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Editorial

Coronavirus disease-2019 emerged as an international pandemic in 2020 and also has impacted countless lives. Minimal access surgical training of surgeons and gynecologists has been considerably affected by this pandemic. Yet, the specific result stays unidentified but lack of hands-on training has given a lot of sets back in training programs. We looked to survey laparoscopic surgical treatment numbers in various superspecialty hospitals in India to analyze the impact of COVID-19 on surgical resident training and education.

Medical students interested in learning minimal access surgery perceive the COVID-19 pandemic as harming their education, due to a reduction in clinical exposure. Actions need to be required to make certain that laparoscopic surgeons and gynecologists are properly planned for fellowship and independent practice despite the substantially decreased situation quantities throughout this pandemic.

Laparoscopic surgery training programs need to concentrate on providing nontechnical clinical training and expert advancement during this time around. When current optional laparoscopic surgery restrictions are raised, a factor to consider must be given to suspending the existing 'efficiency' model in favor of making sure that trainees are proctored via these cases to fix the accumulated training deficit aggravated by the pandemic. This might aid to alleviate the impacts of the pandemic and ensure the continued education program of the top-quality trainees for which our training programs are internationally renowned.

We strongly believe that the job of a minimal access surgeon is mainly professional and also skill development and both of these elements were highly damaged by the COVID-19 pandemic. The existing situation will not be sustainable for a lot more time and we require to be prepared with specific programs in case of another pandemic takes place. The World Association of Laparoscopic Surgeons has started many online webinars to fill this gap. We have also tried to invite top-class clinical articles from surgeons all over World to make WJOLS more interesting in this COVID-19 era. We strove to improve and also promote among surgeons all sorts of self-education material, from webinars to video-based education and learning, consisting of pelvic-trainer simulation.

RK Mishra
Editor-in-Chief
Chairman
World Laparoscopy Hospital
Gurugram, Haryana, India

ORIGINAL ARTICLE

Comparison between Laparoscopic Ultrasound and Intraoperative Cholangiogram in Detection of Common Bile Duct Stones during Laparoscopic Cholecystectomy for Cholelithiasis: A Prospective Study

Mohamed Elkerkary[1], Gouda Ellabban[2], Mohamed Shams[3], Mostafa Abdel-Raheem[4], Hamdy Shaban[5], Ahmed Hassan[6]

Abstract

Introduction: Intraoperative cholangiography (IOC) during laparoscopic cholecystectomy (LC) is valuable in the detection of biliary abnormalities. In this study, we aimed to investigate the diagnostic accuracy of IOC during LC for the detection of anatomic variations of the biliary system, as well as the visualization ability of IOC on determining the normal anatomy of the biliary tree.

Materials and methods: This cross-sectional study was conducted on patients who were presented to the surgery outpatient clinic and were scheduled for elective LC for symptomatic cholelithiasis. Patients underwent intraoperative laparoscopic ultrasound (LUS) before the dissection of Calot's triangle and IOC video fluoroscopy examination of the extrahepatic biliary tree.

Results: Our study enrolled 53 patients. No intraoperative complications occurred in all enrolled patients. LUS was successful in all 53 (100%) cases, while IOC was successful in 50 (94.3%) cases. IOC had accuracy rate of 100% (50 patients) in defining biliary ducts at the porta hepatis compared to 84.91% (45 patients) for LUS with a failure rate of 15.09% ($p = 0.60$). Concerning stones detection, LUS accuracy indexes were as follows: sensitivity = 80%; specificity = 95.83%; positive predictive value (PPV) = 66.67%; negative predictive value (NPV) = 97.87% 99; and diagnostic odds ratio (DOR) = 92. IOC accuracy indexes were as follows: sensitivity = 80%; specificity = 93.33%; PPV = 57.14%; NPV = 90%; and DOR = 56.

Conclusion: The results of the current study encourage using IOC as an effective, accurate, feasible, and safe technique to visualize the biliary tree while performing LC.

Keywords: Diagnostic accuracy, Intraoperative cholangiography, Laparoscopic cholecystectomy.

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Introduction

Throughout recent decades, minimally invasive surgery in several abdominal procedures has been growing. Laparoscopic procedures are the most commonly performed procedures in the last few years.[1] The surgeon's failure to palpate abdominal organs is a downside of this laparoscopic technique. However, laparoscopic cholecystectomy (LC) is an easy and safe procedure as long as there is a clear mapping of the biliary duct.[2,3] Nonetheless, the description and detailed evaluation of biliary pathways are critical for the identification and prevention of the bile duct injury (BDI) of the common bile duct stones (CBDS).[4,5] The invisibility of the biliary tract is the main cause of BDI in 97% of diagnosed cases.[6,7] Moreover, the inadequate skills of surgeons may participate in BDI. To avoid this serious complication that may affect the outcome of the procedure and the quality of life, different techniques have been proposed such as intraoperative cholangiography (IOC), passive infrared cholangiography, dye cholangiography, and laparoscopic ultrasound (LUS).[4,8,9]

Regarding IOC, there is a large debate as to whether IOC should be used routinely or for select cases.[10] However, it is the most commonly used technique to determine the biliary duct.[11] Some limitations were reported for the use of IOC, such as prolongation of the procedure time, cost, and the presence of the risk of an inflamed cystic duct and ionizing radiation.[12,13] LUS is a less invasive, cheaper, and faster technique when compared with IOC.[14] A recent meta-analysis showed that the sensitivity and specificity of IOC and LUC were comparable. However, LUC was associated with lower ionizing radiation, lower failure rate, and much quicker performance and can be repeated safely during the procedure.[15] The success rate of LUC is estimated to be 100% compared to 91.3% for IOC. Moreover, some reports demonstrated that the sensitivity of IOC combined with LUS was greater than that of IOC and LUS took separately.[8,16–18] Therefore, this study aimed to investigate the diagnostic accuracy of IOC in combination with LUC during LC.

[1–3,5,6]Department of Surgery, Faculty of Medicine, Suez Canal University, Ismailia, Egypt

[4]Department of Surgery, Hywel Dda University Health Board, Wales, United Kingdom

Corresponding Author: Mohamed Elkerkary, Department of Surgery, Faculty of Medicine, Suez Canal University, Ismailia, Egypt, e-mail: m_kerkary@med.suez.edu.eg

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Materials and Methods

Study Population

This cross-sectional study was conducted at the Surgery Department of Suez Canal University Hospital, Ismailia, Egypt. It was performed on patients who were presented to the surgery outpatient clinic and were scheduled for elective LC for symptomatic cholelithiasis. This study included patients who were scheduled for LC for symptomatic cholelithiasis and were stratified as low-risk of having CBD stones. The patients who fulfilled the inclusion criteria were allocated to a sampling frame and randomized by simple random sampling. Ethical approval was obtained from the Surgery Department at Suez Canal University Hospital. Patients were notified about the study, and the informed written consent was obtained prior to participation in the study.

We included patients with symptomatic cholelithiasis between the ages of 18 years (for easy laparoscopic instrumentation with LUS 10-mm probe) and 65 years (more comorbidities as a relative contraindication to LC). We excluded patients with contraindications to LC, complicated cholelithiasis (e.g. obstructive jaundice and acute pancreatitis), previous gastrointestinal surgery, contrast hypersensitivity, previous endoscopic retrograde cholangiopancreatography (ERCP), and CBD stent due to radiological falsies, or conversion to open cholecystectomy during LC.

Data Collection

All enrolled patients were subjected to history taking for exclusion criteria and comorbidities, clinical examination for signs of cholelithiasis, laboratory investigations (liver functions and coagulation profile), and a recent transabdominal US examination that includes sizes of the gallbladder and CBD, wall thickness, presence of stones, masses, polyps, or fluid around the gallbladder, as well as the status of the pancreatic head. Patients then underwent intraoperative LUS before dissection of Calot's triangle and IOC video fluoroscopy examination of the extrahepatic biliary tree.

Laparoscopic Ultrasound

We introduced the deflectable multifrequency (7.5–10 MHz) endosonography linear probe through a 10-mm port, while the camera was placed through the midepigastric port. First, the liver was scanned and the CBD was identified. The gallbladder and liver were retracted superiorly and cephalad. Sometimes the junction of the right and left hepatic ducts could be seen. The CBD was followed to the duodenum. A transverse view of the bile duct could be obtained by acute deflection of the transducer.

Intraoperative Cholangiography

We initially dissected the Calot's triangle to identify the cystic duct and artery, which was divided between clips. To apply the cholangiocatheter, we dissected the cystic duct free for about 3 cm and then applied a ligature on the junction of the GB and the cystic duct. The cholangiocatheter was introduced through the midclavicular port or through a separate puncture in the right upper quadrant. Utilizing dynamic fluoroscopy, we obtained a scout film to localize the tip of the cholangiocatheter. First, only 2 to 3 cc of a water-soluble contrast dye with 25% concentration (diatrizoic acid: Gastrografin and sometimes Omnipaque) were injected identifying the cystic duct–CBD junction. The fluoroscopy unit was shifted caudally a few centimeters, and the course of the distal CBD was identified by injecting another 5 cc of contrast. The fluoroscopy arm was shifted cephalad, and another 5 cc of contrast is injected to visualize the common hepatic duct and the proximal hepatic radicals. When the cholangiogram was done, the clamp and catheter were removed and two clips were placed just distal to the ductotomy.

Statistical Analysis

The formula for the sample size was as follows: n (per test) $= [\alpha/2 + \beta/2]^2 * [(p_1 * (1 - p_1)) + (p_2 * (1 - p_2))]/[p_1 - p_2]^2$ where n = the sample size required in each group, p_1 = sensitivity of LUS in choledocholithiasis = 96%, p_2 = sensitivity of IOC in choledocholithiasis = 75%, α depends on desired significance level (95%) = 1.96, and β depends on desired power (90%) = 1.28. Thus, the sample included 53 patients who fulfilled the inclusion criteria. A data entry form was created using Epi Info 7.0, and the same software was utilized for statistical analysis along with the SPSS 16 for advanced statistics. Continuous data were expressed as mean and stander deviation, and categorical data were expressed as frequencies and percentages. Continuous data with normal distribution were compared using the Student's *t*-test or ANOVA, while the Mann–Whitney/Wilcoxon two-sample test was used to compare two-sample variables with other distributions. The accuracy indexes of LUS and IOC were expressed as sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and diagnostic odds ratio (DOR) with 95% confidence interval. The significance level was considered at 0.05×.

Results

Baseline Data

Our study enrolled 53 patients: 17 males and 3 females. The mean ages for male and female groups were 41.35 ± 8.48 and 40.06 ± 11.85 years, respectively (age was statistically comparable between both genders; $p = 0.69$). Of the patients, 22 (41.5%) had multiple stones and 31 (58.5%) had solitary stones on preoperative US.

Intra- and Postoperative Complication Rates

No intraoperative complications occurred in all enrolled patients. In terms of 30 days' follow-up, only nine (17%) had postoperative complications that included chest infections (three), intraabdominal collection (two), urinary tract infection (one), and wound infections (three). No mortalities were recorded during the follow-up period.

LUS vs IOC Success Rates

LUS was successful in all 53 (100%) cases, while IOC was successful in 50 (94.3%) cases. Using the Chi-square test to compare the success rate between LUS and IOC, we observed no significant difference between both tests (OR = 1.0061; $p = 0.08$). The reasons for the three observed failures in IOC included narrow cystic duct, thick valves at cystic duct, and technical failure.

Time to Complete the Procedure

In terms of the time to complete the procedure, LUS took 12.53 ± 2.56 minutes to complete with a range of 6 to 17 minutes, while IOC took 8.66 ± 2.77 minutes to complete with a range of 7 to 15 minutes. Comparing both procedures using the Mann–Whitney/Wilcoxon Test showed a significantly longer

time in LUS compared to IOC ($p = 0.001$). We carried out a linear regression analysis to see if there was a correlation between LUS and IOC regarding time to complete. We found that there was a positive correlation between LUS and IOC for time with Pearson's correlation coefficient of 0.4225. This correlation was statistically significant (p-value <0.0016) (Fig. 1).

The learning curve was longer for LUS than for IOC. LUS took a longer time to complete in the first 30 patients and then started to decline with Pearson's correlation coefficient of −0.8717 and p-value <0.0001 using linear regression analysis. IOC had a less steep learning curve with time to complete dropping by 20 patients and Pearson's correlation coefficient = −0.4788 and p-value <0.0003 using linear regression analysis (Fig. 2).

Accuracy of LUS and IOC in Defining Biliary Tract Structures

IOC had an accuracy rate of 100% (50 patients) in defining biliary ducts at the porta hepatis compared to 84.91% (45 patients) for LUS with a failure rate of 15.09%. Statistical analysis utilizing a 2x2 contingency table showed a nonsignificant difference between the two modalities ($p = 0.60$) (Fig. 3). Similar findings also occurred when evaluating the two modalities for the accuracy in defining extrahepatic biliary ducts (CBD, common hepatic duct (CHD), and cystic duct). LUS had a failure rate of 3.77% (2 patients) and a success rate of 96.23% (51 patients), while IOC was successful in 100% of cases (50 patients) in defining extrahepatic ducts. Statistical analysis utilizing a 2 × 2 contingency table showed a nonsignificant difference between the two modalities (p-value = 0.88) (Fig. 4).

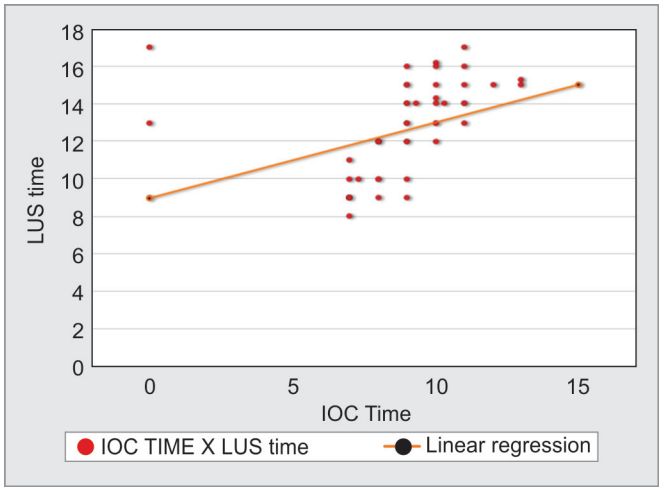


Fig. 1: Correlation between LUS time and IOC time. Pearson's correlation coefficient = 0.4225. p-value <0.0016 using linear regression analysis

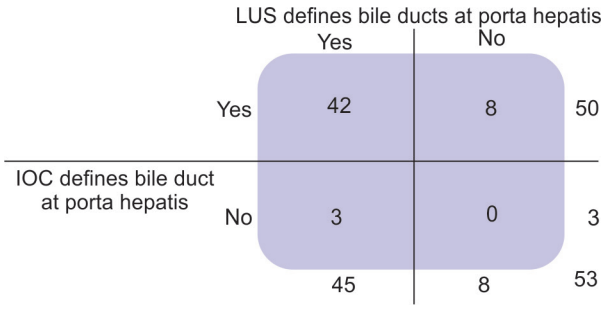


Fig. 3: A 2 × 2 contingency table for accuracy analysis between LUS and IOC in defining bile ducts at porta hepatis. X^2 Fisher-exact one-tailed p-value = 0.60

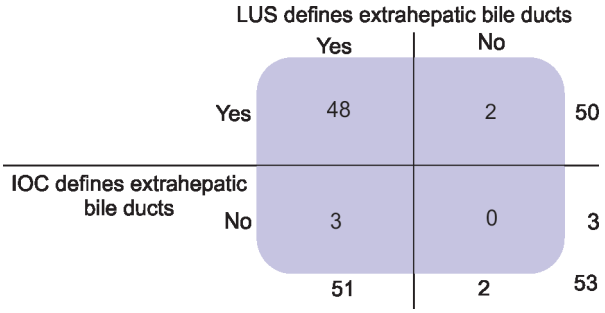
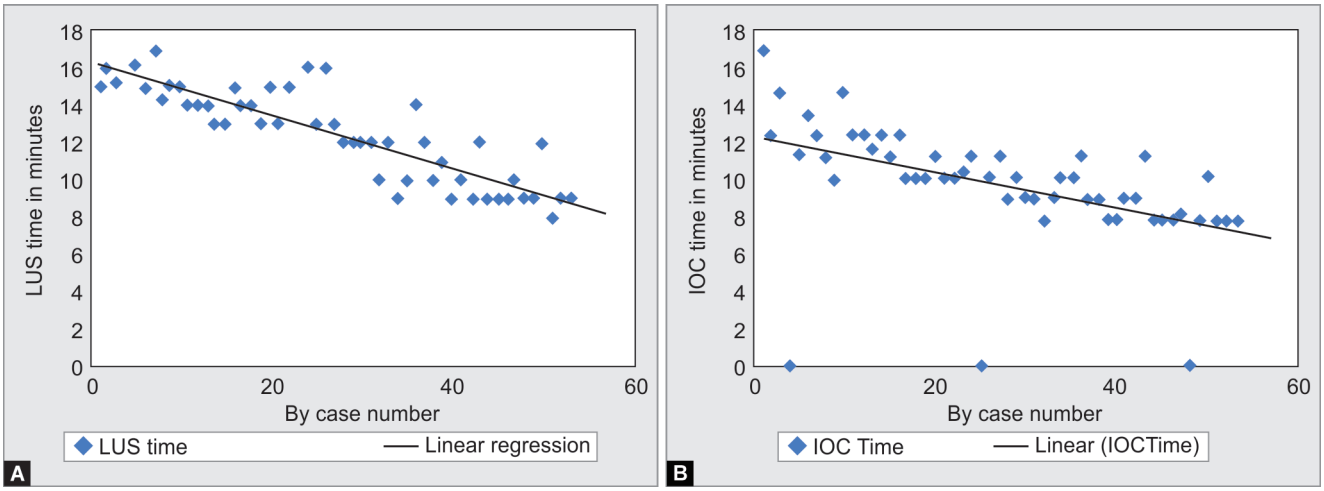


Fig. 4: A 2 × 2 contingency table for accuracy analysis between LUS and IOC in defining extrahepatic bile ducts. X^2 Fisher-exact one-tailed p-value = 0.88



Figs 2A and B: (A) LUS learning curve by time in minutes. Pearson's correlation coefficient = −0.8717. p-value <0.0001 using linear regression analysis; (B) IOC learning curve by time in minutes. Pearson's correlation coefficient = −0.4788. p-value <0.0003 using linear regression analysis

However, LUS failed to detect CD junction anomalies in all patients, while IOC detected these anomalies in 4 patients (8%) out of 50 patients. The anomalies found were medial insertion of cystic duct in one patient (2%) and low insertion of cystic duct in three patients (6%). The incidence of these anomalies was statistically insignificant (p-value = 0.05). While LUS detected vascular structures in 52 patients (98.11%) with an OR of 1.554, it failed to demonstrate anomalies in the vascular structures in all patients (Table 1).

Postoperative CBD Stones

Within the 6-month follow-up period, we suspected postoperative CBD stones in 7 patients (13.2%) among the 53 total sample. Of those seven patients, one patient presented with biliary pancreatitis and was treated conservatively. Two patients had persistent elevation of LFTs. Three patients underwent magnetic resonance cholangiopancreatography (MRCP) postoperatively, who were both IOC and LUS positive for CBD stones and MRCP confirmed the presence of stones. One patient had CBD dilatation on transabdominal US, who also was LUS and IOC positive. These stones were detected after one (three stones), two (one stone), three (two stones), and 4 months (one stone) of follow-up.

All seven patients underwent ERCP (13.21%). This number is quite high due to the fact that the selected sample was the low-risk group for CBD stones. Of the seven patients, who underwent ERCP, five (71.43%) showed CBD stones and were extracted; the finding was included as end point true positive, while in two patients (28.57%), it failed to demonstrate any CBD stones and were included as end point true negatives. The true incidence of concomitant CBD stones in our series was 9.43% by ERCP.

Accuracy of LUS and IOC in Detecting CBD Stones

LUS was true positive in 4 patients (7.55%), false positive in 2 patients (3.77%), false negative in 1 patient (2%), and true negative in 46 patients (86.67%). LUS accuracy indexes were as follow: sensitivity = 80% (95% CI 0.29–0.98); specificity = 95.83% (95% CI 0.85–0.99); PPV = 66.67% (95% CI 0.24–0.94); NPV=97.87% (95% CI 0.87–0.99); and DOR = 92 (95% CI 6.77–1249.72) (Table 2).

IOC was true positive in 4 patients (8%), false positive in 3 patients (6%), false negative in 1 patient (2%), and true negative in 42 patients (84%). IOC accuracy indexes were as follow: sensitivity = 80% (95% CI 0.29–0.98); specificity = 93.33%% (95% CI 0.81–0.98); PPV = 57.14% (95% CI 0.20–0.88); NPV = 90% (95% CI 0.86–0.99); and DOR = 56 (95% CI 4.67–671.89) (Table 3).

A 2 × 2 contingency table for accuracy analysis between LUS and IOC in defining CBD stone was constructed after stratification and adjustment by ERCP end point true-positive results. The p-value was 0.8 that showed no significant difference between the two modalities in detection of CBD stones during LC regarding their accuracy indexes. The analysis was carried out and showed equivalence/noninferiority between both tests by using Fisher-exact test for X^2 (Fig. 5).

Table 1: Accuracy of LUS and IOC in defining biliary tract structures

Bile ducts at porta hepatis	Yes	45 (84.91%)	50 (100%)
	No	8 (15.09%)	0 (0%)
Extrahepatic bile ducts	Yes	51 (96.23%)	50 (100%)
	No	2 (3.77%)	0 (0%)
Biliary ductal anomalies	Yes	0 (0%)	4 (8%)
	No	53 (100%)	46 (92%)
Vascular structures	Yes	52 (98.11%)	0 (0%)
	No	1 (1.89%)	53 (100%)

Table 2: LUS accuracy indexes

LUS	*CBD stone (s) present*	*CBD stone (s) not present*	*Total*
Positive	4 (7.55%)	2 (3.77%)	6 (11.32%)
Negative	1 (2%)	46 (86.68%)	47 (88.68%)
Total	5 (9.55%)	48 (90.45%)	53 (100%)

Table 3: IOC accuracy indexes

IOC	*CBD stone (s) present N (%)*	*CBD stone (s) not present N (%)*	*Total N (%)*
Positive	4 (8%)	3 (6%)	7 (14%)
Negative	1 (2%)	42 (84%)	43 (86%)
Total	5 (10%)	45 (90%)	50 (100%)

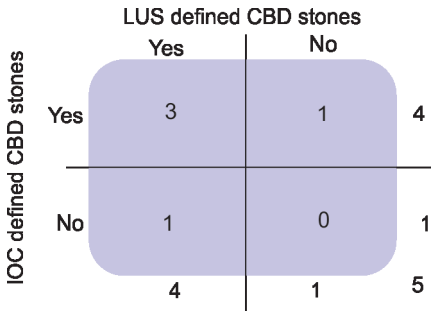


Fig. 5: A 2 × 2 contingency table for accuracy analysis between LUS and IOC in defining CBD stones. X^2 Fisher-exact one-tailed p-value = 0.8 after stratification by true-positive results of CBD stones presence

Discussion

CBD imaging during cholecystectomy has been an issue of debate for decades; some surgeons will routinely image the CBD for all cholecystectomy cases and others will use it selectively based on preoperative indicators.[19] The mainstay imaging modality was IOC, in which the biliary tree is cannulated and a contrast material will be injected through the biliary system with either spot films or dynamic fluoroscopy.[20] The issue of the clinical relevance of this technique is at least questionable, and with the search of the literature, a definitive answer could not be found. LUS is another modality, which was introduced into clinical practice, but was never widely adopted.[21] The data from the literature are promising, but no enough evidence could be found with few superiority or equality/noninferiority studies.Both techniques are not regularly utilized in our institution as biliary imaging is carried out only by IOC in selected patients based on individualized patient criteria.

We performed a cross-sectional study of low-risk patients for CBD stones. Sample size calculation yielded 53 patients who underwent LC as planned with evaluation of the biliary tree by both LUS and IOC. We adopted an equality/noninferiority analysis to assess statistical significance because our data did not enable superiority analysis. Patients who demonstrated filling defects by both modalities were managed expectantly and followed up for 6 months to assess the clinically significant CBD stones; the end

point was assurance of true-positive results, which was defined as CBD stone extraction by ERCP for the clinically manifested CBD stones if evident during follow-up.

LUS was successfully carried out in all 53 patients with a success rate of 100%, while IOC was successful in 50 patients (94.34%). The difference in the success rate between LUS and IOC was statistically insignificant ($p = 0.08$). These results correlates with the literature as the IOC success rate was reported to range from 83 to 100% by several studies, such as the systematic review by Ford and colleagues.[22] IOC failure was due to technical problem in the C-arm, narrow cystic duct that could not be cannulated and thick valves of Heister at the cystic duct totally obscuring the duct lumen.

IOC took less time to complete compared to LUS in our series, and this difference was statistically significant ($p = 0.001$). This can be explained in part by the fact that LUS takes a longer learning curve,[23,24] and in this study, it was the first time to utilize this modality; in another part, the IOC requires less laparoscopic surgical skills with little familiarity with the technique. We carried out a linear regression analysis to see if there was a correlation between LUS and IOC regarding time to complete. We found a significant positive correlation between LUS and IOC time. The learning curve was longer for LUS than for IOC. LUS took a longer time to complete in the first 30 patients and then started to decline. IOC had less steep learning curve with time to complete dropping by 20 patients.

IOC had an accuracy rate of 100% in defining biliary ducts at the porta hepatis compared to 84.9% (45 patients) for LUS with a failure rate of 15.1%. Data analysis showed a nonsignificant difference between the two modalities ($p = 0.6$). This failure rate can be explained by the difficulty in locating the US probe with good alignment to obtain images of biliary structures at the porta hepatis. Further, the imaging planes of LUS are totally different from the classical transverse and longitudinal planes of transabdominal US. This issue was raised by several authors and came to the same conclusion.[25] Similar findings also occurred when evaluating the two modalities for the accuracy in defining extrahepatic biliary ducts (CBD, CHD, and cystic duct). The failure of LUS was mainly at the area of the distal CBD, where it was covered by the gases of the duodenum, and probably with the increase in the learning curve, this issue can be resolved. Several studies demonstrated similar results, making IOC the gold standard in defining biliary anatomy.[25] While LUS detected vascular structures in 52 patients, it failed to demonstrate anomalies in the vascular structures in all patients. Owing to the wide variability of vascular anomalies in this region of the human body, the false-negative results have high probability. In the absence of a gold standard test to compare, these results cannot be ascertained.

LUS detected CBD stones in 6 out of 53 patients (11.32%), while IOC detected CBD stones in 7 out of 50 patients (14%). The difference in the rate of detection of CBD stones by the two modalities was statistically insignificant ($p = 0.45$). Several studies showed that the incidence of concomitant gallstones and CBD stones range from 11 to 21% at time of surgery.[26,27] In our study, we wanted to assess the true-positive incidence of CBD stones and to evaluate the clinically significant proportion. All patients were followed up postoperatively for 6 months with expectant approach and were informed about the possibility of having CBD stones. They were informed about warning symptoms and instructed to return to the hospital if any occurred plus their follow-up appointments. During follow-up, seven patients (13.21%) were suspected of having CBD stones. A former study reported that CBD stones may take up to 18 months from LC to manifest clinically.[28]

All seven patients underwent ERCP (13.2%). This proportion was statistically insignificant ($p = 0.8$) due to the fact that the selected sample was the low-risk group for CBD stones. Of the seven patients who underwent ERCP, five showed CBD stones and were extracted, and the finding was included as end point true positive. The true incidence of concomitant CBD stones in our series was 9.43% by ERCP. Our results of accuracy indexes analysis of LUS and IOC correlate with the literature we reviewed regarding diagnosis of CBD stones.[25]

The study limitations include the relatively small sample size, which may have hindered the detection of significant differences between the two modalities. Further, one of the secondary objectives (the evaluation of the liver parenchyma using LUS) could not be investigated, which was due to time restrictions. Future studies should enroll a larger sample size and attempt to avoid the restrictions mentioned in our study. Further, longer-term follow-up may provide more data regarding this comparison.

In conclusion, our analysis showed noninferiority between IOC and LUS in terms of CBD stone detection; however, IOC had a higher ability to visualize the anatomy of the biliary tracts and vascular structures/anomalies.

Orcid

Mohamed Elkerkary https://orcid.org/0000-0002-3998-265X

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ORIGINAL ARTICLE

Surgical Aspects of the Possover LION Procedure: An Emerging Procedure for Recovery of Visceral Functions and Locomotion in Paraplegics

Uffe S Løve[1], Soren B Elmgreen[2], Axel Forman[3], Ivan Arsic[4], Marc Possover[5], Anette B Jønsson[6], Helge Kasch[7]

Abstract

Background: Traumatic spinal cord injury (SCI) may be a devastating life event. Motor and sensory recovery after 6 months post-injury is sparse, despite intensive neurorehabilitation. Long-term disabling consequences may further reduce self-supportiveness and the quality of life. A new surgical intervention, the Possover LION procedure (Laparoscopic Implantation of Neuroprosthesis), may improve long-term perspectives providing the patient with an implantable pulse generator (IPG), and leads to pelvic situated nerves (sciatic and femoral nerves) to regain substantial motor and sensory functions in lower extremities.

Objective: To report from the surgical point of view, the experience of implementing an IPG system for direct nerve stimulation of pelvic nerves in a series of chronic traumatic SCI patients.

Methods: From two substudies, a feasibility study and a controlled clinical study, data from 21 SCI patients with severe paraplegia who had undergone the Possover LION procedure were obtained. The Possover LION procedure was implemented in a surgical department with skilled surgeons in close collaboration with neurological expertise. The developer of the procedure performed the first operations and afterward provided guidance and collaboration.

Results: Twenty patients (F = 3, M = 17, age = 36.9 ± 9.0, ISCNSCI AIS A = 19, AIS B = 1) with lesion between Th3 and L1 had IPG and four leads implanted. One patient had a "frozen pelvis" and could not be operated. During operation, severe bleeding was seen in one patient that could be stopped using on-site applied hemostats, with no need of transfusion. One patient had initial normalization of infection parameters postoperatively, but developed *Staphylococcus aureus* infection near the IPG, removal of IPG and leads was needed. Clinically significant dislocation of leads was seen in two patients and dislocation/tilting of IPG in one patient. Hardware problems with possible lead breakage were observed in one patient.

Conclusion: Posttraumatic SCI patients with paraplegia can be elected for the LION procedure by a specialist team of neurorehabilitation experts (neurologists, PTs), and skilled surgeons in the neuro-pelvic area, with Possover LION expertise. Complication rates for the Possover LION procedure are comparable to or better than those seen with spinal cord stimulation, and the procedure is generally safe. We recommend the monitoring of implanted leads and IPG using CT abdomen.

Keywords: Laparoscopy, Neurostimulation, Possover LION procedure, Traumatic spinal cord injury.

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Introduction

Spinal cord injury (SCI) is frequent. The World Health Organization estimates an annual incidence of 250,000 to 500,000 cases. Individuals living with the consequences of SCI face numerous medical complications and reduced life expectancy as a direct or indirect result of their disability.[1] Detrusor overactivity and sphincter dyssynergy are encountered in 85% of cases, and improved control of micturition and defecation closely follows the restoration of ambulation as primary rehabilitation goals of patients with SCI.[2] Inpatient rehabilitation entails training and to some extent restoration of body functions via conventional physiotherapy and occupational therapy augmented by electrical stimulation, be it either neuromuscular or functional. Nevertheless, recovery after the initial inpatient rehabilitation is at best modest, and the conversion rate of the American Spinal Injury Association Impairment Scale grade remains poor for grades A and B.[3,4] Likewise, the rate of motor improvement declines over time, leaving many patients with permanent motor, sensory, and autonomic deficits. After 12 months from the sustained injury, a majority of SCI persons have essentially exhausted their possibility of further recovery.[4,5]

[1]Department of Surgery, Hospitalsenhed Midt, Viborg, Denmark
[2]Department of Clinical Medicine, Aarhus University, Aarhus, Denmark
[3]Department of Obstetrics and Gynecology, Aarhus University Hospital, Aarhus, Denmark
[4]Department of Radiology, Hospitalsenhed Midt, Viborg, Denmark
[5]Possover International Medical Center, Zürich, Switzerland
[6]Department of Neurology, Spinal Cord Injury Center of Western Denmark, Viborg, Denmark
[7]Department of Neurology, Hospitalsenhed Midt, Viborg, Denmark

Corresponding Author: Uffe S Løve, Department of Surgery, Hospitalsenhed Midt, Viborg, Denmark, Phone: +78446496, e-mail: skovloeven@gmail.com

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A minimally invasive and fully reversible laparoscopic technique, the laparoscopic implantation of neuroprosthesis (the LION procedure), was developed by Possover for the precise placement of an implantable pulse generator (IPG) and placement of one to four leads for stimulating nerves of the lumbosacral plexus. A substantial number of published cases support the effect of the technique regarding the treatment of overactive and atonic bladder disturbances, neurogenic bowel dysfunction, and abdominopelvic neuropathic pain.[6–10] Unexpectedly, the clinical observation was made that four patients with either complete or incomplete chronic traumatic SCI significantly regained motor and sensory function afterward having the LION procedure performed for bladder and bowel dysfunction.[9] An updated case series of 18 SCI patients having the LION procedure performed report that 16 are now capable of weight bearing standing and 12 are furthermore capable of voluntary stepping.[11] Recently, the LION procedure has been carried out in collaboration between The Spinal Cord Injury Center of Western Denmark, Aarhus University Hospital, and Department of Surgery at Viborg Regional Hospital with the guidance and support from Professor Possover.

The Possover LION procedure has never before been described through a controlled, randomized trial, and potential side effects and safety aspects have not been prospectively evaluated.

The present study reports the surgical aspects and safety results and observed complications from (a) a feasibility study and (b) a randomized controlled study evaluating the effect of the Possover LION procedure.

Materials and Methods

The present study reports are obtained from a series of 21 eligible SCI patients having surgery at Viborg Regional Hospital, Denmark, with the Possover LION procedure. The presented study material is derived from two substudies: first, a feasibility study (substudy 1) with four eligible SCI patients and second, a randomized controlled study with two treatment arms (substudy 2) with the active group allocated to direct surgical intervention with performed Possover LION procedure and subsequent neurorehabilitation, and the control group allocated to delayed surgical intervention with 12 month of preconditioning using guided self-training with external neuromuscular electrical stimulation. Inclusion criteria: Traumatic SCI below level Th5 with spastic paraplegia, AIS grades A, B or C. Age between 18 and 50 years. Exclusion criteria: other implanted devices (e.g., cardiac pacemakers, baclofen pumps), severe episodes of dysautonomia, drug or alcohol abuse, unstable medical or psychiatric disorder, previous pelvic disorder or surgery that may interfere with the Possover LION procedure, planned pregnancy, known compliance issues, logistic obstacles (e.g., planned journeys, other planned surgery).

Patients

Twenty patients undergoing the Possover LION procedure at Viborg Regional Hospital were included in this study. One additional patient underwent operation, but the operation was aborted, and the patient failed to have the electrodes implanted due to a frozen pelvis.

Ethics

The study was conducted in accordance with the Helsinki II declaration. Patients gave verbal and written informed consent. Substudy 1 did not need further approval. Substudy 2 was approved by the regional ethical committee (1-16-02-129-16) and the Danish Medical Agency (Journal no. 2017080415).

Hardware

Substudy 1. In the feasibility part of the study, the St. Jude system with an EON mini IPG and four quattrode leads were implanted and the IPG programming was done using the St. Jude/Abbott Rapid Programmer System.

Substudy 2. In the controlled study, we used the Boston Scientific Precision Spectra IPG with four linear ST leads of 50 or 70 cm (model no. M365SC2218500 and M365SC2218700), the FreeLink remote control system (model no. M365SC52500), and the standard wireless charging system (model no.M365SC641230); all programming was done using the Clinician Programmer (model no. M365SC7150400) and associated programming software, the BionicNavigator 01.2.

Paraclinical Investigations

Diagnostic Imaging

Eight patients had bedside ultrasound of the pacemaker site performed by a physician including a clinical examination after 3, 7, 14, 21, and 42 days.

Eight patients had a postoperative CT scan performed approximately 10 days and 8 weeks after surgery to check for lead migration/displacement.

All CT scans were performed without intravenous contrast as diagnostic scans (not low dose), from the umbilical region and downward to the proximal femur region. The average cumulative radiation dose per patient was 8 mSv (range: 6–10.9). Coronal and sagittal, 2 mm slice thickness, reconstructions were made.

