianal fistula in 1-year follow-up in any of the group.

Discussion

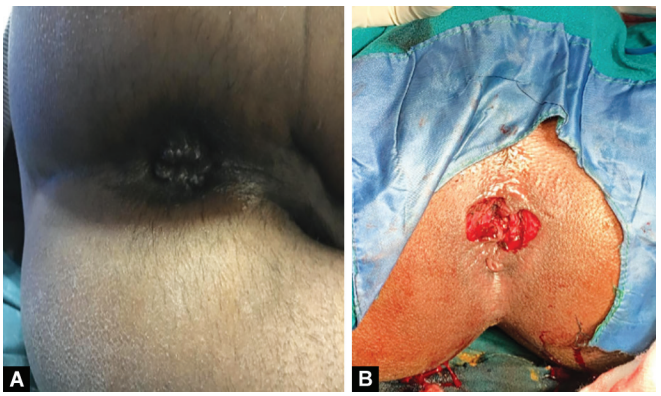
There are promising results of comparison of stapler hemorrhoidectomy with open hemorrhoidectomy. Stapler hemorrhoidectomy group had significantly reduced postoperative pain compared to open hemorrhoidectomy group. In the stapler Group IV, patients had no pain on the first operative day. Results of this study are similar with five randomized trials[4–8] on stapler versus open hemorrhoidectomy. In our open hemorrhoidectomy group, after postoperative day 4, pain was less as compared to above studies because we used to apply mixture of metronidazole with povidone-iodine ointment and lignocaine jelly. More and longer duration of pain in open hemorrhoidectomy was because of larger raw area, and we have to operate in the sensitive part of anal canal (Fig. 2).

Stapler hemorrhoidectomy had significantly less operative duration compared to open technique (mean 34 vs 40 minutes).

Other than one intraoperative minor bleeding episode, no local or systemic complications were seen in the stapler

Table 2: Postoperative complications

Complications	*Bleeding*	*Urinary retention*
Stapler group	1	—
Open group	—	1



Figs 2A and B: Postoperative images of stapler (left) and open (right) hemorrhoidectomy

hemorrhoidectomy.[8] The bleeding was due to a minute vessel in stapler line which is preventable complication by examining the staple line for bleeding after removing circular stapler.

Stapler hemorrhoidectomy has a probable risk of strictures after rectal wall resection.[9] There was no complain and clinical sign on examination for rectal strictures or stenosis after 12 months in our study.

In our study, after fifth postoperative day, no patient presented with complain of pain in stapler hemorrhoidectomy. This is because the stapler line remains 3–5 cm above the dentate line comparable to Longo study[10] and others,[3,11] and it is insensitive part of rectum and anal canal. Both groups had equal access to minor analgesics and considering that stapler hemorrhoidectomy had considerably less amount of pain than open hemorrhoidectomy as per our VAS score for pain on postoperative days 1–4.

Another finding was over 1-year follow-up; there was no recurrence in either group but a longer follow-up should be observed for study of recurrence.[8] Furthermore, recurrence also depends on diet and bowel habits of patients which is very important postoperative advice to be given to patient. We have advised all of our postoperative patients to avoid constipating diet and straining during defecation. We have advised our patient to avoid maida and its products, coffee, pomegranate, and such constipation-causing dietary habits and were encouraged to eat high-fiber diet such as green leafy vegetables and adequate amount of water with regular exercise. According to our study, all of the above advice given to patient also helps in reducing the constipation and recurrence.

Stapler hemorrhoidectomy is better option as compared to open hemorrhoidectomy in the form of pain, early discharge from the hospital, early regaining of work and equivocal complication rate. However, specialized training is required for stapler hemorrhoidectomy and also stapler is of single use disposable one so it increases the cost of surgery. Also, in patients with both internal with external hemorrhoids, we do not recommend stapler hemorrhoidectomy procedure because external hemorrhoids are needed to be separately removed which eliminate the advantages of stapler hemorrhoidectomy in the form of pain, hospital stay, and early return to work.

According to our study, stapler hemorrhoidectomy is better from the patient point of view, but a surgeon requires longer learning curve with specialized training.

Conclusion

We conclude that resection line should be kept at least three cm above the dentate line and proper hemostasis during surgery is a must requirement in stapler hemorrhoidectomy. Proper training and expertise are also required in stapler hemorrhoidectomy. In this manner, stapler hemorrhoidectomy is a procedure of choice in treatment of second and third grade hemorrhoids as it is safe and reliable. Clinical outcomes of stapler hemorrhoidectomy are very good in the form as it offers a similar clinical outcome as open hemorrhoidectomy, and it takes considerably less operating time, considerably less postoperative pain, and an earlier gaining of work. Further clinical trials are required to prove results of our study; stapler hemorrhoidectomy might become a gold standard for the second- to third-degree hemorrhoid treatment.

Clinical Significance

Stapler hemorrhoidectomy can be a good option as compared to open hemorrhoidectomy in the form of less postoperative pain, hospital stay, and early return to work in second- and third-degree hemorrhoids without added noticeable complications.

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ORIGINAL ARTICLE

Study of Difficult Laparoscopic Cholecystectomy and Its Outcome According to Peroperative Scoring System

Keyur N Surati[1], Ronak Modi[2], Sourabh Damani[3], Kushal Prajapati[4], Aneri Shah[5], Monil Patel[6]

Abstract

Aims: To study comparison of peroperative finding in difficult cholecystectomy with a scoring system, to evaluate the amount of complexity in the surgery and its outcome.

Materials and methods: A study of 50 patients undergoing elective difficult laparoscopic cholecystectomy was done. In difficult cholecystectomy, peroperative scoring was carried out, and based on these findings evaluation of the amount of complexity and results of the surgery was assessed according to the scoring system.

Results: Patients with chronic calculous cholecystitis were 16 and degree of difficulty had an average score of 5 while of acute calculous cholecystitis were 28 patients with an average score of 6 and mucocele of gall bladder were 3 cases with an average score of 7. Two cases of empyema gall bladder and one case of gangrenous gall bladder both with an average score of 8. All extreme difficulty cases with a score of 8 were converted to open. Increased severity of score is proportional to the increased complexity of the surgery. Conversion to open surgery is indicated in an extreme degree of difficulty with a score of 8.

Conclusion: This intraoperative scoring system is important in the evaluation of the complexity of cholecystectomy surgery and evaluating the amount of complexity in carrying out laparoscopic cholecystectomy.

Clinical significance: In mild, moderate, and severe degrees of difficult cholecystectomy according to the peroperative scoring system (5–7), can be completed laparoscopically without complication. In extreme level difficult cholecystectomy, peroperative scoring system (≥8) can guide us to make the decision to convert it into open surgery and also help in preventing life-threatening complications like bile duct injury.

Keywords: Cholecystitis, Degree of difficulty, Laparoscopic cholecystectomy, Severity grading.

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Introduction

Laparoscopic cholecystectomy is one of the commonly performed general surgical operations both in a planned and emergency situation. There is lots of evolution in the management of cholecystitis.[1] Laparoscopic cholecystectomy has done marked revolution since it was introduced.[2] Currently cholelithiasis is best managed by laparoscopic cholecystectomy (gold standard method).[3] But difficulty in performing cholecystectomy depends on different peroperative findings. The scoring system is helpful in the conversion of laparoscopic cholecystectomy to open to make the procedure safer surgical practice. If peroperative finding score is high (≥8) then for prevention of complications like bile duct injury, or if prolonged time is taken for laparoscopic surgery, the scoring system helps in decision making of conversion into open surgery.[4] Nowadays the significance of early surgery in acute cholecystitis has been recommended.[5] There are few international guidelines that suggested a protocol of treatment. According to those guidelines, standardized definitions of cholecystitis have been made.[6,7]

According to those guidelines, there are so many variabilities to approach in difficult cholecystectomy by peroperative finding in management of difficult cholecystectomy.[8] Out of few scoring systems reported there is no operative definition of findings at laparoscopic surgery.[9,10] That is why there are hurdles to carry out and compare results or to give a protocol for future study. This study was carried out to observe peroperative finding and evaluate the amount of complexity in difficult laparoscopic cholecystectomy by means of peroperative scoring system structured by Sugrue et al.[3]

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Conflict of interest: None

Methods and Materials

The study was carried out among 50 patients who underwent laparoscopic cholecystectomy admitted to our hospital, AMC MET Medical College, Ahmedabad. The study was carried out after taking permission from the local ethical committee. Patients were informed about the procedure and written consent was taken. Peroperative blood investigations and imaging was done in all the cases. Elective laparoscopic cholecystectomy was done in all the cases and a few of them had acute cholecystitis. We have excluded mild and moderate cases of severity index (score <5) in laparoscopic cholecystectomy. To the best of our knowledge,

difficult cholecystectomy is defined as a score ≥5 that is included in our study.[11]

Intraoperative findings were assessed on the basis of five key aspects which includes:[11]

- Appearance of gallbladder and amount of adhesions;
- Distension/contraction of the gallbladder;
- Access to the peritoneal cavity;
- Any local/septic complications;
- Time taken to dissect the Calot's triangle.

All the patients were accessed by the intraoperative scoring system and evaluated for the amount of complexity and results of the surgery were studied by the above scoring system (Tables 1 and 2).[11]

Result

This study was carried out on 50 cases of difficult laparoscopic cholecystectomy among them 45 patients were female (90%) and males were 5 (10%). Most females were 22–55 years of age. Males were between 48 and 70 years. All of them are evaluated according to scoring and categorized into difficult laparoscopic cholecystectomy. Various operative findings were scored from 5 to 10 as per the operative predictors for difficult laparoscopic cholecystectomy (Table 3).

Table 1: Scoring according to peroperative finding

Cholecystitis scoring according to peroperative finding	*Score*
Appearance	
Adhesions <50% of GB	1
Adhesions >50% but GB buried	2
Completely buried GB	3 (max)
Distension/contraction	
Distended GB or contracted shrilled GB	1
Inability to grasp without decompression	1
Stone >1 cm impacted in Hartmann's pouch	1
Access	
BMI >30	1
Adhesions from previous surgery limiting surgery	1
Sepsis and complications	
Free bile or pus outside the gallbladder	1
Fistula	1
Total possible	10

Table 2: Grading of difficulty

Grading of degree of difficulty according to peroperative finding	
Mild	<2
Moderate	2–4
Severe	5–7
Extreme	8–10

The Score of 5–7 (Severe Degree of Difficulty)

Out of 50 patients, 16 patients (34%) with chronic calculous cholecystitis were considered in the study and a severe degree of difficulty was encountered with a mean score of 5 during laparoscopic cholecystectomy. The duration of the surgery was between 45 and 60 minutes.

Total 28 (56%) cases of acute calculus cholecystitis were operated and a severe amount of complexity was faced with mean scoring of 6. About 60–70 minutes was the time taken to complete all laparoscopic cholecystectomies in the above patients.

In 3 (6%) cases of mucocele, the gallbladder was operated and a severe degree of difficulty was encountered with a mean score of 7 in these cases in performing laparoscopic cholecystectomy. About 54–81 minutes was the time taken to complete all laparoscopic cholecystectomies in the above patients. In one case cystic duct stump was transfixed with vicryl (3'0) by laparoscopic intracorporeal suturing.

The Score of 8–10 (Extreme Degree of Difficulty)

Two of the patients were found to havie empyema of the gall bladder and an extreme degree of difficulty was found in those cases with a mean score of 8. These cases were converted to open cholecystectomy. The inability to dissect Calot's triangle with dense adhesion is the indication for conversion into open surgery. To prevent damage to the bile duct in one case subtotal cholecystectomy was done.

In one more case of gangrenous gall bladder with irresectable Calot's triangle and dense adhesions, we found an extreme amount of complexity with a score of 8 and was converted to open.

These three cases of extreme difficulty were required to be converted into open surgeries even after the usage of advanced energy devices (ligasure scalpel) to prevent bile duct injury.

Among all 50 cases, we have completed laparoscopic cholecystectomy successfully in 47 patients with a severe amount of complexity. While three cases with an extreme amount of complexity were converted to open surgery.

Discussion

Due to unpredictable intraoperative findings, laparoscopic cholecystectomy is one of the most surprising operations in general surgery.[12] An unexpected amount of complexity of surgery was found in some cases while in some cases it is very easy.[13] In about 6–35% of cases, laparoscopy cholecystectomy is converted to open.[14] In this study, 6% of patients were also converted to open. Inability to dissect the Calot's triangle due to dense adhesions and

Table 3: Overview of whole study

Degree of difficulty (according to peroperative scoring system)	*Diagnosis*	*Mean severity score*	*Number of cases*	*Mean duration of surgery (in minutes)*	*Number of cases converted into open cholecystectomy*	*Peroperative complications*
Severe (score: 5–7)	Chronic calculous cholecystitis	5	16	45–60	0	0
	Acute calculous cholecystitis	6	28	55–70	0	0
	Mucocele of gall bladder	7	3	60–80	0	0
Extreme (score: 8–10)	Empyema of gall bladder	8	2	100–120	2	0
	Gangrenous gall bladder	8	1	125	1	0

difficult anatomy in an extreme degree of complex cholecystectomy is the reason for conversion to open.[15,16] Difficult cholecystectomy is judged by a few peroperative scoring systems with some amount of accuracy.[17]

Recently acute cholecystitis is operated by laparoscopic method within 48 hours with the increasing trend rather than interval cholecystectomy. So, to make the decision for conversion to open surgery intraoperative scoring system will provide indications.[18] Scoring and evaluating intraoperative findings gives us a standardized protocol to judge the complexity of the disease. Above all, it guides us to convert the procedure to open and good outcome measurement with the score.

In this study chronic calculous cholecystitis has a mean score of 5 and acute calculous cholecystitis has a mean score of 6, so even though acute calculous cholecystitis has more degree of difficulty according to the scoring system we have managed them laparoscopically without any complications but the time taken to complete acute calculous cholecystitis was around 10 minutes more as compared to chronic calculous cholecystitis.

In this study, 47 (94%) patients have encountered a severe amount of complexity. Laparoscopic cholecystectomy was completed successfully when there was a score of ≤7. It was converted to open surgery when the score was ≥8. With a score of eight extreme amount of complexity was faced and our three patients of this score were converted to open surgery.

So, according to our findings higher the peroperative score, there might be higher chances of conversion to open surgery, and if the score is ≥8 the chances of successful completion of surgery by the laparoscopic method is very low.

None of our cases had any complications like bile duct injury. So, the scoring system has also guided us in the prevention of life-threatening peroperative complications.

Conclusion

This intraoperative scoring system according to peroperative finding is important in the evaluation of the mild, moderate, severe, and extreme amount of complexity in carrying out laparoscopic cholecystectomy. According to the scoring system, severe and extreme categories fall into difficult cholecystectomy. Most of the difficult cholecystectomy can be completed laparoscopically while only an extreme degree of peroperative finding has to be converted to open surgery thus the scoring system also provides indication for conversion.

However, this is a small and single-center study. Further, large multicentric study are required.

Clinical Significance

In mild, moderate, and severe degrees of difficult cholecystectomy according to the peroperative scoring system surgery can be successfully completed laparoscopically without complication. On an extreme level difficult cholecystectomy, peroperative scoring system can help and provide guidance for conversion to open surgery and also help in preventing life-threatening complications like bile duct injury.

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ORIGINAL ARTICLE

A Comparative Study of Extracorporeal Knotting vs Clips for Ligating Cystic Duct in Laparoscopic Cholecystectomy

Hebbatam Vishnu Teja[1], Deepak R Chavan[2], Girish Kullolli[3]

Abstract

The aims of present study were as following: To compare extracorporeal knotting vs clips for ligating cystic duct in laparoscopic cholecystectomy in terms of feasibility operative time (incision to closer) based on types of cholecystitis postoperative pain, operative cost, and associated morbidities like gallbladder perforation, bile leak, liver bed injury, port site infection, migration of clips, and slipping of knot.

Methodology: All the patients were assigned by randomization into either of two groups: study group—patients in whom extracorporeal knotting was done for ligation of cystic duct, and control group—patients in whom clips were used for clipping of cystic duct. Period of study was from November 2018 to June 2020.

Results: This was a case series analysis conducted from November 2018 to June 2020; i.e., for a period of 20 months, 60 cases were subjected to laparoscopic cholecystectomy. In the control group, 11 patients had intraoperative complications, and no complications in the study group. In the study group, mean time taken for the operation was 67.37 minutes when compared to control group of 61.83 minutes. The cost of the suture material used in study group was 302 rupees, and the average cost of the titanium clips used in control group was 500 rupees.

Conclusion: In laparoscopic cholecystectomy, extracorporeal knotting has the advantages over clipping of cystic duct in operative cost and lesser intraoperative complications with the only limitation being operative time.

Keywords: Clipping, Cystic duct, Extracorporeal knotting, Laparoscopic cholecystectomy.

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Introduction

Cholecystectomy is the common operation of the biliary system.[1] In cholecystectomy, cystic duct is ligated with the sutures or clips. The conception of laparoscopy has revolutionized the art of surgery due to its advantages over open technique. The lately innovated laparoscopic cholecystectomy has been drastically refined over the years by better exploration of ergonomics, new energy sources, and endo suturing.[2] The conventional four-port access technique has been modified to three ports, two ports, and single incision laparoscopic surgery. Cystic duct ligation methods using metallic clips, harmonic scalpel, plasma kinetic, and intracorporeal and extracorporeal suturing techniques have been tried with gratifying results.[3–8] Open cholecystectomy is replaced by the gold standard procedure, i.e., laparoscopic cholecystectomy in the treatment of gallbladder diseases.

Using clips will reduce the intraoperative time which has advantage over the extracorporeal knotting, whereas clips have the drawback of slippage, resulting in leakage or hemorrhage, and there are situations such as wide cystic duct where clipping is difficult; in such cases, using the extracorporeal knotting for occluding the cystic duct is best alternative. Extracorporeal knotting with absorbable suture material is feasible, practical, economic, and safe as well.

In 5–10% of the cases, there are chances of conversion to open cholecystectomy from laparoscopic cholecystectomy.

Aims and Objective of Study

The aims of present study were as following: To compare extracorporeal knotting vs clips for ligating cystic duct in laparoscopic cholecystectomy in terms of feasibility, operative time (incision to closer) based on types of cholecystitis, postoperative pain, operative cost, and associated morbidities like gallbladder perforation, bile leak, liver bed injury, port site infection, migration of clips, and slipping of knot.

Methodology

This was a case series analysis done in patients who underwent laparoscopic cholecystectomy in Department of Surgery at a tertiary hospital in North Karnataka.

All the patients were grouped into study group and control group based on computerized random number tables: Study group—patients in whom extracorporeal knotting was done for ligation of cystic duct. Control group—patients in whom clips were used for clipping of cystic duct. Period of study was from November 2018 to June 2020.

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Sampling (Prospective, Interventional Study)

On the basis of a study done by Kuldip Singh et al. at Patiala,[1] the anticipated mean ± SD of operating time by extracorporeal knotting vs using clips was 60.50 ± 14.93 and 47.83 ± 14.77, respectively. The minimum sample size was 30 per group with 95% level of significance and 80% power.

Formula used was as follows:

$$N = 2\left[\frac{\left(Z_{1-\alpha/2} + Z_{\beta}\right) * S}{d}\right]^2$$

$Z_{1-\alpha/2}$—level of significance = 95%
$Z_{1-\beta}$—power of the study = 80%
d = clinically significant difference between two parameters
SD = common standard deviation

Statistical Analysis

Data were represented using mean ± SD, percentages, and diagrams. Significant difference between quantitative data was found using unpaired *t* test/Wilcoxon signed rank test. Significant difference between qualitative data was found using Chi-square or Fisher's exact test.

Method of Collection of Data

Patients admitted for cholecystectomy were included in the study and allocated to study and control groups alternatively.

Detailed history was taken, and thorough clinical examination and investigations were performed for all the patients in both the study and control groups. A pro forma was used to collect all the relevant data from the patients pre-, intra-, and postoperatively. All cases were followed up to discharge and subsequently for a follow-up of 3 months. After the evaluation, patient was taken for laparoscopic cholecystectomy and time taken from incision to closure, bile/stone spillage and cost of clips/suture was noted. Postoperatively, cases were followed up for any complication.

Inclusion Criteria

Patients with cholecystitis—calculous/acalculous and cholelithiasis were included in the study.

Exclusion Criteria

Patients with cardiac disease, pregnant women, those who were unfit for general anesthesia, and patients with CBD stone were excluded.

Results

This case series analysis was conducted from November 2018 to June 2020, i.e., for a period of 20 months; 60 cases were subjected to laparoscopic cholecystectomy, and the following results were observed.

In the study group, there were no intraoperative complications noted among the 30 patients. In the control group, 11 patients had intraoperative complications, seven patients had clip slippage and stone spilling into the peritoneal cavity from the gallbladder, three patients had clip slippage and bile spillage into the peritoneal cavity from the gallbladder, and 1 patient had clip migration (Table 1). In the study group, mean time taken for the operation was 67.37 minutes when compared to control group of 61.83 minutes. In the study group, maximum time taken was 105 minutes and the minimum time taken was 35 minutes. In the control group, maximum time taken was 80 minutes and the minimum time taken was 38 minutes (Table 2). The average cost of the suture material used in study group was 302 rupees, and the average cost of the titanium clips used in control group was 500 rupees (Table 3).

Table 1: Distribution of subjects according to intraoperative complications

	Study group		*Control group*			
Intraoperative complications	*N*	*%*	*N*	*%*	*Chi-square test*	*Remark*
Bile leak	0	0	0	0	$\chi^2 = 13.469$	$p = 0.0037^*$
Clip migration	0	0	1	3.3		
Clip slippage, bile leak	0	0	3	10		
Clip slippage, stone spillage	0	0	7	23.3		
Nil	30	100	19	63.3		
Total	30	100.0	30	100.0		

*Highly significant

Table 2: Comparison of operation time (minutes) between study and control groups

Operation time (minutes)	*Mean*	*±SD*	*Difference in mean (%)*	*Unpaired t test*	*p value*	*Remarks*
Study	67.37	15.230	4.68 (6.94%)	$t = 1.636$	$p = 0.107$	NS
Control	61.83	10.55				

NS, not significant

Table 3: Comparison of cost of suture/clips (in rupees) between study and control groups

Cost of suture/clips (rupees)	*Mean*	*±SD*	*Difference in mean (%)*	*Mann–Whitney U test*	*p value*	*Remarks*
Study	302.00	0.000	198 (39.6%)	NA		
Control	500.00	0.000				

NA, not applicable (SD = 0)

Follow-up

All patients were followed up for a period of 1 month, and no significant complication was noted.

Discussion

The mankind was affected with gall stones from centuries, and the best treatment for the symptomatic gall stone disease is cholecystectomy. In elective cholecystectomy, laparoscopic cholecystectomy is considered best and feasible. Laparoscopic cholecystectomy yields good results and better prognosis when compared to the open cholecystectomy in terms of early postoperative recovery, pain, shorter hospital stays, and early getting back to routine life style.

In laparoscopic cholecystectomy, preferably titanium clips are used to clip the cystic duct. In recent times, different ways of suturing and knotting are used by either intracorporeal or extracorporeal technique. However, there are only few case series analyzes that compare the cystic duct occlusion with knotting and using titanium clips in laparoscopic cholecystectomy.

In the present study, for extracorporeal knotting, Vicryl No 1 was used for ligating the cystic duct and knots are pushed using a knot pusher. The duct was ligated in two places, once near to the common bile duct and another one distally near the gallbladder (Fig. 1). Cystic duct is cut in between the two knots, and gallbladder is dissected from the liver bed. In 90% of the patients, gallbladder was extracted by using sterile glove and, in few affordable patients, sterile bags were used.

In Obstructive jaundice due to accidental ligation of common bile duct was seen with clip ligation as compared to with suture ligation. This result is further supported by a study by Bali and Singal who concluded that silk suture can be tied near the common bile duct, as risk of involving the common bile duct wall is very little as compared to clips.[9]

In the present study, the maximum percentage of patients who underwent laparoscopic cholecystectomy were under the age-group of 30–49 years of age, i.e., 77%; another study done by Nidoni et al. on predicting difficult laparoscopic cholecystectomy based on clinicoradiological assessment in 180 patients also reported that 30–50 years was the most common age-group to undergo laparoscopic cholecystectomy.[10]

Another study done by Kuldip Singh et al. on extracorporeal knotting with silk vs liga clips for ligating cystic duct in laparoscopic cholecystectomy in 60 patients reported that most common age-group of presentation was between 30 and 50 years.[1]

In this study, the male-to-female ratio is almost 1:1; a study done by Nidoni et al. on predicting difficult laparoscopic cholecystectomy based on clinicoradiological assessment in 180 patients reported that male-to-female ratio was 1:1.76.[10]

Another study done by Kuldip Singh et al. on extracorporeal knotting with silk vs liga clips for ligating cystic duct in laparoscopic cholecystectomy in 60 patients reported that there was a female predominance, i.e., 90%.[1]

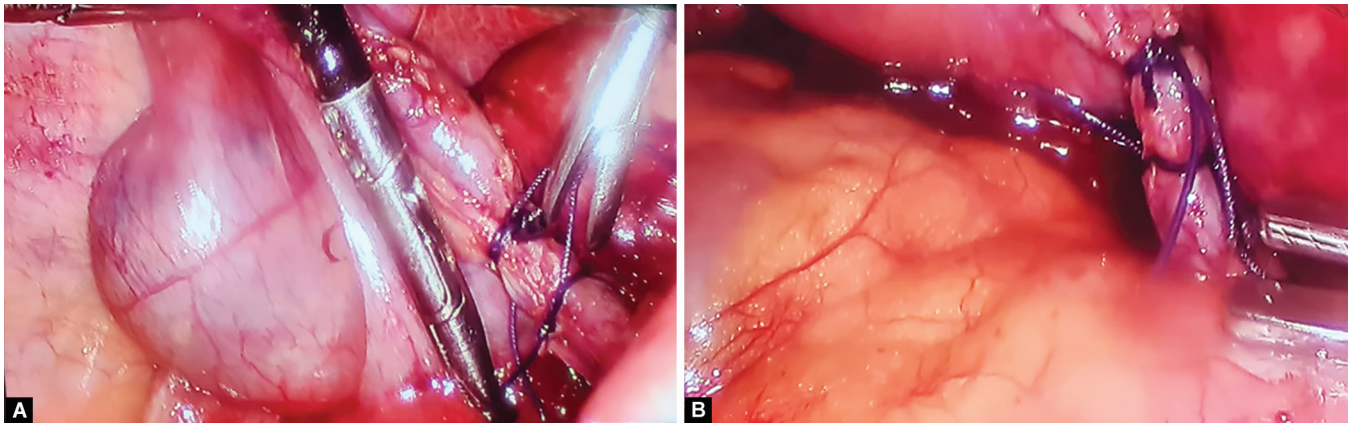
In the present study, the mean operating time for group in which extracorporeal knotting done was 67.37 minutes when compared to control group using clips was 61.83 minutes. However, statistical analysis showed that the difference between the two groups was not significant. Using clips reduce the intraoperative time which has advantage over the extracorporeal knotting, whereas clips have the drawback of slippage resulting in leakage or hemorrhage and there are situations such as wide cystic duct where clipping is difficult, in such cases using the extracorporeal knotting for occluding the cystic duct is best alternative. Extracorporeal knotting with absorbable suture material is feasible, practical, economic, and safe as well.

However, the difference in the operating time between the two groups was mainly because surgeons do not commonly use the extracorporeal knotting when compared to the frequently used clips during laparoscopic cholecystectomy and also there was technical skill associated with extracorporeal knotting. As skill increase with extracorporeal knotting, we have observed that operating time decreased.

Intracorporeal knotting is another method of knotting the cystic duct. There is a need to learn the skill, and it is little difficult while knotting as compared to extracorporeal technique of knotting (Fig. 1).

In the present study, cost of the suture (Vicryl No 1 Round Body) used was 302 rupees when compared to titanium clips that cost 500 rupees.

A study done by Kuldip Singh et al. on extracorporeal knotting with silk vs liga clips for ligating cystic duct in laparoscopic cholecystectomy in 60 patients concluded that though it takes more time for extracorporeal knotting of cystic duct when compared to liga clips, it makes a significant difference with respect to cost without affecting the safety and efficacy in laparoscopic cholecystectomy.[1]



Figs 1A and B: Extracorporeal knotting of cystic duct

In the present study, majority of the control group patients where titanium clips were used had complications such as adhesions, empyema gallbladder, and obese patients due to which dissection of Calot's triangle became difficult which resulted in complications in those patients.

In the present study, using clips had some drawbacks with respect to the intraoperative complications; in seven cases, there was clip slippage and stone spillage seen during the dissection of gallbladder from the liver bed and during extraction. Finding and retrieving the spilled stones in the peritoneum were again a difficult task which extended the operating time.

In three cases, there was clip slippage at the specimen side and bile was spilled into the peritoneal cavity; in all these cases, peritoneal cavity was irrigated with normal saline.

In the present study, in one case, there was clip migration seen during the final inspection, which needed clipping again.

There were two patients from the control group in which clipping was planned, which had to be converted to extracorporeal knotting due to the wider cystic duct.

In the present study, there was no case with cystic duct leak postoperatively in both the groups, i.e., either with extracorporeal knotting or clipping of cystic duct, which indicates that cystic duct was safely secured in both the groups. Gallbladder wall thickness was not considered in our study.

Conclusion

In laparoscopic cholecystectomy, extracorporeal knotting has the advantages over clipping of cystic duct in operative cost and lesser intraoperative complications with the only limitation being operative time.

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ORIGINAL ARTICLE

Our Experience of Laparoscopic Cholecystectomy in Situs Inversus Totalis

MR Attri[1], Rajni[2], Abdul H Samoon[3], Irshad A Kumar[4]

Abstract

Introduction: First laparoscopic cholecystectomy in situs inversus totalis (SIT) patients was described by Campos and Sipes. We present a retrospective study of five cases in whom laparoscopic cholecystectomy was done for symptomatic cholelithiasis.

Methodology: This is a retrospective study from 2005 to 2021. All the patients in the study were done by a single surgeon at various hospitals in the state. All recorded data from patients and from hospitals was taken and analyzed.

Results: Our study included five patients with the mean age of 31.6 years. All the patients were females. Our patients presented with complaints of epigastric pain (2), dyspepsia (1), and pain in the left upper abdomen (2). There was no associated cardiac anomaly in our patients. The first three patients were operated on using conventional mirror image technique, the fourth one by modified mirror image, and the last one using French technique. In initial cases operating time was 45–50 minutes which decreased up to 35–40 minutes in the last cases. All patients were discharged on the first postoperative day after tolerating orals and with the satisfactory condition on discharge. There was no intra- or postoperative complication in our study. There was no 30-day mortality in our patients.

Conclusion: SIT is a rare congenital anomaly. A laparoscopic cholecystectomy is a safe approach with meticulous dissection in these patients with cholelithiasis. Technical difficulties could be overcome due to learning and better understatement of ergonomics of these patients.

Keywords: Laparoscopic cholecystectomy, Mirror image, Situs inversus.

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Introduction

Situs inversus is a rare recessive congenital anomaly with an incidence of 1:10,000–1:20,000.[1] Fabricius first reported situs inversus totalis (SIT) in 1,600.[2] Genetically it shows an autosomal recessive pattern and the genetic defect occurs in 2nd week of embryonic life.[3] In SIT, the transposition of organs is opposite to their normal position and hence gallbladder is present in the left hypochondrium instead of right hypochondrium.[4] Cardiac anomalies and a triad known as Kartagener Triad (Bronchiectasis, Sinusitis, Situs inversus) have been associated with this condition.[5] Male and female gender have equal incidence.[3] In literature no higher association is reported with cholelithiasis.[5] Laparoscopic cholecystectomy since its introduction in 1987 has revolutionized the world and has set new principles of minimal invasiveness in the surgical field.[6] Laparoscopic cholecystectomy is widely accepted as the treatment of choice for cholelithiasis in SIT patients despite the difficulties in the orientation and the ergonomics of the surgical field.[7,8] First laparoscopic cholecystectomy in SIT patients was described by Campos and Sipes.[9] Since then more than 90 cases have been described.[10] We present a retrospective study of five cases in whom laparoscopic cholecystectomy was done for symptomatic cholelithiasis.

Methodology

This is a retrospective study from 2005 to 2021. All of the patients in the study were done by a single surgeon at various hospitals of the state. All recorded data from patients and from hospitals was taken and analyzed. All patients with SIT with laparoscopic cholecystectomy done by the single surgeon were included. A total of five patients were included in the study. All our patients were evaluated by baseline blood tests, ultrasonography, and chest X-ray, which showed cholelithiasis and confirmed patients of SIT. Magnetic resonance cholangiopancreatography (MRCP) was done to confirm cholelithiasis and to rule out any other biliary anomaly. ECHO cardiography was done to rule out any cardiac anomaly. After all necessary investigations' patients were listed in elective lists for laparoscopic cholecystectomy.

The patients were operated using mirror image technique, modified mirror image, and French technique for laparoscopic cholecystectomy. In the mirror image technique all instruments, surgeons, assistants, and ports were the mirror image of the conventional laparoscopic cholecystectomy. While in modified mirror image technique 10-mm port was used at the midclavicular line as the main working port and for gall bladder removal. While a 5-mm port was used at the epigastric point. In the French technique, the difference with the modified mirror image technique was the placement of the surgeon in between legs instead of the right side of the patient. Calot's triangle was

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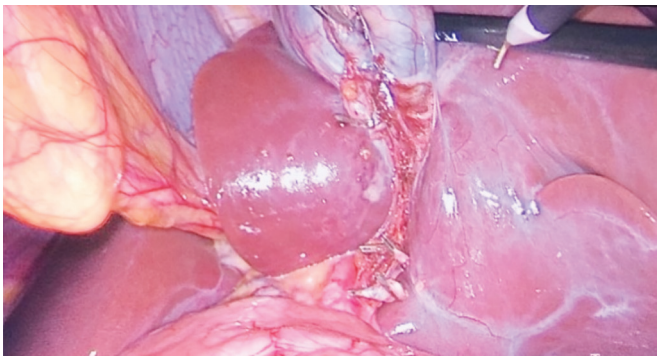

Fig. 1: Showing gallbladder dissection from the liver bed

Table 1: Descriptive data of patients

Sl. No.	*Age (years)*	*Gender*	*Comorbidity*	*Operative technique*	*Year*	*Postoperative complication*
1	45	Female	Hypothyroid, hypertension	Conventional mirror image	2005	Nil
2	34	Female	Nil	Conventional mirror image	2006	Nil
3	33	Female	Nil	Conventional mirror image	2011	Nil
4	32	Female	Nil	Modified mirror image	2012	Nil
5	14	Female	Nil	French	2021	Nil

delineated and cholecystectomy was done using the duct first method (Fig. 1). The gallbladder was retrieved either through the epigastric or midclavicular port. All recorded data was analyzed and results were interpreted.

Results

Our study included five patients with the mean age of 31.6 years (14–45 years). As shown in Table 1. All the patients were females. Our patients presented with complaints of epigastric pain (2), dyspepsia (1), and pain in the left upper abdomen (2). There was no associated cardiac anomaly in our patients. Only a single patient was hypothyroid and had hypertension, and was on optimum treatment. The first three patients were operated using the conventional mirror image technique, the fourth one by modified mirror image and the last one using French technique. In initial cases, operating time was 45–50 minutes which decreased up to 35–40 minutes in the last cases. This decrease in operating time was due to a better understanding of operative ergonomics in SIT patients. All patients were discharged on the first postoperative day after tolerating orals and with the satisfactory condition on discharge. There was no intra- or postoperative complication in our study. There was no 30-day mortality in our patients.

Discussion

SIT is a rare congenital anomaly with a global prevalence of about 0.01%.[11] The characteristics of SIT is that all the organs of the body have an exact mirror image position than their normal counterparts.[12]

Biliary colic diagnosis in these patients is a challenge owing to the anatomical variation if earlier diagnosis of SIT is not known. The patients usually present with pain left upper abdomen or epigastrium and leading to misdiagnosis and treatment. There is no evidence of increased incidence of cholelithiasis in SIT patients.[13] In our study each 40% of patients presented with pain left upper abdomen and epigastric pain while the rest 20% with dyspepsia only. This is similar to the studies done earlier.[10]

The first laparoscopic cholecystectomy in SIT patients was performed by Campos and Sipes.[9] Since then, more than 90 cases have been reported in the literature and none has mentioned any complication despite the difficulty in ergonomics in SIT patients. However multiple techniques have been put forward in order to ease the biliary dissection.[14] In our study we used multiple techniques like a conventional mirror image, modified mirror image, and French technique. In neither case, any complication occurred despite dissection difficulty in mirror image, nor was any case converted to open. The meticulous dissection is the only option of safety in this group of people. Our study had similar results as other case reports, studies or, reviews done earlier.[10,15]

Conclusion

SIT is a rare congenital anomaly. A laparoscopic cholecystectomy is a safe approach with meticulous dissection in these patients with cholelithiasis. Technical difficulties could be overcome due to learning and better understatement of ergonomics of these patients.

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ORIGINAL ARTICLE

Efficacy of Prophylaxis Protocol in Prevention of Venous Thromboembolism in Bariatric Surgery Patients

Ahmed Hassan[1], Mohamed Adel[2], Islam Khaled[3], Haitham Gbr[4], Mohamed A Elkerkary[5]

Abstract

Background: In patients undergoing bariatric surgery, different techniques have been used to avoid venous thromboembolism (VTE), including pharmacological prophylaxis and mechanical prophylaxis. Our aim was to determine the effectiveness of the prophylaxis procedure (pharmacological and mechanical prophylaxis) to prevent VTE following bariatric surgery.

Patients and methods: We performed the present cross-sectional study on patients with morbid obesity who were scheduled to undergo bariatric surgery. The primary outcome of the present stud was the incidence of VTE. The diagnosis of VTE was based on a duplex ultrasound. Patients were followed up for 1 month after the procedure.

Results: Two patients develop pulmonary embolism (6.1%). The first patient was female aged 40-years-old who underwent a sleeve gastrectomy (SG). Her body mass index (BMI) was 43 kg/m^2 and she had a history of diabetes, hypertension (HTN), and VTE 5 years ago. On the 5th postoperative day, she complained of shortness of breath and chest pain, which was followed by the diagnosis of pulmonary embolism and ICU admission. The second patient was a female aged 49-years-old who underwent one anastomosis gastric bypass (OAGB) operation. Her BMI was 55 kg/m^2 and she had a history of diabetes, HTN, and chronic obstructive pulmonary disease (COPD). Twelve days after operation, she complained of chest pain, palpitations, and shortness of breath, which was followed by the diagnosis of pulmonary embolism and ICU admission.

Conclusion: In conclusion, VTE is associated with an increased risk of morbidity and mortality after bariatric surgery; however, it can be prevented using an extensive course of thromboprophylaxis. For the best regime in VTE prevention after the bariatric operation, more prospective experiments are needed.

Keywords: Bariatric surgery, Obesity, Prophylaxis, Venous thromboembolism.

