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The first case of monkeypox in WHO South-East Asia Region has been reported from India in a 35-year-old man who arrived from the Middle East earlier this week. The Region has been on alert for monkeypox. Monkeypox can spread to anyone—children and adults, healthy or immunocompromised. The primary mode of transmission is skin-to-skin contact. This contact may include direct contact with monkeypox rash, scabs, or body fluids, including respiratory secretions from a person with monkeypox.

Initial symptoms of monkeypox include fever, body aches, fatigue, and sometimes enlarged lymph nodes. The disease can result in rashes that lead to red bumps on the skin that can appear on hands, feet, face, mouth, or even genitals. These rashes can transform into raised bumps or painful puss-filled red papules.

Polycymaking for the continuity of surgical care in epidemiological crises of monkeypox constitutes the most vital step. Surgical services would not support a cessation of activities, since it would not only have consequences as an increase in morbidity and mortality, but also for the national economy and the survival of the surgeon. Thankfully as a laparoscopic surgeon, chances of contamination to a surgeon is very less as interior milieu is maintained and in minimal access surgery, there is no direct contact of surgeon to patient's wound.

Therefore, it is important to carry out a rapid and effective preparation in the emergency and surgical services in the recognition of these patients, being clear about their symptoms, forms of diagnosis and therapy. Therefore, we suggest some important recommendations from admission to the emergency room, during surgery, hospitalization and hospital discharge, following the recommendations given by the WHO.



### Monkeypox surgical safety recommendations

<b>Basic Knowledge</b>		
Health personnel must know the definitions of confirmed or suspected cases according to the guidelines stipulated in each country.		
<b>MEDICAL ATTENTION</b>		
<p><i>Outpatient care or in emergency services/ preoperative:</i></p> <ol style="list-style-type: none"> <li>1. Complete medical history, looking for signs of flu or skin lesions.</li> <li>2. Timely diagnosis in the case of suspicious patients.</li> <li>3. If the patient is a confirmed case, it should be evaluated together with the surgeon to consider the relevance of the procedure.</li> <li>4. Exclusive office for the care of patients confirmed with MPX.</li> <li>5. Proper use of personal protection elements.</li> <li>6. In case the patient is not an emergency, the procedure must be monitored in-person or virtually.</li> </ol>	<p><i>Operating theaters:</i></p> <ol style="list-style-type: none"> <li>1. Only necessary personnel.</li> <li>2. Adequate use of personal protection elements.</li> <li>3. Reduction in surgical times.</li> <li>4. Minimally invasive procedures.</li> <li>5. Adequate disinfection of the surgical environment before and after the procedure.</li> </ol>	<p><i>After surgery and hospitalization:</i></p> <ol style="list-style-type: none"> <li>1. According to national and institutional health regulations, the entry of visitors will be considered.</li> <li>2. Decrease in hospital stay.</li> <li>3. Hospitalization in single-person rooms or adequate classification of patients with or without a diagnosis of MPX.</li> <li>4. Proper use of personal protection elements.</li> <li>5. Directions and recommendations for departures.</li> </ol>

Our belief is that the monkeypox outbreak should not be a cause for the closure of surgical services, as the health service has been strengthened increasing hospital capacity, intensive care unit beds, and a higher percentage of qualified health personnel, in addition to multiple laboratories available at national level with the capacity to perform molecular tests for the timely diagnosis of this disease.

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# Intraoperative Measurement of Esophageal Hiatus Normal Area Size in Patients without Hiatus Hernia or Gastroesophageal Reflux Disease

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## ABSTRACT

**Background:** Untreated gastroesophageal reflux disease (GERD) and the associated reflux esophagitis have been negatively impacting the quality of life to a great extent. Data about the normal size of the hiatus opening seems to be prophylactic against the possible anti-reflux surgery postoperative wrap herniation into the thorax that occurs as a result of inadequate crural closure or its disrupted closure. This study aimed at determination of normal size of esophageal hiatus in adults, in an attempt to improve the outcome of anti-reflux surgeries.

**Patients and methods:** This is a prospective study that was conducted on adult patients consecutively scheduled for abdominal surgery, either open or laparoscopic. Intraoperatively, a calibrated 36-French bougie with a balloon was introduced to the stomach through the mouth. The diameter of the balloon was measured when it was insufflated with the maximum volume that could pass through the hiatus.

**Results:** Esophageal hiatus area ranged from 2 cm to 6.6 cm<sup>2</sup> with a mean value of 3.8 cm<sup>2</sup>. No significant difference was found between males and females in the measured parameters ( $p > 0.05$ ). No significant correlation was found between the hiatus surface area and the patient's age, height, weight, BMI, chest circumference, or the esophageal parameters ( $p > 0.05$ ).

**Conclusion:** This study reported a new mean value of the normal hiatus surface area in order to give a hand in improving the anti-reflux surgery outcome. Further studies on a large cohort are needed to estimate normal variations in regard to age and sex to help in improvement of anti-reflux surgery outcome.

**Keywords:** Esophageal hiatus, Intraoperative, Normal size.

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## INTRODUCTION

Gastroesophageal reflux disease is a common upper gastrointestinal (GIT) disorder affecting persons at any age.<sup>1</sup> Untreated GERD and the associated reflux esophagitis have been assumed to be negatively impacting the quality of life, even more than other diseases such as hypertension and angina pectoris.<sup>2</sup>

Hiatus hernia (HH) is usually manifested by annoying symptoms, such as dysphagia, nausea, vomiting, and chest pain. It is frequently associated with worsening of the GERD, and may be complicated by gastric volvulus, which is a life-threatening condition.<sup>3</sup> Recently, HH is encountering a growing number of patients and representing a main concern of GIT surgical practices.<sup>4</sup> Laparoscopic surgery, as a choice of HH treatment has been a safe effective method for the majority of patients.<sup>5</sup> Hence, HH repair by laparoscopic surgery is now a standardized practice.<sup>3</sup>

The esophageal hiatus is a rather central opening in the diaphragm, through which the esophagus takes its course from the chest to the abdominal cavity. It is formed mainly by the right diaphragmatic crus. Variable contribution is made by the left crus.<sup>6</sup> These crura are providing anti-reflux mechanism through augmentation of the lower esophageal sphincter.<sup>7</sup>

Availability of data about the normal size of hiatus opening seems to be of great value. This would be prophylactic against the possible anti-reflux surgery postoperative wrap herniation into the thorax that occurs as a result of inadequate crural closure or its disrupted closure.<sup>8</sup> Moreover, some surgeons adopt modifying the hiatus repair technique according to the size of hiatus opening.<sup>9</sup>

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In view of the lacking knowledge about the normal measures of the hiatus, this study aimed at determination of normal size of esophageal hiatus in adults, in an attempt to improve the outcome of anti-reflux surgeries.

## PATIENTS AND METHODS

This is a prospective study that was carried out after the approval of the regional ethical committee. The study was conducted on adult patients consecutively scheduled for abdominal surgery, either open or laparoscopic, at the Surgical Department of Kasr El Ainy Hospital, in the period from October 2018 to May 2020. Patients with a history of GERD, hiatus hernia, or those with previous operations involving the esophagus, the stomach, or the hiatus were excluded from the study. One hundred and six patients were eligible for the

study. A written informed consent was obtained from each patient before starting the procedure.

The included patients underwent detailed history taking, including personal history, history for GERD symptoms, and previous medical therapy, especially anti-reflux medications, e.g., PPI, previous surgeries, and hospital admissions. Proper physical examination as regard height, weight, BMI, and chest circumference was performed.

Routine preoperative workup was conducted. Patients were instructed to fast for at least 6 hours before induction of anesthesia. The surgery team for the study was different from the surgery team for the originally indicated operation.

### Operative Technique

The patient was positioned supine on the operating table. After insufflation of the abdomen, esophageal hiatus was inspected for the presence of masses or accidentally discovered hiatus hernia. Based on this, six patients were further excluded due to the incidental detection of HH during the operation. Finally, the study included 100 patients.

A calibrated 36-french bougie with a balloon was introduced to the stomach through the mouth after being fully lubricated. In open surgery, the bougie was palpated in the stomach, while in laparoscopic surgery the bougie was seen while entering the stomach. The balloon was first insufflated near its maximum by about 30 cc of air, it was pulled out through the mouth until it hung at the cardia, and then the length of the whole esophagus was measured from the central incisors till the cardia. After that, the balloon was deflated gradually until it passed through the cardia. The bougie was then pulled till the balloon rehanged at the hiatus. The length from central incisors to the hiatus was measured. The balloon was again gradually deflated until it passed through the hiatus and the maximum volume that can pass through it was observed. Finally, the bougie was extracted out of the mouth after being completely deflated.

The length of the abdominal part of the esophagus was calculated by subtracting the length from central incisures to the hiatus and from that to the cardia.

The diameter of the balloon was measured when it was insufflated with the maximum volume that could pass through the hiatus from the formula:  $\text{volume} = 4/3\pi r^3$ , where  $\pi = 3.14$ . Based on this, the hiatus surface area was calculated from the formula:  $\text{area} = r^2 \times \pi$ .

### Study Outcomes

The primary outcome of this study was the estimation of normal values of the hiatus surface area, and the secondary outcome was to assess the possible correlations between the hiatus surface area and the patient's measured parameters.

### Statistical Analysis

All collected data were revised and then transferred to the Statistical Package of Social Science Software program (SPSS), version 22 for statistical analysis. Numerical data were presented as range, mean, and standard deviation, while categorical data were presented as frequency and percentage. Independent *t*-test, Chi-square test, or Fisher's exact test were used for comparison as appropriate. Pearson correlation test was used to analyze the association between the hiatus area and the patient's parameters. *p*-values were considered statistically significant if they were less than 0.05.

## RESULTS

This study included 100 patients, 60% of them were females. The patient's age ranged between 12 and 68 years with a mean of 40.2 years. They showed mean weight of 100.6 kg, mean height of 166 cm, and mean BMI of 36.7 kg/m<sup>2</sup>. Patients chest circumferences were ranging between 65 and 145 cm with a mean value of 107 cm. Ninety-five percent of the patients had laparoscopic operations and the remainder had open surgeries (Table 1).

The length of the esophagus from central incisors till cardia showed a mean of 35.6 cm, the length of the esophagus from central incisors till the hiatus showed a mean value of 31.4 cm, and the calculated abdominal esophagus showed a mean value of 4.2 cm (Table 2).

The area of the esophageal hiatus was found to be ranged from 2 cm<sup>2</sup> to 6.6 cm<sup>2</sup> with a mean value of 3.8 cm<sup>2</sup>.

No significant difference was found between males and females in the measured parameters (*p* > 0.05) (Table 3).

**Table 1:** Demographic and clinical data of the studied subjects and the received treatment

		All patients (n = 100)
Age (years)		
Range		12.0–68.0
Mean ± SD		40.2 ± 12.4
Gender		
Male		40 (40%)
Female		60 (60%)
Height (cm)		
Range		140.0–185.0
Mean ± SD		166.0 ± 11.0
Weight (kg)		
Range		49–200
Mean ± SD		100.6 ± 25.3
BMI (kg/m <sup>2</sup> )		
Range		19.9–67.6
Mean ± SD		36.7 ± 9.4
Chest circumference (cm)		
Range		65–145
Mean ± SD		107 ± 19.3
Type of operation		
Open	Sleeve gastrectomy	25 (25%)
	Cholecystectomy	66 (66%)
	Antral GIST	1 (1%)
	Inguinal hernia	2 (2%)
	Varicolectomy	1 (1%)
Laparoscopic	Cancer colon	3 (3%)
	Incisional hernia	2 (2%)

There was no significant correlation between the measured hiatus surface area and the patient's age, height, weight, BMI, chest circumference, or the esophageal parameters ( $p > 0.05$ ) (Table 4).

**Table 2:** Esophageal parameters of the studied subjects

All patients (n = 100)	
Length of esophagus till cardia (cm)	
Range	24.0–44.0
Mean ± SD	35.6 ± 4.2
Length of abdominal esophagus (cm)	
Range	2.0–7.0
Mean ± SD	4.2 ± 1.2
Diameter of esophageal hiatus (cm)	
Range	1.6–2.9
Mean ± SD	2.2 ± 0.3

**DISCUSSION**

The protrusion of abdominal organs into the chest cavity via the widened hiatus opening is called HH. There is still lacking in the data about the normal hiatus size. Determination of the hiatus normal size is important in calibrating to what extent the crura should be closed during the anti-reflux surgery. Knowledge of the normal anatomy of the esophageal hiatus is intimately related to the proper evaluation and management of HH and GERD.

The size of the hiatus in normal subjects is scarcely reported in the literature, no available normal values help to estimate the needed degree of crural closure and hiatus reinforcement. The few available data on the hiatus size were obtained in patients with GERD or HH or obtained from cadavers of normal subjects.<sup>7,10–13</sup> Such circumstances might render the accuracy suboptimum.

Granderath et al. study documented a method for determining the HSA approximately using surgical measurements and derived the approximate area based on geometric assumptions.<sup>12</sup> Granderath formula was later then used to estimate the approximate HSA

**Table 3:** Comparison of all parameters regarding sex

	Male	Female	p-value
Age	42.9 ± 11.9	38.4 ± 12.6	0.076
Weight	102.3 ± 33.5	99.5 ± 18.3	0.593
Height	165.9 ± 10.9	166.2 ± 11.1	0.903
BMI	37.1 ± 11.1	36.4 ± 8.2	0.734
Chest circumference	108.1 ± 21.5	106.2 ± 17.7	0.634
Length of esophagus till cardia	35.8 ± 4.4	35.5 ± 4.2	0.738
Length of esophagus till hiatus	31.4 ± 4.2	31.4 ± 4.1	0.945
Abdominal esophagus	4.3 ± 1.2	4.1 ± 1.1	0.379
Diameter of esophageal hiatus in cm	2.2 ± 0.31	2.2 ± 0.28	1
Hiatus surface area in cm <sup>2</sup>	3.8 ± 0.075	3.8 ± 0.062	1

**Table 4:** Correlations between esophageal parameters with each other and with other demographic parameters

		Length of esophagus till cardia	Length of esophagus till hiatus	Abdominal esophagus	Area of the hiatus
Length of esophagus till hiatus	r	0.962			
	p	<0.001			
Abdominal esophagus	r	0.267	0.018		
	p	0.007	0.855		
Diameter of esophageal hiatus in cm	r	0.051	0.042	0.078	
	p	0.612	0.680	0.442	
Age	r	0.008	-0.025	0.104	-0.012
	p	0.936	0.807	0.304	0.906
Weight	r	0.167	0.149	0.106	-0.100
	p	0.097	0.139	0.292	0.321
Height	r	0.786	0.739	0.293	0.119
	p	<0.001	<0.001	0.003	0.240
BMI	r	-0.206	-0.207	-0.003	-0.159
	p	0.040	0.038	0.979	0.114
Chest circumference	r	0.160	0.168	-0.006	-0.030
	p	0.112	0.095	0.954	0.770

in several studies.<sup>7,8,11,14</sup> In the study of Batirel et al., the authors calculated the HSA from an intraoperative photograph shot.<sup>15</sup> All these studies estimated the HSA in patients during surgeries for GERD or HH surgical repair. Therefore, the hiatal configuration might be distorted during the manipulation of the esophagus and stomach.

We have adopted an alternative manner to measure the surface area of the esophageal hiatus in patients without GERD or HH in an attempt to provide normal mean values of hiatus area. This was achieved via introduction of a calibrated 36-french bougie with balloon to the stomach through the mouth. The diameter of the balloon was calculated based on the maximum volume that could pass through the hiatus. Subsequently the hiatus surface area was calculated.

In our study, the mean value of hiatal surface area was 3.8 cm<sup>2</sup> ranging from 2 cm<sup>2</sup> to 6.6 cm<sup>2</sup>. Only two studies examined the values of HSA in patients having no GERD or HH could be reached. Those were the study of Shamiyeh et al.<sup>7</sup> and the study of Ouyang et al. In the former, fifty cadavers were examined in regard to the esophageal as well as the general physical measures. They reported mean esophageal hiatal surface area of 5.84 cm<sup>2</sup>.<sup>7</sup> This value is higher than that found in the current study, which may be attributed to that their study on deceased persons was affected by the redundancy of diaphragmatic muscles. In the study of Ouyang et al., the authors assessed the HSA using multiplanar CT and they reported mean HSA of 2.5 cm<sup>2</sup>. This was a simple noninvasive reproducible method for HSA measurement. Nevertheless, in view of the fact that the patient should be in full inspiration to obtain CT images, this induces contractions of the hiatus muscular margin, and makes the HSA in its smallest state.<sup>9</sup> This could explain their reported less value than that achieved in this study.

The present study showed no significant differences between both sexes concerning either of the measured patient's parameters.

In our study, the secondary outcome was the potential association of the HSA with the patient physical measures. The current study did not demonstrate any statistically significant correlation between the hiatus area and the age, height, weight, BMI, chest circumference, or esophageal measures. Also, no significant difference was noted between males and females in the HH area. In accordance with our findings, Batirel et al. also found no correlation between the hiatus surface area and BMI,<sup>15</sup> Koch et al. found no significant correlation between hiatus area and patients demographic data (age, sex, or BMI),<sup>15</sup> the same findings were reported in their later study.<sup>16</sup> Shamiyeh et al. reported no significant correlation between height, weight, BMI, gender, and the hiatal size. However, they found that the chest circumference was significantly correlated to the hiatus area.<sup>7</sup>

## STRENGTH AND LIMITATIONS

The strength of the present work is being a prospective study, adding to the very scarce evidence about the normal HSA in subjects without GERD or HH, and the use of alternative manner to assess the HSA without anatomical distortion of the hiatus opening. This study is however limited by the abdominal CO<sub>2</sub> insufflation that is required for abdominal surgeries and leads to obscuring the respiratory changes in the hiatus region, and the effect of general anesthesia on the diaphragmatic muscles.

## CONCLUSION

This study reported a new mean value of the normal hiatus surface area in order to give a hand in improving the anti-reflux surgery

outcome. Further studies on a large cohort are needed to estimate normal variations in regard to age and sex to help in improvement of anti-reflux surgery outcome.

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# Efficacy of Serious Game Training in Comparison with the Traditional Training in Learning the Laparoscopic Cholecystectomy Skills: An Interventional Analytic Study

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## ABSTRACT

**Background:** Performing a laparoscopic cholecystectomy (LC) surgery requires a high level of experience, and complementary training methods are demanded. In this study, we evaluated the efficacy of serious game LC training compared to the traditional LC training in laparoscopic cholecystectomy skills of junior residents.

**Materials and methods:** Forty-four junior residents with no history of LC performance were assigned to either the serious game training group (case group,  $n = 22$ ) or the traditional (Zollinger's Atlas of Surgical Operations) training group (control group,  $n = 22$ ). Participants were allowed to perform the operation only when they achieved a score of more than 80% in the theory checklist.

**Results:** The mean LC skills score based on the pre-surgery theory checklist was  $84.5 \pm 11.1\%$  in the case group and  $68.2 \pm 17.6\%$  in the control group ( $p = 0.021$ ). The total number of attempts needed to reach an 80% score in the theory checklist was  $2.97 \pm 1.40$  in the case and  $4.17 \pm 2.03$  in the control group ( $p = 0.001$ ). The mean operation time and the number of attempts needed to complete the operation without complications were significantly lower in the case group ( $p = 0.028$  and  $p = 0.041$ , respectively). The final skills score was  $90.8 \pm 9.2\%$  in the case group and  $80.1 \pm 14.2\%$  in the control group ( $p = 0.012$ ).

**Conclusion:** Serious game training was more effective than traditional training in all aspects of LC performance. Therefore, broader usage of the serious game for LC training is recommended.

**Keywords:** Laparoscopic cholecystectomy, Serious game, Touch Surgery™.

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## INTRODUCTION

Traditionally, surgical learning and teaching are largely based on the use of animals and cadavers. The advent of minimal invasive surgeries (MIS) has led to decreased surgical morbidity.<sup>1</sup> Meanwhile, MIS techniques are associated with an increased demand for education and training because of a very small workspace and lack of a direct view of the organs under operation.<sup>1</sup> Therefore, the development of new learning and teaching approaches are of considerable value to improve surgical skills such as eye-hand coordination in the context of MIS procedures.<sup>1</sup>

Laparoscopic cholecystectomy is a widely used MIS technique that is associated with significant improvement in patient outcomes and considerable reduction in the healthcare burden for patients with biliary tract disease.<sup>2,3</sup> Despite these advantages, similar to the other MIS techniques, LC requires a high level of experience to result in satisfactory outcomes.<sup>3</sup> Therefore, extra education of surgeons through an attractive alternative way of learning is of critical importance.

Currently, training using computer simulation, also known as virtual reality (VR) training, is widely used for laparoscopic training and has proved to be an effective tool for improving laparoscopic skills, particularly for those surgical residents who underutilize traditional simulation training.<sup>4</sup> Serious games are referred to the games with the primary purpose of teaching and learning instead of entertainment. These innovative VR training applications contain a high simulation potential for skills that are required for specific surgeries. The complex interactive context of serious games engages

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the trainees, thereby offering a challenging yet motivational opportunity to learn due skills.<sup>5</sup>

Touch Surgery™ is considered as a serious gaming mobile application designed for surgical training, and its validity for cognitive training and assessment of key LC steps has been demonstrated.<sup>6</sup> In this study, we evaluate how it affects the clinical skills of surgical assistants when compared with the traditional training modality.

**Table 1:** Comparison of the baseline characteristic features between the two study groups

Variable	Group		p-value
	Serious game LC education (n = 22)	Traditional LC education (n = 22)	
Age (year)	29.75 ± 6.11	30.46 ± 4.8	0.89
Sex			
Male	18 (81.8%)	17 (77.2%)	0.12
Female	4 (18.2%)	5 (22.8%)	
History of participation or laparoscopic surgery (number)	1.92 ± 1.2	2.21 ± 1.4	0.65
Watching training videos before surgery (min/day)	19.2 ± 8.30	21.3 ± 6.8	0.58
Experience in using computer games and educational, social networks (min/day)	43.18 ± 20.84	45.11 ± 26.11	0.54

Data are presented as mean ± SD or number (%).  $p < 0.05$  is considered significant. LC, laparoscopic cholecystectomy

## MATERIALS AND METHODS

This interventional analytical study was approved by the Review Board of our institute. Participants were general surgery residents of the two educational hospitals in their second years of clinical education. Detailed information about the study design and purpose was provided for all participants. The residents were included if they had never been in the LC operating room. The residents of one hospital were randomly assigned into the serious game LC training group ( $n = 22$ ), and the residents of the other hospital were included in the traditional LC training group ( $n = 22$ ). Group matching was performed for age, sex, last promotion score, experience in using computer games, educational social networks, and history of participation in laparoscopic surgery variables between the two groups. Normally, there was no communication between the residents of the two hospitals.

### Serious Game Design and Implication

The serious LC game was checked by nine professors of general surgery and laparoscopy and corrected according to their suggestions. Then, the game was installed on the dedicated tablets and delivered to the participants of the serious game group the day before the surgery.

### Measurements

On the day of the surgery, first, the amount of time and the number of times that the participants successfully completed all stages of the game were extracted from the game software memory and recorded in the checklist. In the next step, we asked the participants to express the steps of surgery in theory, and the result was entered in the checklist designed by the nine involved professors of general surgery and laparoscopy. This checklist was designed based on the scoring to have the necessary skills to perform different stages of surgery and included six main subheadings, including Port insertion and gallbladder exposure, Dissection of Calot's triangle, Critical view of safety, Ligation of cystic duct and artery, Gallbladder dissection, and Specimen removal and closure. According to the theory checklist, participants were allowed to perform the operation only when they achieved a score of more than 80%. Patients with uncomplicated cholelithiasis or simple biliary colic were selected based on these criteria: age: 30–45 years, BMI: 25–30, and gallstone size  $\leq 1$  cm for being operated by the residents of two studied groups.

The operation was performed under the supervision of a senior surgeon who was not informed of the assignment group

of the participants. This surgeon also scored the performance of participants, in addition to recording the duration and accuracy of performing different stages of surgery without asking for help. The performance was checked using the same checklist that was designed for checking the participants' competency to perform LC. The final scores were compared between the participants of the serious game training group and the traditional training group.

### Statistical Analysis

We used SPSS for Windows version 16 (SPSS Inc., Chicago, IL, USA) for statistical evaluations. Descriptive data were presented with the mean ± standard deviation (SD) or number and percentage. The Shapiro–Wilk test was used to evaluate the normality of distribution. A comparison of the mean difference between the two study groups was made with an independent *t*-test or its nonparametric counterpart (Mann–Whitney *U* test). Correlation between the variables was checked with a Pearson's or Spearman's correlation coefficient test. A  $p < 0.05$  was considered statistically significant.

## RESULTS

The two study groups were not significantly different in the baseline characteristic features, including age, gender, history of participation or laparoscopic surgery, and experience of using computer games and educational, and social networks (Table 1).

Laparoscopic cholecystectomy skills score based on the pre-surgery theory test was  $84.5 \pm 11.1\%$  in the serious game training group and  $68.2 \pm 17.6\%$  in the traditional training group ( $p = 0.021$ ). The total number of attempts needed to reach an 80% score in theory checklist was  $2.97 \pm 1.40$  in the serious game training group and  $4.17 \pm 2.03$  in the traditional training group ( $p = 0.001$ ). The total LC performance score for the first attempt was  $61.2 \pm 36.2\%$  in the serious game training group and  $48.37 \pm 14.5$  in the traditional training group ( $p = 0.021$ ). The mean operation time and the number of attempts needed to complete the operation without complications were significantly lower in the serious game training group ( $p = 0.028$  and  $p = 0.041$ , respectively). The final skills score was  $90.8 \pm 9.2\%$  in the serious game training group and  $80.1 \pm 14.2\%$  in the traditional training group ( $p = 0.012$ ). Comparison of clinical scores between two study groups is demonstrated in more detail in Table 2.

The mean duration of playing the game was  $62.3 \pm 41.1$  minutes. The mean obtained score was  $69.6 \pm 28.2$ . A significant positive correlation was found between the duration of playing the game

**Table 2:** Comparison of clinical scores between two study groups

Variable	Group		p-value
	Serious game LC training (n = 22)	Traditional LC training (n = 22)	
Skills score based on the pre-surgery theory test	84.5 ± 11.1	68.2 ± 17.6	0.021
Number of attempts needed to reach an 80% score	2.51 ± 1.22	4.11 ± 2.2	0.001
	2.8 ± 1.40	3.9 ± 1.9	
	3.61 ± 1.58	4.5 ± 2.01	
	2.97 ± 1.40	4.17 ± 2.03	
For the first attempt skill score	50.1 ± 16.2	43.2 ± 12.1	0.021
	66.3 ± 11.1	50.33 ± 13.5	
	67.2 ± 8.9	51.6 ± 17.6	
	61.2 ± 36.2	48.37 ± 14.5	
Speed operation time (m)	46.5 ± 10.12	63.31 ± 12.25	0.028
Number of attempts needed to complete the operation without complications	2.11 ± 0.99	2.81 ± 1.2	0.041
Final skills score gained in performing surgery	90.8 ± 9.2	80.1 ± 14.2	0.012

Data are presented as mean ± SD. *p* < 0.05 is considered significant. LC, laparoscopic cholecystectomy

**Table 3:** Correlation between the final skills score and characteristics features of the participants

Variable	Pearson correlation	p-value
Age	-0.12	0.65
Sex	0.085	0.91
History of participation in laparoscopic surgery	0.51	0.029
Experience in using computer games and educational social networks	0.11	0.59
Duration of surgery	-0.66	0.001

and the final skills score ( $r = 0.061, p = 0.001$ ), as well as between the mean obtained score and final skills score ( $r = 0.87, p = 0.001$ ). A significant negative correlation was found between the final skills score and duration of surgery ( $r = -0.66, p = 0.001$ ). The history of participation in laparoscopic surgery was also positively correlated with the final skills score ( $r = 0.51, p = 0.029$ ). The correlation of the final skills score with the characteristics features of the participants is demonstrated in more detail in Table 3.

## DISCUSSION

In this study, we compared the surgical LC skills between the residents who were trained via the serious game and those who were trained traditionally. Based on our results, the serious game training group had a higher skill score on the pre-surgical theory test, a lower number of attempts needed to reach an 80% skill score, shorter surgical duration, lower number of attempts needed to complete the operation without complications, and higher final skills score. The final skills score was significantly correlated with the duration of serious game playing and the mean obtained score.

The learning efficacy of serious games for a variety of health professions education has been evaluated in earlier studies.<sup>7-12</sup> Haoran et al. reviewed the studies evaluating the efficacy of serious game training from 1996. A total of 25 studies were included in

their review, all of which reported significant improvement in learning scores following the use of serious games. In 14 out of 18 publications with a controlled experiment, post-test scores were significantly higher after serious games training compared to the conventional teaching methods. They concluded that health professions training using serious games seems efficacious, at least in the short term.<sup>13</sup> Similarly, the surgical skill score was significantly more in the serious game training group of the present study compared with the traditional training group.

Laparoscopic procedures are acknowledged as a significant source of surgical errors, and therefore, demand special training to obtain the required experience. There is an expanding trend in studies evaluating the efficacy of serious games in laparoscopic training. Graafland et al. investigated whether serious game training improves residents' skills to solve equipment-related problems during laparoscopic surgery. Thirty-one surgical residents without laparoscopic experience were randomly assigned into either the serious game group ( $n = 16$ ) or the traditional curriculum. The laparoscopy task was performed in a pig model, during which three scenarios of standardized equipment malfunction occurred. The serious game group solved more equipment-related problems than the traditional training group (55 vs 33%).<sup>7</sup> We did not evaluate the skills of residents in solving the equipment malfunctions. However, residents of the serious game group outperformed the surgery compared to the traditional training group, which was demonstrated by a higher final skill score of LC performance.

Ijgosse et al. evaluated the construct validity of the serious game *Underground* for laparoscopic skills. The performance was compared between the novices (less than ten prior laparoscopic experiences), intermediates (10-100 prior laparoscopic experiences), and experts (>100 prior laparoscopic experiences). Prior laparoscopic experiences showed a significant effect on the time variable. The experts and intermediates outperformed novices regarding the speed task. The rate of gameplay errors showed a similar trend between different groups. Male gender and prior video game experience were associated with better performance. Accordingly, the construct validity was established for the serious game *Underground*.<sup>14</sup> In comparison with traditional

training, the serious game training group of the present study had significantly shorter operation and a lower number of attempts needed to complete the operation without complications. However, no significant correlation was found between gender and performance.

Kowalewski et al. evaluated the validity of a mobile serious game application named Touch Surgery™ for training and assessment of LC skills. Fifty-four surgeons and 51 medical students completed the study. Surgeons outperformed the medical students in all three modules, including patients' preparations, access and laparoscopy, and LC skills. All the participants agreed that the application was realistic and useful. The students took 2–4 attempts to achieve a 100% score of the serious game. They concluded that Touch Surgery™ contains acceptable construct, face, and content validity in learning cognitive LC aspects and could accompany virtual reality training in a multimodal LC training approach.<sup>6</sup> The serious game design in the present study was based on the Touch Surgery system. Similarly, we observed acceptable content validity and reliability.

The results of the present study, adjunct with the results of earlier investigations, reveal that using serious games could help the junior residents in mastering basic LC skills. However, the present study was not without limitations. The main limitation of the study was the small number of participants. The proportion of female participants was also significantly smaller than the male population. Therefore, future investigations should focus on resolving these limitations to unlock the full potential of serious games for training LC skills.

## CONCLUSION

Touch Surgery™-based serious game contain acceptable content validity in training LC skills. Compared to traditional training, it results in higher skill scores on the pre-surgical theory test, lower number of attempts needed to reach an 80% skill score, shorter surgical duration, lower number of attempts needed to complete the operation without complications, and higher final skills score. Therefore, broader usage of serious games for LC training is recommended.

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# Comparison of Different Types of Mesh in Intraperitoneal Onlay Mesh Ventral Hernia Surgery

George Chilaka Obonna<sup>1</sup>, Martin Chibuikwe Obonna<sup>2</sup>, Rajneesh K Mishra<sup>3</sup>

## ABSTRACT

A ventral hernia does occur on the anterior abdominal wall, and a substantial number are iatrogenic from surgical incisions. Surgical treatment has progressed over the decades using mesh to correct the laxity in the anterior abdominal wall. The Intraperitoneal Onlay Mesh (IPOM) method uses a mesh inserted into the peritoneal space to repair the abdominal defect. The best mesh is the ideal mesh, least associated with complications of mesh implantation such as hematoma formation, mesh failure, and discomfort to the patient.

**Materials and methods:** We evaluated patients who had IPOM in our center from January 2013 to January 2020 prospectively. Polypropylene polyvinylidene fluoride (PPV) mesh and the composite mesh were put under study. Other biological meshes have been used but not assessed. Factors assessed included intestinal obstruction, recurrence rates, and incidence of seroma. Both laparoscopic and open techniques were the procedures adopted in placing the meshes.

**Results:** We had 100 patients under study. Seventy patients presented with primary hernia, while 30 patients presented with incisional hernia. All the patients were followed up for 48 months (2 years). Forty (80%) patients in the PPV group had intestinal obstruction secondary to adhesion, while no patient in the composite group had intestinal obstruction ( $p = 0.0001$ ). No patient in the PPV group had seroma/hematoma, while 12 (24%) patients in the composite group had seroma/hematoma ( $p = 0.0001$ ). Five (10%) of patients in the PPV group had recurrence, while 15% of patients in the composite group had recurrence ( $p = 0.012$ ).

**Conclusion:** Mesh hernioplasty by IPOM is currently a procedure of choice and more preferable than ordinary suture closure of hernia. None of the mesh types are free from possible postoperative complications. A significant drawback in the use of PPV was intestinal obstruction from adhesion formation, but there was no incidence of seroma/hematoma and a much lower incidence of recurrence compared with the composite mesh. Therefore, none can be said to be superior to the other on the mesh type of choice in IPOM hernioplasty for ventral hernias.

**Keywords:** Composite, Intraperitoneal Onlay Mesh, Laparoscopy, Polypropylene polyvinylidene fluoride, Ventral hernia.

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## INTRODUCTION

A ventral (abdominal) hernia occurs when viscera projects through a gap in the wall of its containing cavity. Examples include epigastric, paraumbilical, umbilical, and iatrogenic (incisional) hernias. Ventral hernias can get larger and worsen with time. They cannot get better on their own, and surgery is the way to go by repairing them. Untreated hernias can become difficult to repair and can lead to terrible complications, such as strangulations of parts of the gut. Clinical examination or imaging can discern a ventral hernia.<sup>1</sup> Open mesh placement is an option and so is laparoscopic mesh implant, though laparoscopic repair benefits the patient more in the fact that patient leaves the hospital in time and is minimally invasive with less pain and reduced wound infection rate. Laparoscopic repair gives between 0 and 9%<sup>2,3</sup> recurrence rate, and incisional hernias complicate 2–10% of abdominal surgeries. Suture repair of ventral hernia has been shown to be associated with high recurrence rate up to 54%. This justifies the use of mesh implant. Intraperitoneal Onlay Mesh is a way of mesh placement. In the treatment of incarcerated hernia, combined open and laparoscopic approach in the hybrid IPOM plus method is relevant. In this case, the hernia orifice is sutured, and this helps in reducing the recurrence rate.

Intraperitoneal Onlay Mesh which can be by open or laparoscopic approach involves placing a mesh into the abdominal cavity to cover the hernia orifice. Operative complication rates and recurrence rates are higher in open IPOM. Thus, open IPOM without a bridging scenario will reduce the recurrence rate, since

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in this case, the hernia orifice is suture closed. What this means is that in the open technique direct closure is done after placing the mesh intraperitoneally. In the laparoscopic approach, the mesh is placed intraperitoneally, and the use of tackers or trasfascial sutures peripherally reinforces the mesh. Methods of fixation include tackers and suture glue.

Polypropylene polyvinylidene fluoride is a noncoated, 100% synthetic two-component textile structure. Composite mesh is made from a composite structure of monofilament polyester textile on one side and a hydrophilic absorbable collagen film on the other side which is the side that abuts on the viscera.

**Table 1:** Age of patients who had IPOM

	<i>N</i>	<i>Minimum</i>	<i>Maximum</i>	<i>Mean</i>	<i>Std. deviation</i>	<i>Skewness</i>	
	<i>Statistic</i>	<i>Statistic</i>	<i>Statistic</i>	<i>Statistic</i>	<i>Statistic</i>	<i>Statistic</i>	<i>Std. error</i>
Age	100	20	80	50.50	14.403	0.139	0.241
Valid N (listwise)	100						

**Table 2:** Age-group frequency

		<i>Frequency</i>	<i>Percent</i>	<i>Valid percent</i>	<i>Cumulative percent</i>
Valid	11–20	1	1.0	1.0	1.0
	21–30	5	5.0	5.0	6.0
	31–40	19	19.0	19.0	25.0
	41–50	28	28.0	28.0	53.0
	51–60	20	20.0	20.0	73.0
	61–70	15	15.0	15.0	88.0
	71–80	12	12.0	12.0	100.0
		100	100.0	100.0	

A small hernia defect is less than 4 cm. A 4–10 cm defect represents a medium hernia, while greater than 10 cm fascial defect indicates a large hernia. A high BMI is body mass index greater than 30 kg/m<sup>2</sup>.