Optimal lead placement was defined as the location of the sciatic nerve electrode leads near the greater sciatic foramen. Distance from the acetabular roof to the SNEL, chiefly measured in sagittal reconstructions, was used to evaluate the precise migration/displacement.

Femoral nerve electrode lead (FNEL) near to the musculus iliopsoas and inguinal canal was decided as an optimal placement. Distance from the superior iliac spine anterior to the FNEL top on coronal reconstructions was used to evaluate the precise migration/displacement. See Figure 1 for an example of well-placed leads. Arrows indicate the lead and IPG placement.

Blood Samples

Blood samples measuring C-reactive peptide (CRP) were drawn on the day of operation and daily until discharge from the hospital. Patients had a clinical follow-up between postoperative days 7 to 10, where CRP measures were obtained as well.

Clinical Assessment

Eligible patients were examined by specialist neurologists and evaluated by trained neurorehabilitation physiotherapists regarding compliance before participation.

Study Procedure

The Possover LION procedure involved laparoscopic exposure of both the femoral and sciatic nerves bilaterally. For a comprehensive description, we refer to the International School of Neuropelveology textbook 2015.

Pneumoperitoneum was formed, an umbilical 12-mm port was introduced for the camera, and further three 12-mm ports were placed in the lower abdomen.

Exposure of the femoral nerves was done by incising the fascia parallel to the lateral border of the psoas muscle (see Fig. 2). The femoral nerve was located by deepening this parallel dissection into the space between the psoas and iliac muscles.

Exposure of the lumbosacral truncus and sciatic nerves was achieved by pursuing the space between the medial border of the psoas muscle and the external iliac vessels, the lumbosacral space (see Fig. 3). The lumbosacral trunk and sciatic nerves were located in the bottom of the lumbosacral space.

After exposure of the femoral and sciatic nerves bilaterally, a tunneling device was introduced through the lower port holes on each side. This was introduced retroperitoneally down to the exposed femoral and sciatic nerves. The tunneling device was covered by an introducer sheath, and when the device was removed, leads were introduced and placed along the nerves (see Fig. 4).

The leads were then tunneled subcutaneously to the IPG site. Intraoperative impedance measurements and stimulation tests were employed to ensure lead continuity and placement. Leads were then connected to the IPG, which was placed in a subcutaneous pocket on the abdominal wall and firmly fixed with non-resorbable sutures to prevent displacement. The skin was closed with subcutaneous sutures and staples.

Stimulation Procedure

After implantation, three different modes of stimulation were compiled into four subject-activated programs uploaded to the IPG (see Table 1); all program settings were based on Possover's original constructs. Program A was initiated after 2 weeks, programs B and C were initiated after 6 weeks, and program D was only initiated when sufficient muscle strength had developed to support standing (approximately 20–26 weeks).

Patient demographics are reported in Table 2. Twenty eligible SCI persons (3 women and 17 men) who had sustained a traumatic SCI, with an age of (mean ± SD) 36.3 ± 9.0, had the procedure performed. The marital status was married/common law in 10 and single in nine patients, respectively. The educational level was common school in four patients, high school in four patients, bachelor/profession in 10 patients,

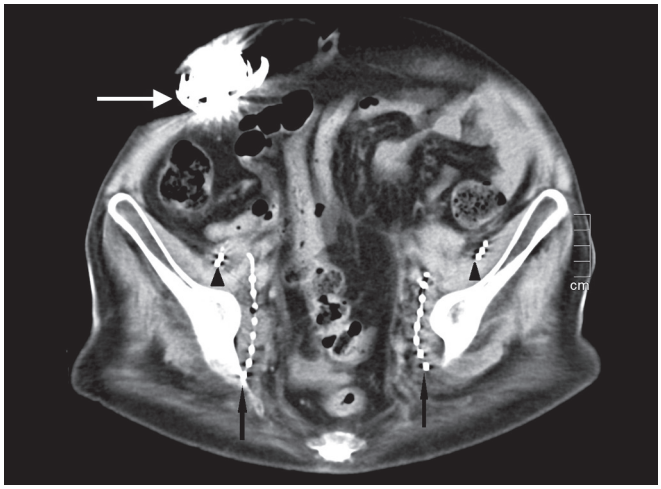

Fig. 1: CT scan showing the correct placement of IPG, femoral lead, and sciatic lead

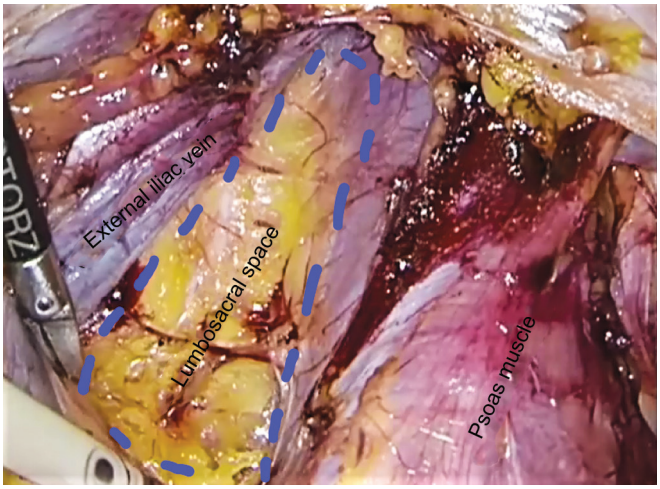

Fig. 3: Laparoscopic exposure of the lumbosacral space

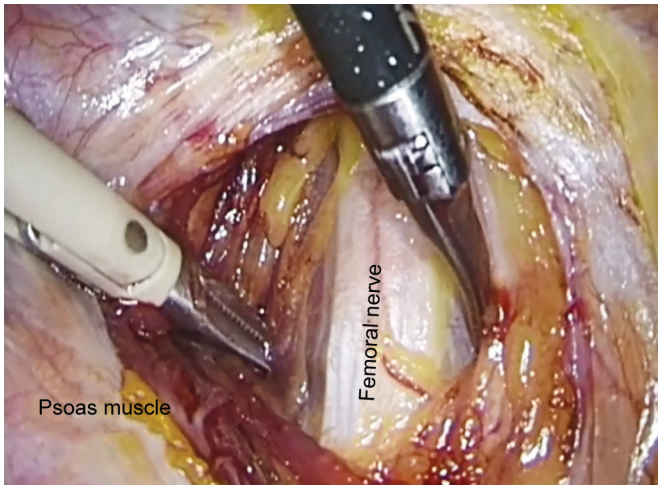

Fig. 2: Laparoscopic exposure of the femoral nerve

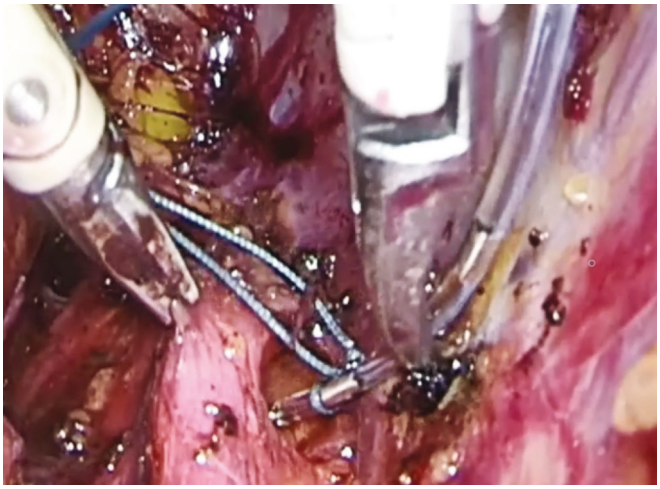

Fig. 4: Placement of lead under the sciatic nerve

Table 1: IPG programs

Program A	Continuous stimulation using all four leads with the lowest current intensity needed for subclinical skeletal muscle contraction. • Frequency: 5–10 Hz • Pulse width: 50–150 µs • Current intensity: variable
Programs B and C	Stimulation for 20–30 minutes during training sessions every other day with current intensities needed for minimal–maximal knee extension (B, femoral leads) and gluteal contractions (C, sciatic leads). • Frequency: 30–60 Hz • Pulse width: 50–150 µs • Current intensity: variable
Program D	Stimulation on all four leads for training of stance and gait. • Frequency: 30–60 Hz • Pulse width: 50–150 µs • Current intensity: variable

and university degree in two patients. Nineteen patients had complete paraplegia ISCNSCI AIS A, while one patient was incomplete ISNCSCI AIS B. The spinal cord lesion was situated between Th3-Th6 in 10 patients and between Th7-Th12 in seven patients and between L1-4 in three patients.

Bleeding

During operation, one patient had major bleeding of 900 mL, which was stopped by locally applied hemostats. No transfusion was required.

One patient presented with an intramuscular hematoma of both pectineus muscles 8 weeks post-surgery, confirmed by CT scan. This was caused by stretching of the muscles during physiotherapy and ongoing stimulation and resolved without further problems.

Infections

Pre- and postoperative blood samples (CRP) were obtained.

One patient presented with infection in close vicinity to the IPG 30 days post-surgery. Before this, the patient's CRP values were normalized on postoperative day 7. The discharge was sent for culture and sensitivity, uncovering a bacterial infection with *Staphylococcus aureus*. The infection was managed with antibiotics (dicloxacillin) and negative pressure wound therapy; however, the infection did not resolve, and subsequently, the IPG and the two leads were surgically removed.

One patient suffered from a bladder infection that was treated with antibiotics.

IPG-related Complications

Displacement of the IPG was observed in one patient. The IPG tilted away from the fascia obstructing recharging the IPG. The patient was electively re-operated and had the IPG replaced. After this, no further complications followed. One patient developed localized necrosis of the skin covering the IPG site. The skin healed by locally applied negative pressure wound therapy.

Diagnostic Imaging

In one patient, bedside ultrasonography showed a fluid collection around the IPG on day 7. The patient had no other complaints nor clinically observable findings; the minor seroma had disappeared on day 14. The results from the CT scans are presented in Table 3. Two patients did not show up for the CT scan on week 8 (marked as "missing"). No patients had seroma formation along the leads or IPG.

One patient had a visible displacement of two leads to the femoral and sciatic nerves on day 10, requiring a surgical intervention with repositioning off the leads. A control CT 8 weeks postoperatively showed that all leads were in place.

CT scans 8 weeks postoperatively revealed further displacement of the leads in three patients; clinically significant displacement requiring surgery was found in one patient. Replacement of the leads was not possible due to fibrosis in the lumbosacral space, and the leads and IPG were removed.

Right SNEL in patient 13 migrated 1.5 cm up on control CT but was still in contact to the sciatic nerve. Left FNEL migrated 4 cm up, and right FNEL migrated slightly medially in patient 13 on control CT. Right FNEL migrated 5 cm up in patient 16 on control CT.

Discussion

The Possover LION procedure is a promising new treatment for paraplegic patients. It shares features with epidural spinal cord stimulation (SCS), which has recently been reported to induce the recovery of some motor function.[12] It is a technically challenging operation, but the presented series show that the procedure is safe and with a similar or even more favorable risk of complications than SCS, which ranges from 8 to 75%.[13,14] The Possover LION procedure may be performed in a day-surgery setting, although we elected to admit patients until post-op day 1 in order to avoid lead displacements.

The effect of both the Possover LION procedure and SCS on motion function in paraplegics is still controversial, and certainly more controlled studies are needed to determine the role of these procedures. Our group will soon publish functional outcomes from the randomized controlled study (substudy 2). A new randomized controlled study is planned for year 2021, in which we will investigate cardiovascular and musculoskeletal effects of the Possover LION procedure. Safety data from the present article will help to justify these new clinical studies.

A CT scan provides an accurate way of detecting lead displacement. Twenty-five percent of the patients undergoing CT scanning had a clinically significant lead dislocation, although of the total patient group, only 10% had clinically significant lead dislocation. The scans were in concordance with the clinical presentation, and patients similarly presented with a loss of muscle activation during stimulation from the dislocated leads, which indicated a need for re-operation. It was possible to access the lumbosacral space around post-op day 10, enabling safe repositioning of the displaced leads. In our experience, surgery in the lumbosacral space past the "surgical window" of approximately 12 days is not possible. This emphasizes the importance of a routine CT scan 10 days post-op. Lead displacement was encountered during the first few days after surgery, but as shown in Table 2, the displacement may occur much later. Infection rates were acceptable, being around 5% in this study, which is comparable to cardiac pacemaker implantations.[15,16] CRP-level measurements postoperatively did not detect the one patient, who afterward developed an infection. The CRP levels were normalized before the patient reported discharge from the IPG site. The infection was localized and posed no threat to the patient. The removal of

Table 2: Patient overview

00	*Age*	*Gender*	*ISNCSCI grades**	*Neurologic level*	*Age of injury (year)*	*Bleeding (mL)*	*Surgery time (minutes)*	*System*	*ULS***	*CT****	*Complications*
1	45.1	Male	A	Th6	22.8	0	172	Boston Spectra IPG	+		None
2	26.3	Female	A	Th7	2.4	0	176	Boston Spectra IPG	+		None
3	28.9	Male	A	Th10	2.7	0	161	Boston Spectra IPG	+		None
4	45.4	Male	A	Th12	16.2	0	191	Boston Spectra IPG	+		IPG dislocation
5	47.4	Male	A	Th6	26.1	900	343	Boston Spectra IPG	+		Bleeding
6	33.7	Male	A	Th3	16.9	0	125	Boston Spectra IPG	+		None
7	22.6	Male	A	Th5	2.4	0	185	Boston Spectra IPG	+		None
8	28.1	Male	A	Th5	9.3	0	224	Boston Spectra IPG	+		None
9	47.0	Male	A	Th6	16.8	0	192	Boston Spectra IPG		+	None
10	49.8	Male	A	L1	24.4	0	309	Boston Spectra IPG		+	Mild/moderate pain in 3–4 days self-limiting
11	35.5	Male	A	Th8	9.1	0	137	Boston Spectra IPG		+	Lead dislocation
12	34.4	Male	A	Th5	17.6	0	213	Boston Spectra IPG		+	Urine blurred at dismission, need for antibiotics 6 d
13	31.3	Male	A	Th11	2.9	0	191	Boston Spectra IPG		+	None
14	46.0	Male	A	Th4	26.5	0	169	Boston Spectra IPG		+	Necrosis of the skin above IPG poche, healed by vacuum therapy
15	43.2	Female	A	Th8	24.7	0	194	Boston Spectra IPG		+	Lead dislocation
16	30.4	Male	A	Th7	8.4	0	139	Boston Spectra IPG		+	None
17	44.8	Male	A	Th4	3.7	0	147	St Jude/ Abbott EON Mini IPG			None
18	26.8	Female	A	Th5	1.3	0	182	St Jude/ Abbott EON Mini IPG			None
19	28.5	Male	A	L3	10.1	0	125	St Jude/ Abbott EON Mini IPG			Neuropraxia, left ischiadic nerve, normalized after several months. Hardware malfunction.
20	21.6	Male	B	Th7	1.6	0	132	St Jude/ Abbott EON Mini IPG			Infection causing explantation of electrodes and IPG

**ISNCSCI*, International Standards for Neurological Classification of Spinal Cord Injury;
**Ultrasound examination of IPG-area;
***Diagnostic CT abdomen, from the umbilical region with coronal and sagittal reconstructions made

the leads and the IPG was done externally without laparoscopy. Within colorectal surgery, postoperative CRP measurements may predict anastomotic leaks,[17] but with the Possover LION procedure, clinical wound examination may be necessary to detect postoperative infection. This corresponds with local infections seen after the implantation of cardiac pacemakers, which are often diagnosed only by swelling, redness, and tenderness of the skin.[18]

Table 3: Postoperative CT controls

Patient No.	*CT scan 10 days after operation*	*CT scan 8 weeks after operation*
9	No dislocation	No dislocations
10	No dislocation	Missing
11	Left femoral lead dislocated	Left + Right femoral leads dislocated from nerves
12	No dislocation	Missing
13	No dislocation	Slight dislocation of three electrodes, still in contact with nerves
14	No dislocation	No dislocation
15	Dislocation of right femoral and sciatic electrodes	After surgical correction, no electrodes dislocated
16	No dislocation	Slight dislocation of the right femoral lead, still in contact with nerve

Conclusion

The Possover LION procedure may be performed safely in patients with thoracolumbar traumatic SCI. The election of suitable patients for the operation should include a specialist team of skilled neurologists, neurorehabilitation physiotherapists, and highly experienced pelvic surgeons. We recommend that the Possover LION procedure is performed only at expert centers with experienced pelvic surgeons and a team of neurologists and physiotherapists dedicated to patient training and follow-up. The International Society of Neuropelveology (ISON) offers theoretical and practical training in the LION procedure, and we highly recommend certification by this Society before undertaking the Possover LION procedure.

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Orcid

Uffe S Løve https://orcid.org/0000-0002-2409-0499

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ORIGINAL ARTICLE

Role of Diagnostic Laparoscopy in Nonspecific Chronic Pain Abdomen

Subhash[1], Tanweer Karim[2], Atul Jain[3], Nabal K Mishra[4], Gaurav Patel[5], Subhajeet Dey[6]

Abstract

Introduction: Laparoscopy has established its role (diagnostic as well as therapeutic role) in patients with nonspecific chronic pain abdomen. In case of diagnostic dilemma and uncertainty, use of laparoscopy can help to avoid unnecessary laparotomy, provides accurate diagnosis, and helps to plan for surgical intervention if required. However, the role of laparoscopy in nonspecific chronic pain abdomen is still debated.

Aims and objectives: To assess the accuracy of laparoscopy in the diagnosis of nonspecific chronic pain abdomen and its ability to avoid unnecessary exploratory laparotomy with complications and limitations associated with laparoscopy including failure rate.

Materials and methods: This prospective descriptive study was conducted for a period of 1 year in patients with nonspecific chronic pain abdomen for more than 3 months attending the outpatient department or emergency department when clinical features and investigations are not conclusive.

Results: Sixty-two patients in age-group from 15 to 60 years were studied. Overall 85.48% of patients had resolution of pain after diagnostic laparoscopy with diagnostic accuracy in our study of 88.7%.

Conclusion: Diagnostic laparoscopy should be considered as one of the gold standard tests for diagnosing the nonspecific chronic pain abdomen, when noninvasive diagnostic modality failed in diagnosing cause.

Keywords: Diagnostic laparoscopy, Nonspecific chronic pain abdomen, NCPA, chronic pelvic pain.

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Introduction

Nonspecific chronic abdominal pain is a diagnostic challenge for a clinician. These patients generally visit different physicians and many investigations are done for reaching the diagnosis in this process. Chronic abdominal pain without any specific etiological diagnosis at the end of diagnostic workup for more than 3 months is called as nonspecific chronic pain abdomen (NCPA).[1–3] It can lead to poor quality of life with appearance of depressive symptoms with time.[4]

Surgical consultation is often sought late after other modalities have failed to reach a conclusion or provide relief in their symptomatology. NCPA is a significant clinical problem which accounts for 13 to 40% of all surgical admissions and can often lead to repeated laparotomies.[5] Chronic pelvic pain has a prevalence of 3.8% in young females and it accounts for 10% of all outdoor patients visit to gynecologist and 40% of laparoscopy by gynecologists.[6]

The use of laparoscopy in the diagnosis and management of NCPA has been tried in previous studies. The main aim of laparoscopic evaluation in NCPA is to detect the presence or absence of intra-abdominal organic lesion and also it can diagnose as well as treat different intrabdominal pathologies that are difficult to diagnose by other conventional methods.[3] It is a safe and effective tool which can establish the etiology and allows for appropriate intervention at the same time or a better planning in such cases.[7]

Adhesions and bands are commonly seen findings, especially in patients with a past history of laparotomy or other abdominal operations.[8] Other findings such as appendicular pathology, hepatobiliary causes, and endometriosis can be discovered and dealt with laparoscopically.[9]

[1–6]Department of Surgery, ESI PGIMSR and Hospital, Delhi, India

Corresponding Author: Atul Jain, Department of Surgery, ESI PGIMSR and Hospital, Delhi, India, e-mail: docatuljain@gmail.com

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The role of laparoscopy for diagnosis in NCPA is still debated by a number of authors who deny its value in adhesiolysis and consider it controversial and not evidence-based, and therefore, do not recommend it as a part of evaluation and treatment in patients with NCPA.[10]

Although laparoscopy is very frequently used by surgeons in all fields for a wide spectrum of surgical procedures around the globe, its utility for diagnosis in cases of chronic abdominal pain was not favored initially, either due to insufficient data on its effectiveness as a diagnostic modality, lack of training or expertise, or lack of awareness among patients and even doctors.[11]

Diagnostic laparoscopy when compared to open laparotomy is better in terms of visualization and access with minimal trauma except in some retroperitoneal lesions. Laparoscopy also has limitation of tactile sensations and lesions cannot be palpated as compared to open laparotomy.[12] However, procedure allows quick and thorough inspection of whole peritoneal cavity and pelvic cavity and it is an emerging tool in diagnosis of nonspecific chronic pain abdominal.[13]

Aims and Objectives

The study was done to assess the accuracy of laparoscopy in the diagnosis of NCPA (by comparing its findings with radiological investigations), its ability to avoid unnecessary exploratory laparotomy with complications and limitations associated with laparoscopy including failure rate.

Materials and Methods

This prospective descriptive study was conducted in a teaching hospital in north India for a period of 1 year. Clinical material for present study comprises the patients with NCPA for more than 3 months attending the outpatient department or emergency department where other clinical symptoms and investigations are not conclusive.

Inclusion Criteria

- Chronic pain abdomen of more than 3 months of uncertain etiology unexplained by clinical symptoms and signs and other investigations including CECT.
- Age-group of 15 to 60 years.

Exclusion Criteria

- ASA Grade III, ASA Grade IV.
- Uncorrected coagulopathy.
- Pregnancy.

Diagnostic laparoscopy was performed with standard method after proper preanesthetic checkup and wherever biopsy or other surgical intervention (laparoscopic/open) was required, it was done.

Results

A total of 62 patients, who fulfill the inclusion and exclusion criteria were included in the study.

Age and Sex Distribution

In our study, youngest patient was 15 years and oldest was 60 years. The mean age of presentation was 37.37 (Table 1). There was predominance of female gender, who were 34 (54.8%) in comparison to male gender 28 (45.2%).

Duration of pain before diagnostic laparoscopy: patients with duration of 3 or more months of NCPA were included. Mean duration was 4.6 months. (Fig. 1).

The final diagnosis reached in our study is shown in Table 2 showing the most common cause was recurrent appendicitis (32.2%).

In our total 62 cases, 54 (87.1%) cases were diagnosed by laparoscopic procedure (i.e., radiological given diagnosis totally different from laparoscopic findings), rest 8 (12.9%) cases were radiological as well as laparoscopically same diagnosis.

Conversion and Complications

In total 62 cases, 50 (80.6%) cases were treated completely with laparoscopic approach and in remaining 12 (19.4%) cases, laparoscopy was converted to laparotomy. In these 12 patients, 5 patients underwent lap-assisted right hemicolectomy [HPE-1 mucormycosis (Fig. 2), 3 adenocarcinoma of intestine, 1 diverticulitis], 2 patients had resection of stricture followed by end-to-end anastomosis, HPE revealed adenocarcinoma of intestine with negative resected margins, 2 radical cholecystectomy for

Table 1: Age distribution of patients with nonspecific chronic pain abdomen (NCPA)

Age-group (years)	*Number of patients*	*Percentage (%)*
15–30 years	18	29.0
31–45 years	28	45.2
46–60 years	16	25.8
Total	62	100.0
Mean	37.37	
Min–max	15–60	

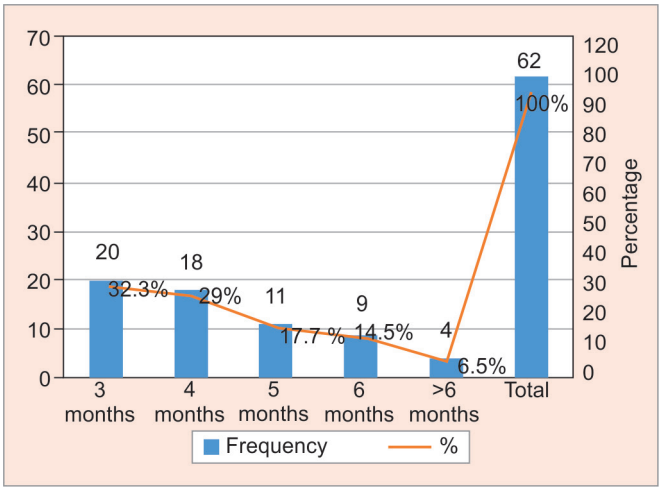

Fig. 1: Showing duration of pain abdomen before diagnostic laparoscopy

Table 2: Frequency and percentage distribution of patients according to final diagnosis

Final diagnosis	*Frequency*	*Percentage (%)*
Appendicitis (recurrent appendicitis)	20	32.25
Normal study	7	11.29
Reactive mesenteric lymphadenopathy	6	9.67
CA intestine	5	8.06
Bands and adhesions	4	6.45
Chronic cholecystitis	3	4.83
TB of IC junction	3	4.83
Normal appendix	1	1.61
Gallbladder carcinoma	2	3.22
Diverticulitis	1	1.61
Granulomatous pancreatitis	1	1.61
Granuloma of parietal wall	1	1.61
Normal gallbladder	1	1.61
Pancreatic tuberculosis	1	1.61
Adrenal lipoma	1	1.61
IC junction intususception	1	1.61
Mucormycosis	1	1.61
Mesenteric cyst	1	1.61
Renal cyst	1	1.61
Ovarian cyst	1	1.61
Total	62	100

carcinoma of gall bladder, 1 open cholecystectomy for sealed gall bladder perforation. One Whipple's procedure for bulky head of pancreas histopathology (HPE) revealed as granulomatous pancreatitis (Fig. 3), and one open adrenal lipoma excision. There are no postprocedure complications in all 62 cases.

Table 3 shows sensitivity, specificity, and accuracy along with *p* value significance level of radiological investigations, which was compared with final diagnosis for diagnosing of NCPA. Sensitivity—16.4%, specificity—57.1%, and accuracy—21.0%, *p*-value is 0.125 (*p*-value significance level is <0.05).

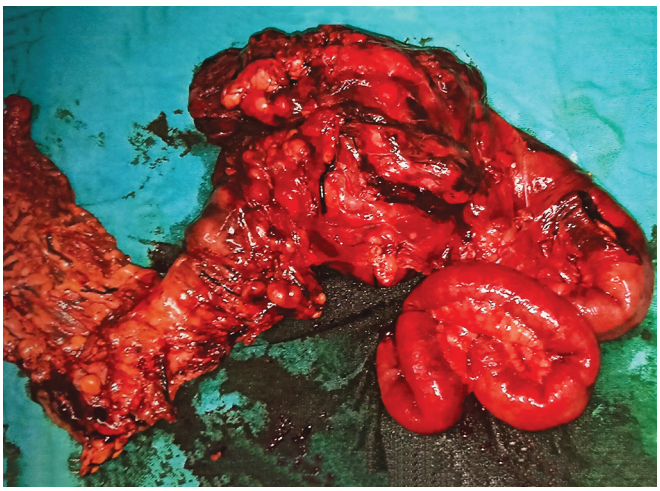

Fig. 2: Intestinal mucormycosis specimen

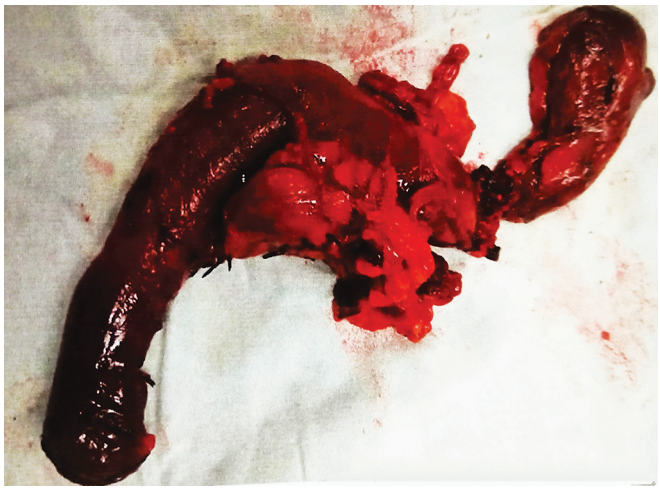

Fig. 3: Whipple's procedure specimen—granulomatous pancreatitis

Table 4 shows sensitivity, specificity, and accuracy along with *p* value significance level of laparoscopic findings which was compared with final diagnosis in diagnosing of NCPA, sensitivity—98.2%, specificity—100.0%, and accuracy—98.4%, *p*-value is <0.001 (*p*-value significance level is <0.05).

Table 5 shows radiological findings sensitivity, specificity and accuracy along with *p* value significance level which was compared with laparoscopic findings for diagnosing of NCPA, sensitivity—16.7%, specificity—62.5%, and accuracy—22.6%, *p*-value is 0.177 (*p*-value significance level is <0.05).

Effect of Diagnostic Laparoscopy on Diagnosis

In this study of 62 cases, in 45 (72.58%) cases, the final diagnosis was same as that of diagnostic laparoscopy, in 6 (9.6%) cases, the final diagnosis was made after HPE, in 7 cases, the diagnostic laparoscopy (DL) failed to diagnose the cause (normal findings), and in 4 cases, the final and laparoscopic diagnosis were both different (Table 6).

Discussion

NCPA is a frequent problem, dealt with by different medical specialists. Even after an extensive workup in some patients, no specific cause or pathological condition is found by use of noninvasive investigation, and the pain is often attributed to unsubstantiated diagnosis. Despite of advanced diagnostic machinery with sophisticated methodology to image abdominal contents, establishment of a diagnosis prior to surgery remains difficult for several conditions. Unnecessary or negative laparotomy is painful, increases hospital stay, increases hospital cost, and is associated with a morbidity of 5 to 20%.

Overall in 62 patients, radiological imaging modality gave probable diagnosis in 28 (45.16%) patients, normal study in 10 (16.12%) patients, and in remaining 24 (38.70%) patients, diagnosis was inconclusive. Subsequent DL and HPE reveled that out of these 24 cases, 15 (62.5%) patients are having appendicitis. Based on USG findings, 11 patients were diagnosed as having ileocecal thickening (Fig. 4) and mesenteric lymphadenopathy with tuberculosis (TB) as first differential diagnosis. However, CECT confirmed ileocecal tuberculosis in six cases only. All of them have undergone colonoscopy and biopsy. Colonoscopy biopsy failed to prove tuberculosis in any one of them. Only one of these six cases was finally diagnosed as having ileocecal tuberculosis on HPE following resection of affected segments. Therefore recurrent vague pain in lower abdomen with nonspecific radiological finding may be consistent feature of recurrent or chronic appendicitis and DL seems to be more useful.

In a similar study on 88 patients by Ahmad et al.,[14] 38 (43.10%) patients' abdominal ultrasound was normal. The most common finding noted on USG abdomen and pelvis was

Table 3: Radiological findings compared with final diagnosis

	Final diagnosis				
	Positive		*Negative*		
Radiological findings	*Frequency*	*Percentage (%)*	*Frequency*	*Percentage (%)*	*p value*
Positive	9	16.4	3	42.9	
Negative	46	83.6	4	57.1	0.125
Total	55	100	7	100	
Sensitivity	Specificity	PPV	NPV	Accuracy	
16.4%	57.1%	75.0%	8.0%	21.0%	

Table 4: Laparoscopic findings compared with final diagnosis

	Final diagnosis				
	Positive		*Negative*		
Laparoscopic findings	*Frequency*	*Percentage (%)*	*Frequency*	*Percentage (%)*	*p value*
Positive	54	98.2	0	0.0	
Negative	1	1.8	7	100.0	<0.001
Total	55	100	7	100	
Sensitivity	Specificity	PPV	NPV	Accuracy	
98.2%	100.0%	100.0%	87.5%	98.4%	

Table 5: Radiological findings compared with laparoscopic findings

	Laparoscopic findings				
	Positive		*Negative*		
Radiological findings	*Frequency*	*Percentage (%)*	*Frequency*	*Percentage (%)*	*p value*
Positive	9	16.7	3	37.5	
Negative	45	83.3	5	62.5	0.177
Total	54	100	8	100	
Sensitivity	Specificity	PPV	NPV	Accuracy	
16.7%	62.5%	75.0%	10.0%	22.6%	

Table 6: Effect of diagnostic laparoscopy on diagnosis

Diagnosis status	*Frequency*	*Percentage (%)*
Confirmed diagnosis	45	72.58
Failed in diagnosing	7	11.29
Diagnosed after laparoscopy	6	9.67
Changed diagnosis	4	6.45
Total	62	100

Table 7: Comparison of diagnostic accuracy of laparoscopy in various study

Study	*Diagnostic accuracy (%)*
Mehta's et al.	88
Al-Akeely et al.	94
El-Labban et al.	83.3
Ahmad et al.	85.2
Present study	88.7

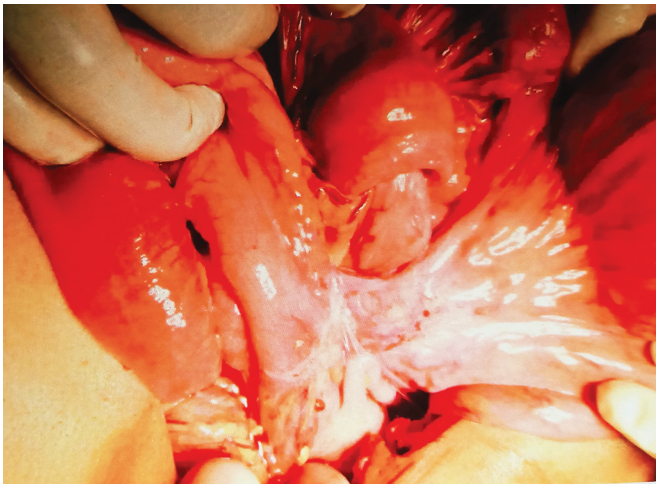

Fig. 4: Ileocecal mass

distended bowel loops in RIF. Benign hypertrophy of prostate was reported in two patients. USG pelvis in 51 of 59 patients was normal. In the remaining patients, minimal free fluid in cul-de-sac was reported. All subjects underwent CT scanning, out of which, 63 (52.5%) patients had a change in findings when compared with the findings on USG. The CT scan was better able to suggest dilation of gut loops and reteroperitoneal/mesentric lymphadenopathy. Twenty-four subjects out of 88 cases (24.2%) had altogether new findings, while 64 (72.4%) cases had findings like the radiological means. Twenty-five out of 64 had new finding along with previous finding. Therefore, DL enables the surgeon to visualize surface anatomy of intra-abdominal organs with greater details better than any other imaging modality.

DL has been used as a diagnostic tool in patients in nonspecific pain abdomen in numerous studies. However, it is still not a standard of care for this subset of patients. In our series, 62 (100%) patients of NCPA were subjected to DL and reached to final definitive diagnosis in 55 (88.7%) patients, and in 7 (11.3%) patients, we could not reach to any diagnosis (i.e., normal study). DL could establish diagnosis in 88% cases in Mehta's series,[15] whereas in the series of Al-Akeely et al.,[16] it was 94%. Our series had a diagnostic accuracy of 88.7%. Ahmad et al.[14] could reach to final diagnosis in 75 of 88 cases of NCPA after DL. This is like the study carried by Labban and Hokkam et al.[17] in which DL provided a definitive diagnosis in 25 (83.3%) of the 30 cases of NCPA.

Diagnostic Accuracy

DL was able to establish diagnosis in 88% of cases in Mehta's series, whereas in the series of Al-Akeely, it was 94%. Our series had a diagnostic accuracy of 88.7% (Table 7).

In this study, appendicitis (recurrent appendicitis) was most common diagnosis, seen in 20 (32.25%) patients, and laparoscopic

appendectomy was done in all of them. In a study by Ahmad et al., appendicular pathology was present in 32.9% of cases and in a study by Ates et al., 47.2% of patients were diagnosed with appendicitis.[18]

In a study by Fayez et al.,[19] records of chronic abdominal pain undergoing appendectomy were reviewed; 92% of patient's appendices had abnormal histological findings and the 95% of patients had resolution of pain. Raymond et al.[20] reported improvement of pain in 74% of patients with chronic right lower abdominal pain.

In our study, out of 62 patients, 21 (33.87%) patients who underwent appendectomy for NCPA, in that 20 (95.23%) patient's HPE revealed as recurrent appendicitis, in these patient's pain was resolved, one (4.76%) patient HPE revealed as normal appendix; in this patient, pain was not resolved. So our study also correlating with study by Fayez et al. and Raymond et al. in alleviating pain in patients with NCPA.