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Introduction

Venous thromboembolism (VTE) is considered the most prevalent cause of postsurgical morbidity and mortality.[1] About 150,000 individuals die annually from pulmonary embolism (PE) in the United States, most of them due to deep venous thrombosis (DVT).[2] DVT typically has nonspecific symptoms and signs and is usually difficult to detect in patients who are morbidly obese.[3] Physical examination is very difficult in obese patients, and they often have subtle first signs so that minimally symptomatic DVT can quickly progress to fatal PE.

Obesity is an abnormal accumulation of body fat to the extent that it may have a negative effect on health.[4] A strong correlation between obesity and type II diabetes, hypertension (HTN), dyslipidemia, cardiovascular disease, sleep apnea syndrome, and several types of cancer is confirmed by long-term research.[5] Obesity contributes to a deterioration of the quality of life.[6] In both developed and developing countries, the prevalence of obesity is growing rapidly and is considered one of the most severe public health issues.[7,8]

Bariatric surgeries, including sleeve gastrectomy (SG) and gastric bypass surgery (GBS), play a significant and well-established role in the care of obese and morbidly obese patients.[9] In 2013, the number of bariatric surgeries alone in the United States was close to 180,000.[10] Bariatric surgeries are very successful in reducing morbid obese patients' weight and improving obesity and associated complications.[11] Accurate, evidence-based risk evaluation methods for VTE in bariatric patients are currently not available, but many risk factors that need to be addressed are identified in the literature to evaluate a prophylaxis strategy.[12] Higher age, gender, body mass index (BMI), immobility, venous stasis disease, operative time, and type and approach of the procedure can be included in these risk factors.

Obesity also interferes with the mechanisms of anticoagulants, leading to a hyper coagulating state.[13] In obese patients, plasma concentrations of von Willebrand, fibrinogen, and factor VII are substantially elevated, while platelet aggregation due to leptin is promoted.[14] There is evidence that some of the above abnormalities may be partly reversed by the treatment of morbid obesity, as weight loss is associated with a substantial decrease in fibrinogen, plasminogen activator inhibitor-1, and an increase in antithrombin III deficiency.[15]

In patients undergoing bariatric surgery, different techniques have been used to avoid VTE, including pharmacological prophylaxis and mechanical prophylaxis; pharmacological prophylaxis involves

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low-molecular-weight heparin (LMWH), and mechanical prophylaxis includes intermittent compression devices, elastic stockings, and early ambulation after surgery.[16,17] Our aim was to determine the effectiveness of the prophylaxis procedure (pharmacological and mechanical prophylaxis) to prevent VTE following bariatric surgery. Moreover, to demonstrate that the regimen of prophylaxis played a significant role in preventing VTE following bariatric surgery.

Patients and Methods

Study Design and Patients

We performed the present cross-sectional study at the Department of Surgery, Faculty of Medicine, Suez Canal University from January 2019 to February 2020. Patients aged more than 16-years-old were deemed eligible if they had documented morbid obesity, defined as BMI ≥40 kg/m^2 or ≥35 kg/m^2 with comorbidities, and were scheduled to undergo bariatric surgery. Patients were excluded if they aged more than 65-years-old, had documented coronary artery disease, malignancy, chronic hepatic or renal impairments, mental or cognitive illness, history of VTE, history of heparin-induced thrombocytopenia, coagulation defects, and/or history of concomitant anticoagulant/antiplatelet therapy for other risk factors. We excluded pregnant women as well.

Our protocol was approved by the institutional review board at Suez Canal University and all participants signed informed written consent before the procedure.

Sampling

The required sample size was calculated based on the following equation.

$$n = \left[\frac{Z_{\propto/2}}{E}\right]^2 * P(1-P)$$

where n = required sample size; $Z_{(\propto/2)} = 1.96$; P = prevalence of the outcome (estimated to be 2%);[15] and E = margin of error determined to be 0.05.

Thus, the calculated sample size was 30 participants. By calculating the nonresponse rate which is 10% based on previous studies, the required sample size was 33 participants.

Data Collection and Prophylaxis Protocol

We collected the following routine preoperative characteristics of the patients: demographics, BMI, comorbidities, and risk factors for VTE. Besides, we collected the type of procedure, operative time, postoperative complications, hospital stay, and the incidence of VTE. The VTE prophylaxis protocol in our institution consists of mechanical modalities (such as lower extremity compression and early mobilization) and pharmacological modalities in the form of Enoxaparin 40 mg once daily the day before surgery (preoperative) and continued 15 days after the procedure.

Outcome Measures

The primary outcome of the present stud was the incidence of VTE. The diagnosis of VTE clinically was based on painful, tender calf muscles, sudden shortness of breath, chest pain, and cough and radiologically by duplex ultrasound and CT chest angiography if needed. Patients were followed up for 1 month after the procedure.

Statistical Analysis

For descriptive statistics, we used the mean ± standard deviation, while for categorical parameters, we used the count (%). To analyze the association between baseline data and outcomes, we used Chi-square or Fisher's exact tests (for categorical) and *t*-test (for numerical data) depending on data normality. All statistical analyzes were performed using the *SPSS* (version 22 for Windows, IBM, Armonk, New York). A two-sided *p*-values <0.05 were considered statistically significant.

Results

Baseline Characteristics

A total of 33 patients were included with a mean age of 32.6 ± 6.1 years and female predominance (66.7%). Our patients had a mean BMI of 47 ± 5.9 kg/m^2. All patients had hyperlipidemia (100%), 66.6% had diabetes mellitus, and 51.5% had hypertension. Besides, 12.2% of the patients had a previous history of DVT. Most of the patients did laparoscopic sleeve gastrectomy (LSG) operation (81.8%) and 18.2% did one anastomosis gastric bypass (OAGB). Concerning the risk factors for VTE, 33.3% of patients were smokers, 30.3% had varicose vein, 27.3% on contraceptive therapy, 9.1% did major surgery in the last 3 months, 12.1% had previous DVT, and 6.1% had previous CVS disease (Table 1).

Operative and Postoperative Characteristics

The mean operative time was 71.67 ± 23.61 minutes; OAGB operation had a significantly longer mean operative duration of 120.0 ± 9.49 minutes than SG operation 60.93 ± 3.11 minute

Table 1: Preoperative characteristics

Variables	*(N = 33)*	
Age	(Mean ± SD) Range	32.6 ± 6.1 (23–55)
Gender		
Male	11	33.3
Female	22	66.7
BMI	(Mean ± SD) Range	47 ± 5.9 (38–60)
Comorbidities	*N*	%
Hypertension	17	51.5
Diabetes mellitus	21	66.6
Dyslipidemia	33	100
Previous history of VTE	4	12.2
Heart failure	0	0
COPD	2	6.1
Operation type	*N*	%
Sleeve	27	81.8
Mini gastric bypass	6	18.2
Roux-en-Y operation	0	0
Others	0	0
Risk factors for DVT		
Varicose vein	10	30.3
Previous DVT	4	12.1
Previous pulmonary embolism	0	0
Major surgery in last 3 months	3	9.1
Previous MI	0	0
Previous CVS disease	2	6.1
Smoking	11	33.3
Heart failure	0	0
Contraceptive therapy	9	27.3

Table 2: Operative data of surgeries

		(N = 33)
Operative time (minute)	Mean ± SD	71.67 ± 23.61
Complications	Bleeding	0 (0%)
	Leakage and/or fistulas	0 (0%)
	Stricture	0 (0%)
	Twist	0 (0%)
	Pulmonary emboli	2 (6.1%)
	DVT	0 (0%)
	Re-operation	0 (0%)
	Re-admission	0 (0%)
	Mortality	2 (6.1%)
Hospital stay (days)	(Mean ± SD) Range	2.0 ± 0.0 (2–2)

Table 3: Criteria of patient develop in PE regarding different parameters

		(N = 2)
Age	Mean ± SD Range	44.50 ± 5.36 40–49
Sex	Male	0 (0%)
	Female	2 (100%)
Type of surgery	Sleeve	1 (50%)
	Mini gastric bypass	1 (50%)
BMI	Mean ± SD Range	49.0 ± 8.49 43–55
Type of prophylaxis	Mechanical pharmacological	2 (100%)
Time of incidence PE after surgery (days)	Mean ± SD Range	8.50 ± 4.95 5–12

(p <0.001). The mean hospital stay was 2 days. Regarding postoperative complications, 6.1% of patients had PE as a postoperative complication and two patients (6.1%) died (Table 2).

Incidence of VTE at the End of Follow-up

Two patients developed PE (6.1%). The first patient was female aged 40-years-old who underwent (SG). Her BMI was 43 kg/m^2 and she had a history of diabetes, hypertension, and VTE 5 years ago. On the 5th postoperative day, she complained of shortness of breath and chest pain, which was followed by the diagnosis of PE and ICU admission. The second patient was a female aged 49-years-old who underwent OAGB operation. Her BMI was 55 kg/m^2 and she had a history of diabetes, HTN, and chronic obstructive pulmonary disease (COPD). Twelve days after the operation, she complained of chest pain, palpitations, shortness of breath, which was followed by the diagnosis of PE and ICU admission (Table 3).

Discussion

VTE is a disease that can be prevented, and thromboprophylaxis is a key strategy to minimize post-bariatric VTE mortality and morbidity.[18] The reverse placement of Trendelenburg and pneumoperitoneum use during laparoscopy reduces the venous return to the heart, further increasing the prothrombotic state.[17,19] VTE risk is also increased by postoperative pain and poor ambulation.[20] Even with the challenges of preventing these complications, rates of VTE incidents after bariatric surgery range from 0.3 to 2.2%. The optimal dose or duration of thromboprophylaxis is still debatable. Since most VTE complications occur posthospital discharge, a comprehensive approach to thromboprophylaxis is necessary, particularly in patients at high risk.[21] After bariatric surgery, LMWH was confirmed to be superior to unfractionated heparin (UFH) for thromboprophylaxis, with a comparable risk of bleeding.

In this descriptive cross-sectional study, 6.1% of patients had PE as a postoperative complication, and two patients (6.1%) died. Moreover, we demonstrated that mini-gastric bypass operation had a significantly longer mean operative duration of 120.0 ± 9.49 minutes than sleeve operation 60.93 ± 3.11 minutes (p <0.001). In terms of the predictors of postoperative VTE, old age (p = 0.013), long duration of peroration (p = 0.005), and previous history of VTE (p = 0.045) were associated with a higher risk of developing postoperative VTE. Magee et al.,[22] reported that among 735 patients who underwent bariatric surgery and received up to 3 weeks of LMWH, the incidence of postoperative VTE and bleeding was 0%. Similarly, in those managed with 10 days of tinzaparin, Tseng et al. reported a 0.5% postoperative VTE.[23] Similarly, the incidence of postoperative bleeding varies from 0 to 6%.[18] On the contrary, Froehling et al.[24] showed that VTE's cumulative incidence ranged between 0.3 and 2.1% in patients who underwent 402 bariatric operations. Furthermore, they highlighted that the patients' age was an independent predictor of postoperative VTE (HR = 1.89, 95% CI: 1.01, 3.55). This variance in the occurrence of postoperative VTE is possibly attributable to variations in patient condition, type of procedure, thromboprophylaxis dose and duration, and assessed outcomes.

In the bariatric surgery population, fatal PE is a common cause of postoperative mortality.[25,26] The previous studies reported that old age, postoperative anastomotic leakage, history of smoking, and previous VTE are associated with a higher risk of VTE following bariatric surgery.[27] In several studies, male sex was associated with an increased VTE risk among patients with bariatric surgery.[26,28] Two studies reported a significant association between patient smoking status and VTE's potential risk.[27,29] The presence of potential hypercoagulability markers among patients in the bariatric procedure has also been evaluated, but there was no observed association with clinical VTE.[30,31]

With regards to procedure-related factors, procedure type, operative time, and postoperative complications are the main risk factors of VTE. Compared to laparoscopic procedures, the open procedure was reported to be associated with a higher risk of VTE.[32] Regarding the duration of the procedure, Finks et al. recorded an increased risk (86%) of VTE with an operative time of more than 3 hours.[28] Chan et al. found that operatives with long-duration excessed 3 hours are associated with an increased risk of postoperative VTE.[33] Regarding the type of surgery, revision surgeries were reported to be correlated with an increased VTE risk.[34] It was also reported that Roux en Y gastric bypass (RYGB) was associated with the postoperative anastomotic leak, which in turn increases the VTE risk.[35] In contrast to adjustable gastric band procedures, Finks et al. found an increased risk of VTE with (SG), laparoscopic gastric bypass, and open RYGB.[28] Masoomi et al. found that in comparison with other bariatric procedures, GBS carries greater VTE risks.[36]

Our study has some limitations, including the cross-sectional nature, which is associated with several risks of bias. Moreover, the

relatively small sample size and short follow-up duration may hinder the generalizability of these findings.

Conclusion

In conclusion, VTE is associated with an increased risk of morbidity and mortality after bariatric surgery; however, it can be prevented using an extensive course of thromboprophylaxis. For the best regime in VTE prevention after the bariatric operation, more prospective experiments are needed.

Criteria for Inclusion in the Authors'/Contributors' List

AS contributed to study's concept, study design, data collection, and manuscript writing; HS contributed to study design, data collection, and manuscript writing; ME contributed to study design, data collection, and manuscript writing; OA contributed to study design, data collection, and statistical analysis; MKE and MA contributed to study design and data collection.

We confirm that the manuscript has been read and approved by all the authors, that the requirements for authorship as stated earlier in this document have been met, and that each author believes that the manuscript represents honest work if that information is not provided in another form.

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ORIGINAL ARTICLE

Short-term Outcomes after Bariatric Surgery during the COVID-19 Pandemic

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Abstract

Background: Elective surgery, especially bariatric surgery, was stopped during the coronavirus disease-2019 (COVID-19) pandemic in the United Kingdom. Obesity is a major risk factor for COVID-19-related mortality. As the COVID-19 infection and mortality rates in Devon had been relatively low, bariatric procedures resumed with the necessary precautions in Plymouth with the easing of lockdown restrictions in mid-May. The aim of this study was to examine the outcome of bariatric surgery during the COVID-19 pandemic.

Methods: Details of 38 patients, who underwent bariatric surgery between June 2020 and November 2020, were analyzed prospectively. All patients underwent a COVID-19 swab test 24–48 hours prior to the surgery. The primary outcome measure was COVID-19-related morbidity. Secondary outcomes were non-COVID-19-related morbidity, mortality, and weight loss at 6-week follow-up.

Results: Thirty-eight patients [24 females; median age 51 (24–63) years, median body mass indices (BMI) at surgery 42.9 (32.4–62.5) kg/m^2] underwent bariatric surgery. Thirty-seven patients were of White British ethnicity. No patient tested positive for COVID-19 pre- and postoperatively. No patient had any COVID-19-related morbidity or mortality. One patient developed a staple line bleed and returned to theater for relook laparoscopy and hemostasis. One patient developed an anastomotic leak and had a relook laparotomy for lavage and drain placement. The median length of hospital stay was 1 day. One patient was preplanned for intensive care admission and he stayed in a high dependency unit (HDU) for 1 day. All patients were followed up for 6 weeks and the median (range) excess weight loss (%EWL), at 6 weeks, was 24.4% (–0.9–53.6).

Conclusion: Bariatric surgery can be performed safely in an area of low COVID-19 prevalence with the necessary precautions.

Keywords: Bariatric surgery, COVID-19 pandemic, Precautions, Roux-en-Y gastric bypass, Sleeve gastrectomy.

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Introduction

The World Health Organization (WHO) declared the coronavirus disease-2019 (COVID-19) pandemic on March 11, 2020, with more than 11 million cases reported worldwide and over 540,000 deaths.[1] Indeed, most organizations including the International Federation for the Surgery of Obesity and Metabolic Diseases (IFSO) have recommended postponing all elective and endoscopic procedures related to bariatric surgery.[2] The American College of Surgeons has also triaged procedures on the morbidly obese and recommended delaying all elective bariatric procedures.[3] The aim was to minimize risks to the patient and healthcare team and to reduce unnecessary usage of limited resources. The results from a large international study involving over 1,000 patients in 24 countries have documented a significant risk of mortality following perioperative COVID-19 infection in elective surgical patients.[4] However, these were stratified neither according to surgical procedure nor country and local infection rates.

The prevalence of COVID-19 infection varies throughout the United Kingdom. While London and the North West had an infection rate of 40 per 100,000, Devon and Cornwall counties in the southwest had less than 20 confirmed cases per 100,000.[5] Mortality rates at 41 per 100,000 had also remained much lower here than most of England (137 per 100,000 in London).[6] Routine operations at our hospital had ceased with the announcement of national lockdown on March 23, 2020. However, certain urgent elective procedures, including cancer and emergency procedures, continued with close adherence to the evolving national and local safety guidelines. Encouraged by the favorable outcomes from these procedures, bariatric surgery was restarted as the rate of infection decreased and lockdown restrictions eased. The aim of this study was to determine the outcomes of elective bariatric surgery during this phase of the COVID-19 pandemic.

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Methods

As this was a review of current practice, no formal ethical approval was required. Informed consent was obtained from all patients. Our local review board approved this study.

Details of 38 consecutive patients, who underwent elective bariatric surgery between June 1, 2020, and November 30, 2020, as performed by three bariatric surgeons in a tertiary care hospital, were analyzed prospectively according to the STROBE guidelines.[7]

The primary outcome measure was COVID-19-related mortality and morbidity at a 6-week follow-up. The secondary outcome measures were non-COVID-19-related morbidity as defined by the Clavien-Dindo classification,[8] in-hospital mortality, and length of hospital stay.

Standard of Care

Patients with body mass indices (BMI) greater than 40 kg/m^2 or 35–39.9 kg/m^2, with at least one obesity-related comorbidity, were offered bariatric surgery following successful completion of a supervised tier-3 weight management program. A multidisciplinary team that includes a bariatric medical specialist, specialist bariatric nurse, dietitian, and surgeon is involved in a comprehensive assessment of the patient. Formal psychological assessment is undertaken following a routine screening questionnaire. In general, patients are given a choice between Roux-en-Y gastric bypass (RYGB) and sleeve gastrectomy (SG). RYGB is preferred if patients suffer from gastroesophageal reflux disease. SG is usually offered to patients with a BMI greater than 60 kg/m^2. Patients undergo a supervised low-calorie liver-reducing diet for 3 weeks prior to surgery.

Our technique of RYGB involves the creation of an approximately 30-mL gastric pouch. The small bowel is divided 50 cm from the ligament of Treitz creating the proximal biliopancreatic limb, which is then anastomosed to a 100-cm-long alimentary limb. The alimentary limb is then advanced to the gastric pouch for an antecolic antegastric end-to-side gastrojejunostomy, which is then closed with a double-layered 3/0 STRATAFIX™ (Johnson & Johnson). The SG involves an initial 60-mm green stapler (Powered ECHELON FLEX™ GST System, Johnson & Johnson) with reducing staple height according to tissue thickness over a 34-French orogastric bougie, starting at least 3 cm from the pylorus and ending at 2 cm from the gastroesophageal junction. After the gastric mobilization is completed, 20 mg of hyoscine butylbromide is given intravenously. The systolic blood pressure is reduced to approximately 100 mm Hg prior to stapling and then increased to 140 mm Hg after stapling is completed, to reveal any staple line bleeding. Active bleeding points are then either clipped or sutured with 2/0 PDS^R II (polydiaxonone, Johnson & Johnson). All patients receive 1 g of tranexamic acid routinely at the beginning of the procedure. A leak test is performed routinely on all patients. Dual consultant operating occurred only for mentoring purposes and in selected patients.

Ward-based care is provided for all patients unless preoperative anesthetic assessment recommends a higher level of care. Patients are allowed to drink free fluids postoperatively. Patients are discharged on the first postoperative day if well, on a liquid diet for 2 weeks. This is increased to a pureed diet for further 2 weeks. Patients are reviewed initially after 1 week by phone followed by a clinical review in 6 weeks, 3 months, and 6 months. Excess weight loss (%EWL) is calculated with a target BMI of 25 kg/m^2. Patients are then reviewed at 1 and 2 years prior to being discharged to their general practitioner if there are no ongoing concerns. Nutritional supplements and blood tests are in line with British Obesity & Metabolic Surgery Society (BOMSS) recommendations.[9]

COVID-19 Precautions and Deviations from Standard of Care

Preoperative

We resumed bariatric surgery with patients who had been categorized as urgent from our waiting list. All patients were requested to self-isolate for 14 days prior to surgery. Preoperative COVID-19 swab tests were performed between 24 and 48 hours prior to surgery. Results were available within 24 hours. Computed tomography (CT) of the thorax was not routinely performed preoperatively. Patients were informed that there was a slightly increased risk of developing COVID-19-related morbidity as part of the consent process but no detailed figures on risk were given.

Intraoperative

Based on evolving national and local guidelines, anesthesia and surgery were performed in amber personal protective equipment (PPE) (visor/goggles, standard surgical masks). A closed filtration system was used to safely evacuate pneumoperitoneum before trocar removal and closure.[10]

Postoperative

Patients were nursed in a COVID-19 light ward. Asymptomatic elective patients with a negative COVID-19 swab test who had been isolating for 14 days were admitted there. Emergency patients were only admitted there after 24 hours, in our Surgical Admissions Unit (SAU) in addition to ensuring that they were asymptomatic from COVID-19 point of view with negative swab tests. COVID-19 swab tests were performed if patients developed a temperature.

Results

Demographic and treatment details are listed in Table 1. All patients underwent preoperative COVID-19 swab tests. No patients were diagnosed with COVID-19 in the preoperative screening process. All patients who were offered surgery agreed to undergo the procedure. Two patients required postoperative COVID-19 swab test according to hospital testing protocol and had negative results. All procedures were completed laparoscopically. One patient who developed an anastomotic leak had a re-look laparotomy, lavage, and drain placement.

Outcomes are detailed in Table 2. One patient, who underwent a SG re-laparoscopy on day 1 for a staple line bleed, had no active bleeding point but a hematoma around the staple line was evacuated. This was managed by lavage and partial oversewing of the staple line. The patient was monitored on the high

Table 1: Demographic and treatment details

Total number	38
Male:female	14:24
Median age (range) years	51 (24–63)
Median BMI at surgery, kg/m^2	42.9 (32.4–62.5)
Ethnicities	37 White British; 1 Black British/Caribbean
Comorbidities	
Diabetes	21
Hypertension	13
Osteoarthritis	19
Respiratory disease	9
Chronic kidney disease	4
Nonalcoholic fatty liver disease (NAFLD)	7
Polycystic ovarian disease	2
Obstructive sleep apnea	11
Surgical approach	
Laparoscopic	38
Open	0

Table 2: Outcomes (Clavien-Dindo classification—CD)

Overall morbidity	3
Postoperative intractable nausea and vomiting (PONV)	1 (CD i)
Postoperative bleed	1 (CD iiib)
Anastomotic/staple line leak	1 (CD iiib)
Wound infection	1
Pneumonia	1 (CD ii)
Acute kidney injury	1 (CD iva)
In-hospital mortality	0
Median length of hospital stay, days	1 (1–44)
30-day readmission rate	1

dependency unit (HDU) for 3 days and she was discharged on the 7th postoperative day. One patient underwent preplanned monitoring in HDU due to preexisting dialysis-dependent chronic kidney disease. He was transferred to the surgical ward on day 1 and discharged on the following day. One patient with RYGB presented to emergency department with complaints of severe nausea and vomiting 10 days following surgery. A barium swallow did not reveal any mechanical obstruction. Her symptoms settled with antiemetics and she was discharged home the next day. One patient who underwent RYGB developed hemodynamic instability on the second postoperative day. A relook laparoscopy was converted to a laparotomy, washout, and drain placement for a leak at the gastrojejunal anastomosis. He suffered acute kidney injury and required intensive therapy unit (ITU) support for 10 days. He was discharged after 44 days, eating and drinking when a barium swallow confirmed resolution of leak.

All patients were followed up at 6 weeks. The median (range) excess weight loss (%EWL) was 24.4% (−0.9–53.6), taking a BMI of 25 kg/m^2 as target. The median difference in BMI was 4.2 (−0.4–9.6). The median loss of weight in kilograms was 12.8 (−1.2–25.4) which translated to a median 9.52% (−0.5–21.1) loss of total body weight. No patients developed any respiratory symptoms suggestive of COVID-19 even during the "second wave" of the pandemic in the United Kingdom (UK). There were no patients lost to follow-up.

Discussion

The COVID-19 pandemic has highlighted the significance of the obesity crisis as it is an independent risk factor for severe illness and death from COVID-19.[11,12] Even prior to the COVID-19 outbreak, the stigma surrounding obesity has been known to lead to delays and underutilization of bariatric surgery.[13]

The pandemic will result in further delays because of limited resources and the misconception that such surgery should be the last resort.[14] A lack of understanding about the complex nature of obesity has led to the suggestion that these patients can simply be put on a diet until the pandemic is over. The increased morbidity and mortality in obese patients with COVID-19 have understandably resulted in a cautious approach toward the resumption of elective bariatric procedures in the current climate. However, our patient population are reporting increased levels of anxiety over the media coverage regarding the link between obesity and adverse outcomes with COVID-19. Patients are anxious to undergo their bariatric surgery to reduce these risks that have been documented in the published literature.[15–17]

Numerous societies including the IFSO, Diabetes Surgery Summit (DSS), and Società Italiana di Chirurgia dell'Obesità e malattie metaboliche (SICOB) have recommended the cessation of bariatric surgery.[2,18,19] However, The American Society of Bariatric and Metabolic Surgery have categorically stated that metabolic surgery is not elective and disagrees with the concept that bariatric surgery should be postponed until the pandemic is declared over.[20] Studies confirm a survival benefit with metabolic surgery and its ability to significantly improve life-threatening obesity-related conditions.[21,22] Moreover, Prachand et al. have labeled this as "medically necessary time-sensitive surgery."[23] Delays for months and potentially years, given the huge backlog, will unquestionably lead to the detriment of these patients and result in an increased burden on the healthcare system.

As the COVID-19 infection and mortality rates in Devon had been relatively low, urgent elective and cancer surgery continued throughout the pandemic with good outcomes.[24] Along with a thorough risk assessment and support from hospital management, bariatric surgery was restarted as the rate of infection decreased and lockdown restrictions eased from June 2020 onward. The principle finding of this study is that bariatric surgery can be safely performed with the necessary precautions in an area with a relatively low infection rate. We have steadily continued with bariatric procedures even through the second UK lockdown (from November 5 to December 3, 2020). As far as we are aware, there have been no reports on outcomes after bariatric surgery during the COVID-19 pandemic. Our cohort of patients had a median age of 51 years and a median BMI of 42.9 with over 75% of patients classed as "severely obese." Over two-thirds of them had more than one obesity-related comorbidity. In addition, training occurred in almost half the cases. Despite this, complication rates compare favorably with international standards.[25–27]

This study has potential limitations. Observational studies are understandably prone to selection bias. However, this was minimized as we reported a consecutive series of patients prospectively and we followed our usual practice of operating on patients according to their place on our urgent waiting list. There was no additional screening of patients to gauge their suitability for bariatric surgery, outside of the usual tier-3 weight management program. This is a 6-month cohort with adequate follow-up and we felt it was important to report our encouraging outcomes to provide evidence for the resumption of elective bariatric surgery during this phase of the pandemic, with COVID cases continuing to be reported in the community amid ongoing vaccination programs.

There are numerous factors that allowed us to recommence this service safely. Firstly, patients were subjected to early and rapid testing. The relatively low rate of COVID-19 infection in our population meant that our hospital was not overwhelmed with infected cases, thus reducing the risk of in-hospital transmission. There are various ways of measuring the rate of infection and risk of transmission in a population. The reproduction number or R number is the average number of secondary infections produced by one infected person.[28] Although this has limitations in areas with a small number of cases and geographies smaller than at regional level, it can be a guide to aid decision-making for restarting bariatric services. Interestingly nationally reported R numbers for the southwest were consistently less than one during the time period under review. As widespread and increasingly more convenient methods of antibody testing are being implemented, this may prove to be another tool for decision-making in the near future.[29,30]

The definite diagnosis of COVID-19 is based on virus isolation or a positive result of polymerase chain reaction (PCR) test from

sputum, nasal, or throat swabs.[31] Despite the relatively high false-negative rates,[32] we proceeded with performing bariatric surgeries in amber PPE. Given that the patients were from an area with a low local infection rate, were asymptomatic, and had undergone 14 days of self-isolation prior to the procedure, we felt that the risks of missing a true-positive result were minimal. In the initial phase of the pandemic, for the first 8 weeks, intubation of all theater cases in our hospital had been performed in red PPE (visor/goggles, FFP3 face mask, and double gloving) as it was deemed a high-risk aerosol-generating procedure. However, in the following phase when we resumed bariatric surgeries, uniformly good outcomes with our preoperative COVID-19 protocol for urgent elective surgery meant that we were confident to go ahead with amber PPE for intubation as well. This controlled use of resources ensured that PPE was in adequate supply for use in an unequivocally high-risk environment. This also meant that we were able to resume our full operative capacity of five all-day theater lists after 8 weeks.

Bariatric surgery was the first of many procedures to be postponed at the start of the pandemic. The huge backlog of cases that have been generated by the lockdown and the tremendous costs to patient health and well-being make it imperative that we resume bariatric surgery. This patient population constitutes some of the most comorbid patients on our "benign" waiting lists. The separation of patients into having benign disease (including obesity alongside biliary disease and gastroesophageal reflux disease) or cancer is too simplistic and fails to reflect the disease burden faced by the morbidly obese. We believe that policies on restarting surgery should be driven locally while giving consideration to national guidelines. This would entail consideration of a sustained reduction in new cases, availability of rapid testing, adequate PPE, and availability of essential perioperative services.[33] A decision on recommencing bariatric services should be prioritized. A degree of pragmatism and a balanced risk assessment without overthinking minutiae are required and would go a long way in getting this essential service back on track.

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ORIGINAL ARTICLE

Role of *Helicobacter pylori* in Chronic Abdominal Pain and Endoscopy-suggested Gastritis

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Abstract

Aim and background: *Helicobacter pylori* (*H. pylori*) infection can cause chronic gastritis and gastric malignancy. Upper gastrointestinal endoscopy is performed to assess the symptoms of abdominal pain but endoscopy alone is not confirmatory. Therefore, either pathological evaluation of biopsies of mucosa or detection of urease in the mucosa by rapid urease test (RUT) produces accurate diagnosis. The study aimed to assess the role of *H. pylori* infection among patients with chronic abdominal pain and endoscopy-suggested chronic gastritis and also to evaluate the association of endoscopic findings and RUT.

Materials and methods: The prospective randomized study was performed on 50 patients with clinical findings suggestive of chronic gastritis or abdominal pain of unknown etiology. Data regarding patient history and routine physical and clinical examination were recorded. Upper gastrointestinal endoscopy was performed in all patients. Organs including the esophagus, stomach, and duodenum were examined for abnormality and biopsy was performed at various sites of the affected organ. The obtained specimen from biopsy was subjected to RUT.

Results: Endoscopic finding suggested gastritis in 6% ($n = 38$) of the patients among which 31 patients were RUT positive. A significant association was found between endoscopic findings and RUT ($p = 0.013$). Patients of 31–40 years of age ($n = 11$) and males were found to be more commonly affected as indicated by a positive reaction to RUT ($n = 27$).

Conclusion: RUT facilitates rapid and accurate diagnosis of *H. pylori* infection, and along with endoscopy, can be used in the diagnosis of *H. pylori* infection in chronic gastritis.

Clinical significance: Early diagnosis of *H. pylori* is essential to formulate early and appropriate clinical strategies for better management of the patient. RUT is a well-known diagnostic test that is rapid, cheap, and simple. It detects urease in or on gastric mucosa produced by the bacteria.

Keywords: Diagnostic test, Gastric mucosa, *Helicobacter pylori*, Prospective studies, Urea, Urease.

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Introduction

Globally the prevalence of chronic gastritis and gastric ulceration is high. *Helicobacter pylori* (*H. pylori*) infection is the main cause of chronic active gastritis and has complications such as gastric adenocarcinoma and mucosa-associated lymphoid tissue lymphoma (MALT lymphoma).[1–3] The prevalence of the infection in a developed country is 10% and is as high as 80% in developing countries such as India.[4]

The associated complication with *H. pylori* infection is due to untreated chronic gastritis. Hence, identification of the etiology of gastritis is of great value in eliminating carcinoma.[5] Furthermore, the rate of mucosal damage caused by *H. pylori* is unpredictable, and infection is always transmissible. It is recommended that whenever a *H. pylori* infection is detected, it should be treated unless there is a compelling reason that would mitigate that choice.[6] The diagnosis *H. pylori* infection plays an important role in effective treatment. The tests used in diagnosis are classified as invasive and noninvasive. Invasive tests are endoscopy-based include histology, rapid urease test (RUT), culture, and polymerase chain reaction, whereas noninvasive tests including serological, urea breath test, and stool antigen test.[7] Early diagnosis of *H. pylori* is essential to formulate early and appropriate clinical strategies for better management of the patient.[5] RUT is a well-known diagnostic test that is rapid, cheap, and simple. It detects urease in or on gastric mucosa produced by the bacteria.[8] The study aimed to assess the role of *H. pylori* infection among patients with chronic abdominal pain and endoscopy suggested chronic gastritis and to evaluate the association of endoscopic findings and RUT.

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Materials and Methods

Upon obtaining institutional ethics committee approval, the prospective randomized study was carried out over a period of two years. Sample size was calculated using the formula:

$$N = \frac{z^2 \times p(1-p)}{d^2}$$

Calculated sample size was $n = 43$.

In this study $n = 50$ patients with endoscopically proved features suggestive of mucosal changes, chronic gastritis, and patients with abdominal pain with normal clinical and laboratory findings were included and informed consent was obtained.

Patients with abdominal pain due to gall stone, renal stone, chronic pancreatitis, hiatus hernia, esophagitis, and esophageal candidiasis were excluded.

Detailed patient history and data obtained from the routine clinical and physical examination were recorded in pro forma. Upper gastrointestinal endoscopy was performed using local anesthesia in the left lateral position with flexed knees and hips and hands between the legs. A plastic mouth gag was placed and held firmly by the assistant. The endoscope was passed into the oropharynx crossing the cricopharynx into the esophagus, asking the patient to swallow until the passage from the cricopharyngeal sphincter. The esophagus, stomach, first and the second part of the duodenum were viewed and screened for pathology. If the patient was detected with gastritis (mucosa inflamed and edematous associated with congestion), then biopsy was performed at various sites in the antrum of the stomach. If the patient with duodenum pain for more than 6 months and was normal to radiological examinations, then biopsy was performed on normal mucosa.

The specimen obtained from the biopsy was subjected to a RUT. Commercially prepared liquid urea broth medium was used for the test. Immediately after collection, the sample was incubated using 1.5–2 mL of urea broth at 37°C for 36 hours. Change in the color of the liquid urea broth from pale yellow to deep pink was considered a positive test.[9] Depending upon endoscopy findings, severity, and urease test, appropriate treatment was given. Patients were advised for follow-up a week after.

Statistical Analysis

Data were analyzed using R Studio V 1.2.5001 software. Categorical and continuous variables were expressed in frequency and mean ± SD, respectively. A Chi-square test was used to find the association between variables. $p < 0.05$ was considered statistically significant.

Results

The average age of the patients was 42.64 ± 14.30 years. Most of the patients of the study were male (74%). The endoscopic investigation suggested gastritis in 76% ($n = 38$) of patients among which $n = 31$ patients were positive to the RUT. In patients of normal endoscopic findings (24%, $n = 12$), the RUT was positive in $n = 5$ patients. A significant association was found between endoscopy suggested gastritis and RUT ($p = 0.013$). Patients of 31–40 years of age ($n = 11$) were most commonly affected with the *H. pylori*. The detailed distribution of RUTs according to the patient's age-group is shown in Table 1.

RUT was predominantly positive in males (75%, $n = 27$) compared to females (25%, $n = 9$). Distribution of the patients according to occupation revealed that the laborer was commonly found positive to the RUT ($n = 17$) (Table 2).

In 11 and 19 patients of positive urease test, the duration of abdominal pain was 3–6 months and 6–12 months, respectively (Table 3).

Retrosternal burning ($n = 30$), nocturnal association ($n = 17$), and periodicity ($n = 18$) were the commonly observed symptoms in patients. Whereas, loss of appetite and weight loss were observed in five and four patients, respectively.

Table 1: Distribution of RUT according to age

Age (years)	*Number of patients (n)*	*Positive RUT % (n)*
11–20	2	0
21–30	9	6 (66.67)
31–40	15	11 (73.33)
41–50	9	7 (77.78)
51–60	8	7 (87.50)
>60	7	5 (71.43)

RUT, rapid urease test

Discussion

The most common cause of gastritis is an infection of *H. pylori*. It is a microaerobic bacterium found in the gastric mucosa. The prevalence of this bacterium is affected by various factors such as geographic distribution, age, race, and socioeconomic status. Its diagnosis is categorized based on endoscopic and nonendoscopic tests.[10] The serological test for antibody shows exposure to bacteria; however, it is insufficient in the assessment of active infection.[10] RUT provides evidence regarding infection by identifying the presence of nonmammalian enzyme, i.e., urease, in, or on the gastric mucosa.[1] The study aimed to assess the role of *H. pylori* infection among patients with chronic abdominal pain and endoscopy suggested chronic gastritis and also to evaluate the association of endoscopic findings and RUT.

Upper gastrointestinal endoscopy is usually performed to assess the symptoms of upper abdominal pain.[11] However, the endoscopic diagnosis of *H. pylori* gastritis based on the gross appearance of the gastric mucosa is not recommended. Either pathological evaluation of biopsy of gastric mucosa or detection of urease in the mucosa by RUT produces accurate diagnosis of *H. pylori* infection.[5] *H. pylori* genes code for bacterial urease, which is essential for its metabolism and colonization of the gastric mucosa. The presence of this enzyme in the sample is visualized by hydrolyzing urea in a test medium to form ammonia and carbon dioxide. The color change from pale yellow to pink is considered as positive RUT.[8,12] In this study, endoscopy investigation suggested gastritis in 76% of the patients. Among these patients, 62% were positive to RUT. In the study of Mahesh et al., endoscopy gastritis was found in 81.54% of patients and RUT was positive in 83.54% of the patients.[10] Similarly, the study

Table 2: Distribution of RUT according to occupation

Occupation	*Number of patients (n)*	*Positive RUT % (n)*
Laborer	21	89.95 (17)
Housewife	11	63.64 (7)
Business/service	10	70 (7)
Student	8	62.50 (5)

RUT, rapid urease test

Table 3: Distribution of RUT according to the duration of abdominal pain

Duration of abdominal pain (months)	*Number of patients*	*Positive RUT % (n)*
<3	4	25 (1)
3–6	16	68.75 (11)
6–12	24	79.17 (19)
>12	6	83.33 (5)

RUT, rapid urease test

of Thapa et al. reported endoscopic gastritis in 76% of the patients and the study of Uotani et al. and McNicholl et al. suggested 87 and 85.9% positive cases of RUT, respectively.[8,13,14] The difference in the results may be due to the difference in the geographic distribution of the studies, variability in the studied patients. Moreover, the sensitivity and specificity of the commercial kits used in the studies can also influence the results.[5,8,10] Here, endoscopic findings were found to be significantly associated with RUT ($p = 0.013$); this suggests that endoscopic findings are a sensitive indicator of *H. pylori* infection. This is in accordance with the previous reports.[1,10] It is reported that the incidence of *H. pylori*-induced gastritis increases with the increase in the age of the cases.[10] A similar trend of infection was observed in this study, which follows the findings of the previous report.[15] However, the study performed on patients of the industrial belt of India showed a higher incidence of *H. pylori* infection in 15–30 and 46–60 year age-group.[16] The difference in the results may be due to the consumption of unhygienic fast food. Among RUT positive patients, the prevalence of infection was predominantly higher in males (75%) than females (25%) which may be due to the habit and lifestyle of the males compared to females. These findings are similar to the previous reports.[15–18]

Moayyedi et al. showed that *H. pylori* infection was more common in the lower socioeconomic strata and increased risk of infection in manual workers compared with nonmanual workers.[19] Similarly, in this study, manual laborers ($n = 17$) were most commonly infected by *H. pylori* followed by housewives ($n = 7$), business/servicemen ($n = 7$), and students ($n = 5$). This can be attributed to poor personal hygiene, lifestyle, malnutrition, and inability to afford health care.[20] In this study, most of the patients had abdominal pain for 6–12 months ($n = 19$) followed by 3–6 months ($n = 11$). Retrosternal burning ($n = 30$), nocturnal relationship ($n = 17$), and periodicity ($n = 18$) were the commonly observed symptoms in patients.