Current concepts in mesh implants include the newer meshes: surgisis, alloderm, and proceed. Surgisis is porcine intestinal submucosa. It is a collagen biomatrix, naturally occurring and acellular with 18 months shelf life. It supports the surgical site, while the body’s natural healing process replaces the graft with new host tissue. Alloderm is biological dermal matrix from processed donated human tissue. Proceed is soft polypropylene mesh covered with polydioxanone sulfate and oxidized regenerated cellulose fabric.

**MATERIALS AND METHODS**

This study of IPOM in our hospital: the University of Medical Science Teaching Hospital and the State Specialist Hospital, Okitipupa, Ondo state, Nigeria. Data were collected and analyzed using SPSS version 22.

**RESULTS**

Analysis of data was done on demographics, and categorical data were compared using the Chi-square test. Qualitative variables were represented as percentages. *p* values of less than 0.05 were considered as statically significant.

A total of 100 patients had mesh hernioplasty by IPOM between January 2013 and January 2020.

Seventy patients (70%) presented with congenital (primary) hernia, while 30 patients (30%) presented with incisional hernia.

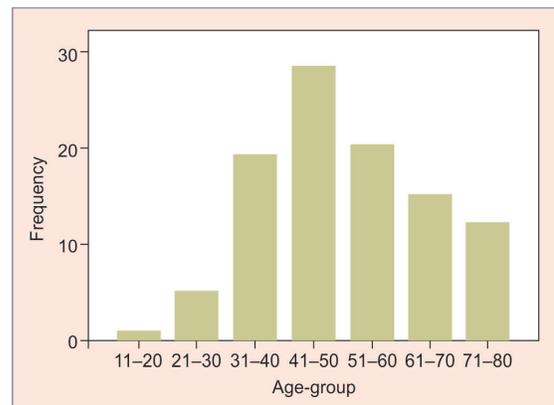
Sixty-five patients (65%) had open procedure, while 35 (35%) had laparoscopic repair.

Sixty-five patients (65%) were female, while 35 (35%) were male, giving a male to female ration 1:1.86. Twenty-eight patients (28%) were in the age range of 41–50 years, and the overall age range is 11–80 years as shown in [Figures 1 and 2](#) and [Tables 1 to 3](#).

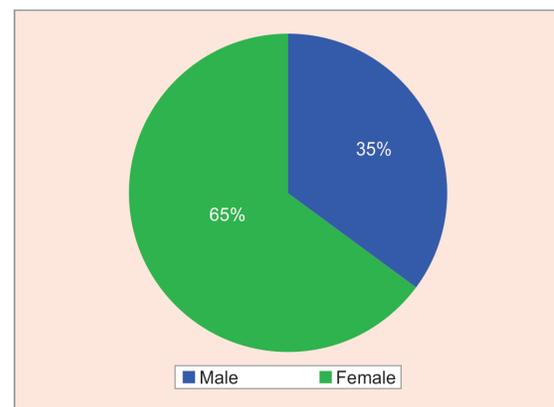
The mean age is 50.5 ± 14.4 years. The median follow-up was 48 months. Fifty patients (50%) had hernia repair using PPV, while 50 patients also (50%) had hernia repair using composite mesh.

**Table 3:** Sex distribution according to mesh used at IPOM

	<i>Male (n = 35)</i>		<i>Female (n = 65)</i>	
	<i>Mesh type</i>		<i>Mesh type</i>	
	PPV	Composite	PPV	Composite
	20	15	30	35



**Fig. 1:** Age-group frequency



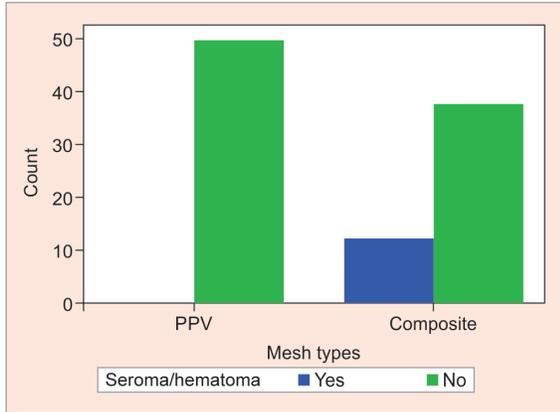
**Fig. 2:** Showing gender of patients that had IPOM

**Table 4:** Distribution of seroma/hematoma vs type of mesh used

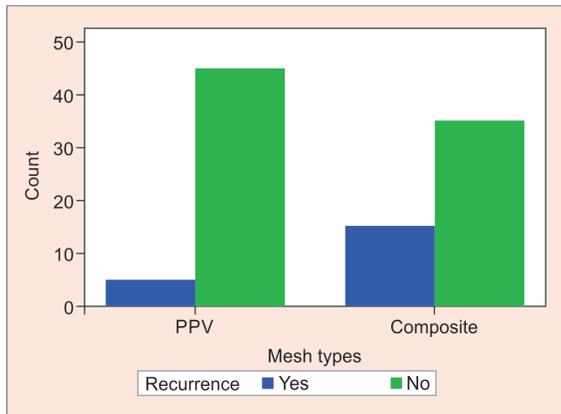
Mesh types	Seroma/hematoma		Total
	Yes (n = 12)	No (n = 88)	
PPV	0	50	50
Composite	12	38	50
Total	12	88	100

**Table 5:** Chi-square tests for seroma/hematoma

	Value	df	Asymp. sig. (two-sided)
Pearson Chi-square	13.636	1	0.000



**Fig. 3:** Frequency of seroma/hematoma

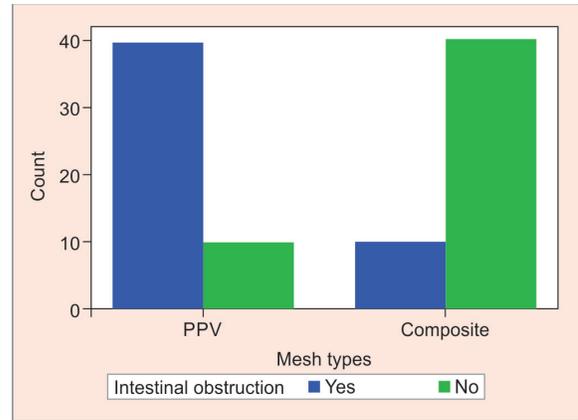


**Fig. 4:** Showing recurrence distribution

**Table 6:** Distribution of recurrence vs type of mesh used

Mesh types	Recurrence		Total
	Yes	No	
PPV	5	45	50
Composite	15	35	50
Total	20	80	100

Forty (80%) of patients in the PPV group had intestinal obstruction secondary to adhesions, while no patient in the composite group had intestinal obstruction ( $p = 0.0001$ ). No patient in the PPV group had seroma/hematoma, while 12 (24%) of patients in the composite group had seroma/hematoma ( $p = 0.0001$ ).



**Fig. 5:** Intestinal obstruction distribution

**Table 7:** Chi-square tests for recurrence

	Value	df	Asymp. sig. (two-sided)
Pearson Chi-square	6.250	1	0.012

**Table 8:** Distribution of intestinal obstruction vs type of mesh used

Mesh types	Intestinal obstruction		Total
	Yes	No	
PPV	40	10	50
Composite	10	40	50
Total	50	50	100

**Table 9:** Chi-square tests for intestinal obstruction

	Value	df	Asymp. sig. (two-sided)
Pearson Chi-square	36.000	1	0.000

Five (10%) of patients in the PPV group had recurrence while 15% of patients in the composite group had recurrence ( $p = 0.012$ ) as shown in Figures 3 to 5 and Tables 4 to 9.

For the patients who presented with intestinal obstruction, simple conservative management resolved the obstruction. An ultrasonography scan was used to confirm patients who clinically had hematoma/seroma, and this occurred in the early postoperative period and settled spontaneously in follow-up and required no further intervention. In the laparoscopic repair, mesh fixation was by the use of proTack™, while in the open repair, unobservable nylon suture was used.

There was no mortality in the study. There was no history of chest infection, peritonitis, wound infection, or sinus formation. Standard aseptic protocol and proper coverage of the patient with broad-spectrum prophylactic antibiotics were instituted in all the cases.

The average operation time was 2 hours in the open procedure and 2.5 hours in the laparoscopic procedure.

The mean duration of hospital stay was 72 hours in the open procedure and 48 hours in the laparoscopic approach.

## DISCUSSION

The introduction of polypropylene mesh repair by an usher in 1958 opened a new era of tension-free herniorrhaphy. Recurrence rates with prosthetic mesh decreased to 10–20%. Subsequently, it was

realized that the placement and fixation of the mesh were more crucial in determining the outcome of the repairs.

The placement of the mesh in the preperitoneal, retromuscular position with a wide overlap of at least 5 cm over hernia defect in all directions was introduced in the late 1980s. The extensive dissection in open procedure accounted for most of its complications

Omphalocele, gastroschisis, and divarication of rectus abdominis account for a congenital visceral hernia. Latrogenic factor accounts for incisional hernias. The faulty technique of closing the 10 mm port after surgery can also account for incisional hernias. Systemic and other comorbid conditions can also account for the development of incisional hernia such as cough, steroid intake, wound infection, cancer, morbid obesity, nutritional imbalance, and wound infection. These reduce collagen synthesis and wound healing.

Other factors include duration of the operation, crossing incisions, ineffective wound drainage, and excessive wound tension. Two other important variables include nutritional aspects as well as the presence of cancer<sup>4</sup> which overall reduces the ability for wound healing and collagen deposition in the wound. Three to thirteen percent of laparotomy patients develop incisional hernias. Multiple defects (Swiss cheese hernias) are best done by laparoscopy as all defects unlike in the open approach get directly visualized and appropriately covered by a single mesh.

Contraindication of laparoscopic repair of ventral hernia is very large hernia with huge protrusion of skin which is thin enough, and skin fold is necessary to correct by abdominoplasty. Dense intra-abdominal adhesions are also a relative contraindication of laparoscopic repair of ventral hernia.

Clinical evidence suggests that omental adhesion is common, but bowel adhesion is not common and as such usage of PPV is safe.<sup>5</sup>

Incisional hernias mostly become clinically manifest between 2 and 5 years after surgery, and studies have shown that the process starts within the first postoperative month. They are said to occur as a result of the biochemical failure of the acute fascial wound coupled with clinically relevant impediments to acute tissue repair and normal support function of the abdominal wall. Our findings suggest that there were related complications with the use of both meshes.

In our series, PPV was associated with a significant incidence of bowel obstruction caused by adhesion and this has been proven histologically.<sup>6</sup> Various experimental modes and studies suggest decreased adhesion formation with the use of composite mesh<sup>7-11</sup> with most questioning that coated meshes perform better with less adhesion formation. There may be individual idiosyncrasies to these meshes. However, more work has to be done to elucidate these variations. A higher rate of seroma/hematoma formation 24% was noted in the composite group in our study. Coated meshes that are commonly used in intraperitoneal mesh repairs are typically associated with seroma formation because of the resulting impaired drainage of fluid due to the barrier coating. There may be other contributing factors such as the number and size of the defects, the difficulty of dissection, mesh fixation technique, and operation time.

Titanium-coated lightweight mesh versus standard composite mesh comparison showed no differences in recurrence rate but a lower incidence of pain-related complications in the titanium-coated mesh group.<sup>12</sup>

In our study, a significant recurrence rate of 15% was noted in the composite mesh group as compared to 10% in the PPV group.

Comparable single-institution case series and one multicenter randomized study reported recurrence rates as low as 0–2.5%.<sup>13-17</sup>

Our study showed no significant relation between mesh fixation by use of suture passer with transfascial sutures and nonabsorbable tackers and recurrence of the hernia, which is consistent with the existing literature.<sup>14,15</sup> There has been a recent focus on the use of glue for mesh fixation, particularly in areas such as the subcostal margins and close to the xiphisternum and pelvis. Other studies have emphasized that mesh fixation using fibrin glue in patients with a ventral hernia is associated with less postoperative pain.<sup>18-20</sup>

## CONCLUSION

Intraperitoneal Onlay Mesh is an acceptable technique. In our study, even though PPV is shown to be associated with a significantly higher incidence of adhesion-related intestinal obstruction, it is still feasible to use because intestinal obstruction resulting from its usage easily gets relieved by simple conservative treatment as can be seen in our cases. Also, this study will further promote its usage as can be seen in the lower incidence of recurrence, seroma, and hematoma formation as compared to the composite mesh and also for the fact that it is cheaper than composite mesh. The composite mesh, however, can equally be used if the patients can afford it, especially in a resource-poor setting such as ours. However, for the newer meshes such as proceed and the biological meshes (surgisis and alloderm), more studies should be done.

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# Comparative Study of the Effect of Various Bariatric Surgery Methods on Liver Enzymes and Grading of Nonalcoholic Fatty Liver Based on Ultrasound Scans in Children and Adults

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## ABSTRACT

**Introduction:** Bariatric surgery is one of the most effective treatments for patients with morbid obesity. Rapid weight loss can accelerate the process of fibrosis, and weight loss alone can improve the process of steatohepatitis. The conflict has confused the effect of these surgeries on the severity of the fatty liver disease. This retrospective study aimed to compare the effects of different types of bariatric surgery on the grading and severity of the nonalcoholic fatty liver disease (NAFLD).

**Materials and methods:** Using the National Obesity Surgery Database, data were extracted from 900 patients with a body mass index (BMI) above 35 who underwent sleeve, classic bypass, or mini-bypass surgery or who did not undergo surgery for any reason. Body mass index, aspartate transaminase (AST), alanine transaminase (ALT), NAFLD fibrosis score, and liver ultrasound were evaluated before and after surgery in four different groups.

**Results:** All three surgical procedures effectively reduced BMI. Among the various surgical procedures, the rate of BMI reduction was significantly higher in the mini-gastric bypass procedure than in the other two methods. The reduction of AST and ALT was significant in all three surgical methods compared to the nonsurgical group, with the highest reduction in sleeve surgery. Fatty liver based on ultrasound in the nonsurgical group in the second time got worse but improved significantly in all the operated groups, and all these changes including the development of fatty liver in the nonsurgical group and its improvement in the operated groups were significant ( $p < 0.05$ ) and NAFLD fibrosis score (NFS) decreased in all groups. This reduction was small and insignificant for the nonsurgical group while it was significant in the three operated groups.

**Keywords:** Bariatric surgery, Fatty liver, Liver function test, Nonalcoholic fatty liver disease, Radiologic information, Sonography.

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## INTRODUCTION

Given the increasing prevalence of the Western lifestyle, and its significant complications such as diabetes, metabolic syndrome, and obesity, mortality due to the complications of these diseases constitute a major share of the causes of overall mortality.<sup>1</sup> Obviously, many of these complications can be prevented by early diagnosis and current effective treatments, as well as the development of preventive approaches. Along with the increasing prevalence of obesity, the related diseases also find a special place.<sup>2</sup> With a prevalence of about 30% in the general population and about 90% in obese individuals, NAFLD seems to be the most common cause of cirrhosis and liver transplantation.<sup>3</sup> Obesity surgery, the most effective and lasting method in weight loss, is currently considered an effective method in improving the complications of obesity, including metabolic syndrome and NAFLD.<sup>4</sup> Bariatric surgery methods are among relatively new treatment methods for patients with morbid obesity.<sup>5</sup> Despite their relatively short lifespan, such surgeries have been able to gain a prominent place among the available treatments. However, due to the lack of long-term studies, the complications of these surgeries are not yet fully understood.<sup>6</sup> Rapid weight loss, which is one of the known complications of such surgeries, can increase fibrosis in these patients; on the other hand, weight loss alone can improve steatohepatitis in obese patients. This conflict has confused the effect of bariatric surgery on the incidence and severity of fatty liver disease.<sup>7</sup> Many studies have been performed on the effects of some bariatric surgery methods on liver enzymes, liver steatosis, and pathological findings of non-alcoholic steatohepatitis (NASH), while some other methods such as mini-gastric bypass have received very

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little attention.<sup>7</sup> Fewer studies have been performed on the effects of bariatric surgery, imaging findings and fibrosis based on non-invasive

indicators. Among the studies, the insufficient number of RCTs plays an important role in the lack of strong expression of the effects of obesity surgery as the treatment of choice for NAFLD.

Non-alcoholic fatty liver disease includes a range of diseases that include simple accumulation of fat in the liver (steatosis without evidence of inflammation and cell damage) known as non-alcoholic fatty liver, NASH (evidence of inflammation and cell damage in the liver), and finally cirrhosis.<sup>3</sup> According to global studies, the prevalence is 25–33%, which varies in different populations. The prevalence of fatty liver in diabetic patients is 75% and in patients with morbid obesity is 90–95%.<sup>8</sup> One of the primary imaging procedures for diagnosing liver steatosis is ultrasound scan. Ultrasound scan measures the echogenicity of the liver compared to the spleen and kidneys such that increased liver echogenicity indicates fatty liver. Ultrasound scan sensitivity is reported to be about 60–94%, and specificity is 84–95%, which increases with increasing liver fat.<sup>9</sup> The NAFLD fibrosis score is one of the most widely used non-invasive indicators for assessing liver status in this disease.<sup>10</sup>

Six variables are used in calculating NFS: Age, BMI, hyperglycemia [impaired fasting glucose (IFG) or diabetes mellitus (DM)], platelet count, albumin, and AST/ALT ratio. These variables are entered into the following formula:

$$\text{NFS} = -1.675 + 0.037 (\text{Age in year}) + 0.094 \times \text{BMI (kg/m}^2) + 1.13 \times \text{IFG or DM: yes} = 0, \text{ No} = 1 + 0.99 \text{ASTALT} - 0.013 (\text{Platelet count}) 109 \text{L} \times -0.66 \times \text{Alb (gm/dL)}$$

The result is categorized as follows:  $-1.5 > \text{NFS}$  indicates the absence of fibrosis (low probability) and (high probability)  $\text{NFS} > 0.67$  indicates advanced fibrosis and NFS between  $-1.4$  and  $0.66$  indicates intermediate fibrosis.<sup>10</sup>

Also, the existence of few studies showing an increase in fibrosis after bariatric surgery requires further research. Moreover, the insufficient research on comparing different types of bariatric surgery methods and their effects on NAFLD and comparing them with the nonsurgical method became a double motivation that due to the existence of a robust database in this field—optional and comprehensive of various dimensions of NAFLD. In this study, an attempt was made to remove the limitations of previous studies, such as low sample size and one-dimensional NAFLD study as much as possible. In this research project, we decided to compare the effects of different types of bariatric surgeries on the grading and severity of NAFLD and NASH in a retrospective descriptive study.

Some prospective studies have suggested the possibility of increased liver fibrosis after bariatric surgery.<sup>11</sup> A study conducted by Ooi et al. in 2016 on 84 patients with NAFLD showed that the fatty liver in these patients improved shortly after surgery, and weight loss decreased by 10–15%—becomes significant in ALT levels.<sup>12</sup>

A 2010 review published by Chavez–Tapia et al. reported that no clinical trials had been conducted on the effects of bariatric surgery on NAFLD in obese patients. They reported only 21 retrospective and prospective studies in which the severity of steatosis and inflammation improved, and four studies that showed an increase in postoperative fibrosis.<sup>7</sup>

A large 2010 study by Karcz et al. on 236 patients who underwent laparoscopic sleeve surgery and were followed for 3 years showed that, first, there was a strong association between high levels of transaminases and NASH based on the pathologic diagnosis. Among patients with NASH, liver enzymes decreased by more than 50%.<sup>13</sup>

According to Harrison's internal medicine textbook, most studies report obesity surgery to improve hepatic steatosis as

well as necrosis and inflammation of the liver, but there are variable results about its effect on the rate of liver fibrosis. Kafi has not recommended obesity surgery as a primary treatment for fatty liver.<sup>14</sup>

In the first phase of a study by Aldoheyan et al. published in March 2017, it states that fibrosis, steatosis, and NASH improved in varying degrees at the end of 3 months in 27 patients undergoing obesity surgery.<sup>15</sup>

Furthermore, few studies compared the effects of various surgical procedures on liver and LFT tests. For example, a study by Kalinowski et al. in 2017 found that LFT worsens shortly after Roux-en-Y gastric bypass (RYGB) surgery and returns to baseline after 1 year and that this increase in liver tests after sleeve surgery is less.<sup>16</sup>

There are a number of separate surgical procedures in this area. For example, a study conducted in 2017 by Ruiz–Tovar J et al. showed that liver steatosis assessed by ultrasound showed 90% complete recovery after sleeve surgery.<sup>17</sup>

Another study by Manco et al. in 2017 showed that sleeve surgery was able to eliminate NASH in all patients in general. It also reversed stage 2 fibrosis in 90% of patients. They lost significantly less weight using a gastric balloon, and it was almost insignificant in people who lost weight by nonsurgical methods.<sup>18</sup>

In a study on 40 patients by Nascimento et al. in 2015, it was found that the degree of liver fibrosis measured by the NFS ranged 0–7.1% in patients undergoing surgery in private centers and in patients undergoing surgery. Surgery in government centers decreased from 30.8 to 23%.<sup>19</sup>

In a 2017 review by Keneally S et al. eight RCTs examining the combined effects of diet and exercise showed improved NAFLD activity based on pathology, BMI and liver enzymes, particularly ALT.<sup>20</sup>

Among the few studies with different results, there is a 2004 study by Kral et al. on 104 patients who underwent BPD surgery. According to this study, severe fibrosis decreased in 27% of patients after surgery, but mild fibrosis appeared in 40% of patients after surgery.<sup>21</sup>

Few studies have examined imaging findings, among which is a study by Major et al. in 2017 on 20 patients. In this study, ultrasound findings and liver enzymes were evaluated before and 12 months after surgery. It was found that the amount of fatty liver decreased after surgery compared to before, based on ultrasound findings using the Sheriff–Saadeh criterion. The ALT also changed from 64.5 to 27.95 and the AST from 54.4 to 27.2.<sup>22</sup>

Few studies have compared the effects of different surgical procedures on NAFLD. Among them is a 2016 study by Nickel et al. on 100 patients who underwent classic sleeve and bypass surgery. This study compared non-invasive factors of liver fibrosis including NFS and showed that this index decreases significantly after surgery. Furthermore, they mentioned this reduction is higher after classical bypass surgery than that after sleeve surgery, although the difference disappeared 18 months after surgery.<sup>23</sup>

## MATERIALS AND METHODS

This study was performed using the Iranian National Obesity Surgery Database ([www.obesitysurgery.ir](http://www.obesitysurgery.ir)) (INOSD). Iranian National Obesity Surgery Database includes a computerized medical record of obese patients. This database provides detailed information on demographics, prescribed drugs, clinical events, professional referrals, and hospital admissions. This study was a retrospective cohort in the period 2010–2017, and the study population was obese patients who had undergone obstructive surgeries or were not surgically diagnosed for various reasons. Inclusion criteria were

patients undergoing one of the following surgeries: classical bypass, sleeve, and gastric bypasses with anastomosis, or not undergoing surgery for any reason and receiving diet and exercise regimen for weight loss despite the indication for surgery. Exclusion criteria included alcohol intake or consumption of one of the drugs, including amiodarone, methotrexate, tamoxifen, prednisolone, dexamethasone, haloperidol, chlorpromazine, fluphenazine, perphenazine, terclooperazine, aripiprazole, clozapine, olanzapine, quithiazin, risperidone at any time before surgery, or being suspected of autoimmune hepatitis, viral hepatitis, Wilson’s disease, or hemochromatosis.

Data from each patient, including age, sex, BMI, type of surgery, presence or absence of IFG or diabetes, laboratory parameters (AST, ALT, AIP, Alb, Plt), and liver ultrasound, preoperative and 6 months after the operation were obtained from the above-mentioned database.

After examining the patients, 900 patients were finally enrolled in the study, 750 of whom underwent surgery with three surgical ways, and 150 received diet and exercise recommendations. Then, the patients were divided into four groups: classical bypass surgery group, sleeve surgery group, gastric bypass surgery with anastomosis group, and nonsurgical group. In each group, age, sex, BMI, AST, ALT, fatty liver grade, and NFS were evaluated before and 6 months after the intervention. The NFS was calculated to predict the presence or absence of advanced fibrosis in patients with NAFLD according to the following formula, where  $-1.455 > \text{NFS}$  indicates a lack of fibrosis, and  $\text{NFS} > 0.676$  represents advanced fibrosis.<sup>1</sup>

$$\text{NFS} = -1.675 + 0.037 (\text{Age in year}) + 0.094 \times \text{BMI} (\text{kg/m}^2) + 1.13 \times \text{IFG or DM: yes} = 0, \text{ No} = 1 + 0.99\text{ASTALT} - 0.013 \text{Platelet count } 109 \text{ L} \times -0.66 \times \text{Alb} (\text{gm/dL})$$

The Shapiro–Wilk test was used to check the normality of the data. Continuous variables are described as mean  $\pm$  standard deviation (SD) and categorical variables by frequency and percentage. Normal continuous variables were analyzed with *t*-test, non-normal continuous variables were analyzed with Wilcoxon signed ranks test and Kruskal–Wallis test. Random variables were analyzed with Pearson’s Chi-squared test. The significance level was set at  $p < 0.05$  and SPSS, version 23, was used for statistical analyses.

## RESULT

A total of 1,000 patients were enrolled in the study, with 250 patients in the control group (nonsurgical), 250 patients in the gastric sleeve surgical group, 250 patients in the mini-gastric bypass group, and 250 patients in the RY surgical group.

The frequency of males and females in different groups is shown in Figures 1 to 8. Chi-squared test showed a significantly higher proportion of female patients in all groups ( $p < 0.001$ ). The frequency of female gender in patients in the control group (nonsurgical), gastric sleeve surgery, mini-gastric bypass surgery, and RY gastric bypass surgery were 77.1, 80.2, 80.5, and 91.2%, respectively. According to the Kolmogorov–Smirnov test, age had a normal distribution in all four groups ( $p > 0.05$ ). The results of the analysis of variance (ANOVA) test showed a significant difference in the mean age of patients in different groups ( $p < 0.001$ ). The lowest mean age was observed in the gastric sleeve surgery group with a mean of 23.62 years, and the highest mean age was observed in the mini-gastric bypass group with 23.9 years.

According to the Kolmogorov–Smirnov test, BMI had a normal distribution in all four groups ( $p > 0.05$ ). The results of ANOVA test

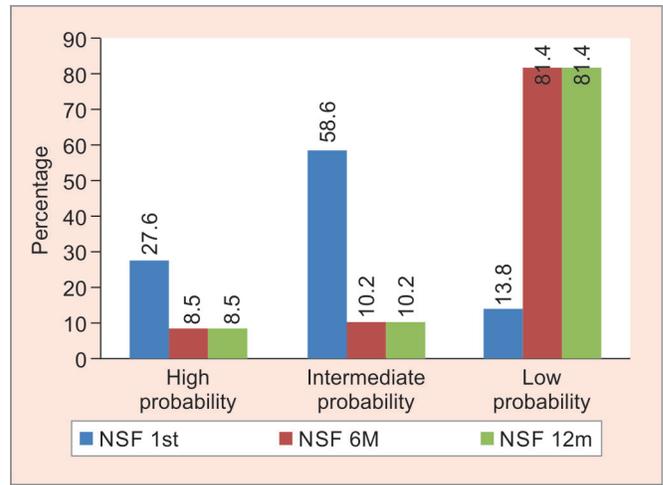


Fig. 1: Comparison of mean NSF score in the gastric sleeve group during follow-up

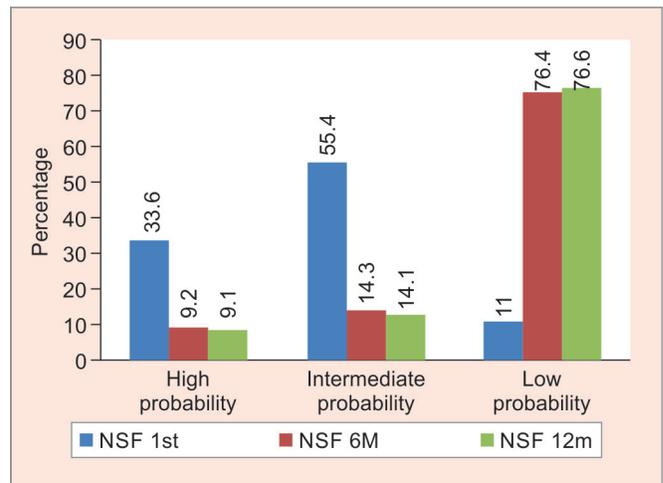


Fig. 2: Comparison of mean NSF score in mini-gastric bypass group during follow-up

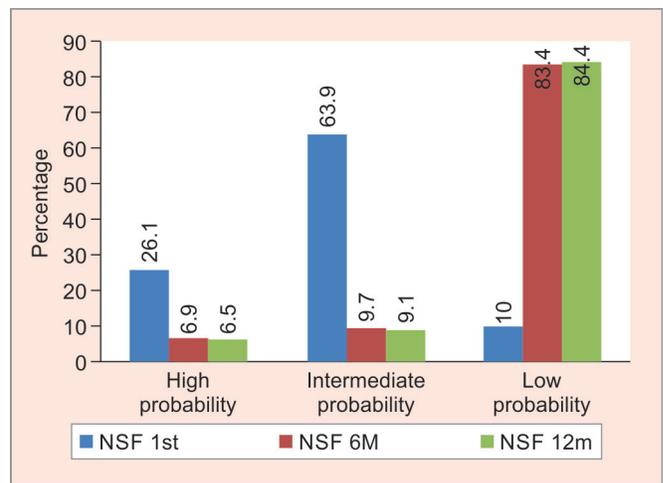


Fig. 3: Comparison of mean NSF score in RY gastric bypass group during follow-up



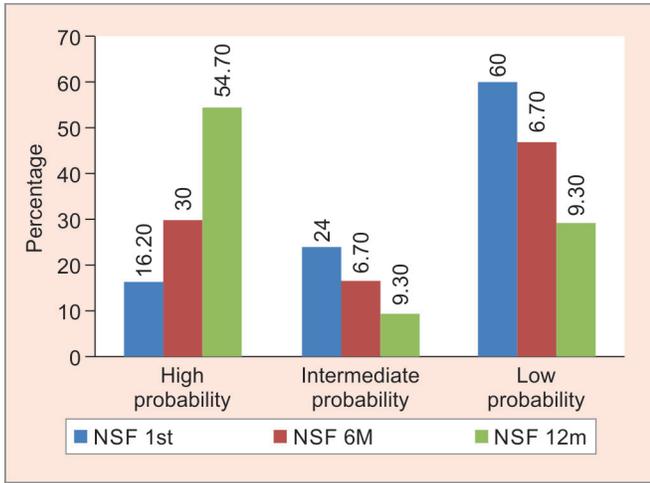


Fig. 4: Comparison of mean NSF score in control group during follow-up

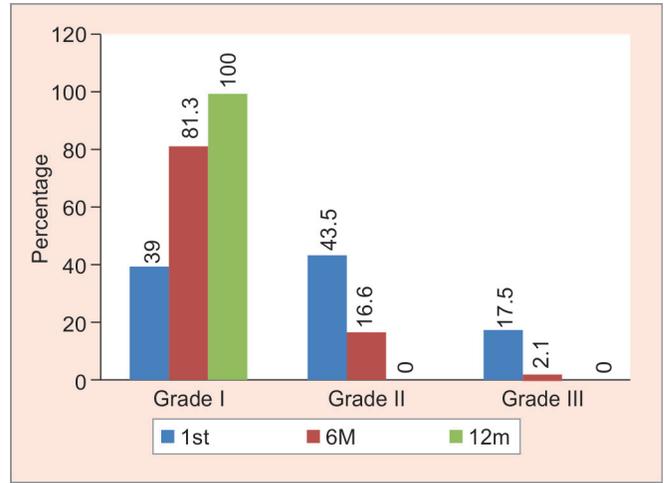


Fig. 7: Comparison of the frequency of fatty liver grade in the RY gastric bypass group during follow-up

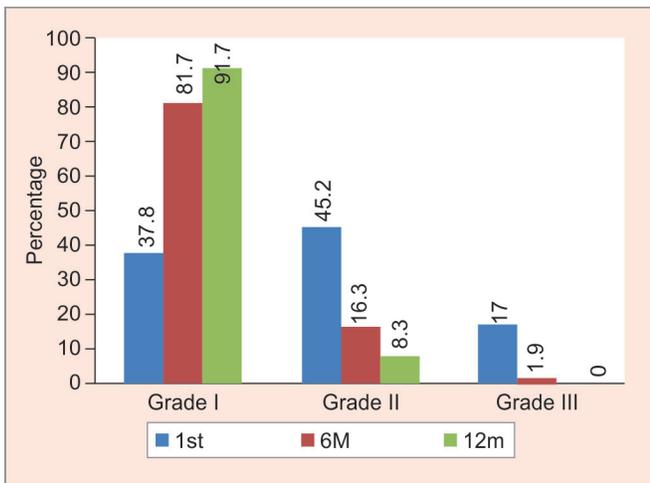


Fig. 5: Comparison of the frequency of fatty liver grade in the gastric sleeve group during follow-up

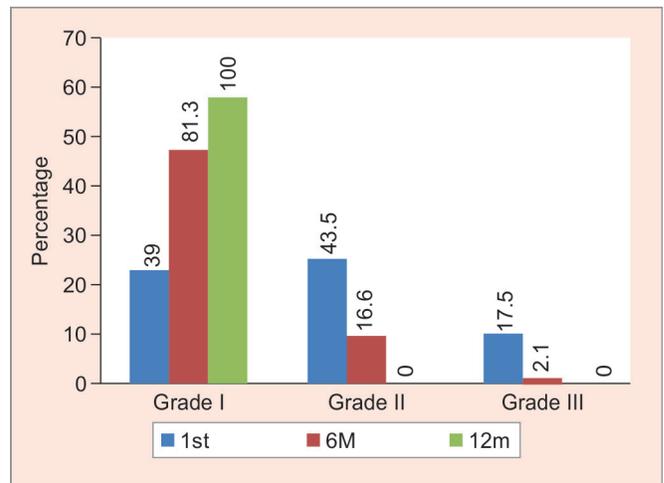


Fig. 8: Comparison of the frequency of fatty liver grade in the control group during follow-up

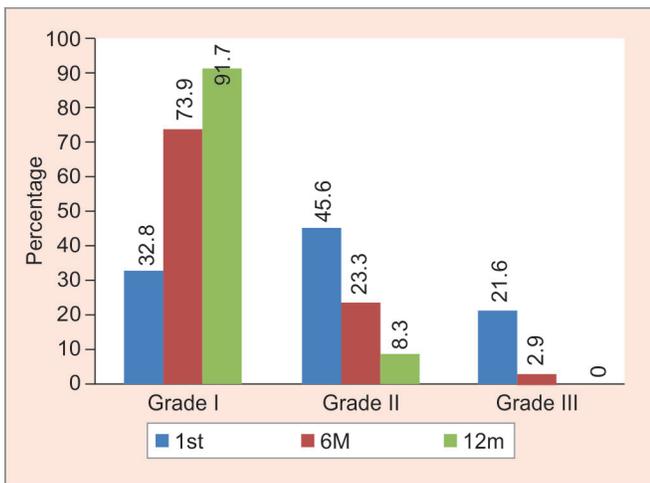


Fig. 6: Comparison of the frequency of fatty liver grade in the mini-gastric bypass group during follow-up

showed a significant difference in the mean BMI of patients in different groups before and after surgery ( $p < 0.001$ ). The mean BMI of patients in all three groups decreased significantly 12 months after surgery compared to before surgery ( $p < 0.001$ ). The percentage of decrease in patients' BMI from before surgery to 12 months after surgery was 33.53, 34.95, and 32.77% in the gastric sleeve, mini-gastric bypass, and RY gastric bypass groups, respectively. However, in the nonsurgical group, the baseline BMI increased by 6.20% until 12 months later. Therefore, the highest decrease in patients' BMI was observed in the mini-gastric bypass group with 34.95%.

According to the Kolmogorov–Smirnov test, AST had a normal distribution in all four groups ( $p > 0.05$ ). The results of ANOVA test showed a significant difference in the mean AST of patients in different groups before and after surgery. The mean AST of patients in all three groups had an insignificant decrease 12 months after surgery compared to before surgery. The percentage of reduction in AST of patients from 12 months after surgery compared to before surgery was 8.69, 2.24, and 0.81% in gastric sleeve, mini-gastric bypass, and RY gastric bypass groups, respectively. However, in the

nonsurgical group, baseline AST levels increased up to 36.20%, 12 months after surgery. Therefore, the highest decrease in patients' AST was observed in the gastric sleeve group with 34.95%.

According to Kolmogorov–Smirnov test, ALT had a normal distribution in all four groups ( $p > 0.05$ ). The results of ANOVA test showed a significant difference in the mean ALT of patients in different groups before and after surgery. Mean ALT in patients significantly decreased from 19.58 to 18.9% in the gastric sleeve group 12 months after surgery compared to before surgery ( $p = 0.017$ ). The percentage of ALT reduction was 19.58, 18.9 in patients 12 months after surgery compared to before surgery in the gastric sleeve and mini-gastric bypass groups, respectively. The ALT levels in patients receiving RY gastric bypass surgery decreased by 15.18%, 12 months after surgery compared to before surgery. However, in the nonsurgical group, baseline ALT levels increased up to 12.51%, 12 months after surgery compared to before surgery. Therefore, the highest decrease in patients' AST was observed in the gastric sleeve group with 19.58%.