For comparison of therapeutic efficiency of laparoscopy, Raymond et al. study reported that more than 70% of patients had long term pain relief and Paajanen et al. in their study reported that laparoscopy alleviates the symptoms in more than 70% of patients. In our study out of 62 patients, 53 (85.48%) patients had pain relief after DL. Remaining nine patient pain was not relieved (in that seven patient's final diagnosis revealed as normal study, one patient appendicular pathology revealed normal, another one patient diagnosed case of abdominal tuberculosis). These two studies correlate well with our study and it should be considered if other diagnostic tests are inconclusive (Table 8).

In a study by Palanivelu et al.[21] out of 230 patients diagnosed to have abdominal TB by DL, 132 (57.4%) were males and 98 (42.6%) females. The peritoneal TB cases were treated by DL, peritoneal biopsy, followed by antitubercular treatment. In a study by Rai et al.[22] on the role of DL on abdominal TB, 36 patients were included in which 24 (66.6%) patients were male and 12 (33.4%) female. In our study, four patients diagnosed to have abdominal TB out of which three (4.83%) are female and one (1.61%) male. All patients were managed with CAT—1 ATT.

Our study report revealed improvement or resolution of pain abdomen in patients with abdominal tuberculosis is 75%.

Arya and Gaur study revealed out of 49 patients, bands and adhesions in 4 (8.16%) patients, no organic cause found in 5 (10.20%) patients, and diverticulitis in 1 (2.04%) patient.[23]

In our study out of 62 patients, no organic cause found in 7 (11.29%) patients, diverticulitis in 1 (1.61%) patient, and 4 (6.45%) patients had bands and adhesions for that adhesiolysis done as a definitive procedure, and all 4% patients had resolution of their pain after adhesiolysis. So our study well correlated with Arya et al. study.

Compared to series of Mehta et al. out of 21 patients, 4 who underwent laparotomy, conversion rate was 19%. In another series, Al-Akeely had 6% conversion rate.

In our series out of 62 patients, 12 who underwent laparotomy, conversion rate is 19.4%. With the growing availability of trained and experienced laparoscopic surgeons along with improved machinery, the morbidity of laparoscopy is much less and not, and with improved skills, conversion rates should be low.

Table 8: Comparison of therapeutic efficiency of laparoscopy in various studies

Study	*Therapeutic efficiency (%)*
Raymond et al.[20]	>70
Paajanen et al.[3]	>70
Present study	85.48

Conclusion

DL should be considered as one of the gold standard test for diagnosing the NCPA, when noninvasive diagnostic modality failed in diagnosing cause. It can prevent the delay in definitive diagnosis and negative laparotomies in these cases. It has diagnostic, therapeutic use and in some cases can have placebo effect as well.

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ORIGINAL ARTICLE

Role of Laparoscopic-assisted Transversus Abdominis Plane Block during Elective Laparoscopic Cholecystectomy

Apoorv Goel[1], Roli Bansal[2], Prakhar Garg[3], Shyam Kothari[4]

Abstract

Background: In today's era of minimally invasive surgery, early postoperative pain reduction, early recovery, and return to normal activities are also important aspects. This study has been designed to analyze and compare the effect of laparoscopically administered transversus abdominis plane (TAP) block with port-site infiltration of long-acting local anesthetic agent (0.25% bupivacaine) in cases of elective laparoscopic cholecystectomy.

Materials and methods: This is a comparative study carried out at St Joseph Hospital, Ghaziabad, from September 2019 to March 2020 on 154 patients who underwent standard four-port laparoscopic cholecystectomy. Seventy-seven patients in group I received TAP block with 0.25% bupivacaine and seventy-seven patients in group II received 20 mL of 0.25% bupivacaine infiltration over port sites, including 10 mL each at epigastric and umbilical port and 5 mL each at midclavicular line and anterior axillary line ports, respectively. Various parameters were assessed during the intraoperative and postoperative periods. The pain was analyzed using visual analog scoring (VAS) for the first 24 hours at an interval of 3, 6, 12, and 24 hours. A note was made of any additional analgesic requirement.

Results: Postoperative pain at 3, 6, and 12 hours was significantly reduced in group I who received TAP block as compared to those who received port-site infiltration. Hospital stay duration was significantly shorter in group I.

Conclusion: Laparoscopic-assisted TAP block significantly reduces early postoperative pain, shortens hospital stay after elective laparoscopic cholecystectomy, and is a safe and cost-effective method without any extra requirement of specialized equipment and skills.

Keywords: Cholelithiasis, Laparoscopic cholecystectomy, Transversus abdominis plane block.

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Introduction

Laparoscopic cholecystectomy is one of the most commonly performed laparoscopic surgeries. Laparoscopic surgery has provided fast recovery, short hospital stay, early return to work, and minimum scar, but postoperative pain management still remains a concern.[1,2]

Pain after laparoscopic cholecystectomy can occur within hours usually over the port sites or at the right shoulder or it can be a generalized pain. Pain following laparoscopic cholecystectomy is multifactorial. Pain occurring over port sites is due to somatic component whereas pain over right shoulder or diffuse abdominal pain is because of visceral component caused by stretching due to pneumoperitoneum.[1–3] On the basis of this theory, various techniques have been described to reduce this pain. Pain can be mild to severe and even require injectable analgesics, such as diclofenac sodium or opioids. This pain can delay recovery, lengthen hospitalization, and hampers routine activity. Pain killers like opioids and diclofenac sodium have their own adverse effects.[4]

There are numerous studies on the reduction of early postoperative pain following laparoscopic cholecystectomy, including port-site infiltration of local anesthetics, laparoscopically delivered transversus abdominis plane (TAP) block, intraperitoneal instillation of local anesthetics, and various other methods out of which TAP block and port-site infiltration with long-acting local anesthetic agents are commonly used techniques.[1–3]

TAP block is a technique in which a long-acting local anesthetic drug like bupivacaine is administered into the fascial plane between the fibers of internal oblique and transversus abdominis muscle. Somatic nerve from T6 to L1 run in this fascial plane to innervate the anterior abdominal wall layers from skin to parietal peritoneum.[4–9]

[1,3]Department of General Surgery, Santosh Medical College and Hospital, Santosh University, Ghaziabad, Uttar Pradesh, India

[2]Department of Medicine (Division of Nephrology), UCMS and GTB Hospital, Delhi, India

[4]Department of Surgery, St Joseph Hospital, Ghaziabad, Uttar Pradesh, India

Corresponding Author: Apoorv Goel, Department of General Surgery, Santosh Medical College and Hospital, Santosh University, Ghaziabad, Uttar Pradesh, India, e-mail: drapurvgoel@gmail.com

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Various techniques of TAP block had been described. In 2001, a blind 'double pop' technique was defined to infiltrate the fascial plane with local anesthetics. Ultrasound-guided TAP block was introduced in 2007, a technique better than blind infiltration but still operator dependent.[5,9] Later laparoscopy-guided infiltration of the fascial plane with long-acting local anesthetics like bupivacaine was introduced. Studies confirmed that laparoscopy-guided infiltration is more accurate as it is done under direct visualization.[7,8]

This study aim is designed to analyze and compare the effects of TAP block with port-site infiltration in cases of elective laparoscopic cholecystectomy.

Materials and Methods

This is a comparative study conducted at St Joseph Hospital, Ghaziabad from October 2019 to March 2020. All cases of symptomatic cholelithiasis aged between 18 years and 65 years and American Society of Anesthesiologists (ASA) class I and II were included in the study and underwent elective laparoscopic cholecystectomy. Patients of ASA class III, IV, and V and patients with coagulopathies, liver or renal failure, choledocholithiasis, intraoperative drain placement, post-ERCP, surgery duration more than two hours, previous upper abdominal surgeries, conversion to open cholecystectomy, and difficult extraction of gallbladder were excluded from the study. A total of 154 patients participated in the study and were randomized into two groups of 77 patients each using a computerized random number table. Informed consent was obtained from the patients. All patients underwent standard four-port laparoscopic cholecystectomy performed by a single team of surgeons experienced in laparoscopic surgeries. Pneumoperitoneum was maintained at 12 to 14 mmHg. The gallbladder was delivered through epigastric port in all patients. Group I received TAP block under laparoscopy guidance in which TAP block using 0.25% bupivacaine was instilled using a 23-gauge needle at following 4 points, bilateral subcostal infiltration between anterior axillary line and midclavicular line (10 mL each), and bilaterally just above the iliac crest in midaxillary line (15 mL each). Direct visualization of needle and the bulge with the laparoscope confirmed the proper instillation of drug in the plane containing thin fibers of transversus abdominis muscle (Fig. 1). Group II patients received 20 mL 0.25% bupivacaine divided into 6 mL each for umbilical and epigastric port and 4 mL each for right midclavicular line and anterior axillary line port, respectively, and infiltrated in the subcutaneous plane before closure. All patients in both groups received 50 mg tramadol injection in the immediate postoperative period as standard protocol.

Pain intensity was recorded by the same team using a visual analogue scoring (VAS) system at intervals of 3, 6, 12, 24, and 48 hours, respectively. Intramuscular diclofenac sodium 75 mg was used as rescue analgesia for patients with VAS score >5.

Data analysis was performed using the Statistical Package for Social Sciences Version 17.0 software (SPSS Inc.; Chicago, IL, USA). A p-value <0.05 was considered statistically significant.

Results

A total of 154 patients underwent laparoscopic cholecystectomy out of which 136 were females. The average age of patients was 38.84 ± 2.67 years. There was no significant difference seen in the duration of surgery and time taken for return to normal activity in both the groups. Mean hospital stay was significantly less for group I patients as compared with group II (Table 1).

The mean VAS score of patients in group I at 3, 6, and 12 hours was significantly low as compared with group II, and the requirement of rescue analgesia was also significantly less in group I. At 24 and 48 hours, there was no significant difference in pain intensity in both the groups (Table 2).

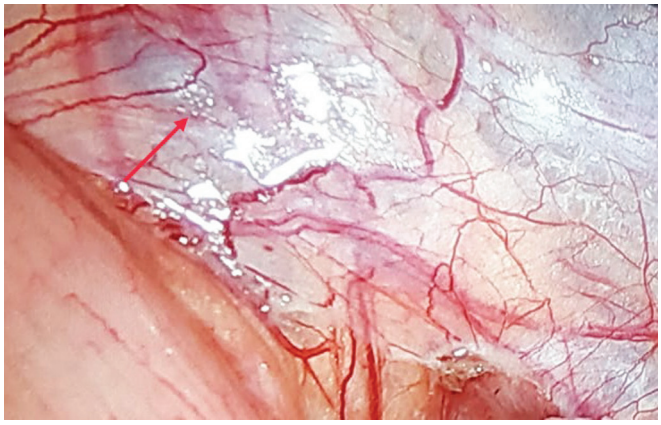

Fig. 1: Laparoscopic-assisted TAP block

Discussion

Laparoscopic cholecystectomy is the gold standard procedure for symptomatic cholelithiasis and most commonly performed laparoscopic procedure worldwide.[1] Though the pain, discomfort, and duration of stay after minimally invasive procedure are less as compared to open technique, but early postoperative pain after laparoscopic cholecystectomy is still prevalent and it may increase patient stay and discomfort following surgery.[1–3]

There are various factors responsible for the pain after laparoscopic cholecystectomy. It may arise from incision site (somatic pain), from gallbladder bed (visceral pain), or may be due to stretching caused by pneumoperitoneum.[2]

Many studies and researches had been conducted in the last 30 years for the pain management after laparoscopic cholecystectomy. Various methods like infiltration of local

Table 1: Patients characteristics, other intraoperative and postoperative factors

Intraoperative factors	*TAP block group (group I) n = 77*	*Bupivacaine group (group II) n = 77*	*p value*
Mean age (years)	39.54 ± 3.23	38.48.2 ± 2.55	0.89 (NS)
Sex			
Male	8 (10.38%)	10 (12.98%)	0.94 (NS)
Female	69 (89.62%)	67 (87.02%)	0.85 (NS)
Mean duration of surgery (minutes)	50.45 ± 3.6	52.63 ± 4.5	0.78 (NS)
Mean duration of stay in hospital (days)	1.55 ± 0.56	2.2 ± 0.68	0.022(HS)
Return to routine activities (days)	3.23 ± 1.56	3.55 ± 1.07	0.21(NS)

TAP, transversus abdominis plane block; NS, nonsignificant; HS, highly significant

Table 2: Comparative analysis of postoperative pain using VAS (visual analog scoring) and requirement of rescue analgesia

Time interval (hr)	*TAP block group (group I)*	*Bupivacaine group (group II)*	*p value*
3	1.38 ± 0.23	3.83 ± 0.76	<0.001(HS)
6	2.12 ± 0.54	3.45 ± 0.30	<0.001 (HS)
12	2.01 ± 0.87	3.67 ± 1.20	<0.001 (HS)
24	2.65 ± 1.53	2.14 ± 1.11	0.65 (NS)
48	1.56 ± 0.56	1.69 ± 0.79	0.89 (NS)
Requirement of rescue analgesia (n)	12	22	0.012 (HS)

TAP, transversus abdominis plane block; NS, nonsignificant; HS, highly significant

anesthetic at port sites, intraperitoneal instillation at gallbladder bed, and TAP block were used for early postoperative pain control.[3,8,10] Many studies have shown a significant reduction in postoperative pain after infiltration at incision sites whereas few studies had shown no statistical difference in pain or duration of stay.[5–16]

In our study, we have analyzed and compared the effect of laparoscopically delivered TAP block with port-site infiltration of 0.25% bupivacaine in reduction of early postoperative pain, early recovery, and return to routine activity after elective laparoscopic cholecystectomy. Our results had shown significant reduction in early postoperative pain specifically at 3, 6 and 12 hours in the group receiving TAP block; however, there was no significant difference at 24 and 48 hours in both the groups. Subsequently, the need for additional analgesia was significantly less in patients receiving TAP block. The hospital stay in TAP block group was shorter and statistically significant.

TAP block was introduced in 2001 as a blind technique for pain relief following abdominal surgeries. Later ultrasound-guided TAP block was introduced, and in 2009, El-Dawlatly et al. conducted a study that showed significant pain relief and decreased analgesic requirement post-laparoscopic cholecystectomy in patients receiving ultrasound-guided TAP block.[6] In 2011, Chetwood et al. described laparoscopically delivered TAP block in cases of laparoscopic nephrectomy[7] and Magee et al. described laparoscopic TAP block in laparoscopic cholecystectomy with promising results and significant relief in postoperative pain.[11] Zaghiyan et al. described the superiority of laparoscopic TAP block over ultrasound-guided TAP block.[13]

Studies by Elamin et al. and Tihan et al. also described the efficiency and superiority of laparoscopic TAP block over port-site infiltration of local anesthetic agent.[8,16]

Few studies and a meta-analysis also showed no significant difference in postoperative pain reduction following laparoscopic TAP block and periportal infiltration in cases of laparoscopic cholecystectomy.[10,12,15]

Another advantage of laparoscopic TAP block is that it can be safely given by the operating surgeon and does not require any additional equipment.

Thus with significant early postoperative pain reduction and shorter hospital stay, laparoscopically delivered TAP can be good alternative for postoperative pain relief in elective laparoscopic cholecystectomy; however, its efficiency needs to be explored in emergency settings.

Conclusion

Laparoscopically delivered TAP block is a safe and efficient method for early postoperative pain relief in cases of laparoscopic cholecystectomy that can be safely performed by an operating surgeon without additional requirement of specialized equipment and skills.

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ORIGINAL ARTICLE

Laparoscopic First-stage Approach in a Two-stage Hepatectomy for Bilobar Colorectal Liver Metastases

Yuki Takahashi[1], Kuniya Tanaka[2], Tetsuji Wakabayshi[3], Toshimitsu Shiozawa[4]

Abstract

Aim: We reviewed a retrospectively collected database of 64 patients undergoing two-stage hepatectomy for colorectal liver metastases with special attention to cases involving a laparoscopic first stage.

Materials and methods: Three patients undergoing laparoscopic first-stage hepatectomy were analyzed and compared with 61 other patients who underwent two-stage hepatectomy using open surgery for the first stage.

Results: In three patients with a laparoscopic approach, the first-stage operation was a laparoscopic lateral sectionectomy or resection of segment 3, combined with portal vein embolization via the iliac vein directed at the contralateral hemiliver. No postoperative morbidity or mortality resulted. After a mean interval of 37.3 days, second-stage hepatectomy was performed for clearance of tumors in the right hemiliver (two in an open approach and one in a hybrid laparoscopic and open approach), with morbidity in 67% of patients (Clavien–Dindo classes I and IIIb in one patient each) but no mortality. When these three patients were compared with 61 patients treated with an open approach, numbers of metastatic tumors tended to be less in patients with a laparoscopic first stage. Duration of the first-stage hepatectomy ($p < 0.01$) and hospital stay after that hepatectomy were shorter in patients with laparoscopic resection than in patients with open resection ($p = 0.03$).

Conclusion: Our preliminary data support the feasibility and safety of the laparoscopic approach for the first-stage resection during two-stage hepatectomy.

Clinical significance: First-stage laparoscopic clearance for patients with relatively small numbers of tumors who are anticipating two-stage hepatectomy for bilobar metastases becomes a standard option.

Keywords: Colorectal cancer, Laparoscopic resection, Liver metastases, Two-stage hepatectomy.

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Introduction

Two-stage hepatectomy has emerged as a valuable strategy for curative treatment of patients with marginally resectable bilobar colorectal liver metastases that cannot be removed by a single hepatectomy without unacceptable risk of liver failure. At present, this procedure is performed routinely for patients with bilobar liver metastases from aggressive colorectal or neuroendocrine cancers at many hepatobiliary centers worldwide. Two-stage hepatectomy has improved resectability rates by 10 to 50% in unresectable or borderline-resectable patients,[1–4] but this strategy risks considerable morbidity and high risk of disease progression after the first stage, leading to a reported drop-out rate of 15 to 30%.[5]

Ongoing experience with laparoscopic liver resection has gradually expanded indications for laparoscopic surgery to include major as well as minor hepatectomies. Although many reported case series have shown favorable results after open two-stage hepatectomy, reports evaluating a laparoscopic approach to two-stage hepatectomy have remained limited, impeding discussion of a laparoscopic first stage in a two-stage hepatectomy. Laparoscopic resection for the first stage could reduce morbidity and possibly simplify the second operation by limiting adhesions. In fact, laparoscopy might allow one and possibly both stages to be performed with only minimal invasiveness.

Here, we report a small series of three patients undergoing a two-stage hepatectomy with a laparoscopic first-stage resection for colorectal liver metastases, providing some preliminary data regarding feasibility and safety.

[1–4]General and Gastroenterological Surgery, Showa University Fujigaoka Hospital, Yokohama, Kanagawa, Japan

Corresponding Author: Kuniya Tanaka, General and Gastroenterological Surgery, Showa University Fujigaoka Hospital, Yokohama, Kanagawa, Japan, Phone: +81-45-971-1151, e-mail: u1792ts235@med.showa-u.ac.jp

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Materials and Methods

Patients

A database including 64 patients with colorectal liver metastases undergoing two-stage hepatectomy was reviewed. Among these patients, three had a laparoscopic first-stage hepatectomy. Here, we report details comparing these three patients to the 61 patients undergoing open two-stage hepatectomy. We further reviewed previously reported clinical series involving laparoscopic first stages in two-stage hepatectomy. The study protocol was approved by the ethics committee at our institutions (IRB protocol approval numbers, B110707040 and F2020C25). Written informed consent was obtained from all patients involved in this study.

Strategy for Hepatectomy

Two-stage hepatectomy was indicated for advanced metastases requiring extensive liver resection. A prediction score[6] of 50 or more, calculated using the formula −84.6 + 0.933a + 1.11b + 0.999c with a as the anticipated resection fraction (%), b as the indocyanine green retention rate at 15 minutes (ICGR15, %), and c as patient age in years indicated treatment with a two-stage hepatectomy.

Most first procedures involved resection of metastases from the hemiliver intended to become the future liver remnant (FLR), followed by portal vein embolization (PVE) directed to the contralateral hemiliver. FLR volume was measured by computed tomography 3 weeks after the first hepatectomy. The second hepatectomy to resect the deportalized hemiliver typically was performed 4 weeks after the first procedure. When FLR volume was considered insufficient, completion surgery was postponed until sufficient FLR volume was attained or a smaller hepatectomy that initially planned was considered because of rapid tumor growth during the interval period.

Laparoscopic Procedures

The laparoscopic procedure began with the open insertion of an umbilical 12-mm port; five or six additional ports were used as well. Diagnostic laparoscopy was performed initially to confirm the absence of metastases in extrahepatic sites. Liver parenchymal transection was performed while maintaining a 12 mm Hg pneumoperitoneum, which was increased to up to 20 mm Hg if bleeding was encountered. Laparoscopic intraoperative ultrasonography was used routinely to guide resection and confirm resectability. Parenchymal transection was performed with a combination of a cavitron ultrasonic surgical aspirator system (Valley Lab, Boulder, Colorado) and a soft-coagulation system (ERBE Elektromedizin, Tübingen, Germany). During parenchymal transection, Pringle's maneuver was performed to control vascular inflow, with 15 minutes of occlusion followed by 5 minutes of release. The resected specimen was placed in a plastic bag and retrieved through the umbilical incision after both cranial and caudal extensions.

PVE was attempted through the extended umbilical incision after retrieval of the specimen. The ileum was pulled out through the extended incision. For PVE, a 7-Fr catheter was inserted through an ileocolic vein, after which the portal branches of the hemiliver targeted for resection were embolized. The embolic material was a mixture of gelatin pellets (Gelfoam powder; Upjohn, Kalamazoo, Michigan) and oleic acid monoethanolamine (Oldamine; Grelan, Tokyo, Japan). After restaging following PVE, patients were suitably scheduled for a second-stage resection to remove tumors from the remnant liver.

Our standard approach at the second-stage hepatectomy following a laparoscopic first hepatectomy is a hybrid of laparoscopic and open approaches. Generally, mobilization of the right hemiliver is performed laparoscopically, and transection of liver parenchyma is performed under minimum laparotomy as previously reported.[7] Planning for the second procedure must be flexible, with minimization when FLR hypertrophy is suboptimal. Multiple small resections avoiding excessive tumor-free margins are performed using an open approach.

Terminology and Analyzed Parameters

The Brisbane 2000 terminology of the International Hepato-Pancreato-Biliary Association was used to designate operative procedures.[8] Morbidities were assessed according to the Clavien–Dindo (CD) classification.[9]

Statistical Analysis

Continuous variables, analyzed using the Mann–Whitney *U* test, are expressed as the mean ± standard deviation. Categorical variables, expressed as numbers followed by percentages in parentheses, were analyzed with Fisher's exact test. A difference was considered significant when the two-sided *p*-value was below 0.05. All statistical analyses were carried out using SPSS statistical software (version 23; IBC SPSS, Chicago, Illinois).

Results

Details of three patients with laparoscopic two-stage hepatectomy (two men, and one woman; mean age, 67.0 ± 7.2 years) are shown in Table 1. The first-stage hepatectomy consisted of laparoscopic lateral sectionectomy or resection of segment 3. All three patients underwent PVE to the contralateral hemiliver via the iliac vein during the first-stage laparoscopic hepatectomy. Second-stage hepatectomy was performed after a mean interval of 37.3 ± 10.7 days following first-stage resection. Adhesions were considered minimal on assessment during the second-stage procedure in all patients. Metastatic tumors were removed from the right hemiliver at second-stage hepatectomy using an open approach in two patients and a hybrid laparoscopic and open approach in the other patient. In the two patients undergoing open second-stage hepatectomy, part of the deportalized hemiliver was left in place because remnant liver hypertrophy and liver function were compromised by prehepatectomy chemotherapy. We resected segment 8 and performed multiple partial hepatectomies in one patient. Another underwent resection of segment 7 extending to 8 in addition to resection of the right hepatic vein (with preservation of the right inferior hepatic vein) and partial resection of segments 5 and 6. The third patient was treated with a hybrid approach including posterior sectionectomy extended to segment 8 with preservation of the right

Table 1: Characteristics and operative feasibility of patients undergoing two-stage hepatectomy

	Gender	*No. of tumors*	*Maximum diameter, mm*	*PVE*	*Procedures*	*Resected volume, gm*	*Duration, minute*	*Blood loss, mL*	*Morbidity, %*	*Hospital stay, days*
					First/second	*First/second*	*First/second*	*First/second*	*First/second*	*First/second*
1	Male	11	35	Performed	Lateral section/ segment 8 + P	175/223	230/374	500/700	None/none	8/10
2	Female	6	40	Performed	Lateral section/ Ext. posterior section	190/317	255/455	378/700	None/CD-I	5/14
3	Male	5	33	Performed	Segment 3/Ext. segment 7 + P	54/264	238/559	380/635	None/CD-IIIb	9/31

No., number; PVE, portal vein embolization; first, first hepatectomy; second, second hepatectomy; section, sectionectomy; segment, segmentectomy; P, partial hepatectomy; Ext., extended to; CD, Clavien–Dindo

hepatic vein because insufficient FLR hypertrophy precluded right hemihepatectomy.

No morbidity or mortality followed the first-stage liver resection. The second-stage resection was associated with no mortality, but two of three patients experienced operative morbidity. Complications after the second resection included a prolonged inflammatory state of unknown cause requiring antibiotic administration (CD class I) in one patient and postoperative bleeding requiring surgical intervention (CD class IIIb) in another.

When these three patients were compared with 61 who underwent an open first stage, small numbers precluded statistical significance. Metastatic tumors tended to be fewer in the patients undergoing laparoscopic surgery. Although hepatectomy procedures differed between the laparoscopic and the open group at both first- second-stage hepatectomy (p <0.001 and p = 0.013, respectively), duration of the first-stage hepatectomy (p <0.01) and hospital stay after the first-stage hepatectomy (p = 0.03) were shorter in patients with laparoscopic resection than open resection. Total resected volume at second-stage hepatectomy was smaller in the laparoscopic group than in the open group (p = 0.016) because the procedures in the laparoscopic group had to be minimized because of insufficient remnant liver volume and functional hypertrophy (Table 2).

Table 2: Comparison of two-stage hepatectomies between laparoscopic and open approaches

		Laparoscopic (n = 3)	*Open* (n = 61)	*p value*
Age, years		67.0 ± 7.2	61.5 ± 10.5	0.409
Gender	Male	2 (67%)	36 (59%)	>0.999
	Female	1 (33%)	25 (41%)	
Timing of metastases relative to primary				
	Synchronous	3 (100%)	54 (89%)	>0.999
	Metachronous	0	7 (11%)	
Tumor number		7.3 ± 3.2	13.1 ± 8.5	0.214
Maximum tumor size, mm		36.0 ± 3.6	53.3 ± 35.9	0.583
Extrahepatic metastases present		2 (67%)	15 (25%)	0.170
Preoperative serum CEA, ng/mL		14.1 ± 4.1	400.4 ± 1446.2	0.651
Prehepatectomy chemotherapy				
	Performed	3 (100%)	52 (85%)	>0.999
First hepatectomy				
Extent of resection	Partial	0	14 (23%)	<0.001
	Multiple partial	0	34 (56%)	
	Segment or more	1 (33%)	0	
	Section or more	2 (67%)	10 (16%)	
	Hemiliver	0	3 (5%)	
Duration, min		241 ± 12.8	423.6 ± 112.2	0008
Bleeding, mL		419.3 ± 69.9	722.0 ± 848.8	0.906
Resected volume, gm		139.7 ± 74.6	155.5 ± 200.3	0.537
Morbidity, %		0	21 (33%)	0.545
Hospital stay, days		7.3 ± 2.1	18.6 ± 11.8	0.029
Portal vein embolization performed	3 (100%)	52 (85%)	0.999	
Interval, days	37.3 ± 10.7	72.1 ± 60.2	0.263	
Second hepatectomy				
Extent of resection	Multiple partial	0	3 (6%)	0.013
	Segment or more	2 (67%)	2 (4%)	
	Section or more	1 (33%)	4 (8%)	
	Hemiliver	0	20 (38%)	
	Bisections or more	0	2 (4%)	
	Extended hemiliver	0	18 (35%)	
	Trisections	0	3 (6%)	
Duration, min		462.7 ± 92.7	471.2 ± 147.2	0.699
Bleeding, mL		578.3 ± 157.8	1592.6 ± 1728.9	0.152
Resected volume, gm		268.0 ± 47.1	567.6 ± 263.3	0.016
Morbidity, %		2 (67%)	17 (33%)	0.555
Hospital stay, days		18.3 ± 11.2	25.5 ± 18.9	0.548
Mortality, %		0	1 (2%)	>0.999

CEA, carcinoembryonic antigen. Continuous data are expressed as the mean ± standard deviation

Discussion

In two-stage hepatectomy, complication rates have varied from 0 to 30%[2,10,11] for the first stage and ranged up to 60%[1] for the second. Higher complication rates after second-stage surgery are widely acknowledged and likely are related to prolonged prehepatectomy chemotherapy, complicated surgical procedures, and massive volumes of liver resection.[12] Advantages of laparoscopic approach to liver resection have been well described, including less postoperative pain, fewer intra-abdominal adhesions, and shorter hospital stays.[13–15] Recently, laparoscopic approaches are gradually being applied to two-stage hepatectomy,[16–20] offering the benefit of less invasiveness. However, overall surgical feasibility of two-stage hepatectomy using a laparoscopic approach remained an ongoing concern.

In this study, the total number of metastases tended to be smaller in patients undergoing the laparoscopic approach than in those treated with an open approach. However, as expected, laparoscopy decreased length of the operation and the hospital stay and was associated with somewhat fewer postoperative complications after first-stage hepatectomy. The laparoscopic first-stage approach provoked fewer adhesions, which should facilitate the second stage.

Generally, inflammation of the portal pedicle after PVE is associated with dense abdominal and perihepatic adhesions, and anatomy is distorted by liver hypertrophy following the previous resection. As a result, laparoscopic second-stage hepatectomy can be technically challenging, requiring exceptional expertise in both laparoscopic maneuvers and hepatobiliary surgery. A hybrid procedure combining laparoscopic and open approaches for the second hepatectomy is the least invasive strategy that we now can apply. Unfortunately, multiple small resections within the deportalized liver in lieu of major hepatectomy via an open approach were required in two patients with insufficient functional hypertrophy according to liver function parameters compromised by perioperative chemotherapy. The other patient could not tolerate right hemihepatectomy, so we performed posterior sectionectomy extended to segment 8 using a hybrid approach. In spite of these limitations, our short-term outcome was comparable or slightly better in terms of intraoperative bleeding and duration of hospital stay than the same measures in 61 patients with an open approach.

According to previous reports regarding laparoscopic two-stage hepatectomy (Table 3), laparoscopic second-stage hepatectomy was completed in 58 of 82 patients (70.7%). This high completion rate for laparoscopic second resection could be explained by the restriction of some studies to patients eligible for laparoscopic resection at both stages and also by stringent criteria, including a limited number of liver metastases. The mean or median total number of metastatic tumors was about 5 in these reported series; such a small number of metastases might have been managed with only a single hepatectomy in some instances. Further, the mortality rate in two reports in Table 3[18,20] with a high completion rate for laparoscopic resections in both stages was about 3%, which is similar to or slightly greater than mortality in open two-stage hepatectomy.[2,10,11,20] Based on these results, laparoscopic second-stage resection should be limited to patients with relatively few remaining metastases. General application of laparoscopic resection to both stages now remains an elusive goal.

Given our small numbers of patients, long-term results would be difficult to generalize. However, at this writing, all three patients remain alive at 90, 445, and 1,345 postoperative days. Some controversy exists regarding the risk of compromising oncologic principles when a minimally invasive approach is adopted. However, recently reported long-term results for patients with laparoscopic two-stage hepatectomy were comparable to results for open two-stage hepatectomy.[20] A laparoscopic approach might not adversely affect the oncologic course of patients with two-stage hepatectomy for bilobar colorectal liver metastases.

Conclusion

Our preliminary data support the feasibility and safety of the laparoscopic approach for first-stage liver resection. Advantages of first-stage laparoscopic hepatectomy include fewer adhesions and rapid postoperative recovery. This approach should be offered to patients with relatively small numbers of tumors who

Table 3: Reported series of laparoscopic two-stage hepatectomy

Authors	*No. of patients First/ Second*	*No. of tumors*	*PVE performed*	*Approach (pure/ conversion/open)* *First/ Second*	*Duration, minute* *First/ Second*	*Blood loss, mL* *First/ Second*	*Morbidity, %* *First/ Second*	*Hospital stay, days* *First/ Second*	*Overall mortality, %*
Di Fabio[16]	8/8	4 (2–6)	7	8/0/0	139 ± 45/	132 ± 103/	0/50	6 (4–10)/	0
				2/1/5	243 ± 85	1,225 ± 468		15.5 (6–43)	
Sandri[17]	4/4		4	4/0/0	189/304	22/425	0	3.5/8	0
				0/0/4			—		
Fuks[18]	34/26	6.0 ± 7.1	20	32/2/0	210 ± 114/	150 ± 143/	50/54	6.1 ± 5.2/	3
				22/4/0	250 ± 139	250 ± 203		9 ± 8.2	
Kilburn[19]	7/6	4 (3–10)	7	7/0/0	100 (60–170)/	100 (50–400)/	0/50	3 (2–5)/	0
				0/1/5	158 (120–220)	420 (100–600)		6.5 (5–23)	
Okumura[20]	38/38	6 (2–13)	25	37/1/0	159 (70–415)/	50 (0–350)/	16/26	6 (0–34)/	2.6
				34/4/0	305 (150–480)	225 (50–1,300)		9 (4–49)	

No., number; PVE, portal vein embolization; pure, pure laparoscopic; conversion, conversion from laparoscopic to open surgery; open, open-abdomen; first, first hepatectomy; second, second hepatectomy. Data are expressed as the mean ± standard deviation or the median followed by range in parentheses

are anticipating two-stage hepatectomy for bilobar metastases. With time, first-stage laparoscopic clearance of the left hemiliver becomes a standard option.

Clinical Significance

First-stage laparoscopic clearance for patients with relatively small numbers of tumors who are anticipating two-stage hepatectomy for bilobar metastases becomes a standard option.

Orcid

Kuniya Tanaka https://orcid.org/0000-0002-3871-8208

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ORIGINAL ARTICLE

Laparoscopic Subtotal Cholecystectomy: Our Experience

George C Obonna[1], Martin C Obonna[2], Rajneesh K Mishra[3]

Abstract

Background: The gold standard for gallbladder (GB) surgery worldwide is laparoscopic cholecystectomy. At the same time, complications that may arise from performing cholecystectomy can be horrifying. This is because in some cases, the complex anatomy can predispose the patient to the dangerous arteriovenous and biliary injuries. A subtotal cholecystectomy (STC) can, thus, obviate these complications.

Aim: To examine the clinical spectrum of STC and the postoperative turnout of this procedure.

Materials and methods: Our health management information system was used to collate our 10-year data (January 2010–January 2020) from the secondary and tertiary health facilities owned by Ondo State of Nigeria. Information on patients' biodata, indication for surgery, surgical approach, laboratory evaluation, and radiological assessment was entered into a spreadsheet and analyzed using Statistical Package for the Social Sciences (SPSS) version 20 (OBM Incorporation).

STC occurs when there is a remnant of the GB after GB surgery exclusive of the cystic duct.

Results: A total of 60 (15%) out of 400 patients underwent laparoscopic STC. Closely compacted, complexly crowded constituents and adhesions at the Calot's triangle were the main indications for STC. Ten patients (16.7%) had bile leakage after surgery. There were no biliovascular injuries, and 1-month mortality was zero.

There was no case of surgical site infection. Over a consistent follow-up of 1 year, clinical examination, liver function test, and ultrasonography revealed no abnormality in any of the patients.

Conclusion: STC is a rescue mission during difficult GB surgery. Early consideration for STC before conversion to open surgery is more acceptable. Intraoperative injuries are obviated, and the postoperative outcomes are satisfactory.

Keywords: Biliovascular injury, STC.

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Introduction

The popular procedure of cholecystectomy even performed by laparoscopy is not devoid of the dangerous complications of biliovascular injury. Despite innovation in the management of biliary disease and the current approach using indocyanine fluorescent imaging, the rates of intraoperative injury to structures at the Calot's triangle remain consistent. Figure 1 depicts the procedure of laparoscopic cholecystectomy.