H. pylori is Gram-negative bacteria commonly found in deep part of the mucous gel covering the gastric mucosa or between the mucous layer and the gastric epithelium. In addition to chronic gastritis, *H. pylori* has a strong association with gastric adenocarcinoma and MALToma. *H. pylori* infection is most common in old age and poor socioeconomic strata, and lower levels of education can increase the risk of colonization of this organism.[21] RUT can provide a definitive diagnosis of *H. pylori* infection with the use of the endoscope and a significant association of endoscopic findings with RUT is also present. The study demonstrates that as age advances the incidence of *H. pylori* is increased. The infection was more common in the lower economic group. The limitations of the study were the small sample size, varied diet habits of the patients, and that the sensitivity and specificity of RUT were not assessed. A comparative study with other tests and a combination of two tests in the diagnosis of *H. pylori* infection with a large sample size including all variables is further recommended.

Conclusion

RUT facilitates rapid and accurate diagnosis of *H. pylori* infection. The incidence of infection was more common in males than females, and as age increased, the incidence of infection also increased. A significant association was found between RUT and endoscopy suggested gastritis. RUT and endoscopy can be used in the diagnosis of *H. pylori* infection in chronic gastritis. Further studies are warranted to confound these findings.

Ethics Committee Approval

This study has been approved by institutional ethics committee.

Clinical Significance

Early diagnosis of *H. pylori* is essential to formulate early and appropriate clinical strategies for better management of the patient. RUT is a well-known diagnostic test that is rapid, cheap, and simple. It detects urease in or on gastric mucosa produced by the bacteria.

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ORIGINAL ARTICLE

A Study of Clinical Profile and Outcome of Open Mesh Repair vs Laparoscopic Mesh Repair of Umbilical Hernia in Public Sector Hospital

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Abstract

Background: When a viscus or part of a viscus protrudes through the umbilicus, it is known as umbilical hernia. These hernias constitute as one of the common hernias of adults. Umbilical hernias are common in individuals with increased intra-abdominal pressure such as obesity, ascites, or chronic abdominal distension including malignancy. Mesh repair in umbilical hernia can be open mesh repair or laparoscopic mesh repair with each having their own advantages and disadvantages. This study attempts to evaluate various operative procedures and postoperative results of umbilical hernia in public sector hospital.

Methods: Study was an interventional study with a total sample size of 80. Study population were all the patients admitted with umbilical hernia to the surgical wards of hospitals associated with Bangalore Medical College and Research Institute. The study was conducted from November 2018 to May 2020. After admission, patients fulfilling the inclusion criteria were enrolled into the study and informed written consent was obtained. All the details and investigations of each patient were recorded in the case record form at the baseline visit. In 40 patients, open mesh repair of umbilical hernia was done, and in another 40 patients, laparoscopic mesh repair of umbilical hernia was done. The duration of surgery and various other postoperative complications were recorded.

Results: Eighty cases of umbilical hernia were operated, out of which, in 40 patients, open mesh repair was done and, in another 40 patients, laparoscopic mesh repair was done. Thirty-six of 40 patients were females, and 4 of 40 patients were males in the laparoscopic mesh group. Thirty-two of 40 patients were females, and 8 of 40 patients were males who underwent open mesh repair. Mean age was 45.0 years, and mean operating time was 64.75 minutes for open mesh repair group, whereas mean age was 42.37 years and mean operating time was 50.38 minutes for laparoscopic mesh repair group. Operating time showed statistical significance.

Conclusion: Laparoscopic mesh repair of umbilical hernia is becoming the procedure of choice in public sector hospitals in terms of decrease operating time, early recovery, less pain and less complications in postoperative period, and reduced duration of hospital stay as compared to open mesh repair of umbilical hernia.

Keywords: Laparoscopic mesh repair, Open mesh repair, Umbilical hernia.

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Introduction

In Latin, the word hernia means rupture. An abnormal protrusion of an organ or tissue through a defect in its surrounding walls defines hernia. When a viscus or part of a viscus protrudes through the umbilicus, it is known as umbilical hernia. It is a full thickness protrusion of the umbilicus with an underlying fascial defect and may contain peritoneal fluid, preperitoneal fat, intestine, or omentum as the content.[1]

Umbilical hernia in infants is common and congenital, whereas in adults, it is largely acquired. Umbilical hernia is commonly seen in females and in patients with conditions that result in increased intra-abdominal pressure such as obesity, pregnancy, ascites, or chronic abdominal distension.[2]

The physical examination or ultrasound has identified up to 50% of all individuals having fascial defect of umbilical ring.[3] Patients with umbilical hernia usually present as a soft bulge located anterior or adjacent to the umbilicus.[4]

Umbilical hernia is the second commonest type of hernia. The surgical management of umbilical hernia has developed over the years, and umbilical hernia can be treated by anatomical repair, open mesh repair, or laparoscopic mesh repair. The absolute indications for surgery are incarcerated hernia requiring reduction, strangulated hernia, perforation, and evisceration. The persistence and appearance of hernia are relative indications for operative repair.[5]

This study is done to estimate the prevalence, clinical findings, and risk factors associated with the umbilical hernia in adults and also compare the operative techniques of umbilical hernia repair. This study also compares the postoperative outcomes of the umbilical hernia repair by open mesh repair and laparoscopic mesh repair.

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Objectives of the Study

- To study the clinical profile of patients opting for open mesh repair or laparoscopic mesh repair of umbilical hernia.
- To study the outcomes of open mesh repair and laparoscopic repair of umbilical hernia.

Materials

Study was prospective interventional study, and study population were all the patients admitted with umbilical hernia to the surgical wards of hospitals associated with Bangalore Medical College and Research Institute. The study was conducted from November 2018 to May 2020. Institutional ethical committee approval was taken. Sample size selected was 80. Study sample was selected based on inclusion and exclusion criteria.

Inclusion Criteria

- Patients with age more than 18 years, admitted with umbilical hernia without complications and willing for informed written consent.

Exclusion Criteria

- All patients with defect size more than 3 cm.
- Patients with obstructed/strangulated/complicated umbilical hernia.
- Patients having abdominal malignancies.
- Patients having coagulopathy, severe cardiopulmonary disease, ascites, and renal failure.
- Patients not fit for surgery.

Methods

Institutional ethical committee clearance and written informed consent were obtained, patients were then admitted in the surgical wards with the diagnosis of umbilical hernia, and those coming under the inclusion criteria were enrolled into the study. A total number of patients with umbilical hernia enrolled into the study were 80, among them 40 patients were operated by open mesh repair technique and 40 patients were operated by laparoscopic mesh repair technique. Each patient was given a unique identity number. Demographic data, medical history, and history of concomitant medications were taken at the baseline visit. Physical examination, clinical examination, and other details according to the proforma were recorded, and relevant investigations were also done at the baseline visit. After relevant investigations and confirmation of diagnosis, preanesthetic evaluation is done and patients were randomly selected for open or LAP mesh repair. Operated patients were divided into two groups.

- Group I (LAP) patients undergoing laparoscopic mesh repair.
- Group II (OPEN) patients undergoing open mesh repair.

Postoperative evaluation was done until the patient was discharged and followed up at 2, 4, and 12 weeks. At the follow-up visits, detailed physical and clinical examinations were conducted.

Data were collected during preoperative and postoperative evaluation. All the data were compiled and subjected to statistical analysis. Collected data were subjected to descriptive statistics such as mean, median, standard deviation, interquartile range, percentages, tables, and graphs wherever necessary. Chi-square test and independent *t*-test were used for significant difference between the two groups, and $p < 0.05$ was considered statistically significant.

Results

Among the 40 (100%) subjects in LAP group, 18 (45%) were aged between 36 and 45 years, whereas in open group, 15 (37.5%) subjects were aged between 36 and 45 years. Chi-square test was used to check the association and showed nonsignificant association with respect to age ($\chi^2 = 1.349$; $p = 0.717$) (Table 1).

Mean age was higher for open group (42.37 years) as compared to LAP group (45.0 years). Independent sample *t*-test was used to compare the age between the two groups and showed nonsignificant difference between the groups ($p = 0.2309$) with respect to age (Table 2).

Females were higher in both the groups, 36 (90%) in LAP group and 32 (80%) in open group. Chi-square test was used to check the association and showed nonsignificant association with respect to gender ($\chi^2 = 1.56$; $p = 0.21$) (Table 3).

Out of 40 subjects in LAP group, majority 36 (90.0%) subjects had only swelling, whereas in open group, 35 (87.5%) had only swelling. Remaining subjects had mild pain with swelling. Chi-square test was used to check the association and showed nonsignificant association with respect to symptoms ($\chi^2 = 0.1252$; $p = 0.7234$) (Table 4).

Diabetes mellitus with hypertension was present in five (12.5%) subjects in LAP group, whereas in open group, there were seven (17.5%) subjects who had diabetes mellitus with hypertension. Chi-square test was used to check the association and showed nonsignificant association with respect to comorbidities ($\chi^2 = 1.041$; $p = 0.7913$) (Table 5).

Mean defect size was higher for open group (1.70) as compared to LAP group (1.66). Independent sample *t*-test was applied to compare the defect size between the two groups and showed nonsignificant difference between the groups ($p = 0.691$) with respect to defect size (Table 6).

Table 1: Agewise distribution of the subjects

	Groups		
	Lap	*Open*	*Total*
25–35 years			
Count	8	6	14
Percent	20%	15.0%	17.50%
36–45 years			
Count	18	15	33
Percent	45.0%	37.5%	41.25%
46–55 years			
Count	10	13	23
Percent	25.0%	32.5%	28.75%
Above 55 years			
Count	4	6	10
Percent	10.0%	15.0%	12.50%
Total			
Count	40	40	80
Percent	100.0%	100.0%	100.0%

Chi-square value—1.349; *p* value—0.717

Table 2: Comparison of age between the groups using independent sample *t*-test

	Min	*Max*	*Mean*	*Std. deviation*	*Mean diff*	*p value*
Lap	25	60	42.37	9.220	−2.63	0.2309
Open	25	68	45.00	10.201		

Table 3: Genderwise distribution of the subjects

	Groups		
	Lap	*Open*	*Total*
Females			
Count	36	32	68
Percent	90.0%	80.0%	85.0%
Males			
Count	4	8	12
Percent	10.0%	20.0%	15.0%
Total			
Count	40	40	80
Percent	100.0%	100.0%	100.0%

Chi-square value—1.56; *p* value—0.21; Significance level, 0.05

Table 4: Distribution of the subjects based on symptoms

	Groups		
	Lap	*Open*	*Total*
Swelling			
Count	36	35	71
Percent	90.0%	87.5%	88.75%
Swelling, Pain			
Count	4	5	9
Percent	10.0%	12.5%	11.25%
Total			
Count	40	40	80
Percent	100.0%	100.0%	100.0%

Chi-square value—0.1252; *p* value—0.7234; Significance level, 0.05

Table 5: Distribution of the subjects based on comorbidities

	Groups		
	Lap	*Open*	*Total*
DM			
Count	4	6	10
Percent	10.0%	15.0%	12.5%
DM, HTN			
Count	5	7	12
Percent			
HTN			
Count	3	3	6
Percent	7.5%	7.5%	7.5%
NIL			
Count	28	24	52
Percent	70.0%	60.0%	65.0%
Total			
Count	40	40	80
Percent	100.0%	100.0%	100.0%

Chi-square value—1.041; *p* value—0.7913; Significance level, 0.05

Table 6: Comparison of defect size between the groups using independent sample *t*-test

	Min	*Max*	*Mean*	*Std. deviation*	*Mean diff*	*p value*
Lap	1.0	2.6	1.66	0.4634	−0.04	0.691
Open	0.9	2.6	1.70	0.4338		

Table 7: Comparison of duration of procedure (in minutes) between the groups using independent sample *t*-test

	Min	*Max*	*Mean*	*Std. deviation*	*Mean diff*	*p value*
Lap	40	65	50.38	6.444	−14.37	0.00
Open	45	90	64.75	10.497		

Mean time of procedure was more for open group (64.75 ± 10.497) as compared to LAP group (50.38 ± 6.44). Independent sample *t*-test was used to compare the duration of procedure between the groups and showed statistically significant difference between the groups ($p < 0.001$) with respect to duration of procedure (Table 7).

Table 8 shows the distribution of the subjects based on postoperative complications. Postoperative pain was present in 35 subjects (12 in LAP group and 23 in open group). Seroma was present only in open group 14 (35%). Wound infection was present in seven (17.5%) subjects in open group. Chi-square test showed statistically significant association with respect to postoperative pain ($p = 0.013$), seroma ($p < 0.001$), and wound infection ($p = 0.006$).

Mean duration of hospital stay was higher for open group (8.00 ± 2.582) as compared to LAP group (3.30 ± 0.464). Independent sample *t*-test was applied to compare the duration of hospital stay between the groups. Independent sample *t*-test showed statistically significant difference between the groups ($p < 0.001$) with respect to duration of hospital stay (Table 9).

Discussion

Umbilical hernias are among one of the most common abdominal wall hernias, which is 10% of primary hernias in adult population.[6] Umbilical hernia can either be acquired or congenital. The pathophysiology of umbilical hernia is related to a combination of mechanical deficits of the abdominal wall and/or mechanical factors impacting the abdominal wall.[7] Umbilical hernia occurs as a consequence of pull of the abdominal muscles and connective tissue deterioration.[8] There are no absolute contraindications to umbilical hernia repair.[9] The repair of umbilical hernia can be by either open mesh repair technique or laparoscopic mesh repair technique. The mesh can be placed either onlay, underlay, or inlay.[6] The risk of mesh infection is high as it acts as a foreign body. Nevertheless, tension-free mesh repair is considered ideal for umbilical hernia repair as primary repair of umbilical hernia is associated with higher recurrence rate.[1] Laparoscopic mesh repair allows for clear visualization of the abdominal wall, wide mesh coverage beyond defect, and secure fixation to the fascia of abdominal wall. The laparoscopic method is the best approach in morbidly obese patient and in patients with very large hernia.[10]

This study attempts to evaluate the clinical profile of patients presenting with umbilical hernia and also to compare the outcomes of open mesh repair and laparoscopic mesh repair of umbilical hernia. Eighty patients with umbilical hernia admitted in the surgical wards of hospitals associated with Bangalore Medical College and Research Institute, Bengaluru, from November 2018

Table 8: Distribution of the subjects based on post op complications

			Groups				
			Lap	*Open*	*Total*	*Chi-square value*	*p value*
Postoperative pain	N	Count	28	17	45	6.14	0.013*
		%	70.0%	42.5%	56.3%		
	Y	Count	12	23	35		
		%	30.0%	57.5%	43.8%		
Seroma	N	Count	40	26	66	16.97	0.00*
		%	100.0%	65.0%	82.5%		
	Y	Count	0	14	14		
		%	0.0%	35.0%	17.5%		
Wound infection	N	Count	40	33	73	7.67	0.006*
		%	100.0%	82.5%	91.3%		
	Y	Count	0	7	7		
		%	0.0%	17.5%	8.8%		

*Significant; Significance level, 0.05

Table 9: Comparison of duration of hospital stay between the groups using independent sample *t*-test

	Min	*Max*	*Mean*	*Std. deviation*	*Mean diff*	*p value*
Lap	3	4	3.30	0.464	−4.7	0.00*
Open	5	18	8.00	2.582		

*Significant; Significance level, 0.05

Table 10: Percentage-wise distribution of age-groups

Age	*Total no. of cases*	*Percentage*
25–35 years	14	26.2%
36–45 years	33	38.8%
46–55 years	23	26.2%
Above 55 years	10	8.8%
Total	80	100%

Table 11: Genderwise comparison of different studies

Gender	*Present study*	*Jackson et al.*	*Ellis et al.*
Male	15%	35%	35.4%
Female	85%	65%	64.6%
Total	100%	100%	100%

Table 12: Comparison of presenting complaints between different studies

Presenting complaint	*Present study*	*Jackson et al.*
Swelling	88.75%	89%
Pain	11.25%	11%
Total	100%	100%

to May 2020 were enrolled into the study. Forty patients were operated by open mesh repair method, and 40 patients were operated by laparoscopic mesh repair method, and the results were analyzed.

Age

Of 80 patients of umbilical hernia, most of the patients were in the age-group of 36–45 years (41.25%). A study conducted by Kulacoglu et al. published online on umbilical hernia in the month of October 2011 showed that the mean age of presentation was 48.6 years (24–78 years).[11] A study by Jackson et al. had 25% of patients between the age-group of 41–50 years.[12] In the present study, the mean age of presentation was 43.69 years and the youngest patient was 25 years, while the oldest patient was 68 years (Table 10).

Gender

The international literature shows a female to male ratio of 3:1 of umbilical hernia; this study showed 85% of females and 15% of males that presented with umbilical hernia. Ellis et al. have shown a 64.6% of female patients enrolled in the study.[13] Jackson et al. have shown a 65% of female patients enrolled in the study, while 35% were males (Table 11).[12]

Presenting Complaints

In this study, 88.75% of patients presented with swelling over the umbilicus, while 11.25% of patients presented with swelling over the umbilicus associated with pain. A study conducted Jackson et al. showed that 11% of patients presented with swelling and pain, while 89% of patients presented with swelling similar to this study (Table 12).[12]

Defect Size

The mean defect size in this study was 1.70 cm in the group of patients who underwent open mesh repair. The smallest defect size was 1.0 cm, and the largest defect size was 2.6 cm. The mean defect size in this study for the laparoscopic mesh repair group was 1.66. The smallest defect size was 0.9 cm, and the largest defect size was 2.6 cm.

Mean Duration of Surgery

The mean operating time in this study was higher for open mesh repair which was about 64.75 ± 10.497 minutes as compared to the laparoscopic mesh repair which was 50.38 ± 6.44 minutes. The *p*-value was <0.001 which is statistically significant. The study performed by Gonzalez et al. showed that the mean operating time was 82 ± 9 minutes for open mesh repair and 62 ± 9 minutes for laparoscopic mesh repair of umbilical hernia (Table 13).[14]

Table 13: Comparison of operating time between different studies

Method of repair	*Present study*	*Gonzalez et al.*
Laparoscopic mesh repair	50.38 ± 6.44 minutes	62 ± 9 minutes
Open mesh repair	64.75 ± 10.49 minutes	82 ± 9 minutes

Table 14: Comparison of duration of hospital stay between different studies

Method of repair	*Present study*	*Gonzalez et al.*
Laparoscopic mesh repair	3.30 ± 0.464	1.12 ± 0.125
Open mesh repair	8.0 ± 2.52	3.79 ± 2.2

Duration of Stay in the Hospital

In this study, the mean duration of stay in the hospital was 8.00 ± 2.52 days for the open mesh repair, while it was 3.30 ± 0.464 days for laparoscopic mesh repair of umbilical hernia. The study conducted by Gonzalez et al. showed that the mean duration of hospital stay for open mesh repair group was 3.79 ± 2.2 days and 1.12 ± 0.125 days for laparoscopic mesh repair group (Table 14).

Conclusion

Umbilical hernia is the most common type of ventral hernia. Women were more commonly affected by umbilical hernia as compared to men. The laparoscopic mesh repair of umbilical hernia takes statistically less time for surgery. The postoperative complications such as seroma formation, postoperative pain, and wound infection were found to be more with open mesh repair as compared with the laparoscopic mesh repair of umbilical hernia. Duration of stay in the hospital was more in patients who underwent open mesh repair of umbilical hernia. Therefore, according to our study, we arrive at a conclusion that the laparoscopic mesh repair of umbilical hernia is superior as compared to the open mesh repair of umbilical hernia.

Laparoscopic method of umbilical hernia repair is becoming the procedure of choice in public sector hospitals in terms of operating time, early recovery, less pain after surgery, less complications after surgery, and reduced duration of stay in the hospital as compared to open mesh repair of umbilical hernia. But two main limiting factors of laparoscopic umbilical hernia mesh repair noted in a public sector hospital are the availability of dual composite laparoscopic mesh which costs more as compared to the open repair mesh, and other is the availability of an experienced surgeon to perform the laparoscopic mesh repair. If state is able to provide free dual layer mesh and train the surgeon in this field, then these limiting factors can be overcome.

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ORIGINAL ARTICLE

Use of Laparoscopic vs Open Repair for Perforated Peptic Ulcers is Determined by Surgeon Experience

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Abstract

Introduction: The incidence of perforated peptic ulcers (PPU) has decreased with effective medical treatment such that surgical repair has become a relatively infrequent procedure. We hypothesized that the surgeon's experience and the patient's clinical presentation are the most influential factors that determined the surgical approach.

Methods: A retrospective chart review of PPU repairs in the last 10 years was performed to collect surgeon demographics, patient clinical condition, comorbidities, and whether surgeries were done at a regional or tertiary site. Outcome variables included length of stay, complications, and readmissions. A multivariate analysis was used to establish statistically significant correlations.

Results: Of 219 operations for PPU, 49 were started laparoscopic (23.2%), 12 were converted to open (5.7%), and 162 were performed open (76.5%). The open and laparoscopic cohorts were similar without statistical difference between the groups in terms of age, sex, comorbidities, previous steroid use, NSAID, and anticoagulation use. Surgeons who attempted laparoscopy were more likely to have completed MIS fellowship (60.2%, p <0.001). The patients who had laparoscopic repair had a significantly shorter length of stay (8.5 vs 12.6 days; p <0.01). The patients who had an open repair had slightly more complications (18.4 vs 5.4%), readmissions (5.2 vs 2.7%), and hospital mortality (12.1 vs 5.4%) than their laparoscopically treated counterparts, although none was statistically significant.

Conclusion: Surgeons who completed a minimally invasive fellowship were more likely to perform a laparoscopic repair of perforated peptic ulcer, regardless of the patient's clinical presentation, comorbid conditions, and demographics. Patients who underwent laparoscopic repair had a significantly shorter LOS. Educational efforts directed toward community surgeons who do not have prior MIS training are likely to benefit patients with PUD by increasing access to laparoscopic surgery for PPU.

Keywords: Laparoscopic, Minimally invasive surgery, Perforated peptic ulcer.

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Introduction

The incidence of perforated peptic ulcer disease (PPU) has decreased over the years such that surgical repair has become a relatively infrequent operation.[1,2] This is due to the effective medical management of peptic ulcers, mainly proton pump inhibitor (PPI) therapy.[3] Additionally, endoscopy has led to earlier diagnosis of peptic ulcer disease (PUD) before complications such as perforation can occur, as well as recognition and treatment of *Helicobacter pylori*.[4] Nonetheless, PPU remains a surgical emergency that every general surgeon will encounter.

Several studies have demonstrated the viability and advantages of a laparoscopic repair when compared directly to the open approach for PPU.[5–11] Despite laparoscopic surgery being a core skill in current surgical training, the majority of PPU are repaired using an open approach. Our study aimed to address the reasons for this discrepancy. We hypothesized that the decision to repair a PPU laparoscopically over the open approach was based on the surgeon's experience (i.e., surgeon's training). The clinical presentation of the patient, and other circumstantial reasons not related to patient or surgeon factors (i.e., time of day, preoperative diagnosis, or localization of perforation, etc.).

The primary objective of our study was to establish specific characteristics of patients and surgeons that contribute to a surgeon choosing laparoscopic PPU repair over open repair. The secondary objective of this study was to analyze the outcomes of laparoscopic PPU repair vs open PPU repair, including mortality, complications, readmission, and length of stay (LOS).

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Methods

Our study was a retrospective chart review of patients admitted for perforated peptic ulcers (PPU) from 2007 to 2017. We used ICD-10 codes for primary perforated gastric or duodenal ulcers to select patients from the database. Surgeries were performed in both tertiary care centers and community hospitals within the

hospital network. IRB approval was obtained before proceeding with the study.

Adult patients who presented with PPU and underwent surgery were divided into two groups—laparoscopic or open repair. Patients who underwent laparoscopic converted to open repair were considered laparoscopic on an intention-to-treat basis, but were included in the open group for outcome analysis. Patients with iatrogenic bowel injury or those who developed a perforated peptic ulcer during an unrelated hospital admission were excluded.

We assessed several surgeon specific factors that could influence the surgical approach chosen. This included the surgeon's level of training (residency only vs fellowship training), surgeon's graduation year, and hospital level of care (i.e., tertiary referral center vs community hospital). The level of training was determined based on the information provided in the hospital credentialing information system. MIS fellowship trained surgeons were analyzed as a subgroup of the fellowship training category.

Circumstantial factors evaluated include the time of presentation, ability to localize the perforation on imaging, and time of diagnosis. Patient factors included vital signs in the emergency department, medical comorbidities, and preoperative labs. Patients who met the criteria for sepsis or systemic inflammatory response syndrome on presentation were categorized as being septic in the statistical analysis. Outcome variables analyzed included LOS, complications, readmissions, and discharge disposition.

Laparoscopic and open surgical approaches were compared based on demographics, clinical characteristics, and lab variables by using Chi-square, Fisher's exact, and Wilcoxon rank-sum tests. Multiple logistic regressions were used to establish relevant associations and to calculate adjusted odds ratios, expressed as odds ratios, and 95% confidence intervals. The patient presentation and surgeon specific variables were analyzed on an intention to treat basis. With regard to the outcome variables, the laparoscopic surgeries that were converted to open were analyzed within the open repair group. An additional analysis was performed that excluded patients with missing laboratory values ($n = 49$). Variables included in this regression model were selected by forward stepwise regression. All tests were two-tailed and statistical significance was defined as $p < 0.05$. Statistical analysis was performed with the use of R software version 4.0.0 (Vienna, Austria).

Results

A total of 219 observations were included (52 laparoscopic, 167 open) that underwent surgical management of ulcer disease. There were a total of 77 unique surgeons in the data set. Of these, 25 surgeons were responsible for the 52 laparoscopic repairs performed. The maximum number of PPU repairs performed by a single surgeon was 11 and the average was 2.84. The maximum number of laparoscopic repairs of PPU by a single surgeon was 5 with an average of 2.08 laparoscopic repairs.

Intention to Treat Data Analysis

Surgeries that started laparoscopic but converted open were analyzed on an intention to treat basis with respect to the patient demographic and presentation data. Overall, the groups were comparable in terms of their presentation and demographics with no statistically significant factors distinguishing the laparoscopic and open repair groups. The median age of the patients undergoing laparoscopic vs open surgery was (59.9 vs 63; $p = 0.394$), NSAID use (30.8 vs 28.7%; $p = 0.916$), PPI use (21.2 vs 12.6%; $p = 0.192$), previous surgery (44.9 vs 33.7%; $p = 0.210$). Patient comorbidities such as COPD (13.5 vs 12.6%; $p = 1.000$), CHF (5.77 vs 8.38%; $p = 0.768$), CKD (3.85 vs 11%; $p = 0.738$) were also not significant in determining the surgical approach (Reference Table 1 for complete patient demographic data). In terms of the clinical presentation of the patient (Table 2), 36.1% of patients ($n = 79$) were deemed septic upon presentation based on SIRS criteria; however, this was not a statistically significant factor in determining the operative approach (28.8% laparoscopic vs 38.3% open; $p = 0.281$). Very few patients ($n = 9$) presented with hypotension and only 16 patients presented with an abnormal INR above 2—factors not found influential in choosing the type of repair (5.7 vs 10.2% open; $p = 0.531$).

A subset of factors in Table 2 were circumstantial factors relating to the case that may have an influence on the surgeon's operative choice. These factors did not relate specifically to the characteristics of the patient or surgeon and included the time of day, location of the ulcer, and preoperative imaging localization. Intraoperative ulcer sites were found 42.9% of the time in the stomach (28.8% laparoscopic, 47.3% open) and 57.1% in the duodenum (71.2% laparoscopic, 52.7% open). Of the 52 laparoscopic repairs of PPU, 37 were found to be in the duodenum which was statistically significant (71.2% laparoscopic; $p = 0.029$). PPU was localized on preoperative imaging (duodenal vs stomach) in 59.4% of total cases (61.5% laparoscopic, 58.7% open); however, its relation to operative planning was not found statistically significant. The time of diagnosis was 55.3% in the daytime defined as 7 am–7 pm (61.5% laparoscopic, 53.3% open; $p = 0.838$), but this association was not statistically significant in determining the surgical approach.

Surgeon specific characteristics were also analyzed in the laparoscopic and open groups on an intention to treat basis (Table 3). A total of 56 surgeries (25.6%) were performed by surgeons with MIS fellowship training and these surgeons were found to perform laparoscopic repair of PPU more frequently (46.2% open vs 63.8% laparoscopic; $p \leq 0.0001$). The median year of residency graduation was 2006; however, the length of time the surgeon has been practicing was not found to be significantly correlated with the surgical approach. The majority of surgeries performed were by surgeons who trained at tertiary care centers rather than community hospital residencies (64.8 vs 35.2%; $p = 0.054$), but training at a tertiary center alone was not correlated with surgical approach. The hospital level of care (community hospital vs tertiary care center) was relatively evenly split, with 53% of surgeries being performed at community hospitals and 47% at tertiary care centers; however, the level of care was not significant in the choice of a laparoscopic approach (33 laparoscopic repairs in community hospitals vs 20 in tertiary centers).

As there were not many factors specific to the demographics or patient presentation that were clinically significant in choosing a laparoscopic over open repair, an additional analysis was conducted that excluded patients with missing variables, namely, INR ($n = 49$) and hypotension ($n = 9$) (Table 4). Since most patients presumably had their coagulopathy or hypotension corrected before proceeding to the operating room, these factors were deemed clinically irrelevant. A new forward stepwise regression analysis was then conducted excluding the variables INR and hypotension. The final model contained five relevant factors: BMI, comorbidities, residency type—tertiary vs community, fellowship, MIS fellowship.

Table 1: Patient demographics

	All	*Laparoscopic*	*Open*	
	N = 219	*N = 52*	*N = 167*	*p overall*
Sex, *N* (%)				
Female	108 (49.3%)	28 (53.8%)	80 (47.9%)	
Male	111 (50.7%)	24 (46.2%)	87 (52.1%)	
Age, median (25th; 75th)	62.6 (53.6; 74.6)	59.9 (53.3; 73.0)	63.0 (54.4; 74.7)	0.394
BMI, median (25th; 75th)	26.3 (22.6; 31.2)	26.4 (22.9; 30.7)	26.2 (22.5; 31.3)	0.614
Medication use: *N* (%)				
PPI	32 (14.6%)	11 (21.2%)	21 (12.6%)	0.192
NSAIDs	64 (29.2%)	16 (30.8%)	48 (28.7%)	0.916
Immunosuppressant	32 (14.6%)	7 (13.5%)	25 (15.0%)	0.965
Anticoagulation	18 (8.22%)	3 (5.77%)	15 (8.98%)	0.574
Comorbidities: *N* (%)				
COPD	28 (12.8%)	7 (13.5%)	21 (12.6%)	1.000
DM	35 (16.0%)	7 (13.5%)	28 (16.8%)	0.725
HTN	119 (54.3%)	27 (51.9%)	92 (55.1%)	0.810
CHF	17 (7.76%)	3 (5.77%)	14 (8.38%)	0.768
CKD	13 (5.94%)	2 (3.85%)	11 (6.59%)	0.738
Cirrhosis	8 (3.65%)	0 (0.00%)	8 (4.79%)	0.203
Previous *H. pylori*	6 (2.74%)	0 (0.00%)	6 (3.59%)	0.340
Previous surgery, *N* (%)	77 (36.3%)	22 (44.9%)	55 (33.7%)	0.210

PPI, proton pump inhibitor; NSAIDs, nonsteroidal anti-inflammatory drugs; COPD, chronic obstructive pulmonary disease; DM, diabetes mellitus; HTN, hypertension; CHF, congestive heart failure; CKD, chronic kidney disease

Table 2: Clinical presentation data

	All	*Laparoscopic*	*Open*	
	N = 219	*N = 52*	*N = 167*	*p overall*
Hospital setting *N* (%)				
Community	116 (53.0%)	33 (63.5%)	83 (49.7%)	0.115
Tertiary	104 (47.5%)	20 (38.5%)	84 (50.3%)	0.182
Vitals Median (25th; 75th)				
Heart rate	85.0 (74.0; 95.5)	79.0 (70.0; 93.2)	86.0 (75.5; 97.0)	0.050
Respiratory rate	18.0 (18.0; 20.0)	18.0 (16.0; 18.0)	18.0 (18.0; 20.0)	0.068
Temperature (F)	98.1 (97.7; 98.6)	98.0 (97.7; 98.4)	98.1 (97.7; 98.6)	0.629
SBP (mm Hg)	127 (112; 140)	127 (115; 139)	127 (112; 140)	0.803
DBP (mm Hg)	70.0 (60.0; 79.0)	68.0 (59.0; 76.2)	71.0 (60.0; 80.5)	0.299
Lab values Median (25th; 75th)				
WBC	13.2 (8.85; 20.6)	13.9 (9.19; 25.8)	13.1 (8.71; 20.1)	0.842
Hgb	12.5 (10.2; 14.3)	12.9 (10.1; 14.3)	12.3 (10.4; 14.2)	0.946
Plt	271 (200; 368)	282 (227; 375)	268 (194; 366)	0.288

[1]Abnormal Hgb, *N* (%)	48 (21.9%)	12 (23.1%)	36 (21.6%)	
[2]Hypotension, *N* (%)	9 (4.11%)	0 (0.00%)	9 (5.39%)	
[3]Normal INR, *N* (%)	156 (90.7%)	33 (94.3%)	123 (89.8%)	
Sepsis, *N* (%)	79 (36.1%)	15 (28.8%)	64 (38.3%)	0.281
Ulcer location, *N* (%)				0.029
Stomach	94 (42.9%)	15 (28.8%)	79 (47.3%)	
Duodenum	125 (57.1%)	37 (71.2%)	88 (52.7%)	
Preoperative CT scan, *N* (%)	193 (88.1%)	46 (88.5%)	147 (88.0%)	1.000
Image localized perforation, *N* (%)	130 (59.4%)	32 (61.5%)	98 (58.7%)	0.838
Time of diagnosis, *N* (%)				0.376
[4]Daytime	121 (55.3%)	32 (61.5%)	89 (53.3%)	
[5]Nighttime	98 (44.7%)	20 (38.5%)	78 (46.7%)	

SBP, systolic blood pressure; DBP, diastolic blood pressure; WBC, white blood cell ($\times 10^3/\mu L$); Hgb, hemoglobin (g/dL); Plt, platelets ($\times 10^3/\mu L$); INR, international normalized ratio; 1, any deviation from normal range for age and sex; 2, SBP <90 mm Hg; 3, INR >2; 4, between 7 am and 7 pm; 5, 7 pm 7 am

Table 3: Surgeon demographics

	All	*Laparoscopic*	*Open*	
	N = 219 (%)	*N = 52 (%)*	*N = 167 (%)*	*p overall*
Residency graduation after 2006	122 (55.7%)	32 (61.5%)	90 (53.9%)	
Residency hospital type				
Community	77 (35.2%)	12 (23.1%)	65 (38.9%)	
Tertiary	142 (64.8%)	40 (76.9%)	102 (61.1%)	
Fellowship	133 (60.7%)	33 (63.5%)	100 (59.9%)	0.765
MIS fellowship	56 (25.6%)	24 (46.2%)	32 (19.2%)	<0.001

MIS, minimally invasive surgery

Table 4: Final stepwise regression analysis

	Group = "Laparoscopic"			*Group = "Laparoscopic"*		
Predictors	*Odds ratios*	*CI*	*p*	*Odds ratios*	*CI*	*p*
(Intercept)	0.14	0.00–6.96	0.328	0.07	0.02–0.31	**<0.001**
Age	0.99	0.97–1.02	0.481			
Sex: Male vs Female	0.79	0.37–1.70	0.545			
BMI	1.05	1.00–1.11	**0.050**	1.05	1.01–1.10	**0.027**
PPI: Yes vs No	1.68	0.64–4.39	0.292			
NSAID: Yes vs No	0.81	0.37–1.77	0.591			
Immunosuppression: Yes vs No	0.79	0.28–2.29	0.670			
Anticoagulation use: Yes vs No	0.77	0.18–3.28	0.726			
Comorbidity: Yes vs No	0.47	0.20–1.13	0.091	0.50	0.24–1.02	0.056
Previous surgery: Yes vs No	1.53	0.69–3.39	0.300			
Surgeon graduation: 2006 and After vs Before 2006	1.13	0.51–2.54	0.760			
Residency type: Tertiary vs Community	2.31	0.98–5.45	0.057	2.23	0.97–5.11	0.058
Fellowship: Yes vs No	0.32	0.12–0.86	**0.024**	0.35	0.14–0.87	**0.024**
MIS fellow: Yes vs No	5.36	1.99–14.42	**0.001**	6.42	2.63–15.66	**<0.001**
DBP	1.00	0.97–1.03	0.746			
Preoperative CT scan : Yes vs No	1.61	0.47–5.52	0.448			
Imaging localization: Yes vs No	0.78	0.35–1.71	0.528			
Hemoglobin: Normal vs Abnormal	0.93	0.39–2.21	0.876			
Septic: Yes vs No	0.68	0.32–1.45	0.314			
Ulcer location: Duodenum vs Stomach	1.45	0.65–3.26	0.368			

(Contd...)