Chi-squared test showed that gastric sleeve surgery significantly reduced NSF score 12 months after surgery compared to before surgery. While 27.6% of patients in this group were considered high-risk, 12 months after surgery, the percentage of these people decreased to 13.8%. In other words, it reduced 13.8% of high-risk patients with NSF (or NSF above 0.67). On the other hand, the rate of patients with low-risk or NSF below  $-1.5$  after 6 months and 12 months of gastric sleeve surgery increased from 13.8 to 81.4%. In other words, it resulted in an increase of 67.6% of patients with NSF in the low-risk or normal range.

Chi-squared test showed that mini-gastric bypass surgery significantly reduced the NSF score 12 months after surgery compared to before. While 33.6% of patients in this group were considered high-risk at the beginning of the study, this percentage decreased to 9.1%, 12 months after surgery. In other words, it resulted in a 24.5% reduction in patients with NSF in the high-risk range (or NSF above 0.67). On the other hand, the rate of patients with low-risk or NSF lower than  $-1.5$ , 12 months after mini-gastric bypass surgery increased from 11.0% at the beginning of the study to 76.6%. In other words, it resulted in a 65% increase in patients with NSF in the low-risk or normal range.

Chi-square test showed that RY gastric bypass surgery significantly reduced the NSF score 12 months after surgery compared to before. While 26.1% of patients in this group were considered high-risk at the beginning of the study, this percentage decreased to 6.5%, 12 months after surgery. In other words, it reduced 19.6% of patients with NSF in the high-risk range (or NSF above 0.67). On the other hand, the rate of patients with low-risk or NSF below  $-1.5$  after 12 months of RY gastric bypass surgery increased from 10.0% at the beginning of the study to 84.4%. In other words, it resulted in an increase of 74.4% of patients with NSF in the low-risk or normal range.

The Chi-squared test showed that a significant increase was observed in the percentage of high-risk patients during follow-up. While 16.2% of patients in this group were considered high-risk at the beginning of the study, 12 months after surgery, this percentage increased to 54.7%. In other words, it increased 38.5% of patients with NSF in the high-risk range (or NSF above 0.67). On the other hand, the rate of patients with low-risk or NSF below  $-1.5$  decreased from 24.0% at the beginning of the study to 9.3% after 12 months. In other words, it resulted in a reduction of 14.7% of patients with NSF in the low-risk or normal range.

The Chi-squared test showed that mini-gastric bypass surgery significantly reduced grade III fatty liver 12 months after surgery compared to before. While 21.6% of patients in this group had grade III fatty liver, 12 months after surgery, the percentage of these patients decreased to zero. In other words, it led to a 21.6% reduction in patients with grade III fatty liver. On the other hand, the rate of patients with low-risk or grade I fatty liver increased from 32.8 to 91.2%, 12 months after mini-gastric bypass surgery. In other words, it increased 58.4% of patients with grade I fatty liver.

The Chi-squared test showed that RY gastric bypass surgery significantly reduced grade III fatty liver 12 months after surgery compared to before. While 17.5% of patients in this group had grade III fatty liver, 12 months after surgery, this percentage decreased to zero. In other words, it reduced 17.5% of patients with grade III fatty liver. On the other hand, the rate of patients with low-risk or grade I fatty liver increased from 39.8 to 100.0%, 12 months after RY gastric bypass surgery. In other words, it increased 61.0% of patients with grade I fatty liver.

While 16.9% of patients in this group had grade III fatty liver at the beginning of the study, 12 months later the percentage increased to 58%. In other words, it led to an increase of 41.1% in patients with grade III fatty liver. On the other hand, the rate of patients with low-risk or grade I fatty liver decreased from 34.9 to 12.7% after 12 months. In other words, it resulted in a reduction of 22.0% of patients with grade I fatty liver in this group.

## DISCUSSION

Since NAFLD is the most common chronic liver disease, proper treatment can prevent its complications, such as cirrhosis or liver fibrosis. Although diet, exercise, and weight loss are the main treatment options for NAFLD, diet and exercise for weight loss in patients with morbid obesity have little success. For this reason, today, a variety of surgical methods for weight loss and thus prevention of liver complications is being studied. Therefore, further studies are necessary because few studies have been conducted on the effect of obesity surgery as the most effective and lasting method of weight loss in these patients on the improvement of NAFLD, and research suggests increased liver fibrosis after obesity surgery. The background shows there are no significant studies comparing the effects of different types of obesity surgery on fatty liver. Therefore, we examined the effect of three types of obesity surgery methods (including gastric sleeve, mini-gastric bypass, and RY gastric bypass) on liver enzymes and grading of NAFLD based on ultrasound in 900 adult and pediatric patients. In this study, most patients in all four groups were of female gender. The patients underwent follow-up at the beginning of the study and then 6 and 12 months after surgery. The results of our study showed that all three types of surgery had a significant effect on BMI reduction 6 and 12 months after the surgery, such that the rate of BMI reduction in patients were 33.53%, 34.95%, and 32.77%, respectively, in gastric groups sleeve, mini-gastric bypass and RY gastric bypass 12 months after surgery compared to before. Therefore, the highest decrease in patients' BMI was observed in the mini-gastric bypass group with 34.95%. Conversely, in the control group, a 6.2% increase in patients' BMI was observed 12 months after follow-up. These results indicated that all three of these surgeries had a significant effect on reducing the BMI of obese patients.

The results of our study also showed that all three types of surgery significantly reduced AST and ALT enzymes 6 and

**Table 1:** Comparison of liver fibrosis scores in different groups before surgery

NFS		Groups				p
		Control	Gastric sleeve	Mini-gastric bypass	RY gastric bypass	
High probability	High probability	24 16.2%	69 27.6%	84 33.6%	65 26.1%	<0.001
NSF1 low probability	Low probability	36 23.8%	34 13.8%	27 11.0%	25 0.0%	
Intermediate probability	Intermediate probability	90 60.0%	147 58.6%	139 55.4%	160 63.9%	

**Table 2:** Comparison of liver fibrosis scores in different groups 12 months after surgery

NFS		Groups				p
		Control	Gastric sleeve	Mini-gastric bypass	RY gastric bypass	
NSF3 High probability	High probability	82 54.7%	21 8.5%	24 9.1%	16 6.5%	<0.001
Low probability	Low probability	14 9.3%	204 81.4%	192 76.6%	211 84.4%	
Intermediate probability	Intermediate probability	44 29.3%	25 10.2%	35 14.1%	23 9.1%	

12 months after surgery, such that the rate of AST reduction in patients was 8.69, 2.24, and 0.81%, respectively, in the gastric sleeve, mini-gastric bypass, and RY gastric bypass groups 12 months after surgery compared to before. Therefore, the highest decrease in patients' AST was observed in the gastric sleeve group with 8.69%. Conversely, in the control group, a 36.2% increase was observed in patients' AST 12 months after surgery. Also, the rate of ALT reduction in patients was equal to 19.58, 18.9, and 15.18%, respectively, in the gastric sleeve, mini-gastric bypass, and RY gastric bypass groups 12 months after surgery compared to before. Therefore, the highest decrease in ALT of patients was observed in the gastric sleeve group with 19.58%. Conversely, in the control group, a 15.51% increase in patients' AST was observed 12 months after surgery. Therefore, these results indicate that performing all three types of surgeries, especially sleeve surgery, plays an important role in reducing AST and ALT in obese patients.

In this study, liver fibrosis status was one of the factors that were evaluated in patients of all four groups at baseline and 6 and 12 months after surgery. Our results showed that all three types of surgery significantly reduced the risk of liver fibrosis during 6- and 12-months follow-up, such that the rate of reduction of high-risk NSF (or NSF above 0.67) of patients was 13.8, 24.5, and 19.6%, respectively, in the gastric sleeve, mini-gastric bypass, and RY gastric bypass groups 12 months after surgery compared to before. On the other hand, the increase in patients with low-risk or NSF below -1.5 was 67.6, 65.0, and 74.4%, respectively, in the gastric sleeve, mini-gastric bypass, and RY gastric bypass groups 12 months after surgery compared to before. Conversely, in the control group, a 38.5% increase in the frequency of high-risk NSF was observed in patients 12 months after surgery. Therefore, these results indicate that performing all three types of surgery significantly reduces high-risk NSF in obese patients (Tables 1 and 2).

The ultrasound results of the patients during different time points showed that all three types of surgery significantly reduced grade III of fatty liver during 6- and 12-months follow-up such that the rate of reduction of grade III fatty liver in patients were 17.0, 21.6, and 39.8% in the gastric sleeve, mini-gastric bypass and RY gastric

bypass groups, respectively, 12 months after surgery compared to before. Therefore, the highest decrease in patients' grade III fatty liver was observed in the RY gastric bypass group with 38.8%. Conversely, in the control group, a 41.9% increase in grade III fatty liver was observed in patients 12 months after surgery. Therefore, these results indicate that performing all three types of surgeries significantly reduces the fatty liver grade III in obese patients (Tables 3 and 4).

Therefore, the results of this study showed that all three types of surgery have a significant role in the results of ultrasound and fatty liver grading compared to the nonsurgical group. In this regard, several studies have examined various parameters such as the degree and stage of fatty liver, the severity of fibrosis, liver enzymes, liver steatosis before and after surgery, and their results are largely in line with our research findings. For example, a prospective cohort study by Aldoheyan et al. evaluated surgeon impact bariatric on histological, metabolic, and hepatic function status of 27 patients for 3 months.<sup>15</sup> Most patients (75%) were of female gender, which is consistent with our study. Their results showed that bariatric surgery significantly leads to histopathological changes in the liver with weight loss, reduction of liver stasis, liver fibrosis, and NAFLD activity three months after surgery. These results are largely in line with our research findings. Although the duration of follow-up varied, in our study, all three types of surgery significantly reduced BMI, the risk of liver fibrosis, and grade III fatty liver in patients.

Another study by Ooi et al. on 84 patients with NAFLD showed that the fatty liver in these patients improved shortly after bariatric surgery and weight loss (10–15%) and caused a significant decrease in ALT.<sup>12</sup> These results are largely in line with our research findings. In our study, all three types of surgery significantly reduced BMI, thereby reducing the risk of hepatic fibrosis and grade III fatty liver in patients. In our study, the reduction in BMI of patients was 33.53, 34.95, and 32.77%, respectively, in the groups of gastric sleeve, mini-gastric bypass and RY gastric bypass 12 months after surgery compared to before, which is almost twice the amount reported in a study by Ooi et al.

**Table 3:** Comparison of fatty liver grade in different groups before surgery

Fatty liver grade	Groups				p
	Control	Gastric sleeve	Mini-gastric bypass	RY gastric bypass	
Grade I	53 34.9%	94 37.8%	82 32.8%	97 39.0%	0.19
Grade II	73 48.2%	113 45.2%	114 45.6%	109 43.5%	
Grade III	26 16.9%	43 17.0%	54 21.6%	44 17.5%	

**Table 4:** Comparison of fatty liver grade in different groups 12 months after surgery

Fatty liver grade	Groups				p
	Control	Gastric sleeve	Mini-gastric bypass	RY gastric bypass	
Grade I	19 12.7%	11 91.7%	103 91.2%	32 100.0%	<0.001
Grade II	44 29.3%	1 8.3%	10 8.8%	0 0.0%	
Grade III	87 58%	0 0	0 0	0 0	

A review by Chavez–Tapia et al. showed that to date, no clinical trials have been conducted on the effect of obesity surgery on NAFLD in obese patients. Only 21 retrospective and prospective studies were performed in which the severity of steatosis and inflammation improved, and four studies showed an increase in postoperative fibrosis.<sup>7</sup>

In a study by Karcz et al. 236 obese patients underwent laparoscopic sleeve surgery and were followed up for 3 years.<sup>13</sup> The results of this study showed that, firstly, there is a strong association between high levels of transaminases and NASH diagnosed based on pathology. Among the patients with NASH, the amount of liver enzymes decreased by more than 50% after surgery. The results of this study are somewhat consistent with the findings of our study. However, in our study, the rate of decrease in the level of liver enzymes after surgery was less than this report, which probably affects the baseline levels of these enzymes and the disease grade, and the number of patients. In our study, all three types of surgery significantly reduced AST and ALT enzymes during 6 and 12 months follow-up, such that the rate of AST reduction in patients were equal to 8.69, 2.24, and 0.81%, respectively, in gastric sleeve, mini-gastric bypass, and RY gastric bypass groups 12 months after surgery compared to before, and the rate of ALT reduction in patients were 19.58, 18.9, and 15.18%, respectively, in gastric sleeve, mini-gastric bypass, and RY gastric bypass 12 months after surgery compared to before.

In another study, Aldoheyan et al. reported that fibrosis, steatosis, and NASH improved to varying degrees at the end of 3 months in 27 patients undergoing obesity surgery.<sup>15</sup> The findings of this study are largely in line with the results of our research.

Also, few studies have compared the effects of various surgical procedures on liver and LFT tests. For example, Kalinowski et al. reported that LFT worsens shortly after RYGB surgery and returns to baseline after 1 year, and this increase in liver tests is less after sleeve surgery.<sup>16</sup> In another study, Ruiz–Tovar et al. reported that hepatic steatosis evaluated by ultrasound completely improved by up to 90% after sleeve surgery.<sup>17</sup> In another study, Manco et al. showed that sleeve surgery was able to completely eliminate NASH in all patients. It also reversed stage 2 fibrosis in 90% of

patients, while these two findings were found in people who used the gastric balloon had lost significantly less weight and was almost insignificant in people who had lost weight by nonsurgical methods.<sup>18</sup> Also, in another study conducted by Nascimento et al. on 40 people, it was shown that the degree of liver fibrosis measured by NFS in patients undergoing surgery in private centers from 7.1 to 0% and in patients undergoing surgery in governmental centers decreased from 30.8 to 23%.<sup>24</sup> Therefore, the results of these studies indicate the positive effect of surgery on the improvement of NFS, which is largely in line with our research findings. In our study, all three types of surgery significantly reduced the risk of liver fibrosis during 6 and 12 months of follow-up in patients, such that the rate of reduction of high-risk NSF (or NSF above 0.67) of patients was 13.8, 24.5, and 19.6%, respectively, in the gastric sleeve, mini-gastric bypass and RY gastric bypass groups 12 months after surgery compared to before. On the other hand, the increase in patients with low-risk or NSF below –1.5 was 67.6, 65.0, and 74.4%, respectively, 12 months after surgery in the gastric sleeve, mini-gastric bypass and RY gastric bypass groups. Conversely, in the control group, a 38.5% increase in the frequency of high-risk NSF was observed in patients 12 months after surgery. So, these results indicate that performing all three types of surgeries have a significant effect on reducing high-risk NSF in obese patients.

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# Role of Hysteroscopy in Evaluation of Subfertility

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## ABSTRACT

**Introduction:** Diagnosing and treating subfertility is a most rapidly evolving area in modern medicine. Advances in endoscopic surgery have revolutionized the diagnostic and management approach to an infertile couple. Unlike USG and HSG, hysteroscopy single-handedly provides information regarding uterine, ovarian, tubal, as well as pelvic pathology.

**Materials and methods:** A prospective analysis was performed at BEST Institute and Research Centre, AV hospital, Bengaluru, over a period of 2 years. Couples presenting to the infertility clinic were subjected for thorough history taking, general examination, and gynecological examination. All necessary investigations were performed. Women who approached with fertility issues as a complaint and who could be potentially benefited from hysteroscopy were included in the study.

**Results:** A total of 102 patients were evaluated in the study, out of which 67 (65.7%) women had primary infertility and the rest (34.3%) had secondary infertility. Ovarian pathologies such as ovarian cysts, endometriosis of the ovary, and PCOS were the most common abnormality detected on laparoscopy followed by uterine pathologies. The most common hysteroscopic pathology was a polyp.

**Conclusion:** Combined hysteroscopy is a safe, effective, and reliable tool in comprehensive evaluation of subfertility. It should be considered as a definitive day-care procedure for evaluation and treatment of female subfertility.

**Keywords:** Diagnostic laparoscopy, Infertility, Hysteroscopy.

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## INTRODUCTION

The World Health Organization (WHO) defines infertility as “inability of a sexually active, non-contracepting couple to achieve pregnancy in one year”.<sup>1</sup> The couple who have never conceived before are classified as primary infertility and who have had at least one prior conception, irrespective of the outcome, are classified as secondary infertility. Subfertility describes any form of reduced fertility. The desire for children is not universal, but childlessness is a tragedy to many couples, even in developed countries. Relationships between couples can become strained when children are not forthcoming, and the onus of sub/infertility in most societies is placed on the woman. Infertility in women was ranked the 5th highest serious global disability.<sup>1</sup> World Health Organization estimates that 60–80 million couples worldwide currently suffer from infertility and the overall prevalence of primary infertility in India to be between 3.9 and 16.8%.<sup>2</sup>

Diagnosing and treating subfertility is the most rapidly evolving area in modern medicine. Whenever a sub-/infertile couple visits a specialist, they undergo thorough examination and a battery of tests to help pinpoint the cause of sub-/infertility. There are a number of diagnostic assessment methods such as evaluation of the female hormonal system, semen analysis, ultrasound, hysterosalpingography (HSG), and hysteroscopy. Ultrasound is most frequently used in detection of uterine pathologies and adnexal masses. Fallopian tubes are not routinely seen on ultrasound, unless if there is a hydrosalpinx. Hysterosalpingography has been a standard test in the workup of infertile couples for evaluating tubal patency. The sonohysterogram (SHG) is also an addition for intrauterine evaluation recently.<sup>3</sup>

Advances in endoscopic surgery have revolutionized the diagnostic and management approach to an infertile couple. Unlike USG and HSG, hysteroscopy single-handedly provides information regarding uterine, ovarian, tubal, as well as pelvic pathology. It is one of the most effective tools in diagnosing certain

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significant pathologies that are missed by above all diagnostic modalities such as pelvic inflammatory disease, endometriosis, adhesions, tubal pathology, and genital tuberculosis, and it is also proved effective in long-term unexplained subfertility.<sup>4</sup> Pelvic pathology is best identified by laparoscopy. Additionally, pathologies warranting surgical procedures and tubal patency testing can be done in the same sitting. Though hysteroscopy is effective in managing infertile women, it cannot be used as a primary diagnostic tool as it is an invasive procedure. However, due to its lower complication rates, minimal invasiveness, and a day-care facility, it is widely accepted among gynecologists. One of the significant causes of infertility in India, genital tuberculosis, can be easily diagnosed with laparoscopy.<sup>5</sup> The present study aims to highlight the effectiveness of hysteroscopy in evaluating female subfertility.

## MATERIALS AND METHODS

A prospective analysis was performed at BEST Institute and Research Centre, AV hospital, Bengaluru, over a period of 2 years. Couples presenting to the infertility clinic were subjected for

thorough history taking, general examination, and gynecological examination. All necessary investigations such as CBC, baseline endocrinal parameters (T3, T4, TSH, Prolactin, AMH, FSH, and LH), blood sugar, ultrasound of the abdomen pelvis for female partners, and husband semen analysis were performed. Women who approached with subfertility as a complaint in any group and who could be potentially benefitted from hysterolaparoscopy were included in the study. Patients with abnormal HSG findings were included in the study and confirmed by DHL. Patients having any relative and absolute contraindication to laparoscopy were excluded. Infertile couples fulfilling the inclusion criteria were counseled for hysterolaparoscopy with due explanation of the procedure, advantages, and risks. Written and informed consent was taken from all the patients.

Hysterolaparoscopy was performed in the preovulatory phase (6–11 days). Patients were admitted on the morning of the surgery and were advised to stay nil orally for 8 hours prior to surgery. Enema or catheterization was not followed routinely. They were asked to void completely before entering the operation theater. The procedure was carried out under general anesthesia with endotracheal intubation. Speculum and bimanual examinations were repeated under anesthesia.

Hysteroscopy was first performed with a 2.9 mm 30° deflection-angle hysteroscope with NS-distension media for all patients. Under vision, the hysteroscope was introduced in the cervical canal and examined. The uterine cavity was examined for polyp, septum, fibroid, synechiae, fibrotic bands, and uterine malformation. Bilateral tubal ostia were visualized and looked for patency. The condition of the endometrium all over the uterine cavity was noted. Any procedure that was indicated, depending upon the pathology, was performed.

Diagnostic laparoscopy was performed with a 5 mm 30° deflection-angle telescope and 5 mm ports after adequate pneumoperitoneum were created. Inspection of pelvic organs, pouch of Douglas, and upper abdomen was done through the laparoscope. Uterine size, shape, symmetry, position, and surface were noted and examined for fibroid, endometriotic spots, adenomyosis, and adhesions. Bilateral tubes were traced till the fimbrial end to note any pathology such as hydrosalpinx, kinking, stricture, and peritoneal adhesions. Bilateral ovaries and ovarian fossa were examined for PCOS, ovarian cysts, and endometriosis. Pelvic peritoneum near pouch of Douglas and bilateral uterosacral ligaments were examined for evidence of endometriosis. Upper-abdominal organs such as liver were examined for any signs of chlamydial infection.

Chromopertubation was performed to test the patency of the tubes. Leech Wilkinson cannula was inserted into the cervix, and dilute methylene blue was injected with a 20-mL syringe into the uterus. Free spillage of dye from the fimbrial end of the tube was visualized. Indicated therapeutic laparoscopic procedures were performed, depending upon the pathology noted. After the procedure, the patient was transferred to postoperative ward and monitored. For minor procedures, patients were started orally after 4 hours and discharged the same day.

All the findings of hysterolaparoscopy were tabulated in Microsoft Excel sheet, and statistical analysis was done using SPSS software version 16. The variables were expressed as mean ± SD and percentages.

**RESULTS**

A total of 102 patients were evaluated in the study, out of which, 67 (65.7%) women had primary infertility and the rest (34.3%) had

**Table 1:** Number of abnormal findings and number of cases detected

Sl. no.	Abnormalities detected	Primary infertility (n = 67)	Secondary infertility (n = 35)
1	Total no. of abnormalities detected during DHL	53	29
2	Single	34	11
3	Multiple	19	18
4	% of abnormalities identified	79.1 %	82.8%

**Table 2:** Abnormal hysterolaparoscopic findings

Sl. no.	Abnormalities detected in laparoscopy	Primary infertility (n = 67)	Secondary infertility (n = 35)
1	Tubal	19 (28.4%)	19 (54.3%)
2	Uterine	28 (41.8%)	20 (57.1%)
3	Pelvic peritoneal	8 (11.9%)	11 (31.4%)
4	Ovarian	54 (80.6%)	20 (57.1%)

secondary infertility. The mean age of patients in the primary infertility group were 27.2 ± 2 SD years and 30.6 ± 2 SD years for those in the secondary group. The average duration of infertility in primary was 4.2 ± 2 SD years and 6.8 ± 2 SD years for secondary infertility.

Out of 102 women, 53 (79.1%) among primary infertility and 29 (82.8%) out of secondary infertility had single/multiple abnormalities detected on hysterolaparoscopy. Single pathology was noted in 34 cases of primary infertility (50.7%) as compared with 11 cases of secondary infertility (31.4%). Multiple (≥two) pathologies could be detected in 19 cases of primary infertility (28.3%) as compared with 18 cases of secondary infertility (51.4%). Major degree of pelvic adhesion with endometriosis, leiomyoma with polyp, leiomyoma with PCO, endometriotic cyst with adhesion, hydrosalpinx with PCO, and hydrosalpinx with adhesion, etc., were considered as multiple pathologies (Table 1).

Ovarian pathologies such as ovarian cysts, endometriosis of ovary, PCOS, etc., were the most common abnormality detected on hysterolaparoscopy followed by uterine pathologies (myoma, bicornuate uterus, septate uterus, polyp, etc.) and tubal pathologies (hydrosalpinx, tubal blocks). Peritoneal pathologies such as adhesions, features of PID, and endometriosis involving the POD were also detected as shown in Table 2.

The most common hysteroscopic pathology was endometrial polyp and its incidence being 13.4% in primary and 11.4% in secondary infertility. Other attributing pathologies in hysteroscopy were uterine septum (7.5% in primary and 2.8% in secondary), submucous myoma (4.5% in primary and 5.7% in secondary), bicornuate uterus (1.5%), synechiae (11.4% in secondary), periosteal adhesions, and deeply seated ostia (Table 3).

PCOS (58.2%) was the most common laparoscopic finding in primary infertility, whereas, in secondary infertility, both endometriosis (34.3%) and PCOS (34.3%) were the major abnormalities detected. Leiomyoma was found in 13.4 and 8.6% in primary and secondary groups, respectively. Endometriosis was found in 22.3% of primary infertility. Peritoneal adhesions were noted more in secondary (11.3%) than in primary (1.5%) infertility. Hydrosalpinx was found in 3 cases in secondary and 1 in primary group, where 2 cases had bilateral, and 2 cases had unilateral

**Table 3:** Abnormal hysteroscopic findings

Sl. no.	Abnormalities detected in hysteroscopy	Primary infertility (n = 67)	Secondary infertility (n = 35)
1	Septum	5 (7.5%)	1 (2.8%)
2	Myoma	3 (4.5%)	2 (5.7%)
3	Polyp	9 (13.4%)	4 (11.4%)
4	Bicornuate uterus	1 (1.5%)	0
5	Synechiae	0	4 (11.4%)
6	Deep-seated ostia	3 (4.5%)	1 (2.8%)
7	Periosteal adhesions	3 (4.5%)	0

**Table 4:** Laparoscopic abnormalities

Sl. no.	Abnormalities detected in hysteroscopy	Primary infertility (n = 67)	Secondary infertility (n = 35)
1	Myoma	9 (13.4%)	3 (8.6%)
2	Endometriosis	15 (22.3%)	12 (34.3%)
3	Adhesions	1 (1.5%)	4 (11.3%)
4	Hydrosalpinx	1 (1.5%)	3 (8.6%)
5	Ovarian cyst	7 (10.5%)	3 (8.6%)
6	PCOD	39 (58.2%)	12 (34.3%)
7	Uterine anomaly	1 (1.5%)	0

**Table 5:** Chromopertubation

Sl. no.	Chromopertubation	Primary infertility (n = 67)	Secondary infertility (n = 35)	Total (n = 102)
1	B/L spill	49 (73.1%)	19 (54.3%)	68
2	Unilateral spill	16 (23.9%)	12 (34.3%)	28
3	No spill	2 (2.9%)	4 (11.4%)	6
	Total	67	35	102

hydrosalpinx. The ovarian cyst was found in 10.5% of primary infertility, out of which 2 were dermoid cysts. Three patients with secondary infertility had ovarian cysts (Table 4).

On chromopertubation, there was no spillage in 2.9% of primary and 11.4% of secondary infertile women. Unilateral spillage of dye was found in 23.9 and 34.3% of women in the primary and secondary groups, respectively, the rest of them had free bilateral spillage of dye (Table 5).

Pathologies warranting simultaneous surgical procedures were identified. Necessary surgical interventions were carried out either by laparoscopy or by hysteroscopy, namely adhesiolysis, ovarian drilling, ovarian cystectomy, myomectomy, removal of subserous fibroid, fulguration of endometriotic spots, salpingostomy, and polypectomy.

## DISCUSSION

Perspectives of evaluating infertile women have changed recently due to developments in gynecological endoscopy. Current approach to infertility is no longer based on diagnosing an exact etiology. The investigation of infertile couples should be rapid and inexpensive, using minimally invasive tests.<sup>6</sup> Laparoscopy is

the gold standard technique in evaluating tubal and peritoneal pathology, as these can be missed easily on ultrasound. It also plays an important role in predicting future pregnancy outcomes in many infertile women.<sup>7</sup>

The present study showed ovarian pathology to be the most common one detected by hysterolaparoscopy in women with primary infertility, similar to the previous literature.<sup>8,9</sup> In the secondary-infertility group, tubal, uterine, and ovarian pathology were almost in similar distribution. Tubal pathology was found to be about 28.4 and 54.3% in both groups, and pelvic peritoneal pathology in about 11.9 and 31.4%, these pathologies could solely be detected by laparoscopy, and the following corrective measures were taken in the same setting. Without the help of these endoscopic surgeries, this class of pathologies causing subfertility would be missed.

Major hysteroscopic abnormalities in the present study were polyp followed by septate uterus, myoma, periosteal adhesions, and deep-seated Ostia in primary infertility, whereas among the secondary infertility group, polyp and synechiae were the most common causes. This finding is consistent with the findings of other studies.<sup>10,11</sup> PCOS and endometriosis were major abnormalities found on laparoscopy in both the groups. The incidence of tubal blockage was high in the secondary subfertility group.

The goal of endoscopic surgeries is to restore the anatomy as far as possible. The major advantage of these endoscopic surgeries is that they follow the principles of microsurgery. "Microsurgery" is a set of principles developed to improve fertility surgery outcomes. Laparoscopy and hysteroscopy are the cornerstones of reproductive microsurgery with fertility outcome as the endpoint. Postoperative adhesions are the key cause of failure of fertility-enhancing surgeries, laparoscopy primarily addresses this issue with its ability to reduce postoperative adhesions to minimum by following microsurgical principles.

## CONCLUSION

Combined hysterolaparoscopy is a safe, effective, and reliable tool in comprehensive evaluation of infertility. Correctable structural abnormalities in the pelvis may be unfortunately missed by routine pelvic examination and imaging procedures that can be detected by hysterolaparoscopy. Reversible causes such as adnexal adhesions, tubal blockade, uterine synechiae, etc., can easily be diagnosed and treated by hysterolaparoscopy in the same sitting. It should be considered as a definitive day-care procedure for evaluation and treatment of female infertility. Fertility-enhancing endoscopic procedures can be performed easily as there is minimal handling of pelvic organs due to better application of microsurgical principles and very limited side effects.

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# Analyzing the Outcomes of Laparoscopic Appendectomies in Children: Lessons Learned from 153 Consecutive Surgeries

Aniket Agrawal<sup>1</sup>, Vivek Viswanathan<sup>2</sup>, Gursev Sandlas<sup>3</sup>, Anoli Agrawal<sup>4</sup>

## ABSTRACT

**Introduction and discussion:** Appendicitis is one of the most common causes of acute abdomen presenting in the pediatric age-group. Surgical management is still the gold standard management for this condition. The introduction of the minimally invasive laparoscopic approach *vis-à-vis* the conventional laparoscopic and open approaches has overhauled the surgical management of this condition. The first laparoscopic appendectomy was performed by Semm in 1983 in an adult patient; however, it was not until 1992 when the first laparoscopic appendectomy was done in the pediatric age-group by Ure et al.

**Objective:** Our goal with this study was to analyze if laparoscopic surgery can be used as the standard of care for appendectomies, regardless of the type of appendicitis, complicated or uncomplicated.

**Results:** The results of our study suggest that in the pediatric age-group, males presented with appendicitis more commonly than females. We also found that the most patients had an average length of stay (ALOS) between 48 and 72 hours, regardless of the type of appendicitis, complicated or uncomplicated.

**Conclusion:** This study only reaffirms the fact that a pediatric laparoscopic appendectomy is a safe approach in all types of appendicitis, complicated or uncomplicated, but it does have a learning curve.

**Keywords:** Laparoscopic appendectomy, Laparoscopy, Minimally invasive approach, Open and Laparoscopic surgery, Pediatric laparoscopic surgery.

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## INTRODUCTION

Appendicitis is one of the most common causes for acute abdomen in the pediatric age-group. Surgical management is still the gold standard management for this condition. The introduction of the minimally invasive laparoscopic approach *vis-à-vis* the conventional laparoscopic and open approaches has overhauled the surgical management of this condition.

The first appendectomy was performed over 200 years later by Claudius Amyand in 1735, whereas the first laparoscopic appendectomy was done over two centuries later in 1983 in adults, and even later in 1992 is when the first pediatric laparoscopic appendectomy was done by Ure et al. However, it was Gilchrist et al. who first presented a paper explaining the benefits of laparoscopic appendectomy over open appendectomy.

Our goal with this study was to look at whether laparoscopic surgery can be used as the standard of care for any type of appendectomy, complicated or uncomplicated in pediatric patients.

## MATERIALS AND METHODS

We did a retrospective analysis of our prospectively maintained databases of pediatric patients who presented with acute appendicitis and underwent laparoscopic appendectomy in our tertiary care center. The data was collected prospectively from January 2015 to August 2021. The parameters compared were the age and sex of the patients, the ALOS, and the complications if any.

### Inclusion Criteria

- Diagnosed case of acute appendicitis
- Operated for appendectomy
- Less than 20 years of age

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**Conflict of interest:** None

### Exclusion Criteria

- Any conversion to open procedure

## RESULTS

Our study aimed to look at three specific parameters, namely, the demographic in terms of age and sex distribution for appendicitis in the pediatric age-group, the ALOS, and complications if any.

### Demographics (Gender)

**Figure 1** depicts the demographic distribution of the sex of the patients who presented with appendicitis at our institution. The

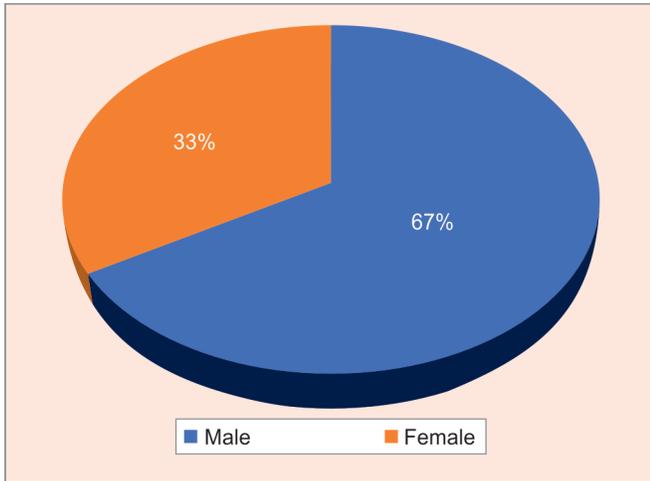


Fig. 1: Demographics (gender)

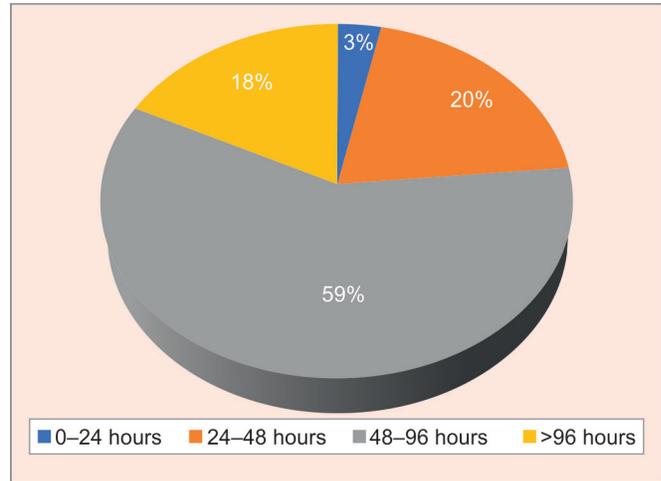


Fig. 3: Average length of stay

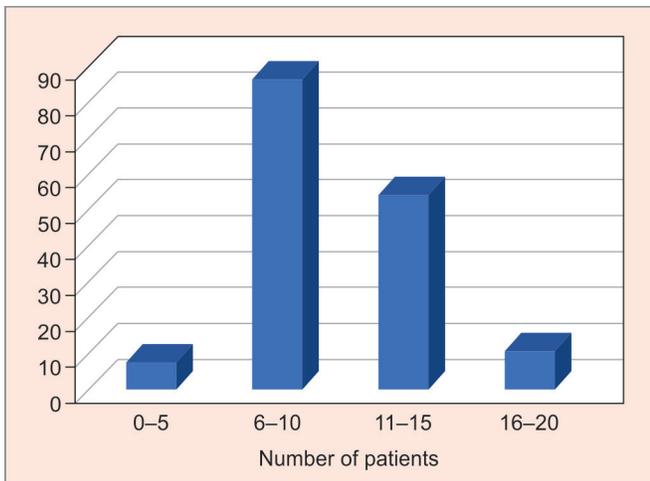


Fig. 2: Demographics (age)

pie chart suggests that males tend to have a higher incidence of appendicitis in the pediatric age-group compared to females, approximately in the ratio of 2:1 (males:females).

### Demographics (Age)

Figure 2 depicts the demographic distribution of the age of patients who presented with appendicitis at our institution. The graph suggests that patients presenting with appendicitis are most commonly in the age-group of 6–10 years old followed by 11–15-year old which was the second most common.

### Average Length of Stay

Figure 3 depicts the distribution of the ALOS of the patients [measured (in hours) from the time of admission to the time of discharge] irrespective of the type of appendicitis operated i.e., complicated or uncomplicated. The pie chart suggests that most patients were discharged from the hospital within 48–96 hours of admission for the surgery irrespective of the type of appendicitis operated, i.e., complicated or uncomplicated.

### Adverse Events

In our study cohort, we encountered adverse events in 12 patients. The adverse events were divided into two groups, namely,

complications and unrelated events. Out of the 12 patients, complications were encountered in 11 patients and 1 patient developed an unassociated event during the hospital stay. The complications were graded as per the Clavein–Dindo criteria and further divided into two groups, namely, minor (grades I and II) and major (grade  $\geq$ III).

- Complications
  - Minor (grades I and II): 6
  - Major (grade  $\geq$ III): 5
- Unrelated event
  - Testicular torsion: 1

An interesting point to be noted here is that out of the 11 patients who encountered complications, only 6 patients presented with and were operated on for complicated appendicitis while the other 5 patients had uncomplicated appendicitis, giving us more than 50% chance of patients with postoperative complications having a history of complicated appendicitis.