Conditions that predispose to serious complications at total cholecystectomy include empyema gallbladder (GB), frozen Calot's triangle, sessile GB, short/wide cystic duct, and biliovascular anomalies. In these situations, a resort to open cholecystectomy may not improve the plane of dissection, and there still exists the complication of biliovascular injuries. Various authors have demonstrated biliovascular injuries despite conversion to open cholecystectomy.[1–3] Subtotal cholecystectomy (STC) thus provides the window for removing the GB without subsequent destruction of surrounding structures. It was in 1995 that madding provided the term of STC in three cases and further description of the safety of the procedure was done by Bornman and Terbanch, and Michalowski et al. They described the steps of laparoscopic STC.[4,5]

The definition of STC, which is the inability of a surgeon to safely divide the cystic duct which is not accepted, was provided by Lidsky et al.[6] and classification types of STC by Palanivelu et al.,[7] Shin et al.,[8] and Strasberg et al.[9] Figure 1 elucidates the steps in laparoscopic STC. In our study, we evaluated our 10 years of STC.

[1]Department of Surgery, University of Medical Sciences, Ondo, Nigeria

[2]Faculty of Basic Medical Sciences, ABSU, Uturu, Nigeria

[3]World Laparoscopy Hospital, Gurugram, Haryana, India

Corresponding Author: George C Obonna, Department of Surgery, University of Medical Sciences, Ondo, Nigeria, Phone: +2348038584310, e-mail: obonnadr@gmail.com

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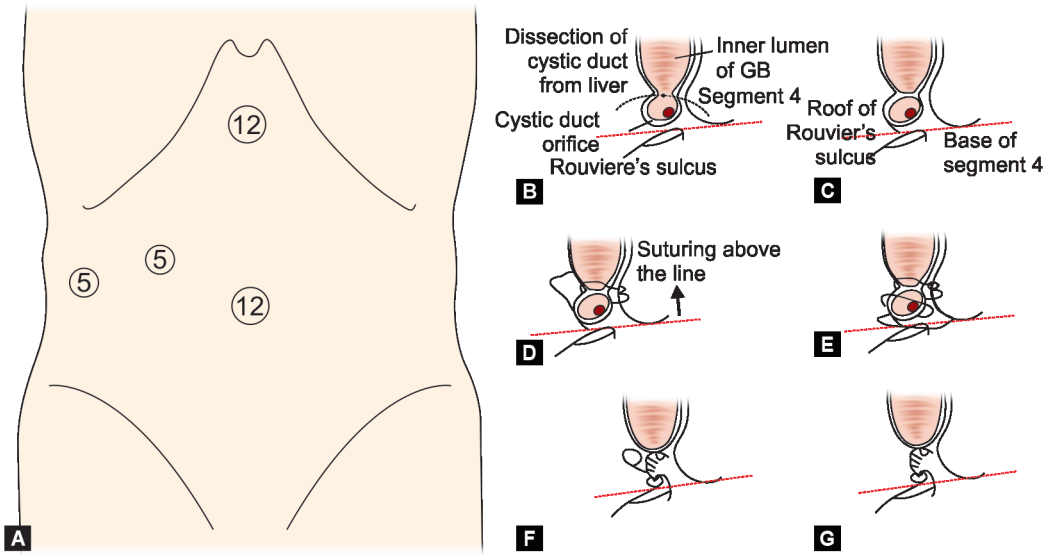
Materials and Methods

This is a retrospective, descriptive cross-sectional study. Our health management information system provided data from January 2010 to January 2020. Cases of cholecystectomy were evaluated. STC in our research was defined as leaving behind any portion of the GB other than the cystic duct. The follow-up data of the cases were noted, and all the patients had abdominal ultrasonography (USG) and liver function test (LFT). The primary aim of the study is to evaluate the turnout of STC, demographics, indications, and surgical method.

The patients evaluated are those who do not have concurrent common bile duct stone confirmed by appropriate imaging.

All patients who required an STC had their GB opened and remnant cleared of any stones during the surgery. The remnant



Figs 1A to G: Port placement for LSC and surgical procedures of LSC. (A) The scopist used the umbilical port and main surgeon stood left side of the patient; (B) Making incision on the GB and identification of cystic duct orifice from the inner lumen of GB leaving a part of GB wall on the liver bed. Dissection of cystic duct from the liver; (C) Isolation of cystic duct and identification of the line between the base of Segment 4 and the roof of Rouviere's sulcus; (D to G) Suture using an absorbable 3–0 V-Loc above the line

mucosa was ablated using the coagulation mode of electrosurgical unit.

The amount of GB left behind was minimum in which a safe transection away from hilar structures could be performed. We did not proceed to objective measurement of the remnant.

Results

Four hundred patients underwent cholecystectomy for gallstone disease in our hospital from January 2010 to January 2020. Of the 300 patients who had laparoscopic cholecystectomy, 200 patients (66.6%) had undergone total cholecystectomy while 60 patients (20.0%) had STC. The remaining 40 patients who had laparoscopic cholecystectomy were converted to open procedure in view of the anticipated difficulty, advanced age, and comorbidities precluding general anesthesia (Tables 1 and 2).

Adhesions and inability to delineate the Calot's triangle anatomy were the most common reasons for an STC, and atrophy hypertrophy complex causing hilar rotation and a branch of high hepatic artery running parallel to GB wall and entering the liver also constituted an indication for STC. In 43 patients, the remnant GB was tackled with interrupted sutures, while in 15 patients, a purse string was used.

The endoscopic cutting stapler was used in two patients (Fig. 2). Vicry1 (polyglactin 90) was used as the suture material.

Drains were placed in all but three patients. Ten patients (16.7%) had a bile leakage in the postoperative period. Nine were managed conservatively with a wait-and-watch policy.

One patient required laparotomy. There were no biliary/vascular injuries, and 1-month mortality was zero. There was no case of surgical site infection (SSI).

In the long term, all the patients were assessed over a period of 1 year by clinical examination, LFT, and USG. Except for one patient who had mild epigastric pain, no abnormality was detected in any of the patients.

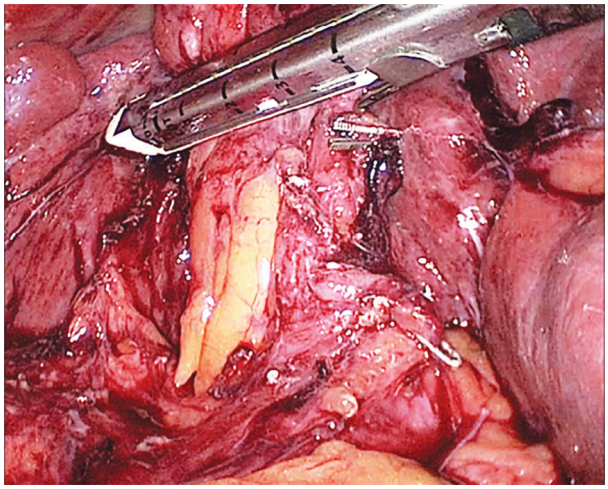


Fig. 2: Stapled STC performed in an unclear Carlot's anatomy.

Discussion

The possibility of biliovascular injury at the time of cholecystectomy cannot be overlooked. These injuries can thus increase the morbidity and mortality after biliary surgery. An STC has been shown to prevent such disaster.

Males constituted the most in this study correlating with available data worldwide, advanced age and male sex being the predictors of difficult cholecystectomy. The rate of STC (20%) was profoundly high compared to that reported (3.3%) by Chowbey et al.[10,11] This is in keeping with the extended catchment of our health facility.

The most common reason for STC, that is, dense adhesions due to chronic inflammation, is in keeping with the results of reviews by Elshaer et al. and Henneman et al. independently.[12,13]

Table 1: Demographic profile of STC patients

Age	*n = 60*
<40	8
40–49	10
50–59	12
60–69	20
>70	10
Gender	
Male	40
Female	20

Table 2: Operative findings and tackling remnant of GB

Indications for STC	*n = 60*
Dense adhesions/frozen Calot's triangle	34
High insertion/short or wide cystic duct	5
Intrahepatic GB	5
GB perforation/empyema	
Mirizzi	4
Collaterals on GB wall	3
Others	2
Methods of closure of remnant	
Interrupted suture	43
Purse-string suture	15
Stapler	2

Conversion to an open procedure may not prevent biliovascular injury.[14]

We had no case of biliary damage. Taking an early decision for an STC can obviate the danger of injury and very often prevent unnecessary conversion to open procedure.

Ten (16.7%) out of 60 patients developed a bile leakage and were managed effectively by watchful waiting except one who had laparotomy because he developed biliary peritonitis. We discovered a nidus of remnant GB for that patient, and peritoneal lavage and drainage was done.

None of our patients developed a wound infection. Meta-analysis by Elshaer et al. showed that laparoscopic STC had lower rates of intra-abdominal collections, SSI, or reoperation rate. From our experience, STC via the laparoscopic approach whenever we can in case of difficulty gives faster recovery, less chances of SSI, and acceptable long-term outcomes. Studies by Van Dijk et al.[15] are in keeping with our findings.

Removing the majority of the distensible portion of the GB prevents any further stagnation/saturation of bile. It can be argued that a remnant GB might have been missed on ultrasonography imaging. We, however, preferred not subjecting our patient to cross-sectional imaging in the absence of any symptoms or biochemical abnormalities. In the general population, 80% of the diseased GBs are asymptomatic, and it cannot be justified to subject them to any kind of investigation or treatment.[16]

Regarding the risk of neoplasia, the mere presence of gallstones is not a risk factor for malignancy. It may be argued that with the removal of the offending agent, further inflammation may subside. There remains a risk of recurrent stone; however, it would be preferable to manage a remnant GB than a biliary cripple.

We conclude that STC is a useful alternative during the difficult GB surgery. Due consideration for STC must be given initially before rushing to the conclusion of conversion to an open procedure. STC averts biliovascular injuries. The short-term and later outcomes of STC are encouraging.

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ORIGINAL RESEARCH

Comparative Evaluation of Vaginoscopic vs Traditional Hysteroscopy

Neena Gupta[1], Uruj Jahan[2], Anuradha Yadav[3], Rashmi Kumari[4]

Abstract

Aim: A randomized case–control study was performed to compare the traditional using a speculum vs vaginoscopic hysteroscopy in terms of pain score and procedure time.

Materials and methods: A total of 100 patients aged 20 to 60 years old, including nulliparous, multiparous, and postmenopausal, were randomized in two groups: group A undergoing traditional hysteroscopy with speculum and vulselum (50 patients) and group B undergoing "no-touch" vaginoscopic hysteroscopy.

Results: Vaginoscopy was significantly more successful than the traditional hysteroscopy. The total pain was calculated for each group, it was significantly lower in the vaginoscopic technique ($p = 0.026$). The mean time was 5.71 for traditional hysteroscopy and 4.44 for vaginoscopic hysteroscopy. The time taken to perform hysteroscopy was significantly shorter with vaginoscopic hysteroscopy. There was no difference in failure rates.

Conclusion: The vaginoscopic approach is better tolerated, quicker to perform, less painful, and therefore, more successful than the traditional hysteroscopy using the speculum. It should be preferred in an outpatient setting.

Keywords: Hysteroscopy, Outpatient, Pain score, Procedure time, Traditional, Vaginoscopic.

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Introduction

Hysteroscopy word is derived from Latin word "haustera," i.e., womb. In the present scenario, hysteroscopy has become the gold standard while evaluating the vagina, cervix, cervical canal, and uterine cavity. It is the process of viewing and operating in the endometrial cavity from a transcervical approach, offering the advantage of direct visualization of the uterine cavity while giving the option of collecting histological biopsy samples under visual control. Ambulatory hysteroscopy is a safe, feasible, and accurate procedure for diagnosing intrauterine pathology[1] and treating many intrauterine, endocervical problems. It can be used for the evaluation of the uterine cavity in cases of abnormal uterine bleeding (AUB), infertility, and recurrent pregnancy loss. Diagnostic hysteroscopy was then performed using two different techniques:

- Traditional technique: A Sims speculum was inserted into the vagina to visualize the cervix, and a vulselum was then applied to the anterior lip of uterine cervix to create countertraction to facilitate the insertion of the hysteroscope.
- No-touch technique: Also known as vaginoscopy is an alternative technique where hysteroscope is first introduced into the introitus of the vagina and avoids the use of the speculum[2] and a tenaculum to grasp or steady the cervix.[3] The vagina is then distended with the saline distention medium and hysteroscope directed toward the cervix, the cervical canal, and then into the uterine cavity. This study tries to evaluate the role of hysteroscopy as a diagnostic tool in women with different gynecological problems and compare the two approaches of hysteroscopy—traditional and vaginoscopic.

[1–4]Department of Obstetrics and Gynecology, GSVM Medical College, Kanpur, Uttar Pradesh, India

Corresponding Author: Rashmi Kumari, Department of Obstetrics and Gynecology, GSVM Medical College, Kanpur, Uttar Pradesh, India, Phone: +91 09076568314, e-mail: insh6142@gmail.com

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Aims and Objectives

To compare vaginoscopic hysteroscopy and traditional hysteroscopy in terms of the following:

- Comparative evaluation of pain during an intraoperative period in both procedures.
- An intraoperative complication in both studies (cervical lip tearing, bleeding, and uterine perforation)
- Evaluation of procedure time in both procedures.
- Comparative evaluation of the success of the procedure in both studies.
- Evaluation of causes of the failure in both procedures.

Materials and Methods

This randomized case–control study was carried out in the Obstetrics and Gynecology Department in the GSVM Medical College, Kanpur, during a study period from December 2017 to

May 2019. The study included 100 women aged 20 to 60 years old including nulliparous, multiparous, and postmenopausal. These 100 women were randomly allocated into two groups. Group A had 50 women who had undergone traditional hysteroscopy and group B had 50 women who had undergone vaginoscopic hysteroscopy. Few patients were lost to follow-up. Eventually, 44 patients were included in group A and 42 patients in group B (Fig. 1).

Selection of Cases

- All patients of infertility.
- Dysfunctional uterine bleeding (DUB).
- Postmenopausal bleeding.
- Other gynecological complaints in which hysteroscopy indicated.

Exclusion Criteria

- Pregnant women.
- Cancer of the cervix.
- Active infection of the genital tract.
- Cardiovascular disease.
- Severe obstructive airway disease.
- Acute generalized peritonitis.
- Blood dyscrasias and coagulopathy.

A thorough history was taken which included menstrual history, obstetrical history, and medical history, including any history of diabetes, hypertension, and cardiovascular disease. Personal history regarding smoking and alcohol intake was taken.

General examination and systemic examination were done. Basic routine blood investigations were done. Transabdominal ultrasound and transvaginal sonography were done where indicated.

A simple hysteroscope with a telescope of rigid 4 mm diameter was used. The timing of the examination was during the proliferative phase of the menstrual cycle. The insertion of hysteroscope through cervical canal was done under direct vision and in vaginoscopy without cervical dilatation or passage of sound as a tight cervix acts as a good seal to prevent leakage of the distending media and allow examination of the cervical canal and inspection of undamaged endometrium. Pain score (according to Wong–Baker Faces pain rating scale), procedure time, and complications were noted.

Results

The flow of patients and their allocation through the study is shown in Figure 1. Patient characteristics and demography are shown in Table 1. No significant differences in age, parity, and socioeconomic status between patients of groups A and B were observed.

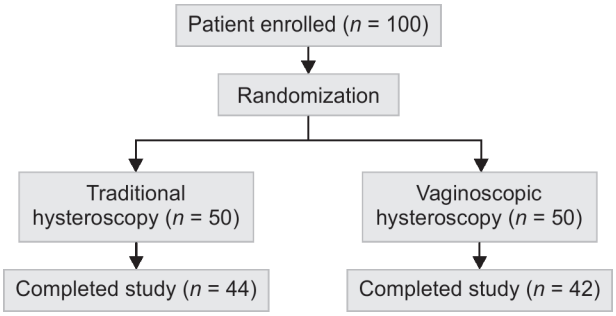

Fig. 1: Study design and patient randomization

Data on pain score at various stages are shown in Table 2. Analysis showed that the *p* value was 0.026, i.e., a significant difference was found in the pain score. A maximum number of patients (68%) perceived the pain of grade 4 during the grasping of the cervix with vulselum during the traditional hysteroscopy. In vaginoscopic hysteroscopy as there is direct introduction of hysteroscope, pain is perceived only in two steps.

No-touch vaginoscopic hysteroscopy was quicker to perform. Time required in the procedures is summarized in Table 3. In the diagnostic study during vaginoscopic procedure, 32 patients (76.19%) had completed their procedure in between 3 and 5 minutes. In traditional hysteroscopy, procedure time is 5 to 7 minutes in 34 patients (77.27%).

No major side effects were recorded during the procedure performed in any of the groups. The procedure failed in few patients, the most common cause being cervical stenosis.

Table 1: Comparative evaluation of demographic distribution of patients

	Group A (Traditional) N = 44		*Group B (Vaginoscopic) N = 42*	
Age (years)				
<20	00	0	0	0
20–29	10	22.7%	08	42.8%
30–39	17	38.6%	14	33%
40–49	09	20.4%	10	23.8%
>50	08	18.1%	10	23.8%
Parity				
Nulliparous	7	15.9%	08	19%
Multiparous	21	47.7%	24	57.1%
Postmenopausal	16	36.3%	10	23.8%
Socioeconomic status				
Low	25	56.8%	24	57.1%
Middle	14	31.8%	12	28.5%
Upper	05	11.3%	06	14.2%
Habitat				
Rural	24	54.5%	22	52.3%
Urban	20	45.4%	20	47.6%

Table 2: Evaluation of pain

			Mean	*SD*	*p*
1	During speculum placement	Group A	0.186	0.5878	
2	Cervix grasping with vulselum	Group A	2.46	1.0544	
3	Cervical dilatation	Group A	3.44	6.4339	
4	Introduction of hysteroscope	Group A	3.02	1.3360	0.026
		Group B	2.00	0.8944	
5	During hysteroscopy	Group A	2.51	1.1623	
		Group B	1.9	0.8889	
	Postoperative pain	Group A	1.76	0.8954	
		Group B	1.71	0.9975	

Table 3: Comparative evaluation of procedure time in each group

	Mean	*SD*	*Difference*	*95% CI*	*p value*
1 Group A	5.71	1.209	−1.270	−1.7567 to −0.7833	<0.0001
2 Group B	4.44	1.050			

Discussion

In both groups A and B, a maximum number of patients were in the age-group 30 to 39 years, followed by those in age-group 40 to 49 years. The results are comparable to results in the study which found that the most common age affected with AUB was 31 to 40 years (56%). Menorrhagia (36%) is the most common bleeding pattern. The most common pathology was proliferative endometrium (36%), followed by polyp (10%), secretory (8%), and hyperplastic (6%).[4]

Most of the patients were multiparous (64%), followed by postmenopausal women (30%) and nulliparous women (16%). AUB was seen more in multiparous women (64.8%).[5] Fibroid uterus being the commonest cause comprising 52.7%, 41.2% had DUB and 1.3% uterine malignancy.

Women were asked to rate their degree of pain during the four phases of the procedure: introduction of speculum or hysteroscope. Comparison between corresponding phases of the procedure showed the only significant difference during introduction into the vagina.[6] In our study during traditional hysteroscopy, 68% of patients perceived pain of grade 4 during grasping of the cervix by vulselum. During cervical dilatation, 22% perceive the pain of grade 4, followed by 4.5% of patients who perceive the pain of grade 6 (Figs 2 and 3).

Pain continues to represent the main limiting factor to a large-scale use of office hysteroscopy.[7] However, although a reduction in pain is clearly advantageous in the outpatient procedures to optimize acceptability to patients, the review does not demonstrate any improvement in procedural feasibility (i.e., the successful completion of hysteroscopy) as a consequence of minimizing discomfort. Vaginoscopic approach to outpatient hysteroscopy is successful and significantly reduces pain experienced[8] (Fig. 4).

Bettocchi and Selvaggi[9,10] reported their experience with more than 11,000 hysteroscopic procedures performed using the vaginoscopic technique, eliminating the use of a speculum and a tenaculum. They found that as many as 99.1% of the patients reported no discomfort related to the procedure. The mean pain score was significantly lower in the group without the use of speculum.[11]

In vaginoscopic hysteroscopy, there is a direct introduction of hysteroscope in the cervix through the vagina. Pain is perceived only during two steps. During introduction, 59% of patients have the pain of grade 2 and 9% have the pain of grade 4 followed by four women of grade 6. During the postoperative period in group A, 72.72% of patients have the pain of grade 2 followed by 11.36% of patients of grade 4. In group B during vaginoscopic hysteroscopy, 65.98% of patients have the pain of grade 2 followed by 7.1% of patients of grade 4. In our study, pain perception was statistically significantly lower in patients who underwent vaginoscopic hysteroscopy.

Technical modifications, especially reduction of the hysteroscope caliber, a rare need for anesthetics and introduction of vaginoscopy, have improved both tolerance and efficacy in retrospective studies and in randomized prospective trials.[12–14] Studies also show that saline is better tolerated than carbon dioxide and does not impair visual quality.[12,15]

In the study by Guida et al.,[6] the results were similar to that in our study, during vaginoscopic procedure, 32 patients (76.19%) had completed their procedure in between 3 and 5 minutes. Rest of the 10 patients (22.72%) completed in 5 and 7 minutes. In traditional hysteroscopy, procedure time is 5 to 7 minutes in 34

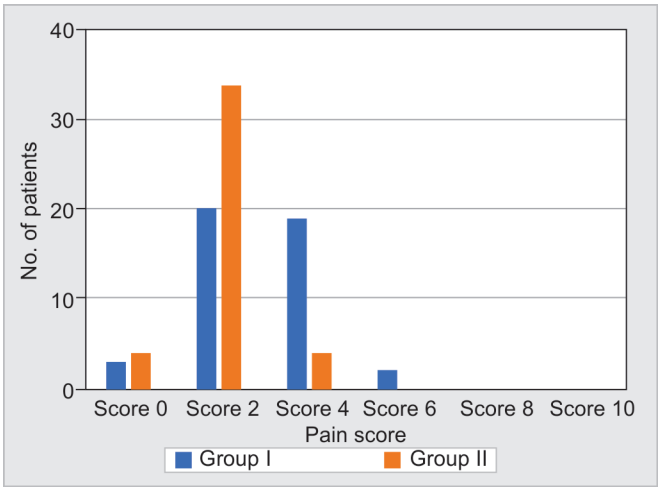

Fig. 2: Pain score distribution during the introduction of hysteroscope

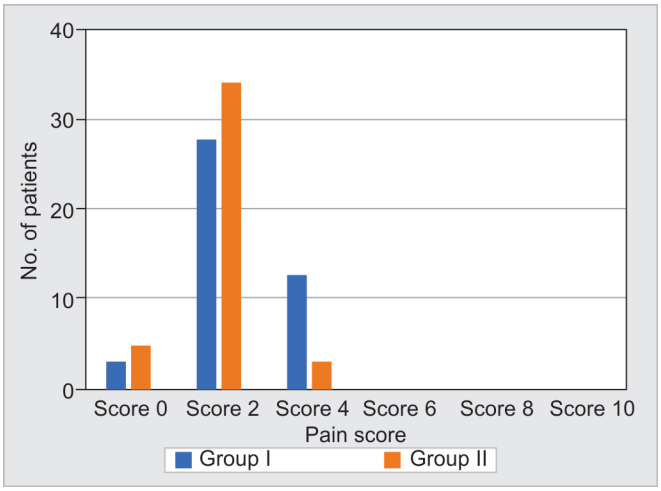

Fig. 3: Pain score distribution during the procedure of hysteroscopy

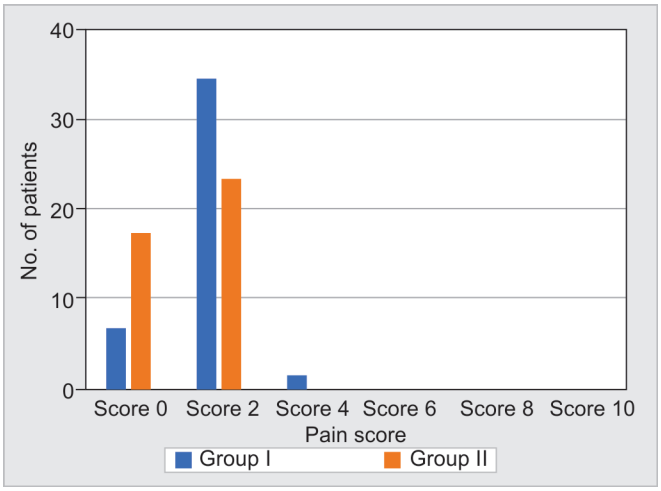

Fig. 4: Comparison of postoperative pain in both the groups

Table 4: Intraoperative complications in each group

	Complication	*Group A (Traditional) N = 44*		*Group B (Vaginoscopic) N = 42*	
1	No complication	43	97.72%	41	97.61%
2	Anesthesia-related				
	a. Apnea	—	—	—	—
	b. Tachycardia	1	2.27%	—	—
	c. Bradycardia	—	—	1	2.38%
3	Distention media				
	a. Complication				
	b. CO_2 embolism	—	—	—	—
4	Fluid overload	—	—	—	—
	Uterine perforation	—	—	—	—

Table 5: Causes of failure

	Causes	*Group A (Traditional)*		*Group B (Vaginoscopic)*	
1	Cervical stenosis	2	4%	5	10%
2	Cervix high-up	2	4%	1	2%
3	Acutely anteverted or retroverted uterus	1	2%	2	4%
4	Bleeding	1	2%	Nil	0%

patients (77.27%). Rest of the 10 patients (22.72%) completed in 3 and 5 minutes. There is a significant difference in procedure time $p < 0.05$ during diagnostic hysteroscopy in both the procedures.

Those who underwent "no-touch hysteroscopy" had the lowest requirement of local anesthetic. Also the time taken was significantly shorter with "no-touch" hysteroscopy.[16] A study goes on to conclude that the traditional approach should only be used when vaginoscopy fails or when the need for cervical dilatation is anticipated.[17]

In the study, the percentage of complications is rarely seen. Only one patient (2.27%) had experienced tachycardia during traditional hysteroscopy. While one (2.38%) had bradycardia during vaginoscopic hysteroscopy. Complications of this standard procedure are relatively rare[18] (Table 4).

There was no significant difference in the number of failed procedures between the vaginoscopic and traditional approaches to hysteroscopy. The most common cause of failure of vaginoscopic hysteroscopy is cervical stenosis in five patients[19] (Table 5). In traditional hysteroscopy, causes of failure of procedure are cervical stenosis in two patients (4%) and cervix high-up in two patients (4%), followed by acutely anteverted or retroverted uterus (2%) and bleeding (2%).

With the transvaginal approach, operative hysteroscopy is possible right after or even at the same time as the diagnostic examination, without anesthesia. This would require a surgical hysteroscope, an experienced operator, a cooperative patient, and limited disease. Outpatient hysteroscopy is easy to perform, takes less time, and is cost-efficient, making it a convenient office procedure using local anesthesia.[20]

Conclusion

The study provides evidence that vaginoscopy is more successful than the traditional hysteroscopy as it is quicker to perform and is associated with less pain and low procedure failure. The use of hysteroscope has eliminated the use of any premedication rendering the procedure faster and less associated complication rate. Narrower hysteroscopes reduce pain while giving a satisfactory view of the endometrial cavity with lower failure rates.

Orcid

Rashmi Kumari https://orcid.org/0000-0001-7844-374X

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RESEARCH ARTICLE

A Study on Effects of Leaking Carbon Dioxide Gas on Surgeons during Laparoscopic Surgeries

Mallikarjuna Manangi[1], Ranjitha Gangadharaiah[2], Santhosh S Chikkanayakanahalli[3], Madhuri G Naik[4], Arun Balagatte Jayappa[5]

Abstract

Background: Laparoscopic surgery is gold standard for treating various abdominal diseases. Carbon dioxide, having high safety profile, is the most commonly used gas for insufflating peritoneal cavity for accurate visualization and operative manipulation. Despite the fact that CO_2 is naturally present in the atmosphere, i.e., 0.035% (350 ppm), it is one of the most overlooked toxic gases. CO_2 breathing causes numerous cardiorespiratory responses and psychological reactions, such as impaired vision, diminished motor control, slowed responses, disorientation, or reduced attentional capacities that may jeopardize a worker's health and safety. At high concentrations (8%), it has been shown to cause unconsciousness almost instantaneously and respiratory arrest within 1 minute. As laparoscopic surgeons are under constant exposure of leaking CO_2 gas, this study is taken up to evaluate the effects of CO_2 on them by a noninvasive technique that measures end-tidal CO_2 of operating surgeons at the beginning and end of laparoscopic surgeries.

Objective: To evaluate the effects of leaking CO_2 gas on surgeons during laparoscopic surgeries.

Methods: A Mini-Mental State Exam (MMSE) score and $EtCO_2$ levels (using a capnometer with 4 L of oxygen/minute) of operating surgeons were obtained before the start of surgery. After surgery, MMSE scores and $EtCO_2$ levels were again documented, compared, and analyzed using SPSS software.

Results: The mean $EtCO_2$ before surgery was found to be 30.86 with standard deviation of 4.03 and that after surgery was 31.23 with standard deviation of 3.85 with mean duration of surgery being 73 minutes. Correlation of individual $EtCO_2$ values before and after surgery did not show significant changes (p value = 0.534). The difference in MMSE scale scores before and after surgery for all participated surgeons was insignificant.

Conclusion: In healthy surgeons performing laparoscopic surgeries, there are no effects following exposure to leaking carbon dioxide.

Keywords: Air quality, Carbon dioxide, CO_2, $EtCO_2$, Laparoscopic surgeries, Laparoscopy, Leaking CO_2.

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Introduction

Laparoscopic surgery has established itself as a gold standard for treating various abdominal diseases in the recent decades, with benefits including but not limited to improved cosmesis, reduced surgical trauma and postoperative pain, and expedited patient recovery times.[1] Carbon dioxide (CO_2), because of its high safety profile, is the most commonly used gas for insufflating the peritoneal cavity for accurate visualization and operative manipulation. Despite the fact that CO_2 is naturally present in the atmosphere, i.e., 0.035% (350 ppm) and we exhale it while breathing, CO_2 is one of the most overlooked toxic gases. CO_2 is heavier than air with a density of 1.5 times that of fresh air. When it is released into an enclosed space, it tends to settle to the bottom, reaching the highest concentration in the lowest parts of space. Carbon dioxide breathing causes numerous cardiorespiratory responses, but there appear to be no disabling physiological effects or clinical symptoms associated with breathing up to 5% CO_2.[2–4] Nonetheless, there still may be psychological reactions, such as impaired vision, diminished motor control, slowed reactions and responses, disorientation, or reduced attentional capacities that may jeopardize a worker's health and safety.[5,6] The physiological effects of carbon dioxide on the central nervous system have been roughly classified. They are both direct and indirect in their mechanism of stimulation.

- Direct stimulation of the respiratory centers in the medulla and spinal cord.
- Stimulation of the special nerve endings (chemoreceptors) in the carotid bodies and aortic arch, with the resultant vasodilator action on the cerebral blood vessels.
- Direct stimulation of the vasomotor centers in the hypothalamus, midbrain, and medulla.
- Direct action on the cerebral blood vessels.
- Effect on the affinity of blood for oxygen.[7]

The most important control of cerebral blood flow is chemical. The cerebral vascular bed is extremely sensitive to changes in arterial CO_2 tension and also to a lesser extent to decrease in O_2 tension.[8]

US Occupational Safety and Health Administration (OSHA) has established a permissible exposure limit (PEL) for carbon dioxide of 5000 ppm (0.5%) averaged over an 8-hour workday.

[1,3,4]Department of General Surgery, Bangalore Medical College and Research Institute, Bengaluru, Karnataka, India

[2]Department of Anaesthesiology, Bangalore Medical College and Research Institute, Bengaluru, Karnataka, India

[5]Department of Pulmonology, Bangalore Medical College and Research Institute, Bengaluru, Karnataka, India

Corresponding Author: Madhuri G Naik, Department of General Surgery, Bangalore Medical College and Research Institute, Bengaluru, Karnataka, India, Phone: +91 08123639816, e-mail: naikmadhurig@gmail.com

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Symptoms of Different Levels of Carbon Dioxide Exposure

- 10000 ppm (1.0%): Typically no effects, possible drowsiness.
- 15000 ppm (1.5%): Mild respiratory stimulation for some people.
- 30000 ppm (3.0%): Moderate respiratory stimulation, increased heart rate, and blood pressure.
- 50000 ppm (5.0%): Strong respiratory stimulation, dizziness, confusion, headache, and shortness of breath.
- 80000 ppm (8%): Dimmed sight, sweating, tremor, unconsciousness, and possible death.[9]

Since the likelihood of laparoscopic surgeons getting exposed to CO_2 gas due to leaky or faulty instruments or even during normal circumstances cannot be ruled out, this study is taken up to evaluate the effects of leaking CO_2 on them.

End-tidal CO_2 ($EtCO_2$) monitoring is a noninvasive technique that measures the partial pressure or maximal concentration of carbon dioxide at the end of an exhaled breath, which is expressed as a percentage of CO_2 or mm Hg. The normal values are 5 to 6% CO_2 in exhaled breath, which is equivalent to 35 to 45 mm Hg. When CO_2 diffuses out of the lungs into the exhaled air, a device called capnometer measures the partial pressure or maximal concentration of CO_2 at the end of exhalation.

Capnometry is a measurement of end-tidal CO_2 partial pressure ($PEtCO_2$). $PEtCO_2$ closely approximates $PaCO_2$ at the end of normal expiration in conditions with normal perfusion and ventilation and therefore makes the difference between $PaCO_2$ and $PEtCO_2$ minimal. In healthy individuals, there is essentially no alveolar dead space, which represents the volume of gases in non-perfused alveoli. This means that $PEtCO_2$ equals $PaCO_2$, and with correct sampling, $P(a-a)CO_2$ difference equals $P(a-et)CO_2$ difference, which makes $PEtCO_2$ a good estimate of $PaCO_2$.[10]

Objective of the Study

To evaluate the effects of leaking CO_2 gas on surgeons during laparoscopic surgeries.

Materials and Methods

Type of the study: Prospective cohort study

Time period: August 2018 to September 2018

Sample size: Based on pilot study, the difference in $EtCO_2$ was about 3 to 4 mm Hg.

Assuming a 10% difference in $EtCO_2$ before and after surgery with a power of 80% and alpha error of 0.05, a sample size of 10 was required. For further validation of the study and assuming a dropout rate of 10%, a total sample size of 20 was taken.

Inclusion Criteria

- Surgeons and surgical residents willing to give written informed consent.
- Surgeons and surgical residents of either sex aged 25 to 65 years.
- Surgeons and surgical residents performing laparoscopic procedures for more than 1 hour.

Exclusion Criteria

- Not willing to participate in the study.
- Age <25 years and age >65 years.
- Preexisting pulmonary conditions.
- Pregnancy.
- Surgeries spanning less than 1 hour.
- Chronic smokers.
- Hematological disorders.

Source of data: Clinical data are collected from the surgeons performing laparoscopic procedures in Victoria hospitals from August 2018 to September 2018.

Methodology

Ten surgeons performing laparoscopic surgeries for more than 1 hour in departments of general surgery in Victoria hospitals from August 2018 to September 2018 willing to give consent and meeting the inclusion criteria were included in the study after the clearance by ethical committee. A Mini-Mental State Exam (MMSE) score and $EtCO_2$ levels (using a side-stream capnometer with 4 L of oxygen/minute) of operating surgeons were recorded just before the beginning and immediately after the completion of the surgery. The data were recorded, compared, and analyzed using SPSS software version 24. Surgeons were enquired for symptoms such as dizziness, confusion, headache, shortness of breath, and visual disturbances.

Results

The mean $EtCO_2$ before surgery was found to be 30.86 with standard deviation of 4.03 and that after surgery was 31.23 with standard deviation of 3.85. Mean duration of laparoscopic surgeries was 73 minutes. Correlation of individual $EtCO_2$ values before and after surgery did not show significant changes (p value = 0.534). The difference in MMSE scale scores before and after surgery for all participated surgeons was insignificant. No effects were noted on decision-making, steadiness, and postural sway. The operating surgeons did not have any complaints in the postoperative period.