Table 4: *(Contd...)*

	Group = "Laparoscopic"			*Group = "Laparoscopic"*		
Predictors	*Odds ratios*	*CI*	*p*	*Odds ratios*	*CI*	*p*
Time visit: Nighttime vs Daytime	0.69	0.33–1.41	0.304			
Observations	219			219		
Tjur's R^2		0.169			0.128	

BMI, body mass index; DBP, diastolic blood; Bold value indicate statistically significant variables

Table 5: Outcomes after conversion to open surgery

	All	*Laparoscopic*	*Open*	
	N = 219 (%)	*N = 40 (%)*	*N = 179 (%)*	*p overall*
Length of stay (days) Median (25th; 75th)	8.00 (6.00; 15.5)	6.00 (5.00; 10.5)	9.00 (6.00; 16.0)	0.002
Mortality	24 (11.0%)	2 (5.00%)	22 (12.3%)	0.264
Readmission	11 (5.02%)	1 (2.50%)	10 (5.59%)	0.694
Complication	36 (16.4%)	3 (7.50%)	33 (18.4%)	0.147
Leak	11 (5.02%)	0 (0.00%)	11 (6.15%)	0.222
Intra-abdominal abscess	9 (4.11%)	1 (2.50%)	8 (4.47%)	1.000
SSI	5 (2.28%)	0 (0.00%)	5 (2.79%)	0.587
DVT/PE	3 (1.37%)	0 (0.00%)	3 (1.68%)	1.000
UTI	12 (5.48%)	2 (5.00%)	10 (5.59%)	1.000
Cardiovascular	6 (2.74%)	1 (2.50%)	5 (2.79%)	1.000
Bleeding	1 (0.46%)	0 (0.00%)	1 (0.56%)	1.000
Return to OR	20 (9.13%)	3 (7.50%)	17 (9.50%)	1.000
Discharge disposition				0.003
Home	123 (56.2%)	32 (80.0%)	91 (50.8%)	
SNF/LTACH	73 (33.3%)	6 (15.0%)	67 (37.4%)	
Death	23 (10.5%)	2 (5.00%)	21 (11.7%)	

SSI, surgical site infection; DVT/PE, deep vein thrombosis/pulmonary embolism; UTI, urinary tract infection; SNF, skilled nursing facility; LTACH, long-term acute care hospital

Of these, MIS training ($p = 0.001$), fellowship training ($p = 0.024$), and BMI ($p = 0.027$) were found to be statistically significant.

Operative Outcome Data

Analysis of postoperative outcomes is shown in Table 5. The 12 patients who underwent laparoscopic converted to open repair were included in the open repair group. Overall, the patients who underwent laparoscopic repair fared better with regard to postoperative outcomes. Patients who underwent open repair had longer lengths of stay (6 vs 9 days; $p = 0.002$) and they were less likely to be discharged home (80 vs 50.8%; $p = 0.003$). Surgeries performed laparoscopic had lower rates of complications compared to open procedures (7.5 vs 18.4%), but the difference did not reach statistical significance ($p = 0.147$).

Discussion

Our study revealed that MIS fellowship trained surgeons more frequently performed a laparoscopic repair of PPU regardless of the patient's clinical presentation, comorbid conditions, and demographics. Additionally, patients who underwent laparoscopic repair had better outcomes with a statistically significant shorter LOS and disposition home rather than a skilled nursing facility (SNF).

The literature overwhelmingly supports the idea that laparoscopic surgery is a safe and effective alternative to open surgery.[6–10,12] Laparoscopic surgery is the preferred approach (avoid standard of care without a citation) for many surgical emergencies such as acute appendicitis and cholecystitis.[13,14] Our study found that laparoscopic repair of PUD is safe and effective as the laparoscopic group was shown to have better outcomes without any statistical difference in mortality rates. This is not a finding that is unique to our study as there have been numerous other studies that support our finding with regard to laparoscopic outcomes.[6,7,9,10] In the study by Guadagni et al.,[8] there was no significant difference in morbidity or mortality of the patients who underwent laparoscopic repair of perforated PUD compared to the group that underwent open repair. Furthermore, Cirocchi et al., conducted a meta-analysis that concluded there was no clinically significant difference in outcomes between laparoscopic and open repair of PPU.[12] Although it was not statistically significant, our study found that the laparoscopic group had less complications than the open group. There were no complications related to surgical site infections and this likely contributed to the decreased LOS (6 vs 9 days; $p = 0.002$) found in the laparoscopic group over the open group. This finding was supported in Cirocchi et al. study as patients who underwent laparoscopic repair of PPU also were found to have less wound infections compared to the open repair group. Our study also revealed that the laparoscopic group was more likely to be discharged home, rather than to a SNF (80 vs 56.2%, respectively, $p = 0.003$) which is likely related to the decreased complication rate.

The goal of our study was to distinguish which factors were most influential in surgical decision making to repair a PPU laparoscopically. These factors were broken down into three main groups; the clinical status of the patient, the surgeon's experience, and circumstantial factors relating to the case. Of the many patient factors analyzed, only BMI and ulcer location (duodenum) were found to be statistically significant for choosing laparoscopic over open repair. Laparoscopic surgery in obese patients has decreased rates of wound infection and incisional hernias.[13] Open repair in very obese patient can be more difficult to perform, and this would lead a surgeon to opt for a laparoscopic approach.

Based on our data, the ulcer location being found in the duodenum is difficult to explain as it is an intraoperative finding that could not definitively be confirmed in preoperative planning. Additionally, the preoperative imaging localization on the CT scan was not found to be a significant factor for the surgeon choosing laparoscopic repair or open. For this reason, we do not feel it is a relevant factor in determining the operative approach. Given the BMI was the only significant patient related factor, we can infer that the decision for a surgeon to repair a PPU laparoscopically was otherwise only influenced by the surgeon's experience. MIS fellowship training (46.2% laparoscopic if MIS fellowship vs 19.2% laparoscopic if no MIS fellowship $p \leq 0.001$) proved to be the most important factor in determining the operative approach. Patient characteristics that typically indicate a patient to be a poor laparoscopic candidate were not found to be significant. These factors included prior abdominal surgeries, septic presentation, medical comorbidities, and anticoagulation. This finding suggests that a MIS trained surgeon was more willing to resuscitate the patient, reverse anticoagulation, provide supportive measures for their patients' comorbidities, and still proceed with laparoscopic surgery rather than choosing to proceed with the open procedure due to the known benefits of laparoscopic surgery.

Our study was limited by the fact that it was a retrospective chart review and this inherently makes the study prone to selection bias. Our data may have been a reflection of surgeons at our specific hospital network rather than the surgical community as a whole as only 25 or the 77 surgeons in the study accounted for the laparoscopic group. Further randomized control trials need to be performed to combat this type of bias.

One particular obstacle to address regarding the adoption of laparoscopic repair of PPU is the surgeon's comfort with intracorporeal suturing. Lim et al. study cited this particular issue as a "barrier to the greater adoption" of MIS.[15] Laparoscopic knot tying was inferior to open knot tying across all levels of surgical training.[16] Surgeons who are performing laparoscopic PPU repair are likely more technically proficient laparoscopic surgeons due to their training (i.e., MIS fellowship). The improved outcomes found in our laparoscopic group may not be reflective of surgeons who do not have the same level of laparoscopic training.

Although the data did not ultimately reveal a clear and specific subgroup of patients or "indications" to perform laparoscopic surgery, the question must be asked; should we be performing more PPU repairs laparoscopically? Based on our findings, laparoscopic PPU disease repair is safe, decreases LOS, and improves overall patient outcomes when compared to open repair. Many surgeries that were done as open procedures are now done laparoscopically.[14,17] And thus, we believe the management of PPU disease should also evolve. Surgeon experience is a modifiable factor, and with better surgical education and laparoscopic training, we feel more surgeons would be capable of performing a laparoscopic repair of PPU disease. Specifically, educational efforts should be directed to community surgeons without MIS training, as it will benefit their patient population.

Conclusion

Our study further validates the use of laparoscopic repair for PPU disease as an option with better outcomes. The majority of surgeons do not perform laparoscopic repair of PPU because the choice to perform laparoscopic PPU repair is based largely on the experience and technical ability of the surgeon. Surgeons may benefit from education and training to laparoscopically address PPU, particularly community surgeons without MIS fellowship training. This additional investment in training would benefit both the patient and reduce hospital costs by decreasing LOS and the need for SNF discharges.

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ORIGINAL ARTICLE

Prevention of Mesh-related Complications at the Hiatus: A Novel Technique Using Falciform Ligament

Pranav Mandovra[1], Vishakha R Kalikar[2], Roy V Patankar[3]

Abstract

Aim: In this study, a technical modification has been performed by using falciform ligament between the mesh and esophagus thereby preventing mesh to come in direct contact with the hollow viscera so reducing mesh-related complications.

Materials and methods: From January 2016 to December 2017, patients requiring the use of prosthetic mesh at the hiatus during laparoscopic antireflux surgery (LARS) surgery were included in the study. Principles of an ideal LARS have adhered. After mesh repair at hiatus and appropriate fundoplication, the falciform ligament was released from its attachment to the ventral abdominal wall and was placed between the mesh and the posterior esophagus avoiding direct contact between the mesh and hollow viscera. Postoperatively patients were followed up for a minimum of 2 years. A retrospective analysis was done of the prospectively collected data.

Results: Sixteen patients were included in the study (12 patients had redo surgery and four had large hiatus hernia requiring prosthesis). Average age of the patients was 48.5 years and the average BMI was 24.8. The mean operative time was 128.2 minutes. None of the patients had a recurrence of hiatus hernia, long-term dysphagia, any mesh-related complication, or any unexpected event related to surgery on 2-year follow-up.

Conclusion: This innovative technique of using falciform ligament as a bridge between the mesh and the esophagus prevents the mesh-related complication without compromising the strength of hiatal repair.

Clinical significance: To prevent the recurrence of hiatus hernia, the use of prosthetic meshes is advocated in patients with large hiatal surface areas. Concern about the safety of mesh at the hiatus has been there. This technique helps in reducing the mesh-related complication at the hiatus.

Keywords: Falciform ligament, Mesh at hiatus, Prevention of mesh complications.

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Background

Laparoscopic cruroplasty with fundoplication has emerged as a standard of care for patients with symptomatic hiatus hernia and paraesophageal hernias. Reconstructing the widened esophageal hiatus forms an integral part of the surgery for hiatus hernia. Primary suture repair and doing only cruroplasty for large hiatal hernias are associated with high recurrence rates.[1,2] To prevent the recurrence of hiatus hernia, the use of prosthetic meshes has been well advocated in patients with large hiatal surface areas.[3] With the increasing use of mesh at the hiatus, few reports of intraluminal mesh erosion were published.[4,5] This rose the concern about the safety of mesh use at the hiatus. Even the composite meshes are known to erode intraluminally.

In this study, a technical modification has been performed to use falciform ligament between the mesh and esophagus preventing mesh to come in direct contact with the hollow viscera thereby reducing mesh-related complications.

Methods and Materials

This is a pilot study with a limited sample size but an innovative concept performed at a tertiary healthcare center in Mumbai, India. Patients undergoing laparoscopic antireflux surgery (either primary or redo surgeries for hiatus hernia) from January 2016 to December 2017 requiring the use of prosthetic mesh at the hiatus were included in the study. Patients undergoing LARS in whom prosthetic mesh was not used were excluded from this study. This study was approved by the ethics committee of our institution.

In all the symptomatic patients a thorough preoperative evaluation was done including upper GI scopy, upper GI manometry, and CT scan. Patients were carefully selected for LARS. The prosthetic mesh was used in all patients with redo LARS for recurrence of hiatus hernia or wrap migration or patients undergoing primary LARS with a large hiatus hernia with a maximum intercrural distance of more than 5 cm at the end of dissection.

Operative Technique

All the principles of an ideal LARS were adhered. Adequate mobilization with a minimum 5 cm length of the intra-abdominal esophagus was achieved. An attempt was made to achieve tension-free crural closure, but in cases of large defect at hiatus where tension-free suturing was not possible darning sutures were taken to create a bed for the mesh. A composite mesh was refashioned with a "U"-shaped slit that was created in the mesh which was used at the hiatus posterior to the esophagus in such a way that the "U"

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slit in the mesh accommodates the esophagus and the prolene surface directed toward the diaphragm and composite surface facing the peritoneal cavity. Appropriate fundoplication wrap was carried out. Falciform ligament was released from its attachment to the ventral abdominal wall taking care of not hampering its vascularity (Fig. 1) and then it was placed in between the mesh and the posterior esophagus to avoid direct contact between the mesh and the hollow viscera (Figs 2 and 3).

Postoperative Course

Patients were started on liquid diet 4 hours following surgery. For the initial 1 week, patients were given only liquid diet to prevent the initial transient dysphagia which may occur due to postoperative edema at the gastroesophageal (GE) junction. Gradually from the 2nd week onward, patients were started on solid food. For the assessment of the integrity of the cruroplasty and wrap in all the subjects, postoperative UGI scopy and CT scan were done at 12 and 24 months following surgery.

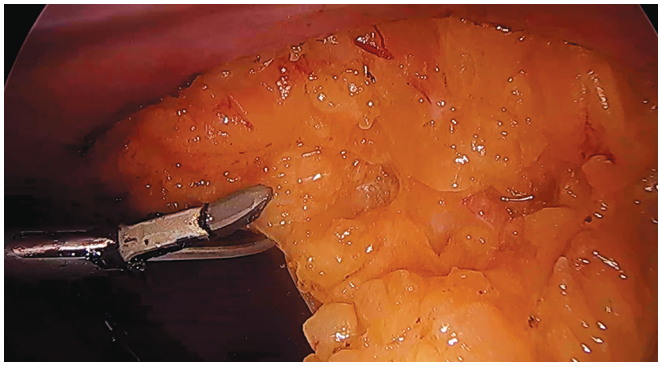

Fig. 1: Releasing falciform ligament from the ventral abdominal wall

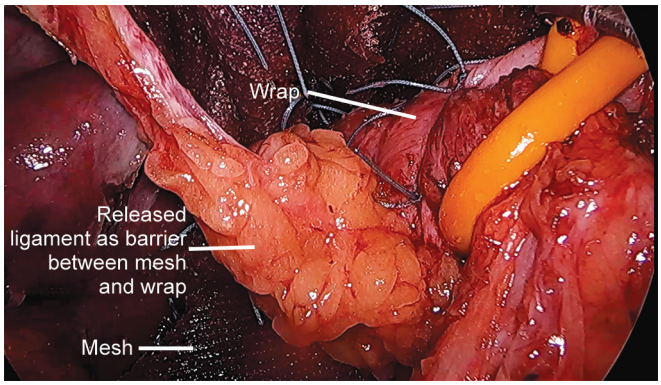

Fig. 2: Falciform ligament placed between mesh and the posterior esophagus/wrap (view from the right side)

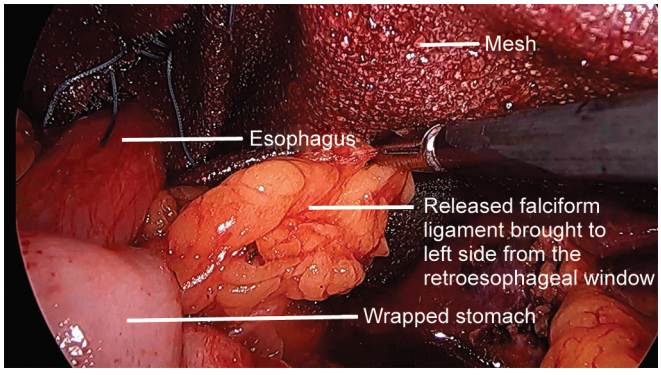

Fig. 3: Falciform ligament placed between mesh and the posterior esophagus/wrap (view from the left side)

Results

Sixteen patients were included in the study (60% females). Twelve patients had been operated on for redo hiatus hernia surgery for recurrence and four patients were operated on for a large hiatus hernia. The average age of the patients was 48.5 ± 11.5 years (mean ± SD) and the average BMI of the patients was 24.8 ± 1.6 (mean ± SD). All patients had undergone pre and postoperative manometry and UGI scopy. The operative time was 128.2 ± 24.2 minutes (mean ± SD) after the insertion of the first trocar and the average hospital stay for patients was 72 hours. In all the patients in this study group, a composite prosthetic mesh was used for augmentation of the hiatal closure and released ligamentum teres were placed between the mesh and esophagus preventing the mesh to come in direct contact with the hollow viscera thereby reducing mesh-related complications. None of the patients had a recurrence of hiatus hernia or had any long-term dysphagia following surgery. In none of the patients, any mesh-related complications were observed on 2-year follow-up. No unexpected event was observed in these patients following the addition of a simple step of ligamentum teres pedicle between the mesh and the hollow viscera during LARS with mesh prosthesis at the hiatus.

Discussion

Use of prosthetic mesh at the hiatus in large hiatus hernias or in redo hiatal hernia surgeries has been well documented and practiced. But the concern about its use at the hiatus has also been raised due to the complications like mesh directly eroding into the digestive lumen.[6,7] In our series of over 1,500 hiatal hernia surgeries, the composite mesh was used in only 30 patients. In this very small subset of patients with mesh used at hiatus, we encountered a case of mesh eroding into the stomach. Hence mesh erosion is a significant problem that is not uncommon and has been underreported in the literature.

The benefit of using mesh at hiatus in large hiatus hernias or redo surgeries is certainly present to prevent the recurrence. With the two randomized trials,[8,9] it becomes obvious that using a prosthetic mesh at hiatus for large defects prevents long-term recurrence and is a better-quality repair compared to simple suture repair. But the complication like mesh erosion raises the concern about its use. A significant morbidity is associated with mesh erosion.[10] Role of biologic mesh for long-term prevention of recurrence of hiatus hernia has also been questioned. Oelschlager et al. in their long-term follow-up with the use of biological mesh at the hiatus did not find any mesh-related complications but were not able to determine the benefit of using biological mesh to prevent long-term recurrence of large hiatus hernia.[11]

The use of falciform ligament to buttress the cruroplasty to provide strength to primary suture repair has also been described in the literature.[12,13] Its long-term results are not present and there has been no randomized trial comparing the use of mesh to the

use of falciform ligament to buttress the crural repair evaluating the recurrences in long-term.

Li et al. in their study on cadavers found the average length of the falciform ligament to be 8.3 cm.[14] Location of falciform ligament in the body is such that it can be easily released and rotated under the left lobe of the liver and that vascularized pedicle can be placed at the hiatus with no trouble. Hence this is an easy and simple technique that is easily reproducible. With this novel technique described here in this series, using falciform ligament between the mesh and the esophagus prevents the direct contact of mesh with the esophagus thereby providing the strength of mesh repair and also reducing mesh-related complications.

However, further multicentric studies with larger sample size are needed to propose this novel technique in the standard operative protocol.

Conclusion

This innovative technique of using falciform ligament as a bridge between the mesh and the esophagus prevents the mesh-related complication without compromising the strength of hiatal repair.

Clinical Significance

To prevent the recurrence of hiatus hernia, the use of prosthetic meshes is advocated in patients with large hiatal surface areas. Concern about the safety of mesh at the hiatus has been there. This technique helps in reducing the mesh-related complication at the hiatus.

Authorship Declaration

We, all the authors declare that all of us have contributed to this manuscript and are in complete agreement with the content of the manuscript.

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ORIGINAL ARTICLE

Conversion to a Banded Gastric Bypass is a Safe and Effective Option after Sleeve Gastrectomy: A Indian Single-center Experience

Mahak Bhandari[1], Susmit Kosta[2], Manoj Reddy[3], Winni Mathur[4], Mohit Bhandari[5]

Abstract

Revision bariatric surgery has become a standard technique in bariatric surgery processes. Patients who have experienced insufficient weight reduction or subsequent weight gain following an initial surgery have a variety of options for revision. The objective of this report was to explore the role of a sleeve gastrectomy (SG) revision to a banded gastric bypass (BGBP) for inadequate weight loss or weight gain. Patients who had BGBP revision surgery after SG were identified in a prospectively kept database and information on comorbidity resolution and weight was obtained. The effects of the revision activities were evaluated and analyzed. Sixty-two patients underwent reconsideration of SG to BGBP. The average time for the revision was 27 months in the range 7–60 and the follow-up after BGBP was 6–36 months. In this study the average initialism weight before the SG was 113.5 ± 20.5 kg and the body mass index (BMI) was 41.71 ± 8.1 kg/m^2. The mean percentage of weight loss %TWL at revision and at the nadir weight was 18.5 and 13.5%, respectively. The average %TWL was 25.9 ± 10.1, 29.7 ± 9.2, and 26.9 ± 9.6 at first-, second-, and third-year follow-up, respectively, after revision to BGBP. Type II diabetes (T2D) and hyperaeration (HTN) were resolved in 70 and 78.6% of the patients, respectively. With no complications or mortality AI revisions were done laparoscopically. It is practically feasible and safe to switch from SG to BGBP. The weight reduction from the BGBP sleeve is not only more desired than the weight loss from the primary sleeve, but it also results in successful comorbidity resolution. BGBP is a better bet to changing for altering SG for insufficient weight regain or weight loss.

Keywords: Banded gastric bypass, Insufficient weight-loss, Revision, Sleeve gastrectomy.

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Introduction

As a primary weight loss procedure, the sleeve gastrectomy (SG) has gained growing acceptability as a safe and effective surgery for morbid obesity. Good weight reduction, resolution of comorbidities, a very straightforward surgery with a short operation time, and a low incidence of complications are all advantages of laparoscopic SG. Over the years, several bariatric surgeons have contemplated it as a standard bariatric operation. Despite many advantages following SG, as with all other bariatric procedures, with time and increased number of cases performed, After the SG, significant numbers of patients experience insufficient weight loss and weight return.[1–3] Patients who require revision due to insufficient weight reduction or weight gain have had endoscopic plication, surgical re-SG, or both,[4,5] or a Roux-en-Y gastric bypass (RYGB),[6] one anastomosis gastric bypass (OAGB),[7] banded gastric bypass (BGBP), or biliopancreatic diversion with a duodenal switch (BPD-DS).[8,9] We offer patients with sleeves who have inadequate weight loss or significant weight regain revision to a BGBP based on our experience with the BGBP, which we have reported to provide better weight loss than the RYGB and systematic analysis has shown the BGBP to be equivalent to the BPD-DS. This retrospective study was conducted to investigate the result of SG to BGBP revision for insufficient weight loss and weight recovery in our experience with up to 3 years of follow-up after the revision.

Materials and Methods

This is a retrospective analysis of data gathered from a prospectively maintained database at a dedicated high-volume bariatric center, India. Patients who had a SG and subsequent revision to BGBP between February 2009 and December 2019 were identified from the database. The patient profile, age, gender, BMI, comorbid conditions, the year of the first operation, the year of the revision, the starting weight, the weight at the time of the revision, the weight 3 years later, additional comorbidity resolution, and complications, if any, were also recorded.

Surgical Technique

All of the initial and revision surgeries were performed laparoscopically. There was no conversion to open surgery.

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Sleeve Gastrectomy

Veress needle is used to get access to the abdomen. The optics are implanted through a 12 mm supra umbilical port. In the midclavicular line, a second 12 mm port is put under vision in line with the optical port. In the midclavicular line, two 5 mm ports are inserted in the right and left subcostal regions. The liver is retracted using a Nathanson liver retractor. Transecting the omentum along the larger curvature away from the stomach, commencing at a location 2–3 cm from the pylorus up to the gastro esophageal junction, exposing the left crus, is how a laparoscopic SG is conducted. The sleeve is created by transecting the stomach with a green Ethicon stapler starting 5 cm from the pylorus. The stapled resection of the stomach is completed using blue staplers and a 36 Fr bougie in the stomach, resulting in a 70–90 cc sleeve. Endoscopy is used after surgery to check for leaks, internal hemorrhage, pouch patency, and a clean distal channel. Clips are used to produce hemostasis. Normally, no drains are installed. If vital indicators are normal, patients are started on a liquid diet the day after.

Banded Gastric Bypass

To get access within the abdomen, a veress needle is utilized. For the optics, a 12 mm supra umbilical port is used. In the midclavicular line, another 12 mm port is put under eyesight in line with the optical port. In the midclavicular line, two 5 mm ports are inserted in the right and left subcostal regions. For the retraction of the liver, a Nathanson liver retractor is used. A harmonic scalpel is used to detach adhesions. To minimize harm to the remaining sleeve's serosa, careful dissection is performed to mobilize the omentum linked to the larger curvature.

The lesser omentum is dissected at a location 6–7 cm from the gastroesophageal junction to create a gastric pouch. A horizontal blue cartridge is shot when the smaller sac is inserted, followed by two vertical loads fired close to a 36 Fr bougie. The specimen is the extra sleeve pouch that has been transected. A 7-cm GaBP ring is wrapped around the pouch 3–5 cm below the gastroesophageal junction. A nonabsorbable suture is used to secure the ring to the staple line on the larger curvature. The ligament of Treitz is used to produce a 120 cm Roux limb and an 80 cm biliopancreatic limb. End to side, a gastrointestinal anastomosis of 2–3 cm is created between the pouch and the Roux limb. At least 2 cm above the anastomosis, the ring should be placed. Nonabsorbable sutures are used to close the Peterson's and mesenteric defects. Clips are used to produce hemostasis. Normally, no drains are installed. If vital indicators are normal, patients are started on a liquid diet the day after.

Statistical Analysis

The means and standard deviations of descriptive and continuous variables were provided. The number of cases (*n*) and percentages was used to represent categorical variables. In continuous variables, a general linear repeat measurement test was used to estimate averages between revision surgery at one, two, and 3 years. To determine if differences were significant, the two-sample *t* test or two-proportions technique was utilized. All two-sided *p* values of <0.05 were commonly considered statistically significant.

Results

A total of 62 patients underwent conversion of a SG to BGBP at our institution. The mean time to revision was 27.0 ± 13.1 months (range 7–60). Follow-up rate was 70.2% after the revision at 1, 2, and 3 years, for patients eligible for a 3-year follow-up after BGBP.

Mean patient age was 43.2 ± 12.8 years and 32 (51.6%) were female. Before the SG, the average starting weight in this study was 113.5 ± 20.5 kg and the BMI 41.71 ± 8.1 kg/m^2. Thirteen (20.9%) had Type II diabetes mellitus (T2D), 21 (33.8%) hypertension (HTN), and 10 (16.12%) sleep apnea (SA) (Table 1). At the nadir, the average weight was 92.4 ± 16.1 kg and at revision was 100.5 ± 14.9 kg. After conversion, the average additional weight loss was 15.02.6 kg, which was statistically significant ($p = 0.001$). The mean weight after conversion were 25.9 ± 10.1, 29.7 ± 9.2, and 26.9 ± 9.6 at 1-, 2-, and 3-year follow-up, respectively. Weight loss trends %TWL and %EWL and rates are summarized in Figure 1 and Table 2.

At the time of revision, T2D and HTN resolution rates were 50.0 and 62.5%, respectively. With the revision procedure, the resolution of comorbidities was marginally improved (70.0 and 78.6%). All of the T2D patients had a hemoglobin A1-C (HbA1-c) level of less than 6% and were not on any diabetic medicines. Patients with HTN now had blood pressure (BP) of less than 120/80 mm Hg without taking any drugs, and there were no patients with SA based on no subjective symptoms. Comorbidity resolution trends showed in Figure 2.

At our center, the average operational time for primary BGBP is 693.5 minutes. As a result, reoperative surgery took 21 minutes longer on average ($p = 0.003$). The average length of stay in the hospital after surgery was 3 days. There were no anastomotic

Table 1: Preoperative: patient profile at baseline

Initial SG (n = 62)	
Age*; years	43.24 ± 12.84
Gender Male/Female†; *n* (%)	30 (48.4%)/32 (51.6%)
Weight*; kg	113.5 ± 20.5
Height*; cm	1.65 ± 0.10
Body mass index*; kg/m^2	41.71 ± 8.1
Diabetes†; *n* (%)	13 (20.9%)
Hyperseptation†; *n* (%)	21 (33.8%)
Sleep apnea†; *n* (%)	10 (16.12%)

*Data showed as means with standard deviation; †Categorical variables showed as number of cases (*n*) and percentages

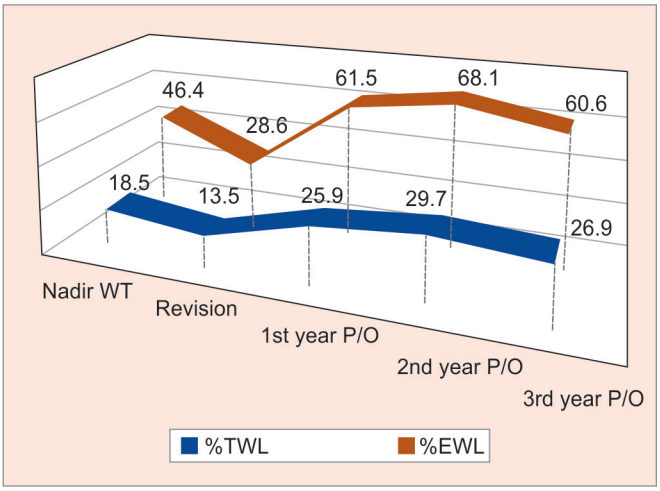

Fig. 1: Weight loss trends after BGBP conversion (%TWL and %EWL)

Table 2: Change in weight loss metrics from nadir weight to 3-year follow-up after BGBP conversion

	Nadir WT	*Revision*	*1st year P/O*	*2nd year P/O*	*3rd year P/O*
WT	92.4 ± 16.1	100.5 ± 14.9	85.5 ± 10.5	82.5 ± 9.7	85.9 ± 7.1
BMI	32.5 ± 4.3	35.7 ± 4.3	29.9 ± 3.8	30.1 ± 3.8	31.3 ± 4.2
%TWL	18.5 ± 12.2	13.5 ± 10.3	25.9 ± 10.1	29.7 ± 9.2	26.9 ± 9.6
%EWL	46.4 ± 14.3	28.6 ± 11.4	61.5 ± 10.3	68.1 ± 9.4	60.6 ± 9.2

WT, weight; BMI, body mass index; %EWL, percentage of excess weight loss; %TWL, percentage of total weight loss

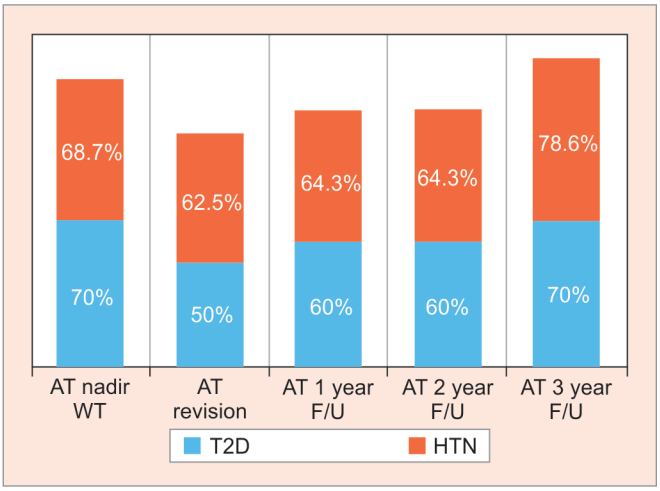

Fig. 2: Comorbidity resolution trends (revision from SG to BGBP)

leaks or marginal ulcers after surgery. In this study, there were no early or late problems. There was also no mortality in this series. Patients with epigastric discomfort were identified by endoscopy and treated well with medication therapy.

Discussion

Weight regains should be expected following all bariatric procedures to some extent, but a considerable rise in weight, defined as a 10 kg increase in body weight from nadir, might suggest a surgery failure.[9,10] Age more than 40 and a preoperative BMI greater than 50 are immutable risk factors for failure.[11] Procedures that do not include an intestinal bypass, such as the SG, are particularly vulnerable. Re-sleeve was described by Gagner and Rogula in a patient with a dialled pouch. UGIs revealed a dilated antrum and/or a dilated stomach fundus. The causes of residual gastric dilatation, on the other hand, are unknown; it might be due to a technical fault or a natural process of stomach tissue dilatation. A dissection that began more than 6 cm from the pylorus might be the most technical reason for wider antrum. In prospective randomized research,[9] Abdallah et al. found that a 2 cm pylorus resection length is associated with improved weight reduction without an increase in the risk of problems. After 2 years, there was a reduced weight recovered rate of 1.9% at 2 cm as opposed to 9.4% at 6 cm (distance from the pylorus). As a result, the stomach should be removed at a distance of less than 4 cm from the pylorus. Lemmens[12] attempted to avoid pouch dilation by strengthening the gastroenterostomy anastomotic site with a silastic ring prosthesis, which he did. This method, however, was abandoned due to an overwhelming rate of band erosion. Fobi[13] reintroduced the ring by placing a silastic ring 2–3 cm below the OG junction and 2 cm above the anastomosis on a vertical pouch. Since then, a variety of prosthetic devices have been released to the market, the most of which are silastic rings that may be inserted around the pouch, proximal to the anastomosis, and are either (laparoscopically) convertible (MiniMizer®) or nonconvertible (GaBP Ring™). Other materials, such as linea alba, fascia lata, porcine, meshes, and bovine grafts, have been developed; nonetheless, surgeons favor silastic rings.[14] It has been reported that a silicone band forms a pseudocapsule, which leads to less adhesion and is simpler to remove than other materials, but other meshes have been demonstrated to cause scar tissue and are harder to remove.[15]

We believe that dilatation of the proximal jejunum, distal to the gastroenterostomy, plays a significant role in the creation of the neo-stomach, leading to a complete loss of restriction. The stomach pouch becomes more flexible over a period of time, and (all) stomas dilate. As a result, all unsuccessful SG conversions have been addressed by converting them to bypass procedures and placing a band across the RYGB's small gastric pouch. This has the effect of restricting and starvation in the patients, resulting in successful weight loss.

Conclusion

Revisional surgery is challenging but safe when performed by professional. Revision from SG to BGBP is technically feasible and safe. For insufficient weight loss or weight regain, conversion SG to BGBP should be one of the possibilities. The overall weight reduction following the BGBP revision is greater than the main SG's maximal weight loss. The resolution of comorbidities improves marginally after revision surgery, but not significantly. More research and a longer follow-up period are needed to corroborate the findings of this study.

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ORIGINAL RESEARCH

Laparoscopic vs Open Appendectomy: Comparison on Clinical Outcome

Ahmed Salim Khazaal

Abstract

Aim: In the past years, studies have reported the superiority of laparoscopic appendectomy (LA) over open appendectomy (OA) in randomized studies. Hence, this prospective study was designed to evaluate the clinical outcome of LA compared to the OA.

Methods: All the patients who were diagnosed with appendicitis and visited Tikrit Teaching Hospital in the study period were included in this study. They were divided into two groups: LA and OA groups. The two groups were compared on operating time, hospital stay, the incidence of surgical site infection, and other postsurgical complications.

Results: In the present study, a total of 128 patients (who visited Tikrit Teaching Hospital in Iraq) were included. Among them, 63 were included in the LA group and 65 people were in the OA group. The only significant difference that was observed in LA and OA group was in CRP count. In the OA group, the CRP count was significantly higher compared to the LA group ($p = 0.024$). The mean operating time was almost comparable between the LA and OA group. Blood loss was higher in the OA group and the difference was statistically significant ($p = 0.038$). Even hospital stay was also shown to be statistically higher in the OA group. A significant difference was reported in the wound infection among the LA and OA groups. In the OA group, wound infection was significantly higher (10.75%) than in the LA group (3.17%). No other adverse events were reported to be statistically different.

Conclusion: Our findings revealed that LA has many advantages over OA, including a shorter hospital stay, earlier return to work, and a lower risk of wound infection.

Clinical significance: LA significantly reduces postoperative complications and improves the surgical outcome.

Keywords: Appendicitis, Hospital stay, Laparoscopic appendectomy.

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Introduction

The most common surgical emergency encountered in any surgical unit is appendicitis. It is the most common condition requiring appendectomy. The lifetime risk of appendicitis is 6%. In the general population, acute appendicitis is reported in approximately 7–10% of people. The most commonly acute appendicitis is reported in people who are in their second or third decade of life.[1]

However, it was reported that the rate of morbidity associated with open appendectomy (OA) is around 11% with an overall mortality rate of 0.3%.[2]

Laparoscopic appendectomy (LA) was introduced in 1983 by a German gynecologist named Kurt Semm. After the introduction of LA, it became popular. In the field of cholecystectomy, the laparoscopic approach has become the gold standard and encouraged by its success in this field even in other surgical fields; also this technique has gained popularity.[3]

In the past years, studies have reported the superiority of LA over OA in randomized studies.[3,4] This technique had shown to have advantages over OA procedures in terms of lower wound infections, fewer incidences of vomiting, less pain, and also shown to be associated with reduced hospital stays and faster recovery time.[5,6] In contrast, it was also reported that operating time is more in the LA group and is associated with higher cost.[6] Moreover, some of the studies failed to show any higher efficacy of LA over OA.[7,8]

The most common complication faced in the OA is the surgical site infection (SSI). This is the most common problem that increases the hospital stay and cost of the procedure. It was noted that in OA the chances of SSI are more and this significantly increases the length of the hospital stay.[9]

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Hence, it is quite evident that, unlike other laparoscopic procedures, in appendectomy, there exists no consensus whether LA is a better option compared with OA. Further, it is also not clear if this procedure can be performed regularly for all the patients. Moreover, in developing countries like India, there are not many studies that have been done in this field.

Hence, this prospective study was designed to evaluate the clinical outcome of LA compared to the OA including the hospital stay, operating time, development of postoperative complications, and time to resume normal activity.

Materials and Methods

This prospective study was conducted in Tikrit Teaching Hospital in Iraq, from a period between May 2019 and December 2020. At the beginning of the study ethical clearance was taken from the institutional ethics committee. All the patients who were diagnosed

with appendicitis and visited the hospital in the study period were included in this study. Patients who were presented with other chronic illnesses and required intensive care, pregnant women, and patients who were not willing were excluded from the study. At the beginning of the study, patients were informed about the study procedure and informed consent was signed. The patients were also informed about both the procedures and the risk and benefits associated with them.

After the patients were confirmed they were randomly divided into two groups, the OA group and the LA group. Each patient was assigned computer-generated numbers for treatment purposes. All the demographic data were collected using a special data format.

Surgical Procedure and Postoperative Procedure

The operations were performed under general anesthesia under the guidance of consultant experienced surgeons. All these surgeons were experienced enough to perform both the procedures and were unknown to the data-collecting procedure. For laparoscopic technique, a standardized 3-port technique was used that uses the open (Hasson) method for establishing pneumoperitoneum. Electrocautery was used for dissection of the mesoappendix. The base of the appendix was tied and then it was divided between two endo-loops with laparoscopic scissors. The specimen was retrieved inside the extraction bag.

Open appendectomy was performed in the standard fashion. After the ligation of the mesoappendix, the appendix was divided at the base followed by its removal without performing invagination. All the specimens were sent for microscopic examination. All the patients received an antibiotic regimen. In case of any technical difficulty, laparoscopic surgeries were converted into OA.

In the postoperative period, bowel sounds were monitored every 12 hours, and once the sound was clear, the patients were put on a liquid diet. After the liquid diet was tolerated, patients were put on a regular diet.

Outcome Measures

The clinical outcome measures were recorded into a prerecorded pro forma including hospital stay, operative time, blood loss, and time to resume the normal activity and diet. The postoperative pain regimen was followed in a standardized fashion including paracetamol 500 mg tablets and intramuscular doses of diclofenac sodium. The different postoperative complications were also recorded for all the patients. The patients were followed up for the next 3 months for any further complications. They were instructed to report to the outpatient department at weekly intervals for 3 months.