### DISCUSSION

Appendicitis is the most common acute abdominal emergency.<sup>1</sup> The mention of this condition can be dated back to as early as 30 AD, where its presence was recorded by Aretaeus the Cappadocean.<sup>2</sup> However, the first description of the appendix was given by the anatomist Berengario de Carpi in 1521, and the first appendectomy was performed over 200 years later by Claudius Amyand in 1735.<sup>2</sup> The term “appendicitis” was coined by the pathologist–physician Reginald Fitz in 1886;<sup>2</sup> however, it was Robert Tait who first diagnosed an appendicitis and then surgically removed the appendix in 1880, and in 1889, he also became the first one to split open and drain an appendix without removing it.<sup>3</sup>

The well-renowned Mcburney’s point as well as Mcburney’s incision were first described and named after Charles Mcburney, who proposed a muscle splitting incision in 1893, which was later modified by Robert Weir in 1900.<sup>3</sup>

The shortcoming of Mcburney’s, also known as Gridiron incision, that is, a non-cosmetic scar was overcome by Elliot of Boston and Otto Lanz. Lanz described an incision one-third of the way along the interspinal line, which paved way for a cosmetically acceptable scar which formed the principle behind a laparoscopic appendectomy.<sup>4</sup>

Appendicitis is a condition that does not just affect adults but is also very commonly seen in the pediatric age-group. In the pediatric age-group, the lifetime risk of appendicitis is about 7–9% and the mortality risk from the same is about 0.01% (non-perforated appendicitis) to 0.06% (perforated appendicitis).<sup>5</sup>

Thanks to surgical advancements, especially in the last 40 years, the approach for appendectomies has shifted from an open surgical approach towards a minimally invasive approach. The first-ever laparoscopic appendectomy was performed by Semm in 1983 in an adult patient,<sup>6</sup> and the first-ever laparoscopic appendectomy in a pediatric patient was done about a decade later in 1992 by Ure et al. However, it was Gilchrist et al. who first presented evidence explaining the benefits of laparoscopic appendectomies over the open surgical approach.<sup>7</sup> The one drawback that is still of concern is the cost of laparoscopic appendectomy over the open approach. However, the reduced postoperative pain, shortened length of hospital stay as well as recovery time along with minimal abdominal scarring with the former approach are the advantages that can help reduce the cost difference.<sup>8,9</sup>

The minimally invasive approach initially only included the conventional laparoscopic approach; however, in recent years, laparoscopic appendectomy *via* single incision has gained popularity, as it offers advantages such as less pain, better cosmetics, and an overall reduced operative time.

Canty Sr, et al. and Foulds et al., in their series of pediatric laparoscopic appendectomies, have mentioned that they found a significant improvement in terms of operative time and risk of conversion to open appendectomy after 5 years of laparoscopic experience.<sup>10,11</sup> This makes it reasonable to assume that the learning curve for laparoscopic appendectomies is ~20 procedures and as the experience increases, the proficiency of the surgeon also increases.<sup>12</sup> This has been shown in the study done by York et al., where they found that after the completion of the learning curve, laparoscopic appendectomies become comparable to the open approach in terms of operative time and the former has a decreased postoperative length of stay and faster recovery of bowel function to normal compared to the latter.<sup>12</sup>

In our study, we aimed to determine whether the laparoscopic approach can be used as a standard of care for any type of appendectomy, complicated or uncomplicated. We retrospectively analyzed a prospectively collected data of 153 consecutive laparoscopic appendectomies done at our institution over the course of 6.5 years, between January 2015 to August 2021. The various parameters that we looked into were the demographics of presentation in terms of age and sex of the patients, as well as the ALOS in hospital and postoperative complications if any.

After analyzing our data, we found that in our cohort of 153 patients, males ( $n = 102$ ) were twice as likely to present with appendicitis requiring appendectomies compared to females ( $n = 51$ ) (male:female = 2:1). Our data also suggests that out of 153 patients, most of the patients presenting with appendicitis were in the age-group of 6–10 years of age ( $n = 84$ ), followed by 11–15 years ( $n = 48$ ). Vernon et al. in their study on pediatric laparoscopic appendectomy in acute appendicitis in 200 patients reported that there was an equivalent number of patients presenting with appendicitis in both genders and that there was an equivalent number of patients of all ages up to the age of 16 years. They also found that laparoscopic appendectomy was used more in heavier patients and that patients treated with laparoscopic

approach had a shorter ALOS compared to those treated with an open approach.<sup>13</sup>

The common postoperative complications, within 30 days postoperative appendectomy, include drainage of surgical wound infections, intra-abdominal abscesses, and postoperative adhesions causing bowel obstruction. The rate of complications in our study was divided into 3 groups of 51 surgeries each, that is, 1–51 surgeries (first group), 52–102 surgeries (second group), and 103–153 surgeries (third group). In these 3 groups, we had 2 postoperative complications related to the appendix in the first 51 surgeries, whereas no postoperative complications in the second and third groups which demonstrates that with increased experience, the postoperative complication rates for laparoscopic appendectomies showed a decreasing trend.

Out of 153 patients, only 3 patients required reoperation, 1 of which was for a post-appendectomy abscess which was reoperated and treated with insertion of a pig-tail for drainage, the other was reoperated for postoperative adhesive obstruction and the third case was reoperated for removal of a retained fecolith. We have a strict policy regarding the use of disposable trocars and EndoCatch bags especially in cases of complicated appendicitis. In our view, the use of this equipment has contributed to and helped us achieve a lower postoperative complication rate in our study. Similar findings were seen, where the use of an endoscopic loop to retrieve the appendix to reduce the potential for wound infections by preventing contact of the specimen with the abdominal wall during removal, in the study done by Goudet et al. in their modified technique for laparoscopic appendectomy.<sup>14</sup> The use of these may increase the cost of surgery upfront but it may save the cost in terms of postoperative complications requiring re-operation, which have been seen to occur at a higher incidence rate when this equipment is not used.<sup>15</sup>

An important intraoperative complication was the rate of conversion from laparoscopic to open surgery. In our study, we had a 0% conversion rate, in both complicated as well as uncomplicated appendectomies. Gosemann et al. in their nationwide cohort analysis found that they had a conversion rate of 1.2% which was associated with increased risk of complication compared to individual laparoscopic or open surgery groups.<sup>16</sup> They also found a higher conversion rate in surgeries performed by pediatric surgeons, whereas in our study all the surgeries were performed by trained pediatric surgeons but had a 0% conversion rate. This could be attributed to increased surgical experience and the findings seen in Gosemann's study may be a confounding factor.

Markus Schäfer et al. also in their study reported a 6.8 and a 25.5% conversion rate in overall and perforated appendicitis cases.<sup>17</sup> They also reported an overall reoperation rate of 3%, which was close to our number of 1.96%.

## CONCLUSION

In conclusion, our study only reiterates the fact that a pediatric laparoscopic appendectomy is a safe approach in all types of appendicitis, complicated or uncomplicated, in reducing complications and ensuring a reduced rate of conversion, but it does have a learning curve, which when achieved, makes the laparoscopic approach comparable to open approach in terms of operative time and offers advantages over the latter in terms of postoperative pain, length of hospital stay and earlier return of bowel function to normal.

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# Simultaneous Management of Retrocaval Ureter with Ipsilateral Renal Stone Disease: Single Center Experience

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## ABSTRACT

**Aim:** To report our experience in managing retrocaval ureter and ipsilateral renal stone disease.

**Materials and methods:** Till now we have managed five such cases. Physical examination and laboratory investigations were unremarkable in all patients. Ultrasonography revealed right moderate hydronephrosis and a single upper calyceal stone in two, inferior calyceal calculus in two, and a pelvic calculus in one patient. A CT urography and Tc-99m diethylene-triamine-penta-acetic acid (DTPA) scan were done in all patients. In all patients, the renal scan was suggestive of reduced function with a right obstructed drainage pattern.

**Results:** All patients were managed successfully by a combined laparoscopic and endourological approach. No intraoperative or major postoperative complications were noted. On follow-up renal scan done at 1 year, all patients had unobstructed drainage and improved or stable split function.

**Conclusion:** Combined laparoscopic and endourologic approach is the adequate modality of treatment of patients with obstructed retrocaval ureter with ipsilateral renal calculi.

**Keywords:** Laparoscopy, Retrocaval ureter, Stone disease.

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## INTRODUCTION

Retrocaval ureter is a rare congenital anomaly of the upper urinary tract. It is more common in males with 2.8-fold male predominance with a reported incidence of approximately 1 in 1,100.<sup>1,2</sup> It was first observed and reported by Hochstetter in 1893.<sup>3</sup> It usually presents with symptoms in the third and fourth decades of life, due to obstruction leading to hydronephrosis. Hydronephrosis may be a result of pressure on the ureter at the kinked site, an adynamic segment, or compression on the retrocaval part against the psoas muscle.<sup>4</sup> The course of the retrocaval ureter is variable and is classified on intravenous urography as type I having S-shaped, fish hook or J-shaped or type II having sickle-shaped retrocaval course, a lesser common form and associated with a mild degree of hydronephrosis.<sup>4,5</sup> The usual management in symptomatic individuals is mobilization of the ureter all along its course usually till the pelvic brim including the retrocaval part and then performing a ureteroureterostomy.<sup>6</sup> In patients with a retrocaval ureter along with the presence of renal calculi, it is a clinical dilemma whether to treat the renal calculus alone or to treat the ureteral obstruction also. There is a paucity of the literature describing simultaneous laparoscopic/endoscopic management of renal calculi in the presence of a retrocaval ureter. Till now we have managed five cases of the obstructed retrocaval ureter with ipsilateral renal stone disease. We are discussing our cases of the retrocaval ureter (type I) with obstructive drainage and renal calculi which were successfully managed with the combined endoscopic and laparoscopic approach.

## MATERIALS AND METHODS

Between August 2012 and January 2020, five patients (three males and two females) were operated on for type I retrocaval ureter with obstructive drainage and renal calculi. The median age of patients was 38 years (19–45 years). Pain in the right flank was the

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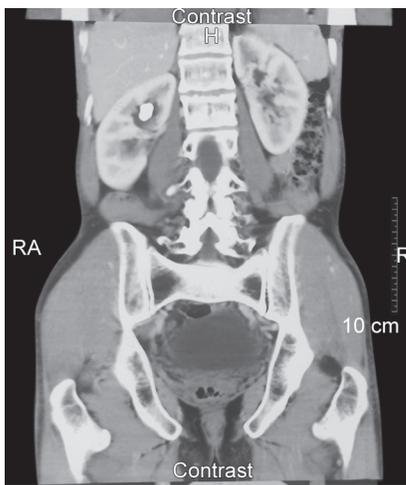
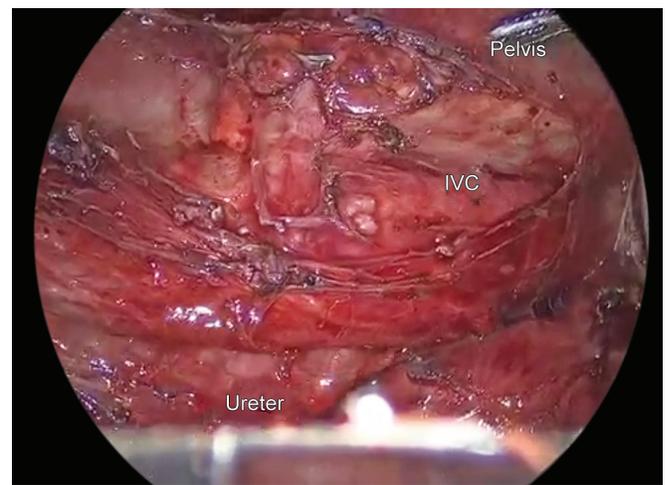
most common presenting feature. It was intermittent in nature and relieved by analgesics. One male and one female had a history of recurrent episodes of a UTI. There was no significant finding on clinical examination of the abdomen. Blood investigations including renal function test, general blood picture, and electrolytes were within normal limits. Ultrasonography, CT urography, and diuretic renal scan (Tc-99m diethylene-triamine-penta-acetic acid, DTPA) were done for all patients (Table 1).

## OPERATIVE TECHNIQUE

Informed consent was taken by all patients. Cystoscopy and right retrograde pyelography were performed, which showed findings suggestive of the right retrocaval ureter. A 6-F ureteric catheter was negotiated in the right ureter and with some difficulty, it could be negotiated till the right renal pelvis. In one of the patients who had a 2.2 cm inferior calyceal stone, percutaneous nephrolithotomy

**Table 1:** Demographic profile and procedure

Patient No.	Age/sex	Obstructed drainage (Yes/No)	Location of stone and size	Symptoms	Procedure
1	35/M	Yes	Superior calyx 1.3 × 1.4 cm	Flank pain	Laparoscopic transperitoneal pyeloureterostomy with rigid nephroscopy
2	45/M	Yes	Superior calyx 1.6 × 1.5 cm	Flank pain	Laparoscopic transperitoneal pyeloureterostomy with rigid nephroscopy
3	19/F	Yes	Inferior calyx 1.2 × 1.1 cm	Flank pain, dysuria, fever	Laparoscopic transperitoneal pyeloureterostomy with flexible nephroscopy + laser lithotripsy
4	26/F	Yes	Pelvis 1.9 × 1.8 cm	Flank pain	Laparoscopic transperitoneal pyeloureterostomy with rigid nephroscopy
5	33/M	Yes	Inferior calyx 2.2 × 1.9 cm	Flank pain, dysuria	PCNL followed by laparoscopic transperitoneal pyeloureterostomy (same sitting)

**Fig. 1:** Contrast enhances computed tomography image showing retrocaval ureter with upper calyceal stone**Fig. 2:** Intraoperative image suggestive of retrocaval ureter

(PCNL) was performed in a prone position. After the completion of PCNL, he was then positioned in the right lateral position. The rest of the patients were directly placed in a left lateral position with a slight tilt to the left side and four ports were placed. The right colon and duodenum were reflected, and the ureter was identified above the pelvic brim and traced to the point where it was passing in front of and behind the inferior vena cava (IVC). The IVC was mobilized and lifted with atraumatic forceps and mobilization of the ureter was done in the interaortocaval region, where it was passing posterior to the IVC. The ureter above was mobilized till the pelvi-ureteric junction (PUJ) level. Care was taken not to do any jerky movements. Similarly, the pelvis was dissected away from the IVC and psoas sheath. The ureter at the PUJ was transected and in two patients who had a stone in the upper calyx, a rigid nephroscope (Olympus 24F) was introduced through the lower port and the insufflation pressures were kept below 8 mm of Hg so that the distance between the abdominal wall and the pelvis is reduced for easy manipulation of the nephroscope. The stones were retrieved with a biprong stone-grasping forceps (a different camera system was used for this purpose). In one patient, flexible ureteroscopy was done through the upper subcostal port. A 100 W power Ho:Yag laser system (Lumenis, Inc.) was used along with a 272-micron laser fiber. The energy setting was kept between 0.2 and 0.5 J and the frequency varied between

20 and 50 Hz, giving a total power of 4–30 W. Initially, the settings of dusting (0.2–0.5 J/40–50 Hz) were used and later on switched to pop dusting [(0.5–0.6 J), (20–40 Hz)] for the completion of the procedure. Care was taken to keep the flow rate high as there was some loss of gas adjacent to the ureteroscope. The stone was then fragmented with the help of holmium laser and removed with the help of a nitinol basket. Thorough suctioning of the fluid accumulated in the abdominal cavity was done. Then, the retrocaval unhealthy portion (approximately 2 cm in length) was excised; following which, the ureter was spatulated for 2 cm. Ureteropelvic anastomosis was performed with a 4-0 polyglactin suture in a continuous fashion and a double-J stent 6F/26 cm was inserted after the completion of the posterior layer (Figs 1 to 4). A 16-F continuous suction drain was placed in the right renal area at the end of the laparoscopic surgery. X-ray KUB done in the postoperative period showed no residual fragment. The urethral catheter was removed on postoperative day 2 and the drain was removed on postoperative day 3. The nephrostomy tube which was placed after PCNL was removed on day 1. Double-J stent removal was done after 4–5 weeks of surgery. All patients were asymptomatic at 1 year of follow-up. Renal scan (Tc-99 m DTPA) and ultrasonography done at 6 months and 1 year showed mild right hydronephrosis with normal drainage and stable or improved renal function in all.

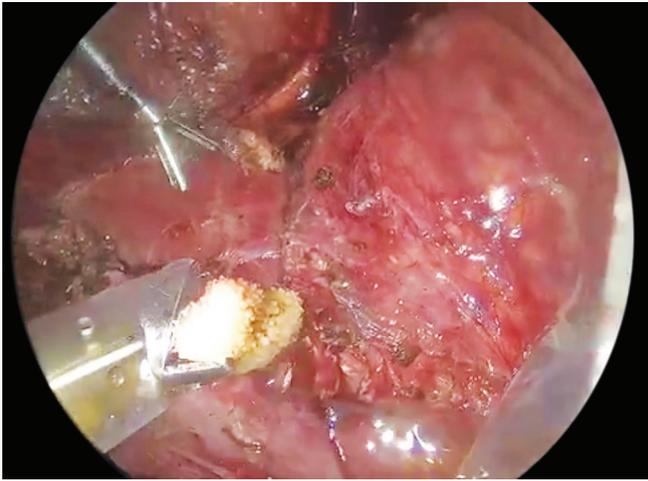


Fig. 3: Stone being retrieved through rigid nephroscope



Fig. 4: Pyeloureterostomy being performed

## DISCUSSION

Retrocaval ureter is a rare congenital anomaly and is also termed circumcaval ureter.<sup>7,8</sup> The proposed cause of this anomaly is that there is the persistence of the subcardinal vein as the infrarenal IVC, thus crossing anterior to the ureter in its midportion and resulting in its circumcaval course.<sup>9</sup> It most commonly occurs on the right ureter, and if it occurs on the left ureter, then it is usually associated with a duplicated IVC or situs inversus.<sup>10,11</sup> Retrocaval ureter may be identified incidentally on radiological imaging for some other problems and can be asymptomatic.<sup>12</sup> Contrast-enhanced computed tomography scan of the abdomen is the investigation of choice for the retrocaval ureter.<sup>13</sup> In symptomatic patients with documented renal functional obstruction, dismembered pyeloplasty or ureteroureterostomy or pyeloureterostomy, with or without the excision of the diseased segment, is the gold standard treatment.<sup>14,15</sup> Baba et al. reported the first case of managing a circumcaval ureter laparoscopically by performing a transperitoneal dismembered pyeloplasty.<sup>16</sup> Surgical management is reserved for type I cases that are usually symptomatic.<sup>17</sup> Patients who are asymptomatic and have minimal calyceal dilation do not require surgical intervention although they should be followed up carefully.<sup>17,18</sup> Few reports are mentioned in the literature describing the simultaneous association of retrocaval ureter and renal calculi and their management. Simultaneous treatment of renal stone and retrocaval ureter with laparoscopic technique has been reported by Simforoosh et al.<sup>19</sup> Mugiya et al. in their case report described that simultaneous management of retrocaval ureter and upper ureteric calculus was done during the same procedure.<sup>20</sup> Similarly, Singh et al. also managed a case of retrocaval ureter and renal stone by simultaneously performing a dismembered pyeloplasty and pyelolithotomy.<sup>21</sup> Our experience of simultaneous management of retrocaval ureter and stone is perhaps the largest to date. We managed five such cases using both the laparoscopic and endourology armamentarium with minimal complications (Tables 1 and 2). So, to conclude, a transperitoneal laparoscopic approach is a good treatment option for managing both the retrocaval ureter and the associated stone disease. One of the reasons is that the transperitoneal approach gives one more freedom to maneuver the endoscopic instruments and also the accumulated irrigation fluid does not hinder the vision much. This could be a problem with the retroperitoneal approach. In the presence of retrocaval

Table 2: Results

Number of patients	5
Age (years)	33 (19–45)
Operative time (minute)	115 (90–130)
Intraoperative blood loss (mL)	50 (45–80)
Hospitalization (days)	2.2 (2–4)
Complications (modified Clavien–Dindo)	One patient: Grade III: Port-site incisional hernia)

ureter and associated renal calculi, if the renal scan is suggestive of obstructed drainage and management of only calculi is not sufficient, simultaneous management of both the entities should be considered in the same sitting.

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# Preoperative Scoring System to Predict Difficult Laparoscopic Cholecystectomy

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## ABSTRACT

**Background:** Laparoscopic cholecystectomy (LC) is considered as the most common laparoscopic procedure in the world and is now the Gold standard treatment for cholelithiasis. Gallstone disease (cholelithiasis) has increasingly become one of the major causes of abdominal pain and discomfort in the developing world. Its occurrence has been found to be high (7.4%) in the adult population in the cities of Chandigarh and New Delhi in North India, which is one of the highest in the world. Gallstones are more common in the female population (61%) as compared to males (39%). The most common age-group affected is 45–60 years (38.5%) among females and above 60 years in males (20.8%). A relatively higher prevalence of 39% among males when compared to reports from past studies indicates a significant shift in the pattern of prevalence of gallstone disease. Many risk factors for cholelithiasis cannot be modifiable, such as ethnic background, advancing age, female gender, family history or genetics. The modifiable risks for cholelithiasis are obesity, quick weight loss, an idle lifestyle. A rising epidemic of obesity and the metabolic syndrome predicts an escalation in gallstones. Frequent risk factors for biliary sludge include pregnancy, drugs like ceftriaxone, octreotide, and thiazide diuretics, total parenteral nutrition, and fasting. Diseases like cirrhosis, chronic hemolysis, and Crohn's disease are a few risk factors for black pigment stones. In our hospital setup (RL Jalappa Hospital and Research Center, Tamaka, Kolar, Karnataka), in the Department of Surgery, a total of 166 cholecystectomies were performed in the period between October 2015 and September 2018. In total, 134 of these cases were elective laparoscopic cholecystectomy and twenty five of them were elective open cholecystectomies. There were a total of 7 cases that had to be changed from laparoscopic to open procedure due to intraoperative difficulty involved. That gives us a conversion rate of 4.96% over the past 3 years in our hospital setup. Preoperative prediction for the likelihood of conversion to open or difficulty of operation is an important aspect of planning laparoscopic surgery as the prevalence of gallbladder disease is increasing in India, and laparoscopic surgery is becoming more accessible. Arogya Karnataka Scheme, which can be used in our hospital setup, has laparoscopic cholecystectomy as one of its schemes for impoverished patients bringing the chance of laparoscopic surgery to the public. As a result, the number of laparoscopic cholecystectomies as a whole as well as the risk of conversion increases, making the need for study all the more important.

**Aims and objectives:** (1) To validate that a scoring system based on history, physical examination, and ultrasonographic findings is a reliable predictor of the difficulty of laparoscopic cholecystectomy. (2) To help in choosing a favorable treatment modality depending on the score. (3) To help predict the duration of hospital stay and postoperative complications with the help of this system.

**Methods:** A prospective and comparative study, considering 70 patients admitted and undergoing laparoscopic cholecystectomy at RL Jalappa Hospital and Research Center attached to Sri Devaraj Urs Academy of Higher Education Tamaka, Kolar, during the period of November 2018 and 10th October 2020.

**Results:** The preoperative scoring system devised is excellent at predicting the intraoperative difficulties encountered by surgeons while performing laparoscopic cholecystectomy with a sensitivity of 88.9% and a specificity of 92.3%. The scoring system also predicted intraoperative complications with a specificity of 94.2% when the score is >7. There was also a very strong correlation between the preoperative score and the duration of surgery ( $r = 0.752, p < 0.001$ ) and also between the preoperative score and the duration of hospital stay ( $r = 0.788, p < 0.001$ ).

**Conclusion:** Preoperative prediction of the risk of conversion or difficulty of operation is an important aspect of planning laparoscopic surgery. I would conclude that the scoring system evaluated in our study can be used to predict difficult cases.

**Keywords:** Cholecystectomy, Laparoscopic, Predictive factors, Preoperative, Scoring system.

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## INTRODUCTION

Gallbladder diseases are a relatively common disorder in large parts of the world. The prevalence of cholelithiasis in the USA and much of Western Europe is between 10 and 20%.<sup>1,2</sup> The prevalence is seen to increase with age in both sexes. However, it has been observed around the world that gallbladder diseases are predominantly a disease affecting females.

In India too, the gallstone disease follows the pattern seen in Western countries and is relatively common with overall prevalence in the order of 10–20%<sup>3</sup> and affecting females predominantly.<sup>4,5</sup> The results in this issue of the journal by Gaharwar et al.<sup>6</sup> are no different.

There is a difference in the burden of gallbladder diseases between Northern and Southern states in India (commoner in North), a phenomenon which is poorly understood.<sup>5–8</sup> The pattern

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of prevalence of gallstone disease has seen a significant shift when compared to past studies, with a higher than expected prevalence of 39% among males.<sup>9</sup>

Advancing age, ethnic background, family history, female gender, and or genetics are some risk factors for cholelithiasis which cannot be modified. The risks which can be modified for gallstones are an idle lifestyle, sudden weight loss, and obesity. A rise in gallstone frequency is expected with the rising epidemic of obesity and its associated metabolic syndrome. Drugs such as thiazide diuretics, ceftriaxone, octreotide, pregnancy, total parenteral nutrition, and fasting are some of the risk factors for biliary sludge. Chronic hemolysis, cirrhosis, and Crohn's disease are a few risk factors for the formation of black pigment stones.<sup>10</sup>

The first cholecystectomy was performed on a patient who suffered from cholelithiasis by Carl Johann August Langenbuch, who pioneered Cholecystectomy in 1882. It has since been considered the surgery of choice for gallstone disease (cholelithiasis). The gold standard for treatment of most of the gallbladder diseases is considered to be LC. Shorter duration of hospital stay, less postoperative pain, faster return of bowel function, better cosmesis, and also quicker return to full activity are some of the advantages of LC.

Although LC is the gold standard, there are instances of LC, when the surgery becomes difficult. There are instances of surgery taking a longer than expected duration with bile/stone spillage, iatrogenic injury of common bile/hepatic duct, and thickly adherent gallbladder, and occasionally some surgeries require conversion to open cholecystectomy (OC). Predicting preoperatively, the degree of difficulty of surgery is a high impossible task with many confounding factors. There is no standardized and widely recognized scoring system available to predict the difficulty of LC preoperatively at present. In my study, we have attempted to devise a scoring system for predicting the difficulty in LC preoperatively using easily available parameters and correlating the same with our observed intraoperative findings and difficulty encountered. My study attempts to recognize the factors which help to predict increased difficulty in LC, and thus surgical complications can be predicted and necessary precautions taken or altogether prevented.

## PREOPERATIVE PREDICTIVE FACTORS

In our study, the preoperative degree of difficulty is assessed by taking the following factors into consideration, and it is compared with our intraoperative observations and experiences. Patients with gallstone disease confirmed on ultrasound scan will be posted for LC. The following patient factors are evaluated preoperatively: *History* – History of previous hospitalization for cholecystitis, sex, and age; *Clinical findings* – Palpable gallbladder, abdominal scar, and BMI; *Sonology findings* – wall thickness, impacted stone, and pericholecystic collection.

In a study conducted by Mittalgodu Anantha Krishna et al. at Kasturba Medical College, Manipal University, Mangaluru, which tried to establish a predictive scoring method for difficult LC, they used a number of USG, preoperative and intraoperative parameters analyzed against the endpoint of difficult LC. Our study uses far fewer parameters and aims for similar results.<sup>11</sup>

### History

- H/o previous hospitalization (abdominal surgeries/cholecystitis/pancreatitis)
- Age
- Sex

HISTORY			MAX SCORING
AGE	<50 yrs (0)	>50 yrs (1)	1
Sex	Female	Male(1)	1
H/O Hospitalisation	N (0)	Y(4)	4
BMI	<25 (0)	25-27.5(1) >27.5 (2)	2
Abdominal Scar	N (0)	Infraumbilical (1) Supraumbilical (2)	2
Palpable GB	N(0)	Y(1)	1
Wall Thickness	Thin (0)	Thick>4 mm(2)	2
Pericholecystic Collection	N (0)	Y(1)	1
Impacted Stone	N (0)	Y(1)	1

Maximum score -15  
Score upto 5 - easy,  
6-10 - difficult  
11-15 - very difficult

Fig. 1: Preoperative scoring system with the various parameters and their respective scores

### Clinical

- Abdominal scar infraumbilical or supraumbilical
- Palpable gallbladder
- BMI

### Imaging

- Pericholecystic collection.
- Impacted stone.
- Gallbladder wall thickness.
- These factors were selected based on the previous studies and their respective association with LC (Fig. 1).<sup>12,13</sup>

Following evaluation, the patient will be subjected to LC. Factors noted are given as follows:

- Biliary/stone spillage.
- Operative time taken incision to port closure.
- Injury to duct/artery.
- Bleeding during surgery.
- Placement of drain.
- Need for conversion regarding upon the difficulty of the case.

Accordingly the cases are classified into one of the following categories:

### Easy

- Time taken is <60 min
- No injury to duct, artery
- No bile spillage

### Difficult

- Time taken is 60–120 min
- Injury to duct
- Bile/stone spillage
- No conversion

**Table 1:** Validity of a test in screening of disease

Screening test results	Diagnosis		Total
	Diseased	Healthy	
Positive	a (True positive)	b (False positive)	a + b
Negative	c (False negative)	d (True negative)	c + d
Total	a + c	b + d	a + b + c + d

**Very difficult**

- Conversion
- Time taken is >120 min

All the cases have had preanesthetic fitness, a routine work-up, and were taken up for surgery by a single surgeon. The duration of surgery was calculated from incision to port closure. We have calculated the preoperative degree of difficulty using our predictive parameters and are going to compare the outcome to our intraoperative findings. Duration of hospital stay was also tabulated.

**RESULTS**

**Statistical Analysis**

Data were entered into Microsoft Excel data sheet and were analyzed using SPSS 22 version software. Continuous data were represented as mean and standard deviation. Categorical data were represented in the form of frequencies and proportions. Chi-square test was used as test of significance for qualitative data (Table 1).<sup>14-16</sup>

- Sensitivity =  $a/(a + c) \times 100 = \text{True positive}/\text{True positive} + \text{False negative}$
- Specificity =  $d/(b + d) \times 100 = \text{True negative}/\text{True negative} + \text{False positive}$
- Positive predictive value =  $a/(a + b) \times 100 = \text{True positive}/\text{True positive} + \text{False positive}$
- Negative predictive value =  $d/(c + d) \times 100 = \text{True negative}/\text{True negative} + \text{False negative}$
- Diagnostic accuracy =  $a + d/a + b + c + d = \text{True positive} + \text{True negative}/\text{Total}$

**Specificity:** It is the ability of a test to identify correctly those who do not have disease, i.e., true negative.

**Sensitivity:** Defined as possibility of a test to identify correctly all those who have the disease, i.e., true positive

**Negative predictive value (NPV):** The proportion of patients who test negative who are actually free of the disease.

**Positive predictive value (PPV):** The proportion of patients who test positive who actually have the disease.

**Diagnostic accuracy:** Is the ability of screening tests to detect true positives and true negatives in the total population studied.

**p value:** (Probability that the result is true) of <0.05 was considered as statistically significant after assuming all the rules of statistical tests.

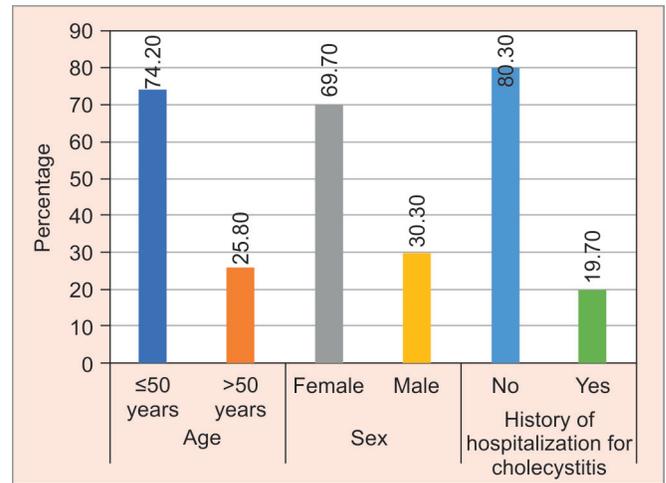
**Graphical representation of data:** MS Excel and MS word were used to obtain various types of graphs such as bar diagrams, Pie diagrams, ROC curve, and scatter plots.

**Statistical software:** MS Excel, SPSS version 22 (IBM SPSS Statistics, Somers NY, USA) was used to analyze data.

In the study, 49 (74.2%) subjects were ≤50 years and 17 (25.8%) were >50 years, in which 46 (69.7%) were female and 20 (30.3%) were male. In total, 13 (19.7%) had previous history of hospitalization for cholecystitis, while 53 (80.3%) patients did not (Table 2) (Fig. 2).

**Table 2:** History parameters distribution (total number of patients = 66)

	Count	%	
Age	≤50 years	49	74.2
	>50 years	17	25.8
Sex	Female	46	69.7
	Male	20	30.3
History of hospitalization for cholecystitis	No	53	80.3
	Yes	13	19.7



**Fig. 2:** Bar diagram showing history parameters distribution

**Table 3:** Clinical examination findings distribution (total number of patients = 66)

	Count	%	
BMI	<25	21	31.8
	25-27.5	15	22.7
	>27.5	30	45.5
Abdominal scar	No	25	37.9
	Infraumbilical	31	47.0
	Supraumbilical	10	15.2
Palpable gallbladder	No	66	100.0

In the study, BMI was <25 in 21 (31.8%), 25-27.5 in 15 (22.7%), and >27.5 in 30 (45.5%) subjects. In total, 31 (47.0%) subjects had infraumbilical abdominal scar, while 10 (15.2%) had supraumbilical scar and 25 (37.9%) had none. No subject presented with a palpable gallbladder (Table 3, Fig. 3).

On sonologic findings, wall thickness was thin or <4 mm in 36 (54.5%) and thick ≥4 mm in 30 (45.5%). Pericholecystic collection was seen in 13 (19.7%) subjects, while 14 (21.2%) presented with an impacted stone (Table 4, Fig. 4).

In the study, as per the preoperative score system, 39 (59.1%) were predicted to have an easy procedure, 23 (34.8%) were predicted to have a difficult procedure, and 4 (6.1%) to have a very difficult one (Table 5, Fig. 5).

In the study, 11 (16.7%) had placement of drain (Table 6, Fig. 6).

There is a significant positive correlation between the preoperative score and the duration of surgery ( $p < 0.001$ ), and the duration of hospital stay.

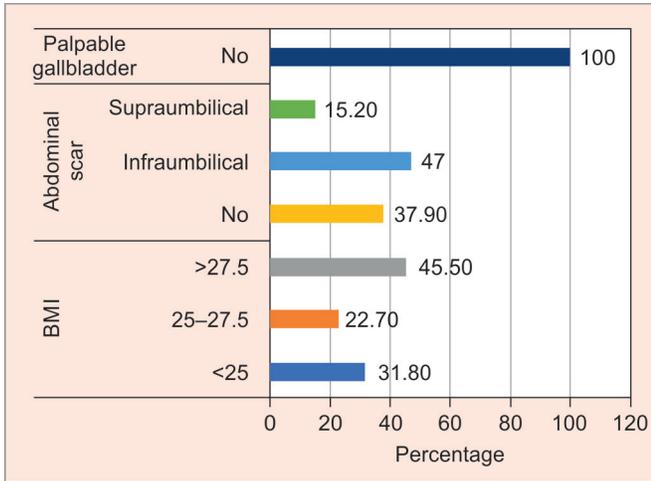


Fig. 3: Column diagram showing clinical examination findings distribution

Table 4: Sonologic findings distribution (total number of patients = 66)

		Count	%
Wall thickness	Thin <4 mm	36	54.5
	Thick ≥4 mm	30	45.5
Pericholecystic collection	No	53	80.3
	Yes	13	19.7
Impacted stone	No	52	78.8
	Yes	14	21.2

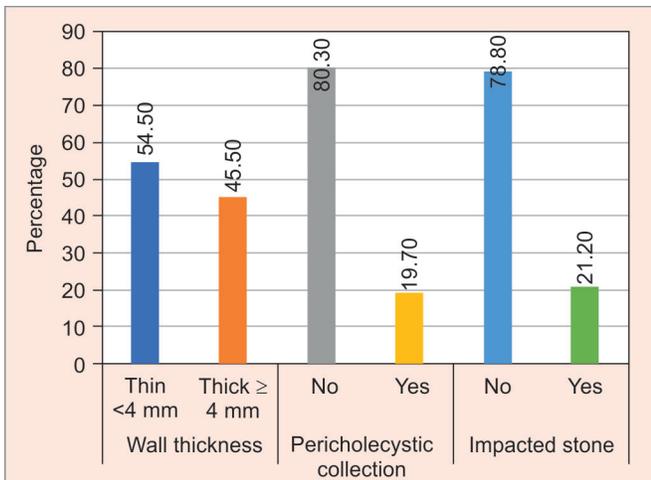


Fig. 4: Bar diagram showing sonologic findings distribution

Table 5: Preoperative scoring distribution (total number of patients = 66)

		Count	%
Preoperative score grading	Easy	39	59.1
	Difficult	23	34.8
	Very difficult	4	6.1

Out of 66 patients, 52 (78.8%) had no intraoperative complications, while 14 (21.2%) had intraoperative complications, 4 (6.1%) had iatrogenic perforation of the gallbladder, 3 (4.5%)

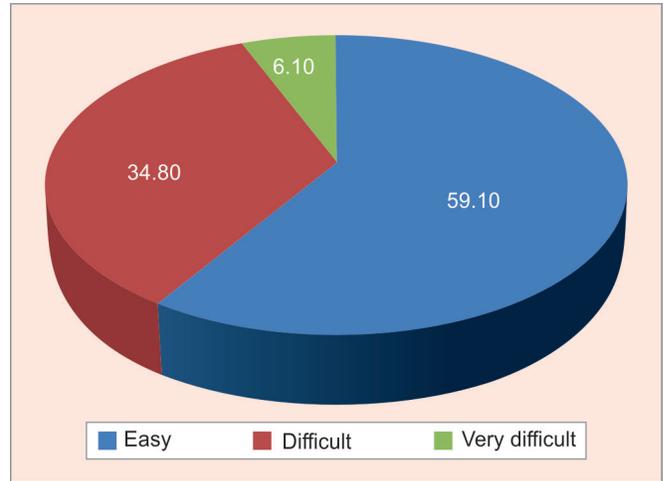


Fig. 5: Pie diagram showing preoperative score grading distribution

Table 6: Operative findings distribution (total number of patients = 66)

		Count	%
Placement of drain	No	55	83.3
	Yes	11	16.7

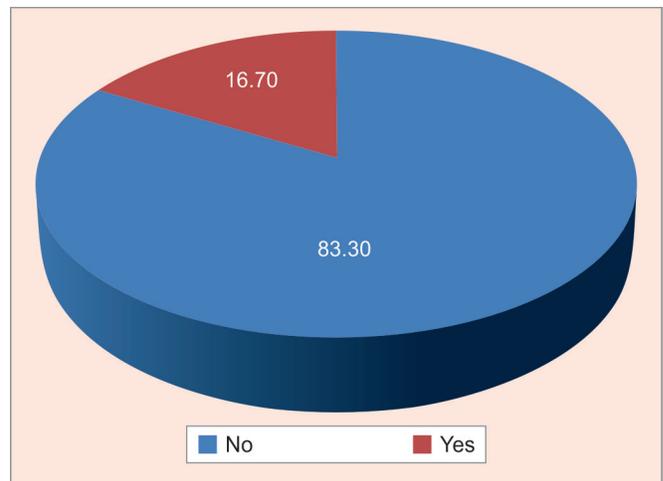


Fig. 6: Pie diagram showing placement of drain distribution

had bleeding from cystic artery, 3 (4.5%) had thickly adherent gallbladder, 2 (3%) had spilled gallstones, 1 (1.5%) had bleeding from abdominal wall (port) and 1 (1.5%) had bleeding from tissues adjacent to the gallbladder (Tables 7 and 8, Figs 7 and 8).