Discussion

Carbon dioxide (CO_2) is the product of cellular aerobic metabolism. It diffuses easily from cells into blood and erythrocytes and is transported to the lungs by venous blood through the function of cardiac output. Under normal conditions of circulation and ventilation, the partial pressure of CO_2 approaches 50 mm Hg at the level of tissues, and 45 mm Hg in the venous blood. The difference between the latter and alveolar CO_2 partial pressure ($PaCO_2$), which is around 40 mm Hg, is responsible for the diffusion of CO_2 into the alveoli. There, CO_2 is eliminated from the body with minute ventilation. Arterial CO_2 partial pressure ($PaCO_2$) normally varies from 35 to 45 mm Hg.[10]

Carbon dioxide is a colorless, odorless, and nonflammable gas, which because of its high safety profile is widely used to insufflate peritoneal cavities during laparoscopic surgeries. Being a highly soluble gas, it gets dissolved in blood soon after it is inhaled. It then binds to hemoglobin, and carboxyhemoglobin is formed, lowering hemoglobin's affinity for oxygen via Bohr's effect.[11] Carbon dioxide does not only cause asphyxiation by hypoxia but also acts as a toxicant. At high concentrations (8%), it has been shown to cause unconsciousness almost instantaneously and respiratory arrest within 1 minute.[12]

Thus, during laparoscopic surgeries following exposure to leaking carbon dioxide, CO_2 can be readily absorbed into the bloodstream and may result in significant hypercarbia.

In our study, we observed that there was no significant increase in the $EtCO_2$ values before and after laparoscopic surgery in the surgeons. Considering the occupational safety and health administration guidelines, CO_2 chromatography is advised for CO_2 monitoring at workplaces, to prevent any untoward incidents. And when any such incident is confronted, necessary immediate and appropriate supportive care is provided.

In conclusion, our current study shows that despite being exposed to leaking CO_2 during laparoscopic surgeries, the operating surgeons did not have significant changes in end-tidal carbon dioxide levels and the difference in MMSE scale scores was also insignificant. However, further studies involving a larger number of volunteers and prolonged duration of exposures need to be done with the specific monitoring of various blood parameters for a better understanding of the effects of CO_2 exposure.

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RESEARCH ARTICLE

Short-term Outcome of Laparoscopic vs Open Gastrectomy for Gastric Cancer: A Randomized Controlled Trial

Mostafa M Sayed[1], Mohamed G Taher[2], Salah I Mohamed[3], Mostafa A Hamad[4]

Abstract

Background: Gastric cancer (GC) is a crucial cause of morbidity and mortality worldwide. In Egypt, GC ranked as the 12th most common cancer. During the last two decades, laparoscopic gastrectomy (LG) has proved to be popular and effective. This study aims to compare the short-term outcomes of LG vs open gastrectomy (OG) in resectable GC patients.

Patients and methods: This is a randomized controlled trial, where patients presented to Assiut university hospital with resectable GC, in the period from January 2017 to December 2019, were randomly allocated to OG (group A) or LG (group B).

Results: During the study period, 46 patients were randomized: 23 patients for OG and 23 for LG. Advanced cases after exploration were excluded from both the groups ended up with a total of 36 patients (20 for OG and 16 for LG). The mean follow-up time was 5 months ranging from 40 days to 10 months. There were no statistically significant differences between the two groups in the baseline clinicopathological data. The mean operative time was longer in LG (260.6 ± 46.7 vs 191.0 ± 24.7 minutes in OG) with a *p*-value <0.001. The postoperative hospital stay was more in OG compared to LG (8.0 ± 4.1 vs 6.9 ± 2.6 days, *p*-value = 0.361). Postoperative complications were more among OG (4/20) compared to (2/16) in LG (*p*-value = 0.549). Just one mortality was reported in the OG.

Conclusion: For GC cases, LG shows comparable outcomes to OG in short-term results, and it is a promising minimally invasive surgery in such cases.

Keywords: Gastrectomy, Gastric cancer, Laparoscopic surgery.

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Introduction

Gastric cancer (GC) is one of the crucial causes of cancer morbidity and mortality worldwide. Globally, East Asia (Korea, Mongolia, Japan, and China) represents the highest percentage of cases and deaths from GC.[1]

In Egypt according to the national population-based cancer registry program, GC ranked as the 12th most common cancer representing 1.6% of the total cancers and 2.2% of the total cancer deaths. The incidence varies among the different regions of Egypt (higher in Upper Egypt 2.48% compared to Lower Egypt 0.98%).[2]

Surgery is the only cure for GC. According to the resection extent, gastrectomy is classified into distal gastrectomy, total gastrectomy, and proximal gastrectomy. Also, the extent of lymph node (LN) dissection is very important. In general, most studies report D1 (dissection of the perigastric LNs) or D2 (dissection of the LNs around the big gastric vessels), which means that at least a D1 LN dissection should be done. However, as mentioned in the 4th Japanese Gastric Cancer Treatment Guidelines for resectable GC, D2 LN dissection is strongly recommended and considered as the standard of care for GC patients.[3]

Laparoscopic gastrectomy (LG) for GC, initially introduced by Kitano et al. in 1993, has been studied in many countries, and nowadays, it became one of the important procedures for the treatment of early GC. Additionally, it has shown comparable short- and long-term outcomes as open gastrectomy (OG), mainly in Far East countries as Korea and Japan.[4,5] Furthermore, as surgical experiences increased and with development of instruments, some experts have extended their use of LG from early GC (EGC) to advanced GC (AGC).[4,6] However, the implementation of LG in our region is challenging because of the low number of cases and high cost of the equipment.

[1–4]General Surgery Department, Faculty of Medicine, Assiut University, Assiut, Egypt

Corresponding Author: Mohamed G Taher, General Surgery Department, Faculty of Medicine, Assiut University, Assiut, Egypt, Phone: +2 01091289046, e-mail: mohamedamin022@aun.edu.eg

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This study aims to compare the short-term outcomes of LG vs OG in resectable GC patients at our center in Upper Egypt (Assiut University Hospital, Egypt).

Patients and Methods

This randomized controlled trial conducted at the Department of General Surgery in the Assiut University Hospital (one of the largest tertiary centers in Egypt that serves most of Upper Egypt patients) in the period from January 2017 to December 2019, including all GC patients admitted to Assiut university hospital during this period.

The research protocol was approved via the Ethical Review Committee of Assiut Faculty of Medicine before starting the study. Written informed consent was obtained from recruited patients, and this trial was registered in clinicaltrial.gov (NCT02789826). Any adult patient with primary and resectable gastric carcinoma was eligible for the study. All GC patients have been diagnosed by

upper endoscopy and biopsy. Surgical resectability was assessed by multislice computed tomography abdomen (with IV and oral contrast), where resectable tumors, according to TNM classification, had to be T1-3, N0-1, and M0. All patients with infiltrating or metastatic cancer, peritoneal deposits, surgically unfit patient, or pregnant women were excluded from the study. After the diagnosis and assessment of eligibility, patients were randomized into two groups: group A had OG and group B had LG. Random assignment was done by the sealed envelope technique.

All patients had signed an informed consent after a complete explanation of the risks and advantages of the surgery being planned for them.

Baseline clinicopathological data were collected as age, sex, and tumor site.

Surgical Techniques

Laparoscopic Gastrectomy

The patient was placed in supine position for the induction of general anesthesia with cuffed endotracheal tube and then placed in French position. The operator stands between the legs of the patient. The cameraman stood on the patient's right side, while the first assistant stood on the patient's left side and the tower is placed near the patient's head.

A 10-mm camera port was created superior or inferior to the umbilicus by open method, and pneumoperitoneum with carbon dioxide was induced to a pressure of up to 15 mm Hg.

The peritoneal cavity was carefully checked for any secondaries. The table was turned into the steep reverse-Trendelenburg position, and four other trocars (one 12-mm and three 5-mm trocars) were placed carefully using laparoscopic vision. Thereafter, laparoscopic D2 gastrectomy was performed as follows.

We start by dividing the gastrocolic ligament along its transverse colon attachment using ultrasonic shears (Harmonic Scalpel TM; Ethicon Endo-Surgery Inc., Cincinnati, Ohio, United States). We started at the avascular plane to the left of the midline and dissected toward the spleen till it reaches the left gastroepiploic vessels that were divided. Division of the greater omentum was continued in the direction of the first part of the duodenum, and the roots of the right gastroepiploic vessels were divided. The soft tissues attached to the duodenum were dissected.

All LNs around the gastroepiploic vessels (stations 4d and 4sb) were dissected followed by the infra-pyloric LNs (station 6), which were dissected from the pylorus. At this stage, careful dissection was usually done to avoid injury of gastrocolic trunk of Helen, which, if happened, will result in unnecessary bleeding. The lesser omentum was then entered at the pars flaccida, and the origin of the right gastric artery was divided.

In the case of distally located tumors, the distal resection margin was the duodenum 1 to 2 cm distal to the pylorus using a COVIDIEN Endo GIA Ultra Universal Stapler, 12 mm.

The left gastric vein and artery were exposed by raising the stomach upward and to the right, completing dissection till the origin of the left gastric artery from the celiac trunks, where the artery was divided at its origin (station 7) using both clips and the ultrasonic shears. At this point, the LNs around the common hepatic artery were exposed and dissected. The perigastric LNs were dissected along the lesser curvature reaching the esophagogastric junction. At least a proximal 5-cm resection margin starts from the grossly malignant margin is done using COVIDIEN Endo GIA Ultra Universal Stapler, 12 mm (according to gastric wall thickness). Afterward, we dissected the adipose tissue over the anterosuperior border of the pancreas and LNs along the splenic vessels (station 11).

In locating proximal tumors, the proximal resection margin involved the whole proximal gastric segment with 2 to 3 cm esophageal safety margin using linear endo GIA stapler, 45 mm, blue cartilage and a distal resection line of 5 cm safety margin.

In tumors occupying a large area of the stomach, total gastrectomy was done with the duodenum transected 1 to 2 cm distal to the pylorus and the esophagus transected 2 to 3 cm proximal to the stomach.

Reconstruction was done by Roux-en-Y jejunal anastomosis for total and distal resection and esophagogastric anastomosis in upper radical resection.

A nasogastric tube inserted at the start of the operation was then advanced to cross the anastomosis, just beforehand sewing the opening left after the side-to-side stapling. Finally, the resected specimens after putting in a retrieval bag were taken out through a 6-cm vertical supraumbilical incision that starts at the umbilicus. The specimen was then checked for safety margins. A subphrenic tubal drain was then inserted and left until the patient starts semisolid meals without evidence of anastomotic leaks or bleeding, usually for 3 to 5 days.

Open Gastrectomy

A 10–15-cm incision length from the xiphisternum till below the umbilicus was used. Abdominal exploration was routinely done to assess the tumor and exclude metastasis before proceeding to the radical gastric resection. In general, we used the same steps as in the laparoscopic resection.

Pre- and Postoperative Management

Pre- and postoperative management was the same for the two groups. All patients received broad-spectrum antibiotics for 48 hours during their postoperative hospitalization. Feeding was started after passage of flatus. When the patients have adequate pain control, tolerance of oral intake, ability to mobilize and self-care, and no abnormal physical signs or laboratory test they were discharged.

Perioperative data such as operative time, estimated intraoperative blood loss, intraoperative organ injury, postoperative complications, histopathology of the tumor, and clinicopathological TNM stage (according to the International Union Against Cancer staging 10) were recorded. Postoperatively, 30-day follow-up data were collected to assess any complications, hospital stay duration, and need for ICU admission.

Data Management

Data management including data entry and statistical analysis were done by using IBM SPSS software, version 20. Quantitative variables were presented in terms of mean ± SD, and qualitative variables were expressed as frequency and percentage. Student's *t*-test and Chi-square test were used to compare the outcomes of two groups. The level of significance *p*-value was evaluated, where *p*-value <0.05 was considered statistically significant.

Results

During the study period, 73 patients were admitted to the department of general surgery at Assiut university hospital having GC and assessed for eligibility for possibility of curative resection. Twenty-seven patients were excluded as they were not meeting

the eligibility criteria or refusing to be recruited in the study. The remaining 46 patients were randomized: 23 patients for OG (group A) and 23 for LG (group B). After assignment, four patients had been refused to complete the study (early withdrawal): one from OG group and three from LG group. Locally advanced cases received palliative resection and were excluded from both the groups. The study ended up with a total of 36 patients (20 for OG and 16 for LG) (Fig. 1). The mean time of follow-up was 5 months ranging from 40 days to 10 months.

Although there was no statistical difference between the two groups in the clinicopathological data, we noticed the following. The mean age of recruited patients was 52.5 ± 11.4 years old ranging from 33 to 78 years old. There were 24 males and 12 females. As regards tumors, they were more distally located (69.4%), all were adenocarcinoma with 86.1% differentiated, and 55.6% had TNM stage II. (Table 1)

The mean operative time was 260.6 ± 46.7 minutes in LG vs 191.0 ± 24.7 minutes in OG group (p-value <0.001) (Fig. 2). Blood loss was more in OG 372.5 ± 125.1 mL compared to 296.6 ± 124.2 mL in LG with a nonsignificant p-value = 0.077. The number of harvested LNs was nonsignificantly higher in OG 21.0 ± 6.5 compared to LG 16.8 ± 6.5 (p-value = 0.064). Intraoperative injury occurred in one case of open group (5%), where the middle colic artery was injured leading to colonic ischemia that required resection with primary anastomosis. In another case in LG group (6.25%), pleural injury that was dealt with by simple airtight repair was reported with no need for intercostal tube insertion (Table 2).

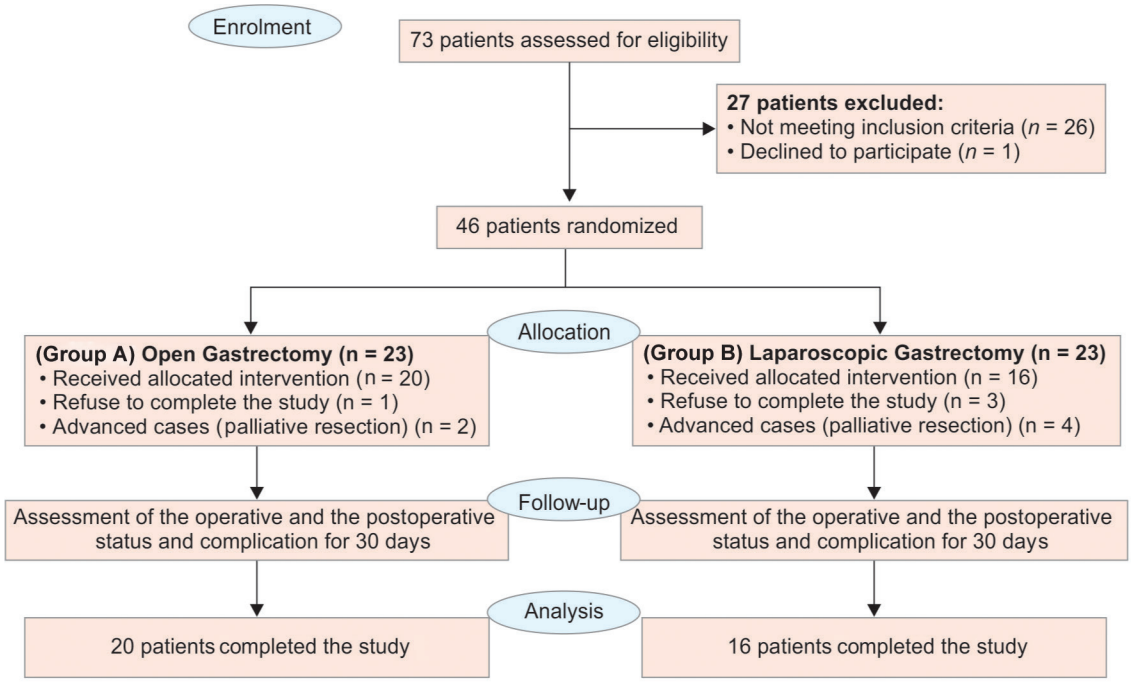

Fig. 1: CONSORT flow diagram of the study

Table 1: Clinicopathological characteristics of studied groups

		Total (N = 36)	*OG (N = 20)*	*LG (N = 16)*	*p value*[†]
	Age	52.5 ± 11.4	54.7 ± 13.7	49.7 ± 7.0	0.192
Sex	Male	24 (66.7%)	13 (65.0%)	11 (68.8%)	0.813
	Female	12 (33.3%)	7 (35.0%)	5 (31.2%)	
Site of tumor	Upper	10 (27.8%)	6 (30%)	4 (25.0%)	0.514
	Middle	1 (2.8%)	0	1 (6.2%)	
	Distal	25 (69.4%)	14 (70%)	11 (68.8%)	
Histopathology	Differentiated	31 (86.1%)	18 (90.0%)	13 (81.2%)	0.451
	Not differentiated	5 (13.9%)	2 (1.0%)	3 (18.8%)	
Resection type	Distal	24 (66.7%)	13 (65.0%)	11 (68.8%)	0.940
	Proximal	10 (27.8%)	6 (30.0%)	4 (25.0%)	
	Total	2 (5.6%)	1 (5.0%)	1 (6.2%)	
TNM stage	II	20 (55.6%)	10 (50%)	10 (62.5%)	0.453
	III	16 (44.4%)	10 (50%)	6 (37.5%)	

Data presented as mean ± SD or number and percentage *n* (%);
[†]Student's *t*-test and Chi-square test were used

The patients were followed up for 30 days. Hospital stay was increased nonsignificantly among OG group 8.0 ± 4.1 days compared to LG group 6.9 ± 2.6 days (p-value = 0.361). Time to first flatus was nonsignificantly longer in OG group (2.4 ± 0.51 days) compared to LG group (2.5 ± 0.52 days) with p value = 0.773 (Table 3). As regard postoperative complications, four complications were recorded in the OG group (20%) including one anastomotic leak in total gastrectomy, two luminal bleedings, and one chest infections. On the contrary, only two complications were recorded in LG group (12.5%), which were two anastomotic leaks (one total and one distal gastrectomy) (Fig. 3). All anastomotic leakages were low output and managed successfully by conservation in both groups. In the OG group, cases which developed luminal bleeding (bleeding less than 100 mL/hour) did not require any emergency procedure. There was no mortality in LG group compared to one patient of OG group (due to massive pulmonary embolism).

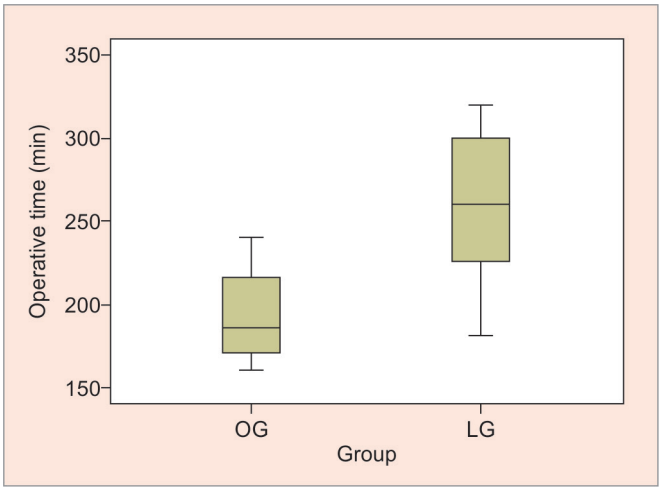

Fig. 2: Boxplot of operative time of studied groups

Table 2: Operative outcomes of studied groups

	OG (N = 20)	*LG (N = 16)*	*p value*†
Operative time (minutes)	191.0 ± 24.7	260.6 ± 46.7	<0.001*
Estimated blood loss (mL)	372.5 ± 125.1	296.6 ± 124.2	0.077
Number of harvested LN	21.0 ± 6.5	16.8 ± 6.5	0.064
Intraoperative organ injury	1 (5.0%)	1 (6.2%)	0.871

Data presented as mean ± SD or number and percentage *n* (%);
†Student's *t*-test and Chi-square test were used;
*Significant *p*-value

Table 3: Postoperative outcomes of studied groups

	OG (N = 20)	*LG (N = 16)*	*p value*†
Length of hospital stay (days)	8.0 ± 4.1	6.9 ± 2.6	0.361
Time to first flatus (days)	2.4 ± 0.51	2.5 ± 0.52	0.773
Diet start time (days)	2.5 ± 0.51	2.3 ± 0.48	0.415
ICU admission	5 (25.0%)	1 (6.2%)	0.134
Postoperative fever	3 (15.0%)	3 (18.8%)	0.764
Blood transfusion	3 (15.0%)	2 (12.5%)	0.829
Complications	4 (20.0%)	2 (12.5%)	0.549
Mortality	1 (5.0%)	0	0.364

Data presented as mean ± SD or number and percentage *n* (%);
†Student's *t*-test and Chi-square test were used

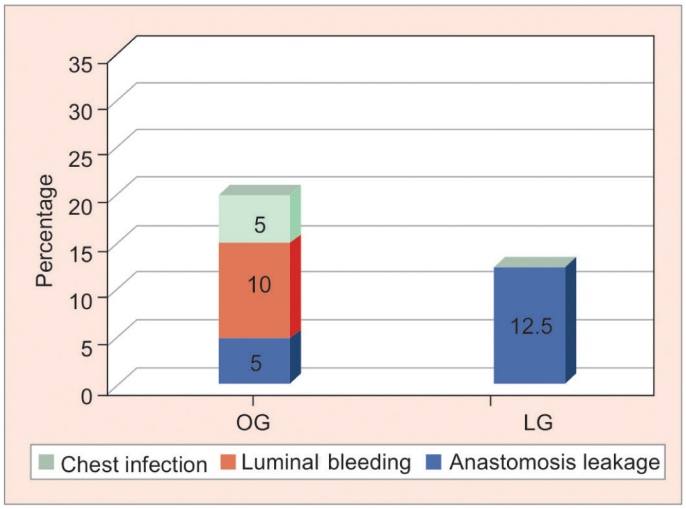

Fig. 3: Postoperative complications of studied groups

Discussion

During the last two decades, minimally invasive surgery has been implemented in gastrointestinal cancer therapy to reduce operative morbidity and enhance recovery, without affecting the oncological outcome.[7] Nowadays, LG is considered to be a promising technique that minimize patient suffering and ensure comparable or, sometimes, improved surgical outcomes.

In our trial, the operative time was significantly longer in LG compared to OG. Other studies reported that LG takes longer time than OG and the time usually depends on the surgeon's experience. As mentioned by Kim et al., the learning curve for LG especially distal gastrectomy has two plateaus: first plateau after the first 10 cases when the operative time reached (230–240 minutes/operation) and then reached a second plateau (<200 minute/operation) for the next 30 cases.[8,9] The same also concluded by Marchesi et al. that at the beginning of the learning curve, the time element was significantly higher in LG patients (301.5 vs 232 minutes, $p = 0.023$), with an evident learning curve effect.[10] In Egypt, we have a lower incidence of GC than in Far East countries, and our study included 16 LGs. This may explain the longer operative time in this study compared to studies conducted in Far East countries as Japan and China where GC is prevalent.

Regarding the pathologic data as number of excised LNs and surgical margins, there was no statistically significant difference between the two groups. The same was reported in the study done by Gong et al.[11] Moreover, a systematic review and meta-analysis done by Beyer et al. showed that laparoscopic approach does not impair D2 lymphadenectomy, indicating oncological equivalence to the open approach.[12]

Furthermore, we noticed more blood loss among the OG group although not statistically significant (p-value = 0.077). This is supported by other studies and generally considered as one of the advantages of laparoscopic surgery.[4,11,13,14]

The present study showed that the postoperative short-term surgical outcomes of LG are comparable to those of the open surgery. We reported less hospital stay among the LG group

that was not statistically significant , which was supported by other authors.[6,15] The postoperative overall complication rate was 20.0% in OG vs 12.5% in LG, a difference that was not statistically significant. Anastomosis leakage was reported more in LG and more at total gastrectomy patients. This was supported by other studies which reported that anastomosis leakage occurred in 0 to 17% of total gastrectomy patients, in 1.1 to 2.7% of distal gastrectomy patients, and more liability of fistula in LG patients.[14,16,17]

Luminal bleeding is a serious complication that can lead to severe morbidity and even mortality if not treated properly. Other authors reported rates of anastomotic hemorrhage ranged from 0 to 2.0%.[18] but it is lethal if not treated immediately. Methods: Of 1400 patients with gastric cancer who underwent gastrectomy between September 2002 and December 2007, postoperative anastomotic hemorrhage was observed in 6 patients. The surgical procedures, bleeding sites, methods of hemostasis, and clinical courses of these 6 patients were analyzed. Results: Of the 1400 patients, 878, 72, and 450 underwent distal, proximal, and total gastrectomy, respectively. The bleeding sites were as follows: transection line of the stomach using a linear stapler ($n = 1$ In our study, we reported two cases of luminal bleeding who were treated successfully by conservative management. Although only one mortality was reported only in OG group, the difference was not statistically significant. This agrees with the results of the Korean multicenter trial named KLASS (Korean Laparoendoscopic Gastrointestinal Surgery Study; NCT00452751), which concluded that there was no significant difference in the morbidity and mortality between the OG and LG groups of GC resection.[19]

The current study has some limitations as the small number of patients and being a single-center study. Further clinical trials on larger number of patients and involving multiple centers are still needed.

In conclusion, for resectable GC cases, early results showed that laparoscopic D2 gastrectomy has comparable outcomes to OG regarding intraoperative blood loss, number of harvested LN, operative organ injury, length of hospital stay, time to first flatus, postoperative morbidity, and mortality. However, the laparoscopic approach was longer than the open one for the early surgeon's experience. Larger trials are needed for further evaluation of the early and late outcomes.

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Orcid

Mohamed G Taher https://orcid.org/0000-0003-0786-6045

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RESEARCH ARTICLE

Influence of Sonographic Imaging on Patients with Anterior Abdominal Wall Hernias to Prevent Reoperations

Ali Enshaie[1], Saeed Kashefi[2], Vahideh Aghamohammadi[3], Seyfollah Rezaie[4], Niloofar Afshari[5], Khadijeh Nasiri[6]

Abstract

Background: Hernia is defined as an area of weakness or complete disruption of the body wall's fibromuscular tissues. Structures arising from the cavity contained by the body wall can pass through, or herniate, through such a defect. The typical clinical finding is a bulged mass increasing in size when intra-abdominal pressure rises. The hernia is asymptomatic or may cause severe pain for patients. Arising of intra-abdominal pressure for each reason can generate anterior abdominal wall hernias; on the contrary, each synchronous surgically treatable intra-abdominal disease can be revealed with the same symptoms, and distinction of this disease prior to the surgery is important.

Materials and methods: This study was conducted on 90 patients who were candidates for anterior abdominal wall herniorrhaphy. All patients were screened for the coexistence of intra-abdominal surgically treatable diseases using the abdominopelvic sonographic examination. According to our project, patients with a synchronous intra-abdominal illness were treated with single surgery for their hernia and surgically treatable disease. Other patients with the healthy sonographic report were only subject to herniorrhaphy.

Results: The sonographic report was normal in 53 patients and abnormal (including cholelithiasis or any synchronous surgically treatable disease) in 37 patients. The study of the population using the Chi-square test to determine the need for further surgery (normal sonographic report rate) showed a statistical difference between hernia groups ($p = 0.001$). In the umbilical hernia group, the need for further surgery is significantly lower than that in the other groups ($p < 0.001$).

Conclusions: The coexistence of intra-abdominal surgically treatable disease with anterior abdominal wall hernias and their possible recurrence due to the remaining of the intra-abdominal illness as a source for intra-abdominal cavity pressure convinced surgeons to carefully check patients for each surgically treatable intra-abdominal disease before surgery.

Keywords: Abdominal wall hernia, Cholelithiasis, Sonography.

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Introduction

Anterior abdominal wall hernias are described as the weakness in the fibromuscular layer of the abdominal wall, which can be congenital or acquired. Based on their arising anatomic region, hernias are divided into umbilical, epigastric, primary ventral, secondary ventral (incisional), and Spigelian subtypes. An umbilical hernia is the most common type of hernia and is generally prevalent in premature newborns. The incidence of umbilical hernia in the adult is mostly unknown, but most cases are thought to be acquired rather than congenital. It is known to occur more commonly in adult females (with a 3:1 ratio). An umbilical hernia is more commonly found in association with processes that increase intra-abdominal pressure.[1] Almost all surgeons prefer conservative treatment for umbilical hernia in children up to 5 years old.[2] Epigastric hernias occurring between umbilicus and xiphoid processes are prevalently detected in older adults versus women with a 3:1 ratio.[1] Secondary ventral hernias prevalently occur after abdominal incisions, and small incisions can prevent such hernias. Risk factors for these hernias include increasing age, malnutrition, ascites, diabetes, obesity, smoking, long-term corticosteroid consumption, sepsis after surgery, wound infections, and emergency surgeries. Spigelian hernia is present near the arcuate line exactly lateral to rectus abdominis muscle. The diagnosis of Spigelian hernia is associated with challenges because of its complex regional anatomy.[1] European Hernia Association has presented a general classification of primary anterior abdominal wall hernias, the consideration of which is helpful to conduct the study. Based on this classification, anterior abdominal hernias are at midline or lateral of the abdomen, namely medial to oblique and lateral to the lateral border of rectus abdominis muscle, respectively. In terms of size, they are small (<2 cm), midsize (2–4 cm), or large (>4 cm).[3] Diagnosis of all hernia types is made clinically, and they can be treated by laparoscopic or classic methods.[1] Another aspect of this study was related to synchronous intra-abdominal surgically treatable diseases, the most prevalent of which is cholelithiasis.

[1,2,4]Department of General Surgery, School of Medicine, Urmia University of Medical Sciences, Urmia, Iran

[3]Department of Nutrition, Khalkhal University of Medical Sciences, Khalkhal, Iran

[5]Department of Dermatology, School of Medicine, Tabriz University of Medical Sciences, Tabriz, Iran

[6]Department of Nursing, Khalkhal University of Medical Sciences, Khalkhal, Iran

Corresponding Author: Saeed Kashefi, Department of General Surgery, School of Medicine, Urmia University of Medical Sciences, Urmia, Iran, Phone: +984431988000, +989143478332, e-mail: s.kashefi.s1986@gmail.com

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Gallstone formation is a widespread disease in the gastrointestinal system, and the following factors can increase its incidence rate: Increasing age, female gender, obesity, pregnancy, familial heredity and nutritional habits, Crohn, spherocytosis, sickle cell anemia, thalassemia, and patients experiencing gastric or ileal resections.[2] Diagnostic sonography is the primary modality to detect gallstones. Pathophysiology of anterior abdominal wall hernias can be related to two series of factors. The first is related to each problem that elevates intra-abdominal pressure, including obesity, pregnancy, ascites, bowel obstruction, and peritoneal dialysis. The second is associated with structural and functional weakness of muscles, tendons, and fascia of the abdominal wall.[1] Congenital or acquired impairment in the metabolism of the collagen production cycle (for example, due to smoking or malnutrition) plays an essential role in creating the disease. The deficiency in the collagen production cycle causes two classes of disorders: Molecular-cellular and extracellular matrix diseases. Extracellular matrix disease is the primary pathophysiology of ventral hernias.[4] Having common risk factors for anterior abdominal hernias and cholelithiasis (as the most common synchronous surgically treatable disease) and its synchronous existence probability if not considered, it would be harmful to patients and healthcare systems.[5,6] Since the demonstration of the simultaneous existence of intra-abdominal surgically treatable diseases has two main advantages for patients, first, the time to diagnose and evaluate the synchronous condition and second, saving laparoscopy as a surgical option for the treatment of patients. This approach to anterior abdominal wall hernias has a lot of financial benefits for healthcare systems.

Materials and Methods

Ninety patients referred to the general surgery clinic of Urmia Imam Khomeini Hospital for anterior abdominal wall herniorrhaphy were studied from September 2017 to September 2018. Our inclusion criteria were the patients who had anterior abdominal hernias. This trial, approved by the Medical Ethics Committee of the Urmia University of Medical Sciences, Urmia, Iran, is in accordance with the Declaration of Helsinki (approval number: IR. UMSU. REC. 97.1857). Subjects meeting the inclusion criteria were recruited in this study after obtaining their written consent. Exclusion criteria were incarcerated, or strangulated hernias, pregnant women, patients with a history of psychiatric drug consumption, and patients with end-stage cardiopulmonary disease or chronic renal failure, and none of the patients had a history of opium addiction. In this step, all patients screened with the abdominopelvic sonographic examination. The patients were divided into four groups: Umbilical, epigastric, ventral, and Spigelian hernias; and two sub-types: Group 1 (with normal sonographic report) treated only with herniorrhaphy and group 2 (including cholelithiasis or any synchronous surgically treatable disease) who were subject to a single surgery for treating both disorders. All patients were screened with a complete abdominopelvic sonographic examination.

Statistical Analysis

All statistical analyses were fulfilled using IBM SPSS Statistics software (version 24) (IBM SPSS Statistics, Armonk, United States). A p-value of less than 0.05 was regarded to be statistically significant. A Chi-square test was used for categorical data to identify significant differences. The comparisons of the age difference between the hernia types were performed with the analysis of variance (ANOVA).

Results

Ninety patients admitted for anterior abdominal wall herniorrhaphy from September 2017 to September 2018 were studied. The mean average age of the population was 49.17 ± 12.17 years. The intra-abdominal surgically treatable disease was reported in 37 patients, and the report was normal in 53 patients. The characteristics of the subjects in the hernia groups are shown in Table 1. The age means of participants between the hernia groups using one-way ANOVA showed no statistical significance ($p = 0.524$), which was confirmed by the post hoc test ($p > 0.05$). Concerning gender ratio in the population, a majority of patients were women (82.2% women vs 17.8% men), and hernia groups had significant difference regarding sex ratio ($p = 0.019$). Sonographic reports of patients were interpreted as follows. In the umbilical hernia group, eight cases of cholelithiasis and six cases of an abdominal mass (including two cases of uterine myoma, two cases of ovarian cancer, a case of HCC, and a case of sigmoid cancer) were reported. In the epigastric hernia group, four cases of cholelithiasis and three cases of an abdominal mass (including two cases of simple ovarian cysts and a gastric gastrointestinal stromal tumor) were observed (Table 2). Two cases of cholelithiasis and six cases of an abdominal mass (including two cases of the myomatous uterus, two cases of large uterine myoma, and two cases of advanced uterine cancer) were reported in the ventral hernia group. All reports of the Spigelian hernia group were normal. In other words, there were 14 cases from 58 umbilical hernia patients, 7 cases from 20 epigastric hernia patients, and 8 cases from 10 ventral hernia patients, requiring a single surgery for their concomitant hernia and intra-abdominal disease. The study of the population using the Chi-square test to determine the need for further surgery (normal sonographic report rate) showed a statistical difference between the hernia groups ($p = 0.001$). In the umbilical hernia group, the need for further surgery is significantly lower than that in the other groups ($p < 0.001$) (Table 2).