Statistical Analysis

The data were collected and were evaluated using SPSS software. The data were calculated as percentages and frequencies for categorical parameters. Pearson's Chi-square test was performed for detecting the significance among continuous variables. $p < 0.05$ was taken as statistically significant.

Result

In the present study, a total of 128 patients were included. The demographic variables were represented in Table 1. Among them, 63 were included in the LA group and 65 people were in the OA group. In the LA group, the patients were in the age-group of 8–85.1 years with a mean age of 35 ± 15.15 years. In the OA group, the mean age was 38.5 ± 17.12 years. No significant difference was reported in the mean age of the participants ($p = 0.12$). Similarly, no statistically significant difference was reported in the number of male and female participants ($p = 0.453$).

No significant difference was reported in terms of co-morbidities also. The most common comorbidity reported in both the group was hypertension followed by COPD. The total WBC count also showed a significant difference in both the groups ($p = 0.16$).

The only significant difference that was observed in LA and OA group was in CRP count. In the OA group, the CRP count was significantly higher compared to the LA group ($p = 0.024$).

Among the study participants, 84.1% of the patients in the LA group had uncomplicated acute appendicitis, while only 61.5% in the OA group had the same. Gangrenous appendicitis was reported in 4.76% of the cases in the LA group and 9.23% of the patients in the OA group (Table 2).

Clinical Outcome and Postoperative Complications

Table 3 describes the outcome parameter of the LA and OA procedures. The mean operating time was almost comparable between the LA and OA group. In the OA group, the operating time was 64 minutes and when compared to the LA group it was 61.5 minutes. Further analysis revealed no such statistically significant difference in the operating time. Blood loss was higher in the OA group and the difference was statistically significant ($p = 0.038$). Even hospital stay was also shown to be statistically higher in the OA group (average 7 days).

Patients who had undergone OA took more time to get back to their normal activities (15 ± 3.1). On the other hand, patients who underwent LA tool-less time to resume normal activity (12 ± 2.3).

Table 1: The characteristics of the patients before surgery according to the procedure

	LA (N = 63)	*OA (N = 65)*	*p value*
Age (years)	35 ± 15.15 (8–85.1)	38.5 ± 17.12 (7–86.5)	0.12
Gender (F/M)	40/23	45/20	0.453
CRP (mg/dL)	1.91 (0.05–26.8)	3.9 (0.03–28.3)	0.024
WBC (10^3/mL)	12.3 (4.3–26.5)	13.0 (4.4–36.4)	0.16
Co-morbidities, *N* (%)			
DM	5 (7.93%)	6 (9.23%)	
Hypertension	10 (15.87%)	12 (18.46%)	
COPD	9 (14.28%)	6 (9.23%)	

Table 2: Surgical findings, *n* (%)

Surgical findings, n (%)	*LA (N = 63)*	*OA (N = 65)*
Uncomplicated acute appendicitis	53 (84.1%)	40 (61.5%)
Gangrenous appendicitis	3 (4.76%)	6 (9.23%)

Table 3: The outcomes according to the procedure

	LA (N = 63)	*OA (N = 65)*	*p value*
Operating time (minutes)	61.5 (28–219)	64 (34–150)	0.67
Blood loss (g)	1 (1–300)	1 (1–848)	0.038*
Hospital stay (days)	5 (2–24)	7 (3–36)	<0.001*
Return to normal life (days)	12 ± 2.3	15 ± 3.1	<0.01

*Statistically significant

Table 4: Number of postoperative complications

Postoperative complication	*LA (N = 63)*	*OA (N = 65)*	*p value*
Surgical site infection (SSI)	2 (3.17%)	7 (10.75%)	0.002
PONV	30 (47.61%)	20 (30.76%)	0.62
Intra-abdominal abscess	1 (1.58%)	1 (1.53%)	0.15
Readmission	0	0	

Table 4 describes the postoperative complications reported in the follow-up period. A significant difference was reported in the wound infection among the LA and OA groups. In the OA group wound infection was significantly higher (10.75%) than in the LA group (3.17%). No other adverse events were reported to be statistically different.

Discussion

Appendicitis is the most common condition that requires surgical intervention. Any patient presenting with an acute abdomen should always consider appendicitis, and proper diagnosis of the condition still poses a challenge.[10] Laparoscopic surgeries have gained much attention in the last decade. In gall stone diseases and many other surgical procedures, the laparoscopic technique has proved to be effective and safe.[11]

After the first report of LA was reported in 1999 in Taiwan, this technique became popular worldwide. In many of the studies, comparison of this technique with the OA was done and it was demonstrated that this technique is well tolerated.[11–13] This technique has several advantages over the open procedures in several surgical sections being a minimally invasive surgery. It was also shown that this procedure with regard to less pain, lower recovery time, and better cosmetic appearance had some of the advantages that this technique has over the OA procedure.[13]

However, contrasting opinions are also available that have reported not many changes between the LA and OA approaches. Hence, no consensus idea exists on this topic. In this present study, the clinical outcome between the OA and LA was conducted and we hope that the study results will be able to help future researchers to conduct a large cohort study.

In the present study among the total 128 patients, 63 were included in the LA group and 65 people were in the OA group. No statistically significant difference was observed between both the groups with respect to age, gender, WBC count, and co-morbidities. However, in the level of C-reactive protein (CRP), a significant difference was observed between LA and CA patients. Patients who underwent OA had a higher level of CRP compared to the LA group. In the past, it was reported that CRP level can predict the occurrence of SSI in appendectomy cases independently.[14]

In the study participants, maximum of the patients had uncomplicated acute appendicitis and gangrenous appendicitis was reported in 4.76% of the cases in the LA group and 9.23% of the patients in the OA group. This is also an interesting finding as other than CRP level pathology of the condition has also shown to be associated with the SSI among appendectomy patients.[14]

In the present study, longer operating time was reported in the OA group. In the LA group, the operating was almost 4 minutes slower than the OA group. However, this difference was not found to be statistically significant. The operating time measured in this study is skin-to-skin time. This present study result is in accordance with the previous studies that have reported a similar lower operating time in LA group.[3–5]

Usually, a longer operating time in LA occurs because of the lower experience of the surgeons performing the surgeries. Two factors are usually dependent on the experience of the surgeons: blood loss and operating time. With the increased experience of the surgeon the blood loss and operating time both decrease. Even, the pathological conditions of appendicitis also dictate the amount of blood loss and operating time.[15] In our study also blood loss was significantly lower in the LA group compared to the OA group.

The present study also reported a shorter hospital stay for the patients who underwent the LA procedure. Hospital stay is another factor that increases the cost of the operation and poses an economic burden on the patient. Though we did not compare the cost of both the technique, it is quite apparent that the cost will be lower in the LA group. Our result is consistent with the early studies that pointed out significant lower hospital stay in LA group.[11,16]

Patients who had undergone OA took more time to get back to their normal activities (15 ± 3.1). On the other hand, patients who underwent the LA took less time to resume normal activity (12 ± 2.3). Our study also reported lower incidences of SSI in the LA group. In the OA group, wound infection was significantly higher (10.75%) than in the LA group (3.17%). This could be because in OA direct exposure of the wound site occurs in the procedure. Whereas, in the LA, the specimen was removed using an extraction bag. This finding also is similar to the previous finding by Shimoda et al.[9] However, the instances of PONV were higher in the LA group. None of the group patients required readmission.

Conclusion

Our findings revealed that LA has many advantages over OA, including a shorter hospital stay, earlier return to work, and a lower risk of wound infection. Also, we discovered that patients in the laparoscopic group had a strong preference (during consent collection) and high satisfaction after surgery.

Clinical Significance

LA should be considered secure and similarly effective to open surgery if surgical experience and equipment are available. It could be used as the first treatment of choice in most cases of suspected appendicitis, as it significantly reduces postoperative complications and improves the surgical outcome.

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ORIGINAL RESEARCH

A Laparoscopic Approach of a Very Large Ovarian Cyst in Young Female

Mukesh Carpenter

Abstract

Large ovarian cysts are ovary tumors with diameters more than 10 cm. Nowadays days these cases are rarely seen because they are diagnosed and managed early due to the ease of access to good imaging modalities. Benign serous cystadenoma is the most common type of epithelial neoplasm with benign serous cystadenoma ¾ and mucinous cystadenoma ¼. During the surgical management of large ovarian cysts in young girls, the main goal to keep in mind is the preservation of the reproductive and hormonal function of the ovaries. In this paper, the author represents a case report of a young female diagnosed with a very large ovarian cyst with a diameter of approximately 30 cm managed using laparoscopic surgery.

Keywords: Benign ovarian cyst, Laparoscopy, Minimal access surgery, Ovary.

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Introduction

The most common cause of pelvic masses in women is ovarian cysts and the majority of the cases can be seen in the fertile age-group. In India, it has been observed that nearly 10% of the female population undergo a surgical approach for ovarian cyst during her lifespan. Epithelial neoplasm of the ovary account for more than half of all ovarian tumors and almost 40% are benign tumors.[1] Most of the large ovarian cysts are benign and are generally treated via. surgical excision such as cystectomy or salpingo-oophorectomy. At the early stage, most cases seem to be asymptomatic and cause symptoms only after reaching a stage of massive dimension. The clinical symptoms mainly include vaginal bleeding, progressive abdominal distension, early satiety, imprecise diffuse abdominal pain, constipation, vomiting, and recurrent micturition.[2,3]

Nowadays benign ovarian cysts of more than 10 cm are rarely encountered due to early diagnosis and treatment. Laparoscopy is the treatment of preference in most cases, but the size of the cyst can be a limiting factor.[4] With the increased ovarian cyst size, the complication of a minimally invasive technique also increases due to problems in creating a pneumoperitoneum, decrease in visibility and surgical mobility. All the listed factors result in a high risk of intraoperative spillage. In literature, several case reports are present where different surgical techniques are used to reduce abdominal spillage, but these techniques are not suitable for a larger ovarian cyst that occupy the whole abdominal cavity. Sevelda et al.[5] also state that the intraoperative rupture of ovarian cyst did not influence the prognosis. The author studied the survival of patients with moderately and poorly differentiated stage 1 ovarian carcinoma and concluded that no differences in the survival rate between the patients with intraoperative cyst rupture.[6,7]

Case Presentation

My patient is a 26-year unmarried female belonging to a middle-class family who came with complaints of progressive abdominal distension, vague abdominal pain, hyperacidity for a few months. She also gave a history of heavy flow during her last two menstruation cycles; her cycles are 28-days 3–4 days of bleeding.

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No bowel and urinary disturbance. No history of any gynecological malignancy in the family. No history of any surgical intervention in past.

On examination abdominal distended above the umbilicus bilateral flanks are full, fluid thrill present. Per vaginal examination fullness is present mainly on the right side. Her routine blood investigation and serum tumor markers were well within the normal range (Beta HCG—0.36 mIU/mL, CA125—8.6). Serum CA-125 assay is a useful tool that helps to distinguish between benign and malignant ovarian masses. The combination of normal findings at serum CA-125 assay, imaging, and clinical findings exclude the possibility of ovarian cancer.[8]

Ultrasound

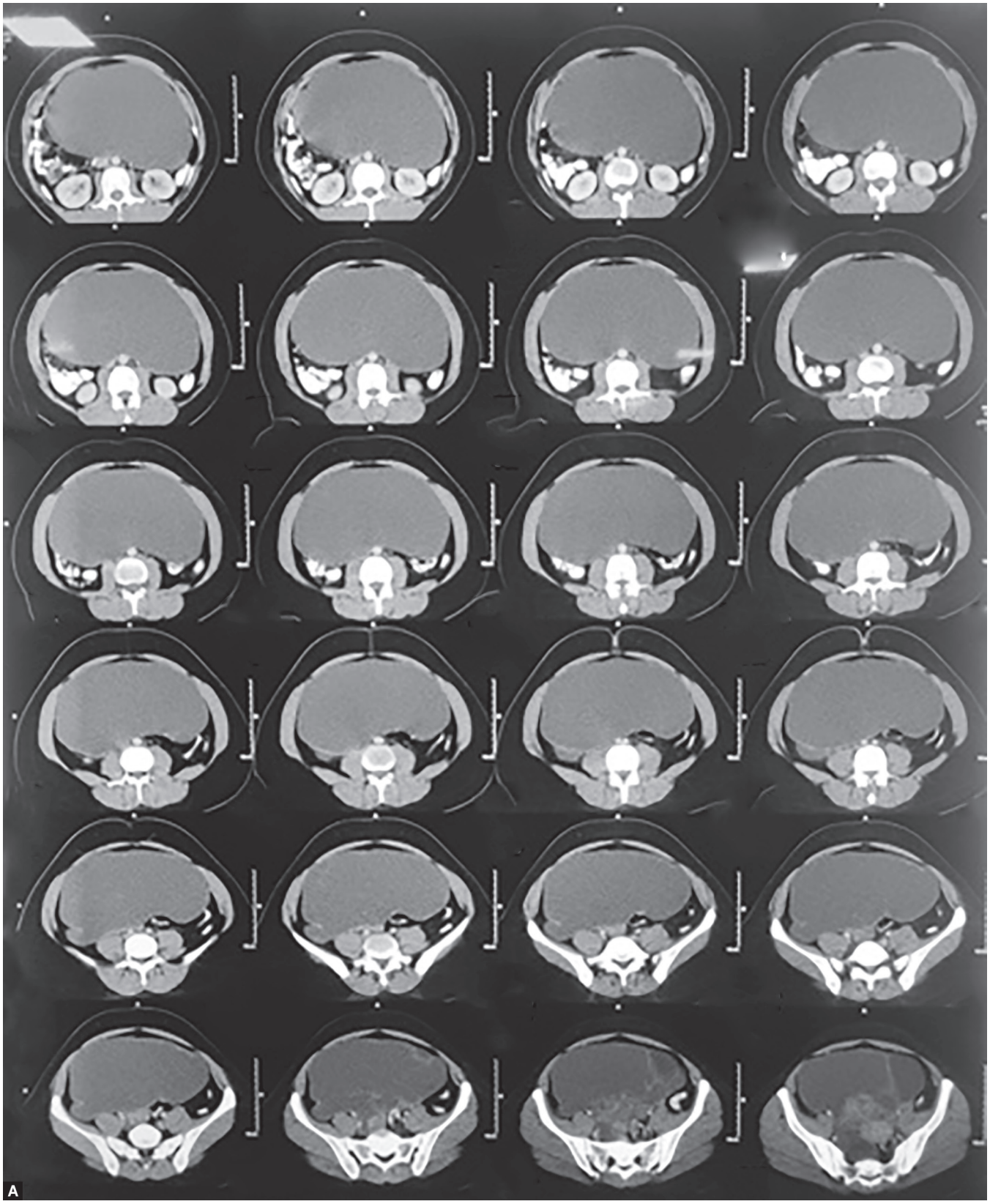
A large anechoic mass with internal septation arising from the pelvis extending up to epigastrium and bilateral lumbar region approximate size 28 cm × 23 cm × 20 cm, volume approximate 4875 mL, displacing the bowel and other visceral organs. Bilateral ovaries are not separately visualized.

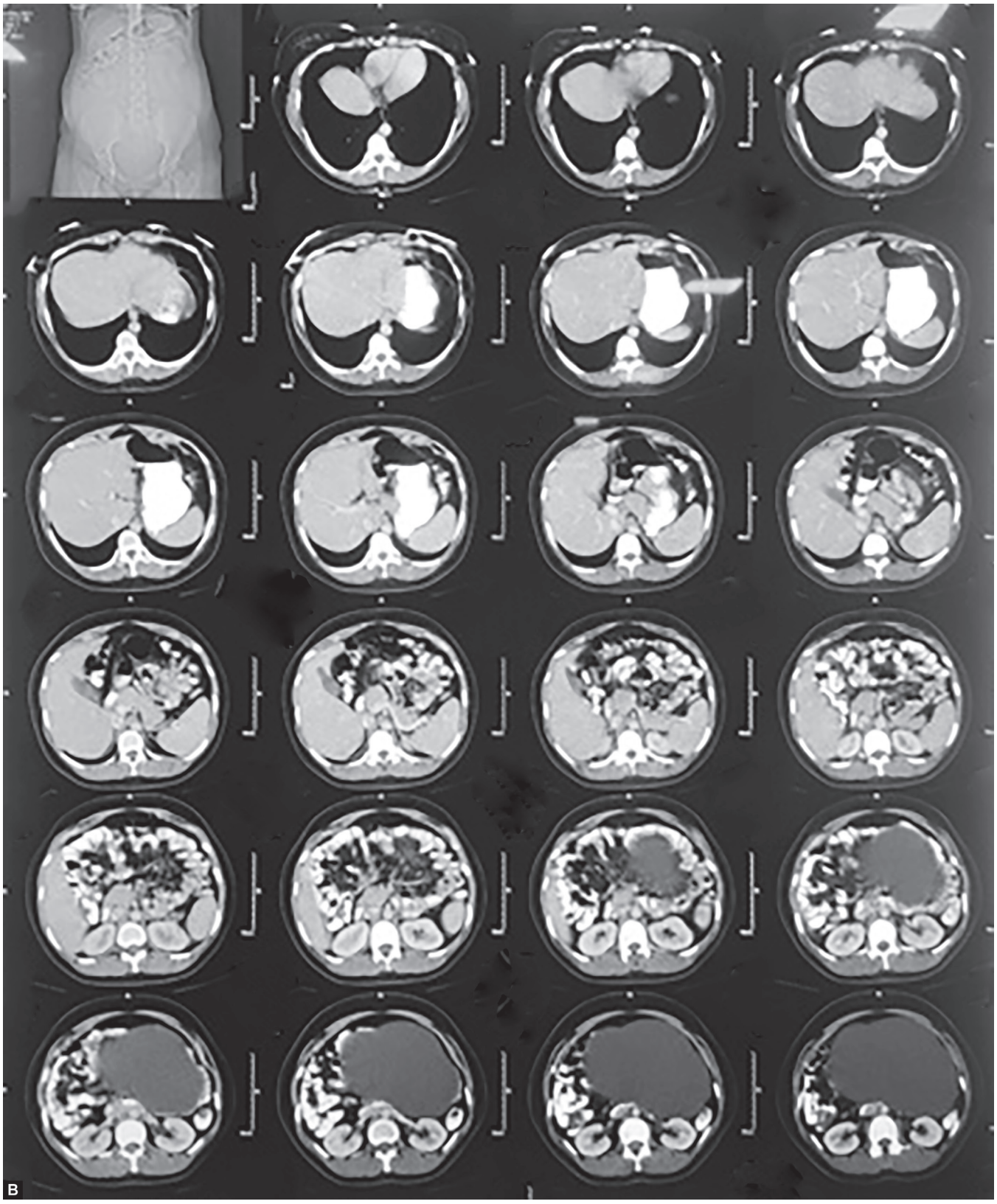
CECT Abdomen and Pelvis

Large nonenhancing capsulated thin-walled with internal septation tubo-ovarian cystic mass arising from the right side of pelvis size 30 cm × 22 cm × 23 cm, volume almost 5000 mL occupying whole abdomen extending up to epigastrium and bilateral lumbar region repelling the bowel and other visceral organs. Uterus pushed to

opposite side left ovary visualized and appears normal. Adhesions present between tubo-ovarian mass, urinary bladder, and uterus as shown in Figure 1.

The patient planned for a laparoscopic procedure after evaluation and preanesthetic checkup. Umbilical port placed using open technique luckily cyst was not punctured in this case.

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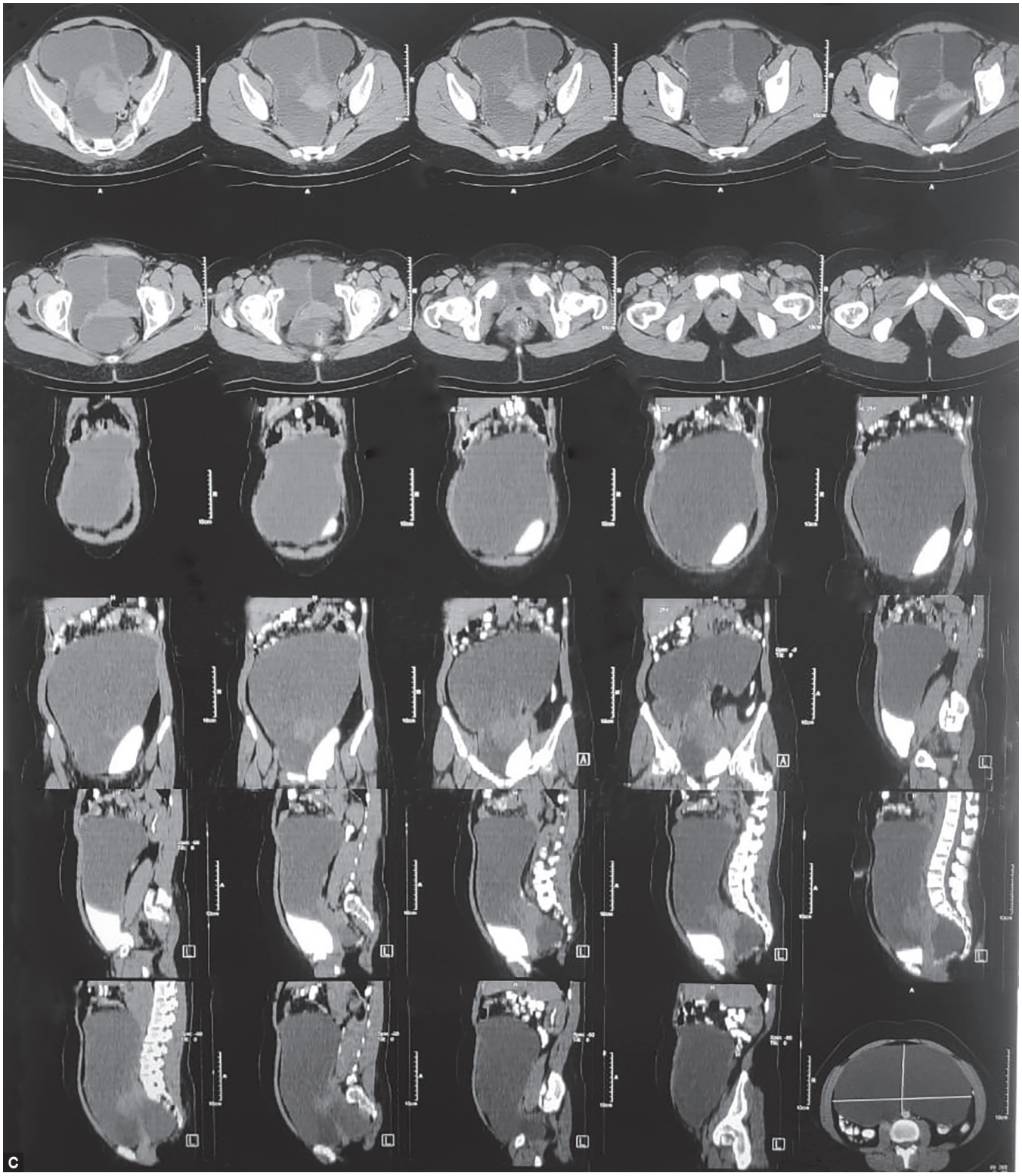

Figs 1A to C: Large tubo-ovarian cystic mass arising from the right side of pelvis occupying almost whole abdomen

After creating pneumoperitoneum and inserting three accessory ports, the cyst was deliberately punctured and approximately 5 L cystic fluid drained after breaking internal septations; sample send for cytological analysis (Figs 2 to 5).

Adhesions present between the cystic wall and right side of bowel loops and rectum. The cystic wall is densely adherent to the urinary bladder and to the uterus. Very hard to find a plane between the urinary bladder and cystic wall. To make the plane visible urinary

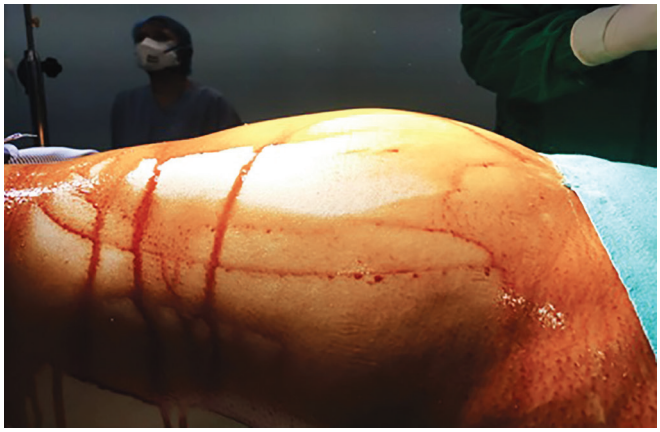

Fig. 2: Patient under general anesthesia (GA)

Fig. 5: Large ovarian cystic fluid

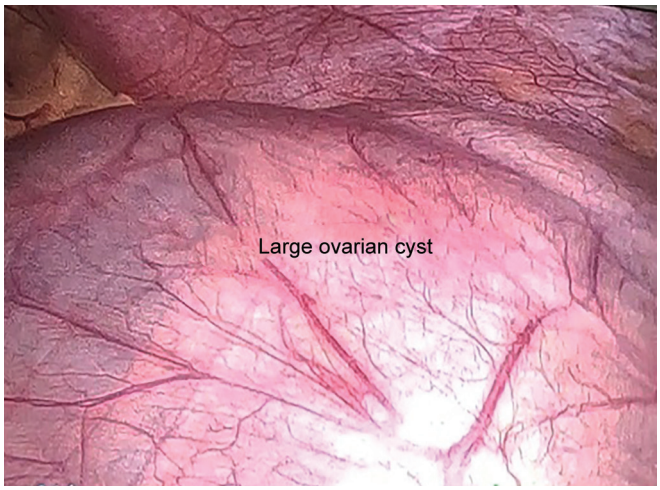

Fig. 3: Laparoscopic view of large ovarian cyst

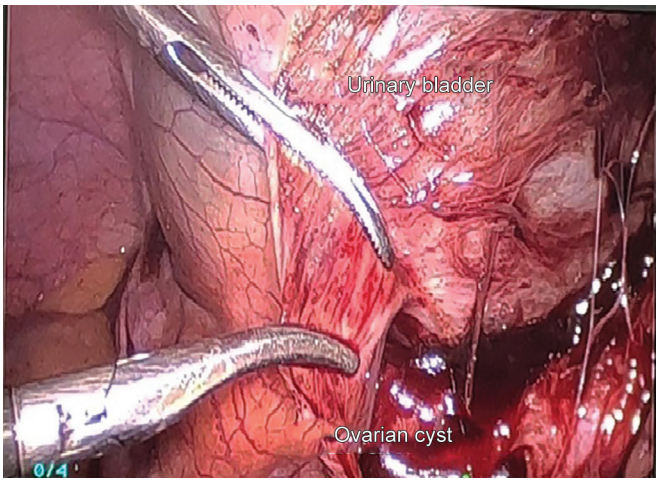

Fig. 6: Adhesions between the urinary bladder and large ovarian cyst wall urinary bladder filled with saline

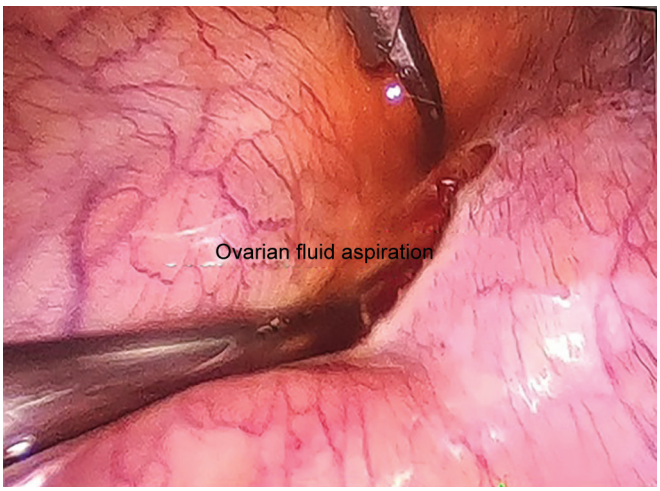

Fig. 4: Ovarian fluid aspiration using a suction catheter

bladder was filled with 500 mL of saline meticulous dissection was done and slowly proceeded. Ovarian cyst wall dissected from the urinary bladder (Fig. 6).

The ovarian cyst was removed after enlarging the left iliac fossa working port to 3–4 cm to remove an ovarian cyst in small pieces. Extracting such a large ovarian cyst through a small incision requires a lot of patience, zigzag movement helps in early extraction. Specimen send for histopathological examination (Fig. 7).

No bowel and bladder injury was encountered during surgery. The left side ovary and fallopian tube are normal. Through wash given using 8–10 L of normal saline. Drain placed in the pelvis (Fig. 8).

The Postoperative patient extubated her vitals were stable.

Postoperative day-1 Hb—9.7 g drain was 600 mL vitals were normal with good urine output. The patient started on liquids after 8 hours of surgery and proceed to a soft diet for the next 24 hours. The postoperative day-2 drain was 400 mL vitals were stable with good urine output and the patient was ambulant tolerating oral soft diet. On postoperative day-2, the patient was discharged with drain and Foley's catheter. The patient called for a review on postoperative day-5 her drain was 60 mL serous (day-3—280 mL, day-4—120 mL) urine output was good 2 L plus in 24 hours. Both drain and Foley's were removed on postoperative day-5. Postoperative day-12 all sutures were removed as Figure 9. Histopathology report: benign serous cystadenoma.

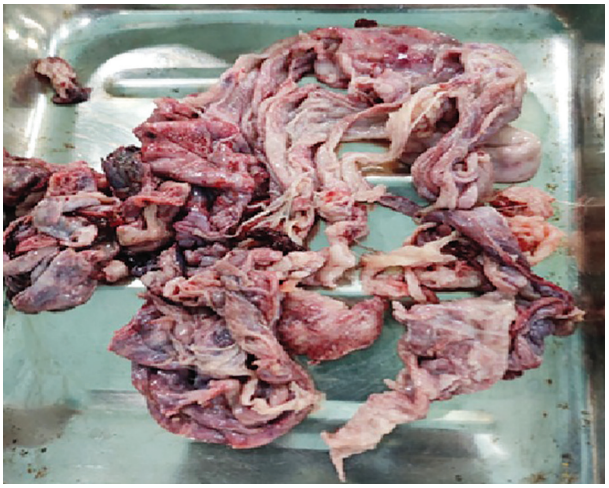

Fig. 7: Large ovarian cyst specimen

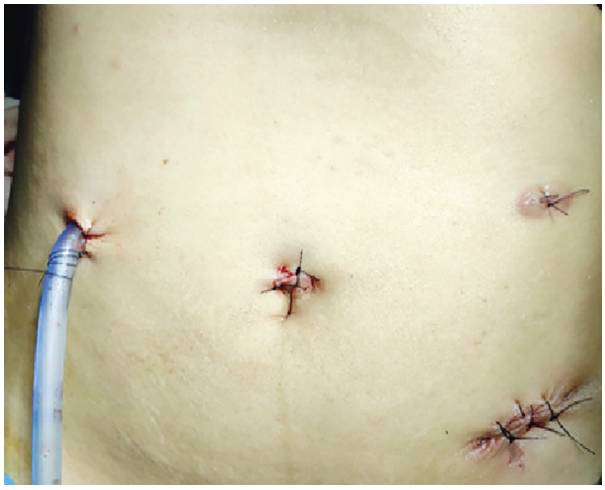

Fig. 8: Post-surgery with drain

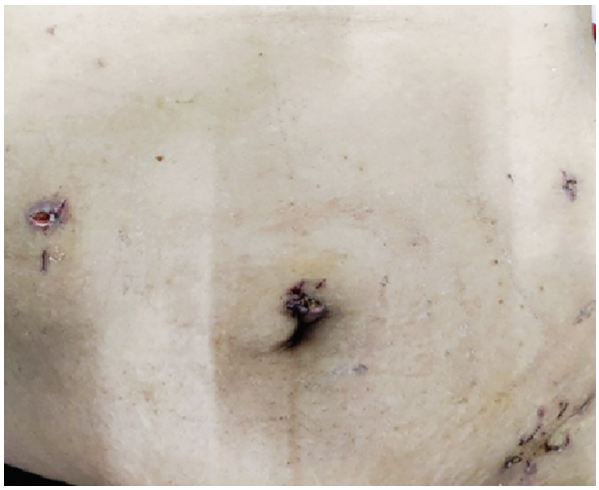

Fig. 9: Minimum scar to the abdomen

Discussion

In the last few years, surgical treatment has become less invasive and conservative. In today's world, a laparoscopic method in the presence of assumed benign cysts has become a gold standard.[9] In the case of laparoscopic surgery treatment depends on several criteria such as age, menstruation cycle status, size, and structure of ovarian cyst.

Minimal invasive surgical management for benign ovarian cysts has become popular nowadays. Various studies demonstrated a clear advantage of laparoscopy as compared to standard open surgery in terms of lesser amount of blood loss and analgesic requirement, better visibility during surgery, minimum postoperative pain, decreased days of hospital stay, and better cosmetic outcomes. The person can resume to normal activity early.[10]

During the surgical management of large ovarian cysts in young girls, the main goal to keep in mind is the preservation of the reproductive and hormonal function of the ovaries. Frequently cysts have dense adhesions with the ovary and persevering ipsilateral ovary could not be possible as encountered in this paper.

The laparoscopic approach for large ovarian cysts presents various difficulties.

- Cyst rupture and spillage during the introduction of trocar/veress needle.
- Less working space.
- Dense adhesions with less space especially in the pelvis make anatomical landmarks almost invisible.
- Extracting such a large cyst is very time-consuming and troublesome work.

The author has taken care of the hormonal and reproductive function of the young girl with a very minimal scar to the abdomen.

Conclusion and Recommendation

Laparoscopic surgical management of very large ovarian cysts is a technically and surgically challenging task. The laparoscopic approach should be considered in young girls whenever feasible who have normal tumor markers and imaging modalities that suggest benign ovarian cyst.

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ORIGINAL RESEARCH

Medtronic I-Drive vs Ethicon Echelon: A Head-to-head Randomized Controlled Trial

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Abstract

The views expressed in this publication/presentation are those of the author(s) and do not reflect the official policy or position of William Beaumont Army Medical Center, Department of the Army, Defense Health Agency, or the US Government.

Background: There have been numerous studies comparing various aspects of bariatric surgery, such as hand sewn vs stapled anastomoses, electronic vs manual staplers, and reinforced vs nonreinforced staple lines. There has never been a randomized controlled trial comparing different staplers in sleeve gastrectomies.

Methods: Our study was a randomized control trial comparing the staple reload time, complications, and stapler cost for the Medtronic I-Drive and the Ethicon Echelon. Our primary endpoints were time, hemostasis, bleeding, necessity for transfusion, and leak rate in a military system.

Results: Sixty-three patients were consented for the study with a final number of 26 in the Echelon arm and 25 in the I-Drive arm after fallout. There were a total of 140 stapler reloads in the Echelon arm and 123 in the I-Drive arm. The median staple reload times were 39.78 seconds for the I-Drive and 41.77 seconds for the Echelon ($p = 0.42$). The total time for sleeve creation was 12.14 minutes in the Echelon arm and 14.26 minutes in the I-Drive arm ($p = 0.04$). There were two misfires in each group (four total) and no positive leak tests, transfusions, or postoperative complications. The average cost for staplers, reloads, and reinforcement for the I-Drive was $2,037.26 for the civilian rate and $2,097.66 for the government rate. The average cost for the Echelon was $1,835.65 for the civilian rate and $2,268.97 for the government rate.

Conclusion: The Medtronic I-Drive and the Ethicon Echelon are comparable in reload time, stapler misfires, leak test rates, and cost.

WBAMC IRB Study Trial Number: NCT02731079.

Keywords: Bariatric surgery, Linear stapler, Minimally invasive surgery.

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Introduction

Obesity rates in the United States continue to rise and with the CDC reporting the prevalence rate of obesity in adults at 42.4% as of 2018.[1] The rate of bariatric surgeries in the United States has risen in a concomitant fashion. The total number almost doubled between 2011 and 2018 with 252,000 bariatric surgeries performed in 2018 and sleeve gastrectomies representing the predominant growth at 61.4% of bariatric interventions.[2]

In the late 1980s, Dr Doug Hess developed the sleeve gastrectomy as an alternative to the vertical gastrectomy, which imparted a restrictive function to the biliopancreatic diversion.[3–5] Addition of a gastrectomy to the biliopancreatic diversion also allowed for a reduction in the length of bowel bypassed without compromising weight loss results and preservation of the pylorus aids in decreasing complications like dumping.[6–8] In the early 2000s, sleeve gastrectomies developed into a shorter, safer initial operation for the super morbidly obese population in preparation for a more extensive operation, such as the Roux-en-Y gastric bypass or the biliopancreatic diversion.[9] However, in recent years, sleeve gastrectomies have established their role as a safe, single-stage operation.[10]

The most significant early postoperative complication is bleeding from the long staple line with reported rates as high as 16% with an average of 3.6%.[11–13] Another serious complication is the development of a gastric leak with reported incidences as high as 3.7%, which are more commonly found at the proximal anastomosis compared to the distal.[14–16] Various proposed modalities for decreasing the rates of these complications include oversewing the staple line, buttressing the staple line with organic or synthetic reinforcement material, and placing biological sealant.[17] There is a general consensus that any staple line reinforcement is superior in preventing leaks compared to no reinforcement, but evidence for a superior type of reinforcement remains controversial.[18–20]

With a rising popularity in sleeve gastrectomies among bariatric surgeons and patients, comprehensively researching all aspects of the operation is critical for optimizing patient outcomes. There have been many studies evaluating the safety and efficacy of sleeve gastrectomies, but to our knowledge, there is a paucity of data available for head-to-head analyzes of the time and cost differential between competing linear stapler devices with an absorbable polymer membrane reinforcement. We sought to compare the Ethicon Echelon Flex with Seamguard bioabsorbable reinforcement (W.L. Gore & Associates, Inc.) with the Covidien Endo GIA reinforced reload with tri-staple technology (Medtronic, Minneapolis, Minnesota, USA).

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Conflict of interest: None

Methods

We designed a randomized control trial that received institutional IRB approval. All patients underwent surgery at our facility after completing our institutional bariatric pathway to include bariatric seminars, support groups, extensive medical workup, and psychological evaluation. We excluded patients from participating in the study if they needed revisional surgery or presented with inflammatory bowel disease. We counseled all patients that each of the linear staplers used in the study are approved devices for their surgery and the surgeons performing the operation trained to operate with both devices. A total of 63 patients consented to participate in the study and randomized to each arm.

The Ethicon Echelon powered stapler—with and without Seamguard—and the Medtronic I-Drive powered stapler with reinforcement comprised the two arms of the study. All laparoscopic sleeve gastrectomies were performed with an absorbable polymer membrane staple line reinforcement. The majority of surgeons in this study elected to use Seamguard on all Echelon loads except for the load most proximal to the gastroesophageal junction. There were 7 staff surgeons and 19 residents that participated in the study. Patients were randomized into each arm at the time of their consent to the study. Two researchers performed the randomization sequence by annotating the study arm on a sheet of paper along with an arbitrary sequential numerical identifier, which were stored in a secure envelope and blindly drawn at the time of consent. We enrolled all patients that consented within the study period, and an interim analysis demonstrated a prohibitive number of participants would be necessary to demonstrate statistically significant data—at which point study recruitment was concluded (Flowchart 1).