Operative outcome was easy in 39 (59.1%), difficult in 20 (30.3%), and very difficult in 7 (10.6%) subjects (Table 9, Fig. 9).

In total, 39 patients out of 66 were preoperatively predicted to have an easy cholecystectomy depending on their scores. In total, 36 (92.3%) patients in whom easy procedure was predicted preoperatively had an easy cholecystectomy. Only 3 (15%) had a difficult procedure in spite of being predicted otherwise, no patients with an easy grading underwent a very difficult procedure (Table 10, Fig. 10).

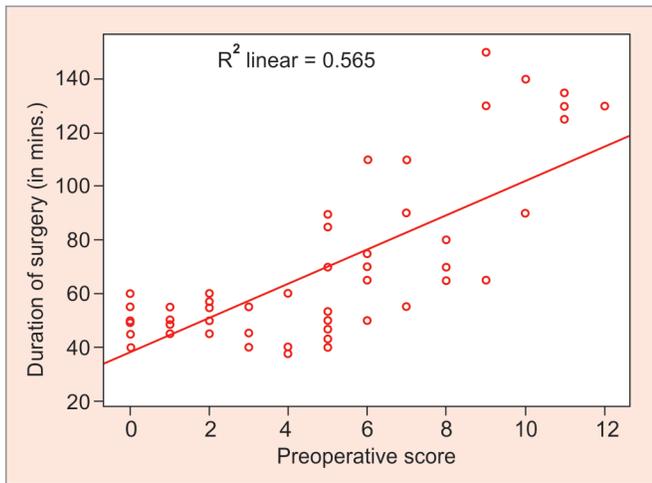
In total, 23 patients out of 66 were preoperatively predicted to have a difficult cholecystectomy depending on their scores. 17 (85%) of patients in whom difficult procedure was predicted preoperatively had an difficult cholecystectomy. 3 (7.5%) had an

**Table 7:** Correlation between preoperative score with duration of surgery and duration of hospital stay

		Preoperative score	
Preoperative score	Pearson correlation (r)	1	
	p-value		
	N	66	
Duration of surgery (in minutes)	Pearson correlation (r)	0.752	
	p-value	<0.001	
	N	66	
Duration of hospital stay	Pearson correlation (r)	0.788	
	p-value	<0.001	
	N	66	

**Table 8:** Intraoperative complications distribution (total number of patients = 66)

		Count	%
Intraoperative complications	Bleeding from abdominal wall (port)	1	1.5
	Bleeding from cystic artery	3	4.5
	Bleeding from tissues adjacent to the gallbladder	1	1.5
	Iatrogenic perforation of the gallbladder	4	6.1
	Spilled gallstones	2	3.0
	Thickly adherent gallbladder	3	4.5
	None	52	78.8

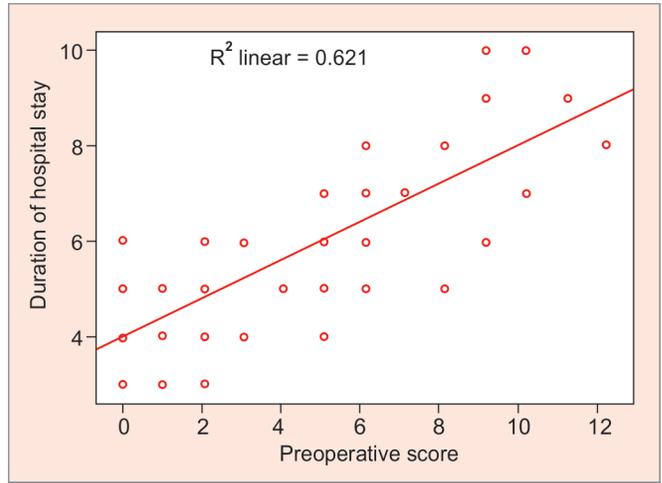


**Fig. 7:** Linear graph showing relationship between preoperative score and the duration of surgery

easy procedure and 3 (7.5%) had a very difficult procedure in spite of being predicted to be difficult.

In total, 4 patients out of 66 were preoperatively predicted to have a very difficult cholecystectomy depending on their scores. 4 (100%) of patients in whom very difficult procedure was predicted preoperatively had a very difficult cholecystectomy.

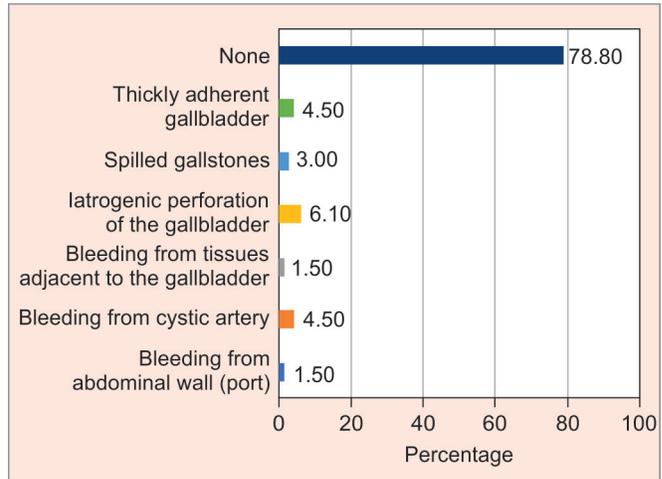
There was a significant difference in association between operative outcome and preoperative score (Table 11, Fig. 11).



**Fig. 8:** Linear graph showing relationship between preoperative score and the duration of hospital stay

**Table 9:** Operative outcome distribution (total number of patients = 66)

		Count	%
Operative outcome	Easy	39	59.1
	Difficult	20	30.3
	Very difficult	7	10.6



**Fig. 9:** Column diagram showing intraoperative complications and their distribution

**Table 10:** Association between operative outcome and preoperative score (total number of patients = 66)

		Operative outcome					
		Easy		Difficult		Very difficult	
		Count	%	Count	%	Count	%
Pre-operative score grading	Easy	36	92.3%	3	15.0%	0	0.0%
	Difficult	3	7.5%	17	85.0%	3	7.5%
	Very difficult	0	0.0%	0	0.0%	4	100%

$\chi^2 = 74.52, df = 4, p < 0.001^*$

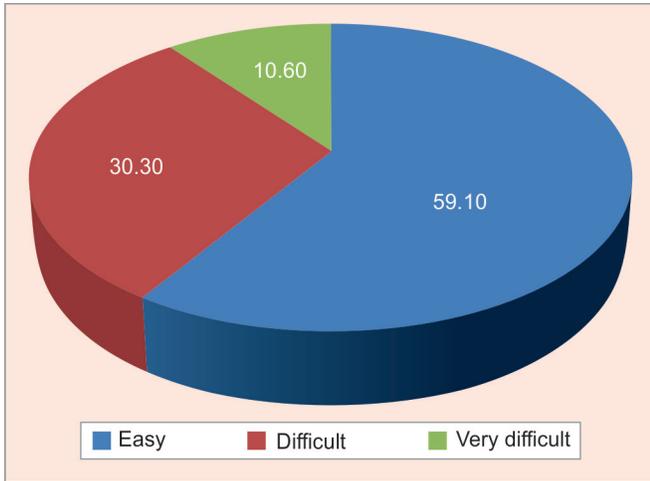


Fig. 10: Pie diagram showing operative outcome distribution

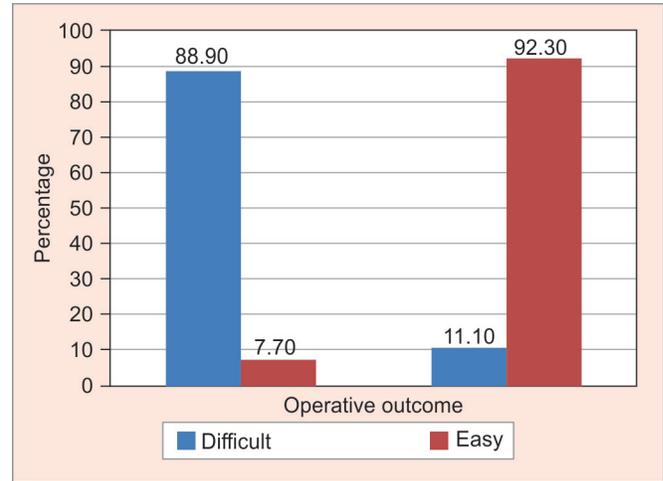


Fig. 12: Bar diagram showing association between operative outcome and preoperative score

Table 11: Association between preoperative grade and operative outcome (total number of patients = 66)

		Operative outcome			
		Difficult		Easy	
		Count	%	Count	%
Preoperative grade	Difficult	24	88.9	3	7.7
	Easy	3	11.1	36	92.3

$\chi^2 = 43.51, df = 1, p < 0.001^*$

Table 13: Validity of preoperative score in differentiating difficult and easy outcome (total number of patients = 66)

Area under the ROC curve (AUC)	0.962
Standard error	0.0194
95% confidence interval	0.883–0.993
z statistic	23.825
Significance level $p$ (area = 0.5)	<0.0001

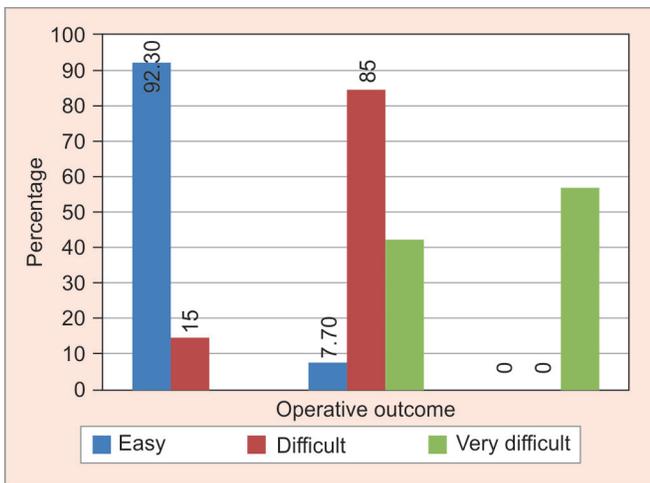


Fig. 11: Bar diagram showing association between operative outcome and preoperative score

Table 12: Association between preoperative grade and intraoperative complications (total number of patients = 66)

		Intraoperative complications			
		Yes		No	
		Count	%	Count	%
Preoperative grade	Difficult	12	85.7	15	28.8
	Easy	2	14.3	37	71.2

$\chi^2 = 14.75, df = 1, p < 0.001^*$

Difficult and very difficult outcomes in operative outcome were clubbed. In total, 6 cases were outliers during the study with respect to the preoperative score and intraoperative outcome

Operative outcome was predicted correctly as difficult in 88.9% and easy in 92.3%. 11.1% (3) had difficult operative outcome when the preoperative grade was easy. 7.7% (3) had easy operative outcome when preoperative grade was difficult.

There was a significant difference in association between preoperative grade and operative outcome.

Intraoperative complications were seen in 14 of the 66 test subjects. 12 (85.7%) of these subjects had a preoperative grade which predicted a difficult procedure. In 2 (14.3%) of these subjects, intraoperative complications were encountered in spite of a preoperative prediction of easy procedure (Table 12, Fig. 12).

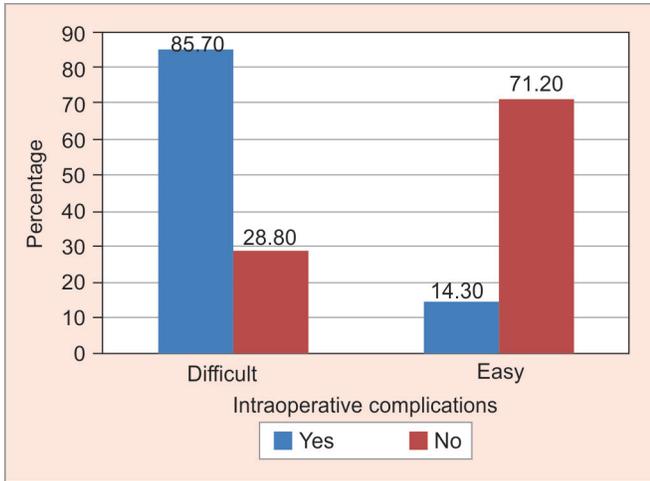
There was a significant difference in association between preoperative grade and intraoperative complications (Table 13, Fig. 13).

The curve shows a sensitivity of 88.9% and a specificity of 92.3% at a preoperative score of >5, which is very significant and shows that the scoring system is a very good predictor of operative outcome (Table 14, Fig. 14).

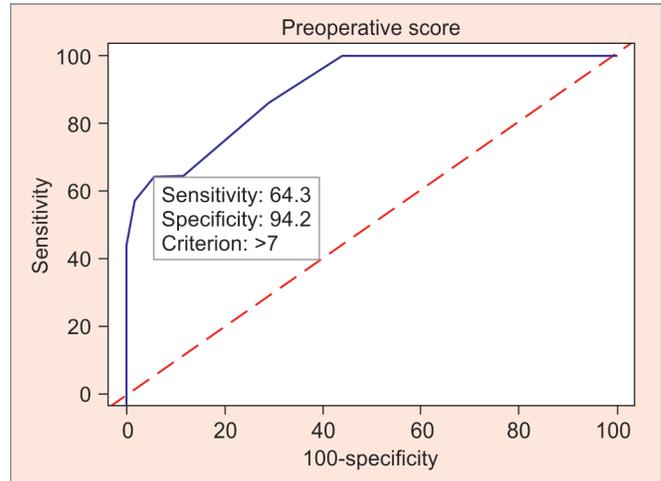
The curve shows a very high specificity of 94.2% at a preoperative score of >7 for predicting intraoperative complications (Fig. 15).

## DISCUSSION

Fillipi, Mall, and Roosma in 1985 first demonstrated Laparoscopic Cholecystectomy in an animal model in 1985.<sup>17</sup> In 1987, the first



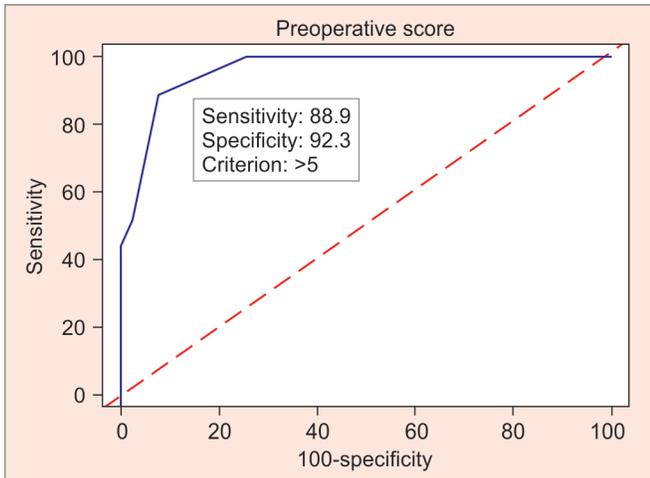
**Fig. 13:** Bar diagram showing association between preoperative grade and intraoperative complications



**Fig. 15:** ROC curve showing validity of preoperative score in predicting intraoperative complications

**Table 14:** Validity of preoperative score in predicting intraoperative complications (total number of patients = 66)

Area under the ROC curve (AUC)	0.900
Standard error	0.0421
95% confidence interval	0.802–0.960
z-statistic	9.508
Significance level <i>p</i> (area = 0.5)	<0.0001



**Fig. 14:** ROC curve showing validity of preoperative score in differentiating difficult and easy outcomes

Laparoscopic cholecystectomy was successfully performed on a human subject suffering from cholelithiasis by Philip Mouret in 1987 using an unmagnified mechanical rigid pipe without doing laparotomy to remove the gallbladder.

The complication rate with LC was high initially but has now reached a remarkably low level at 2.0–6.0% with an increase in the expertise of the procedure and technological advancement.<sup>18</sup> A rate of 7–35% conversion to open cholecystectomy has been reported in literature.<sup>19</sup>

Laparoscopic cholecystectomy is the gold standard treatment of choice for gallbladder disease (mainly symptomatic cholelithiasis).<sup>20</sup> Utmost caution has to be exercised while performing the procedure as this treatment is not devoid of complications, albeit it is lower in experienced hands.<sup>21</sup> My study was aimed to develop a scoring method for difficult LC with a secondary objective of correlating preoperative predictive factors with intraoperative difficulty in LC by assessing the various preoperative predictors (history/clinical imaging). A study of 66 subjects to understand the preoperative predictors of difficult LC revealed that the majority of them were below or equal to 50 years of age (74.2%, *n* = 49), and most of them were females (69.7%, *n* = 46). A majority of the patients were obese, with 30 (45.5%) with a BMI >27.5 and 15 (22.7%) with a BMI between 25 and 27.5 kg/m<sup>2</sup>. In total, 41 out of 66 patients had abdominal scars from previous operations, in which 31 (47%) had an infraumbilical scar, and 10 (15.2%) had a supraumbilical scar. On sonologic examination, 30 (45.5%) patients had a gallbladder wall thickness of more than or equal to 4 mm, while 13 patients showed pericholecystic collection and 14 patients had impacted stones.

In our study, we developed a scoring system to preoperatively ascertain the difficulty in LC based on clinical findings, history, and sonology. The grades were categorized as easy (<5), difficult (5–10), and very difficult (11–15). In total, 57 out of 66 cases were predicted correctly by our scoring system (86.36%).

Randhawa et al.<sup>22</sup> in 2009 (88–92%, easy to difficult) and Dhanke et al.<sup>23</sup> in 2014 (94.05–100%, easy to difficult) published similar findings.

Higher BMI – 22 (73.3%) patients out of 30 with a BMI of >27.5 kg/m<sup>2</sup> had difficult cholecystectomies. Gallbladder thickness >4 mm also correctly predicted difficult cholecystectomies with findings in 23 (76.6) patients, previous history of hospitalization for cholecystitis also showed a positive correlation between it and difficulty in surgery with 11 (84.6) out of 13 patients having difficult cholecystectomies. Pericholecystic collection was the parameter with the highest association with difficulty in laparoscopy, 12 (92.3%) out of 13 patients with collections underwent difficult procedures. History of prior hospitalization, high BMI, and pericholecystic collection are predictors of the difficulty of laparoscopic cholecystectomy as described by Dhanke et al.<sup>23</sup> in 2014 with whom our study is in agreement with. In 2005, Nachnani

et al.<sup>24</sup> also reported that previous history of hospitalization, GB thickness >3 mm, and BMI >30 kg/m<sup>2</sup> are good predictors of the level of difficulty in LC.

In my study, no cases were converted into open. This is a large variation as compared to 27.9% (Oymaci et al., 2014), 19 cases (17%) by Randhawa et al. in 2009, 11.4% (Nachnani et al. in 2005), 5.7% (Bakos et al.,<sup>25</sup> 2008), 5.3% (Ishizaki et al.,<sup>26</sup> 2006), and 0.36% (Singh et al., 2005). This variation can be attributed to the surgeon to surgeon variations, the underlying prognostic determinants of the individual, lack of uniform evaluating system, and difference in sample size. The experience of the surgeons and time spent in perfecting the surgical techniques help in achieving a low rate of complications.

In this study, there is a positive correlation between the operative outcome and the preoperative total score of the participants ( $\chi^2 = 74.52$ ,  $df = 4$ ,  $p < 0.001^*$ ). There is a positive correlation between preoperative grade and operative outcome ( $\chi^2 = 43.51$ ,  $df = 1$ ,  $p < 0.001^*$ ). There is also a positive correlation between the preoperative score and duration of surgery ( $r = 0.752$ ,  $p < 0.001^*$ ) and the length of hospital stay ( $r = 0.788$ ,  $p < 0.001^*$ ). Finally, there is a positive correlation between the preoperative score and the intraoperative complications ( $\chi^2 = 14.75$ ,  $df = 1$ ,  $p < 0.001^*$ ). The validation of the scoring system is limited, owing to the small sample size. On the other hand, individual bias in surgery is avoided by following a single surgeon. An individual surgeon has been followed for the duration of our study, and the results reflect the outcomes of surgery performed by that individual surgeon. A balance has been maintained to avoid the bias from different surgeons and to get an adequate sample size.

Nine cases did not correlate with the correct prediction of outcome from scoring. Three patients with a preoperative score of 5 had difficult cholecystectomies. One of them was a 65-year-old female with a BMI of 28.50 with infraumbilical incision and impacted stone on sonologic examination. It was predicted as easy with a score of 5, but the duration extended to 70 minutes making it difficult. Another two cases were of females with a BMI of >27.5 kg/m<sup>2</sup> with infraumbilical incision and gallbladder wall thickness of >4 mm. They were predicted as easy with a score of 5, but the duration extended to 85 and 90 minutes, making it difficult. This is attributed to the presence of thickly adherent gallbladder in the bladder fossa.

Three patients with a preoperative score between 6 and 10 underwent easy laparoscopic cholecystectomies. One was male of 55 years of age, with a BMI between 25 and 27.5, an infra-abdominal scar (lower midline) and a wall thickness on USG abdomen and pelvis of >4 mm. The preoperative score in this patient was 6, but the operation took only 50 minutes making it easy. The other 2 males were below the age of 50, who had previous history of hospitalization for cholecystitis, one patient had GB wall >4 mm in thickness and one had a BMI of 26. The preoperative grades were 7 and 6, but both patients underwent easy cholecystectomies (55 and 50 minutes).

Three patients with a preoperative score between 6 and 10 underwent very difficult laparoscopic cholecystectomies as opposed to just difficult as predicted. Two of these patients were males above the age of 50 and with a BMI of >27.5. Both had supraumbilical scars, a GB wall thickness of >4 mm, and pericholecystic collections. Both had a preoperative score of 9 but underwent operations exceeding 120 minutes, with one patient having iatrogenic perforation of gallbladder and another having

spilled gallstones. The final patient was a 60-year-old lady with previous hospitalization for cholecystitis, an infra-abdominal scar, GB wall thickness of >4 mm in size, pericholecystic collection, and an impacted stone. The preoperative score was 10, but the patient underwent a 140 minutes surgery and also had intraoperative complications of iatrogenic injury to the gallbladder.

The scoring system used in our study is extremely effective in predicting the difficulty of the LC with very high sensitivity. The ability to accurately predict and discuss the other determinants of difficulty in LC is limited by the small sample size. The focus of future research should be on finding out the exact relationship between the individual variables and the difficulty of the surgical procedure.

## SUMMARY

This study aimed to study a preoperative scoring system to predict difficult laparoscopic cholecystectomies. A prospective observational study was performed using 66 subjects. All the patients had a thorough history taken and a proper clinical examination, and all of them underwent ultrasound abdomen and pelvis scanning. Depending on history (age, sex, H/o hospitalization for attacks of cholecystitis), clinical examination (BMI, abdominal scar, and palpable gallbladder), and USG abdomen and pelvis (wall thickness, pericholecystic collection and impacted stone) parameters, all the subjects were awarded a preoperative score of 0–15. A score of 0–5 was predicted to be an easy cholecystectomy (time taken <60 minutes, no bile spillage, and no injury to duct or artery), a score of 6–10 was predicted to be a difficult cholecystectomy (time taken 60–120 minutes, bile/stone spillage, injury to duct, and no conversion), and a score of 11–15 was predicted to be a very difficult cholecystectomy (time taken >120 minutes or conversion to open).

It was seen that the scoring system evaluated in our study is a reliable, sturdy, and useful benchmark ( $\chi^2 = 43.51$ ,  $df = 1$ ,  $p < 0.001^*$ ) to predict difficult cases. It was excellent in predicting the intraoperative complications (85% of patients with complications had a preoperative grade of difficult), the overall difficulty of the procedure being performed, and also the duration of hospital stay.

## CONCLUSION

This study was aimed to develop a scoring method for difficult LC and to correlate preoperative predictive factors with intraoperative difficulty in laparoscopic cholecystectomy, intraoperative complications, and duration of hospital stay, by assessing various preoperative predictors (history/clinical/imaging). The procedure of choice for management of symptomatic gallstone disease is laparoscopic cholecystectomy.

Here are the conclusions we have drawn from the study: The preoperative scoring system devised is excellent at predicting the intraoperative difficulties encountered by surgeons while performing laparoscopic cholecystectomy with a sensitivity of 88.9% and a specificity of 92.3%. The scoring system also predicted intraoperative complications with a specificity of 94.2% when the score is >7. There was also a very strong correlation between the preoperative score and the duration of surgery ( $r = 0.752$ ,  $p < 0.001$ ) and also between the preoperative score and the duration of hospital stay ( $r = 0.788$ ,  $p < 0.001$ ). Surgeons encounter difficulty when there were dense adhesions in the calot's triangle, fibrotic and contracted GB, acutely inflamed, and pericholecystic

collection. The risk factors which make laparoscopic surgery difficult according to our study were previous hospitalization for attacks of acute cholecystitis, obesity (especially >27.5), previous abdominal surgery, and certain ultrasonographic findings, i.e., thickened gallbladder wall, pericholecystic fluid collection, and impacted stone.

Preoperative prediction of the risk of conversion or difficulty of operation is an important aspect of planning laparoscopic surgery. Our study sample size with the outcome is strengthened in multicentric studies and larger sample size. I would conclude that the scoring system evaluated in our study is a reliable predictor of difficult cholecystectomy cases.

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# Dysphagia after Bougie-guided Crural Repair in Laparoscopic Nissen Fundoplication

Mohab G Elbarbary<sup>1</sup>, Islam Hossam El-Din El-Abbassy<sup>2</sup>, Ahmed Samy Omar<sup>3</sup>, Medhat Helmy Khalil<sup>4</sup>

## ABSTRACT

**Purpose:** Nissen fundoplication is still assumed as the perfect lifelong management for gastroesophageal reflux disease (GERD). Despite the marked progress in performing the operation laparoscopically, dysphagia remains the most common postoperative morbidity. The use of an intraesophageal bougie during fundoplication to decrease the risk of postoperative persistent dysphagia (PD) by a forming proper tension-free wrap has been reported before in the literature. However, the aim of our study was to highlight the role of using a bougie in allowing a more guided way to repair the crura and avoiding blinded posterior repair, and the effect of that in reducing the incidence of postoperative PD in laparoscopic Nissen fundoplication.

**Materials and methods:** A prospective study including 40 patients undergoing laparoscopic Nissen fundoplication for repairing hiatal hernia with refractory GERD. The crural repair was guided by 50 Fr bougie. Postoperative collection of GERD–health-related quality of life (GERD–HRQL) questionnaire was done at 1 and 6 months for all the patients. The postoperative dysphagia was assessed regarding both severity and frequency.

**Results:** The GERD symptoms significantly improved in all patients, with marked postoperative satisfaction. No patients required dilation for postoperative dysphagia. Ten patients (25%) had mild dysphagia that resolved with conservative management, but no recurrence of GERD symptoms was observed.

**Conclusion:** Laparoscopic Nissen fundoplication is more efficient on using a bougie, allowing proper identification of the direction of esophageal descent through the hiatus, resulting in proper crural repair and the formation of an ideal wrap with a low-risk of prolonged dysphagia.

**Keywords:** Bougie, Dysphagia, Gastroesophageal reflux, Hiatal hernia, Nissen fundoplication.

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## INTRODUCTION

Postoperative dysphagia is considered one of the most annoying complications for patients having laparoscopic fundoplication. About 40–70% of patients would suffer from transient dysphagia.<sup>1</sup> Despite the unclearness of the exact cause, the ineffective esophageal motility (IEM) and postoperative edema at the gastroesophageal junction (GEJ) may give an idea about that.<sup>2</sup>

Dysphagia commonly resolves spontaneously within 2–3 months postoperatively;<sup>3</sup> however, PD may occur in 3–24% of patients after Nissen fundoplication.<sup>4</sup> Laparoscopic fundoplication was believed to have a higher incidence of PD than the open approach.<sup>5</sup> Construction of a tight wrap, slippage or displacement of fundoplication, a peptic ulcer stricture, as well as dividing the short gastric vessels during fundus mobilization are all possible causes.<sup>6</sup>

Unfortunately, undiagnosed IEM and unrecognized achalasia preoperatively may have a role in raising the incidence of postoperative PD.<sup>7</sup>

The use of an intraesophageal bougie during fundoplication to decrease the risk of postoperative PD by forming proper tension-free wrap has been reported before in the literature.<sup>8</sup> However, the aim of our study was to highlight the role of using a bougie in allowing a more guided way to repair the crura and avoiding blinded posterior repair and the effect of that in reducing the incidence of postoperative PD in laparoscopic Nissen fundoplication.

## MATERIALS AND METHODS

This was a prospective observational study conducted during the period from July 2017 to December 2019 at Ain Shams University Hospitals, Cairo, Egypt.

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**Source of support:** Nil

**Conflict of interest:** None

We included patients having hiatal hernia with refractory GERD who were not compliant with medical therapy. Patients who suffered from achalasia or any esophageal motility disorders were excluded along with patients having previous esophageal or gastric surgery, or those over 60 years of age. All patients had laparoscopic Nissen fundoplication by a team of two skilled surgeons using the same technique.

We conducted this study in compliance with the principles of the Declaration of Helsinki. The study's protocol was reviewed and approved by the institutional ethical committee. Written informed consent was obtained from all patients included in the study.

A standardized GERD–HRQL questionnaire<sup>9,10</sup> was used for all patients preoperatively and at 1 and 6 months postoperatively.

## Preoperative Evaluation

Preoperative assessment of the patients was done by a detailed history taking and physical examination. A 24-hour PH monitoring, upper gastrointestinal (GI) endoscopy, and esophageal manometry were done for all patients to reach the exact diagnosis of refractory GERD, to exclude esophageal motility disorders or achalasia and also to detect any esophagitis or Barrett's esophagus caused by GERD.

As posted by DeMeester et al., pathologic reflux was defined by esophageal acid exposure with a DeMeester score<sup>11</sup> greater than 14 without having any proton pump inhibitors (PPIs).<sup>1</sup> However, amplitudes of 30 mm Hg of mean distal esophageal contraction and failed peristalsis in less than half of the esophageal contractions were deemed normal. The use of any pre-operative PPIs was recorded.

## Surgical Technique

The operation was carried out under general anesthesia. A prophylactic dose of IV antibiotics was given during the induction.

The patients were placed in a supine position with abducted both legs and arms along with the table in reverse Trendelenburg position where the surgeon stood between the legs and the cameraman to the patient's right side.

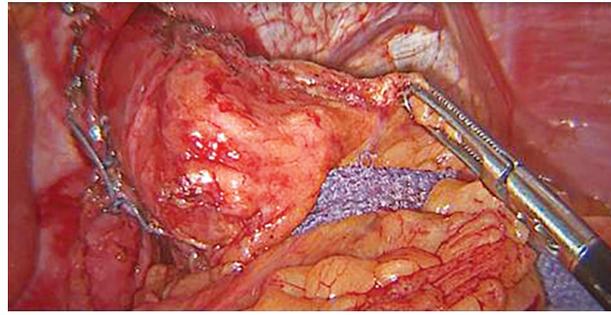
A five-trocar approach was applied, where a 12-mm optical port (used to create pneumoperitoneum) was placed in Palmer's point. A 5-mm trocar was placed just below the xiphoid process; another 5-mm port at the left anterior axillary line and one in the right mid-clavicular line. The liver was retracted by a self-retained S-shaped liver retractor through the upper 5-mm port opening.

Greater omentum was transected with an energy device (Ligasure–Medtronic) starting high up 4-cm distal to the hiatal hernia. Dissection of the greater omentum was done till complete identification of left crus with great importance to divide all the short gastric vessels above the starting point allowing complete mobilization of the fundus of the stomach.

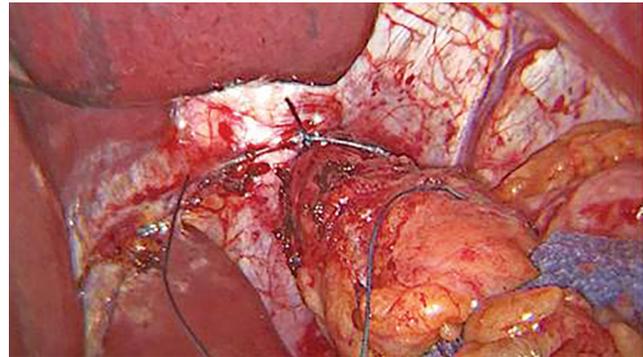
The gastro–hepatic ligament was then transected followed by dissection of the right crus, allowing about 2–3 cm of the distal esophagus to be in the abdomen. Dissection was done carefully with attention not to injure the posterior vagus trunk during the posterior dissection.

After identifying the hiatal hernia and the confluence of both crura, a stitch approximating the right and left crus was taken posteriorly. Then guided by a 50 Fr bougie, inserted by an experienced anesthetist from the mouth down to the stomach, the direction of the esophagus was identified and further stitches to close the hernial defect were taken either posteriorly, anteriorly, or both according to the hiatal size using interrupted non-absorbable 2/0 Ethibond sutures [Figures 1 and 2](#).

A short redundant posterior 360° fundoplication wrap was performed using the properly mobilized fundus. A “shoe-shine” maneuver to ensure a tension-free wrap was done. A 1–2 cm fundoplication wrap was done around the delivered intraabdominal esophagus using interrupted non-absorbable 2/0 Ethibond sutures. The first suture included bites from the fundus of the stomach on both sides of the esophagus and a fine bite of the anterior wall of the esophagus to prevent slippage of the wrap. Then one or two stitches were taken above the first stitch (the first stitch was around the GEJ so all the stitches should be above, but not below, the first stitch to avoid an improper wrapping of the stomach around itself). The second or third stitches were taken only between the stomach sidewall around the esophagus but not fixed to its anterior wall guided by the intraesophageal bougie that moved in and out by the



**Fig. 1:** Bougie introduction after taking a posterior crural stitch showing the direction of the esophageal descent through the hiatus and complete closure of the posterior defect was done guided by the bougie, leaving a small gap anteriorly



**Fig. 2:** Single anterior stitch was taken to close the anterior gap and smooth passage is checked using a 50 Fr bougie

**Table 1:** Frequency and degree of postoperative dysphagia based on the classification of Saeed et al.<sup>12</sup>

<i>Frequency and degree of postoperative dysphagia</i>	
0	Unable to swallow.
I	Swallowing liquids with difficulty, solids impossible.
II	Swallowing liquids without difficulty, solids impossible.
III	Occasionally difficulty swallowing with solids.
IV	Rarely difficulty swallowing with solids.
V	Swallowing normally.

anesthetist to avoid tight wrap. The last stitch was taken between the wrap and the right crus to fix the wrap and prevent its displacement. The operative time and complications either during or after the operation were recorded.

Postoperatively, patients were discharged on the second postoperative day. The oral clear fluids were allowed for the first 24 h, then soft diet for the following 7 days.

Follow-up was carried out by phone or clinic attendance at 2 weeks, 1–6 months postoperatively to assess the postoperative GI symptoms, PPI intake, GERD–HRQL questionnaire which was collected at 1 and 6 months postoperatively for all the patients.

Both frequency and severity of postoperative dysphagia were evaluated using a classification defined by Saeed et al.<sup>12</sup> who scored the ability to swallow from 0 to 5 in which the lowest score was given for the inability to swallow and the highest for normal swallowing ([Table 1](#)). Early dysphagia was defined by having dysphagia that

resolved within 8 weeks postoperatively, while late dysphagia was defined by having PD that time and requires endoscopic intervention and/or surgery for resolution.<sup>13,14</sup>

Any investigations required for postoperative dysphagia were recorded.