Discussion

Anterior abdominal wall hernias are congenital or acquired and are divided into umbilical, epigastric, ventral (incisional), and Spigelian hernias according to their anatomic region. An umbilical hernia is the most common type that is generally prevalent in premature newborns, and familial heredity has a recognized role in the incidence of this disease. Umbilical hernias in adolescents are acquired and more commonplace in women than in men (with a 3:1 ratio). Although our study confirmed the higher incidence of umbilical hernia (64.4%) among

Table 1: Characteristics of the subjects in the hernia groups

Hernia groups (N)	*Age (Mean ± SD)*	p_1	*Men N (%)*	*Women N (%)*	p_2
Umbilical hernia group ($n = 58$)	11.36 ± 47.74	0.524	8 (13.79)	50 (86.2)	0.019
Epigastric hernia group ($n = 20$)	13.53 ± 51.80		8 (40)	12 (60)	
Ventral hernia group ($n = 10$)	14.92 ± 51.60		2 (20)	8 (80)	
Spigelian hernia group ($n = 2$)	3.53 ± 52.50		0 (0)	2 (100)	

p_1, using one-way ANOVA test; p_2, using Chi-square test

Table 2: Types of hernia description and sonographic report among study population

			Sonographic report			
Hernia types	*Frequency*		*Normal*	*Cholelithiasis*	*Abdominal mass*	*p*
Umbilical hernia	*N*	58	44	8	6	>0.001
	%	64.4	75.8	13.8	10.34	
Epigastric hernia	*N*	20	13	4	3	0.035
	%	22.2	65	20	15	
Ventral hernia	*N*	10	2	2	6	0.202
	%	11.1	20	20	60	
Spigelian hernia	*N*	2	2	—	—	—
	%	2.2	100	—	—	

p, using Chi-square test

all the patients, the results about gender prevalence showed higher prevalence in women compared to the previous studies (with a 6:1 ratio). Epigastric hernias are prevalently detected in elderly men than in women with a 3:1 ratio; however, our research showed different results regarding epigastric hernia. In our population, the epigastric hernia was 1.5 times more prevalent in women. Ventral hernias occur after abdominal incisions, and small incisions are preventing factors of this hernia type. Risk factors for a ventral hernia include age, malnutrition, ascites, diabetes, obesity, smoking, long-term corticosteroid use, sepsis after surgery, wound infections, and emergency surgeries.[1]

Nevertheless, our study showed different results; if technical mistakes or the risks as mentioned above are absent, there is an 80% association between ventral hernias and intra-abdominal surgically treatable diseases. Spigelian hernia is observed near the arcuate line exactly lateral to rectus abdominis muscle. Because of its complex regional anatomy, the diagnosis of Spigelian hernia is accompanied by challenges. In our study, only 2.2% of the population had Spigelian hernia, confirming the challenging diagnosis of this type of hernia according to texts. Another aspect of our research was related to the coexistence of intra-abdominal surgically treatable diseases. As a prevalent intra-abdominal disease, cholelithiasis has common risk factors with anterior abdominal wall hernias. There are two main pathophysiologic factors for anterior abdominal wall hernias: First, any factor elevating intra-abdominal pressure such as obesity, pregnancy, ascites, bowel obstruction, and intra-peritoneal dialysis; and second, structural and functional weakness of anterior abdominal wall muscles, tendons, and fascia.[1] This statement has been confirmed by Christian Nordqvist's article published in Medical News Today magazine in 2016, which demonstrated each cause of elevated intra-abdominal pressure, including multiple pregnancies and frequent coughs as the primary pathophysiology of umbilical hernias.[5] Among other researches in this context, the retrospective Briant et al. research conducted from 1962 to 1967 in the Kentucky University Hospital in the USA on 66 women referred to surgery clinic with an umbilical hernia can be mentioned, which confirmed cholelithiasis coexistence in 40% of patients.[6] The two studies, as discussed above, were similar to ours, in which 24.4% of patients with umbilical hernia had a concomitant intra-abdominal surgically treatable disease. Another research by Chen et al.[7] was conducted on 7,570 patients in China, in which 918 cases referred for routine checkups had cholelithiasis. In this study, they proved that patients with metabolic syndrome are at a five times higher risk of cholelithiasis than other patients.[7] In another study by Kaymak et al. conducted on 2015 in Turkey with 78 patients admitted for laparoscopic cholecystectomy, 11 patients (14%) had an umbilical hernia, 39 patients (50%) had metabolic syndrome, and eight patients (10.2%) had both umbilical hernia and metabolic syndrome. This study again emphasized the role of metabolic syndrome as a risk factor for gallstone formation. At the same time, the study results showed that the prevalence of umbilical hernia is higher in cholelithiasis patients. The last two studies predicted the common risk factors of umbilical hernia and cholelithiasis, and our results were similar to them so that there was the coexistence of cholelithiasis among 13.8% of umbilical hernia patients.[8,9]

Conclusion

Emphasizing the results of our study, the probable coexistence of surgically treatable intra-abdominal disease with the same symptoms is not negligible in the patients with anterior abdominal wall hernias. Therefore, it is recommended to perform total abdominopelvic sonographic examination on patients with these hernias before their herniorrhaphies.

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RESEARCH ARTICLE

Intraoperative Predictors of Difficult Laparoscopic Cholecystectomy: AMU Scoring System

Mohammad S Akhtar[1], Parwez Alam[2], Yasir Alvi[3], Isna R Khan[4], Syed AA Rizvi[5], Mohammad H Raza[6]

Abstract

Introduction: With laparoscopy being the surgeon's first choice even in difficult cholecystectomy, a need to objectively grade intraoperative difficulty during laparoscopic cholecystectomy (LC) is gaining popularity. The study was done to design a scoring system to predict the difficult outcome during intraoperative LC.

Materials and methods: The study was done at the General Surgery Department in a tertiary level hospital among patients undergoing LC. The procedures that exceeded 70 minutes in duration and/or converted to open were considered the difficult LC. To develop the predictive score, an association of various factors with difficult cholecystectomy was identified by performing multiple logistic regression analysis, and receiver operating characteristic (ROC) curve was plotted to estimate the cutoff value for the scoring system.

Results: We recruited 200 patients in this study, out of which 85 had difficult cholecystectomy procedures. Among all intraoperative predictors, adhesions, gallbladder (GB) condition, Calot's triangle status and abnormality, and the presence of pericholecystic fluid were associated with a difficult LC. Based on the odds ratio, a new scoring system was designed with a score ranging from 0 to 25. The grading score was created as easy (0–5) and difficult (6 or above) based on the intraoperative factors. At a cutoff score of 6, this scoring system had a sensitivity and specificity of 87.1 and 88.7%, respectively.

Conclusion: This study demonstrates that an intraoperative scoring system can predict the difficult outcome of LC. This can help in minimizing the complication and conversion to open cholecystectomy, especially relevant for funds-limited settings like India.

Keywords: Cholecystectomy, Conversion to open and Calot's triangle, Laparoscopic, Operative scoring system.

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Introduction

Laparoscopic cholecystectomy (LC) has transformed the whole approach to the treatment of symptomatic cholelithiasis. In the beginning, surgeons felt comfortable operating only the simple gallbladders (GB) by LC, but with the increase in expertise and newer armory, it is also becoming surgeon's first choice even in difficult cholecystectomy. However, LC can be difficult in various situations, especially in a surgeon's early career, which makes them a little stressed.[1] Various problem faced includes difficulty in creating pneumoperitoneum, accessing peritoneal cavity, releasing adhesions, identifying the anatomy, anatomical variations, and extracting the GB.[2,3] It can be more difficult in males than in females who are also more commonly diagnosed with cholelithiasis requiring surgery.[4,5]

The term difficult cholecystectomy refers to multiple technical intraoperative difficulties that increase the risk of complications and significantly prolong the operative time.[6] Difficult LC is related to an increased incidence of conversion to open cholecystectomy, probably because of greater difficulty in operation, and therefore, greater is a likelihood of conversion to open technique.[7] At the same time, the level of difficulty may vary with the skill and experience of the surgeon.[7] While many preoperative LC assessments are available, there are only a few intraoperative laparoscopic surgeries difficultly predicting the criteria, leaving a gap in studying important factors that can help in preventing complications beforehand.[8] Thus, this study was done to develop a scoring system to predict the difficult outcome during intraoperative LC.

[1,2,4–6]Department of Surgery, Jawaharlal Nehru Medical College and Hospital, Aligarh Muslim University, Aligarh, Uttar Pradesh, India

[3]Department of Community Medicine, Jawaharlal Nehru Medical College and Hospital, Aligarh Muslim University, Aligarh, Uttar Pradesh, India

Corresponding Author: Parwez Alam, Department of Surgery, Jawaharlal Nehru Medical College and Hospital, Aligarh Muslim University, Aligarh, Uttar Pradesh, India, Phone: +91 9045974632, e-mail: parwez786amu@gmail.com

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Materials and Methods

Study Design and Population

We did a cross-sectional study over a period of 1 year from July 2015 to June 2016. The study population included all patients consulting the surgery outpatient department, Jawaharlal Nehru Medical College, Aligarh, and subsequently diagnosed as a case of cholelithiasis. This hospital is a tertiary referral center and is one of the largest hospitals in the northwest part of the state Uttar Pradesh. A total of 200 patients were diagnosed as cholelithiasis; as per the standard protocol, they were included in the study. Exclusion

criteria were preoperatively proven GB malignancy, refractory coagulopathy pulmonary disease, end-stage liver disease, and any corticobasal degeneration pathology.

Sampling

We decided to include all the eligible cases fulfilling the study criteria by undergoing LC under a single surgeon unit for the study. A single surgeon unit criterion was selected to prevent intraobserver bias. Surgeons with experience of more than 50 LCs did all the surgeries in this study. For the selection of cases, consecutive sampling was done. During the study period, a total of 200 patients undergoing LC who met the study criteria were selected for the study.

Definitions

Difficult cholecystectomy was defined in this study as

- A total duration of more than 70 minutes for LC from the insertion of Veress needle till the extraction of GB
- Requiring more than 20 minutes to dissect the Calot's triangle
- Requiring more than 20 minutes to dissect the GB from the liver bed
- Conversion to open cholecystectomy

Study Procedure

After the approval by Institutional Ethics and Research Advisory Committee, JN Medical College, Aligarh, enrollment was started. The patients fulfilling the selection criteria were explained about the study, and those who gave informed consent were selected. The selected patients who were fit for the laparoscopic surgery after preanesthetic checkup were planned for the surgery. During the LC, the following things were taken into notice:

- Abdominal wall scar mark
- Creation of the pneumoperitoneum
- GB condition
- Separation of all adhesions
- Liver condition
- Skeletonization, ligation, and division of cystic artery and cystic duct
- Excision of GB from the GB fossa of the liver bed
- Extraction of GB.

Overlapping of these intraoperative difficulties was recorded. The total duration of the surgery from the insertion of the Veress needle into the closure of the port site as well as the time for Calot's triangle dissection was noted by stopwatch.

Data Management and Statistics

The data were entered and analyzed in Statistical Package for Social Sciences (SPSS) version 20. Statistical significance was tested first by binary logistic regression analysis, and then, multiple logistic regression analysis was calculated to find out adjusted odds ratio. The odds ratios express how many times a preoperative variable is likely to be found in the difficulty group as compared to the easy group. As adjusted odds ratio had a wide range, to avoid the same for the proposed score, adjusted odds ratios were divided by ten and rounded off to the nearest numerical. The proposed scoring system was tested on the original intraoperative data of the study subjects. The individual score of each patient was calculated. The sensitivity and specificity of the proposed scoring system were computed, and receiver operating characteristic (ROC) curve was plotted to estimate the cutoff value for the scoring system.

Results

We enrolled 200 patients in our study, out of which 85 patients had difficult LC. The majority of the participants were females ($n = 148$), while the mean age of all the participants was 40.95 $\pm$ 11.08 years. Most of the patients were presented with chronic cholecystitis. The detail of study participants has been given in the previous publication.[9] Association of various predictors was analyzed by binary logistic regression analysis, and their adjusted odds ratios were measured as shown in Table 1.

The proposed score for predicting difficult cholecystectomy during intraoperative surgery is given in Table 2. As seen in the ROC curve (Figs 1 and 2), a score of 6 was selected as the best cutoff point compromise between maximum sensitivity and specificity. A cutoff point at 6 has a sensitivity of 87.1% and a specificity of 88.7% (Fig. 2). We also performed internal consistency of the proposed scores by using Cronbach's coefficient alpha, which was 0.71, which is considered adequate for an attitudinal scale.[10]

Discussion

The present study was done to design a scoring system predicting difficult outcomes during intraoperative LC. This scoring system would help in identifying high-risk patients who may have difficulty during LC and thus in preventing complications beforehand. The present study assessed various operative factors for LC and found GB condition; GB adhesion, intra-abdominal adhesion, presence of pericholecystic fluid, Calot's triangle status, and cystic duct and vessels abnormality were predicting difficult LC. On basis of these variables, we devise a grading system to evaluate difficulty during LC.

Our study was supported by various studies that also found that significant factors like intra-abdominal adhesion, inflamed GB, frozen Calot's triangle, as well as abnormal anatomy of vessels and cystic duct were predicting difficult LC, although not with others who also observed obesity and previous abdominal scar mark as predictors.[3,6,11–15] Lal et al. suggest that a difficult LC is one which takes more than 90 minutes for completion and tearing the GB, takes more than 20 minutes in dissecting the GB adhesions, or takes more than 20 minutes in dissecting the Calot's triangle.[6] While the time taken for Calot's triangle dissection varies based on surgical skills and the level of experience, it is usually longer in patients with difficult access, inflammation, and adhesions.[6] In this study, we considered that difficult LC takes 70 minutes in completion and 20 minutes each in the dissection of GB from the liver bed and Calot's triangle.

There is limited success in formulating an intraoperative scoring system in LC. One developed by Vivek et al. is complex having 22 parameters including four intraoperative LCs, thus not easy to use.[13] Their scoring system had a maximum score of 44, and a score of 9 was predicted as difficult LC with sensitivity and specificity of 85 and 97.8%, respectively. Our scoring system has a sensitivity of 87.1% and a specificity of 88.7%, with an area under the ROC curve as 0.953. Another scale proposed by Randhawa et al. was validated in Indian settings by Gupta et al., which graded difficult LC from 0 (easy) to 15 (very difficult).[15,16] Although their scale is easier, but only a few operative features like thickened ($\geq$4 mm) GB wall and impacted stone are given importance.[15] Sugrue et al. conducted

Table 1: Predictors of difficult cholecystectomy based on the results of multiple logistic regression analysis

	Univariate		*Multivariate*		
Predictors	*OR*	*p-value*	*AOR*	*p-value*	*Score weight*
Abdominal wall scar					
No scar	Ref				NA
Scar present	0.94	0.69			NA
Pneumoperitoneum access					
Easy access	Ref				NA
Difficult access by repeated attempt	0.90	0.79			NA
Access requiring open technique	1.76	0.23			NA
Abdominal adhesions					
No adhesions	Ref		Ref		**0**
Easily separable mild adhesions	0.51	0.54	0.000	0.99	**0**
Severe adhesions requiring energy	12.10	<0.01	10.87	0.03	**1**
Intra-abdominal adhesions	8.40	<0.01	39.10	<0.01	**4**
Intra-abdominal and GB adhesions	14.03	<0.01	225.74	<0.01	**5**
Buried GB	High	<0.01	High	<0.01	**5**
GB condition					
Normal	Ref		Ref		**0**
Distended	5.63	<0.01	10.70	0.04	**1**
Edematous and inflamed	5.0	<0.01	6.77	0.03	**1**
Contracted and inflamed	8.36	<0.01	10.51	0.03	**2**
Congested and inflamed	14.30	<0.01	24.49	0.04	**2**
Contracted and congested	21.67	<0.01	34.46	<0.01	**3**
Empyema	High	<0.01	High	<0.01	**5**
Intraoperative pericholecystic fluid					
Absent	Ref		Ref		**0**
Present	6.69	0.02	170.46	<0.01	**5**
Calot's triangle status					
Normal/clear	Ref		Ref		**0**
Partial obscure	3.33	0.02	2.00	0.57	**0**
Cystic duct abnormality	4.44	<0.01	17.98	<0.01	**2**
Vessel abnormality	35.56	<0.01	524.38	<0.01	**5**
Partially obscure with cystic duct/vessel abnormality	17.78	<0.01	229.83	<0.01	**5**
Fully frozen	53.33	<0.01	222.88	<0.01	**5**
Hartman pouch status					
Normal/no stone	Ref		Ref		**0**
Impacted stone	High	<0.01	High	<0.01	**5**
Intraoperative liver status					
Normal	Ref				NA
Fatty	0.79	0.69			NA
Visceroptosis	1.65	0.37			NA
Need for port enlargement/conversion					
No	Ref		Ref		
Yes	2.94	0.01	2.49	0.39	NA

AOR, adjusted odds ratio; OR, odds ratio

a meta-analysis of all on intraoperative LC scoring system taking GB appearance and distension, access, complications, cystic duct, and artery identification into account and proposed a new scoring system.[17] This had a score ranging from 0 to 10, with a score of 2 or more predicted as moderate to severe difficult LC.[17]

We observed predicting a difficult LC is possible with good accuracy by our scoring system. In spite of this, our predicting score has some limitations. Due to nonrandom sampling, small sample size, and nonvalidated scoring system, we could not comment on this generability. It is also observed that defining the level

Table 2: Proposed AMU scoring system of predicting difficult LC

GB condition	Normal	0		No adhesion	0
	Distended	1		Easily separable/mild adhesion	0
	Edematous and inflamed	1	Adhesions	Moderate adhesion requiring energy	1
	Contracted and inflamed	1		Only intra-abdominal adhesion	4
	Congested and inflamed	2		Intra-abdominal and GB adhesions	5
	Contracted and congested	3		Very severe adhesion/buried GB	5
	Empyema	5		Normal/clear	0
Intraoperative pericholecystic fluid	Absent	0		Partially obscure	0
				Cystic duct abnormality	2
	Present	5	Calot's triangle status	Partial obscure with cystic duct/	
Hartman pouch status	Normal/no stone	0		vessel abnormality	5
				Vessel abnormality	5
	Impacted stone	5		Fully obscure frozen	5

AMU: Aligarh Muslim University
Score 0–5: Easy
Score 6 and above: Difficult

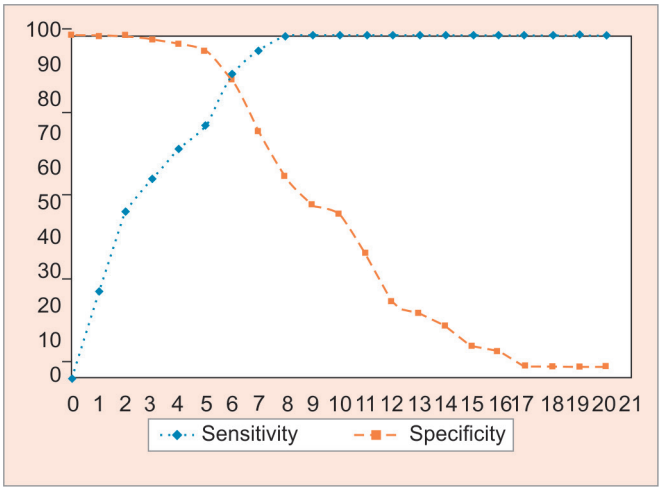

Fig. 1: ROC curve of the proposed score

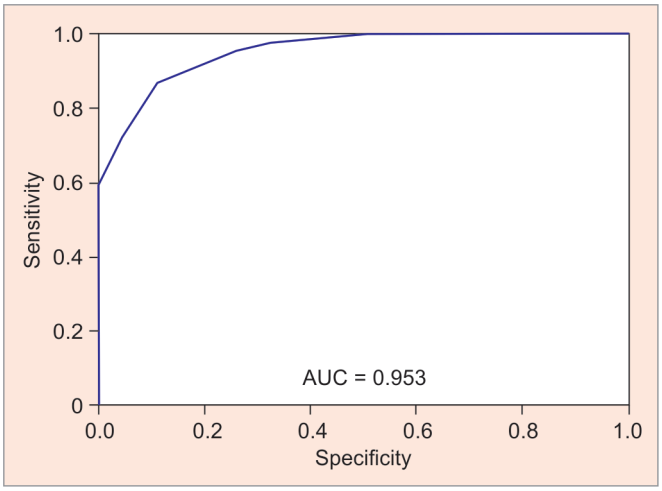

Fig. 2: Specificity and sensitivity curve for calculating the cutoff score

of adhesion, intra-abdominal bleeding, as well as vascularity is nonuniform, and objectifying them may pose difficulties.

Conclusion

From this study, we concluded a scoring system based on an intraoperative procedure that can identify difficult procedures so as to save time and any untoward complications. Features like intraperitoneal adhesions, structural anomalies or distortions distended or contracted GB, and the frozen Calot's triangle are signs that are associated with difficulties during the surgery. These classification systems would be of great help in improving the outcomes of LC.

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RESEARCH ARTICLE

Results Obtained with the Laparoscopic Approach to the Bile Duct for the Treatment of Choledocholithiasis in 101 Cases

Belén Martin Arnau[1], Manuel Rodriguez Blanco[2], Victor Molina Santos[3], Antonio Rabal Fueyo[4], Antonio Moral Duarte[5], Santiago Sánchez Cabús[6]

Abstract

Background: The optimal treatment for choledocholithiasis (CLT) is currently the subject of debate, as there is no clear evidence that a two-step (endoscopic plus surgical) approach is superior to a one-step surgical procedure.

Materials and methods: We analyzed the results obtained from 101 consecutive patients diagnosed with CLT using magnetic resonance cholangiopancreatography (MRCP) or computed tomography (CT) scan undergoing cholecystectomy and laparoscopic exploration of the bile duct, carried out at our center between 2006 and 2019. In this analysis, special emphasis was made on the permanent resolution of the CLT and the associated complications.

Results: The mean surgical time was 142 ± 36.7 minutes. In patients with a CLT diagnostic test more than 7 days previously, the presence of CLT was checked using intraoperative cholangiography (IOC), which was negative in 25% of patients, while in the rest, a primary exploration was performed using a choledochoscope via choledochotomy in 82.2% of patients and via the transcystic approach in two cases. A T-tube drain was inserted in 18.9% of patients. The conversion rate was 0.9%, due to a technical difficulty in removing the CLT in one patient. The laparoscopic approach treated the CLT permanently in 97/101 cases (96%), while four patients (3.9%) required postoperative endoscopic retrograde cholangiopancreatography (ERCP) due to residual cholelithiasis. A total of 15.8% of patients experienced a postoperative biliary fistula, which was resolved using conservative management in 86.7% of them, while two patients required surgical treatment and insertion of a percutaneous drain, respectively. The average postoperative stay duration was 6.5 ± 7.3 days. None of the patients showed signs of biliary stricture in the long-term postoperative follow-up.

Conclusion: In our experience, the laparoscopic approach for one-step elective treatment of CLT is a safe option, with a very small number of complications and satisfactory short- and long-term results. Furthermore, despite preoperative identification of CLT, it helped to avoid unnecessary exploration of the bile duct in 25% of patients.

Keywords: Cholangiopancreatography endoscopic retrograde, Choledocholithiasis, Laparoscopic cholecystectomy, Laparoscopic common bile duct exploration.

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Introduction

Approximately, 9 to 16% of patients with cholelithiasis can experience concomitant choledocholithiasis (CLT).[1,2] For many years, intraoperative cholangiography (IOC) was routinely carried out during open cholecystectomy with the aim of diagnosing inadvertent CLT, and in patients in whom it was diagnosed, an exploration of the main bile duct was carried out.[3,4] Subsequently, with the implementation of laparoscopic surgery to treat cholelithiasis and thanks to the advances in preoperative imaging techniques and the experience gathered in laparoscopy, the approach to CLT treatment has evolved. Nowadays, attempts are made to diagnose CLT preoperatively, and, in general, endoscopic retrograde cholangiopancreatography (ERCP) is carried out, followed by laparoscopic cholecystectomy (LC) (a two-step procedure), which has emerged as the standard treatment.[5]

However, the use of ERCP has been associated with morbidity and mortality rates of up to 15 and 1%, respectively, and it has a CLT recurrence rate of 10 to 15%,[5] as well as an increase in the cost (whether direct or indirect) associated with a two-step procedure. In contrast, the surgical treatment of CLT using a laparoscopic approach is currently feasible thanks to the increase in the experience and availability of choledochoscopes adapted for the laparoscopic approach, allowing for the exploration of the bile duct laparoscopic common bile duct exploration (LCBDE) and cholecystectomy to be carried out simultaneously.[6] Despite its technical difficulty, this approach can have benefits compared to the conventional ERCP and LC procedures, reducing the duration of the hospital stay and the total cost, and even has a higher rate of permanent treatment for CLT.

In this study, we describe the results associated with the use of the one-step laparoscopic approach for treating CLT and cholelithiasis.

Materials and Methods

Between September 2006 and March 2019, we carried out 101 consecutive cholecystectomy procedures with the laparoscopic

[1–6]Department of Digestive Surgery, Hospital Sant Pau, Barcelona, Catalonia, Spain

Corresponding Author: Belén Martin Arnau, Department of Digestive Surgery, Hospital Sant Pau, Barcelona, Catalonia, Spain, e-mail:amartinar@santpau.cat

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exploration of the bile duct in patients with CLT diagnosed via an imaging study.

The data from these patients were collected prospectively in a database and were analyzed retrospectively. The variables analyzed were as follows: Preoperative data: Age, sex, liver function tests, and diagnostic imaging studies [ultrasound, computed tomography (CT) scan, and magnetic resonance cholangiopancreatography (MRCP)]. The intraoperative data included the following: Surgical time, transcystic or transcholedochal approach, the performance of IOC, use of sealants, and the need for conversion. In the postoperative period, we recorded the duration of the hospital stay, postoperative complications (pancreatitis, bile leakage, cholangitis, and bleeding), and follow-up data on the recurrence of stones, as well as the need for subhepatic or biliary drainage, the time to removal of the drain and the associated complications.

Patient Selection

Patients were included who had clinical and laboratory signs that were suggestive of CLT (pain of probable biliary origin and jaundice) that was confirmed with an imaging study, and those with signs of associated cholecystitis were excluded. Radiological diagnosis of CLT was carried out via abdominal ultrasound in 15 patients (14.8%), CT scan in 6 patients (5.9%), and MRCP in 80 patients (79.2%).

Informed consent was obtained from all patients after they had been given information about their disease, the up-to-date treatment options, and the possibility of conversion to conventional open surgery.

Surgical Technique

All patients received antibiotic and antithrombotic prophylaxis in line with the center's policy. The supine position was used, allowing the fluoroscopic C-arm to be inserted to carry out the IOC.

As standard, an IOC was carried out in all patients, except those with CLT demonstrated by an imaging study (abdominal ultrasound, CT scan, or MRCP) in the 7 days prior to the surgical intervention. If an image suggestive of CLT was observed in the IOC (filling defect or no passage of contrast to the duodenum), a surgical exploration of the bile duct was carried out.

The procedure was carried out using a LC technique with the use of four trocars (American technique), as previously described.[7] After completely dissecting the triangle of the Calot, a small incision was made in the cystic duct following proximal clipping of the duct to prevent the stones from sliding into the common hepatic duct. A small-diameter catheter (4.5 Fr) was inserted through the cystic duct to carry out the IOC and to detect any images suggestive of CLT or any anatomical variations, if applicable. If any images minimally suggestive of CLT were observed, surgical exploration with a choledochoscope was indicated.

Transcystic Approach

This approach was used in cases with a large cystic duct, which allowed the material to be inserted for the removal or a single CLT of a smaller size than the cystic duct.

After dilating the cystic duct with the laparoscopic dissector, the stones were removed from the main bile duct using a pressure infusion of saline solution and subsequently, in all cases, with the assistance of a Dormia basket[8] or a balloon catheter (Fogarty®).[9] After the CLT expulsion maneuvers, a flexible choledochoscope was used[10] to check that there was no residual CLT. The LC was then completed in the usual way.

In these patients, given that the main bile duct remained intact, an abdominal drain was not routinely placed.

Choledochotomy Approach

This approach was carried out in cases in which the requirements for a transcystic approach were not met (multiple or large-size CLT, small-diameter cystic duct) or if the transcystic approach was unsuccessful.

Exploration of the bile duct was carried out using a longitudinal choledochotomy on the anterior surface measuring around 2 cm in length. The techniques used to remove the stones were lavage with the saline solution under pressure to facilitate the removal of the small stones and using the Dormia basket and/or balloon catheter to move the stones toward the abdominal cavity via the choledochotomy or else toward the duodenum. In all cases, a choledochoscope was subsequently used in the distal and proximal direction to rule out the presence of the residual CLT.

After the removal of the CLT, the choledochotomy incision was closed over a Kehr drain, which was passed progressively, and in accordance with experience, to the primary closure with individual 4/0 braided absorbable sutures, except in cases of acute cholangitis.

In these patients, a Jackson Pratt® no. 13 low-pressure closed-suction abdominal drain was inserted.[10]

Complication Assessment

We used the ClavienDindo (CD) classification to stratify the severity.[7] Bile leakage was defined as persistent bile drainage of over 50 mL/day for more than 3 days.[7]

Statistics

The continuous variables were compared using the Student's *t*-test or the MannWhitney *U* test, as appropriate. The Chi-squared test was used to compare categorical variables. $p < 0.05$ was considered to be statistically significant. Unless specifically stated otherwise, the data are shown as a mean ± standard deviation.

The statistical analysis was carried out using the commercially available STATA software for Windows version 14.

Results

Between September 2006 and March 2019, we carried out 101 LCBDE procedures due to lithiasis at our center. Table 1 shows the demographic characteristics.

Seventy-two patients (71.2%) had diagnostic radiology studies for CLT carried out more than 7 days before the intervention. These patients underwent an IOC, the result of which showed no CLT in 14/72 patients (19.4%) and a clear presence of CLT in 54/72 patients (75%). In the remaining 4/72 cases (5.5%), normal bile-duct morphology

Table 1: Demographic characteristics of the study population subjected to LCBDE

	(n = 101)	%
Sex (♀/♂)	55/46	54.4/45.6
Middle ages	69.3 ± 16.8	
Abdominal surgical history	24	23.5
Gynecological	11	10.9
Appendectomy	6	5.9
Billroth gastrectomy II	3	2.9
Eventroplasty	2	1.9
Left hemicolectomy	2	1.9

was observed up to the outlet, but with no signs of the passage of contrast to the duodenum. In these cases, pressure infusion of saline solution was carried out, with subsequent insertion of a balloon catheter through the transcystic route. In three cases (4.16%), no stone release was observed and the subsequent IOC was performed normally. In one patient (1.3%), a transcystic choledochoscopy was able to be carried out, which ruled out the presence of the residual stones (Flowchart 1). From the laboratory perspective, the patients with and without CLT (definitively diagnosed during the intervention) did not have significantly different preoperative levels of aspartate aminotransferase (90.6 ± 93.9 vs 107.0 ± 154.9, p = ns), alanine transaminase (131.7 ± 157.8 vs 163.8 ± 156.9, p = ns), total bilirubin (39.0 ± 49.5 vs 23.5 ± 21.1, p = ns), gamma-glutamyl transferase (819.2 ± 848.4 vs 541.7 ± 431.8, p = ns), and alkaline phosphatase (373.0 ± 390.2 vs 275.5 ± 195.9, p = ns). It should be highlighted that these laboratory results were only available for 66 patients in the 3 weeks prior to the surgical intervention.

In the patients with confirmed CLT, the exploration of the bile duct was realized using the transcystic approach in two patients (2.5%) and the transcholedochal approach in 97.5% (81/83). The CLT was satisfactorily resolved in all patients undergoing the transcystic approach, while four patients (3.9%) who underwent the transcholedochal approach had residual CLT. The primary closure of the choledochotomy was carried out in 80.2% (65/81), with choledochorraphy over a Kehr drain in 19.8% (16/81) of patients. The patients with a Kehr drain maintained this *in situ* for 26.3 ± 23.7 days before it was removed.

All procedures were carried out using a laparoscopy except one case (0.9%) in which conversion to open surgery was performed due to difficulties in removing the CLT. There were no statistically significant differences in the conversion rate according to the approach (0.9 vs 0%, p = 0.98).

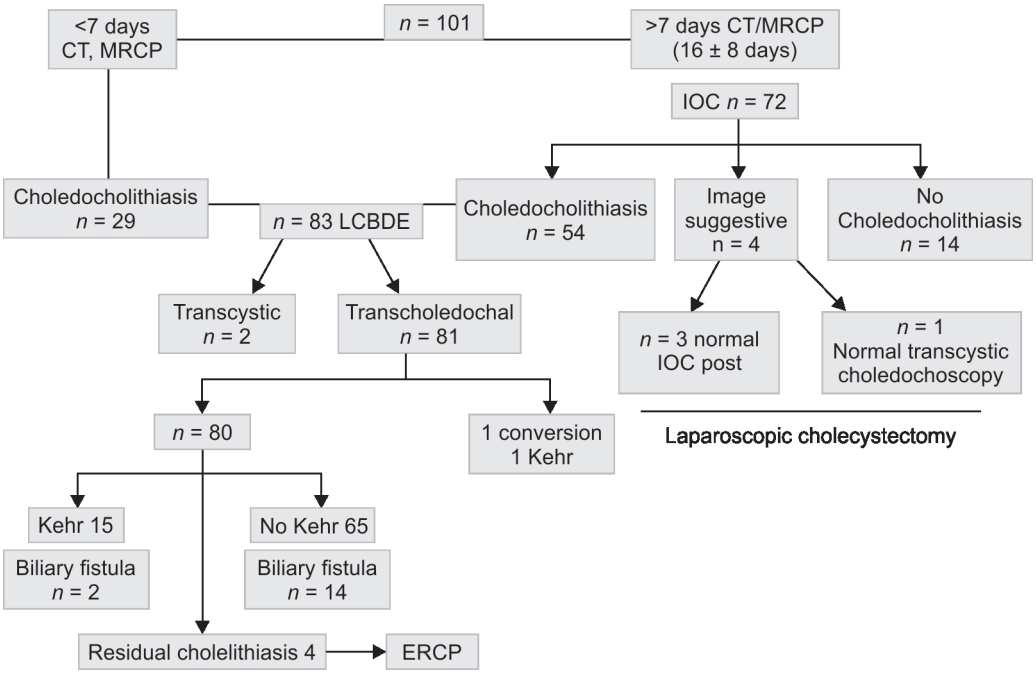
The mean surgical time was 142 ± 36.7 minutes, with the transcystic route being 170 ± 14.1 minutes and the transcholedochal route being 141 ± 36.9 minutes (p = 0.28). The mean postoperative stay duration was 6.5 ± 7.3 days, being longer for the group undergoing the transcholedochal approach (6.7 ± 7.6 days) than for the transcystic approach (2 ± 0.0 days) although without statistically significant differences (p = 0.38).

Sixteen patients (18.5%) experienced a biliary fistula that persisted for 19 ± 17.3 days (International Study Group of Liver Surgery classification of the severity of bile leakage).[31] Two of these patients had a Kehr drain *in situ,* and 14 belonged to the primary-closure group. Conservative management was carried out in 14 patients with the drain remaining *in situ* until resolved. Two patients required treatment to resolve the biliary fistula; one required reintervention for surgical drainage of the biloma, and the other required insertion of a percutaneous drain. Neither of these two cases had a T-tube *in situ*. No statistically significant differences were found between the presence of a biliary fistula in patients with and patients without a Kehr drain (21.5 vs 13.3%, p = 1) (Table 2). The medical complications are summarized in Table 3. A total of six patients experienced medical complications in the form of pneumonia, urinary tract infection, and postoperative adynamic ileus, which progressed well with medical treatment.

The overall mortality for the series was 1.9% (2/101), secondary to bleeding complications. Overall, three patients (2.9%) experienced postoperative bleeding, with two cases requiring reintervention: One patient experienced liver cirrhosis that had not been previously diagnosed, presenting with decompensation and subsequent multiple organ failure following bleeding of the cystic artery, eventually resulting in death; another patient experienced a hypovolemic shock secondary to a pseudoaneurysm of the gastroduodenal artery, eventually resulting in death despite emergency reintervention; the third case of bleeding corresponded to a hematoma in the surgical bed, which was treated conservatively (Tables 3 and 4).

The postoperative stay duration was 6.5 ± 7.3 days. None of the patients showed clinical, laboratory, or radiological signs of biliary stricture in the long-term postoperative follow-up.

Flowchart 1: Outline of the results



Overall, the LCBDE approach achieved full resolution of the CLT in 96.4% of patients (80/83). Three patients (3.6%) required removal of residual CLT via ERCP, two of which were detected via trans-Kehr cholangiography and two as a result of persistent cholestasis confirmed via MRCP due to not having a Kehr drain *in situ*.