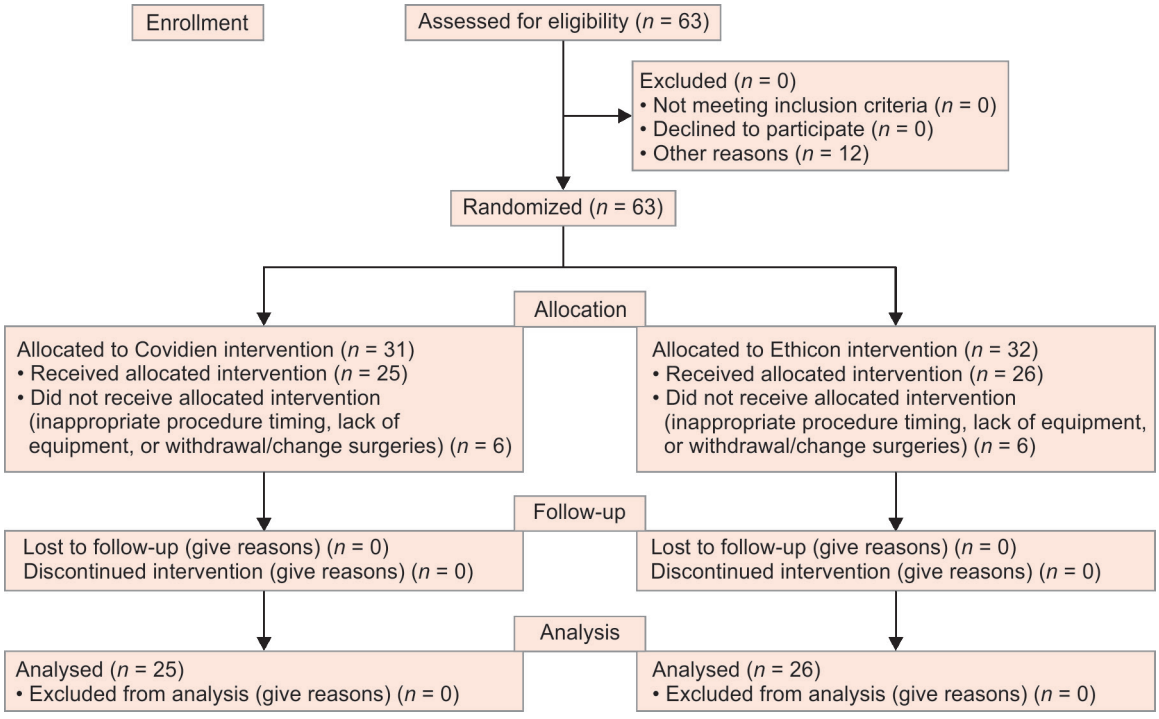
Our primary end points included sleeve creation time (minutes), time to reload (seconds), hemostatic intervention, transfusion, perioperative leak rate, postoperative leak rate, serious complication, mortality rate, and stapler cost (government and commercial rate). The reload time for each staple load was defined as the time from when the stapler exited the trocar until the stapler was ready to be fired again, which we defined as when the stapler was handed back to the surgeon or placed on the Mayo stand if the surgeon was not ready to staple. A physician who was not participating in the operative portion of the case was present to time the surgery. We recorded stapler misfires and results of leak tests, which were determined by the operative surgeon. A Mann-Whitney test was used to compare the distribution of reload times between the two groups.

The cost for civilian vs government institutions for staplers, staple loads, and reinforcements was gathered from the government supply-ordering website and included in the analysis. The cost of each surgery for the Ethicon Echelon was calculated by adding the cost of the color of load, the number of Seamguards that were used, and the cost of the disposable stapler. The Medtronic I-Drive cost was calculated by the cost of the color of load with the pre-attached reinforcement. The cost of the I-Drive stapler was not included as it is not disposable. We did not include the cost of Seamguards or loads that were opened but not used. We performed a pooled *t*-test to compare the two groups.

Results

We consented 63 patients for the study and randomized participants into the Echelon with Seamguard (ESG) or I-Drive with EndoGIA reinforcement arms (GIA-R) between January 2018 and May 2019—we terminated recruitment due to difficulty obtaining additional participants. There were 31 patients in the ESG arm and 32 in the GIA-R arm. After fall-out, a total of 51 patients remained with 26 in the ESG arm and 25 in the GIA-R arm. All patients in the study completed the Bariatric Pathway at our institution. Their baseline demographics are presented in Table 1. All procedures were completed laparoscopically with no

Flowchart 1: Trial profile



intraoperative complications. There were three stapler misfires in the GIA-R arm—a malfunctioning reload requiring physician assist to reload, stapler stuck on staple line, and improper loading resulting in stapler jam. There was one stapler misfire in the ESG arm due to a misfire caused by the Seamguard string not being pulled. All operations had a negative leak test in both the perioperative and postoperative periods.

The primary endpoints are summarized in Table 2. In respect to total time for sleeve creation, 15.63% of sleeve creations using the GIA-R system required a hemostatic intervention compared to 34.38% in the Echelon arm ($p = 0.44$). Half of all staple line bleeds across both arms resolved spontaneously—the remaining half-achieved hemostasis using a surgical clip with one exception requiring a hemostatic agent. All operations did not require blood transfusion and were without serious complications as defined by the American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP).[21] There was no mortality in either group.

There was a mean of 5.38 stapler loads used per sleeve gastrectomy in the ESG group and a mean of 4.92 stapler loads used per sleeve gastrectomy in the GIA-R arm ($p = 0.052$). There were 140 stapler loads used in the ESG arm and 123 used in the GIA-R arm. The median reload time was 41.77 seconds in the ESG group 39.78 seconds in the GIA-R group ($p = 0.4242$). The total time for sleeve creation was 12.14 minutes in the ESG arm and 14.26 minutes in the GIA-R arm ($p = 0.04$).

The total cost for the stapler supplies used in each arm was calculated at both the government rate and the commercial rate listed on the government-ordering website. The mean total government cost for the ESG was $2,449.44 and $2,097.66 for the GIA-R ($p = 0.0002$). The mean total commercial cost for the ESG was $1,982.17 and $2,037.25 for the GIA-R ($p = 0.4774$).

Table 1: Summary of baseline demographics for study participants

	Ethicon Echelon with Seamguard (ESG) (n = 26)	*Covidien I-Drive with GIA reinforcement (GIA-R) (n = 25)*
Age	36.4	33.2
Gender		
Male	5 (20.0%)	1 (3.8%)
Female	20 (80.0%)	25 (96.2%)
Race		
White	12 (48.0%)	15 (57.7%)
Black	5 (20.0%)	1 (3.8%)
Other	8 (32.0%)	10 (38.5%)

Discussion

The laparoscopic sleeve gastrectomy is now the most commonly performed bariatric surgery in the world, owing to its low rates of morbidity and effectiveness in reducing comorbidities in both the adult and pediatric populations.[22–24] However, complication rates of perioperative bleeding and leakage are still suboptimal, though the use of staple line reinforcement as a mitigation strategy for these morbidities is established.[25] Our institution aimed to perform a head-to-head analysis of the time and cost to reload two commonly used powered linear staplers with staple line reinforcement in laparoscopic sleeve gastrectomies.

In respect of time analysis, there are also significant differences between the reloading mechanism of each platform. The Echelon device has a reloadable, staple containing plastic cartridge that is mechanically secured to the powered unit via a snap-in system. The absorbable polymer reinforcement is subsequently attached. In comparison, the entire shaft of the I-Drive platform is exchanged with each staple reload and each reload cartridge contains the staple line reinforcement already attached. However, the powered unit of the I-Drive platform requires a diagnostic systems check with each cartridge reload whereas the Echelon is ready to fire. In our study, each arm did not have a statistically significant difference in the number of staple reloads required to conduct the operation ($p = 0.052$). Moreover, the time required to reload the staple cartridge and add the staple line reinforcement in the Echelon arm was equivalent to the time needed to change the shaft with the pre-attached staple line reinforcement and perform the diagnostic system check in the I-Drive arm ($p = 0.4242$). However, there was a statistically significant faster time to sleeve creation using the Echelon platform at 12.14 minutes vs the Covidien I-Drive platform at 14.26 minutes ($p = 0.04$). Though the difference in time to sleeve creation was statistically significant, we feel that the mean difference of 2.08 minutes is not clinically significant.

In respect of cost analysis, there are differences between the two powered staplers due to the ancillary purchase required to conduct the operation. While the I-Drive is re-usable after re-processing, the Echelon stapling device is disposable and thus, requires purchase with each operation. The cost of the staple reloads with staple line reinforcement in the I-Drive platform range from $413.94 to $472.36. In comparison, the staple reloads for the Echelon range from $156.60 to $178.26. However, the absorbable polymer reinforcement is purchased separately and costs an additional $164.54 for commercial use and $224.03 for government use. Thus, the mean total cost for conducting a sleeve gastrectomy

Table 2: Table of primary end points for the Ethicon Echelon with Seamguard vs Covidien I-Drive with GIA reinforcement

	Ethicon Echelon with Seamguard (ESG) (n = 26)	*Covidien I-Drive with GIA reinforcement (GIA-R) (n = 25)*	*p value*
Sleeve creation time (minutes)	12.14	14.26	0.04
Time to reload (seconds)	41.77	39.78	0.42
Hemostatic intervention	34.38%	15.63%	0.44
Transfusion	None	None	n/a
Perioperative leak rate	None	None	n/a
Postoperative leak rate	None	None	n/a
Serious complication	None	None	n/a
Mortality rate	None	None	n/a
Stapler cost (Government rate)	$2,449.44	$2,097.66	0.0002
Stapler cost (Commercial rate)	$1,982.17	$2,037.25	0.48

with the Echelon and I-Drive powered staplers was $1,906.25 and $2,037.26 in the commercial sector and $2,356.24 and $2,097.66 in the government sector, respectively. The difference in cost between platforms was not statistically significant with a *p*-value of 0.4774 in the commercial sector, but the cost of the I-Drive platform was significantly lower in the government sector with a *p*-value of 0.0002. Thus, our single-center, randomized control trial demonstrated a significant decrease in cost for the I-Drive platform in the government sector, no difference in the time needed to reload the I-Drive and Echelon platforms, a statistically significant—but not clinically significant—overall time to sleeve creation, and no difference in perioperative or postoperative complications such as leak or bleeding rates.

Our study is not without limitations. Previous studies have evaluated patient characteristics, calibration size, and percentage of excess weight lost,[26] which we did not assess in our analysis. The scope of the data reported focuses on the relatively absent cost and time differential between commercially and publicly available powered linear staplers on the market for laparoscopic sleeve gastrectomies in bariatric surgery. Moreover, the absence of a statistically significant difference in our results is potentially a result of modest sample size due to fall-out and suboptimal recruitment prior to randomization in the study.

Conclusion

The cost per sleeve gastrectomy at commercial facilities and the time needed to change staple loads for the Medtronic I-Drive and the Ethicon Echelon powered staplers is not significantly different in our military facility.

Acknowledgments

Though our study is a randomized controlled trial, our data-sharing plan will not include making individual participant data publically available. Because our study was performed at a military facility, individual participant data are considered sensitive government information and will remain classified.

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ORIGINAL RESEARCH

Laparoscopic Ventral Hernia Repair: Our Experience and Review of Literature

Tajamul Rashid[1], Mohammad Mohsin[2], Musharraf Husain[3], Manzoor Ahmad[4]

Abstract

Background: The incidence of primary ventral hernias has been relatively static, while the incidence of incisional hernias has increased over time with the increase in the number of abdominal surgeries performed. The repair of ventral wall hernias continues to be a surgical challenge. Laparoscopic ventral hernia repair is nowadays being performed in every laparoscopic center and has become a preferred treatment methodology of ventral hernias. This approach is a feasible option for almost all ventral hernias.

Materials and methods: This was a prospective observational study, conducted in the Department of Surgery, Hamdard Institute of Medical Sciences and Research, New Delhi over a period of 2 years from December 2016 to December 2018. A total of 40 patients who met the inclusion criteria were included in the study. The procedure was done by a single surgical team. The average follow-up ranged from 6 to 12 months.

Results: Out of 40 patients in the age-group of 30–79 years, 24 were females and 16 were males. Fifty-five percent of the patients had incisional hernias with the average defect size ranging from 2 to 4 cm. The average operative time was 71–90 minutes. The hospital stay ranged from 2 to 4 days. There was no major intraoperative complication in our study. There was no conversion to open. Early postoperative pain was noted in 10 patients. Port site infection was noted in one patient and two patients developed postoperative seroma. Chronic pain was noted in one patient at 6 months follow-up. Port site herniation was noted in none. The recurrence of hernia was noted on one patient at the end of the follow-up.

Conclusion: Laparoscopic ventral hernia repair, although sometimes technically challenging is an extremely safe and effective option in the management of ventral hernias. This approach offers a good cosmetic outcome to the patient without compromising on the results of hernia repair.

Keywords: Incisional hernia, Laparoscopic repair, Ventral hernia.

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Introduction

The word hernia in Greek means "Bud" and in Latin means "Rupture".[1] A hernia is defined as an abnormal protrusion of a viscera or tissue through a defect in its surrounding wall. A ventral hernia usually arises in the abdominal wall where a previous surgical incision was made, hence the name incisional hernia. Hernias in the ventral wall of the abdomen may be primary or acquired later in life. The incidence of primary ventral hernias has been relatively static, while the incidence of incisional hernias has increased over time with the increase in the number of abdominal surgeries performed. In the United States alone, it is estimated that 3–5% of patients who undergo laparotomy will develop ventral wall hernia (incisional hernia).[2,3]

The repair of ventral wall hernias continues to be a surgical challenge. Historically, ventral wall hernias were repaired by open techniques prior to 1993, but at the cost of very high recurrence rates varying from 8 to 63%.[4] Minimally invasive surgery has been a breakthrough in the surgical sciences. Erich Mühe performed the first laparoscopic cholecystectomy in 1985. Thereafter, there was an explosion of laparoscopic procedures. The first laparoscopic ventral hernia repair was done by LeBlanc and Booth.[5]

Laparoscopic ventral hernia repair is nowadays being performed in every laparoscopic center and probably has become a method of choice for the treatment of ventral hernias. About 20–27% of repairs are performed laparoscopically in the United States.[6] With the advent of meshes, the recurrence rates have been brought down to as low as 1–14% as reported in some series.[4] The laparoscopic approach involves safe entry into the abdomen, adhesiolysis, reduction of contents and the sac, with reinforcement or bridging of the fascial defect, with appropriate sized mesh placed posterior to the fascia in the intraperitoneal anatomic space. This approach is a feasible option for almost all ventral hernias. This is particularly beneficial for hernias with multiple defects (Swiss cheese hernias) as a single mesh can cover all the defects. It has benefits of shorter hospital stay, less pain, and better cosmetic results, although it continues to remain a challenging procedure, more so in the reoperative abdomen and in patients with serious comorbidities. The contraindications for laparoscopic ventral hernia repair are the same as those for any major laparoscopic operation. In addition, it is relatively contraindicated in patients who are morbidly obese. Such patients should be counselled for weight loss surgery prior to hernia repair.

Inclusion and Exclusion Criteria

Patients in all age-groups and of both sexes with diagnosed (clinical and radiological), primary or acquired ventral hernias of any size were included in the study. Patients with multiple previous

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laparotomies, chronic liver and lung diseases, strangulated and obstructed hernias, and very large hernias with loss of domain were excluded from the study. In addition, patients with recurrent ventral hernias, morbid obesity, associated malignancies, and those having general contraindications to major laparoscopic surgeries were also excluded from this study.

Materials and Methods

This was a prospective observational study, conducted in the Department of Surgery, Hamdard Institute of Medical Sciences and Research, New Delhi over a period of 2 years from December 2016 to December 2018. A total of 40 patients who met the inclusion criteria were included in the study. The procedure was done by a single surgical team. The average follow-up ranged from 6 to 12 months.

A standard three-port technique was employed with an additional one or two 5 mm ports as and when required. Under general anesthesia, with the patient in supine position with both arms tucked, we accessed the abdomen in all patients via the Palmar's point by the introduction of veress needle with prior deflation of stomach by insertion of an orogastric tube to avoid any visceral injury. After gaining access and creating pneumoperitoneum, a 5 mm port was introduced and the pressure was maintained at 12–15 mm Hg. A 5 mm 30° telescope was introduced and under direct vision, two other ports 12 mm with reducer and 5 mm were made respectively to achieve the diamond-shaped configuration avoiding port insertion directly at any previous scar site. All ports were put on the left side. At this point of time, the 5 mm 30° telescope was replaced by a 10 mm 30° telescope. With gentle traction, the contents of the sac were reduced, largely necessitating prior adhesiolysis by harmonic scalpel or electrocautery with a combination of blunt and sharp dissection. Aggressive dissection was avoided to reduce the densely adherent sacs. The margins and periphery of the defect were evaluated. After complete reduction of contents, the size of the defect was assessed using European Hernia Society Classification (EHS)[7] for ventral wall hernias. A suitable sized dual mesh, that would ensure at least 5 cm overlap beyond the margins of the defect with preplaced nonabsorbable sutures for transfacial fixation was introduced via the 12 mm port in a rolled-up manner. The average size of the mesh used in our study was 15 × 15 cm. The largest mesh used in our study was 20 × 15 cm in size. The mesh was unrolled inside the abdomen, taking care of the orientation before fixation. The preplaced sutures at the periphery and center were pulled out using a transfascial fixation needle, tied and buried in the small stab skin incisions. This was followed by 360° mesh fixation from the periphery to the center by placing 5 mm absorbable tacks at suitable intervals in two rows in a concentric fashion. After ensuring complete hemostasis, pneumoperitoneum was deflated and port sites were closed using nonabsorbable 3'0 prolene sutures. Postoperatively patients were monitored in the ward. Patients were discharged from the hospital once deemed fit and stable in all aspects by clinical examination and were followed up in OPD. Patients were initially followed weekly for 1 month, then monthly for 6 months, and later on every 3 months till follow-up was complete. On follow-up a thorough clinical examination was done and various study parameters were noted (Figs 1 to 4).

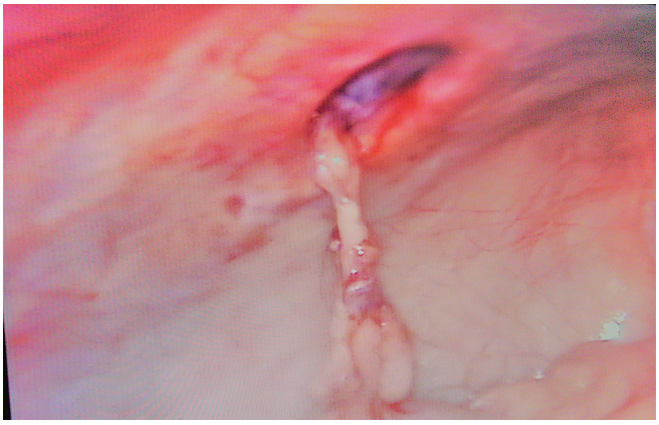

Fig. 1: Umbilical hernia laparoscopic view

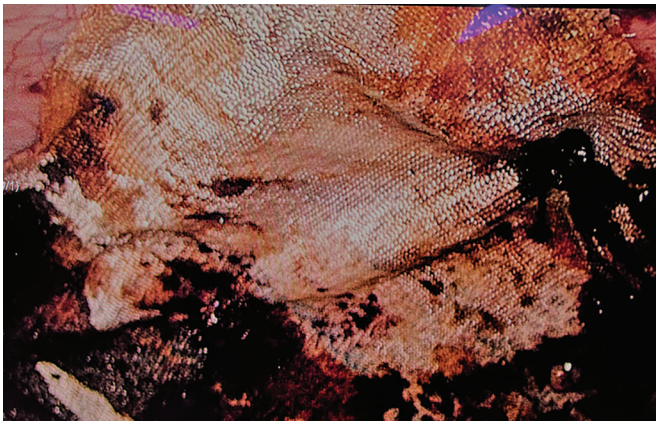

Fig. 2: Mesh placement laparoscopic view

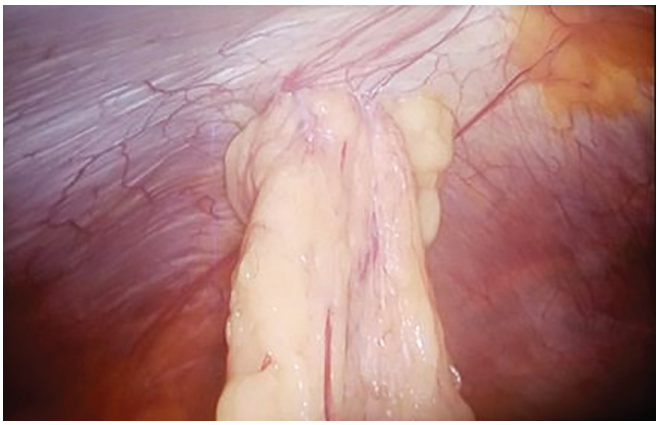

Fig. 3: Umbilical hernia with omentum as content

Results

- **Sex distribution:** Out of 40 patients who underwent laparoscopic ventral hernia repair, 24 were females and 16 males (Table 1).
- **Age distribution:** Fifty-five percent of patients in our study belonged to 40–49 years age-group (30–79 years) (Table 2).

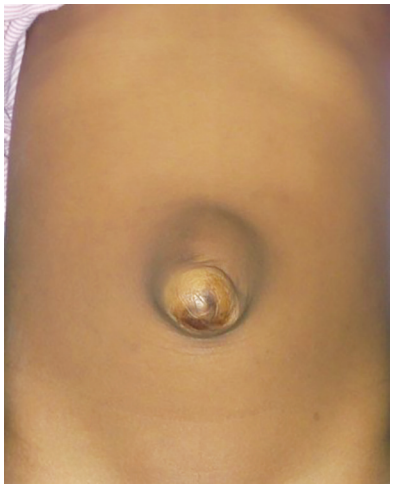

Fig. 4: Umbilical hernia

Table 1: Sex distribution

Sl. No.	*Sex*	*No. of patients*	*Percentage (%)*
1	Male	16	40
2	Female	24	60
	Total	40	100

Table 2: Age distribution

Sl. No.	*Age-group*	*No. of patients*	*Percentage (%)*
1	30–39	08	20
2	40–49	22	55
3	50–59	05	12.5
4	60–69	04	10
5	70–79	01	2.5
	Total	40	100

Table 3: Types of hernia

Sl. No.	*Types of hernia*	*Total number of patients*	*Percentage (%)*
1	Incisional hernia	32	80
2	Umbilical hernia	05	12.5
3	Infraumbilical hernia	03	7.5
	Total	40	100

Table 4: Size of defect

Sl. No.	*Size of defect (cm)*	*No. of patients*	*Percentage (%)*
1	<4	07	17.5
2	≥4–10	24	60.0
3	≥10	09	22.5
	Total	40	

- **Type of hernia:** Thirty-two were incisional hernias, five umbilical hernias, and three infraumbilical umbilical hernias (Table 3).
- **Size of the defect:** The majority of our patients had the defect size ranging from <4 cm EHS Classification (Table 4).
- **Operative time:** The average operative time in our study was 71–90 minutes (Table 5).
- **Size of mesh used:** Dual mesh was used in all patients. A 15 × 15 cm mesh was used in 39 patients and in one patient the size of the mesh used was 20 × 15 cm.
- **Hospital stay and follow-up:** The hospital stay was 2–4 days with an average stay of 2.5 days and the average follow-up period was 12 months.

Complications

Intraoperative Complications

Minor complications like bleeding and difficult dissections were encountered which were taken care of without any long-term consequences. Serosal bowel injury without any spillage occurred in one patient which was managed intraoperatively. There was no major intraoperative complication like major bleeding, bowel injury, or conversion to open.

Early Postoperative Complications

- **Early postoperative pain:** A total of 10 patients complained of moderate to severe pain (analyzed on VAS and need for intravenous analgesia round the clock) on postoperative day 1. This number decreased to 3 by day 3. At the time of discharge, all the patients were pain free. A course of oral analgesics was advised to patients who had mild pain at the time of discharge for 3 days.
- **Postoperative ileus:** Early (6–8 hours postoperatively) oral feeding was encouraged in all patients; however, three patients had postoperative ileus which resolved on conservative management.
- **Port site infection:** One patient developed superficial surgical site infection at 12 mm port site, which was managed conservatively with regular dressings and oral antibiotics as per culture and sensitivity.

Late Postoperative Complications (Table 6)

- **Seroma:** Two patients developed seroma at 1 month of follow-up. Both of these patients were managed conservatively with assurance and regular follow-up examinations. No seroma formation was reported at 12 months of follow-up.

Table 5: Operative time

Sl. No.	*Operative time (minutes)*	*Number of patients*	*Percentage (%)*
1	<50	01	2.5
2	51–70	08	20
3	71–90	29	72.5
4	>90	02	05
	Total	40	100

Table 6: Complications

Sl. No.	*Complication*	*1 month*	*6 months*	*12 months*
1	Seroma	02 (5%)	0	0
2	Chronic pain	03 (7.5%)	02 (5%)	0
4	Port site herniation	0	0	0
5	Recurrence	0	0	01 (2.5%)

- **Chronic pain:** Chronic pain was noted in three patients at 1 month, in two patients at 6 months and none at the follow-up of 12 months.
- **Port site herniation:** Port site herniation was noted in none of our patients.
- **Recurrence:** Recurrence of hernia was noted in one patient at the follow-up of 12 months.

Discussion and Review of Literature

The treatment of various surgical problems including ventral hernias has tremendously evolved since the early 1990s. The advent of laparoscopy is one of them. Laparoscopy has gained universal acceptance by demonstrating improved outcomes. Consequently, various techniques have been introduced ranging from intraperitoneal onlay mesh (IPOM) (a technique employed in our study) to IPOM-PLUS and extended totally extraperitoneal repair (E-TEP) among various others. The goals of laparoscopic ventral hernia repair include minimizing intraoperative and postoperative complications, achieving effective repair, lowest possible recurrence, and early return to normal life, cost–effectiveness, and better cosmetic results.

The operative time is one of the important factors which determines the feasibility of any procedure. The average operative time in our study was 71–90 minutes. This was comparable to other studies reported in the literature. Eker et al. in their study, reported a mean operative time of 100 minutes in the laparoscopic group which was significantly longer than in the open group (76 vs 100 minutes; $p = 0.001$).[8] Longer operative time maybe because of difficult dissection, complicated hernias, inability to achieve a good working space because of misplaced port sites, inability to roll and fix the mesh besides less experience of the surgeon. Nevertheless, many studies published have reported shorter operative times for laparoscopic ventral hernia repair.[9]

No major intraoperative complications were reported in our series. Eker et al. reported a higher overall intraoperative complication rate (enterotomy, serosal bowel injury, and bladder perforation) for laparoscopic repair (10%) than open repair (2%).[8] We had one serosal bowel injury (2.5%). The lower incidence of intraoperative complications in our series may be explained by the fact of proper preoperative patient selection and exclusion of patients with recurrent or complicated ventral hernias; as difficult and more prolonged dissections in such patients are risk factors for increased rate of intraoperative complications.

Pain is a subjective phenomenon and perception of postoperative pain varies among patients accordingly. Early postoperative pain is a usually expected phenomenon, however chronic postoperative pain (lasting for >3 months) is largely because of mesh and its fixation with tacks or transfacial sutures rather than the hernia or wound itself.[10] Our study was no exception to this, although we noticed chronic pain only in two patients, however, we conclude that the incidence of long-lasting pain could be brought down by the better availability of a near-ideal mesh and better methods of mesh fixation techniques. Various studies have reported less need for postoperative analgesia in laparoscopic ventral hernia repair.[11]

Patients are expected to recover and start their normal daily activities faster after any laparoscopic surgery. After laparoscopic incisional hernia repair, many studies have shown a shorter hospital stay compared to open repair.[9,12] Our study reported an average hospital stay of 2.5 days, which is comparable with other studies reported in the literature.

Another concern of laparoscopic ventral hernia repair is seroma formation and port site/wound infection. Several studies have reported that laparoscopic ventral hernia repair reduces the risk of wound infection.[13,14] The results of our study with regards to seroma formation and wound infection did not differ much from those studies that have been already published in the literature.

It has been reported in previous studies that the risk of port site herniation especially from the site of 10- to 12-mm ports ranges from 1 to 5%.[15] We did not report any port site hernia formation in our study.

In this study, we encountered one hernia recurrence (2.5%) at the end of 6 months of follow-up. Many studies have not reported any significant differences in recurrence rates for laparoscopic and open incisional hernia repair.[9,16] Eker et al. in their study, reported a higher rate of recurrence in the laparoscopic ventral hernia repair group.[8] The relatively lower recurrence rate in our study could be attributed to the fact of a small cohort of patients with a short term follow-up.

Limitations of the Study

The major limitations of our study were the absence of any comparative cohort, a smaller number of study patients, and a relatively shorter duration of the follow-up.

Conclusion

Laparoscopic ventral hernia repair, although sometimes technically challenging is an extremely safe and effective option in the management of ventral hernias. This approach offers a good cosmetic outcome to the patient without compromising much on the results of hernia repair. Patients are found to return to normal activity at a much faster rate with minimal loss of occupational income. This technique is easy to reproduce, however, right patient selection needs to be ensured preoperatively.

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RESEARCH ARTICLE

A Clinical Comparative Study of Bipolar Electrocautery vs Clips for Cystic Artery during Laparoscopic Cholecystectomy

Shaileshkumar M Emmi[1], Suhas DS[2]

Abstract

Introduction: Since 1987, laparoscopic cholecystectomy has been regarded as the gold standard treatment for cholelithiasis. Surgical clips, harmonic scalpel and ligature, or bipolar cautery can be used to control the cystic artery during this treatment. In this paper, we examine the use of bipolar electrocautery vs clip ligation to control the cystic artery during laparoscopic cholecystectomy.

Method: This is a clinical comparative study that was carried out in total of 60 patients who underwent laparoscopic cholecystectomy conducted for 3 year duration (2016–2019). The patients were monitored for postoperative hemorrhage and bile leak, as well as differences in hospital stay length and postoperative sequelae.

Results: In our study, the cystic artery was controlled using bipolar electrocautery in 30 patients (group B) and by surgical clips in 30 patients (group A). In both groups, the length of stay in the hospital and the duration of surgery were similar. In Group A, no incidences of intraoperative hemorrhage or bile leak were documented, but Group B had two cases of bile leak and four cases of intraoperative cystic artery bleed.

Conclusion: We conclude that, especially in developing countries, bipolar diathermy and clip application are equally effective strategies for hemostatic control of the cystic artery during laparoscopic cholecystectomy.

Keywords: Bipolar electrocautery, Clips, Cystic artery, Laparoscopic cholecystectomy.

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Introduction

Mühe performed Germany's first endoscopic cholecystectomy in 1985. The National Institutes of Health (NIH) Consensus Development Conference in 1992 concluded that for most individuals with symptomatic gallstones, laparoscopic cholecystectomy provides a safe and effective treatment.[1] Since then, laparoscopic cholecystectomy has been regarded as the gold standard for cholelithiasis therapy.[2] This new procedure was initially linked to a large increase in morbidity, particularly iatrogenic biliary injury and arterial bleeding. The right hepatic artery is the most common source of cystic artery; however, it can also come from the common hepatic, celiac trunk, right gastric, superior mesenteric, and other arteries. Because the cystic artery's course and length in the Calot's triangle are variable,[3,4] hemostasis of the cystic artery is essential because it can cause torrential hemorrhage if not ligated adequately and is the most common cause of postoperative bleeding after laparoscopic cholecystectomy. Clip application, bipolar diathermy, monopolar diathermy, vascular sealing with ultrasonics, harmonics, and other techniques are available for cystic artery control. Clips can slip, dislodge, migrate, internalize, and cause cystic duct necrosis, which can lead to bile leakage and other complications.[5] Because it is both inexpensive and widely available, bipolar electrocoagulation can be utilized to regulate the cystic artery. However, most surgeons are still opposed to using bipolar electrocautery in the Calot's triangle. As a result, in laparoscopic cholecystectomy, we contrasted bipolar electrocautery with clip application to determine the safest and least complicated method for hemostasis of the cystic artery.

Materials and Methods

A retrospective observational study was carried out in SN Medical College and HSK Hospital, Bagalkot. A total of 60 patients (32 females and 28 males) who underwent elective laparoscopic cholecystectomy from April 2015 to July 2017 (27 months) were included in the study.

The cystic artery was clipped with titanium clips in Group A to gain control. We have a standard practice of using two clips. Bipolar diathermy was used to cauterize the cystic artery in group B. All patients gave their informed consent. This study covered all patients with symptomatic gallstone disease. The study did not include patients with acute cholecystitis, empyema gallbladder, chronic renal failure, obstructive jaundice, choledocholithiasis, portal hypertension, pancreatitis, or suspected malignancies. In both groups, a single surgeon with at least 5 years of expertise in minimally invasive surgery conducted laparoscopic cholecystectomy under general anesthesia after a preoperative workup. The surgery was carried out using a four-port procedure. The surgeon stood to the left of the patient, the first assistant to the right of the patient, and the laparoscopic video camera operator to the left of the surgeon, according to the "American" procedure. Pneumoperitoneum was achieved with CO_2 gas via a Veress needle, which was then replaced with a blindly inserted laparoscopic port. The hepatocystic triangle, which is the ventral aspect of the area

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Conflict of interest: None

surrounded by the gallbladder wall and cystic duct, the liver edge, and the common hepatic duct, was dissected; the cystic artery (and hence Calot's triangle) is located within this space. By retracting the gallbladder's infundibulum inferiorly and laterally while keeping the fundus under traction in a superior and medial orientation, the hepatocystic triangle was maximum expanded. The cystic duct was clipped with Ligaclip LT 300 in 30 cases after the Calot's triangle was dissected. On the cystic artery, one clip was placed distally and the other proximally. Between the proximal and distal clips, the cystic artery was separated. A bipolar cautery was used to coagulate the artery in 30 individuals. Just lateral to the Calot's lymph node, an artery was cauterized in spray mode. Any signs of bile leakage and bleeding were noted over divided stumps of cystic duct and artery. The gall bladder was evacuated through the umbilical port after the cholecystectomy was performed according to usual technique. Hemostasis was maintained during the procedure. The derbis and blood clots were removed using suction. Any bile leaks or hemorrhages in the cystic duct and artery stump were re-examined. Bupivacaine was infused into each port incision for postoperative analgesia. One large absorbable suture was used to seal the fascia of the umbilical incision. Xylon 3–0 was used to close the other skin incisions. Any cases of postoperative bleeding or bile leak were observed in the patients. A large bleed was defined as more than 100 mL of fresh blood in the drain bag or abdominal cavity. When all of the patients were deemed fit, they were discharged from the hospital. The length of stay in the hospital as well as any postoperative complications were observed and recorded. All patients were monitored for six months, daily until the seventh postoperative day, and thereafter once a month.

Statistical Analyzes

SPSS 16.0 was used to statistically analyze the results. The mean ± standard deviation (SD) was used to express numerical data. All category data between both groups were compared using the Chi-square test. Independent student *t*-test was used to compare continuous variable data, such as operative time. A statistically significant *p*-value was less than 0.05.

Results

The study consisted of 60 patients who were planned for laparoscopic cholecystectomy. The mean age of the study group A was 50.73 + 11.09 years and group B was 54.13 + 13.2 years. The male:female sex ratio was 1:1 in group A with 15 females and 15 males; in group B it was 1.3:1 with 17 females and 13 males (Table 1).

Among the 60 patients who underwent successful laparoscopic cholecystectomy, hospital stay in group A and group B was similar, i.e., 2.9 + 0.75 days and 2.93 + 0.9 days, respectively, and no statistical significance was established. Mean duration of surgery in Group B with 50.9 + −15 minutes which was lesser when compare to group A was 56.5 + −13 minutes, however, not statistically significant. There was no reporting of intraoperative hemorrhage or bile leak in any of the cases in Group A. But in group B, out of 30 cases, 2 cases of bile leak and 4 cases of intraoperative cystic artery bleed was reported (Table 2).

Table 1: Demographic data of patients

Variables	*Group A*	*Group B*	*p value*
Age (years)	50.73 + −11.09	54.13 + −13.2	0.285
Gender			
Male	13 (43.3%)	15 (50%)	
Female	17 (56.7%)	15 (50%)	

Table 2: Intraoperative and postoperative parameter in both groups

Variables	*Group A*	*Group B*	*p value*
Intraoperative blood loss	0	4 (13.3%)	0.039
Bile leak	0	2 (7.7%)	0.155
Duration of operation (minute)	56.50 + −12.9	50.90 + −15.1	0.128
Hospital stay (days)	2.93 + −0.75	2.93 + −0.9	

Discussion

Mühe conducted the first laparoscopic cholecystectomy in 1986.[6] The gold standard treatment for cholelithiasis is now regarded laparoscopic cholecystectomy.[2] This new procedure was initially linked to a large increase in morbidity, particularly iatrogenic biliary injury and arterial bleeding. To avoid injury to the extrahepatic biliary tree, the surgeon must rely on his thorough understanding of Calot's triangle modifications and perform meticulous dissection.[7] Various methods, such as clip application, monopolar and bipolar cautery, vascular sealers, and ultrasonic devices, can be used to manage the cystic artery during the process.

We compared the results of electrocautery ligation of the cystic artery to those of surgical clip (Ligaclip) application in this study. In both groups, female preponderance was observed in the ratios of 1:1 and 1.3:1, which closely matched the demographic data reported by Hugh et al.[8] in their research of laparoscopic anatomy of the cystic artery. In both groups, the length of stay in the hospital and the duration of surgery were similar. In Group A, no incidences of intraoperative hemorrhage or bile leak were documented, but Group B had two cases of bile leak and four cases of intraoperative cystic artery bleed.

Our findings were consistent with those of Das et al.,[9] Katrina et al.,[10] and Anurag Chauhan et al.,[11] who investigated the use of monopolar cautery for cystic artery management. In terms of postoperative mortality and complications, they observed no difference between the two treatments.

In a research involving 160 patients undergoing laparoscopic cholecystectomy, Redwan[12] compared harmonic scalpel to clips/cautery. They determined that the harmonic scalpel is equally successful as the clip/cautery technique in attaining hemobiliary stasis with a shorter surgical time but is not cost-effective when compared to cautery in laparoscopic cholecystectomy.

In our study, both groups had similar outcomes, particularly in terms of hospital stay and intraoperative complications. There was no extra risk of intraoperative hemorrhage or bile leak when bipolar electrocautery was used instead of surgical clips. Postoperative problems such as clip slippage, dislodgement, ulceration, migration, internalization, and necrosis of the cystic duct with the danger of bile leakage were not a concern with electrocautery. Electrocautery is a more affordable and accessible solution than surgical clips, especially in developing nations.

Because the depth of burn with bipolar electrocautery is unpredictable, simple precautions such as staying close to the gall bladder wall during dissection, avoiding diathermy near metal clips on the cystic duct and control of the cystic artery, preferably lateral to the cystic lymph node, can help to prevent injury.[13] It is critical to

use only short bursts of the bare minimum of energy required to maintain homeostasis.