**RESULTS**

All our 40 patients had laparoscopic Nissen fundoplication using our technique for chronic GERD with sliding hiatal hernia during the given period of time.

The study included 10 males (25%) and 30 females (75%). The median age was 44 years. Sliding hiatal hernias were detected in all patients as proven by preoperative upper GI endoscopy with sizes ranging from 1 to 5 cm. Four patients (10%) showed Barrett’s metaplasia with no dysplasia in the histology taken upon esophagogastroduodenoscopy (EGD) before the procedure. All patients showed various degrees of esophagitis.

The preoperative symptoms were heartburn (*n* = 34, 85%) and regurgitations (*n* = 24, 60%). Aspiration was manifested as chronic cough or asthma with recurrent pneumonia.

All patients were diagnosed to have refractory GERD with prolonged usage of PPIs. Demography and preoperative symptoms are shown in (Table 2).

The median operation time was recorded to be 85 minutes in the range 30–180 minutes. All operations were done laparoscopically with no conversion to open. We had no intraoperative complications. The introduction of the 50 Fr bougie was done by a senior experienced anesthetist with no intraoperative complications associated with its use.

Postoperatively, GERD symptoms (heartburn, regurgitation, and aspiration) significantly improved in all patients and the GERD–HRQL scores showed marked postoperative satisfaction. Symptoms resolved without using PPIs in 38 patients (95%), whereas occasional PPI intake was reported in 2 patients (5%)

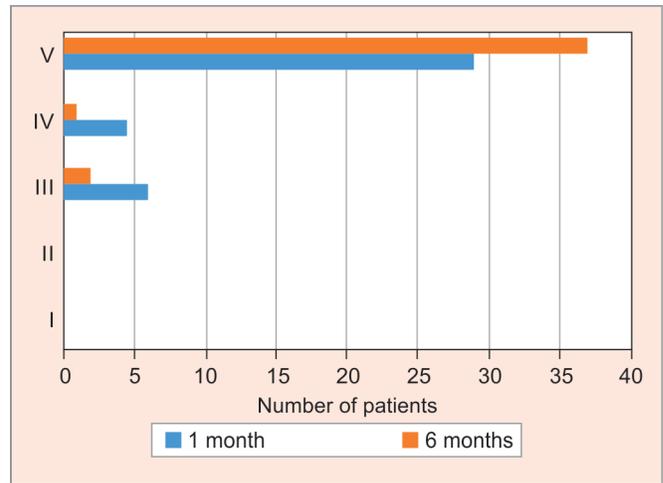
Early dysphagia was reported postoperatively in ten patients (25%). Four patients (10%) had rare difficulties in swallowing solids, whereas six patients (15%) were reported to have occasional difficulties in swallowing solids.

All patients were reachable for follow-up (either by phone or attending the clinic), and they were willing to take part in the questionnaire.

Guided by the classification of Saeed et al.,<sup>12</sup> both severity and frequency of dysphagia following our procedure were evaluated at 1 and 6 months as shown in Figure 3. Postoperative gas-bloat syndrome was reported in 28 patients (70%); however, these symptoms improved in all patients within 4 weeks postoperatively. Only two patients (5%) with repeated vomiting needed postoperative upper GI endoscopy, which showed mild narrowing not requiring dilatation. Those patients were managed conservatively.

**Table 2:** Demographic data and the preoperative findings

Data	Number of patients (total, N = 40)	Percentage (%)
Males	10	25
Females	30	75
Preoperative heartburn	34	85
Preoperative regurgitation	24	60
Barrett’s metaplasia	4	10



**Fig. 3:** Degree of postoperative dysphagia in our patients guided by Saeed et al.<sup>12</sup> classification at 1 and 6 months postoperatively

No further investigations were required for the rest of the patients included in the study influenced by the marked improvement of their symptoms.

**DISCUSSION**

Despite the marked effect of PPIs in treating GERD, the surgical approach is considered the most effective long-term management of the disease. Laparoscopic Nissen fundoplication is still the most effective anti-reflux surgery, with marked patient satisfaction and minimal postoperative complications.<sup>15</sup>

However, the prevalence of complications such as postoperative dysphagia and gas-bloat syndrome may occasionally require further surgical intervention and decrease the postoperative patients’ satisfaction.<sup>16</sup> Postoperative dysphagia could be caused by slipping of the wrap<sup>16</sup> or local edema and hematoma resulting from excessive manipulation during the procedure.<sup>13</sup>

In our study, 25% of our patients were managed conservatively for early dysphagia and only two patients required upper GI endoscopy due to repeated vomiting, which showed mild narrowing not requiring dilatation. The passage of the scope itself may have contributed to achieving some sort of calibration. It has been reported that early postoperative mild dysphagia is common shortly after the operation and improves spontaneously when edema or hematoma subsides, whereas PD that lasts more than 8 weeks occurs in 20% of cases and is considered a challenge in further diagnosis or treatment.<sup>17</sup> Postoperative dysphagia could also be due to possible technical errors by the surgeon due to closing the hiatus too much or making a too-tight wrap.<sup>18</sup> Proper preoperative diagnosis for the cause of GERD is very important as the presence of preoperative dysphagia or esophageal motility disorder, increases the development of PD postoperatively.<sup>19</sup>

There have been some suggestions in the literature to decrease the chance of developing postoperative dysphagia. DeMeester<sup>1</sup> reported that reducing the wrap length from 4 to 1 cm, along with division of the short gastric vessels and increasing the size of the bougie from 36 to 60 Fr was enough to reduce the incidence of postoperative dysphagia from 83 to 40%. However, the effect of division of the short gastric vessels to perform a better tension-free wrap, on decreasing the incidence of PD is still controversial.<sup>20,21</sup> In our study, using a 50 Fr bougie along with doing a short wrap



(1–2 cm) and dividing the short gastric vessels was effective in preventing PD among our patients.

The use of intraesophageal bougie guide during the wrap formation was first adopted by a study in 1986 showing a lower risk of developing postoperative dysphagia when a larger bougie was used.<sup>22</sup> The Society of American Gastrointestinal and Endoscopic Surgeons (SAGES)<sup>23</sup> recommended the bougie use supported by another study.<sup>24</sup> However, on the other hand, several studies assumed that the rates of postoperative dysphagia were not affected and the possible benefit decreased by the risk of esophageal perforation.<sup>22,25,26</sup> In our study, no esophageal perforations were reported while introducing the bougie by experienced anesthetists.

The idea of using a bougie in our study was not only to decrease the risk of postoperative dysphagia by forming proper tension-free wrap but also to allow a more guided way to repair the crura and avoid blinded posterior repair. Due to the presence of posterior esophageal sagging (which commonly occurs with those patients due to repeated reflux and esophageal inflammation), a blinded posterior repair without checking the direction of the esophageal descent through the hiatus may result in incomplete closure of the hiatus or tightening of the hiatal defect resulting in fundoplication failure (by wrap migration into the chest due to wide hiatus or postoperative dysphagia, respectively).

Therefore, in our technique the use of a 50 Fr bougie was considered the gold standard step in deciding how to repair the crura (either anteriorly, posteriorly or both) and forming the ideal wrap, minimizing the risk of too much or too loose crural repair. To our knowledge, our study is the first to highlight the importance of repairing the crura under vision guided by the bougie, whereas there is no documentation in the literature about the effect of crural repair, which may be a cause of the reported incidence of PD after laparoscopic Nissen fundoplication.

No cases of PD were reported in our study, whereas, in other studies where they did not use a bougie during their laparoscopic Nissen fundoplication, PD was reported to range 3–24%.<sup>16,27</sup>

Gas-bloating syndrome with various degrees was reported in 70% of our patients, all of which resolved conservatively within 4 weeks. In the literature, the incidence of postoperative gas-bloating syndrome was reported to reach 85%.<sup>15</sup> This could be related to the extensive division of the short gastric vessels<sup>28</sup> or due to the intraoperative manipulation of the vagal nerves during proper esophageal dissection.<sup>15</sup>

The pre-operative symptoms of our patients were mainly heartburn and regurgitation, which is similar to other studies.<sup>29</sup> In our study, 95% of the preoperative symptoms resolved postoperatively without using PPIs, while 5% reported occasional PPI intake. This is almost similar to other studies that reported 93.8% improvement of preoperative symptoms.<sup>15,30</sup>

The disappearance of the GERD symptoms postoperatively and relatively the low usage of PPIs after our operation, along with the marked patient satisfaction and low-risk of PD are all supportive to encourage other surgeons to repair the crura guided by a bougie (rather than doing the repair blindly) to form an ideal wrap. However, we acknowledge the limited number of patients included in our study and the short period of their follow-up. Therefore, other multicenter studies are encouraged.

## CONCLUSION

A proper diagnosis of the cause of GERD preoperatively may help in avoiding possible postoperative dysphagia. The laparoscopic Nissen

fundoplication is more efficient by using a bougie, allowing proper identification of the direction of esophageal descent through the hiatus resulting in proper crural repair and the formation of an ideal wrap with a low-risk of prolonged dysphagia.

## Clinical Significance

In our technique, the use of a 50 Fr bougie was considered the gold standard step in deciding how to repair the crura (either anteriorly, posteriorly or both) and forming the ideal wrap in laparoscopic Nissen fundoplication, minimizing the risk of too much or too loose crural repair with low-risk of prolonged dysphagia. To our knowledge, our study is the first to highlight the importance of repairing the crura under vision guided by the bougie, whereas there is no documentation in the literature about the effect of crural repair, which may be a cause of the reported incidence of PD after laparoscopic Nissen fundoplication.

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# Resuming Elective Laparoscopic Surgery during COVID-19 Pandemic: Our Experience and Challenges Faced

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## ABSTRACT

**Background:** SARS-CoV-2 virus infection was detected and discovered in Wuhan, China, in December 2019, and it was declared a pandemic by WHO in March 2020. Since then a lot of changes were noticed in surgical practice. Various recommendations were released by eminent surgical associations all over the world. This study was designed to study and analyze the findings and experience after resuming elective minimal invasive surgery during the pandemic.

**Materials and methods:** This observational study was conducted at St Joseph's Hospital, Ghaziabad, from May 2020 to May 2021. Various preoperative and postoperative findings were noticed and analyzed. The presence of SARS-CoV-2 virus was also analyzed in endotracheal aspirate and surgical smoke.

**Observation and results:** A total of 287 cases underwent surgery. Most commonly performed surgery was laparoscopic cholecystectomy. The positivity rate for SARS-CoV-2 during preoperative work-up was 2.87%. Slightly more than 5% of cases in postoperative period had COVID-19-like symptoms. None of those patients were found positive on RT-PCR, and X-ray/CT findings were also suggestive of early postoperative changes only. Presence of SARS-CoV-2 virus was not detected in either endotracheal aspirate or surgical smoke. Neither surgery team nor OT staff had infection during this period. There was no mortality, and only 1 patient was found to be infected 2 weeks after discharge.

**Conclusion:** Minimal invasive surgery for elective cases can be safely performed by taking precautions like PPE and smoke evacuation system during the COVID-19 pandemic. There is no evidence of transmission of infection through endotracheal aspirate or surgical smoke.

**Keywords:** COVID-19 pandemic, Minimal invasive surgery, SARS-CoV-2.

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## INTRODUCTION

SARS-CoV-2 virus is a lipid-enveloped virus from the Coronaviridae family that was first detected in Wuhan, China, and was responsible for the COVID-19 pneumonia outbreak around the globe, which was finally declared a pandemic by WHO in March 2020.<sup>1-3</sup> Since the outbreak of pandemic, lot of changes were brought in surgical practice. Non-emergency and elective cases were postponed immediately as per the recommendations by reputed eminent surgical associations. There was a state of confusion and uncertainty among surgeons regarding their own safety and overall patient care.<sup>4-8</sup> There was clear evidence of high mortality and morbidity among patients suffering from SARS-CoV-2 undergoing surgical procedures.<sup>4</sup> During this crisis, cases like cholelithiasis, hernia, and other benign conditions were put on hold from the declaration of pandemic and implementation of lockdown in the nation.<sup>5-8</sup> Only emergency procedures were performed. In Asian countries like India, where there were no proper guidelines and protocols were available initially as well as testing centers and resources were also limited. Planning and conducting elective minimal invasive surgeries was difficult, and hence, at our institute, it was decided to hold all elective laparoscopic procedures till further recommendations.<sup>9</sup> In late April and May, recommendations by the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES), European Association for Endoscopic Surgeons (EAES), Endoscopic and Laparoscopic Surgeons of Asia (ELSA), and Association of Surgeons of India (ASI) were released, and with availability of reverse transcription-polymerase chain reaction (RT-PCR) tests and personal protective equipment (PPE) kits, it was decided to resume elective laparoscopic surgery in a phased manner.<sup>10-12</sup> Another challenge faced was the reports and studies

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on surgical smoke, abdominal fluid, and aerosol generation during surgery to be a potential source of infection and subsequently increasing risk of transmission. However, there were lot of studies that demonstrated no evidence of any potential risk of transmission from surgical smoke. However other studies also recommended the use of smoke evacuation devices.<sup>13-17</sup>

This study is done to analyze the challenges faced, various preoperative and postoperative parameters, results, and overall experience while resuming elective laparoscopic surgery during COVID-19 pandemic.

## MATERIALS AND METHODS

This observational study was conducted at St Joseph's Hospital, a tertiary care center for a period of 1 year from May 2020 to May 2021. Total 301 patients reported in OPD for minimal invasive surgery, out of which 287 cases were enrolled and underwent laparoscopic surgery, which included laparoscopic cholecystectomy, laparoscopic hernia repair (inguinal and ventral), laparoscopic appendectomy, ovarian cystectomy, salpingectomy, total laparoscopic hysterectomy, diagnostic laparoscopy, and others. All emergency laparoscopic surgeries, cases converted to open, and cases unfit for general anesthesia and laparoscopic surgery were excluded from the study. All patients after screening for fever, cough, cold, and other common symptoms of SARS-CoV-2 infection were seen in OPD and worked up for surgery. Due to precaution in the form of PPE kits, masks, and gloves were taken in OPD during patient examination. A thorough history of any recent contact with infected personnel was also sought. Apart from all relevant investigations and pre-anesthetic clearance, all patients underwent RT-PCR for SARS-CoV-2 at least 24–48 hours prior to surgery, and only those patients who reported negative were admitted a day before surgery. Only 1 attendant was allowed with the patient. Any patient whose RT-PCR report came positive was advised home isolation for 2 weeks and was referred to a physician for management of SARS-CoV-2 infection. These cases were taken up after 4–6 weeks for surgery after getting clearance from a physician, pulmonologist, and anesthetist with a negative RT-PCR report and normal X-ray of the chest. Total of 14 cases were declared unfit due to cardiorespiratory contraindications. All surgeries were performed in modular operation theater with proper air circulation, adequate space, and negative pressure ventilation. The operating surgeon, assistant, scrub nurse, anesthetist, and floor nurse all wore PPE, double gloves, face shield, and N95 masks. We used a low-cost smoke evacuation device in which smoke was evacuated from a single port through intravenous infusion set into a suction jar filled with 1% hypochlorite solution after passing through an HME filter. All cases were done under general anesthesia. Samples of endotracheal aspirate and evacuated surgical smoke (swab from HME filter) were sent for RT-PCR in all cases. All patients in postoperative period were kept in close observation. Any incidence of fever, cough, fall in oxygen saturation level, and other findings were duly noticed. Various preoperative and postoperative parameters were analyzed. Patients were followed up for 1 month in OPD as well as telephonically.

Statistical analysis was performed using Statistical Package for the Social Sciences (SPSS) for Windows (version 24.0), and data were organized using Microsoft Office 2010 software. Categorical variables were described as frequency (percentage), and mean  $\pm$  standard deviation was used for continuous parameters.

## OBSERVATION AND RESULTS

A total of 301 patients were worked up from OPD and 287 underwent surgery over a period of 1 year. The mean age of the patients was 43.56 years. Out of 287, around 60% were female patients. Surgery most frequently performed was laparoscopic cholecystectomy (194 cases) followed by appendectomy and hernia repairs. A total of 15 gynecological cases were done, and 10 diagnostic laparoscopies were done. Total 8 cases were found positive for SARS-CoV-2 infection during work up. They underwent surgery after a gap of 4–6 weeks. None of the infected cases was found unfit for surgery, and all of them recovered well in home

isolation only. Presence of SARS-CoV-2 virus was not detected in either endotracheal aspirate or surgical smoke.

In total, 14 (4.87%) patients had fever postoperatively, and 13 had associated cough. All these patients underwent chest X-rays, and half of them had either pleural effusion or pneumonia. Two patients required a CT scan of the chest. Eleven patients had fall in saturation  $<90\%$  post-operatively and required  $O_2$  support; however, only 4 of them had real breathing discomfort. These patients were managed conservatively and recovered well without a need for intubation and mechanical ventilation. In total, 17 patients had sore throat which resolved with steam and rest. Due to these symptoms, RT-PCR was conducted on 16 patients, and none of the reports were positive. The mean duration of stay was around 2.32 days, and most of the patients were discharged after 24 hours. In follow-up after 2 weeks, 12 patients had wound infections, and 2 developed fever and cough, out of which 1 was found positive for SARS-CoV-2 infection and managed conservatively. None of the healthcare workers, whether surgeons, OT staff, or ward nursing staff contracted infection during the entire period (Table 1).

## DISCUSSION

COVID-19 pandemic emerged as a global threat and created a state of uncertainty and confusion among the surgeons all over the world. The patient's overall safety and own safety was the prime concern. The SARS-CoV-2 infection is transmitted by respiratory droplets, which can be airborne and remain suspended in the air for a significant period. Viral load is seen highest in respiratory secretions. Aerosol-generating procedures like bronchoscopy, laryngoscopy, endoscopy, and endotracheal intubation carry a higher risk of transmission of infection.<sup>3,4</sup> Many previous studies had shown the presence of Human Papilloma Virus (HPV), Hepatitis B virus (HBV), and Human immunodeficiency virus (HIV) in the surgical smoke, which raised a theoretical concern of the presence of SARS-CoV-2 infection in the surgical smoke created during almost all laparoscopic surgeries.<sup>14–17</sup> Laparoscopic surgery is a closed system. Pneumoperitoneum is created through a trochar, and evacuation is also done in a controlled manner through another trochar. We used a low-cost smoke filtration and evacuation during this pandemic. However, almost all the recent studies on COVID-19 had clearly indicated that there is no such evidence of transmission through surgical smoke.<sup>18,19</sup> Our study clearly showed that in patients who were asymptomatic and had negative RT-PCR reports prior to surgery, the SARS-CoV-2 virus was not detected in endotracheal aspirate or surgical smoke.

The most commonly performed elective minimally invasive procedure during this pandemic was laparoscopic cholecystectomy. Study by Manzia et al.<sup>5</sup> also stated that gall stone disease was most commonly postponed surgery during the pandemic. This clearly indicates that cholecystectomy is the most commonly performed elective surgery. It was observed that with proper history taking and screening in OPD, only 2.78% of cases were found positive for SARS-CoV-2 in preoperative work up. All of them were operated after 4 weeks, and none of them had any postoperative complications. However, it was found somewhat challenging to convince patients for RT-PCR test, especially when asymptomatic; however, with proper counseling, RT-PCR test was done for everyone.<sup>9</sup> We cannot rely entirely on RT-PCR results, so history of symptoms and recent travel to an infected zone play a major role during preoperative evaluation. Very few patients had COVID-19-like symptoms in postoperative period, but none of the patients were found to be

**Table 1:** Clinical parameters, preoperative, and postoperative findings

Clinical parameters and findings	Number (Percentage) of patients underwent surgery (N = 287)
Mean age (years)	43.56
Gender	
Male	114 (39.72%)
Female	173 (60.28%)
Surgery performed	
Laparoscopic cholecystectomy	194 (67.59%)
Laparoscopic appendectomy (Interval)	41 (14.28%)
Laparoscopic hernia repair	
Ventral	12 (4.18%)
Inguinal	14 (4.87%)
Diagnostic laparoscopy	10 (3.48%)
Laparoscopic orchiectomy	1 (0.34%)
Laparoscopic ovarian cystectomy	6 (2.09%)
Laparoscopic salpingectomy	4 (1.3%)
Total laparoscopic hysterectomy	5 (1.7%)
Preoperative findings	
SARS-CoV-2 detected with symptoms	3 (1.04%)
SARS-CoV-2 detected (asymptomatic)	5 (1.7%)
Average duration from detection of SARS-CoV-2 infection to surgery (days)	34.46
Postoperative findings	
Fever(>100°F)	14 (4.87%)
Cough	9 (3.13%)
Dry	4 (1.39%)
With expectoration	17 (5.92%)
Sore throat	4 (1.39%)
Breathing difficulty	11 (3.83%)
Fall in O <sub>2</sub> saturation level <90%	11 (3.83%)
Requirement of O <sub>2</sub>	0
Requirement of intubation and ventilator support	2 (0.69%)
Prolonged ICU stay	16 (5.57%)
RT-PCR conducted	0
Positive	15 (5.22%)
X-ray chest conducted	8 (2.78%)
Normal study	5 (1.74%)
Pleural effusion	4 (1.39%)
Unilateral	1 (0.34%)
Bilateral	2 (0.69%)
Pneumonia	2 (0.69%)
Computed tomography (CT) scan of chest	0
Mortality average duration of stay (days)	2.32
Follow-up findings (within 1 month)	
Wound infection	12 (4.18%)
Fever with cough and sore throat	2 (0.69%)
Detection of SARS-CoV-2 by RT-PCR	1 (0.34%)
Mortality	0
Presence of SARS-CoV-2	
Endotracheal aspirate	0
Surgical smoke	0
SARS-CoV-2 transmission among OT team and ward staff (Healthcare workers)	0

positive on RT-PCR testing. The findings in X-ray of these patients can be linked to otherwise known complications of minimal invasive surgery in the early postoperative period. Only 1 patient was found positive for SARS-CoV-2 infection after discharge from the hospital. There was no mortality recorded during this period. The rate of transmission among operating surgeons, anesthesia team, OT staff, and other hospital staff was almost negligible when all recommendations were duly followed. Precautions in form of patient screening, testing, and use of PPE kits, N95 masks along with the use of low-cost smoke filtration devices helped us not to get infected and safely performed elective laparoscopic procedures.<sup>20-22</sup> Use of PPE kits and RT-PCR tests for all cases has increased the cost of surgery, and it's an extra monetary burden on patients.<sup>22</sup> Patient's overall safety is the major concern while performing elective surgeries in this pandemic. All necessary precautions and screening helped in treating the patients who were simply ignored due to the global spread of this horrible disease. COVID-19 pandemic emerged as a global crisis. Elective surgeries should not be neglected. Ensuring safe and cost-effective surgery is a real challenge. Minimal invasive surgery for elective cases can be safely performed by taking adequate precautions like PPE and a low-cost smoke evacuation device. There is no evidence of transmission of infection by surgical smoke.

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# Laparoscopic Ventral Hernia Repair: Intraperitoneal Onlay Mesh Repair vs Transabdominal Retromuscular Repair

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## ABSTRACT

**Background:** Ventral hernia repair has changed over the past years by the introduction of laparoscopy and prosthetic materials. The laparoscopic approach is now broadly done because it offers its advantages for the patients. The broad acceptance of laparoscopic surgery has afforded an alternative to open repair of incisional hernia.

**Objective:** To compare the intraperitoneal onlay mesh (IPOM) repair vs the transabdominal retromuscular (TARM) repair as regards the perioperative data.

**Patients and methods:** This prospective study was conducted on 60 patients with a ventral hernia in the period from May 2018 to August 2019. All eligible fit cases, who were 18-year-old and on with non-complicated ventral hernia (the size defect,  $\leq 60$  mm), were included. They were simply randomized between the two techniques to compare operative time, intraoperative complications, postoperative pain, postoperative hospital stay, postoperative complications, and cosmetic results.

**Results:** The IPOM repair (1st group) was done in 24 patients, while TARM repair was completed in 36 patients. The operative time of group I was significantly shorter than that of group II. The repair in group I was cheaper than that in the other one. There was no significant injury to viscera or vessel and no recurrence in either group. The hospital stay was shorter for both groups ( $28.0 \pm 9.2$  vs  $26.0 \pm 6.93$  hours;  $p = 0.527$ ) as well as return to normal daily activity. More wound infection occurred in group II (16.7%) than in the other group (8.3%) ( $p = 0.511$ ). No important difference statistically was observed between the two groups regarding postoperative pain ( $p = 0.885$ ).

**Conclusion:** Laparoscopic hernia repair by either of both techniques has less postoperative pain, shorter hospital stays, faster return to normal daily activity, a lower rate of postoperative complications as regard wound infection, and ileus. The TARM repair technique is more time-consuming than the other technique, but early results indicate that it can be performed as a cheaper alternative to the other one.

**Keywords:** Intraperitoneal onlay mesh, Laparoscopic, Transabdominal retromuscular, Ventral.

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## INTRODUCTION

Defects in the abdominal wall results in a ventral hernia. They are routinely identified and called by location and etiology. Ventral abdominal hernias can develop spontaneously or at a site of previous scar as an incisional hernia. Incisional hernias form the major group of ventral abdominal hernias and they are the most challenging to reconstruct. Trocars insertion for laparoscopic surgery may also cause defects in the abdominal wall fascia which is called port sites hernia.<sup>1</sup>

Abdominal wall hernias in adults are mostly acquired in origin. Postoperative incisional hernias, a long-term complication of abdominal incisions, are commonly seen with the incidence of 3–13% after laparotomy. The incidence can increase up to 20–40% if the case had considerable surgical site infection (SSI) postoperatively.<sup>2–4</sup>

The incidence of incisional hernias is lower in tiny slit incisions; therefore, it seems to be much less common following laparoscopic port sites than that following large midline abdominal surgeries. At least one-third of incisional hernias will appear within 5–10 years postoperatively. The surgical site infection and open abdomen are the most significant causative factors of the incisional hernia.<sup>5,6</sup> There are many nonsurgical possible causes like uncontrolled diabetes mellitus (DM), smoking, obesity, immunosuppressive therapy, malnutrition, use of steroids, and old age.<sup>7</sup>

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There is no definite clue that defines that the suture type at the index surgery causes hernia occurrence. Patient-associated risk factors contributed to the formation of ventral hernia involve male sex, older age, prostatism, obesity, emphysema, and sleep apnea, it has been claimed that all of these risk factors which are associated with collagen damage in the lung allied to diminish healing of the wound, with a rising incidence of hernia formation.<sup>8</sup>

The most common complications of abdominal ventral hernia are intestinal obstruction, strangulation, incarceration, in addition to frequent postoperative complications associated with hernia surgery such as wound infection, seroma formation, and hernia recurrence. These postoperative complications can frequently be revealed at physical examination.<sup>9</sup>

Cases with ventral abdominal hernia should have an appropriate preoperative preparation to get perfect surgical repair. Obesity or overweight is one of the most significant factors of ventral abdominal hernias. The ideal weight for surgery is the body mass index (BMI) of 18.5–25. Cases should be advised and promoted to cease smoking. Proper preoperative management of many comorbidities should be conducted as respiratory, cardiovascular, diabetes, renal conditions, hypertension, and other general illness. The candidates should be investigated for all of these preoperatively.<sup>10–14</sup>

The management of ventral hernia is surgical hernia repair. These procedures involve 1ry closure of the fascial defect, open hernia repair using a prosthetic mesh, and laparoscopic hernia repair. The concept of tension-free repair of any hernia using mesh has been standardized and customized as being the main technique for most of the hernias, whatever be the size of the defect.<sup>5</sup>

The different types of mesh with the different structure utilized as follows: Polypropylene (prolene) mesh and expanded polytetrafluoroethylene (PTFE) mesh. The prolene mesh is the most commonly used and it contains an inert, durable, non-absorbable, and knitted monofilaments that enhance rapid fibrotic incorporation into the surrounding tissues. The PTFE mesh is a durable, inert, and macrofilament that quickly becomes adherent to the tissues.<sup>5</sup>

Because of the high postoperative incidence of recurrence, repair of an incisional hernia is still one of the most challenging surgeries for general surgeons with high morbidities and rising costs. The frequent postoperative complications include wound infection, seroma formation, and hernia recurrence.<sup>15</sup>

In 1993, LeBlanc and William had started the repair of abdominal wall hernia using laparoscopy. Over many years, ventral hernioplasty using laparoscopy is standardized now and widely done. It may exhibit advantages for the cases from the use of the laparoscopic approach in which there is shorter hospital stay, less operative time, improved the surgical outcome of patients, and fewer morbidities. Deciding the surgical approach, the type of mesh to use, and the type of repair surgery are the principal challenges in hernia treatment, in addition to where to put the mesh to ensure the most powerful repair with the least probability of recurrence.<sup>16–18</sup>

In spite of the wide acceptance of laparoscopic hernioplasty as a standard procedure in elective hernia repair, there are still some concerns regarding challenging learning curve, higher costs, and risks of intestinal injuries from instruments and trocars or from operative manipulation intra-abdominally during the processing of the surgery of hernia repair.<sup>19</sup>

The role of laparoscopy in ventral hernia is still in progress to reach an ideal technique, one of the most accepted techniques is IPOM that include the use of a composite mesh that fixed to the peritoneum with tacks and transfacial sutures, but with IPOM technique, there is a limitation in its use due to the cost of the mesh and the tacks. So, the other alternative technique is the transcomposite mesh after creating a peritoneal flap and

augmentation of the defect with vicryl suture, the usage of either technique still need further studies.<sup>20,21</sup>

The aim of this study was to compare two laparoscopic repair techniques the IPOM repair and TARM repair in non-complicated ventral abdominal hernia regarding operative observations and information, postoperative pain, and recurrence rate, intra and postoperative complications, cost-effectiveness, and return to normal daily activity.

## PATIENTS AND METHODS

### Study Design and Recruitment of Population

It was a prospective clinical trial which had been conducted at the Department of General Surgery, Mansoura University Hospital, Egypt during the period from May 2018 till August 2019. This study involved 60 eligible candidates with uncomplicated ventral abdominal hernia (either primary or incisional), who were simply randomized between two groups: group I had 24 cases, with uncomplicated ventral hernia, for IPOM procedures were done and group II consisted of 36 cases, with abdominal ventral hernia, for whom the TARM procedures were achieved for them.

### Inclusion and Exclusion Criteria

All eligible cases, who were 18-year old and on with non-complicated ventral hernia were included. They should be fit for general anesthesia and accept to share in the research. The size of the hernia defect was less than or 60 mm in diameter to be suitable for the start of the learning curve. Complicated and recurrent ventral hernias were excluded. The patients with uncontrolled medical comorbidities, pregnancy, and psychological instability were also excluded.

All the eligible cases were carefully evaluated and were optimized preoperatively. All details of the techniques were explained to all patients. All patients provided informed consent to participate in the study and for the surgical procedure. The procedure was approved by the local health committee. All routine preoperative measures, such as fasting, administration of a single dose of IV antibiotic, anti-VTE measures, etc., were secured before the procedure for all cases. The study was conducted after securing the ethical approval from the local ethical committee, Institutional Research Board, Faculty of Medicine, Mansoura University.

### Operative Techniques

#### *Intraperitoneal Onlay Mesh Repair*

Pneumoperitoneum creation was performed using the closed method, commonly at the umbilical area or palmer's point according to the location of the ventral hernia. Carbon dioxide gas insufflation was done till reaching a pressure of 14–17 mm Hg intra-abdominally which was a safe one during the performance of all laparoscopic procedures of the study. The telescope was introduced through a 10-mm port and 2 or 3.5-mm ports were put depending on the site of the ventral hernia.

The most common site used for the placement of ports is the left flank region. Adhesions of the omentum and bowel were released by the use of sharp dissection diathermy and reduced. A careful abdominal survey of the inner parietal side using laparoscopy was done to identify the defect of the hernia and to exclude other parietal defects. The defect size was measured by the use of a part of suture or a paper ruler. The ideal placement of the dual mesh of appropriate size was achieved by overlapping 3–5 cm beyond



Fig. 1: Fixation of mesh by transfascial suture



Fig. 4: The mesh placement after retromuscular flap creation



Fig. 2: Double crowning technique for mesh fixation



Fig. 5: Closure of peritoneum over the mesh

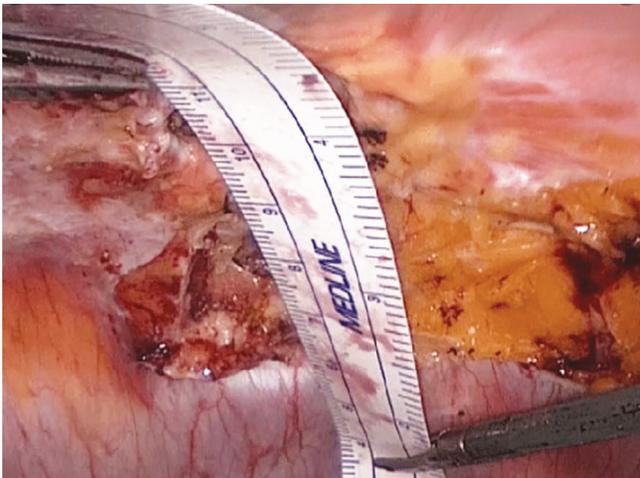


Fig. 3: Measurement of defect size by a paper ruler

the defect margins and anchored to the anterior parietal wall after lowering the pressure down to 6–8 mm Hg. Fixation was performed using transfascial sutures and double crown technique using absorbable tacks (Figs 1 and 2).

We imitated the technique of the previous studies.<sup>20,21</sup> The first row was put right at the defect or the hernia and the second one was placed at the mesh, 5 cm from the defect edge. To avoid adhesions between the mesh and the abdominal organs, created peritoneal flaps, or greater omentum were interfaced. Closure of the skin was completed using 3–0 sutures or skin stapler. A gauze ball was put over the area of the defect, with a gentle pressure dressing applied and kept for 2 weeks allowing its support, obliteration of any space between the mesh and parietal wall, and creation of adhesion in between.

#### Transabdominal Retromuscular Repair

The same steps were followed as IPOM and the same technique of the previous studies was performed.<sup>20,21</sup> The measurement of the defect was done by the use of a paper ruler (Fig. 3). Then start to create a retromuscular flaps through the preperitoneal plane all around the defect, 5-cm distance from the defect edge to create roomy space for mesh placement (Fig. 4). After securing good hemostasis and closure of the fascial defect using non-absorbable suture, the polypropylene mesh placement in retromuscular space was done and fixed using some absorbable tacks with the closure of the peritoneal flaps over the mesh by interrupted sutures using Vicryl 3/0 (Fig. 5).

**Table 1:** Different types of included ventral hernias

Variables	IPOM (N = 24) Group I		TARM (N = 36) Group II		$\chi^2$	p
	No	%	No	%		
Epigastric (1ry)	8	30%	18	50%	1.970	0.961
Paraumbilical (1ry)	10	45%	10	30%		
Incisional	6	25%	8	20%		
No complications	18	75%	20	55.6%	4.013	0.404
Minor bleeding	3	12.5%	6	16.7%		
Tearing of the peritoneum	0	0%	6	16.7%		
Serosal tear of small bowel	0	0%	2	5.6%		
Retromuscular hematoma	0	0%	2	5.6%		
Conversion of the technique	0	0%	3	8.3%		
Operative time (min) (mean $\pm$ SD)	82.17 $\pm$ 20.61		115.83 $\pm$ 29.17		3.456	0.002*

### Postoperative Follow-up

The postoperative assessment of pain was achieved using the visual analog scale (VAS) in the first postoperative day and analgesia, as follows, was given accordingly: Intramuscular diclofenac 50 mg till resumption of oral intake. The clinical follow up of postoperative wounds were conducted with respectation of SSI, hematoma, and seroma. Other complications, such as intestinal injury and internal bleeding, were looked for by clinical evaluation and follow-up ultrasound (US).

The recurrence of hernia was assessed by serial clinical evaluation in the inpatient ward and outpatient clinic. All patients were advised to avoid heavy duties and lifting heavy weights for at least 2 months, and then a gradual return to normal daily activity. Physical follow-up of the patient was performed once weekly during the first month, then once/month. A follow-up duration for 12 months at least was conducted for all cases. Evaluation of postoperative complications was performed regarding SSI, seroma formation, and hernia recurrence.

### Statistical Analysis

All of these data were collected in a special spreading datasheet then tabulated and coded. The data were fed to the computer and analyzed using IBM SPSS software package version 26.0. Qualitative data were described using the number and percent. Quantitative data were described using median (minimum and maximum) and interquartile range for non-parametric data and mean, the standard deviation for parametric data after testing normality using Kolmogorov–Smirnov test. The significance of the obtained results was judged at the 5% level.

### RESULTS

Laparoscopic ventral hernia repair (LVHR) of IPOM technique was performed in 24 patients having a mean age of  $38.58 \pm 7.40$  years; 75% were females, while LVHR was done by TARM technique repair was performed in 36 patients having mean age of  $38.22 \pm 9.33$  years; 50% were females.

In this study, both types of ventral hernia were included (1ry and incisional). Incisional hernia accounted for 25% of the patients in IPOM group (three patients postexploratory, two

cases postappendectomy, and one case of port site hernia) and 20% of patients in TARM group (five patients postexploratory, one postappendectomy, and two cases of port site hernia). The presentations of different ventral hernias were shown in Table 1. The defect size of all hernias was less than or 60 mm to facilitate the start of the learning curve with a mean of  $39.31 \pm 20.23$  mm.