Discussion

Cholelithiasis is a highly prevalent condition in our environment. It is estimated to affect 10% of the population in Spain, and a considerable percentage of these cases (9–16%) can be associated with concomitant CLT.[11,12] This represents a considerable problem that is in need of a suitable strategy to resolve it. For years, the European Association for Endoscopic Surgery has recommended that these patients be treated even when asymptomatic.[13] Treatment options include a one-step procedure [cholecystectomy with exploration of the bile duct, whether via an open or laparoscopic approach (LCBDE)] or a two-step procedure with ERCP before or after LC. While ERCP has emerged as the gold standard for treating CLT, we must not forget that this is a technique that is associated with potentially severe complications, such as acute pancreatitis (1.8–8.6%), cholangitis (1–5%), bleeding (0.76–2.3%), and bowel perforation (0.3–1.2%), following endoscopic sphincterotomy (ES).[14]

Table 2: Biliary fistula

	Fistula		
Kehr drain	Yes	Not	Total
Yes	1.9% (2)	13.8% (14)	16
Not	13.8% (14)	70.2% (71)	85
Total	16	85	101

Two-sided Fisher´s exact = 1

Table 3: Postoperative complications

Complications	*N*	*%*
Biliary fistula	16	15.8
Residual choledocholithiasis	4	3.9
Bleeding	3	2.9
Residual collection	3	2.9
Caledonian stenosis	0	0
Paralytic ileus	1	0.9
Pneumonia	2	1.9
Urinary infection	3	2.9

Table 4: Postoperative complication grouped according to CD classification

Postoperative complication of CD	*N*	*%*
Minor	21	20.8
I	17	16.8
II	4	3.9
Major	8	7.9
IIIa	5	4.9
IIIb	1	0.9
IV	0	0
V	2	1.9

The best approach for treating CLT and cholelithiasis remains the subject of discussion. A Cochrane review concluded that there were no significant differences in morbidity, mortality, and failure rate between the LCBDE approach and the two-step endoscopic approach. However, individual trials have suggested that the one-step procedure gives a lower morbidity result, a shorter duration of hospital stay, and is more cost-effective than the two-step approach.[15–17]

From a theoretical perspective, the LCBDE approach would allow to prevent the inconveniences of two-step treatment of CLT and also the inconveniences of the open exploration.[18,19] However, laparoscopic exploration of the bile duct has not been universally adopted, even to date, more than 30 years after the LC was introduced. The reasons for this delay are the good results and convenience associated with endoscopic treatment, as well as the technical difficulties related to the laparoscopic exploration of the bile duct, as it requires an instrument that is not always available, as well as operating room availability for the procedure to be performed, as it is technically demanding and requires a high level of experience.[20,21]

In this study, we present the experience accumulated at our center in terms of the CEBLAS approach executed in the context of elective treatment of CLT in a series of more than 100 patients carried out over 13 years. We have confirmed that it is feasible and reproducible and is associated with a low number of failures and complications, with a CLT resolution success rate of 96.4% (80/83) in patients diagnosed intraoperatively with CLT with a resolution rate of 97% (98/101) for the whole series. These results are comparable to those reported in the literature regarding exploration with ERCP and open exploration of the main bile duct, with lower morbidity and mortality rates than these approaches.[22–24]

For the whole series, the presence of CLT was confirmed in 82.2% (83/101) either via IOC or via a preoperative imaging study (MRI or CT scan). Seventy-two patients underwent surgery more than 7 days after the diagnostic test, and, as such, the first intraoperative task was to confirm the presence of CLT via IOC. Surprisingly, 14 patients had a normal IOC, and a further 4 patients had an IOC that was unclear. Finally, these 18 patients (25% of the patients with a diagnostic study for CLT more than 7 days previously) did not have CLT, and surgical exploration of the bile duct was, therefore, not necessary. In comparative terms, some authors, such as Del Pozo et al., have reported up to 12.5% "blank ERCP."[25]

The ideal approach for the surgical exploration of the bile duct is the transcystic approach, which is technically easier and has the advantage of keeping the main bile duct intact. However, its use has limitations and indications that are mainly determined by the diameter of the cystic duct, the number and size of the stones, and the potential presence of an endoprosthesis in the main bile duct, as well as the inability to carry out a proximal exploration of the common hepatic duct with the choledochoscope through the cystic duct.[21–23] In our series, this approach could only be used in two patients (1.9%) with a 100% success rate. For the rest of the patients, the transcholedochal approach was used, even though this is a technically demanding approach that requires the advanced laparoscopic experience.[26,27] This approach was used in 97.5% of patients (81/83). The flexible choledochoscope is a highly useful tool in the exploration of the main bile duct, both in direct visualization of the intraluminal calculi and in the removal with the assistance of a Dormia basket or Fogarty vascular catheter.[18,28–30]

We used the choledochoscope in all cases with diagnostic imaging studies more than 7 days previously or in cases with CLT diagnostic IOC to confirm its removal.

The postoperative stay following LC is generally short (from 1 to 3 days) and increases significantly if the procedure includes laparoscopic exploration of the bile duct (from 1 to 7 days).[22,30–32] In our study, the mean postoperative stay duration for all patients was 6.5 ± 7.3 days. As a result of the wide disparity in the number of patients in each group, we did not find any statistically significant differences between the transcystic approach and the choledochotomy group (6.7 ± 7.6 vs 2 days, $p = 0.38$). The transcystic approach is a technique that has very good results, with resolution in 90% of cases if a flexible choledochoscope is available and in 60% when radiology-guided, with a short, rapid postoperative recovery period. Furthermore, it keeps both the main bile duct and the sphincter of Oddi intact, which makes it particularly interesting; whenever possible, this should be the route of choice.[33]

The overall complication rate in our series was 28.7% (29 patients). Most of these complications were of surgical origin, particularly postoperative biliary fistula (16 patients, 15.8%) and residual CLT (4 patients, 3.9%). In terms of biliary fistula, most cases did not require specific treatment, given that these were low-flow fistulas that did not affect the patients' general clinical condition. No relationship was found between the presence of a postoperative biliary fistula and the insertion of a Kehr drain (1.9 vs 13.8%, p = ns). This has already been reported in other studies, such as the recent meta-analysis by Poddal et al., in which no differences were found in terms of a biliary fistula between those with a Kehr drain *in situ* and those without, and they report 3.9% of cases with biliary peritonitis following Kehr removal, with no significance compared to the primary-closure group.[34]

In our study, the choledochotomy was sutured over the Kehr drain in 18.9% of patients. Closure over the Kehr drain provides biliary decompression, as well as drainage in cases of cholangitis, and allows us to obtain images of the biliary system after the operation, providing an access through which residual stones can be removed. It also has its drawbacks, in that it could open up a route for bacteremia, accidental premature dislocation, and obstruction, and it could be associated with bile leakage and peritonitis after its removal. Given this, it was removed in our study after a mean period of 3 weeks (range: 10–105 days).

However, the presence of residual CLT, while uncommon (four cases, 3.9%), always required another invasive procedure to be performed, generally an endoscopic procedure, for it to be resolved. Interestingly, in most cases (3/4), an exploration of the bile duct had been carried out via direct vision with a flexible choledochoscope, which is considered to be the best diagnostic technique for CLT. The reasons behind what happened could be explained by the presence of small-size calculi or their intrahepatic migration; it is worth noting that, of these four patients, two underwent confirmation with IOC and the other two with choledochoscopy. We consider that the surgeon's experience in carrying out the procedure and maneuvering the choledochoscope could have had an effect on there not being any residual CLT observed intraoperatively, as the four cases recorded corresponded to patients from the start of the series. According to the literature, the rate of post-ERCP residual CLT is higher, reaching up to 6% in some series, while this is 1–2% following cholecystectomy.[35]

A randomized trial published by Bansal et al. shows how the rate of complications between the LCBDE approach and the ERCP were comparable, with most of the LCBDE group having a CD classification of I and the ERCP group having sphincterotomy distributed among the rest of the CD classifications.[36] It should be highlighted that, of the rest of the complications, postoperative bleeding was a severe complication in our series, which required reintervention in two patients. In terms of the modified CD classification,[7] most of the complications were minor (20.8%), with 7.9% of major complications. Of these, it is worth highlighting a mortality rate of 1.9% (two cases), both of which were secondary to bleeding. One of the cases was a patient with previously unknown cirrhosis, who presented with decompensation and subsequent multiple organ failure following bleeding, meaning this was a high-risk patient. The other patient experienced hypovolemic shock secondary to pseudoaneurysm of the gastroduodenal artery, with emergency reintervention to control the bleeding, which was a severe complication leading to massive bleeding and eventually resulting in death. Three patients experienced a postoperative residual intra-abdominal collection that progressed well with antibiotic treatment. In most studies, the mortality rate of the laparoscopic exploration of the main bile duct is 0 to 1% in the hands of experienced biliary surgeons. This rate is similar to the incidence found in the open exploration of the bile duct,[37–41] as well as for the endoscopic approach (0–1.5%).[42–44]

Some authors describe postoperative bleeding as a very rare complication but one which is responsible in most cases for early reintervention. It usually occurs after a difficult cholecystectomy or in patients with coagulation abnormalities, with patients with cirrhosis being those at the highest risk. Generally speaking, this type of intervention restricts surgeons to use local hemostatic agents and to insert a suction drain in the subhepatic position. It is important to highlight the serious nature of a reintervention, as 10% of patients undergoing further surgery will have severe complications.[45–47]

After long-term follow-up of over 24 months, we did not observe any cases of bile duct stricture or cholangitis, in line with other studies. We, therefore, consider that another benefits of this approach should be highlighted, as carrying out ERCP with ES causes increasing repeat cholangitis, as we have previously mentioned.

Our study has some limitations, in that it is a retrospective study with a relatively small sample size. This study represents our experience to date in laparoscopic exploration of the bile duct.

Conclusion

In our experience, the laparoscopic approach for one-step elective treatment of CLT and cholelithiasis is a safe option, with a very small number of complications and satisfactory short- and long-terms results, making use of the benefits of the minimally invasive approach and avoiding the inconveniences of ERCP, as well as the open approach. Furthermore, despite preoperative identification of CLT, it allowed us to avoid an unnecessary exploration of the bile duct in 25% of patients.

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RESEARCH ARTICLE

Perioperative Antidepressant Use Improves Body Image to a Greater Extent Compared to Those Not Taking Antidepressants in Patients Who Undergo Bariatric Surgery

David Fipps[1], Sharon Holder[2], Dorothy Schmalz[3], John Scott[4]

Abstract

Introduction: Body image often improves after bariatric surgery; however, those who are depressed are more vulnerable to continuing to have body image concerns. Body image dissatisfaction and depression are associated with poorer quality of life, less weight loss after surgery, and poorer overall physical/mental functioning. Our study aims to determine whether antidepressants influence the improvement seen in body image after bariatric surgery.

Materials and methods: Body-Esteem Scale for Adolescents and Adults (BESAA), a validated tool for trending body image, was administered preoperatively and at 3, 6, and 12 months postoperative follow-ups. Scores were compared for improvement, and linear regression models were used to determine the influence of medications and demographic factors on score improvement.

Results: The study sample was consisted of 47 men and 57 women (22–72 years of age). Preoperative BMI was in the range of 35.87–75.66 (mean: 49.26). Sixty-nine percent (69%) were taking psychiatric medications and 57% of those medications were antidepressants (12 different antidepressants represented). Improvement in BMI was in the range of 1.44–30.77 points (mean: 15.08). The majority (98.07%) showed improved BESAA scores; two factors revealed statistical significance for influence on score magnitude. For every 1 point of BMI improvement, our sample increased BESAA scores by 0.68 points ($p = 0.021$). Those taking antidepressants scored an average of 8.55 points higher than those not taking antidepressants ($p = 0.032$). There were no significant differences found for age, gender, race, type of surgery, use of anxiolytics/hypnotics, or stimulants.

Conclusion: Perioperative antidepressant usage is associated with a greater improvement in body image after bariatric surgery compared to those who are not taking antidepressants. Given the high comorbidity of depression in bariatric surgery patients, this highlights potential for improved outcomes with treatment of psychiatric comorbidities in this population.

Keywords: Antidepressant, Bariatric surgery, Body image.

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Introduction

Body image is defined as an individual's beliefs, emotions, behaviors, cognitions, and perceptions pertaining to his or her physical appearance.[1] Body image is a multifaceted psychosocial construct that forms how we picture our own body in our minds.[2] There are many factors that contribute to one's perception of body image, including societal norms, self-esteem, perfectionism, physical characteristics, interpersonal experiences, and history of depression.[1,3,4] The desire to improve appearance and body image is often reported as being among the most important motives for pursuing bariatric surgery.[2,5,6] Overall, findings from both cross-sectional and longitudinal studies suggest that, in general, body image will improve after bariatric surgery, and this will often correlate to the improvement seen in the body mass index (BMI).[7] However, there are still some individuals who continue to feel dissatisfied with their body image despite appropriate weight loss after bariatric surgery.[7–9] A study by Pona et al. found that bariatric surgery candidates who have a history of psychopathology and other psychological risk factors may be more vulnerable to body image concerns after surgery.[10] Specifically, individuals with poorer body image have been found to have a higher likelihood of depression and depressive symptoms.[11,12]

It has been estimated that 25–30% of bariatric surgery patients report clinically significant depression that has been found to be higher than nonsurgery-seeking adults with morbid obesity in the general population.[8,13–17] Nearly 40% of bariatric surgery candidates are taking psychotropic medications, and antidepressants are the

[1]Department of Psychiatry and Psychology, Mayo Clinic, Rochester, Minnesota, United States

[2]Department of Psychiatry, Executive Director of the Comprehensive Outreach Research and Education (CORE) Institute, Charleston, South Carolina, United States

[3]Department of Parks, Recreation, and Tourism, University of Utah, Salt Lake City, Utah, United States

[4]Department of Surgery, Division of Minimal Access and Bariatric Surgery, University of South Carolina, Greenville, South Carolina, United States

Corresponding Author: David Fipps, Department of Psychiatry and Psychology, Mayo Clinic, Rochester, Minnesota, United States, e-mail: dfipps123@gmail.com

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most frequently prescribed.[18] Furthermore, patients concerned with their body image were more likely to be taking psychotropic medications and to be involved in outpatient therapy.[10] Depression alone has been shown to increase the risk of diabetes 1.4-fold,[19] coronary artery disease 1.5- to 2-fold,[20] and stroke 1.8-fold.[21] However, body image dissatisfaction and depression can further worsen weight loss efforts causing one to feel self-conscious while engaging in physical activity and even doubt one's likelihood of successfully losing weight, which in turn can hinder healthy eating habits and behavioral changes.[8,22] Similarly, body image dissatisfaction and depression in postbariatric patients are associated with less weight loss[23] and can result in regaining of the weight that was lost, nutritional deficiencies, and even increased risk of death.[24,25]

Considering these findings authors suggest that body image should be considered an outcome parameter in assessing health-related quality of life in patients undergoing bariatric surgery.[23,26] It has also been noted that further study to find interventions that increase body satisfaction would be of great value to the field.[23] In this context, this study aims to determine what factors have the greatest influence on the magnitude of body image improvement postbariatric surgery with a particular focus on perioperative antidepressant usage.

Materials and Methods

This study was approved via the institutional review board of an academic tertiary care center. Patients who had been approved for bariatric surgery were consecutively recruited and consented by the attending surgeon of record. Inclusion criteria for the study are patients must be aged 18 years or older with a BMI ≥35 and opting to undergo any type of bariatric surgery. There were no unique factors for exclusion not identified by the inclusion criteria. Those who consented to participate in the study completed a battery of self-administered questionnaires, including a validated metric for trending perceived body image (also termed "body esteem"). These questionnaires were administered by office-based psychologists and dieticians at four time intervals: approximately 1 month prior to surgery and then at 3, 6, and 12 months postoperatively (in tandem with the pre- and postoperative outpatient visits).

The scale that was used to assess trends in body image was the Body-Esteem Scale for Adolescents and Adults (BESAA) a commonly used validated metric for assessing body image and confidence in both psychological and bariatric surgery literature.[27–29] The BESAA is a 22-item questionnaire with scores of 1, 2, 3, 4, and 5 points corresponding answers of "never," "rarely," "sometimes," "often," and "always," respectively. A higher score on the BESAA indicates higher overall body esteem and confidence regarding one's body image. The BESAA scores were compiled at each of the collection time points noted earlier and the presurgical score was compared to the score at the final follow-up appointment. Summary and descriptive statistics were generated for all patients regarding sociodemographic, surgical, and psychiatric characteristics (Table 1).

Linear regression models were employed to assess the relationship between the improvement seen in the BESAA scores and the demographic factors listed in the descriptive statistics table. Results of the linear regression analysis are displayed as coefficients where a positive coefficient indicates a positive influence on the BESAA trend, and a negative coefficient indicates a negative influence on the BESAA trend. The numerical value of the coefficient indicates the number of average points of influence seen by that variable (e.g., a positive 4-point coefficient would indicate, on average, those with the demographic variable had an average of four points higher on the BESAA scores than those without the demographic variable). For nonbinary variables like postoperative improvement in BMI, the coefficient indicates the influence on the BESAA score per 1 point of BMI improvement. Levels of significance were assessed using *t*-test of regression coefficients. *p*-values less

Table 1: Descriptive statistics for study sample

Characteristic	*N = 104*
Age distribution	Range: 22–72 Mean: 44.28
20–29	2.70%
30–39	22.22 %
40–49	30.16%
50–59	20.63%
60–69	12.70%
≥70	1.59%
Sex	
Male	45.2 %
Female	54.8%
Race/ethnicity	
Caucasian	50.96%
African American	18.50%
Hispanic American	10.10%
Asian American	9.03%
Prefer not to respond	11.41%
Preoperative BMI	Range: 35.87–75.66 Mean: 49.26
35–39.99	9.09%
40–49.99	53.25%
50–59.99	25.97%
60–69.99	7.79%
≥70	3.90 %
Postoperative BMI improvement	Range: 1.44–30.77 Mean: 15.08
<10	16.8%
10–19.99	66.23%
20–29.99	15.58%
≥30	1.29%
Surgical procedure	
Roux-en-Y gastric bypass	53.65%
Vertical sleeve gastrectomy	46.35%
Psychiatric medications	
Not on psychiatric medications	31.55%
On psychiatric medications	68.45%
Antidepressants	57.01%
Anxiolytic/hypnotic	25.59%
Stimulant	2.74%

BMI, body mass index

than 0.05 were considered indicative of statistical significance. Data were analyzed using R statistical software via the R Foundation for Statistical Computing 2017 (version 3.43, Vienna, Austria).

Results

The study sample included 47 men and 57 women ranging from 22 to 72 years of age (mean age 44.28 years). Preoperative BMI ranged from 35.87 to 75.66 (mean BMI 49.26). Over 72% (72.63%) provided comparison information for 3 months, (75.78%) 6 months, and (63.15%) 12 months. Sixty-nine percent (69%) of our samples were taking psychiatric medications, and 57% of those medications were antidepressants. Represented antidepressants in our sample included: amitriptyline (5), bupropion (10), citalopram (34), duloxetine (4), escitalopram (9), fluoxetine (6), nortriptyline (1), paroxetine (3), sertraline (4), venlafaxine (1), vilazodone (4), and vortioxetine (3). Noted 35 patients were on >1 psychotropic medication and 9 of those patients were on >1 antidepressant. Fifty-three percent (53.65%) underwent Roux-en-Y gastric bypass and (46.35 %) underwent vertical sleeve gastrectomy. The improvement in BMI ranged from 1.44 points to 30.77 points (average of 15.08 BMI improvement points). For further details of these patient demographics, see Table 1.

The majority (98.07%) of our patient sample demonstrated improved scores on the BESAA metrics and two factors revealed statistical significance regarding the influence of score magnitude. The first factor, as expected, was BMI improvement demonstrating a coefficient of 0.684 ($p = 0.021$). Hence, for every 1 point of BMI improvement, our sample increased their BESAA scores by 0.68 points. The second factor of statistical significance was perioperative antidepressant use with a coefficient of 8.556 ($p = 0.032$). Hence, those in our sample who were taking an antidepressant scored an average of 8.55 points higher on the BESAA scores than those who were not taking an antidepressant. There were no significant differences found regarding the influence on the BESAA scores in age, gender, race, type of surgery, use of anxiolytics/hypnotics, or stimulants (Table 2). We excluded education and employment status due to the lack of patient responses on these surveys.

Table 2: Linear regression for demographic influence on body image improvement

Demographic characteristics	*Coefficient*	*p-value*
Age	0.039	0.784
Sex		
Male*	1.00	1.00
Female	−4.726	0.266
Race/ethnicity		
Caucasian*	1.00	1.00
Non-Caucasian	4.988	0.154
Postoperative BMI improvement	**0.684**	**0.021****
Surgical procedure		
Roux-en-Y gastric bypass*	1.00	1.00
Vertical sleeve gastrectomy	0.039	0.822
Psychiatric medications		
Antidepressant	**8.556**	**0.032****
Anxiolytic/hypnotic	0.993	0.743
Stimulant	4.993	0.366

*Reference groups; **Statistically significant level: $p < 0.05$; BMI, body mass index

Discussion

Our study results indicate that the majority of patients who undergo bariatric surgery will see an improvement in their body image, and the magnitude to which this improvement is seen is influenced by the improvement in the BMI and being on an antidepressant. Specifically for every 1 point of BMI improvement, our sample increased their body image scores by 0.68 points, ($p = 0.021$) and those who were taking an antidepressant scored an average of 8.55 points higher on the body image scores than those who were not taking an antidepressant ($p = 0.032$). The results of our study reflect similar concepts found in the literature. Overall, there are significant improvements seen in body image following bariatric surgery, and these improvements often correlate with the percentage of weight loss and can similarly decompensate if weight is regained.[2,7–9,30–37] In addition, there are multiple studies demonstrating that treating a psychiatric comorbidity can result in more favorable "nonpsychiatric" outcomes. For example, a recent randomized controlled trial (RCT) showed that congestive heart failure patients who achieved clinical remission of depression demonstrated a statistically significant reduction in cardiovascular events compared to the nonremission group.[38] In another RCT, patients with breast cancer undergoing adjuvant hormonal therapy, local radiation, and/or adjuvant chemotherapy reported that antidepressant treatment reduced depressive symptoms, improved quality of life, and increased the likelihood of completion of adjuvant treatment vs the placebo group.[39] Considering the high prevalence of depression in the bariatric surgery population, it is understandable that a treatment for depression could produce a more favorable outlook on one's body image. This trend has been seen with psychotherapeutic interventions perioperatively. For example, cognitive behavioral therapy (CBT) was shown to improve distress related to body image as well as reported self-esteem and depression symptoms.[40–42] In addition, acceptance and commitment therapy demonstrated significant improvements in body image and weight concerns compared to treatment as usual.[7,43,44]

Body image dissatisfaction and depression not only act as single factors that can impede success in a patient's weight loss journey but also interact with each other in a bidirectional manner.[11,12] In fact, poor body image has been proposed to mediate the relationship between obesity and psychological symptoms of depression and low self-esteem.[45] Bodily dissatisfaction and psychological distress can act as a trigger for stress-related eating behaviors.[46] In addition, among individuals seeking bariatric surgery, body image dissatisfaction was associated with binge eating, depression, and lower self-esteem.[7,47] The literature also suggests that if a patient is not prepared psychologically for body image challenges after bariatric surgery, there is a higher likelihood of experiencing disturbed body image postoperatively.[48] As mentioned earlier, depression has been shown to increase the risk of diabetes 1.4-fold,[19] coronary artery disease 1.5- to 2-fold,[20] and stroke 1.8-fold,[21] to name a few. These risk increases are likely mediated by both biological mechanisms and unhealthy behaviors related to poor self-care, diet, exercise, and treatment adherence, thereby contributing to increased morbidity and mortality.[49] In fact, comorbid depression is associated with a 3-fold greater risk of nonadherence to medical treatment ranging from medication nonadherence to missing appointments to not following diet, exercise, or lifestyle recommendations.[50] Studies show that this increased mortality rate persists even after confounding factors

are controlled for: such as smoking, disease severity, and alcohol consumption.[51,52]

Employing strategies targeted to improve body image and appropriately treat psychiatric comorbidities could lead to more improvements in bariatric surgery outcomes. Though recent literature indicates that simply being on an antidepressant does not directly affect the amount of weight loss 1 year after gastric bypass surgery,[53] weight loss cannot be considered the only outcome of focus. Improvement in body image after bariatric surgery is associated with notable improvements in physical and mental quality of life.[32,36] In addition, studies have demonstrated both sexual and psychological functional improvements after bariatric surgery correlated to improved body image metrics.[54] Furthermore, body image satisfaction is associated with less depressive symptoms in postbariatric patients.[23] To that end, appropriately treated depression can represent an opportunity to further improve the patient's quality of life, decrease the patient's risk for suicide, and improve overall treatment compliance.

Limitations

To begin, we systematically explored a relatively large number of explanatory variables with a sample of modest size; therefore, we may not have had sufficient power to detect associations between some demographic characteristics such as other medial comorbidities, employment status, and level of education. Second, self-reporting conditions might underestimate their prevalence. Third, expanding the perioperative evaluation to include postoperative PHQ-9s as well as anxiety screens (GAD-7s) would have provided a helpful tool for trending symptomatic changes in the patients' depression and anxiety. Fourth, this study focused on simply being on an antidepressant and not if the medication dosing was fully optimized to efficacious dosing. As some patients were underdosed according to typical efficacious dosing ranges, there could be potential for an even greater magnitude of improvement if all doses were optimized. This brings about multiple points to incorporate into future prospective studies of similar focus. In addition, future studies could also incorporate the effectiveness of a combination of psychotherapy and antidepressant medication vs therapy alone and antidepressants alone on body image after bariatric surgery.

Conclusion

Perioperative antidepressant usage is associated with a greater improvement in perception of body image after bariatric surgery compared to those who are not on antidepressants. Given the high comorbidity of depression in those who undergo bariatric surgery, this highlights the potential for improved outcomes with the treatment of psychiatric comorbidities in this population.

Orcid

David Fipps https://orcid.org/0000-0001-5758-704X
John Scott https://orcid.org/0000-0002-5619-7637

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REVIEW ARTICLE

Comparison between the Effect of Laparoscopic Sleeve Gastrectomy and Laparoscopic Mini-gastric Bypass on Type 2 Diabetes Mellitus in Obese Patients: A Prospective Study

Mohamed A Elkerkary[1], Osama A Adly[2], Mohamed KE Elhadary[3], Mohammad Farouk[4], Hamdy Shaban[5]

Abstract

Background: One of the major global health burdens is type 2 diabetes mellitus (T2DM). Laparoscopic sleeve gastrectomy (LSG) has recently been shown to be effective and safe for T2DM management. Laparoscopic mini-gastric bypass (LMGB) was introduced as a simple (one anastomosis) operation combining both restrictive and malabsorptive functions thus suitable for obese patients with metabolic derangements like T2DM. This study aims to compare the effect of LSG and LMGB on T2DM in obese patients.

Materials and methods: A cohort study was carried out on obese patients with T2DM submitted for LSG or LMGB in the department of surgery at Suez Canal university hospital and Suez Canal authority hospital, Egypt, from June 2018 to September 2020. The patients were followed up for 12 months.

Results: A total of 20 patients were allocated to each group. The change in the mean body mass index (BMI) was significantly higher in the LSG, compared to the LMGB group ($p<0.05$). Both groups exhibited a significant reduction in the HbA1c at the end of follow-up 12 months after surgery; however, the reduction was significantly higher in the LMGB group ($p<0.05$).Among the LSG group, 75% of the cases showed complete diabetic remission, 15% showed partial remission, and 10% showed improvement in their glycemic control at the end of follow-up. Among the LMGB group, 85% of the cases showed complete diabetic remission and 10% showed partial remission. The difference between the study groups was statistically significant.

Conclusion: The study showed good improvement for T2DM and a great response in losing weight with a significant superiority of LMGB over the LSG.

Keywords: Bariatricsurgery, Metabolic disorders, Obesity, Type 2 diabetes mellitus.

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Introduction

One of the major global health burdens is type 2 diabetes mellitus (T2DM). It has been estimated that the global prevalence of T2DM will increase to 642 million by 2040.[1,2] According to current estimates, end-stage renal disease and coronary artery disease were observed in 45 and 55% of diabetic patients, respectively. Moreover, it was reported that 90% of diabetic patients were obese.[3,4] The present treatment for T2DM involves advising patients to lose weight by dietary changes and administering drugs to restore glycemic regulation by decreasing insulin resistance and enhancing insulin secretion.[5] Bariatric surgery has recently been shown to be very effective in treating not only morbid obesity but also T2DM-related obesity.[6]

Laparoscopic sleeve gastrectomy (LSG) has gained popularity among all bariatric procedures and is the most frequently performed bariatric surgery worldwide.[7,8] LSG is one of the restrictive gastric procedures that limit the gastric volume and restrict the intake of calories.[9] LSG has recently been shown to be effective and safe for T2DM management.[10] Several studies have also recommended LSG as a metabolic procedure for T2DM therapy; however, the available data were only on the short-term follow-up.[11–13]

The laparoscopic mini-gastric bypass (LMGB) was first presented in 2001 by Rutledge.[14] It assures a small gastric pouch with the rapid transfer of gastric material to the jejunum, generating both malabsorptive and restrictive results.[15] Regarding the effect of LMGB on T2DM, it was reported that complete remission rates reached up to 65%.[16] During the first 6 months after surgery, weight loss was greatest and then stabilized later. Comparing the long-term effectiveness of both LSG and LMGB procedures as a treatment for morbid obesity and T2DM has not been demonstrated, taking into consideration the satisfaction, complications, morbidity, and mortality of postoperative patients.Therefore, we aimed to compare the effect of LSG and LMGB on T2DM in obese patients.

[1–3,5]Department of Surgery, Faculty of Medicine, Suez Canal University, Ismailia, Egypt

[4]Department of Surgery, Suez Canal Authority Hospital, Ismailia, Egypt

Corresponding Author: Mohamed A Elkerkary, Department of Surgery, Faculty of Medicine, Suez Canal University, Ismailia, Egypt, Phone: +201005150800, e-mail: m_kerkary@med.suez.edu.eg

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Materials and Methods

Study Design and Population

A prospective, comparative study was carried out on obese patients with T2DM, who were elected to undergo either LSG or LMGB at surgery theater of Suez Canal University teaching hospital, Ismailia, Egypt. The study's protocol gained the official approval of local ethics committee of the University hospital, and all patients signed written informed consents before the procedure. Only patients aged more than 18 years old, had a body mass index (BMI) of ≥35 kg/m^2, and documented diagnosis of T2DM were included. The diagnosis of T2DM was based on the latest version of the American Diabetes Association (ADA) criteria.[17] Patients with history of previous bariatric surgery, contraindications for general anesthesia, and/or cardiac, hepatic, renal, or hematologic disorders were excluded.

Study's Procedures

Preoperatively, all patients underwent history taking and full clinical examination according to the institutions' local protocols. Besides, routine preoperative laboratory evaluation was conducted with special emphasis on fasting blood sugar (FBS) and glycosylated hemoglobin (HbA1c).

All patients were asked to follow a high-protein diet 2 weeks before the procedure. Eight hours prior to the surgery, the patients were asked to fast and were allowed fluids only 4 hours before fasting. All procedures were conducted under general anesthesia. The LSG and LMGB were performed per the institutions' local protocols. Briefly, a total of five ports were used in patients undergoing LSG, which were distributed 5 cm from umbilicus (mainly 12mm for stapling and introduction of laparoscopy), at the left flanks (mainly 15mm for stopping the blood supply to greater curvature, introduction of laparoscopy, and suturing), at epigastrium (5-mm port aiding liver elevation), at right upper quadrant, and at left lateral subcostal area for assistant. Following the devascularization of greater curvature and division of the stomach, a total of six cartridges were employed for stomach stapling. The sleeve was examined by methylene blue to confirm complete and uniform filling, and the resected stomach was removed via the umbilical port. The incision was then sutured after locating intraperitoneal drain.

Patients in LMGB were positioned at the reverse Trendelenburg position, and five ports were distributed in a diamond-like matter 5 cm from umbilicus, midclavicular line 4–6 cm from the costal margin, at 4 to 6 cm from xiphisternum, at midclavicular line 4 to 6 cm from the left costal margin, and at left anterior axillary line-6 cm from the left costal margin. Following mesentery dissection, a 45-mm blue/gold cartridge was placed perpendicular to the lesser curvature and another 60-mm blue stapler was placed parallel to the lesser curvature up to esophagogastric junction. A linear 45-mm blue stapler is used to create a gastrojejunostomy, and the stapler defect is closed with Vicryl 2-0 suture. The incision was then sutured after locating intraperitoneal drain. Throughout the whole intraoperative period, patients were observed for the amount of blood loss.

Patients were then moved to the ward, managed per institutions' protocol, and started liquid oral intake 6 hours postoperatively.

Study's Outcomes

The patients were observed over a follow-up period of 12 months. Primarily, we aimed to compare between LMGB and LSG concerning postoperative changes in glycemic parameters at the end of the first year after the procedure. Other comparative parameters included the incidence of T2DM complete/partial remission, as defined by ADA criteria,[17] change in body weight, and incidence of postoperative complications.

Statistical Analysis

Descriptive statistics were presented as mean ± standard deviation for continuous data and as number and percent for categorical data. Data analysis was conducted by SPSS 15.0 (SPSS Inc., Chicago, Illinois, United States), and p <0.05 was counted as significant difference. To compare continuous variables, an independent t-test and Wilcoxon signed-rank test were used for parametric and nonparametric data, respectively. Chi-square test was used to compare categorical variables.

Results

We constructed two groups, and each included 20 patients: group A correspond to the sleeve group, and group B for the mini-gastric bypass group. We found that the mean age of group A was 37.1 years with a range of 25–60 years. However, group B ranged from 19 to 51 with a mean of 35.4 years. The male gender was more than the female in both groups and accounts for 55% and 65% in group A and group B, respectively. There were no statistically significant differences between both groups regarding comorbidities (Table 1).

The total mean operative time was 105 minutes (98 minutes and 116 minutes among the LSG and LMGB groups, respectively). The difference between both groups was statistically significant. Regarding intraoperative blood loss, the total mean blood loss was 72 mL (70 and 79 mL among the LSG and LMGB groups, respectively). No reoperations were observed in both groups. The mean hospital stay among the LSG group was 3.9 days, and that of the LMGB group was 2.8 days; the difference between the two groups was statistically significant. None of the study groups showed any mortality. Among LSG group regarding intra- and postoperative complications, 5% of the patients showed vascular injury (short gastric artery injury), 5% of the patients suffered from reflux, 15% suffered from marginal ulcer, 20% had iron deficiency anemia, and 15% suffered from wound infection. Among LMGB group, 15% showed vascular injury (left gastric and short gastric artery injury), and one patient had a detected anastomotic leak that was treated intraoperatively. As for the early postoperative complications, one patient suffered from persistent vomiting (treated conservatively) and one patient had DVT (treated medically). Regarding late complications, 30% of the patients suffered from reflux, 25% suffered from marginal ulcer, 35% had iron deficiency anemia, and 5% suffered from wound infection. The

Table 1: Baseline characteristics of the studied subjects (N = 40)

Variable		Group A (sleeve) (n = 20) No	%	Group B (bypass) (n = 20) No	%	p value
Age (years)	Mean ± SD	37.1 ± 8.4		35.4 ± 8.2		>0.05
	Range	25–60		19–51		
Male		11	55%	13	65%	>0.05
Comorbidities	HTN	5	25%	8		>0.05
	OSA	3	15%	5		
	Dyslipidemia	7	35%	9		

difference in the perioperative complications between the study groups was statistically significant (Table 2).

Among the LSG group, the mean preoperative BMI was 53 kg/m^2, it decreased to 50.6 kg/m^{2}1 month after surgery, then to 49.6 kg/m^2 after 3 months, 45.5 kg/m^2 after 6 months, 40 kg/m^{2}after 9 months, and finally 37 kg/m^2 at the end of follow-up 12 months after surgery. Regarding LGMB group, the mean preoperative BMI was 52 kg/m^2, it decreased to 48.1 kg/m^2 1 month after surgery, then to 43.2 kg/m^{2}after 3 months, 40 kg/m^2 after 6 months, 37.4 kg/m^2 after 9 months, and finally 35.1 kg/m^2 at the end of follow-up 12 months after surgery. The difference in the perioperative changes in the mean BMI between the study groups was statistically significant (Fig. 1).

Concerning the primary outcome, among the sleeve group, the mean preoperative HbA1c was 10.1%, it decreased to 8.6% 3 months after surgery, then to 8.1% after 6 months, 7.4% after 9 months, and finally 7% at the end of follow-up 12 months after surgery. Regarding bypass group, the mean preoperative HbA1c was 10.9%, it decreased to 8.1% 3 months after surgery, then to 7.2% after 6 months, 6.9% after 9 months, and finally 6.6% at the end of follow-up 12 months after surgery. The difference in the perioperative changes in the mean HbA1c between the study groups was statistically significant (Fig. 2).

Among the LSG group, 75% of the cases showed complete diabetic remission, 15% showed partial remission, and 10% showed an improvement in their glycemic control at the end of follow-up. Among the LMGB group, 85% of the cases showed complete diabetic remission and 10% showed partial remission. The difference between the study groups was statistically significant (Fig. 3).

Discussion

Laparoscopic bariatric surgery has been widely accepted by surgeons for its efficiency, safety, minimally invasive nature, and physiologic benefits.[18] These benefits are obtained in weight reduction and getting rid of the obesity mechanical comorbidities like obstructive sleep apnea, disk prolapse, and advanced osteoarthritis.[19] Many studies discussed these benefits and the effects of the aforementioned procedures on T2DM, hyperlipidemia, and hypertension either for short-term follow-up or for long-term follow-up with the presence of promising results in controlling many of these comorbidities.[20,21]

Table 2: Intraoperative and postoperative characteristics ($N = 40$)

Variable		*Group A (n = 20)*		*Group B (n = 20)*		*p-value*
Hospital stay (days)	Mean ± SD	3.9 ± 0.5		2.8 ± 0.3		<0.05
	Range	3–5		2–5		
Mortality		0		0		—
Intraoperative	Bleeding	1	5%	3	15%	<0.05
	Intraoperative leak	0	0%	1	5%	
Early postoperative	Postoperative leak	0	0%	0	0%	<0.05
	DVT	0	0%	1	5%	
	Bleeding	0	0%	0	0%	
	Reflux	1	5%	6	30%	
Late postoperative	Iron deficiency anemia	4	20%	7	35%	>0.05
	Wound infection	3	15%	1	5%	

*X2 = 0.03, *p* value

Our study has focused on the effect of both LSG and LMGB on T2DM as our primary objectives; however, other comorbidities (hypertension, dyslipidemia, and obstructive sleep apnea) were also observed. The mean operative time for group A (LSG) was 98 minutes, and that of group B (LMGB) was 116 minutes, which was consistent with a Korean study comparing the two procedures by Park et al. The mean operative time was 100 minutes and 130 minutes for LSG and LMGB, respectively.[22] Also, Piazza et al., reported a mean operative time of 120 minutes;[23] Lee et al. reported 114 minutes of operative time for LMGB.[24] Other studies showed shorter operative duration, as Kular et al., who reported a mean duration of 76 minutes for LSG,[25] and Rutledge, who reported that the average time of LMGB was 37 minutes.[26] These times were obtained due to the increased learning curve of these procedures.