The fact that this is a retrospective study means that there are issues with incomplete and/or inconclusive data. The number of patients is likewise insufficient to draw any significant conclusions. Regardless, it should be emphasized that the cautious application of electrocautery to regulate the cystic artery results in a shorter operative time. In other words, in the hands of a trained professional, bipolar electrocautery is a safer alternative to surgical clips.

Conclusion

We conclude that bipolar diathermy and clip application are equally effective in hemostatic control of the cystic artery during laparoscopic cholecystectomy, particularly in resource-constrained settings where the harmonic scalpel raises concerns about cost and accessibility. To back up our findings, we will need to conduct more randomized control trials.

Clinical Significance

Use of bipolar diathermy is efficacious in terms of cost factor and affordability compared to harmonics and clips in developing countries.

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RESEARCH ARTICLE

A Prospective Observational Study on Single-incision or Conventional Three-port Laparoscopic Totally Extraperitoneal Inguinal Hernia Repair

Yaser Hussain Wani[1], MR Attri[2], Ishfaq Gilkar[3], Safoora Wani[4]

Abstract

Aim: The study was aimed to describe the outcome of single-incision laparoscopic surgery (SILS) and conventional totally extraperitoneal (CTEP) repair for inguinal hernias in terms of the following: (i) operative time; (ii) rate of conversion to open; (iii) postoperative complications; (iv) hospital stay; (v) cost; (vi) time until return to normal daily work; (vii) postoperative pain score; and (viii) cosmesis.

Materials and methods: The present study was a prospective observational study done at the Government Medical College Srinagar, Department of surgery and allied super specialities.

Results: The mean operating time in the CTEP group was 41.2 and 42.8 minutes for SILS TEP. Overall complications were slightly more in CTEP. The mean postoperative hospital stay was 19.2 and 21.8 hours in CTEP and SILS TEP, respectively. The average time to resume normal work was 3.7 $\pm$ 0.8 days in CTEP repair and 3.3 $\pm$ 1.2 days in SILS TEP repair. The mean visual analogue scale score at 6 hours in the CTEP group was 3.1 $\pm$ 2.8 and in the SILS TEP group 2.8 $\pm$ 0.8. The mean cosmetic result was 4.1 $\pm$ 0.9 in the SILS TEP group.

Conclusion: Laparoscopic repair of inguinal hernias is associated with good results in both techniques. SILS TEP inguinal hernia repair using conventional laparoscopic instruments is a safe and feasible alternative to CTEP in experienced hands. The outcomes of SILS TEP for operation time, postoperative complication, hospital stay, time until return to normal activity, and rate of conversion to open are comparable to CTEP. However, the approach provided an advantage in terms of cosmesis and postoperative pain.

Clinical significance: SILS TEP although having a learning curve and difficult to use in large/complete groin hernias is a good technique for use in small hernias using routine laparoscopic instruments in a resource-limited setting with significant outcome in terms of cosmesis.

Keywords: Hernia, Intraperitoneal onlay mesh, Laparoscopic, Laparoscopic hernia repair, Mesh, Mesh repair, Single-incision laparoscopic surgery, Single-port, Single-port access surgery, Totally extraperitoneal, Transabdominal retromuscular, Ventral.

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Introduction

The word "hernia" is derived from the Latin term meaning "rupture."[1] Hernia is defined as an abnormal protrusion of an organ or tissue through a defect in its surrounding walls. Hernia can occur at various sites of the body, most commonly involving the abdominal wall, particularly the inguinal region. The most common sites are the inguinal, femoral, and umbilical areas, linea alba, lower portion of the semilunar line, and previous incisions sites. Strangulation is the most common as well as serious complication of hernia and is seen in only 1–3% of groin hernias.[2]

Inguinal hernias account for 75% of abdominal wall hernias, with a lifetime risk of 27% in men and 3% in women.[3] Inguinal hernias are classified as direct or indirect based upon the site of herniation relative to surrounding structures. The definitive treatment of inguinal hernias is surgical repair.

The goals of herniorrhaphy include the following:

- Minimizing operative and postoperative discomfort for the patient.
- Achieving an effective repair,
- Ensuring the lowest possible recurrence rate,
- Permitting a rapid return to normal activities, and
- Performing a cost-effective procedure.

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Conflict of interest: None

Over the past century, multiple methods of repair have been used. The techniques have progressed from open repair to laparoscopic approaches.

Over the last few years, with increasing demand of better cosmetic results along with better surgical outcome, a newer technique has gained interest among the surgeons. In 2009, the first case of single-incision totally extraperitoneal inguinal hernia repair was reported.[4] However, evaluating this newer technique

with respect to the three-port conventional totally extraperitoneal (CTEP) repair in the management of groin hernias has not been thoroughly published to date.[5–7]

Materials and Methods

The study was a prospective observational study of patients with groin hernia (Fig. 1). There were two study groups. One group of patients has undergone single-incision totally extraperitoneal inguinal hernia repair technique and the other via three-port CTEP repair procedure. The two groups were then compared based on intraoperative and postoperative parameters. The main aim of the study was to observe these two techniques in terms of the following:

- Operative time
- Rate of conversion to open technique
- Postoperative complications
- Hospital stay
- Cost
- Time until return to normal daily work
- Postoperative pain score
- Cosmesis

The study was a prospective observational study. The study cohort was admitted for elective groin hernia surgery in surgical wards of SMHS Hospital Srinagar over 2 years. Patients above 18 years of age, irrespective of the gender presenting with groin hernia were evaluated as per a predetermined proforma.

Following patients were *excluded* from the study.

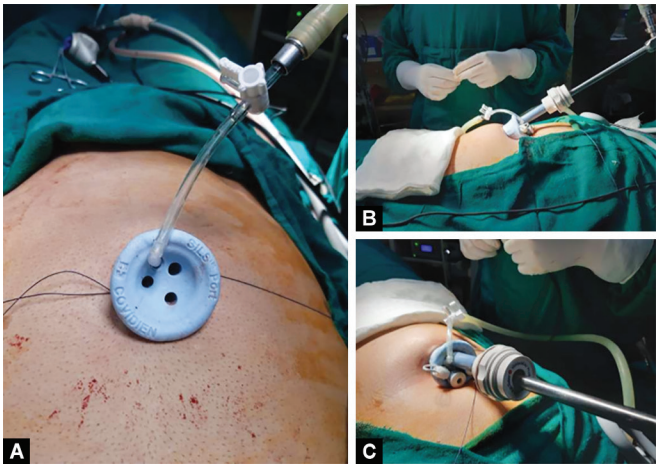
- Age below 18 years.
- Complicated hernia.
- Previous lower abdominal or pelvic surgery.
- Contraindications to general anesthesia or laparoscopic surgery.
- Associated medical comorbidities, like COPD, uncorrected bladder outlet obstruction, and uncorrected chronic constipation.

The patients were admitted after being evaluated on outpatient department basis. Baseline investigations followed by preanesthetic checkup were done in all cases. Preoperative instructions were given and made understandable to the patient in his/her language. Written informed consent was taken before each procedure. Prophylactic antibiotic (injection ceftriaxone) and tetanus toxoid dose were administered before the procedure in each patient. Surgery was performed on a routine elective basis after proper investigation as per following operative techniques.

Single-incision Totally Extraperitoneal Inguinal Hernia Repair Technique

Under general anesthesia, the patient is placed supine with both arms adducted. Later the patient is placed in the Trendelenburg position with the side contralateral to the hernia site tilted down. A 25-mm subumbilical incision is made, followed by dissection of the subcutaneous tissue down to the rectus abdominis sheath. An incision approximately 3 cm in length is made over the anterior rectus sheath and opened, blunt dissection using a finger or gauze is performed between the rectus muscle and the posterior rectus sheath to create a preperitoneal space. The single-port self-retaining access device through which three trocars are inserted is used to maintain the inflation of the preperitoneal space with carbon dioxide gas (Fig. 2). Carbon dioxide is insufflated to a level of 15 mm Hg.

The preperitoneal space is gradually dissected using conventional laparoscopic instruments (initially a 0° telescope) without a dissection balloon (Fig. 3). The boundaries of dissection are similar as for CTEP procedure. A polypropylene mesh is introduced through the 12-mm port half rolled (Fig. 4). The mesh is unrolled along the floorcovering the inguinal floor and fixed (Figs 5 and 6). The fixation is performed by the use of three absorbable



Figs 2A to C: SILS port in use

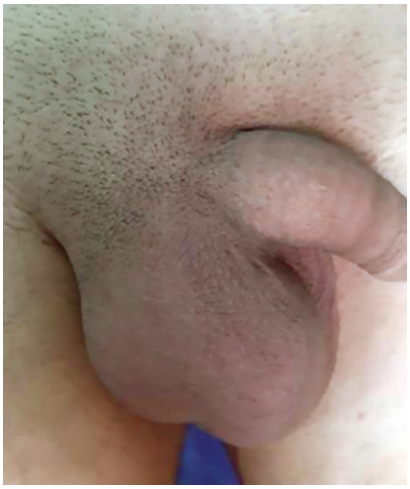


Fig. 1: Inguinal hernia (preoperative)

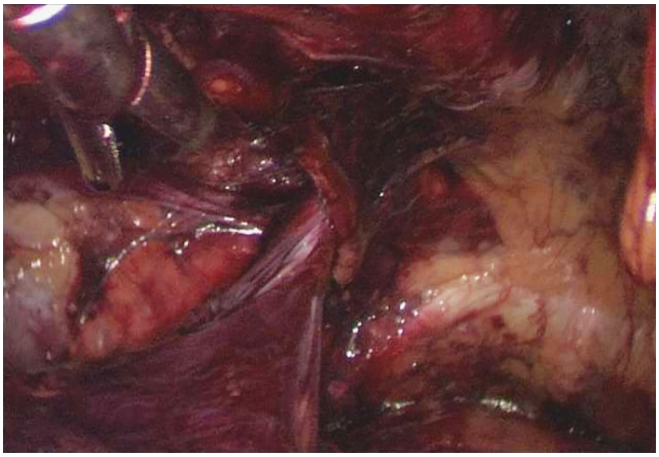
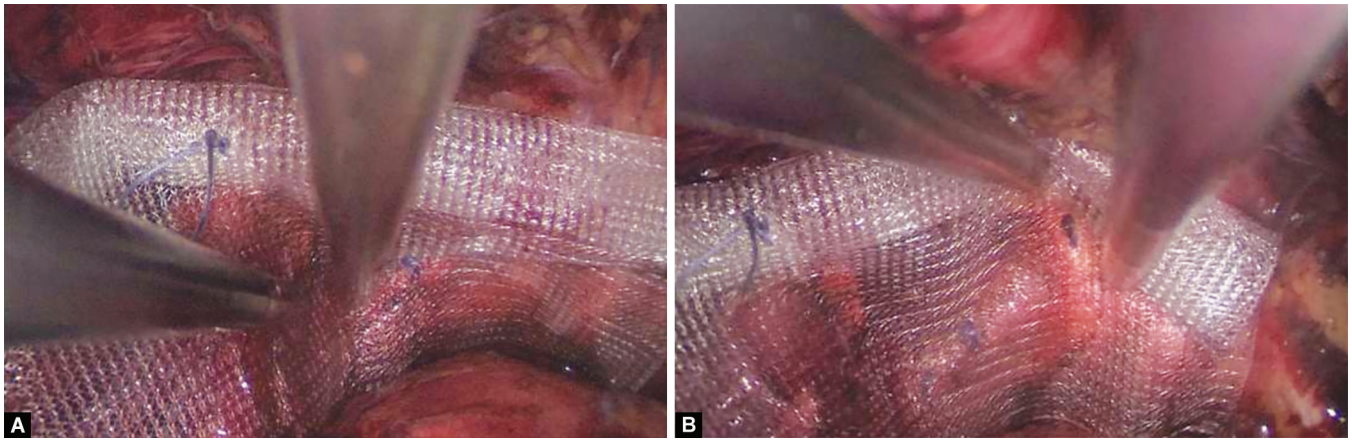


Fig. 3: Intraoperative picture while dissection of sac

Figs 4A and B: Mesh used for the procedure



Figs 5A and B: Placement, unrolling, and fixation of mesh using absorbable secure straps

Fig. 6: Complete unrolling of the mesh over the myopectineal orifice of Fruchaud

tacks—at the pubic bone, at Cooper's ligament, and above the iliopubic tract. After completion, the preperitoneal space is deflated with care to avoid displacing the mesh. The anterior sheath is closed with a 2-0 Vicryl suture, and the skin with a 3-0 silk suture.

Postoperative Care

After the operation, patients were shifted to the respective wards and monitored. Injectable diclofenac sodium 75 mg was used for immediate postoperative pain relief. In both techniques, patients were made ambulatory and orals started on the same day of operation. The patients were discharged from the hospital as soon as the patient became ambulatory and tolerated orals and were pain-free. Patients were followed up at 1 week, 2 weeks, 4 weeks, 3 months, and 6 months.

The following parameters were recorded during our study:

- Information on gender, age, comorbidities, and past surgical history.
- Hernia characteristics, like type of hernia whether indirect, direct, femoral, side of hernia, unilateral or bilateral, primary, or recurrent, were noted.
- Duration of surgery.
- Rate of conversion to open technique.
- Pain score at 6 and 24 hours after the procedure.
  (0—no pain, 2—least pain, 4—mild pain, 6—moderate pain, 8—severe pain, and 10—worst pain possible)
- Postoperative complications, like seroma, hematoma, and urinary retention, if any were recorded.
- Time until return to normal (nonstrenuous) work was noted.
- Cosmetic results were graded subjectively 1 month postoperatively using the following range of choices: 5, very satisfied; 4, satisfied; 3, acceptable; 2, dissatisfied; and 1, very dissatisfied.

Statistical Analysis

Data were expressed as average and percentage. All the inferences for comparison within the group were made using Fisher exact test, Chi-square test, and unpaired Students *t*-test. A *p*-value of <0.05 was considered significant.

Results

Age Distribution

CTEP Group

In our study of 30 patients, CTEP group consisted of 15 patients. There were two cases between the age-group of 30–40 years; four cases in the age-group of 41–50; eight cases between the age-group of 51–60; and one case above the age of 60 years. Majority of cases belong to age-group of 51–60 years with mean age of 50.67 as is shown in the Table 1A and Figure 7A.

SILS TEP Group

In our study of 30 patients, SILS TEP group consisted of 15 patients. There were three patients between the age-group of 30–40 years; four cases in the age-group of 41–50; seven cases between the age-group of 51–60; and one case above the age of 60 years. Majority of cases belong to age-group 51–60 years with mean age of 41.4 as is shown in the Table 1B and Figure 7B.

Table 1A: Age distribution in CTEP group

Age-group	*Number of patients*
30–40	2
41–50	4
51–60	8
>60	1

Table 1B: Age distribution in patients of SILS TEP group

Age-group	*Number of patients*
30–40	3
41–50	4
51–60	7
>60	1

Sex Distribution

CTEP Group

In our study of 30 patients, CTEP group consisted of 15 patients. All the cases were males as is shown in the Table 2A and Figure 8A.

SILS TEP Group

In our study of 30 patients, SILS TEP group consisted of 15 patients. All of cases were males; as is shown in the Table 2B and Figure 8B.

Site of Hernia

CTEP Group

In our study of 30 patients, CTEP group consisted of 15 patients. Right inguinal hernia was present in 10 cases. Left inguinal hernia was present in four cases. Bilateral inguinal hernia was present in one case. Most cases had right-sided inguinal hernia as shown in the Table 3A and Figure 9A.

SILS TEP Group

In our study of 30 patients, SILS TEP group consisted of 15 patients. Right inguinal hernia was present in eight cases. Left inguinal hernia was present in five cases. Bilateral inguinal hernia was present in two cases. Most cases had right-sided inguinal hernia as shown in the Table 3B and Figure 9B.

Type of Hernia

CTEP Group

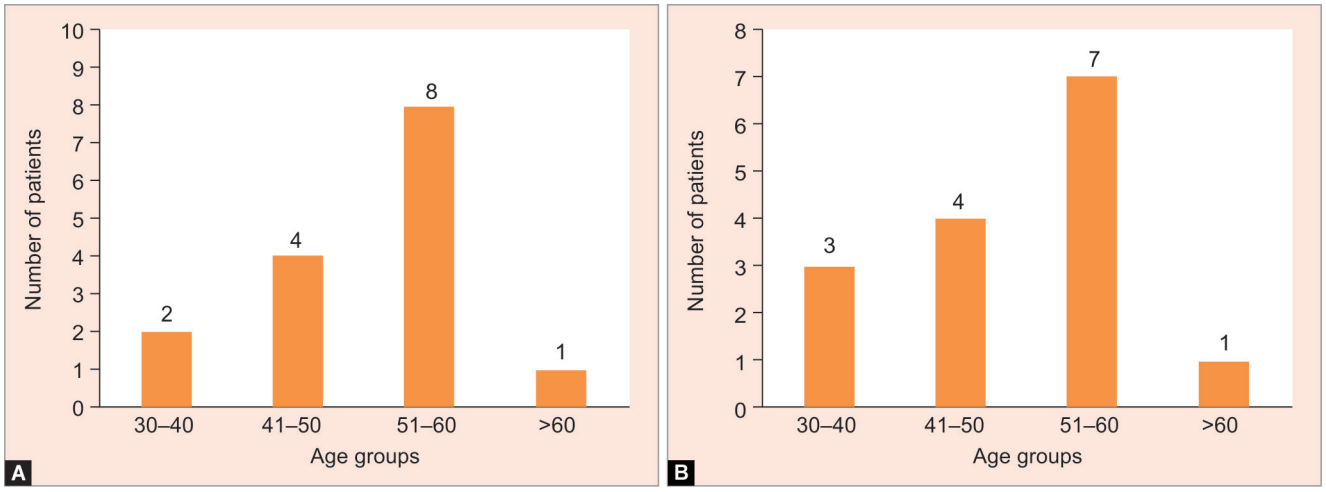
In our study of 30 patients, 15 cases underwent CTEP. Indirect inguinal hernia was seen in eight cases, while seven cases had direct inguinal hernia as is shown in Table 4A and Figure 10A.

Table 2A: Sex distribution in patients of CTEP group

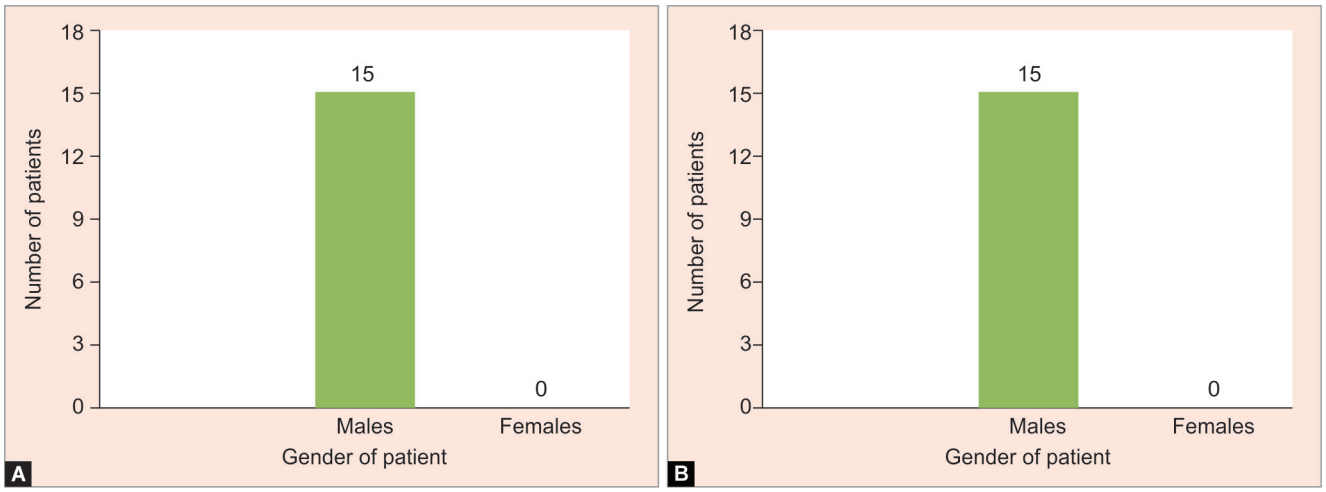
Sex	*Number of patients*
Males	15
Females	0

Table 2B: Sex distribution in patients of SILS TEP group

Sex	*Number of patients*
Males	15
Females	0



Figs 7A and B: (A) Age distribution in CTEP group; (B) Age distribution in patients of SILS TEP group



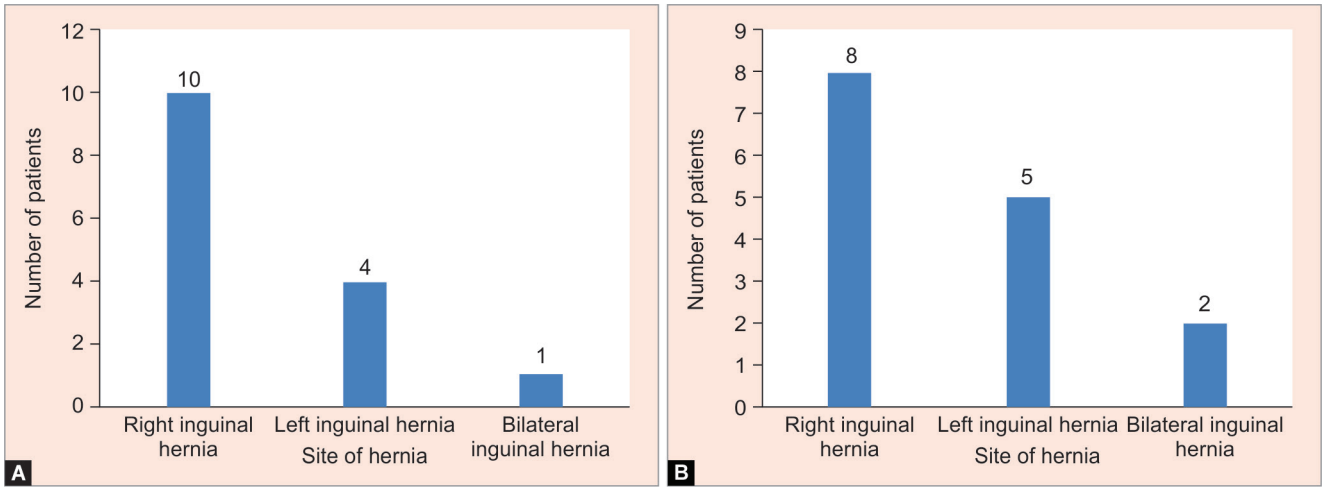
Figs 8A and B: (A) Sex distribution in patients of CTEP group; (B) Sex distribution in patients of SILS TEP group

Table 3A: Site of hernia in CTEP group

Site of hernia	*Number of patients*	*% age of patients*
Right inguinal hernia	10	66.66%
Left inguinal hernia	4	26.66%
Bilateral inguinal hernia	1	6.66%

Table 3B: Site of hernia in patients of SILS TEP

Site of hernia	*Number of patients*	*% age of patients*
Right inguinal hernia	8	53.33%
Left inguinal hernia	5	33.33%
Bilateral inguinal hernia	2	13.33%



Figs 9A and B: (A) Site of hernia in patients of CTEP; (B) Site of hernia in patients of SILS TEP

Table 4A: Type of hernia in patients undergoing CTEP

Type of hernia	*Number of patients*	*% age of patients*
Indirect inguinal hernia	8	53.33%
Direct inguinal hernia	7	46.66%

Table 4B: Type of hernia in patients undergoing SILS TEP

Type of hernia	*Number of patients*	*% age of patients*
Indirect inguinal hernia	9	60%
Direct inguinal hernia	6	40%

STEP Group

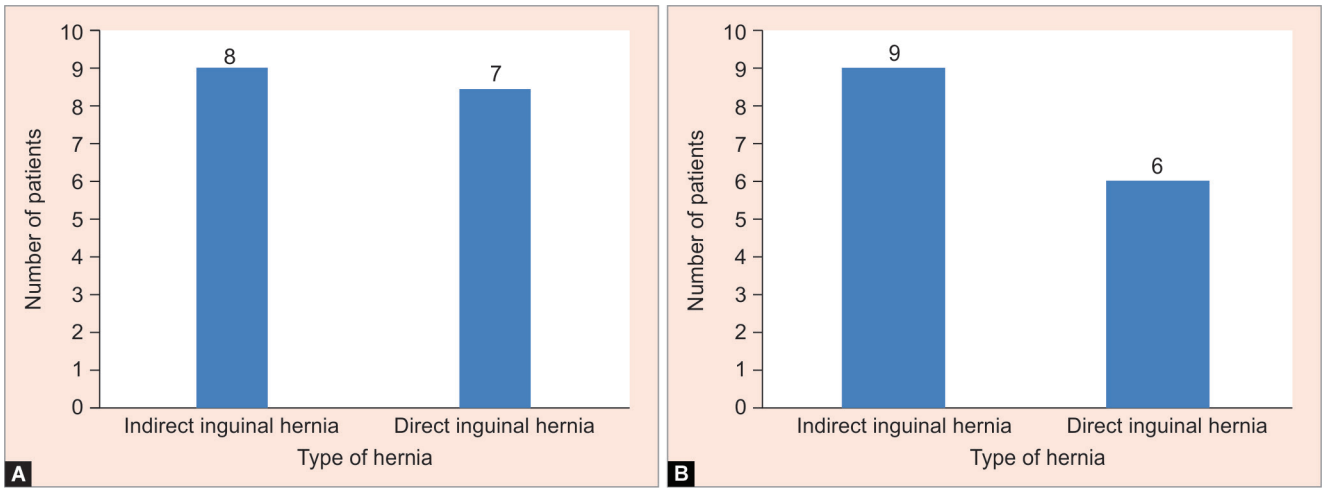
In our study of 30 patients, 15 cases underwent SILS TEP. Indirect inguinal hernia was seen in nine cases, while six cases had direct inguinal hernia as is shown in Table 4B and Figure 10B.

Operative Time

In our study of 30 patients, we calculated operating time from incision to wound closure and we found that the mean operative time of CTEP for unilateral hernia = 41.2 minutes and bilateral hernia = 64.6 minutes; whereas the mean operative time of SILS TEP for unilateral hernia = 42.8 minutes and bilateral hernia = 69.1 minutes with a *p*-value of 0.85 which is statistically insignificant as is shown in Table 5 and Figure 11.

Postoperative Complication

In our study of 30 patients, 15 patients underwent CTEP and 15 underwent SILS TEP. Seroma was seen in three cases of CTEP group



Figs 10A and B: (A) Type of hernia in patients of CTEP; (B) Type of hernia in patients of SILS TEP

Table 5: Comparing the operative time for CTEP and SILS TEP

Type of hernia	*CTEP time (mean) minutes*	*SILS TEP time (mean) minutes*	*p value*
Unilateral	41.2	42.8	0.85
Bilateral	64.6	69.1	

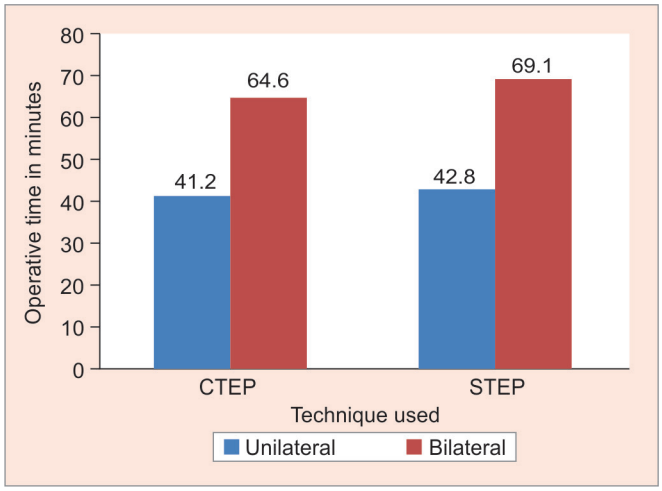


Fig. 11: Chart showing the operative time of CTEP and SILS TEP for unilateral and bilateral hernias

and two cases of SILS TEP group. Hematoma was seen in one case of CTEP and none in SILS TEP group. Urinary retention was seen in one case of both CTEP and SILS TEP groups. However, there were no wound site infections in either group. The postoperative complications have been tabulated and compared as is shown in Table 6 and Figure 12.

Hospital Stay

In our study of 30 patients, 15 cases underwent CTEP and 15 cases underwent SILS TEP. The mean hospital stay of the patients undergoing CTEP was 19.2 hours and for SILS TEP group, it was 21.8 hours with a *p*-value of 0.97 which is statistically insignificant as is shown in Table 7 and Figure 13.

Table 6: Comparing the postoperative complications

	CTEP		*SILS TEP*	
Postoperative complications	*Number of patients*	*% age of patients*	*Number of patients*	*% age of patients*
Seroma	3	20%	2	13.33%
Hematoma	1	6.66%	0	0%
Urinary retention	1	6.66%	1	6.66%
Wound infection	0	0%	0	0%

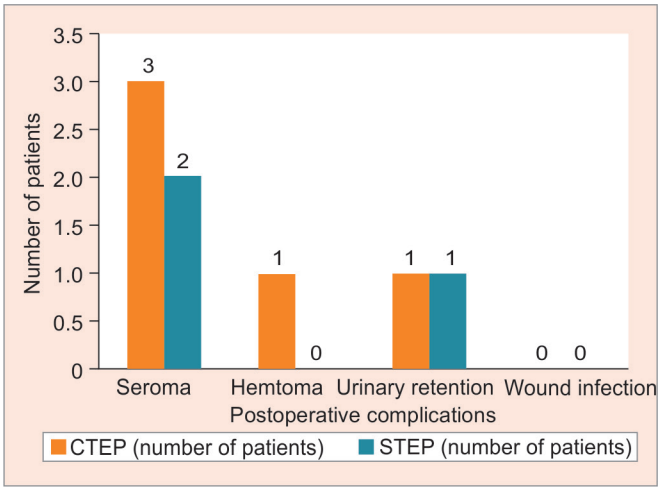


Fig. 12: Comparison of postoperative complications

Table 7: Comparing the length of hospital stay

Type of hernia	*Mean hospital stay for CTEP in hours*	*Mean hospital stay for SILS TEP in hours*	*p value*
Unilateral	19.2	21.8	0.97

Time to Return to Normal (Nonsternous) Work

In this study of total 30 cases, we analyzed the time to return to work after CTEP and SILS TEP. It was observed that time to return to work was slightly lower in SILS TEP group than CTEP group. The time to

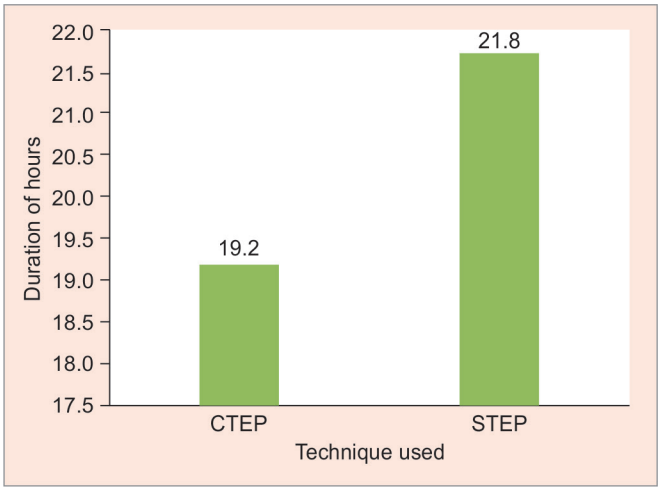


Fig. 13: Comparison of length of hospital stay

Table 8: Comparing the time to return to work after CTEP and SILS TEP

Name of procedure	*Time to return to work (in days)*	*Standard deviation*
CTEP	3.7	0.8
SILS TEP	3.3	1.2

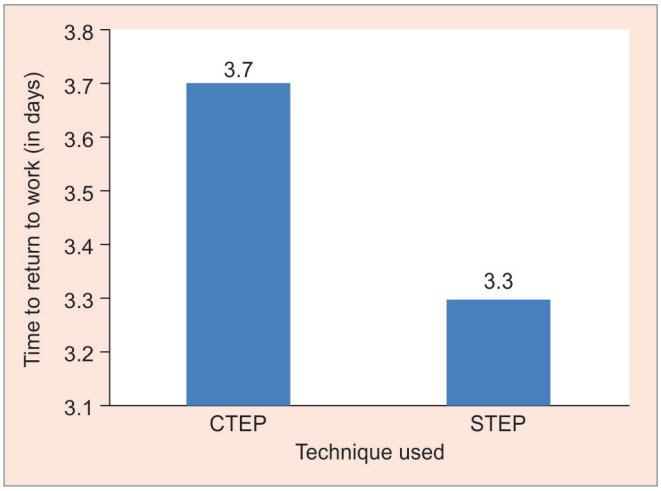


Fig. 14: Comparison of time to return to normal (nonstrenuous) work after CTEP and SILS TEP procedure

return to work in CTEP 3.8 ± 0.8and SILS TEP 3.4 ± 1.2 as shown in Table 8 and Figure 14 with *p*-value of 0.3 which is statistically insignificant.

Postoperative Pain Score

In our study of 30 cases, CTEP was performed on 15 cases and SILS TEP on 15 cases. The postoperative pain score was observed in each group at 6 and 24 hours using visual analogue scale (VAS) score. It was observed that the postoperative pain score was 3.1 and 2 for CTEP group at 6 and 24 hours, respectively. Similarly, the postoperative pain score was 2.8 and 1.2 for SILS TEP group at 6 and 24 hours, respectively, as is shown in Table 9 and Figure 15. The *p*-value was 0.5 at 6 hours and 0.32 at 24 hours.

Table 9: Comparing the postoperative pain score using VAS

Visual analogue scale (VAS)	*CTEP*	*SILS TEP*
At 6 hours	3.1 (±1.2)	2.8 (±0.8)
At 24 hours	2 (±1)	1.2 (±1.1)

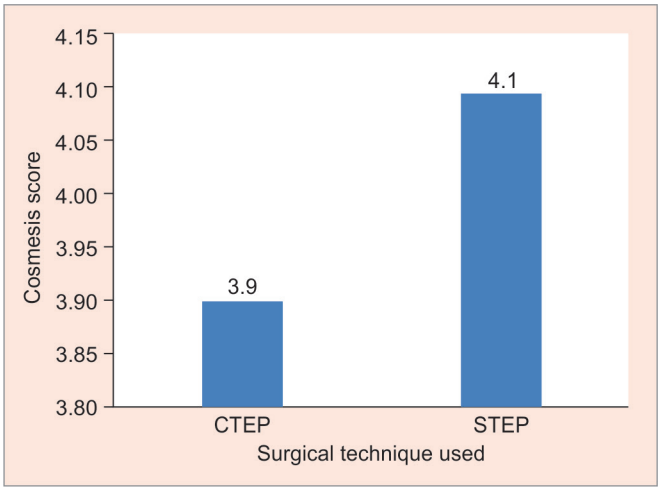


Fig. 15: Comparison of postoperative pain score using VAS

Table 10: Comparing the cosmetic outcome of patients after CTEP and SILS TEP

Name of the procedure	*Cosmetic results mean*	*Standard deviation*
CTEP	3.9	±0.8
SILS TEP	4.1	±0.9

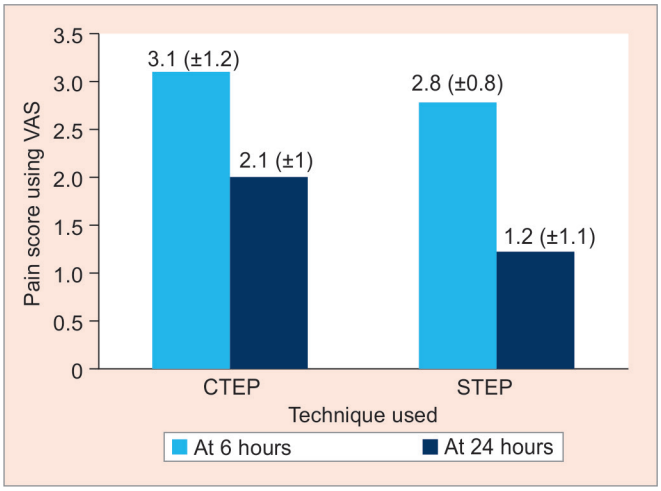


Fig. 16: Comparison of cosmetic outcome in CTEP and SILS TEP procedures

Cosmesis

In our study of 30 cases, 15 cases underwent CTEP and 15 cases underwent SILS TEP. The cosmetic outcome was graded by the patient 1 month postoperatively on a scale of 1–5. It was observed that the mean of cosmetic results was 3.9 and 4.1 for CTEP and SILS TEP, respectively, as is shown in Table 10 and Figure 16 with a *p*-value of 0.23 which is statistically insignificant.

Rate of Conversion to Open Technique

In our study of 30 patients of inguinal hernia undergoing CTEP/SILS TEP, there was no conversion to open technique.

Cost

In our study, the cost in SILS TEP group, using routine laparoscopic instruments was not statistically different from the CTEP group without compromising patient safety. However, the actual cost for SILS TEP when using specialized articulating instruments is significantly higher.

Discussion

Inguinal hernia repair is one of the most common elective procedures performed in general surgery. The goal of hernia repair includes achieving effective repair, lowest possible recurrence, minimizing intraoperative and postoperative complications, rapid return to daily work, and reasons; various methods of inguinal hernia repair have been utilized over the past. The technique of herniorrhaphy has progressed from open to various laparoscopic techniques.

The present study was done to compare and analyze the results of laparoscopic CTEP and SILS TEP mesh repair for inguinal hernia. A total of thirty patients were included in the study. Fifteen patients were operated on by laparoscopic CTEP hernioplasty and other fifteen were operated on by laparoscopic SILS TEP hernioplasty.

Age

The most common age-group in both the methods was 51–60 years showing that groin hernia is most common in the middle age-group. In CTEP group, the mean age was 50.67 years. In SILS TEP group, the mean age was 41.40 years.

Wijerathne et al.[8] in their study reported that the mean age of the patients undergoing CTEP was 50.3 and 47.2 years in patients undergoing SILS TEP.

Choi et al.[9] observed in their study that the mean age in CTEP group was 57.5 years and for the SILS TEP group, it was 59.5 years.

Sex Distribution

All the patients in our study were males. CTEP group consisted of 15 patients, while the SILS TEP group also consisted of 15 patients.

Choi et al.[9] reported that there were no female patients in either of their study groups.

Kim et al.[10] reported in their study that most of the patients were males only accounting for 97% of cases. Two patients were female; statistically, there was no difference between the two groups as far as sex ratio is concerned. With these observations made, it is concluded inguinal hernias occur commonly in males.

Site of Hernia

In our study of 30 patients, most cases had a right-sided inguinal hernia. The CTEP group consisted of 15 patients. The right inguinal hernia was present in 10 (67%) cases. Left inguinal hernia was present in four (27%) cases. The bilateral inguinal hernia was present in one (7%) case. The SILS TEP group consisted of 15 patients. The right inguinal hernia was present in eight (53%) cases. Left inguinal hernia was present in five (33%) cases. The bilateral inguinal hernia was present in two (13%) cases.