The intraoperative complications in both groups were recorded in Table 1; minor bleeding from adhesolysis were noticed in both groups, six patients in a group show tearing of peritoneum, small intestine serosal tear occur in group II in two patients that managed by vicryl suturing of the serosal tear, and retromuscular hematoma occurs in group II in two patients which were managed intraoperatively by aspiration and control of bleeder.

The operative time of laparoscopic repair in both techniques was shown in Table 1. There was a significant difference between the two groups regarding the operative time. It was statistically very significant as  $p = 0.002^*$ .

The postoperative complications of the study population were recorded in Table 2. Postoperative seroma, wound infection, and mesh infection were a little higher in group I than group II. The recurrence rates of hernia were reported in the two techniques. One case, only in group II, presented with postoperative fever and pain. With investigation, there was a mesh infection which was managed by mesh removal, then it was managed like the cases of recurrence by open repair within 6–12 months postoperatively. No bowel injury or vascular injury was noticed in the population of this study.

The 60 cases were given postoperatively one dose of analgesic in the form of intramuscular (IM) injection of non-steroidal anti-inflammatory drugs (NSAIDs). Moreover, 12 cases from group I and 16 cases from group II received extra doses of analgesics with no important difference statistically (Table 3) between the 2 groups as concerning postoperative pain.

Most of the periods of hospital stay did not exceed 48 hours with few patients stayed in hospital for 72 hours (Table 3). The time of return to normal daily activity was shown in Table 3 with no significant difference statistically between the two groups regarding return to daily activity and hospital stay.

As far the analysis of hospital cost of the case of each technique is concerned, it was found that higher hospital costs were observed in IPOM (\$3,080) than the costs of TARM (\$2,210) as shown in Table 4.

**Table 2:** The postoperative complications of the study population

	IPOM (N = 24) Group I		TARM (N = 36) Group II		$\chi^2$	p
	No	%	No	%		
Seroma	8	33.3	15	41.6	0.201	0.654
Wound infection	2	8.3	3	8.3	0.433	0.511
Mesh infection	0	0.0	1	2.7	0.690	0.406
Recurrence	2	8.3	2	5.6	0.062	0.804
Bowel injury	0	0.0	0	0.0		
Ileus	1	4.2	2	5.6	0.675	0.421
Vascular complications	0	0.0	0	0.0		

**Table 3:** Postoperative follow-up data of both groups

(mean $\pm$ SD)	IPOM (N = 24) Group I	TARM (N = 36) Group II	T	p
Postoperative pain	3.42 $\pm$ 0.51	3.44 $\pm$ 0.51	0.145	0.885
Hospital stay (hours)	26.0 $\pm$ 6.93	28.0 $\pm$ 9.2	0.640	0.527
Return to normal activity (days)	3.08 $\pm$ 1.0	3.39 $\pm$ 1.61	0.584	0.564

**Table 4:** Analysis of hospital cost of the case of each procedure

Variables	IPOM (\$)	TARM (\$)	p
Equipment cost	1,900	1,000	0.001
Theater cost	250	250	–
Ward cost/night	650	650	–
Cost of anesthesia	280	310	0.23
The mean cost of the inpatient	3,080	2,210	0.041

## DISCUSSION

The ventral hernias are a group of hernias affecting the abdominal. Repair surgeries of these hernias stay one of the most frequently performed operations with more than 350,000 achieved/year in the US. These hernias carry the risk of bowel ischemia and strangulation, which can lead to serious consequences, In addition to the aesthetic detriment of the hernia.<sup>22</sup>

Laparoscopic ventral hernia repair has many advantages over the open approach mainly due to reduced wound complication rates and faster recovery. Laparoscopic ventral hernia repair uses different prosthetic meshes, which are put either intraperitoneally IPOM or in retromuscular space TARM. Laparoscopic ventral hernia repair is growing rapidly to be a standard technique worldwide due to the low rate of recurrence and all the advantages of laparoscopic surgery.<sup>23,24</sup>

In spite of the marvelous results of LVHR, many experimental and clinical researches have noticed complications resulting from the procedure of IPOM when using prolene mesh. It had a rising rate of complications which were a statistically significant issue. They included formation of adhesions, small intestinal obstruction, and fistula formation.<sup>25,26</sup>

The omental interface can diminish or prevent the adhesion of viscera to prolene mesh. However, in the case series of reoperated patients, they revealed that one-third of the cases had dense adhesion to prolene mesh. Depending on the results of experimental

and clinical researches, it was concluded that TARM placement of prolene mesh is a cost-effective available option and has a reduced rate of postoperative formation of adhesions.<sup>27,28</sup>

This current study was conducted to assess and compare the outcomes of two laparoscopic procedures of LVHR composing of TARM and IPOM placement of mesh. The cases were randomly divided into two groups; group I patients were operated by IPOM procedure and group II patients were operated by TARM placement of mesh.

In this study, the ventral hernia with defect size 39.31  $\pm$  20.23 mm represented in the cases of both groups. Epigastric hernias were true hernias with defect size in the range of 20–60 mm in diameter with no significant difference statistically between the two groups.

Prasad et al. reported that there was no difference in the mean fascial defect size (30.8 cm  $\pm$  24.4 cm vs 29.9 cm  $\pm$  22.0 cm,  $p = 0.78$ ) and the mean size of mesh (237.8 cm  $\pm$  66.8 c, vs 240.3 cm  $\pm$  98.2 cm,  $p = 0.84$ ) used in both techniques.<sup>29</sup>

In the study between our hands, the mean operative time of LVHR by IPOM was (82 minutes) which was significantly shorter than that of laparoscopic TARM repair (115 minutes) ( $p = 0.002$ , statistically significant). The explanation for the longer duration associated with TARM is the need for the creation of peritoneal flaps in the retromuscular space and closure over the mesh by resuturing of the flaps after mesh fixation. In spite of higher operating time, TARM procedure is economical because of the use of cheap prolene mesh, but IPOM procedure involves the use of expensive composite meshes.

This came in agreement with a study<sup>29</sup> who reported that the operative time is longer in TARM group was statistically significant longer than in IPOM group ( $p = 0.001$ ). This also came in accordance with Shetty et al. who showed that the mean operative time in the TARM group was 105  $\pm$  19.8 minutes vs 89.5  $\pm$  26.4 minutes in the IPOM group with statistically significant difference between the two groups.<sup>30</sup>

On the other hand, Gokcal et al. showed that there was no difference in terms of operative times in their cohort studies

between IPOM and TARM techniques. This likely stems from the distribution of cases who required extensive adhesiolysis (>30 minutes) (7.7% in IPOM vs 3.8 in TARM).<sup>31</sup>

In this study, intraoperative complications in both groups, minor bleeding from adhesiolysis accounted for 12.5% in group I and 16.7% in group II, six cases in group II (16.7%) show tearing of peritoneum, small intestine serosal tear occur in group II in two patients that managed by vicryl suturing of the serosal tear, also retromuscular hematoma occurs in group II in two patients and managed intraoperatively by aspiration and control of bleeders. Three cases in TARM repair were converted to IPOM technique due to tearing of the peritoneum, Neither vascular injuries nor intestinal injuries were observed in both groups.

In a previous research, two cases in TARM procedures had an omental bleed while doing adhesiolysis, which was controlled laparoscopically with the placement of a drain for one postoperative day. One case in the IPOM group had an inferior epigastric vessel injury that was managed by clip application. None had any intraoperative complications in IPOM.<sup>30</sup> Prasad et al. reported that bleeding occurred in only one patient (1.4%) with TARM while serosal injury occurred in two patients (2.9%) in TARM group, and five patients (2.3%) in the IPOM group.<sup>29</sup>

Hematomas were more frequent in the IPOM group of another research as well. One possible explanation for this may be stemmed from the more extensive mesh fixation in IPOM repairs, increasing the likelihood of inadvertently injuring perforating vessels.<sup>31</sup>

Regarding the postoperative complications of the cases within the two groups, 12 cases (50%) had complications in the IPOM repair group while in the TARM group, postoperative complications appeared in 21 cases (58.3%). seroma formation was the most commonly reported complication in IPOM and TARM groups (33.3% vs 41.6%, respectively) with no significant difference. All cases of seroma were managed conservatively with no need for surgical interference.

It has been reported that the most commonly noticed complication of LVHR is the formation of seroma. The majority of the seromas occur anterior to the mesh and within retained hernial sac.<sup>32,33</sup> This came in agreement with a previous study which stated that seroma was the most frequent complication in both groups underwent LVHR enrolled in their research (5.8% in the TARM group and 8.3% in the IPOM group) with no significant difference between the two groups.<sup>29</sup>

The fundamental principles of the retromuscular (preperitoneal) repair, described by Stoppa and Rives, that entail placing the mesh in this preperitoneal planes have many advantages. It is a highly vascular plane; hence, it is protective against infection, and, moreover, any SSI occurring in the subcutaneous planes does not reach the mesh, as the mesh is retromuscular in a different deeper plane.<sup>34</sup>

This coincided with our results where mesh infection in the studied patients was only one case in the second group. Five patients developed wound infection—two in the IPOM group and three in the TARM repair group. The minimal surgical interference was needed without the need for mesh removal. One case in the IPOM group and two cases in the TARM group had postoperative paralytic ileus and they were managed conservatively.

On the contrary, Gokcal et al. showed that the rate of development of seromas, hematomas, and SSI, was significantly higher in the IPOM group, though when taken individually, these complications did not reach significance.<sup>31</sup>

In this study, only two patients in the IPOM group and two patients in the TARM group showed postoperative recurrence of the ventral hernia with no significant difference between the two groups. All of those four cases were repaired within 6–12 months postoperatively by open approach.

The previous studies reported that the total recurrence rate of LVHR (IPOM) is 3.8–5.6%.<sup>35,36</sup> Chowbey et al. observed in their series of 34 cases who underwent LVHR with TARM approach that the recurrence rate was 2.5%.<sup>37</sup> However, other study reported no recurrence rates in the two groups of cases included in their study either those underwent IPOM or TARM.<sup>38</sup>

In this study, there is no significant difference between the periods of hospital stay of the two groups. Most of the hospital stay durations in both groups did not exceed 48 hours and only a few cases stayed in the hospital for 72 hours. Return to normal daily activity with a short period for both techniques with no significant difference between both of them.

Prasad et al. showed that the mean of the hospital stay was 1.5–0.6 days in TARM group and 1.4–0.7 days in the IPOM group with no significant difference between the two groups.<sup>29</sup> In another study, the mean postoperative hospital stay was  $2.8 \pm 1.02$  days in the TARM group vs  $3.4 \pm 1.3$  days in the IPOM group.<sup>38</sup> Gokcal et al. showed that the median length of postoperative hospital stay was 0 days (IQR = 0–0) for both groups (range, 0–7 days in IPOM vs 0–4 days in TARM). They reported that a very large majority of patients are discharged on the same day of the surgery.<sup>31</sup>

In this current study, the 60 cases were given postoperatively one dose of analgesic in the form of IM injection of NSAIDs. Moreover, 12 cases from group I and 16 cases from group II received extra doses of analgesics with no important difference statistically. The mean postoperative pain score in the IPOM repair group was  $3.42 \pm 0.51$  vs  $3.44 \pm 0.51$  in the TARM group. There was no significant difference between the two groups regarding the postoperative pain.

Similar results were reported by previous research. There was no statistically significant difference in the pain VAS score between the cases who underwent IPOM or TARM hernia repair at 12 and 24 hours.<sup>38</sup> This came in agreement with Prasad et al. (2011) who revealed by comparison of the VAS pain score in both of the groups included in their study that there was no statistically significant difference between the two groups either in the first day postoperatively or after 30 days.<sup>29</sup> The recent research conducted by Gokcal et al. who did not find a difference in early postoperative pain scores between the two groups.<sup>31</sup>

From our initial experience of these 36 cases done by TARM repair, we feel it may be better to reduce mesh size to 12 cm × 15 cm with 12 cm placed laterally so that lateral nerves are not unduly irritated and to reduce postoperative pain.

Transfascial sutures used in IPOM may result in increased postoperative pain.<sup>29</sup> Another a possible contributing factor to a difference in the perception of pain or discomfort in IPOM cases relates to a potential inflammatory reaction which resulted from the placement of a foreign body within the peritoneal cavity.<sup>39</sup>

However, although shortened operation time due to minimal dissection with IPOM repair, the economic calculation including mesh costs is significantly higher.<sup>40</sup> In regard to the analysis of hospital cost of the case of each technique, it was found also that higher hospital costs were observed in IPOM (\$3,080) than the costs of TARM (\$2,210). The difference was statistically so significant due

to the high cost of composite mesh used in IPOM vs a traditional cheap one used in the TARM approach.

## LIMITATIONS

Transabdominal retromuscular is a feasible procedure for midline ventral hernias. We found that the best approach for epigastric hernias is a three-port suprapubic approach, in lateral three-port placement, we found it ergonomically difficult to suture midline defects in the epigastric region. There was no difficulty in suturing defects in umbilical and infraumbilical regions by the lateral approach. Subxiphoidal port placement is also recommended for an umbilical and infraumbilical hernia.

Difficulties we encountered with this approach were in suturing anterior defects because of interference by breast tissue in female patients and by a costal margin in male patients which interfered to some extent with hand movements. There was also the problem access because of the falciform ligament in 10-mm port subxiphoidal access. Therefore, we gained initial access by 5-mm port with 5-mm telescope in the left subcostal region after pneumoperitoneum by a Veress needle. We then dissected down the falciform ligament distally to proximally and then inserted 10-mm subxiphoidal port under vision.

Of all these approaches, we found the suprapubic approach versatile for epigastric hernias and the lateral approach for umbilical and infraumbilical hernias. The subxiphoidal approach is ergonomically difficult in our experience. Further studies are needed to establish this procedure as the preferred method for the treatment of ventral hernias.

The medium-sized hernias ( $\leq 60$  mm) only were included and it should be extended to include larger sized hernias.

## CONCLUSION

Laparoscopic hernia repair either IPOM or TARM repair techniques had less postoperative pain, shorter hospital stay, faster return to normal daily activity, a lower rate of postoperative complications as regard wound infection and ileus, and better cosmetic appearance. However, we found that TARM repair technique was more time consuming in comparison to the IPOM technique, but early results indicated that TARM could be performed as a cheaper alternative to IPOM mesh repair.

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# Validation of CLOC Score in Predicting the Risk of Conversion from Laparoscopic to Open Cholecystectomy in Dr Cipto Mangunkusumo Hospital

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## ABSTRACT

**Introduction:** Laparoscopic cholecystectomy is the gold standard for treatment of symptomatic cholelithiasis. Although relatively safe and effective, laparoscopic cholecystectomy is a difficult procedure. The rate of conversion to open cholecystectomy is estimated to be 1–15%. A preoperative predictive model may be helpful in determining whether open cholecystectomy is preferred over laparoscopic cholecystectomy to prevent morbidity and mortality associated with conversion. Conversion from laparoscopic to open cholecystectomy (CLOC) score can potentially predict the risk of conversion based on preoperative parameters. The purpose of this study is to validate the application of CLOC score in Dr Cipto Mangunkusumo Hospital's patient population.

**Materials and methods:** This was a retrospective study of patients undergoing laparoscopic cholecystectomy from January 2018 to December 2019 in Dr Cipto Mangunkusumo Hospital. Patient data were obtained from medical records. Descriptive analysis, Chi-square test, logistic regression analysis, and score validation using receiver-operating characteristic (ROC) curve by calculating the area under curve (AUC), sensitivity, and specificity were conducted. Based on the CLOC Score, the patients were stratified into two groups: low-risk (<6) and high-risk (>6).

**Results:** There were 163 subjects with a mean age of  $51.06 \pm 13.3$  years. The rate of conversion was 3.1% ( $n = 5$ ). Most of the subjects were 40–69 years of age (111 subjects, 68.1%). Of all 163 subjects, 103 (63.2%) were female. The indications for surgery were colicky pain (symptomatic gallstone disease) in 144 subjects (88.3%). Based on the logistic regression analysis, common bile duct dilation was found to be the only statistically significant variable [odds ratio (OR) = 10.97; 95% confidence interval (CI): 1.72–69.95]. The AUC approached 78.8% (fair) (95% CI: 58.2–99.4%;  $p = 0.029$ ) for a cut-off value of 6.5 (sensitivity = 80.0%; specificity = 79.1%). The median duration of procedure in the low-risk group vs the high-risk group was 120 minutes (30–330) vs 180 minutes (45–405) ( $p = 0.001$ ), respectively.

**Conclusion:** Common bile duct dilation was the only risk factor found to be significantly associated with conversion of laparoscopic cholecystectomy to open surgery. Other factors, such as age, sex, indication for surgery, gallbladder wall thickness, and ASA score were not found to be statistically significant risk factors. Conversion from laparoscopic to open cholecystectomy score was considered valid and useful in predicting the risk of conversion. A CLOC score of 7 or more was associated with a higher risk of conversion to open surgery.

**Keywords:** Cholecystectomy, CLOC score, Conversion, Laparoscopy.

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## INTRODUCTION

Currently, laparoscopic cholecystectomy is deemed the gold standard in the treatment of symptomatic cholelithiasis. Although considered to be safe and effective, laparoscopic cholecystectomy is a difficult surgical procedure, indicated by the relatively high rate of conversion to open cholecystectomy of approximately 1–15%. Conversion to open cholecystectomy usually increases perioperative time and complication rate in addition to overall healthcare costs. Open conversion is also associated with various complications, including injury to the biliary system, bile leak, hemorrhage, reoperation, need for blood transfusion, and even death.<sup>1–3</sup>

Predicting the risk of conversion from laparoscopic to open cholecystectomy preoperatively is an important aspect of preoperative planning. With the more accurate prediction tool, surgeons can prepare and plan the procedure better to reduce perioperative morbidity and mortality. Patients will also benefit from more accurate information with regards to the procedure so that they may make informed medical decisions better suited to their expectations. Preoperative prediction tools can also improve the assessment and the decision-making in choosing for the more

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appropriate initial approach whether open should be preferred over laparoscopic cholecystectomy in order to avoid morbidity and mortality associated with conversion.<sup>2–4</sup>

The various predictive preoperative scoring systems of conversion from laparoscopic to open cholecystectomy have been proposed. However, the clinical benefits are limited due to small sample sizes and/or lack of validation. Sutcliffe et al. has proposed the CLOC risk score according to the CholeS prospective study involving 8820 subjects. The results were patients with a CLOC score of  $>6$  had a higher risk of conversion to open surgery, specifically six times higher risk compared with those with a CLOC score of  $\leq 6$ . This score had a sensitivity of 77.1% and a specificity of 65.4%; thus, this score may be utilized in the clinical settings to accurately predict the risk of conversion.<sup>4</sup> Other important issue in laparoscopic cholecystectomy is prolonged operative time. Prolonged duration of surgery according to Sutcliffe et al.<sup>4</sup> is an important determinant of overall complication rate, including bile leak, injury to biliary duct, and longer length-of-stay. Among the proposed risk scoring systems, CLOC risk score is the preoperative predictive score that has been developed according to prospective data with a large sample size and has been widely validated. On the other hand, in Indonesia, there has been no data and preoperative conversion risk scoring system. The CLOC risk score may be utilized to reduce the risks of morbidity and mortality associated with conversion to open procedure.

Previously, G10 scoring system for predicting bailout procedure has been validated in Dr Cipto Mangunkusumo Hospital (RSCM). However, this scoring system uses intraoperative parameters and is not specific for predicting conversion to open cholecystectomy. The CLOC scoring system has the advantage of utilizing preoperative parameters. This system can specifically predict the risk of conversion and thus may be utilized for risk estimation and preparation for open cholecystectomy if the patient is considered high-risk. However, in order for this scoring system to be applied in RSCM, it need to be validated accordingly. RSCM will be the first hospital to validate this scoring system outside of the center where this score was developed.

## MATERIALS AND METHODS

### Population

This study is a retrospective study of patients who underwent laparoscopic cholecystectomy procedures in RSCM from January 2018 to December 2019 period. Patients with incomplete medical records were excluded. Data according to CLOC score variables, including age, sex, indication for surgery, ASA class, gallbladder wall, and common biliary duct diameter were collected.

### Data Analysis

Data were analyzed using IBM Statistical Package for the Social Sciences (SPSS) version 20. Data analysis conducted included both descriptive and inferential statistics. Descriptive statistics were provided in the form of table. The Kolmogorov–Smirnov test was opted because the number of subjects for this study was  $>50$  patients. Afterwards, bivariate and multivariate statistical analyses were conducted. Bivariate analysis was conducted using a Chi-square ( $\chi^2$ ) test. Alternatives for Chi-square test were Fisher test or Mann–Whitney test. Multivariate analysis was conducted along with logistic regression test to identify the cause-and-effect relationship among all the parameters/components of the CLOC scoring system and the rate of conversion. Calculation of the sensitivity and specificity of the CLOC scoring system for patients in RSCM were conducted using the ROC curve.

## RESULTS

### Baseline Characteristics

A total of 163 subjects were included in this study, with a mean age of  $51.06 \pm 13.3$  years. Data on subjects' age were distributed normally. There was no statistically significant difference with regards to subjects' age ( $p = 0.483$ ), with an average age of  $55.20 \pm 17.2$  years among those who underwent conversion to open cholecystectomy and an average age of  $50.93 \pm 13.3$  years among those who did not. Based on age-groups, most of the subjects were 40–69 years and only 11 subjects who were  $<30$  years. Most of the subjects were female (103 subjects, 63.2%).

The indication for laparoscopic cholecystectomy in this study was almost exclusively colicky pain (symptomatic gallstones), which comprised of 144 cases (88.3%). A total of 146 subjects (89.0%) in this study also had normal gallbladder wall thickness ( $<4$  mm), and a total of 141 subjects (86.5%) did not have dilated common biliary duct diameter. Based on the ASA classification, a total of 123 subjects (75.5%) were ASA class 2. The only variable found to have statistically significant difference in proportion was dilation of common biliary duct ( $p = 0.010$ ). This result was obtained through Fisher test.

The median duration of surgery in this study was 135 (30–105) minutes, with an interquartile range of 70. Data with regards to duration of surgery were expressed in the form of median and interquartile range due to abnormal distribution. There was a statistically significant difference between the duration of surgery and rate of conversion ( $p < 0.001$ ). The median duration of surgery in the conversion group was 270 (230–300) minutes, compared with 130 (30–405) minutes in the control group. Detailed information on subjects' characteristics was shown in Table 1.

### Association between the CLOC Score and the Rate of Conversion to Open Cholecystectomy

Because the data obtained in this study did not fulfill the criteria for Chi-square test, Fisher's exact test were conducted to obtain the proportion of low-risk ( $\leq 6$ ) and high-risk ( $>6$ ) CLOC score for conversion. Among subjects with low-risk CLOC score, 1 (0.8%) underwent conversion, while the remaining 33 subjects (99.2%) had straightforward laparoscopic cholecystectomy.

There was a statistically significant difference in the rate of conversion between subjects who had a low-risk CLOC score and subjects who did not ( $p = 0.010$ ). The difference in the rate of conversion to open cholecystectomy between those with low-risk score and those with high-risk score was 10.0%. Because the difference in proportion was less than 20%, clinically there was no difference between low-risk and high-risk CLOC score in terms of the rate of conversion in RSCM patients. The slight difference in proportion may be due to the small sample size. The difference in proportion was shown in Table 2.

### Logistic Regression Analysis

Based on the bivariate analysis in Table 1, the variables age, age-group, dilation of common biliary duct diameter, and ASA class had  $p$ -values of  $\leq 0.25$  and thus may be further included in logistic regression analysis. On the other hand, the variables sex, indication for surgery, and gallbladder wall thickness all had  $p$ -values of  $>0.25$  and thus were not included in logistic regression analysis. However, all parameters included in CLOC score theoretically were considered important. Logistic regression analysis was performed with backward methods until the regression model was obtained

**Table 1:** Baseline characteristics of the subjects

Variables	Subjects (n = 163)	Conversion to open		p
		Yes (n = 5)	No (n = 158)	
Age <sup>a</sup> , year	51.06 ± 13.3	55.20 ± 17.2	50.93 ± 13.3	0.483
Age-group <sup>b</sup>				0.683
<30	11 (6.7%)	0 (0%)	11 (100.0%)	
30–39	23 (14.1%)	2 (8.7%)	21 (91.3%)	
40–69	111 (68.1%)	1 (0.9%)	110 (99.1%)	
≥70	18 (11.0%)	2 (3.1%)	16 (88.9%)	
Sex <sup>c</sup>				0.261
Female	103 (63.2%)	2 (1.9%)	101 (98.1%)	
Male	60 (36.8%)	3 (5.0%)	57 (95.0%)	
Indication for surgical intervention <sup>c</sup>				0.466
Colicky pain (symptomatic gallstones)	144 (88.3%)	4 (2.8%)	140 (97.2%)	
Cholecystitis	19 (11.7%)	1 (5.3%)	18 (94.7%)	
CBD stones	0 (0%)	0 (0%)	0 (0%)	
Gallbladder wall thickness <sup>c</sup>				0.447
Normal (<4 mm)	145 (89.0%)	4 (2.8%)	141 (97.2%)	
Increased (≥4 mm)	18 (11.0%)	1 (5.6%)	17 (94.4%)	
Common biliary duct diameter <sup>c</sup>				0.018*
Normal	141 (86.5%)	2 (1.4%)	139 (98.6%)	
Dilated	22 (13.5%)	3 (13.6%)	19 (86.4%)	
ASA classification <sup>b</sup>				0.054
ASA = 1	22 (13.5%)	0 (0%)	22 (100%)	
ASA = 2	123 (75.5%)	3 (2.4%)	120 (97.6%)	
ASA ≥ 3	18 (11.0%)	2 (11.1%)	16 (88.9%)	
Duration of surgery <sup>b</sup> , minutes	135.0 (70.0)	270.0 (62.5)	130.0 (70.0)	<0.001*

<sup>a</sup>Unpaired t-test; <sup>b</sup>Mann–Whitney test; <sup>c</sup>Fisher’s test

\*Statistically significant difference (p <0.05)

SD, standard deviation; IQR, interquartile range; data with normal distribution were expressed in mean ± SD; data with abnormal distribution were expressed in median (IQR)

**Table 2:** Difference in proportion between CLOC risk score and rate of conversion

CLOC score	Conversion				p
	Yes	%	No	%	
Low-risk (≤6)	1	0.8	125	99.2	0.010*
High-risk (>6)	4	10.8	33	89.2	
Total	5	3.1	158	96.9	

Fisher’s exact test

\*Statistically significant result (p <0.05)

after the sixth step, and the other five variables were eliminated. The results of logistic regression analysis were shown in Table 3.

Based on the logistic regression model in Table 3, the p value of diameter coefficient was less than 0.05 and the confidence interval of the odds ratio did not cross the number 1. It was, therefore, concluded that the diameter variable was significantly associated with the risk of conversion in RSCM patients. In addition, this result was considered clinically significant; with an OR of 10.974, patients with common

biliary duct dilation who had laparoscopic cholecystectomy had 10.97 times higher risk for conversion to open cholecystectomy.

### ROC Curve Analysis

Analysis using ROC curve was performed to obtain the optimal cut-off score that may accurately predict the risk of conversion in RSCM patients. The cut-off score obtained was a CLOC score of 6.5, with a sensitivity of 80.0% and a specificity of 79.1%.

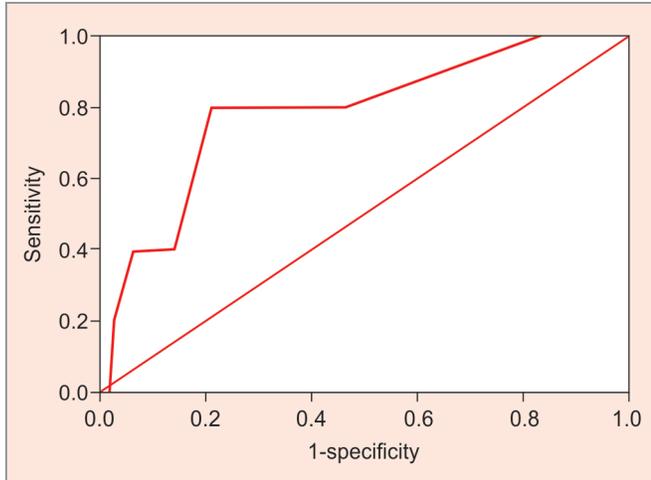
The AUC was 78.8% (95% CI: 58.2–99.4%; p = 0.029). Statistically, the CLOC score had a significant difference compared with the reference line due to a p value of <0.05 and the confidence interval values which did not cross 50%. Clinically, an AUC of 78.8% was considered fairly significant because researcher aimed for the minimal AUC value of 70%. Therefore, it was concluded that there was a significant association between CLOC score with the rate of conversion, both statistically and clinically (Fig. 1).

### CLOC Score and Duration of Surgery

The results of nonparametric Mann–Whitney test showed that the median duration of surgery in the low-risk group was significantly

**Table 3:** Logistic regression model

		Coefficient	df	OR	95% CI		p
					Lower	Upper	
6th step	Diameter (1)	2.396	1	10.974	1.721	69.952	0.011
	Constant	-4.241	1	0.014			0.000



**Fig. 1:** ROC curve of CLOC score and the rate of conversion. Area under the curve (AUC) = 78.8% (95% CI: 58.2–100.0%;  $p = 0.029$ )

**Table 4:** Comparison between CLOC risk score and duration of surgery

Skor CLOC	n	Duration of surgery (minutes)		p
		Median	IQR	
Low-risk ( $\leq 6$ )	126	120.0	50.0	0.001*
High-risk ( $> 6$ )	37	180.0	100.0	
Total	163	135.0	70.0	

Mann-Whitney test

\*Statistically significant difference ( $p < 0.05$ )

IQR, interquartile range

different with the median duration of surgery in the high-risk group [120 (30–330) vs 180 (45–405) minutes;  $p = 0.001$ ]. Results of the comparison were shown in [Table 4](#).

## DISCUSSION

### Subject Characteristics

The rate of conversion to open cholecystectomy in this study was relatively small. However, this number was similar to the study by Sutcliffe et al.,<sup>4</sup> which was 3.3%, and lower than both the study by Tayeb et al.<sup>5</sup> in Pakistan, which was 8.4%, and the study by Amin et al.,<sup>6</sup> which was 7.8%. The indication for conversion was the inability to locate Calot’s triangle during laparoscopic approach.<sup>5,6</sup>

### Risk Factors for Conversion

According to the study by Sutcliffe et al.,<sup>4</sup> there were six variables associated with the rate of conversion: age, sex, ASA class, indication for surgery, gallbladder wall thickness, and dilation of common biliary duct above normal diameter.

In this study, the average age of subjects who needed conversion to open surgery was similar with those who did not

( $55.20 \pm 17.2$  vs  $50.93 \pm 13.3$ ;  $p = 0.483$ ). According to the age-group, the largest difference of proportion is among the age-group 30–39 years, who had an 8.7% higher risk for conversion compared with subjects in the age-group  $< 30$  years. Other risk factors not found to be significantly associated with the rate of conversion in this study are sex, indication for surgery, gallbladder wall thickness, and ASA classification. Dilation of the common biliary duct above the normal diameter was found to be significantly associated with the risk of conversion. The group with dilation of the common biliary duct had a 12.2% higher risk for conversion to open procedure compared with those with normal diameter with a  $p$ -value of 0.018.

The most common surgical indication associated with conversion was mostly colicky pain (symptomatic gallstones), which was found in four subjects (2.8%). This finding was different with the study by Sutcliffe et al.,<sup>4</sup> which reported that the most common indication of conversion to open surgery was CBD calculi (9.1%), in stark contrast with colicky pain (1.2%).

After logistic regression multivariate analysis, only dilation of common biliary duct variable was found to be statistically significant, with an OR of 10.974 (95% CI: 1.271–69.952;  $p = 0.011$ ). RSCM patients with dilation of common biliary duct had a 10.97 times higher risk of conversion to open procedure compared with patients without common biliary duct dilation. Thus, although other factors were found to be not statistically significant, if RSCM patients had the risk factor of dilated common biliary duct above the normal diameter, they had a significantly higher probability of undergoing later conversion. The accuracy of this parameter was up to 74% (95% CI: 47.9–100.0%;  $p = 0.068$ ). Although it was found not statistically significant, clinically this value was important. The association between dilation of common biliary duct and rate of conversion was also reported by several authors.<sup>7–9</sup> In the study by Sutcliffe et al.,<sup>4</sup> the OR was lower, which was 1.70. Dilation of common biliary duct above normal diameter and increased gallbladder wall thickness indicate chronic inflammation due to recurrent cholecystitis. Both of these conditions in various reports are associated with an increased risk of conversion.<sup>10–12</sup>

### Validation of CLOC Score in Predicting Conversion to Open Cholecystectomy

In this study, CLOC score was significantly associated with the rate of conversion ( $p = 0.010$ ). Clinically, the difference in proportion of conversion in the high-risk group and the low-risk group was only 10%; however, this finding may be explained by the low-risk of conversion in our center. Validation of CLOC score was performed by ROC curve analysis, and it was found that CLOC score had a diagnostic accuracy of 78.8% (95% CI: 58.2–99.4%;  $p = 0.029$ ), which were both statistically and clinically significant. The optimal cut-off value was 6.5, with a sensitivity of 80.0% and a specificity of 79.1%. These results mean that 80.0% patients with a CLOC score of  $> 6$  (high-risk) were more likely to undergo conversion and approximately 79.1% patients with a CLOC score of  $\leq 6$  (low-risk) were more likely to not require conversion; however, about 20.9% patients with a low-risk score were still at-risk for conversion.

The sensitivity and specificity values of CLOC score found in this study were considered decent for screening tool. In addition, the optimal cut-off value found in this study was similar to the original study, which was lower risk for conversion in patients with a CLOC score of  $\leq 6$  and higher risk of conversion in patients with a CLOC score of  $> 6$ .<sup>4</sup> Thus, CLOC score may be reliably applied as a predictive tool for conversion to open procedure in patients who will undergo laparoscopic cholecystectomy in RSCM hospital.

### The Association between CLOC Score and Duration of Surgery

The median duration of surgery in the conversion group in this study was significantly different with the median duration in the control group. Patients who underwent conversion had longer median duration of surgery compared with those who did not undergo conversion [270 (230–300) vs 130 (30–405) minutes]. In the study by Sutcliffe et al.,<sup>4</sup> the median duration of laparoscopic surgery was 60 minutes, while the median duration of conversion to open surgery was 120 minutes ( $p < 0.001$ ). The longer duration of laparoscopic surgery in RSCM was possibly related to its status as an academic hospital and thus procedures were more likely to be performed by inexperienced residents or fellows. Longer duration of surgery according to Sutcliffe et al.<sup>4</sup> may be one factor associated with increased rate of overall complications, bile leak, biliary duct injury, and longer length of stay.

In accordance with those findings, CLOC was also found to be associated with the median length of surgery with a  $p = 0.001$ . In the low-risk CLOC score group, the median duration of surgery was 180 (45–405) minutes, which was 60 minutes longer compared with the high-risk CLOC score group, which was 120 (30–330) minutes. This finding supports the reasoning that care of high-risk patients is more complex and thus prolongs their duration of surgery.

An English study by Tafazal et al.<sup>13</sup> reported the difference between mean duration of laparoscopic cholecystectomy procedure between consultant surgeons (52.5 minutes) and trainees (51.4 minutes); however, this difference was not found to be statistically significant. When adjusted and stratified for case complexity, surgeries performed by consultant surgeons were 5 minutes faster compared with operations by trainees. On the other hand, a study by Subhas et al.<sup>14</sup> in Michigan, the duration of laparoscopic cholecystectomy ranged from 3 hours to 6 hours 40 minutes. Average duration of surgery was 3 hours 37 minutes. Causes of prolonged surgery were a previous history of abdominal surgery and bowel adhesion, with an OR of 6.7; obesity (OR 3.1); gallstones measured  $> 2.5$  cm and educational participation of residents during surgery were also found to increase the duration of cholecystectomy.<sup>15,16</sup>

### Study Limitations

The calculation of sample size for this study used the formula for single sample proportion. In that formula, no component of statistical power was calculated, although there was the component of precision or study accuracy (d). At the beginning of calculation, the author had set a precision value of 5%. If re-calculated with such proportion number, a value of 0.03 and a sample size of 163 subjects were obtained. The sample size used in this study exceeded the targeted minimum sample size, which was 50 subjects. The statistical power of this study was 80%, and thus, the findings were not considered preliminary and can be applied widely in various populations.

However, this study did have several limitations. This study did not have any subjects with CBD gallstones; thus, this study cannot yet include CBD gallstones as a risk factor for conversion to open cholecystectomy in RSCM. Subsequent multicenter study encompassing more variable indication for surgery is required. Alternatively, an isolated study identifying patients indicated for cholecystectomy due to CBD gallstones might also be conducted.

### CONCLUSION

Conversion from laparoscopic to open cholecystectomy risk score is deemed valid and applicable for predicting the risk of conversion from laparoscopic to open cholecystectomy in RSCM. A cut-off value of a high-risk score ( $> 6$ ) was associated with the rate of conversion, and a low-risk score ( $\leq 6$ ) was not associated with conversion. Other significant risk factors were dilation of the common biliary duct above normal diameter. Risk factors not found to be significantly associated with conversion were age, sex, indication for surgery, gallbladder wall thickness, and ASA classification. The median duration of laparoscopic cholecystectomy surgery and conversion in RSCM was longer compared with most other studies. The finding of this study suggested that the CLOC risk score may be employed in preoperative assessment of patients planned to undergo cholecystectomy to predict the risk of conversion and prevent the mortality and morbidity risks associated with conversion. During laparoscopic cholecystectomy, procedure may also be prolonged, especially in patients with high-risk CLOC score.