Regarding the effect of the LSG on T2DM, we reported complete remission of diabetes in 75% of patients, which was consistent with other studies. Nocca et al., reported that the complete remission was observed in 76% of 25 patients with T2DM and BMI more than 35 kg/m^2, and therefore, they stopped the diabetes mellitus treatment.[10] Nosso et al., showed that 97% of diabetic patients got

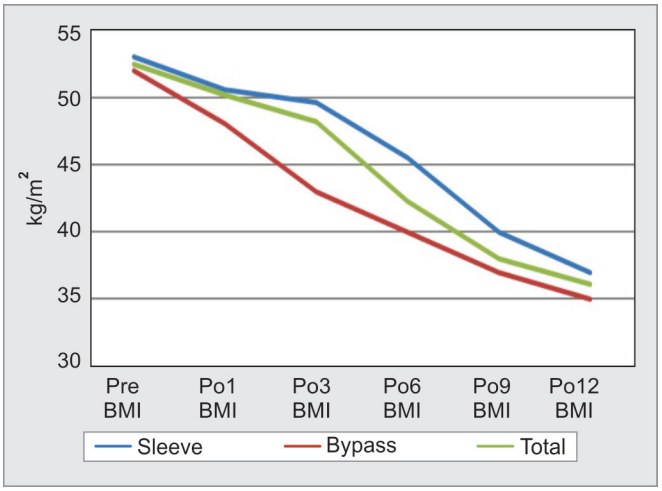

Fig. 1: Graphical presentation to the perioperative change in the case of body mass index (BMI) ($N = 40$). $X^2 = 0.016$, *p* value <0.05

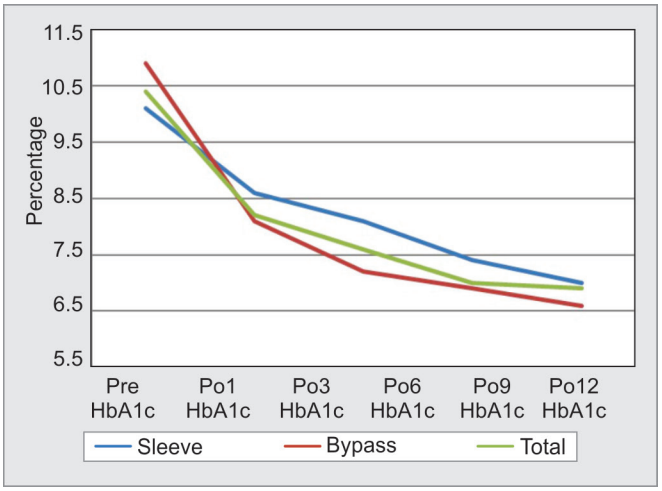

Fig. 2: Graphical presentation to the perioperative change in the case of glycosylated hemoglobin (HbA1c) ($N = 40$). X2 = 0.001, *p* value <0.05

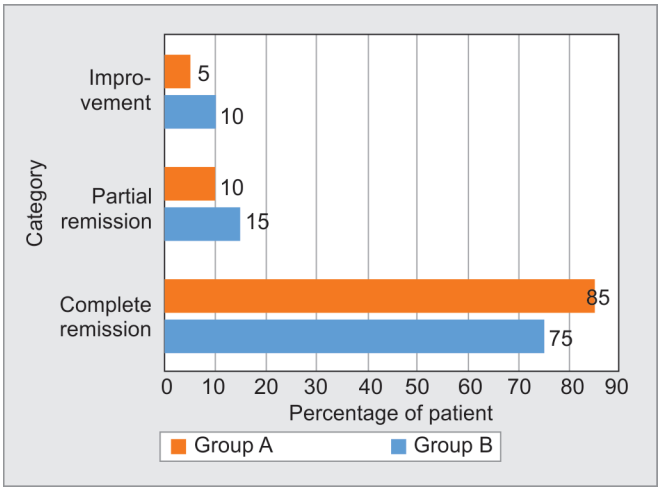

Fig. 3: Graphical presentation to the percentage of patients with partial/complete remission ($N = 40$).X2 = 0.02, p value <0.05

remission of the disease after 1 year of the LSG with a mean HbA1c of 6.5%.[27] However, they did not differentiate between the complete and initial remission. Lee et al., demonstrated a 50% remission after LSG in 20 patients with T2DM; however, their patients' BMI was between 25 and 35 kg/m^{2,} and the mean BMI of our patients was above 50 kg/m^2.[24] Similarly, Schauer et al., reported a 24% remission after LSG in 49 patients with T2DM who were followed for 36 months, obtaining a mean HbAc1 of 6%.[28] This may support the hypothesis of weight regain and the relapse of T2DM with time after LSG. However, these studies may not choose the patient's proper procedure as the LSG is not well designed for sweet eaters, as weight regains in sweet eaters having LSG are well reported. The patients should give up excessive sweets following LSG.

For the LMGB, we reported complete remission of the diabetes mellitus of 85% of the studied population. Rutledge also observed this finding after performing 2410 LMGB; not all of them had diabetes, but they had various comorbidities.[26] After 5 years of follow-up, he found an 84% complete remission of T2DM, which is consistent with our study results. Wang et al. followed 423 patients post LMGB for 2 years and recorded a complete resolution of T2DM in 100% of patients.[29] These findings support the effectiveness of LMGB in the management of T2DM.

For the intraoperative complications, we reported vascular injury and liver tear in both LSG (5 and 10%) and LMGB (15 and 15%), respectively. Intraoperative leakage was reported only in one case (5%) of LMGB; however, all intraoperative complications were controlled intraoperatively and laparoscopically, which is consistent with other studies in the overall percentage of complications. Kular et al.,[25] reported 14% of early complications after LSG in the form of intra-abdominal bleeding (3.3%), early reoperation (0.8%), intra-abdominal abscess (0.8%), and dyspepsia (7%). Late complications were reported in 24% of the patients; however, GERD were reported in 21%, anemia 2.6%, and cholelithiasis 10.5% of the patients. Further, in the study of Park et al., intraoperative complications were reported in 1% of LSG patients in the form of bleeding, and late complications were reported in 5% of the patients; two of them (2%) required reoperation; however, in our study, reoperation was not required in any patient.[22]

In conclusion, the current findings showed that both LSG and LMGB are efficient and safe procedures for losing weight and controlling high blood glucose levels in T2DM. LMGB has a significant superiority over LSG in controlling patients with T2DM and weight reduction. Health education programs should be carried out to increase the population's awareness about the risk of obesity and its concomitant comorbidities, especially diabetes mellitus, which may cost the patient losing an organ, a limb, or even his life.

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REVIEW ARTICLE

Avoiding the Falciform Ligament Sign during the Intraoperative Cholangiogram

Saksham Gupta[1], Simon Whitcher[2]

Abstract

We have observed that the falciform ligament can appear prominently as a vertical lucent artifact making cholangiography difficult during laparoscopic cholecystectomy. Our suspicion is that this is due to the pneumoperitoneum, and once the pneumoperitoneum is released, this artifact disappears. We have presented images displaying this phenomenon that we feel would be useful for general surgeons operating on the gallbladder.

Keywords: Cholangiography, Falciform ligament, Laparoscopic cholecystectomy.

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With the advent of laparoscopic cholecystectomy as the choice for surgery on the gallbladder, the intraoperative cholangiogram has been an adjunct to assess the biliary anatomy to reduce the risk of bile duct injuries.[1] Furthermore, this cholangiogram allows the operating surgeon to evaluate for filling defects within the distal bile duct and confirm flow into the duodenum and becomes necessary for any common bile duct exploration. The surgeon needs to be equipped with strategies on how to achieve the best cholangiography images. We would like to report a simple technique on improving intraoperative cholangiography images during laparoscopic cholecystectomy, which to our knowledge has not yet been described.

The "falciform ligament sign" has been described as a vertical lucent artifact in situations where the patient has a pneumoperitoneum on a plain abdominal radiograph in the setting of hollow viscous perforation.[2,3] With pneumoperitoneum, the falciform ligament becomes taut and lies in the axis of the sagittal plane and in this orientation, would potentially obscure more of the X-ray beam. We have observed a similar sign during the artificial creation of pneumoperitoneum during laparoscopic cholecystectomy. Surgeons need to be weary not to mistake this as a contrast leak or a biliary structure during the intraoperative cholangiogram. Even if this sign is correctly recognized, it can

[1,2]John Hunter Hospital, New Lambton Heights, New South Wales, Australia

Corresponding Author: Saksham Gupta, John Hunter Hospital, New Lambton Heights, New South Wales, Australia, Phone: +61249213000, e-mail: saksham_gupta@live.com.au

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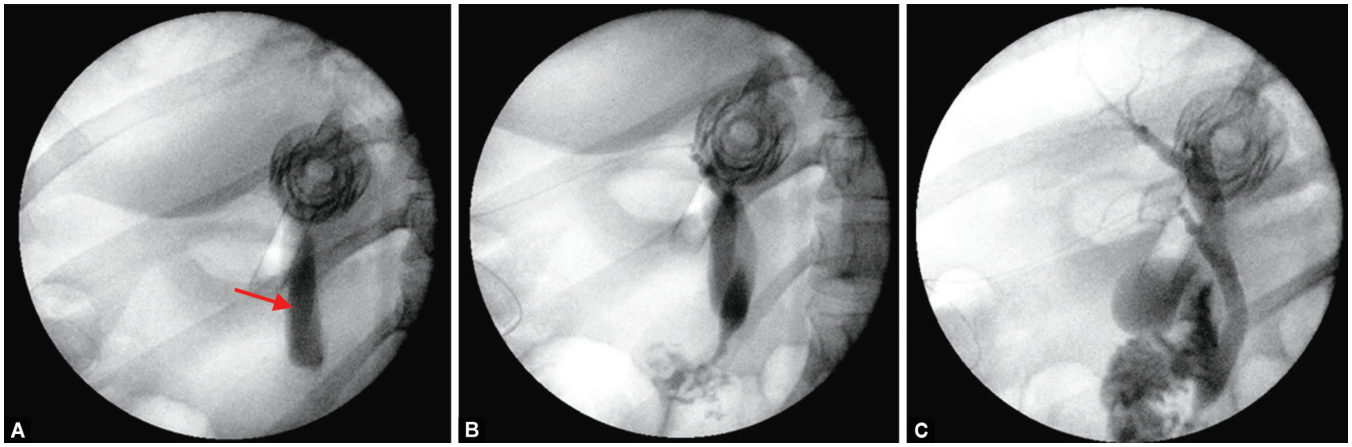

Figs 1A to C: Sequential cholangiogram images taken during an elective laparoscopic cholecystectomy. (A) Scout film taken before the introduction of contrast dye through the cholangiogram catheter. A radiolucent artifact (red arrow) is seen below the epigastric port. This is the falciform ligament sign; (B) Attempt made to achieve cholangiogram image; however, this artifact completely overlies the common bile duct. (C) On removal of the pneumoperitoneum, the shadow disappears, and the common bile duct is better visualized, including the entry of the cystic duct.

obscure the bile ducts making cholangiogram interpretation difficult (Figs 1A and 1B). It has been our practice that if this sign is observed, then the pneumoperitoneum can easily be released for the purpose of the cholangiogram, without any intraoperative complications. This removes the falciform ligament sign from the images, allowing clear cholangiogram images to be seen (Fig. 1C). We feel this is a simple technique that all surgeons could include in their practice during laparoscopic cholecystectomy.

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CASE REPORT

Laparoscopic Management of Ovarian Dermoid Cyst in a 31-year-old Woman: A Case Report

Cipta Pramana

Abstract

Ovarian dermoid cysts, also known as mature teratomas, are one of the ovarian numbers that can develop into malignancy and are mostly found in women aged 20–40 years. Most cases of teratoma mature cystic were discovered accidentally through the imaging examination. We reported a 31-year-old woman with complaints of bleeding from the birth canal for 16 days and accompanied by sharp pain during menstruation. The general condition is good and other vital signs examined were within normal limits. Abdominal ultrasound examination showed a mass in the right adnexa with a size of 12 × 10 × 8 cm and there were longitudinal thin white lines. Laparoscopic right ovarian oophorectomy was performed. After removing the mass was opened and there was a lot of hair in it. There are no complications during surgery and after surgery. The results of the histopathological examination were by the dermoid cyst.

Keywords: Laparoscopy, Ovarian dermoid cyst, Rokitansky nodule.

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Introduction

Dermoid cysts, or more commonly known as mature teratomas, are the most common ovarian tumors. About 15–20% of ovarian tumors are dermoid cysts and occur bilaterally in 10–15% of cases. The prevalence of developing malignancy is reported in 1–3% of cases. The highest incidence rate is found in women aged 20–40 years.[1,2]

These tumors originate from totipotent germ cells, which have the ability to become a well-differentiated tissue from the embryonic germ layer.[3] The cyst may develop from different types of tissues derived from ectoderm, mesoderm, and endoderm, including the hair, bones, teeth, cartilage, nerves, and sebaceous glands. Genetics is a predisposing factor for dermoid cysts, where one study found that the immediate family of patients with dermoid cysts had a higher risk. Common management of dermoid cyst is cystectomy or oophorectomy through surgical laparoscopy.[2] Therefore, it is important to detect it early so that complications from a dermoid cyst can be prevented.

We reported a 31-years-old woman with ovarian dermoid cysts without complications had undergone laparoscopy oophorectomy.

Case Description

A 31-year-old woman P1A0 came to the gynecology clinic with complaints of bleeding from the birth canal. The patient complained of having been menstruating for 16 days and was accompanied by sharp pain during menstruation. Blood pressure 110/70 mm Hg, weight 53 kg, and height 152 cm. Other vital signs examined were within normal limits. On laboratory examination, hemoglobin 11.5 gm/dL; hematocrit 33.90%; platelet count 408/µL; leukocyte count 7.6/µL; and other laboratory tests within normal. Abdominal ultrasound examination revealed a mass in the right adnexa with a size of 12 × 10 × 8 cm and a white longitudinal stripe was seen (Fig. 1).

An exploratory laparoscopy showed a mass in the right adnexa with a size of approximately 13 × 10 cm (Fig. 2) and the left adnexa with a normal tube and ovary. It was decided to do a right ovarian oophorectomy. The mass is reduced by aspiration of fluid and a yellowish liquid came out. Then the mass is wrapped in a plastic bag, tied (Fig. 3), and expelled through the bottom of the umbilicus

Department of Obstetrics and Gynecology, KRMT Wongsonegoro General Hospital, Semarang, Indonesia/Faculty of Medicine, Tarumanagara University, Jakarta, Indonesia

Corresponding Author: Cipta Pramana, Department of Obstetrics and Gynecology, KRMT Wongsonegoro General Hospital, Semarang, Indonesia/Faculty of Medicine, Tarumanagara University, Jakarta, Indonesia, Phone: +6281326118651, e-mail: pramanacipta@yahoo.com

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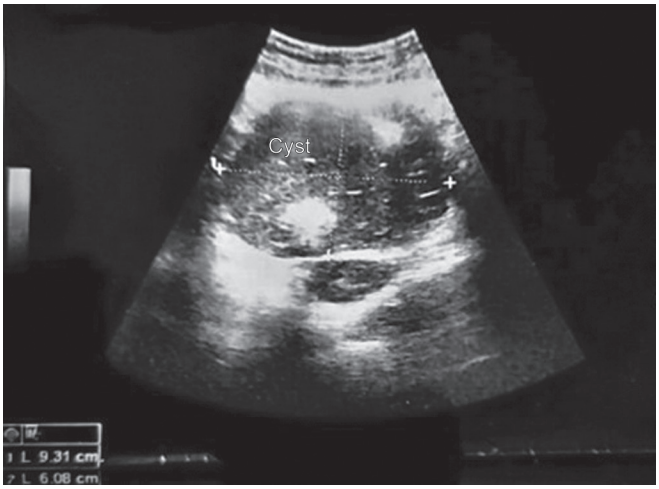

Fig. 1: Ultrasound image of dermoid ovarian cysts

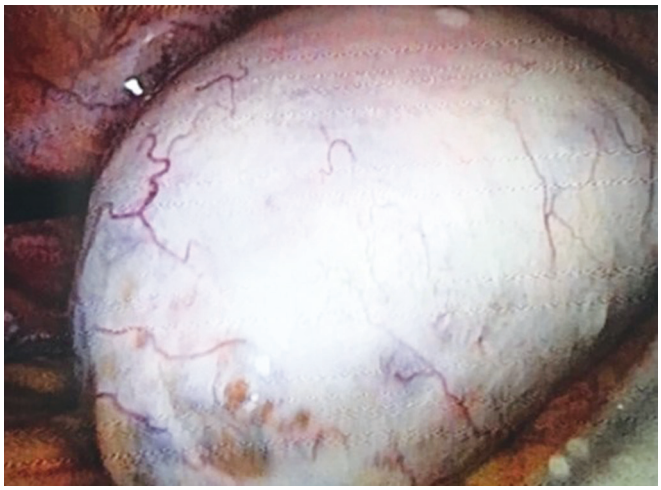

Fig. 2: Dermoid ovarian cyst overview during laparoscopy

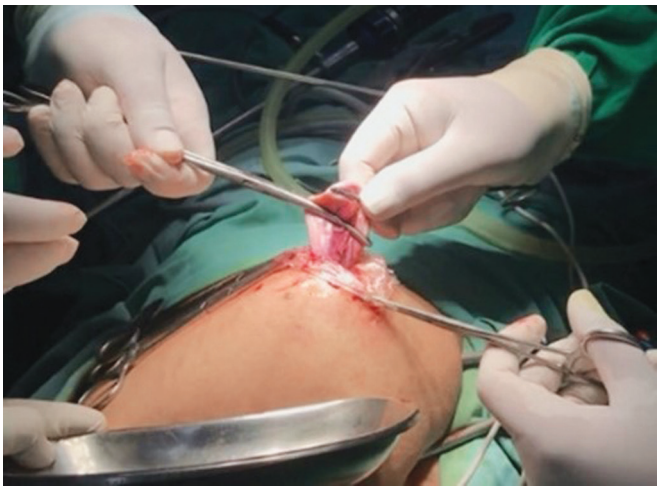

Fig. 4: Dermoid cyst excreted under the umbilicus

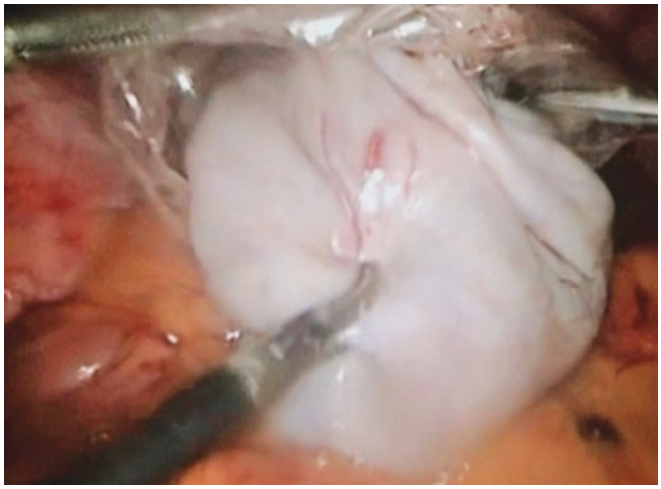

Fig. 3: Dermoid cyst inserted into a plastic bag

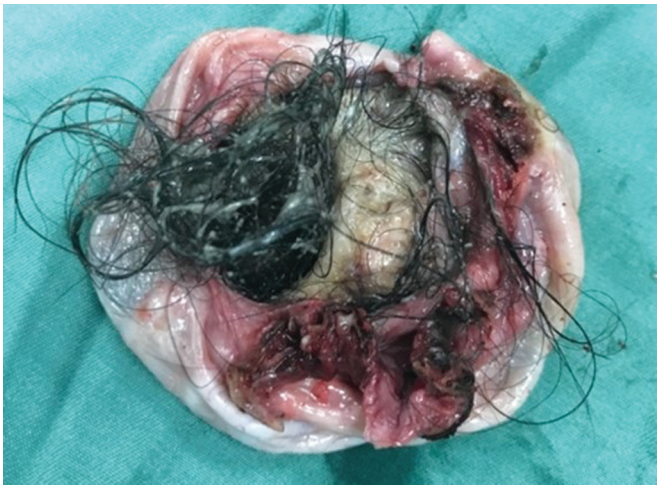

Fig. 5: Dermoid cyst, showing hairs

(Fig. 4). After removing the mass was opened and there was a lot of hair in it (Fig. 5). Ovarian tumors tissue was sent for anatomical pathology examination.

Histopathological examination results: microscopically showed pieces of ovarian tissue lined with stratified squamous epithelium accompanied by keratin with a stroma composed of fibrocollagenous connective tissue including sebaceous glands, hair follicles and several glandular structures lined with simple cuboidal epithelium, no signs of malignancy were seen.

Discussion

Benign mature teratoma is the most common benign tumor at a young age. Most cases of mature cystic teratomas are found incidentally on imaging studies. The most common symptom is lower abdominal pain, which is related to the size of the mass.[4] Because of the association between symptoms and mass effects and doubts about ovarian malignancy, it is necessary to perform resection, usually oophorectomy.[5]

Most mature cystic teratomas can be diagnosed by ultrasound because they have a very characteristic appearance. The following characteristic appearances can be seen on ultrasonography: the unilocular mass of the cystic adnexitis, Rokitansky nodule, or dermoid obstruction; dermoid mesh which showed echogenic band; and the tip of the iceberg can be seen when fat, hair, and shapeless echogenic tissues are in focus in the foreground causing acoustic shadows on the structures behind them and you can also see linear demarcation. Hair is often a component of teratomas and often mixes with sebum and forms a line in the longitudinal plane and points in the transverse plane.[3,6,7] Diagnosis was definitively established at the surgical excision.[5]

Some researchers recommend conservative therapy by laparoscopy to maintain ovarian function in young patients with dermoid cysts.[5] However, there is a general opinion among gynecological surgeons that the rate of leakage of cysts during laparoscopy is higher than that of the laparotomy and that leakage of cyst contents during laparoscopy can potentially cause peritonitis. But it remains questionable whether leakage during laparoscopy can affect the prognosis of the disease. From a literature review with a total of 14 studies documenting 470 cases of laparoscopic dermoid cystectomy, there was leakage of dermoid

cysts in 310 cases, but significant postoperative complications due to leakage of dermoid cysts were seen in only one case, with chronic granulomatous peritonitis occurring 9 months postoperatively. However, the study did not explain the preventive techniques used to avoid leakage or the action of cleaning fluid from leaking cysts. Irrigation using a *jet-wash* technique with an excessive amount of fluid to clean microscopic particles from the contents of the cyst is the gold standard for avoiding postoperative complications. From the research of Osama et al., it is said that laparoscopy allows better cleaning and flushing than laparotomy because it is difficult to re-aspire all irrigation fluids in laparotomy.[2]

The advantages of laparoscopy in ovarian cyst management include less postoperative pain, shorter hospitalization and recovery times, and better cosmetic consequences over laparotomy. Several criteria for laparoscopy in the management of ovarian cysts, namely the patient's age (premenopausal), mass size (≤5 cm), mass characteristics on ultrasound, and normal range of tumor markers. Research from Briones-Landa et al. demonstrated that laparoscopy did not increase complications compared to open surgery for benign ovarian cystectomy.[5]

Conclusion

Dermoid cysts, also known as mature cystic teratomas, are a type of benign tumor of the germ cell ovary. They contain well-differentiated tissues that are normally found in other organs including teeth, hair, skin, fat, muscle, and bones. It has been reported that patients with dermoid ovarian cysts and successful laparoscopic right oophorectomy had no complications during surgery or after surgery. The patient comes home in good health.

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Orcid

Cipta Pramana https://orcid.org/0000-0001-8991-0147

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CASE REPORT

Gastric Remnant Perforation after Roux-en-Y Gastric Bypass: A Case Report and Literature Review

Carlota Tuero[1], Gorka Docio[2], Victor Valenti[3], Alicia Artajona[4], Soledad Monton[5]

Abstract

Aim and objective: The aim and objective of this article was to focus on long-term complications after bariatric surgery, which are usually managed by general surgeons in the emergency department.

Background: Roux-en-Y gastric bypass (RYGBP) is one of the most commonly performed bariatric techniques in the world. Gastric remnant complications after this procedure are infrequent and poorly known. Furthermore, the diagnosis of this pathology may be challenging.

Case description: We present the case of a 54-year-old woman with intense epigastric pain and history of uncomplicated laparoscopic RYGBP 18 years ago. After clinical, laboratory, and radiological examinations, the patient was diagnosed with a gastric remnant perforation. Laparoscopic surgery was performed, and the perforation was successfully repaired with primary suture and omental patch.

Conclusion: Gastric remnant perforation after bariatric surgery is not frequent and usually appears several years after the procedure. This type of pathology is presented without specific clinical manifestations and with few analytical alterations. Complementary radiological studies, such as computed tomography (CT) scan, should be performed. However, pneumoperitoneum and extravasation of oral contrast are usually absent. Depending on the size of the defect, primary suture or gastric remnant resection may be performed. Nevertheless, surgical treatment should not be delayed.

Clinical significance: Long-term complications after bariatric surgery are in many circumstances managed by general practitioner surgeons. The low incidence and scarce manifestations make the diagnosis of this pathology challenging. Furthermore, bariatric surgery is progressively increasing its presence all over the world. Complications after this procedure must be known and kept in mind because an early diagnosis is crucial to give a proper treatment and reduce morbidity and mortality.

Keywords: Bariatric surgery complications, Emergency surgery, Gastric bypass, Gastric remnant perforation, Pyloric perforation.

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Background

Roux-en-Y gastric bypass (RYGBP) is the gold standard treatment for morbid obesity achieving long-term weight loss and comorbidity resolution. Complications after this type of surgery must be known, especially long-term ones that sometimes are managed by general practitioner doctors.

Peptic ulcer disease is not frequent after RYGBP. Diagnosis is usually made after developing complications such as bleeding or perforation. However, literature is scarce, with 18 case reports and 5 case series.[1] The main clinical symptoms are unspecific with epigastric abdominal pain associating with nausea and vomiting.

Gastric remnant perforation is a rare entity that should not be overlooked when exploring any patient with abdominal pain and history of bariatric surgery. It is essential to take this pathology into consideration in the differential diagnosis because altered anatomy may change the clinical presentation and radiological findings in bariatric patients. An early diagnosis and a proper treatment are crucial.

Case Description

A 54-year-old woman with a history of uncomplicated laparoscopic RYGBP and intense abdominal pain 18 years ago was admitted in the emergency department. She complained of epigastric pain for about 1 week, which had progressed in the last few days, radiating to the back. She also developed symptoms such as anorexia, nausea, and dizziness. Recent history was negative for smoking or alcohol abuse, but she claimed to have taken several doses of ibuprofen for lumbar pain.

[1,2,4,5]Department of Surgery, Hospital Garcia Orcoyen, Estella, Navarra, Spain

[3]Department of Surgery, Clinica Universidad de Navarra, Pamplona, Navarra, Spain

Corresponding Author: Carlota Tuero, Department of Surgery, Hospital Garcia Orcoyen, Estella, Navarra, Spain, e-mail: ctuero@unav.es

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On physical examination, the patient was afebrile, without signs of sepsis. She had right upper quadrant and epigastric tenderness with deep palpation without rebound or percussion tenderness. Abdominal auscultation was normal. Her body mass index was 29 kg/m^2.

Laboratory examination showed anemia and elevated lipase and amylase activities. C-reactive protein level and white blood cell count were within normal limits.

No free air was seen on the abdominal X-ray, so a computed tomography (CT) with intravenous and oral contrast was performed. Findings were correlative with acute pancreatitis, so the patient was admitted for observation. On clinical revaluation and despite medical treatment, 48 hours after admission, abdominal pain

increased and laboratory findings worsened. The CT scan was repeated, and a prominent thickness of the anterior gastric antrum with fat stranding, a small amount of free fluid on right paracolic gutter, and a millimetric bubble of free air were observed (Fig. 1). For the diagnosis of perforated gastric remnant, the patient was taken to the operating room.

Laparoscopic surgery was performed where a 1-cm prepyloric perforation in the gastric anterior border with purulent ascites was found (Fig. 2). Cultures were taken, and the defect was closed with nonabsorbable barbed suture. *Helicobacter pylori* stool antigen test was negative. Postoperative course was uneventful, and she was discharged a week after the proton-pump inhibitor (PPI) treatment.

Discussion

Roux-en-Y gastric bypass is an effective technique achieving long-term weight loss reduction and preventing obesity-related comorbidities with reasonably low complication rates.

Gastric remnant complications after RYGBP, such as ischemia, perforation, bleeding, or neoplasia, are unusual. These complications have been described as late as 20 years after RYGBP, so the long-term follow-up is important in these patients.[1,2]

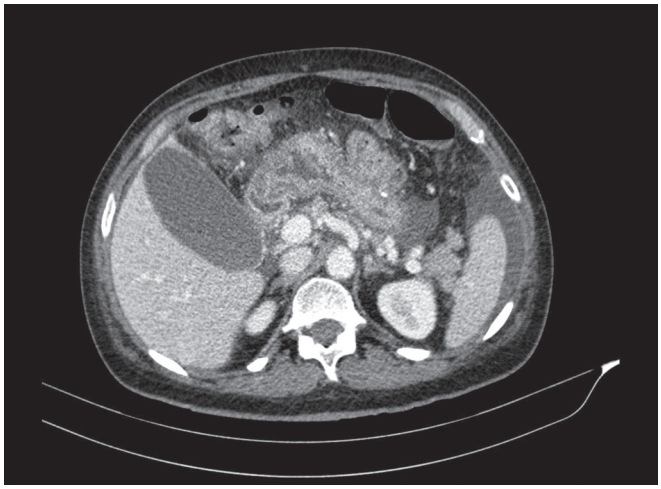

Fig. 1: CT scan: Thickness of the anterior gastric antrum, fat stranding, small amount of free perisplenic fluid, and a millimetric bubble of free air

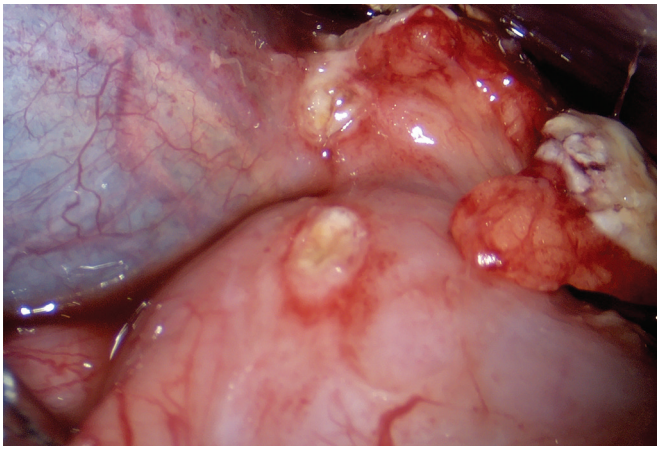

Fig. 2: Laparoscopic findings: 1-cm prepyloric perforation in the gastric anterior border

Risk factors for perforation of the gastric remnant are almost the same as those for marginal gastrojejunal ulcers. Mucosal ulcerations may be caused by excessive alcohol consumption, smoking, or nonsteroidal anti-inflammatory drug intake.[3–5] Gastrin levels are reduced after RYGBP. However, the bypassed gastric segment still maintains its secreting capacities that vary depending on the gastric section hight.[1] Besides, the acid produced in the bypassed stomach is not neutralized by the ingested food or washed out by gastric peristalsis, unlike what happens with normal anatomy.[6] Moreover, the reflux of bile and the delayed bicarbonate secretion may also damage the mucosa.[4,5,7] This chronic inflammatory stimulus may cause gastritis, metaplasia, and dysplasia.

H. pylori is also clearly associated with the formation of gastric ulcers with a prevalence of up to 85% in obese patients.[5,8,9] International guidelines differ in their recommendations regarding the management of this infection. Nevertheless, considering *H. pylori* as a risk factor for gastric cancer and the difficult access to the excluded stomach after RYGBP, prior to surgery, bariatric patients should undergo a routine upper endoscopy in order to diagnose and treat this infection.

In postsurgery patients, urea breath tests are not reliable because there is no direct connection between the excluded stomach and the urea.[10] False negatives may be found unless there is an infection on the gastric pouch, so stool antigen detection is probably the best noninvasive diagnostic method with a sensitivity and specificity of over 90%.[1,10] However, histological confirmation is the gold standard diagnostic technique. If there is an *H. pylori* infection on the bypassed stomach, eradication therapy is mandatory. Nevertheless, there are scarce data regarding treatment success rates in these patients.

Regarding the diagnosis of gastric remnant perforation, epigastric pain is the most frequent symptom, which is sometimes associated with signs of sepsis. Free air in abdominal radiography is rare because the excluded stomach does not contain intraluminal air.[1] Therefore, negative radiological findings should not exclude the diagnosis of this entity. Furthermore, if free air is present in the radiography, a gastrogastric fistula or a jejunojejunostomy obstruction should be suspected.[11] CT scan with oral contrast is the main diagnostic method when a perforated ulcer is suspected in a patient after RYGB. The most common finding in the CT is free peritoneal fluid with an inflammatory process in the right upper quadrant. Conversely, extravasation of oral contrast and/or pneumoperitoneum are seldom-observed.[3,5]

Gastric cancer underlying the ulceration is uncommon but must also be discarded. Ulceration may be a manifestation of this entity. Therefore, histological confirmation and diagnostic visualization are mandatory. In case of gastric cancer confirmation, treatment does not differ from management in patients with prior partial gastrectomy:gastric remnant gastrectomy with D2 lymphadenectomy.[2]

To access the bypassed gastroduodenal segment, upper endoscopy is useless, so different modalities have been described. It is possible to address directly to the excluded stomach with a percutaneous approach guided by ultrasound or CT. Furthermore, a temporary gastrostomy tube can be placed. Other options are retrograde gastroduodenoscopy with a pediatric colonofibroscope and double-balloon enteroscopy. Laparoscopic-assisted transgastric remnant endoscopy is another alternative.[2,7,10]

Surgical treatment of gastric remnant perforation is usually laparoscopic repair with primary defect closure, omental patch, and drainage. However, the scarce data do not allow to make any general

recommendations. If there is an acute perforation with a small defect, the closure after biopsy is usually easy, performing a safe and short laparoscopic procedure. Besides, it is recommendable to enable a gastric remnant access in the same surgery. It is also recommendable to perform a selective vagotomy to reduce the acid production.[1] Gastric resection is sometimes executed in the second stage or when there is a large perforation or ischemia of the gastric remnant.[2] Resecting the excluded stomach may decrease the gastric acid production and avoid the formation of gastrogastric fistula.[3] However, resecting the stomach implies short-term complications such as bleeding of omental vessels, necrosis of omental fat with abscess formation, or duodenal stump leakage. Other complications such as bacterial overgrowth and vitamin B12 deficiency have also been described.[3,10]

Regarding discharge and follow-up, guidelines recommend *H. pylori* eradication when tests were positive, and recommend 1-month treatment with PPI.[1,12]

Conclusion

Bariatric and general surgeons managing RYGBP patients should not overlook gastric remnant complications in their differential diagnosis of abdominal pain. Gastric remnant perforation should be taken into account if a bariatric patient presents with severe, epigastric abdominal pain without important radiological findings. Risk factors are not clear, but *H. pylori* eradication is recommended. Laparoscopic exploration should be performed urgently because the operation time interval once the perforation has occurred is an important predictor for morbidity and mortality. Defect closure or gastric remnant resection may be performed without any general recommendations, but biopsies should be taken.

Orcid

Carlota Tuero https://orcid.org/0000-0001-8577-5603

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