Choi et al.[9] observed in their study that most cases had a right-sided inguinal hernia (69%—CTEP group and 73%—SILS TEP group). However, 31 and 28% of cases of the CTEP group and SILS TEP group, respectively, had left-sided inguinal hernia.

Kim et al.[10] in a study group of 60 patients with inguinal hernias observed that 51.66% of patients had right-sided hernias, 43.33% of patients had left-sided hernias, and 5% patients had bilateral hernias.

Our results were consistent with the literature to find right-sided inguinal hernia more common than left, then followed by bilateral hernia.

Type of Hernia

In our study of 30 patients, most cases had an indirect inguinal hernia. The indirect hernia was more common than the direct hernia, with a ratio of 08/15 (53%) in the CTEP group and 09/15 (60%) in the SILS TEP group.

Kim et al.[10] in their study reported that indirect hernia was present in 40/63 (63%) of cases undergoing SILS TEP. The direct hernia was present in 23/63 (37%) of cases undergoing SILS TEP.

Tai et al.[11] observed in their study that an indirect hernia was more common than a direct hernia, with a ratio of 69/152 (45.4%) in the CTEP group and 58/98 (59%) in the SILS TEP group. The direct hernia was present in 68/152 (44.7%) of cases undergoing CTEP and 39/98 (39%) of cases undergoing SILS TEP.

Thus, on analyzing the above study and present study, it is evident that our results are consistent with the above studies.

Operating Time

In our study, we observed that the mean operating time in the CTEP group was 41.2 and 64.6 minutes for unilateral and bilateral inguinal hernias, respectively. The mean operating time for SILS TEP was found to be 42.8 and 69.1 minutes for unilateral and bilateral inguinal hernias, respectively. It was, however, observed that there was no statistically significant difference in operating time (p-value = 0.85).

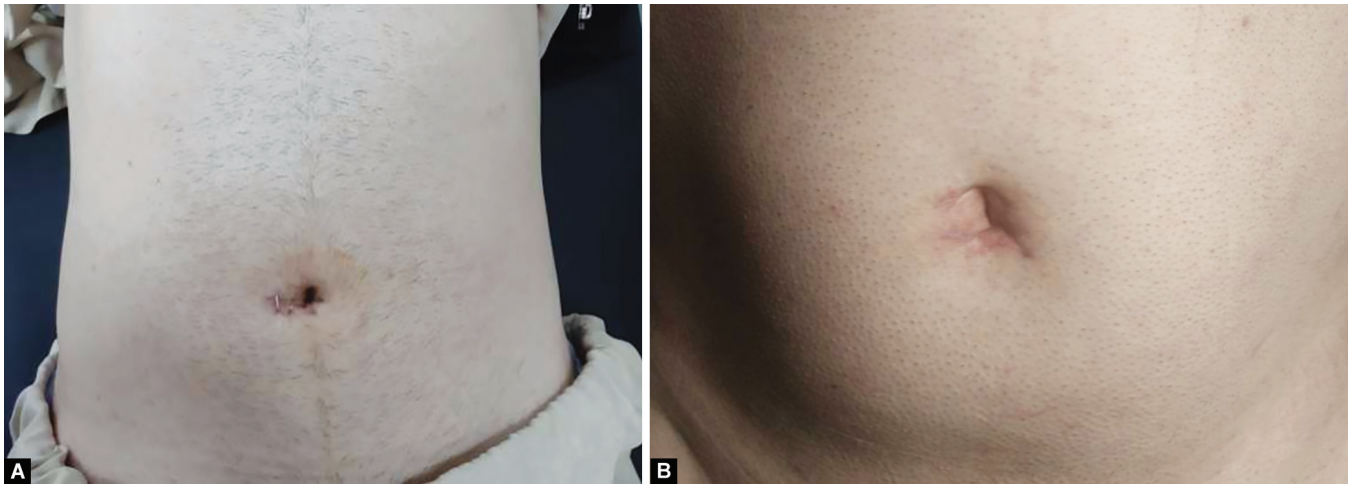
Tai et al.[11] in their study concluded that the mean operative time in the CTEP group was 58.6 and 62.5 minutes for unilateral and bilateral inguinal hernias, respectively; while the mean operative time for SILS TEP was 82.3 and 68.3 minutes, respectively.

Wijerathne et al.[12] concluded in their study that the mean operative time for unilateral inguinal hernias in CTEP and SILS TEP techniques was 50.5 and 63.5 minutes, respectively.

Choi et al.,[9] in their study concluded that the mean operative time for CTEP was 41.6 minutes for unilateral hernias; while for SILS TEP, the mean operative time was 61.7 minutes.

Postoperative Complications

Overall complications were slightly more in the CTEP method than in SILS TEP method five (33.3%) vs three (20%). The most common complication was postoperative seroma in both groups. Three (20%) patients in the CTEP group and two (13%) patients in the SILS TEP group developed postoperative seroma which was noticed at discharge and also at 1-week follow-up, which was conservatively managed. One (7%) patient in the CTEP group developed hematoma (managed conservatively). One (7%) patient in both groups had postoperative urinary retention, managed by catheterization. Observations made in our study were consistent with studies by Choi et al.,[9] in their study have reported overall 24% of complications in the CTEP group and 16% in the SILS TEP group. Postoperative seroma developed in 20% of cases in both groups. Urinary retention developed in 6 and 2% cases in CTEP and SILS TEP, respectively.



Figs 17A and B: Postoperative scar at (A) 1 week; (B) 2 months

Wijerathne et al.[8] reported that postoperative seroma was the most common complication in both methods. All patients with seroma were managed conservatively without any intervention. Postoperative seroma developed in 17% of cases undergoing CTEP and 8% of cases undergoing SILS TEP.

Thus our results are consistent with the above-given studies.

Hospital Stay

Orals were started as soon as postoperative nausea was over and the patient felt hungry. Patients in both groups were advised early ambulation. As the patients became ambulant, tolerated orals, and voided urine, they were discharged. The mean postoperative hospital stay in CTEP repair was 19.2 hours and in SILS TEP repair 21.8 hours; (*p*-value of 0.97—statistically insignificant).

Wijerathne et al.[8] reported the mean hospital stay of 19.7 hours in CTEP group and in SILS TEP group, it was 20.5 hours.

Lomanto et al. reported in their study that the mean hospital stay for CTEP was 19.7 hours and for SILS TEP, it was 22.1 hours.

Time Until Return to Normal Daily Work

In our study, the average time to resume normal nonstrenuous work was 3.7 ± 0.8 days in CTEP repair and 3.3 ± 1.2 days in SILS TEP repair. Thus CTEP group had the almost same time to resume normal work as the SILS TEP group.

Tai et al.[11] observed that patients operated by CTEP repair and SILS TEP repair return to normal work after a mean of 3.8 and 3.4 days which was statistically nonsignificant.

Thus our observations were consistent with the results of other studies.

Postoperative Pain

The postoperative pain was calculated using a VAS score. VAS score was almost the same in CTEP and SILS TEP procedures. VAS score was calculated at 6 and 24 hours after surgery. The mean VAS score at 6 hours in the CTEP group was 3.1 ± 2.8 and in the SILS TEP group 2.8 ± 0.8. VAS score at 24 hours was 2 ± 1 and 1.2 ± 1.1 for CTEP group and SILS TEP group, respectively. At 6 hours, *p*-value = 0.5 and 0.32 at 24 hours after surgery.

Wijerathne et al.[8] concluded that pain score (VAS) at 6 hours, 24 hours, 1 week, 4 weeks, 3 months, and 6 months after surgery was slightly higher in the CTEP group compared to SILS TEP group. VAS score at 6 hours in CTEP was 2.6 ± 1.3 and in the SILS TEP group 2.1 ± 1.5. VAS score at 24 hours was 2.1 ± 1.5 in the CTEP group and SILS TEP group 1.5 ± 1.5. At 6 hours, *p*-value = 0.146 and 0.067 at 24 hours after surgery; hence the difference between CTEP and SILS TEP was not statistically significant.

The observation made in our study favored SILS TEP to be less painful than CTEP, however, statistically insignificant. The findings were consistent with the observation made by Wijerathne et al. when VAS is compared at 6 and 24 hours.

Cosmesis

The cosmetic outcome of the patients was compared after 1 month of surgery. Cosmetic results were graded subjectively 1 month postoperatively using the following range of choices: 5 (very satisfied), 4 (satisfied), 3 (acceptable), 2 (dissatisfied), and 1 (very dissatisfied) (Fig. 17). The mean cosmetic result was 3.9 ± 0.8 in the CTEP group and 4.1 ± 0.9 in the SILS TEP group. The *p*-value = 0.14 which is statistically insignificant.

Tai et al.[11] observe that the cosmetic outcome graded objectively by the patient was 3.9 ± 0.7 and 4.1 ± 0.8 in CTEP and SILS TEP groups, respectively. The *p*-value = 0.14 which is statistically insignificant.

Thus concerning cosmetic outcomes, our results are consistent with the above study.

Conversion to Open

In our study of 30 patients with inguinal hernia undergoing CTEP/SILS TEP, there was no conversion to open technique.

Choi et al.[9] in his study "Single-port versus conventional three-port laparoscopic totally extraperitoneal inguinal hernia repair: a randomized controlled trial" had no conversion to the open technique.

Cost

In our study, the cost in the SILS TEP group, using routine laparoscopic instruments was not statistically different from the CTEP group without compromising patient safety. However, the actual cost for SILS TEP when using specialized articulating instruments is significantly higher.

Observation made in our study was consistent with the study by Rajapandian et al.,[13] who in their study "single incision

versus conventional laparoscopic inguinal hernia repair: A matched comparison" concluded that the cost of SILS TEP using conventional laparoscopic instruments in a resource-poor and cost-sensitive country like India was not statistically different from the conventional group without compromising the safety of the patient.

Conclusion

The outcome of inguinal hernias using laparoscopic modality is associated with good results in both techniques. SILS TEP inguinal hernia repair using conventional laparoscopic instruments is a safe and feasible alternative to CTEP in experienced hands. The outcomes of SILS TEP for operation time, postoperative complication, duration of stay, time until return to normal nonstrenuous activity, and conversion to open are comparable to CTEP.

However, the approach provided advantage in terms of cosmesis and postoperative pain using VAS score.

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RESEARCH ARTICLE

Urgent Elective Laparoscopic Cholecystectomy during the COVID-19 Pandemic

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Abstract

Aim: In April 2020 routine elective surgery in England was suspended in response to coronavirus disease-2019 (COVID-19). Low COVID-19 infection and mortality rates in the South West of England allowed urgent elective surgery in Plymouth to continue with the necessary precautions. The aim of this study was to assess outcomes following elective laparoscopic cholecystectomy during the initial phase of the COVID-19 pandemic.

Materials and methods: Records of 54 consecutive patients undergoing urgent elective laparoscopic cholecystectomy between March 25, 2020, and June 25, 2020, were analyzed retrospectively. Patients were telephoned after 30 days. All patients underwent COVID-19 swab testing 24 to 72 hours prior to surgery and during admission if clinically indicated. The primary outcome measure was COVID-19 related morbidity. Secondary outcome measures were non-COVID-19 related morbidity, mortality, and length of hospital stay.

Results: Fifty-four patients [19 male, 35 female; median age 59 years (20–79); median body mass index (BMI) 31 kg/m^2 (22.9–46.8); median ASA 2] underwent laparoscopic cholecystectomy during the study period. Fifty-one patients (94%) were of White-British ethnicity. One patient tested positive for COVID-19 preoperatively. There were no COVID-19 diagnoses postoperatively and no COVID-19 related morbidity. There were no deaths at 30 days. Forty-four patients (81%) had a day-case procedure. Forty-two (78%) procedures were performed by a supervised trainee.

Conclusion: Elective laparoscopic cholecystectomy can be performed safely and training maintained in areas of low COVID-19 prevalence with the necessary precautions.

Clinical significance: This small study provides some evidence to aid decision-making around the provision of elective surgical services during this ongoing pandemic.

Keywords: Cholecystectomy, Coronavirus, COVID-19, Surgery.

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Introduction

Perioperative coronavirus disease-2019 (COVID-19) infection results in significant mortality and respiratory morbidity, the 30-day mortality rate for elective patients with COVID-19 has been reported as 18.9%.[1] Guidance has been published on the prioritization and management of patients requiring surgery and the recovery of surgical services[2–10] however limited data have been published on the outcomes of elective surgery during the initial phase of the pandemic. The largest study to date included both adults and children and did not stratify results by type of elective surgery or country of origin.[1]

The first UK lockdown was announced on March 23, 2020. It has been estimated that 81.5% of benign upper gastrointestinal/hepatobiliary operations may have been cancelled or postponed worldwide during the initial 12-week peak of the COVID-19 pandemic.[11] In the UK this could represent up to 50,000 laparoscopic cholecystectomies.[12] As part of our hospital's response to increasing resources for COVID-19 patients, routine elective surgery ceased and access to the theater was initially reduced from 5 all-day operating lists per week to 3 for our unit.

The UK has experienced regional variation in COVID-19 prevalence. The number of confirmed cases in the South West of England in June 2020 was less than 20 per 100,000 compared with 40 or more per 100,000 in areas of London and the North West of England.[13] The accompanying mortality rates have also been much lower (41 per 100,000 in the South West of England vs 137 per 100,000 in London, in June 2020).[14] As such, urgent elective surgery including esophagogastric cancer surgery and laparoscopic cholecystectomy continued to be performed at Derriford Hospital in Plymouth throughout the first wave of the pandemic. All necessary precautions were taken perioperatively as national and local guidance evolved.

The aim of this study was to determine outcomes after urgent elective laparoscopic cholecystectomy during the initial phase of the COVID-19 pandemic.

Materials and Methods

Records and laboratory results of consecutive patients who underwent elective laparoscopic cholecystectomy by five surgeons in a single tertiary surgical unit between March 25th 2020, and June 25th 2020, were analyzed retrospectively. Patients were telephoned after 30 days and asked if they had postoperative COVID-19 testing

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Conflict of interest: None

performed, as results from tests arranged in the community were not always accessible. They were also asked if they had been treated for any postoperative complications.

The primary outcome measure was COVID-19 related morbidity. Secondary outcome measures were non-COVID-19 related morbidity as defined by the Clavien-Dindo classification,[15] 30-day mortality, and length of hospital stay.

Only patients from the urgent waiting list were operated on electively during this period. These include patients with cholecystitis, cholangitis, pancreatitis, or recurrent severe biliary colic. No changes to our "urgent" classification were made during this period. Both day-case and inpatient procedures were performed. Operations were performed by a consultant or supervised trainee.

COVID-19 Precautions and Deviations from the Standard of Care

Patient Selection

Patients were booked from the urgent waiting list in our usual manner.

Preoperative

The preoperative assessment took place by telephone, with patients attending in person for blood tests, electrocardiograph (ECG), and methicillin-resistant staphylococcus aureus (MRSA) swabs. COVID-19 screening questions were asked before attendance. COVID-19 swabs were performed 48 hours prior to surgery and patients were asked to self-isolate from this time. Results were available within 24 hours. Thoracic imaging was not routinely requested preoperatively. Our usual admission ward had been reallocated, so patients were admitted for surgery via the day-case recovery area. The risk of perioperative COVID-19 infection was discussed with our patients but no specific figures were given. In all cases, patients were advised that the benefits of surgery outweighed the risks.

Intraoperative

Anesthetists and operating department practitioners (ODPs) performed intubation in "red" personal protective equipment (PPE) (visor/goggles, FFP3 face mask, double gloving, and gown) for the first 6 weeks. "Amber" PPE (visor/goggles, standard surgical mask, gloves, and apron) was used in the following 6 weeks. Surgeons were operating in "red" PPE during the first 2 weeks followed by "amber" PPE in the following 10 weeks. Cholecystectomy was performed in our standard manner. Pneumoperitoneum was safely evacuated via a filtration system before closure and trocar removal.[7] Training was maintained throughout.

Postoperative

The postoperative care was provided in our usual surgical wards and day-case recovery area. These had been designated "green" wards with patients only admitted there if they did not have symptoms or clinical suspicion of COVID-19 and had negative swab tests. COVID-19 swabs were performed on any patients who developed a fever or symptoms, along with prompt patient isolation. All other surgical inpatients were swabbed on admission. In-patient results were available within 4 hours of testing. Routine swabbing of asymptomatic staff was not being performed at the time of this study.

Results

Fifty-four patients underwent elective laparoscopic cholecystectomy during the study period. Five patients could not be contacted postoperatively. Demographic and treatment details are listed in Table 1. Fifty-one patients were of White British ethnicity. All patients underwent preoperative COVID-19 swab tests. Eight patients required a postoperative COVID-19 swab test, all of whom had a negative result. Only one patient was swabbed due to potential COVID-19 symptoms. Six patients were tested routinely as they were readmitted to the hospital. One patient was routinely swabbed by their employer. One asymptomatic patient had a positive COVID-19 swab preoperatively, they were contacted and their surgery was postponed.

Outcomes are detailed in Table 2. There was no COVID-19 related morbidity. Of the six patients (11%) who were readmitted within 30 days of discharge, four were treated for postoperative pain and had normal investigations, including a magnetic resonance cholangiopancreatogram (MRCP). One patient was readmitted with pancreatitis which was managed conservatively following a normal MRCP. One patient was readmitted with an occult trocar injury to the small bowel and underwent two emergency laparotomies during their stay including a small bowel resection and ileostomy. Two

Table 1: Demographic and treatment details

Female:Male	**35:19**
Median age (range), years	59 (20–79)
Median BMI (range), kg/m^2	31 (22.9–46.8)
Median ASA	2
Comorbidities	
Diabetes	8
Hypertension	14
Cardiac	6
Respiratory	7
Indication for surgery	
Cholecystitis	27
Cholecystitis with gallbladder perforation	3
Biliary colic	15
Pancreatitis	9
Surgical approach	
Laparoscopic	54
Open/converted	0
Procedures performed by trainee	42

Table 2: Outcomes

COVID-19 related morbidity	0
Non COVID-19 morbidity	5
Bowel injury	1 (CD IVa)
Pancreatitis	1 (CD II)
Pai	4 (CD I)
Wound infection	1 (CD I)
Nausea	1 (CD I)
Bile leak	0
Bile duct injury	0
30-day mortality	0
Median overall length of stay (range), days	0 (0–3)
30-day readmission rate	6

CD, Clavien-Dindo classification

patients were reviewed by their GP postoperatively for a wound infection, and nausea. There were no bile leaks or bile duct injuries. There were no deaths within 30 days of surgery. Four patients had a cholecystostomy drain in-situ at the time of surgery. All procedures were completed laparoscopically. Forty-two (78%) procedures were performed by a supervised trainee.

Discussion

A survey of over 1,700 surgeons in June 2020 in the UK showed that only 33% had been unable to undertake any elective surgery during the previous 4 weeks, and only 57% of general surgeons who had recommenced were performing surgery for benign disease.[8] While recovery of elective surgical services is now underway in many areas, further suspension or reductions have become necessary over the periods of local or national lockdown, and this is likely to continue for some time. With the effects of the ongoing vaccination program yet to be determined, we must consider how to safely maintain elective services during the ongoing pandemic.

At the time of writing, this was the first UK study to report outcomes for elective laparoscopic cholecystectomy during the COVID-19 pandemic. The principal findings of this study were that laparoscopic cholecystectomy can be performed safely with the necessary precautions in an area with a relatively low infection rate.

This observational study has potential limitations, including the potential for selection bias. At the beginning of the study period, there was reluctance from many patients to accept offers of a date for elective surgery, citing their fears about contracting COVID-19. This cohort of patients could have included older, more comorbid patients, however, our day-case and readmission rates for the unit were unchanged. Uptake did increase throughout the study period, and our usual practices were followed when booking patients from the urgent waiting list for surgery. Five patients were not contactable postoperatively and we were, therefore, unable to exclude the possibility that they were diagnosed with COVID-19 in the community, or had morbidity not requiring hospital admission. Although this is a relatively small cohort with limited follow-up, we felt that it was important to report our outcomes from the first 3 months of the pandemic to provide evidence to support the resumption and continuation of elective surgery.

The main factors that allowed us to continue with urgent elective surgery were the relatively low rate of COVID-19 infection in our population and hospital, access to preoperative testing, and adequate supplies of PPE. In addition, there had been no redeployment of surgical consultants or trainees to other areas. We were able to resume our normal capacity of five all-day theater lists per week after 8 weeks.

Conclusion

Elective surgery was suspended at the beginning of the COVID-19 pandemic in the UK, the prolonged nature of this pandemic with fluctuating local case numbers and several national lockdown periods requires flexibility in the provision of elective surgical services. Policies should be driven locally taking into consideration the rate of new COVID-19 cases, testing capacity, adequate PPE supply, and availability of essential perioperative services.[9,10] This study has shown that laparoscopic cholecystectomy can be performed safely during the COVID-19 pandemic with the necessary precautions, and surgical training maintained, in areas with a low prevalence of COVID-19.

Clinical Significance

This small study provides some evidence to aid decision-making around the provision of elective surgical services during this ongoing pandemic.

Statement of Ethics

Ethics committee approval was not required as this study was approved by the University Hospitals Plymouth Research and Development Department as a service evaluation.

Author Contributions

DC/TW/GS/AA/LH/RJ designed the study, data collection and analysis performed by RJ/AM. Article written by RJ. All authors revised and approved the final version.

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CASE SERIES

Laparoscopic Management of Uncommon Presentations of Ectopic Pregnancy: A Case Series

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Abstract

The incidence of ectopic pregnancy, which constitutes about 2% of all pregnancies, is increasing due to increasing risk factors and availability of better diagnostic modalities. It is one of the important causes for maternal mortality in the first trimester. Some ectopic pregnancies, usually the ones in the uterus, may be missed in the initial ultrasound evaluation and require high index of suspicion. If ultrasound is inconclusive, MRI may help in the diagnosis. Management modalities include expectant, medical, combined medical/surgical, and surgical treatment. In patients opting for surgery, laparoscopy provides excellent visualization of the pathology, decreases maternal morbidity, and improves the fertility outcome in future pregnancies. Here we are discussing four rare ectopic pregnancies: two cases of cesarean scar pregnancy, one case of interstitial pregnancy, and one case of rudimentary horn pregnancy and their successful management by laparoscopy.

Keywords: Cesarean scar pregnancy, Ectopic pregnancy, Interstitial pregnancy, Laparoscopy, Rudimentary horn pregnancy.

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Introduction

Although ectopic pregnancy constitutes only about 2% of all the pregnancies, it is responsible for 6% of all pregnancy related deaths and hence warrants high index of suspicion, proper evaluation, and appropriate treatment.[1] Ectopic pregnancies are known to occur in the fallopian tubes (the most common site), cervix, ovary, abdomen, myometrium, and previous cesarean scar.[2] The risk factors include pelvic inflammatory disease, previous intrauterine instrumentation, previous tubal surgery, previous ectopic, assisted reproductive techniques, and congenital uterine anomalies. Timely intervention, be it expectant, conservative, or definitive, and vigilant follow-up prevent rupture and massive hemorrhage and preserve future fertility.[3] Although traditional surgical management involves laparotomy, laparoscopic approach is now being adopted whenever possible due to its various advantages in experienced hands. Here we are discussing a series of four ectopic pregnancies in uncommon locations and their surgical management by laparoscopy.

Case 1: Cesarean Scar Pregnancy

A 28-year-old gravida 2 para 1 living 1 with previous cesarean section (CS) presented to our hospital with complaints of bleeding per vaginum for 10 days following intake of pills for medical abortion prescribed at 8 weeks of gestation. She was pale with a pulse rate 98/minute and blood pressure (BP) 100/70 mm Hg. On examination, there was lower abdominal tenderness. On per speculum examination, there was minimal bleeding and uterus was of normal size with no forniceal tenderness on per vaginal examination. Ultrasound showed a gestational sac of 3 × 5 cm with fetal pole and no cardiac activity in the anterior part of the lower uterine segment near the utero-cervical junction with empty uterine cavity with extensive vascularity in the area of previous cesarean scar suggesting cesarean scar pregnancy (Fig. 1). Informed written consent for laparoscopic surgery was obtained after explaining different modalities of treatment. On laparoscopy, cesarean scar ectopic of around 5 × 5 cm was noted (Fig. 2). Diluted vasopressin (10 U in 100 mL) was injected into the myometrium near the site of ectopic. Uterovesical (UV) fold of peritoneum was opened, bladder was pushed down, thinned-out myometrium over scar ectopic was incised, and contents were aspirated. The rent was sutured with barbed suture. Patient was discharged on second postoperative day without any complications. Histopathological examination (HPE) revealed products of conception.

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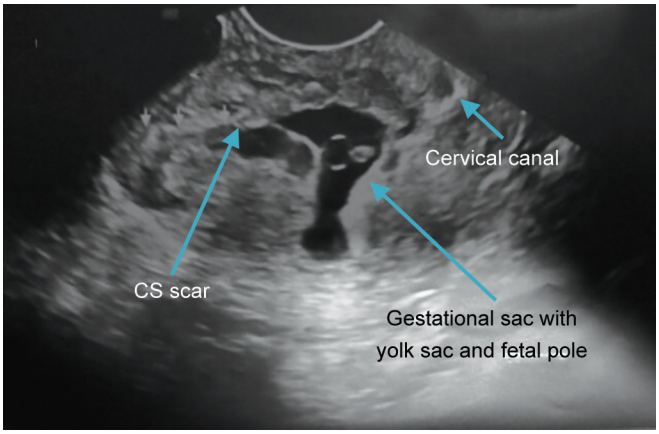
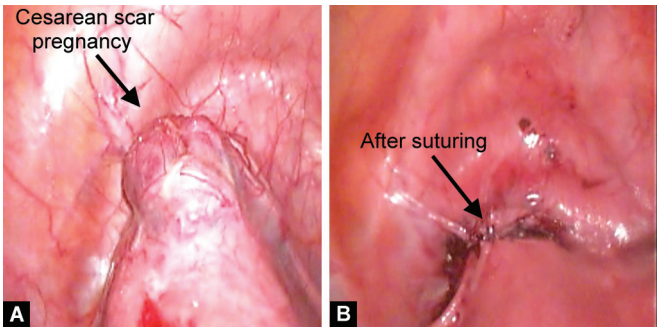


Fig. 1: Transvaginal ultrasound of cesarean scar pregnancy



Figs 2A and B: Laparoscopic picture of cesarean scar pregnancy before and after surgery

Case 2: Cesarean Scar Pregnancy

A 32-year-old gravida 2 para 1 living 1 with previous CS 3 years back with history of 1.5 month amenorrhea presented to a local hospital for termination of pregnancy. Since ultrasound report was intrauterine pregnancy of 7 weeks duration, she was prescribed drugs for medical abortion. As she did not have bleeding she was posted for D and C in the same hospital. Patient had excessive bleeding during the procedure and went into shock. She was stabilized with three units of PRBC and was referred to our hospital for further management. On admission, patient was stable and repeat ultrasound showed a hypo echoic mass measuring 4.7 × 4 cm in the anterior wall in the subserosal and intramural location in the region of the isthmus. The lesion was surrounded by multiple vascular channels. Serum βHCG was 6700 U/L. She was posted for laparoscopy after making a diagnosis of cesarean scar pregnancy and taking informed consent. There was a 4 × 2 cm mass in the isthmic region anteriorly (Fig. 3). Diluted vasopressin was injected near the lesion, UV fold of peritoneum opened, bladder pushed down, incision taken on the mass and contents aspirated. Rent was closed with barbed suture. HPE revealed products of conception.

Case 3: Interstitial Pregnancy

A 30-year-old gravida 3 para 1 living 1 abortion 1 with previous CS came with history of 2 months of amenorrhea. Ultrasound revealed empty uterine cavity with pregnancy of 7 weeks seen to the periphery of the uterus on the right side, with an endomyometrial mantle measuring around 4 mm suggestive of interstitial pregnancy. On laparoscopy, right-sided interstitial pregnancy measuring 4 × 5 cm was noted (Fig. 4). Dilute vasopressin was injected into the myometrium adjacent to the ectopic, incision taken on the mass, and contents were aspirated. Incision was closed with barbed suture. HPE revealed products of conception.

Case 4: Rudimentary Horn Pregnancy

A 36-year-old gravida 2 para 1 living 1 with previous LSCS with 2.5 months of amenorrhea presented to our hospital with ultrasound showing rudimentary horn pregnancy with twin pregnancy, one corresponding to 11 weeks gestation and another one being blighted ovum. On laparoscopy, rudimentary horn pregnancy was noted on the right side with right fallopian tube and ovary attached to the rudimentary horn (Fig. 5). Excision of the same was done with harmonic after injection of dilute vasopressin into the myometrium near the attachment of the rudimentary horn

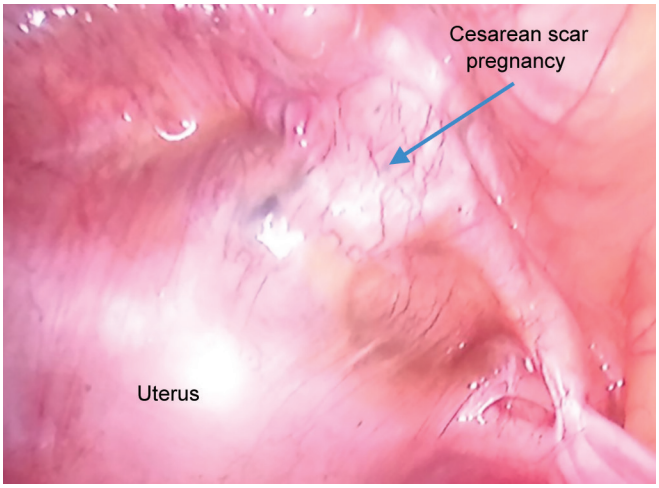
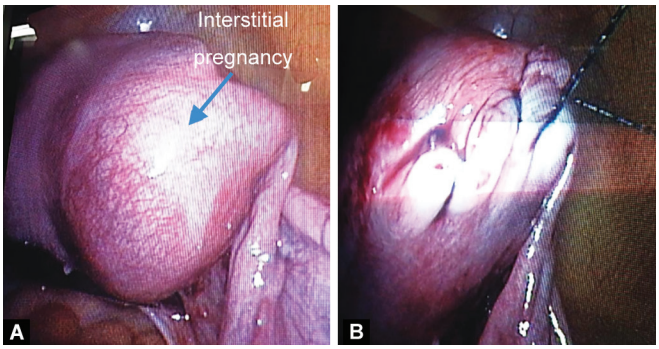
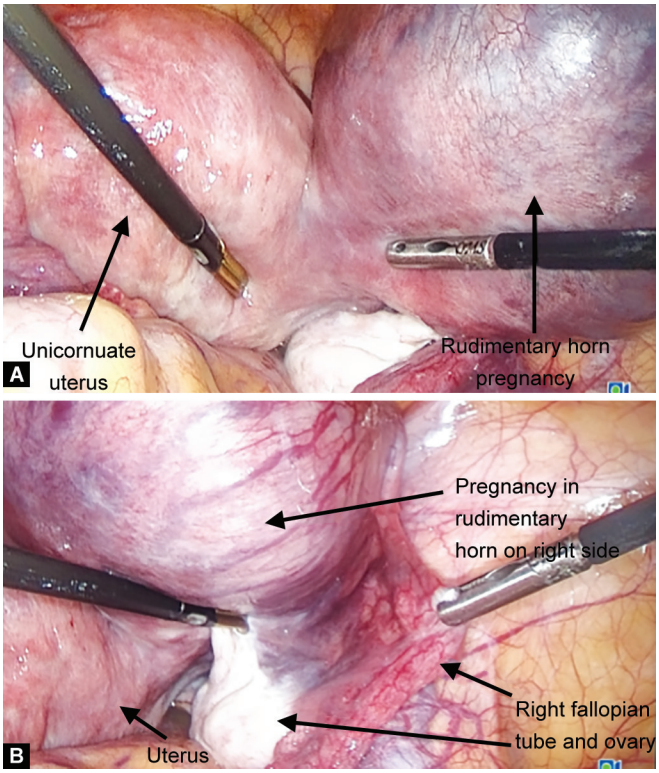


Fig. 3: Laparoscopic picture of cesarean scar pregnancy



Figs 4A and B: Laparoscopic picture of interstitial pregnancy: before and after surgery



Figs 5A and B: Rudimentary horn pregnancy

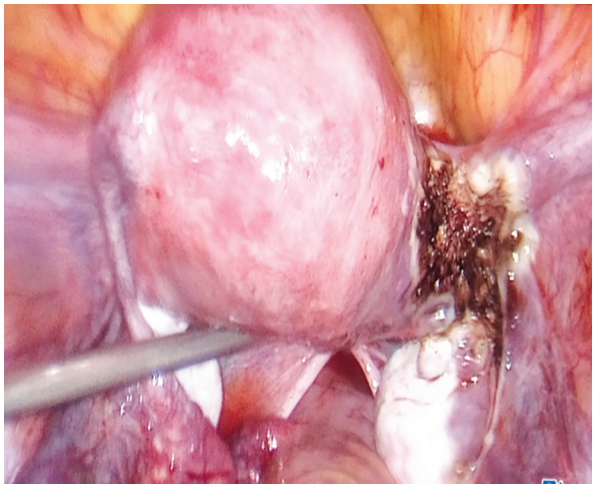


Fig. 6: Rudimentary horn pregnancy after excision

to the uterus and the bleeding points were coagulated (Fig. 6). HPE revealed products of conception in the rudimentary horn.

Discussion

Cesarean Scar Pregnancy

Cesarean scar pregnancy occurs in 1 in 2,000 pregnancies.[2,4] Incidence is on an increasing trend because of increasing primary CS rate.[4] First case of cesarean scar ectopic was mentioned in the English Medical Literature in 1978 by Larsen and Solomon.[5] Improper implantation at prior hysterotomy site occurs due to disruption of the endometrium and the myometrium.[1,5]

In cesarean scar ectopic pregnancy either the implanted gestational sac grows into the uterine cavity or grows toward the serosal surface of the uterine wall. The former might proceed to term with a viable fetus with an increased risk of life-threatening massive postpartum hemorrhage whereas the latter carries the risk of rupture and hemorrhage during the first trimester of pregnancy.[1,6]

Criteria for cesarean scar ectopic pregnancy include:

- Gestational sac embedded eccentrically in the lower uterine segment
- Implantation in the location of a prior cesarean delivery scar
- Empty uterine cavity and cervical canal
- Attenuated myometrium over the scar
- Extensive Doppler vascular flow in the area of the cesarean delivery scar.
- Negative sliding sign—inability to displace the gestational sac from its position at the level of internal OS by gentle pressure applied by the transabdominal probe.[1,2,5]

In both the cases of cesarean scar pregnancy described in this case series, initial ultrasound missed in the diagnosis. Hence high index of suspicion is the key to early diagnosis.

Conservative medical management is indicated in unruptured ectopic pregnancy of <8 weeks gestation with myometrial thickness <2 mm between cesarean scar pregnancy and bladder when the patient is hemodynamically stable. Systemic administration of methotrexate and local intrasac administration of embryocides like methotrexate, potassium chloride, hyperosmolar glucose, or crystalline trichosanthin under ultrasound guidance are other modalities of treatment which have been tried with varied success rates.[7]

Blind uterine curettage is strongly discouraged as it causes scar rupture and severe hemorrhage, as has been seen in the second case we have discussed.[8] Hysteroscopic evacuation is a safer alternative with short operating time, less blood loss, and short postoperative stay.[9] With laparoscopy, cesarean scar ectopic mass is incised and pregnancy tissue removed in endobag. Bleeding can be minimized by local injection of vasopressin and hemostasis achieved by bipolar diathermy and defect closed by endosuturing.[10]

Laparotomy is mandatory when uterine rupture is strongly suspected. Hysterectomy is done when all other treatment modalities fail to control bleeding or repair the defect.[11]

Interstitial Pregnancy

Interstitial pregnancies (IP) constitute 2–6.8% of all ectopic pregnancies. Because of distensibility of myometrium, they tend to grow to an advanced gestation before rupture. Due to proximity to the intramyometrial arcuate vasculature, the bleeding occurring as a consequence of rupture may be catastrophic and this is the reason why IP is associated with mortality rate of 2–2.5% (seven times the average for all ectopic pregnancies). "The diagnosis of IP by ultrasound is based on the following criteria: the GS is located outside the uterine cavity; the interstitial part of fallopian tube is seen adjoining the lateral aspect of the uterine cavity and GS; and the myometrial mantle extends laterally to encircle the GS".[12,13]

Medical management with methotrexate can be considered if the patient is hemodynamically stable with no signs of rupture, i.e., large GS or rapidly increasing β-hCG levels.

Surgical management of IP includes cornual wedge resection, cornuostomy, and hysterectomy either by laparotomy or laparoscopy. For ruptured cornual pregnancy, laparotomy is preferred. Hysterectomy is reserved to cases in which hemorrhage is profuse and life threatening. Other management options include ultrasound-guided transcervical forceps extraction (UTCE) and transcervical suction under laparoscopic and hysteroscopic guidance[13] which have been reported in a few recent case reports. In our patient, cornuostomy was done as it carries lesser risk of uterine rupture in subsequent pregnancy compared with cornual wedge resection.

Rudimentary Horn Pregnancy

Rudimentary horn pregnancy, another rare ectopic pregnancy with incidence of 1 in 76,000 pregnancies, occurs due to the transperitoneal migration of sperm/fertilized ovum from contralateral side or through a microscopic fistulous tract with unicornuate uterus.[14]

Natural fate of rudimentary horn ectopic when left untreated is usually rupture during the last two trimesters due to underdevelopment, poor distensibility of myometrium, and dysfunctional endometrium. Only 10% have been reported to have progressed to full term among which 2% have survived.[15,16] Ultrasound and MRI aid in the diagnosis.

The following criteria have been suggested by Tsafri et al for sonographic diagnosis of rudimentary horn pregnancy: (1) pseudo-pattern of an asymmetrical bicornuate uterus, (2) absent visual continuity between the cervical canal and the lumen of the pregnant horn, and (3) the presence of myometrial tissue surrounding the gestational sac.[17]

Late presentation of rudimentary horn pregnancy is difficult to treat by local/systemic methotrexate but there a few case reports describing successful management with methotrexate.[18]

Management is mainly by resection of the horn with pregnancy *in situ*.[14]

Conclusion

Ectopic pregnancy is on the rising trend. Diagnosis requires high index of suspicion, ultrasound, serum beta HCG, and MRI aid in the diagnosis. Ruptured ectopic causes massive hemorrhage and shock. Timely intervention prevents maternal near miss. Surgical management by laparoscopy in experienced hands reduces maternal morbidity to a greater extent. Since all the ectopic pregnancies described are rare forms of ectopic pregnancies, there is paucity of data comparing different modalities of treatment and more research is needed to know the best line of management. However, laparoscopic management of ectopic pregnancy should be the preferred line of management when possible as it is associated with lesser postoperative pain, shorter hospital stay, faster return to normal function and to work in addition to having cosmetic advantages. Vasopressin was used in all our patients and helped in reducing blood loss significantly.

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