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# Diabetes and Hypertension: Is there Any Linkage to the Hemorrhage after Bariatric Surgery?

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## ABSTRACT

**Background:** Bleeding after bariatric surgery is one of the most common early postoperative complications that can cause morbidity or even mortality. Therefore, in this study, we investigated the relationship between demographic features and postoperative hemorrhage rate.

**Materials and methods:** We reviewed the patients' database who underwent laparoscopic bariatric surgery [sleeve gastrectomy (SG) and one anastomosis gastric bypass (OAGB)] from 2018 to 2020 in Loghman Hakim Hospital, Tehran, Iran. The patients' demographic features such as age, sex, weight, BMI, and history of diabetes mellitus and hypertension were accessed in all patients. Patients who required postoperative blood transfusion were then identified. Red blood cell transfusion or the need for reoperation to control bleeding was considered as significant acute bleeding after surgery. The Hb cut-off for red blood cell (RBC) transfusion was 7 gm/dL. The rate of bleeding was determined. By comparing the two groups (with and without the need for blood transfusion) by Chi-square test and independent *t*-test, the relationship between demographic features and postoperative bleeding was investigated.

**Results:** In total, 1481 morbidly obese patients (257 men and 1224 women) who underwent bariatric surgery SG and OAGB were studied. Twenty patients (0.13%) suffered a postoperative hemorrhage. In SG, 17 patients (1.3%), and in OAGB, 3 patients (4.3%) required blood transfusion. The difference in diabetes ( $p < 0.03$ ) and hypertension ( $p < 0.048$ ) in the two groups (with and without the need for blood transfusion) was statistically significant. Only two patients (10%) who underwent SG were taken to the operating room at the surgeon's discretion to control the bleeding (both had a blood transfusion before reoperation). Diabetes (35%) and hypertension (25.7%) were significantly more common in postoperative bled patients.

**Conclusion:** Despite all measures to reduce hemorrhage during and after bariatric surgery, bleeding is still one of the most common early postoperative complications after bariatric surgery. Therefore, recognizing the risk factors for bleeding is still important. In this study, an association was observed between hypertension and diabetes with postoperative bleeds.

**Keywords:** Bariatric surgery, Bleeding, Diabetes, Hemorrhage, Hypertension, Laparoscopy complications.

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## INTRODUCTION

Bariatric surgery is one of the main and long-term durable treatments for patients with morbid obesity. Due to the increase in morbid obesity, these operations are increasing day by day.<sup>1</sup> Bariatric surgery can cause these people to lose weight by restricting or changing the course of food material through the alimentary tract and causing food to be expelled earlier. Sleeve gastrectomy and OAGB are the most common surgeries. Postoperative bleeding is one of the most common causes of morbidity in patients undergoing bariatric surgery.<sup>2</sup> The bleeding rate was reported at 3.1% after bypass and 2% after gastric sleeve,<sup>3,4</sup> and the problems caused by anemia can cause many related complications in the patients. Red blood cell transfusions can lead to many complications, such as sepsis, multiple organ failure, pulmonary embolism, and even death.<sup>5-7</sup> Some of these problems [including deep vein thrombosis (DVT)] occur due to the release of inflammatory mediators following blood transfusion.<sup>8,9</sup> Bleeding causes the surgeon to avoid starting anticoagulants for the bleeding patient. This issue and the need for blood transfusions can lead to DVT of the legs and pulmonary embolism, which is the second most common cause of death during the peri-bariatric surgery period and the first 30 days after that.<sup>2</sup> Another reason for the importance of bleeding after bariatric surgery is that the patients' surgery time with bleeding is longer; they are hospitalized for a more extended period. They are more likely to have reoperation and readmission.<sup>2</sup> Therefore, knowing more about the risk factors for bleeding after

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bariatric surgery will help reduce this common complication after these operations. In cases where it is not possible to change these risk factors, the surgeon, knowing more high-risk patients, can take more preventive measures to prevent postoperative bleeding in these patients.

Some patient factors reported as a risk factor for perioperative bleeding are a history of obstructive sleep apnea, bleeding disorders, high blood pressure, and diabetes.<sup>2,10</sup> Our center

(Loghman Hakim Hospital in Tehran) is a high-volume bariatric surgery center. Therefore, we aimed to investigate the prevalence of postop bleeding in our center. Demographic features (particularly diabetes and hypertension) were evaluated as postoperative hemorrhage's probable risk factors in this study.

## MATERIALS AND METHODS

We reviewed the patients' database who underwent laparoscopic bariatric surgery (including SG and OAGB) from 2018 to 2020 in Loghman Hakim Hospital, Tehran. The patients' demographic features such as age, sex, weight, BMI, and history of diabetes mellitus and hypertension were accessed in all patients. All data were gathered separately for laparoscopic sleeve gastrectomy (LSG) and laparoscopic OAGB groups. In all SG operations, the stapler line was reinforced by omentopexy.

In our center, OAGB surgery has been the option of choice for patients who are candidates for gastric bypass surgery and had no contraindications such as severe esophagitis or large hiatal hernia for this operation. If OAGB was contraindicated, the patient had undergone Roux-en-Y gastric bypass (LRYGB) and was not included in this study. At the surgeon's discretion, a Jackson-Pratt drain had been selectively placed for OAGB and LSG in patients.

Significant acute postoperative bleeding was evaluated in this study and defined as the need for blood transfusion after surgery or the need for reoperation to control bleeding.

All patients were monitored for blood pressure and vital signs for 12 hours postoperatively, every hour for up to 12 hours, and then every 3 hours until discharge.

The surgeon was suspected of bleeding if such conditions were present: dizziness, tachycardia, pallor, orthostatic hypotension, abnormal abdominal pain, and significant blood drainage into the drain (more than 200 mL). Other possibilities such as leakage and pulmonary embolism were also evaluated in such patients according to the clinical signs and symptoms. The selective evaluations in such patients included charting the drain discharge (if any), oral methylene blue leak test, lab tests (including CBC), upper GI series, sonography, and CT scan (if applicable).

If evaluations were in favor of bleeding after surgery, a CBC (Hb) check was done serially at 6-hour intervals, and continuous vital signs monitoring was also started for the patient. Also, if there was a drain, the amount of blood in the drain had been charted every hour. Along with vital signs control and serial hemoglobin check, if there was evidence of bleeding on postoperative ultrasound, serial ultrasonography had been performed to check the changes in the extent of intra-abdominal hemorrhage.

The RBC transfusion or the need for reoperation for bleeding control was considered acute significant postoperative bleeding (based on The Clavien-Dindo Classification of Surgical Complications class II and III).<sup>11</sup>

The Hb cut-off for RBC transfusion was 7 in non-cardiac and 8 in cardiac patients.

All patients' data, including the need for transfusion or reoperation for bleeding control, were collected. The rate of postop bleeding in all patients who underwent bariatric surgery was calculated. It was then examined whether demographic characteristics and history of diabetes and hypertension had been a potential risk factor for postoperative bleeding or not. For this purpose, all patients who underwent bariatric surgery were divided into two groups (with and without the need for postoperative blood transfusion). In addition to examining the rate of postoperative bleeding in patients

**Table 1:** Patients characteristics

Characteristics	n = 1427
Demographics	
Age (year) <sup>a</sup>	35.9 (9.5)
Sex <sup>b</sup>	
Male	250 (17.5)
Female	1117 (82.5)
Weight (kg) <sup>a</sup>	121.8 (20.4)
Height (cm) <sup>a</sup>	165.2 (28.1)
BMI (kg/m <sup>2</sup> ) <sup>a</sup>	44.8 (6.2)
Comorbidities	
DM <sup>b</sup>	229 (16)
HTN <sup>b</sup>	198 (13.9)
Surgery	
SG <sup>b</sup>	1357 (95.1)
OAGB	70 (4.9)
Transfusion	
RBC transfusion <sup>b</sup>	20 (1.4)

BMI, body mass index; DM, diabetes mellitus; HTN, hypertension; SG, sleeve gastrectomy; OAGB, one anastomosis gastric bypass

<sup>a</sup>Data reported as mean ± standard deviation

<sup>b</sup>Data reported as the number and percentage in parentheses

who had undergone bariatric surgery, the study will examine the role of demographic characteristics and history of diabetes and hypertension on the possibility of postoperative bleeding.

This study has been registered and approved in Shahid Beheshti University of Medical Sciences' research department with the reference code: 24631. Also, the medical ethics committee of this university has approved this study with a tracking code:

IR.SBMU.RETECH.REC.1399.623.

## RESULTS

In this study, 1481 morbidly obese patients (257 men and 1224 women) who underwent bariatric surgery (SG and OAGB) were studied. These patients' mean age was 35.9 (9.6%) (13–76-years-old). Patients with missing data (n = 54) were excluded from the study.

Patients data are presented in Table 1.

As mentioned before, acute significant postoperative bleeding is defined as the need for blood transfusion or reoperation to control bleeding in this study.

None of the patients had cardiovascular problems based on the database study. So, the threshold for RBC was seven or fewer in the current study.

Twenty patients (0.13%) out of these 1481 patients suffered a postoperative hemorrhage.

In patients who underwent GS surgery, 17 patients (1.3%) and patients who underwent gastric bypass (OAGB) surgery, three patients (4.3%) required blood transfusion.

In this study, two patients underwent reoperation to control bleeding; both had undergone gastric sleeve surgery and received blood transfusions before reoperation.

The two groups (with and without the need for blood transfusion), based on mean demographic features (particularly history of diabetes and hypertension), are shown in Table 2.



**Table 2:** Demographic features, diabetes and hypertension, association with RBC transfusion

	With transfusion (n = 20)	Without transfusion (n = 1407)	p value
<b>Demographics</b>			
Age (year) <sup>a</sup>	39 (10.7)	35.8 (9.5)	0.17
<b>Sex</b>			
Male	10 (14.3)	240 (17.7)	0.07
Female	13 (85.7)	1164 (82.7)	
Weight (kg) <sup>a</sup>	124.5 (28.1)	121.8 (20.3)	0.7
Height (cm) <sup>a</sup>	163.8 (10)	165.3 (28.3)	0.38
BMI (kg/m <sup>2</sup> ) <sup>a</sup>	44 (5.5)	44.9 (6.3)	0.001
<b>Comorbidities</b>			
DM	7 (35)	222 (15.8)	0.001
HTN	6 (30)	192 (13.6)	0.007

BMI, body mass index; DM, diabetes mellitus; HTN, hypertension

<sup>a</sup>Data reported as mean ± standard deviation

<sup>b</sup>Data reported as the number and percentage in parentheses

By Chi-square test (or Fisher exact test) and independent t-test, the difference between the two groups (with and without the need for blood transfusion) was statistically significant only in terms of diabetes ( $p < 0.03$ ) and hypertension ( $p < 0.048$ ).

Patients who needed blood transfusion were 2.9 times more likely to have diabetes OR = 2.9 (95% CI: 1.1–7.3). These patients also suffered from hypertension 2.7 times more often than other patients who did not need blood transfusions OR = 2.7 (95% CI: 1.03–7.3).

## DISCUSSION

Bariatric surgery is one of the most effective and long-term durable treatments for patients suffering from morbid obesity. In most bariatric operations, the stomach is manipulated. Excessive gastric perfusion makes these operations prone to bleeding during and after surgery. Moreover, bleeding is still one of the most common early complications after bariatric surgeries. Therefore, knowing more about bleeding risk factors will help take more preventive measures in patients.

In a study by Zafar et al., performed on 168,093 patients from 742 centers, the rate of postoperative bleeding was 1.2%. The rate of postoperative bleeding in the current study was 1.4%.<sup>12</sup>

In a study by Carabajo et al., on 209 patients who underwent OAGB surgery, two patients (0.9) needed reoperation to control bleeding. The study did not mention patients who needed a blood transfusion following bleeding.<sup>13</sup> None of the patients who underwent OAGB required reoperation to control bleeding in the present study, but blood transfusions were given to three patients (4.3%) following hemorrhage.

In the study of Spivak et al., bleeding's relationship after GS surgery and a history of diabetes was investigated. Examining the databases of 394 patients, they found a link between a history of diabetes and postoperative bleeding (OR = 2.6). As in the current study, the criterion for acute postoperative bleeding in that study was the need for postoperative RBC transfusion. Acute bleeding after LSG was reported to be 2.8%, and it was stated that the operation technique was not related to it.<sup>10</sup> The rate of bleeding after LSG was 1.3% in the current study. We also found a link between diabetes and postoperative bleeding (OR = 2.9).

In De Angelis et al.'s study on 870 patients who underwent sleeve gastrectomy, the postoperative bleeding rate was 1.9%. In their study, Buttress material was used to prevent bleeding during the operation. They did not do omentopexy and stapler line routine overswing in gastric sleeve surgery.<sup>14</sup> In the present study, the bleeding rate was 1.3%. We still believe that omentopexy might reduce intra and postoperative bleeding rates.

In a study by Saber et al., omentopexy reduced surgery-related bleeding. He compared 100 patients with and 100 without omentopexy done. They found that omentopexy effectively reduced postoperative bleeding (0.8 vs 2.3%).<sup>15</sup> We also performed omentopexy for all SG patients, and the prevalence of bleeding after this operation was 1.3% in the current study.

In Lim et al., which examined a database of 633 patients, the rate of bleeding after gastric sleeve surgery was 7.4%. Low BMI was reported as a risk factor for postoperative bleeding in this study. They used sealants to strengthen the stapler line, which did not reduce postoperative bleeding.<sup>16</sup> In the current study, BMI did not affect the bleeding rate after bariatric surgery.

In our experience, the best way to reduce bleeding during and after surgery is to prevent it. Accordingly, one way to prevent intraoperative bleeding is complete intraoperative homeostasis. Furthermore, we propose omentopexy in SG to prevent intraoperative and postoperative bleeding.

We still believe that intraoperative drain placement will not be necessary to diagnose postoperative bleeding. We also believe that controlling the patient's vital signs and laboratory tests after surgery would be the best surveillance method for bleeding.

In this study, a clear relationship was seen between the history of diabetes and hypertension with postoperative bleeding. Previous studies have shown an association between intraoperative blood pressure changes and postoperative bleeding,<sup>17</sup> but no association was found between a history of hypertension and postoperative bleeding. Therefore, we assume that proper control of the patient's blood sugar and blood pressure before, during, and after surgery may prevent surgery-related bleeding. However, more postoperative bleeding in diabetic and hypertensive patients may be due to these diseases' long-term effects on the patient's vessels. So, short-term control of blood sugar and blood pressure factors might not be useful for omitting these risk factors. We recommend that in the future, more extensive studies be performed on the exact role of blood sugar, patient's blood pressure, and their fluctuations on bleeding in the perioperative period to develop more accurate protocols for diabetic and hypertensive patients undergoing bariatric surgery.

According to the current study, a history of diabetes and hypertension might be a risk factor for postbariatric surgery hemorrhage. Therefore, it is recommended that bariatric surgeons pay more attention to hemostasis during surgery and postoperative care for such patients to prevent bleeding after surgery.

However, multicentric studies are recommended to investigate the hemorrhage after bariatric surgery associated with diabetes and hypertension.

One of the limitations of this study was the small number of patients who underwent OAGB surgery, so we suggest that these variables be examined more in this operation in the future.

Patients with a lower drop in hemoglobin levels who did not require blood transfusions were not evaluated in this study. Further studies could investigate the risk factors for minor and sub-acute bleeding after bariatric surgery.

Another limitation of this study is that it is descriptive. Therefore, cohort studies are recommended to investigate the relationship between diabetes, hypertension, and other demographic features with hemorrhage after bariatric surgery in the future.

## CONCLUSION

Despite all measures to reduce hemorrhage during and after bariatric surgery, bleeding is still one of the most common early postoperative complications after bariatric surgery. Therefore, recognizing the risk factors for bleeding is still important. In this study, an association was observed between hypertension and diabetes with postoperative bleeds.

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# Rare Case of Ovarian Preserving Surgery in Unmarried Woman with a Case of U/L Salpingo-oophorectomy and Its Management: Oophoropexy

Sowmya Koteswara<sup>1</sup>, Deepika Bohra<sup>2</sup>

## ABSTRACT

Ovarian torsion is one of the common gynecological emergency occurring in women during reproductive age. Here, we are presenting a case of 19-year-old unmarried young girl who came with complaints of pain in abdomen associated with vomiting. She had a history of left-sided ovarian torsion for which she underwent laparoscopic left salpingo-oophorectomy. She underwent right-sided oophoropexy for recurrent torsion.

**Keywords:** Adnexal torsion, Oophoropexy, Ovarian torsion, Salpingo-oophorectomy.

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## INTRODUCTION

Ovarian torsion is rotation/twisting of the ovary along its ligamentous supports causing interrupted blood supply and sometimes, ischemia and necrosis. Traditionally, ovarian torsion was managed with salpingo-oophorectomy, mainly because conserving ischemic adnexa was considered a risk factor for thromboembolic sequel. Later, it is known that the risk of embolic events is low and because ischemic adnexa regain follicular activity, recent studies advocate conservative treatment of ovarian torsion in pre-pubertal and young women.<sup>1</sup> Detorsion and oophoropexy is a conservative surgical approach that should be planned in all young women with ovarian torsion. Oophoropexy for ovarian torsion is easy procedure and can be done either by suturing ovary to, plication of ovarian ligament, lateral pelvic wall, or even fixing to the posterior uterine wall.<sup>2</sup>

## CASE DESCRIPTION

A 19-year-old unmarried young girl came with complaints of the lower abdominal pain in the last 1 day, which was progressive in nature, associated with five episodes of vomiting.

No complaints of dysmenorrhea, white discharge per vagina, burning micturition or increased frequency of micturition, or loose stools. The girl attained menarche at the age of 15 years; LMP = 20 days back. The past cycles were regular, lasting for 3–4 days at interval of 30 days, moderate flow, associated with mild pain and no clots.

The patient gives similar history in the past and was told to have left-sided ovarian torsion for which she underwent laparoscopic left salpingo-oophorectomy 3 years back. On examination, her vitals were stable. There is no pallor, pedal edema. The abdominal examination elicited tenderness in right iliac fossa, no ascites, the previous surgical scar+, healthy, no organomegaly.

Ultrasound was done and showed right adnexal well-defined heteroechoic lesion measuring 7.5 cm × 5.7 cm × 5.8 cm with multiple peripherally arranged follicles and central echogenic stroma, peripheral vascularity noted on color Doppler, right ovary was not visualized separately, adjacent broad ligament showed an increased

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vascularity, minimal ascites noted, left ovary was not visualized (postoperative status). The uterus anteverted, normal size, no free fluid in pouch of Douglas (POD) and was diagnosed with right-sided ovarian cyst with torsion. The patient was taken for laparoscopy which showed normal sized uterus, left-side tube and ovary were not visualized (postop status), right side tube and ovarian torsion noted, congested, necrotic with minimal areas of healthy tissue.

Right ovarian detorsion and ovarian plication was done under spinal anesthesia.

Post-surgery scan done on day 3 showed right adnexal well-defined heteroechoic lesion measuring 6.3 cm × 4.4 cm with multiple peripherally arranged follicles and central echogenic stroma, minimal peripheral vascularity present, and central vascularity in the ovary on color Doppler noted.

The patient resumed her normal menstrual cycle after 2 months of the procedure and was followed up for 1 year. The scan was repeated after 6 months which showed healthy right ovary and tube (Figs 1 to 4).

## DISCUSSION

Adnexal torsion is a common condition among gynecological emergencies. The rate of recurrence in postmenarchal women is high mainly due to hyper-mobile or elongated ovarian ligaments,

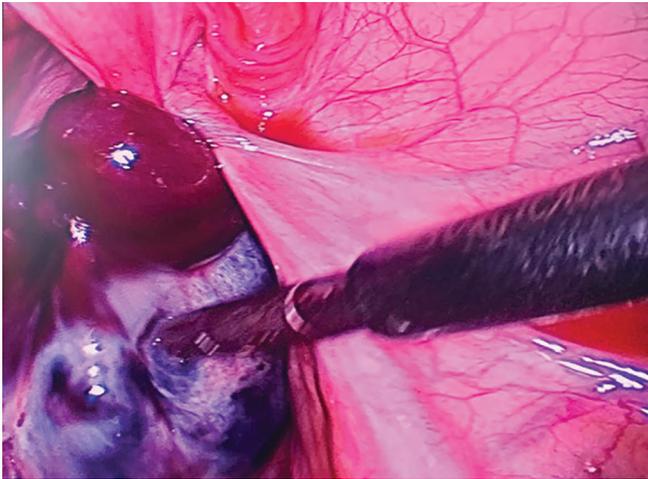


Fig. 1: Detorsion done and reduction in the amount of congestion noted

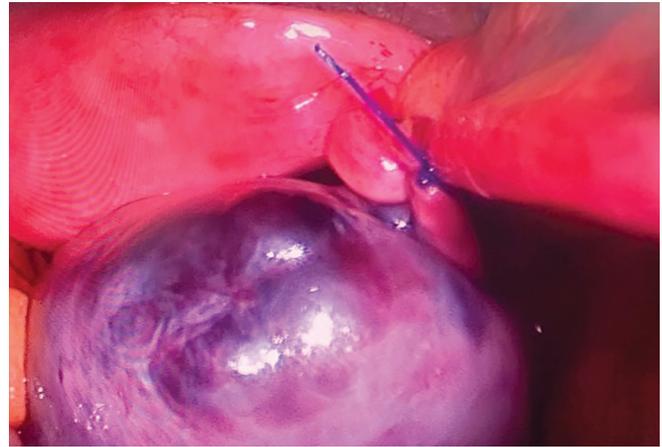


Fig. 4: Post-detorsion, there is reduction in the congestion and regaining of blood supply

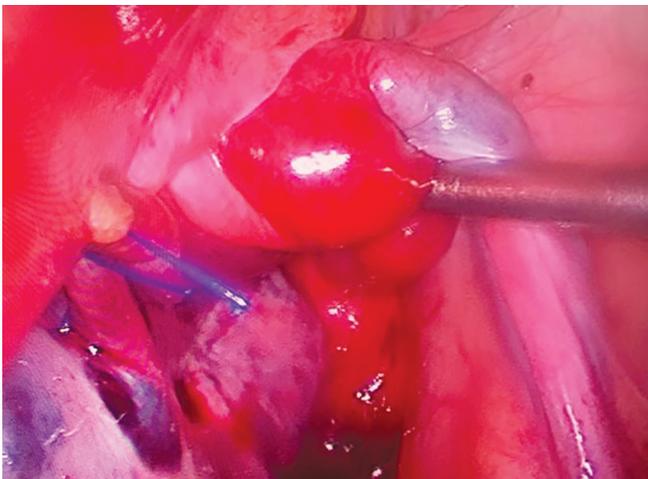


Fig. 2: The ovary was plicated to obliterated umbilical vein using vicryl 1

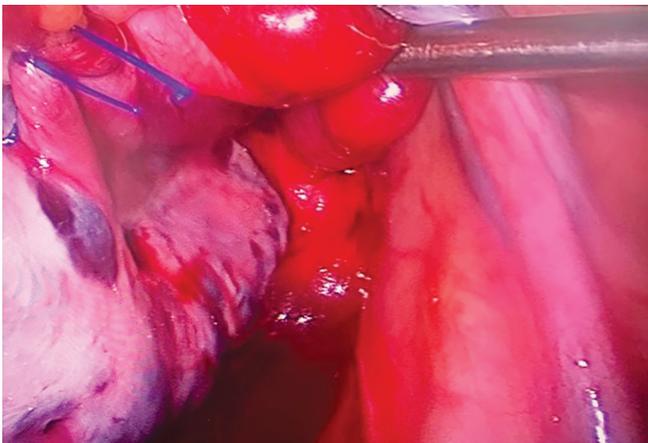


Fig. 3: There is reduced edema and congestion

or loose infundibulopelvic ligament. The ovarian torsion occurs when the ovary rotates around the infundibulopelvic ligament and the ovarian ligament interfering with its blood supply,

partially or completely.<sup>2</sup> Signs and symptoms of ovarian torsion are often similar to those seen with acute appendicitis; therefore, ovarian torsion is often misdiagnosed.<sup>3</sup> The most common clinical symptom being acute abdominal pain that is intermittent, and associated with nausea and vomiting. If the ovarian torsion is suspected, timely intervention with diagnostic laparoscopy is indicated to preserve ovarian function and future fertility.<sup>4</sup> The signs of torsion are fever, tachycardia, diffuse abdominal tenderness, localized guarding, vaginal examination showing adnexal tenderness, and mass.

The ultrasound feature describes the affected ovary as a solid mass with hypo- and hyperechoic areas with hemorrhage and necrosis. The twisted pedicle may be seen as a “whirlpool” on color Doppler.

The surgical management of adnexal torsion is determined by many factors, including the macroscopic appearance of the adnexa, age, menopausal status, presence of preexisting ovarian pathology and desire to preserve fertility. Oophorectomy should be done only if unavoidable, such as in case of severe necrosis; otherwise, oophoropexy should be considered.<sup>4</sup>

In the case in this report, the left ovary had already been removed previously because of ovarian torsion. Intraoperatively detorsion of the right-sided ovary was done and it was fixed to obliterated umbilical vein. This method was chosen as it is easier to perform and the area is relatively avascular and there are no important structures in this area.

## CONCLUSION

Adnexal torsion is the fifth most common gynecologic emergency. A total of 30% among all cases are commonly seen in girls below 20 years of age, with girls above 10 years at high-risk due to the hormonal influences and ovarian growth resulting in an increased incidence of physiological and pathological masses.<sup>4</sup>

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# Pediatric Achalasia: A Rare Differential for Failure to Thrive in a 4-year-old Child

Dhananjay Pandey<sup>1</sup>, Lokesh Yadav<sup>2</sup>, Lakshmi Kona<sup>3</sup>

## ABSTRACT

**Introduction:** Achalasia cardia (AC) is a primary motility disorder of esophagus, characterized by aperistalsis and defective relaxation of lower esophageal sphincter. It is predominantly a disease of adults and the incidence in children is extremely rare, 0.11 in 100,000. The presenting symptoms among children predominantly are dysphagia, regurgitation, vomiting, and failure to thrive. The diagnosis is made by barium studies and esophageal manometry. Per oral endoscopic myotomy (POEM) is a novel technique in adult population but its efficacy and safety in pediatric population is not known. Cardiomyotomy is the treatment of choice for childhood achalasia.

**Case description:** A 4-year-old boy presented to us with complaints of recurrent vomiting since 6 months of age and failure to thrive. He used to vomit immediately after ingestion of both solids and liquids. He had history of bronchopneumonia at around 1 year of age. He was malnourished and less than the third percentile for his age. His barium esophagogram (Fig. 1) showed persistent narrowing at the lower end of esophagus with proximal dilatation suggestive of achalasia. He was nutritionally rehabilitated and taken up for laparoscopic Heller's cardiomyotomy. Post-surgery, he improved well and was able to tolerate both solids and liquids. On follow-up, he had gained weight and was feeding normally.

This case highlights the importance of recognizing the fact that achalasia though rare can present in pediatric age-group as well. Diagnosis is usually delayed or misdiagnosed as gastroesophageal reflux disease (GERD), esophageal webs, etc. Patients usually become extremely malnourished and developmental milestones are delayed. Hence, the early diagnosis and treatment with cardiomyotomy is the key.

**Keywords:** Cardiomyotomy, Malnourishment, Pediatric achalasia, Per oral endoscopic myotomy.

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## INTRODUCTION

Achalasia cardia is a primary motility disorder of esophagus, characterized by aperistalsis, raised/normal lower esophageal sphincter (LES) pressure and defective lower esophageal relaxation. It is predominantly a disease of adults and extremely rare in children with a reported incidence of 0.11 in 100,000.<sup>1,2</sup> *Per se*, there is no population-based epidemiological study in children in India. The presenting symptoms in children predominantly are vomiting, regurgitation, recurrent chest infections, and failure to thrive. The diagnosis is made by barium studies, upper gastrointestinal (GI) endoscopy and esophageal manometry. Heller's myotomy is the most preferred treatment for achalasia in pediatric population as well. Per oral endoscopic myotomy is a novel technique in adult population but its efficacy and safety in pediatric population is not clearly known.

## CASE DESCRIPTION

A 4-year-old boy presented to us with complaints of recurrent vomiting since 6 months of age and failure to thrive. History of vomiting immediately after ingestion of solids and liquids as well and history of recurrent chest infections was present. His barium esophagogram (Fig. 1) revealed a persistent narrowing at the lower end of esophagus with proximal dilation and minimal passage of contrast into stomach. Findings were consistent with achalasia cardia. Esophagogastroduodenoscopy (Fig. 2) showed dilated esophagus with food residues and narrowing of esophagogastric junction with non-passage of scope beyond it. High-resolution manometry (HRM) could not be done due to technical difficulties.

At presentation, the boy weighed 8.1 kg, his height was 91 cm, and his body mass index (BMI) was 9.78; hence, severely malnourished (Fig. 3). His ideal bodyweight as per age should have

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been 16.5 kg with height of 105.7 cm. He was less than the third percentile as per centres for disease control and prevention (CDC) growth chart 2004; hence, severely malnourished.

After the nutritional assessment, a plan was made to improve his nutritional status by giving him parental nutrition (target calories, 1,350 kcal; protein, 24 gm approximately) before taking up the patient for any surgical intervention. His blood biochemistry revealed deranged electrolytes which was corrected in the meantime. After a week of nutritional supplementation and correction of dyselectrolytemia, the patient was reassessed and evaluated by our anesthesia and nutritional team and plan was made to proceed with surgery (laparoscopic Heller's cardiomyotomy with fundoplication).



Fig. 1: Barium swallow showing achalasia cardia



Figs 3A and B: Preoperative images of malnourished child

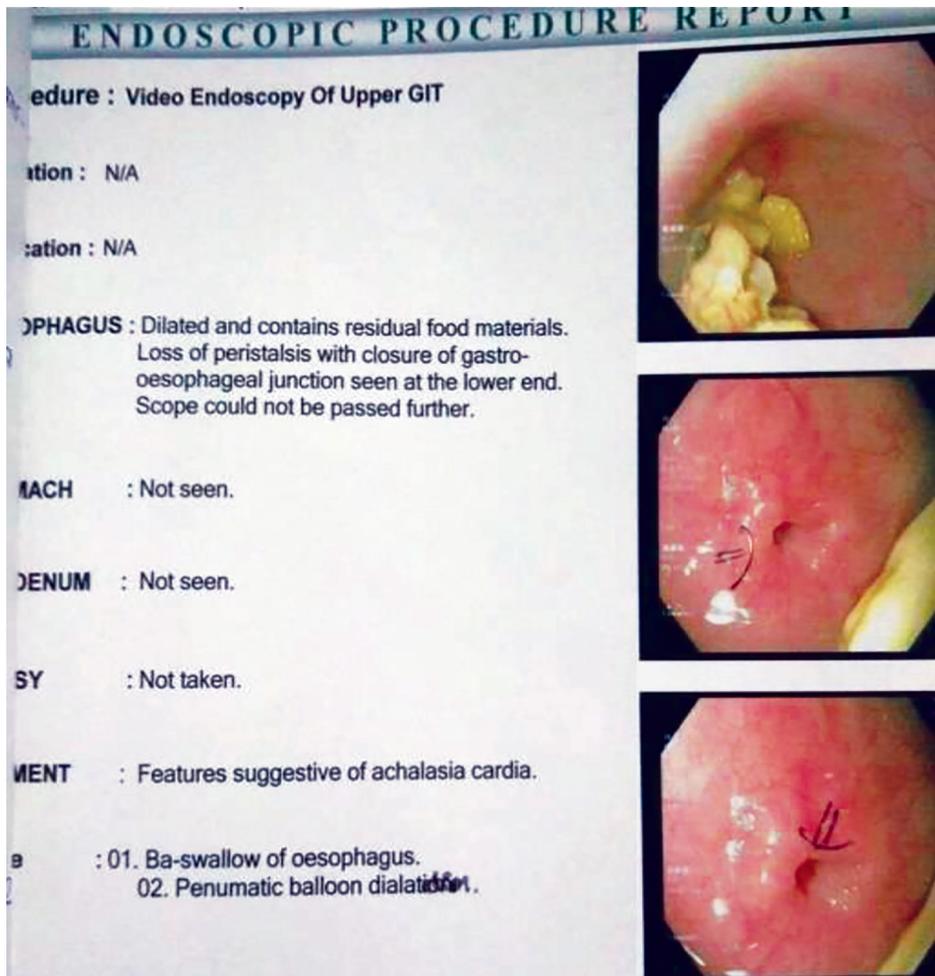
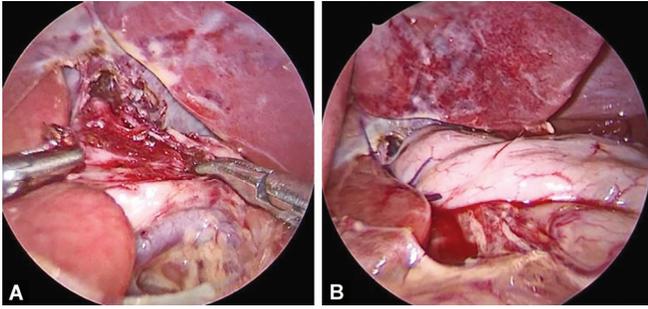


Fig. 2: UGI endoscopy showing features suggestive of achalasia cardia

### Surgical Technique

Pneumoperitoneum was created by open technique and remaining four ports were placed in standard fashion as per adult. Subxiphoid port was used for liver retraction. Hiatus was approached through pars flaccida, identifying and preserving left gastric artery. Presence

of replaced/accessory left hepatic artery was ruled out. The right crus identified and dissection done in plane between right crus and esophagus. Phrenoesophageal ligament was divided in a transverse fashion. Left crus identified and dissected off esophagus. It is advisable to dissect closer to crus while creating plane between crus



**Figs 4A and B:** Intraoperative image showing myotomy and Dor fundoplication



**Fig. 5:** Follow-up image of child at 9 months

and esophagus to avoid inadvertent injury to esophagus. Anterior vagus nerve identified and preserved. As the plan was to do anterior fundoplication, esophagus was not dissected posteriorly. Abdominal part of esophagus was defined and was taken control off by pulling cardioesophageal junction by holding pad of fat through left axillary port. A 12 Fr nasogastric tube was placed orally, over which repair was done. Myotomy started 2–3 cm above the esophagogastric (OG) junction, extended proximally for 5–6 cm and then approximately 2 cm on stomach side (Fig. 4). Longitudinal and circular muscle layer were split bluntly providing good exposure to underlying mucosa. Judicious hemostasis achieved using mechanical pressure with no use of energy sources. Fundus of stomach was mobilized and used for anterior Dor fundoplication using non-absorbable sutures (Fig. 4). Intraoperative period was uneventful. Gastrografin study was done on postoperative day (POD) 1 which showed a normal passage of contrast. The patient tolerated liquid and semisolid diet well and was discharged on POD3 on soft diet for 1 month, following which normal diet was continued.

On follow-up at 6 months, weight gain was 5 kg (weight was 13 kg with a height of 98 cm, and was feeding normally. At 9 months, weight was 15 kg with a height of 102 cm (more than 50th centile) (Fig. 5).

## DISCUSSION

Achalasia cardia is a primary esophageal motility disorder considered to be neurodegenerative in origin. It is exceedingly rare in first two decades of life (5%)<sup>3,4</sup> with only few cases reported in

infants. No familial association has been noted and is found to be more common in male child.<sup>5–8</sup> One of the reasons thought to be responsible for low incidence reported in pediatric population is inability to differentiate it from conditions with similar presentation. It is often confused with GERD, delaying correct diagnosis.<sup>5,6</sup> Typically, symptoms in adults and young children consist of dysphagia to solids and liquids, regurgitation, weight loss, and chest pain. It should also be noted that infant as well as preschool children will not always be able to complain of dysphagia. Therefore, the presentation in this subgroup of patients will primarily consist of recurrent vomiting, regurgitation of feeds, failure to thrive/weight loss or recurrent chest infection. Majority of these patient end up in pediatric clinic in place of surgical clinics that could lead to delayed presentation in them by 6–10 years.<sup>9</sup> Diagnosis is probably delayed due to misdiagnosis or presence of associated diseases. Therefore, it is advised to consider achalasia in differential diagnosis in this subset of patients.

Achalasia has been found to be associated with Chaga's disease, Allgrove syndrome, Congenital hypoventilation syndrome, eating disorders, trisomy 21 to name a few.<sup>9</sup> It is also important to confirm diagnosis prior to instituting treatment and rule out congenital/acquired causes of OG junction obstruction.

Tools to diagnose this condition are well established. Esophagogram is diagnostic in majority. Esophagogastroduodenoscopy should be done to rule out other condition that can cause OG junction obstruction or can be associated with achalasia. High-resolution manometry is considered investigation of choice for diagnosing this disorder. However, HRM is not possible in all cases due to various reasons.

The treatment aims at providing palliation that can be achieved by lowering the pressure gradient across LES as no treatment reverses underlying neuropathological process. Various treatment options are available; pharmacological, botulinum injections, endoscopic balloon dilatation (EBD), and open Heller's myotomy (HM)/laparoscopic Heller's myotomy (LHM). Calcium channel blockers (CCB) are the most commonly used drugs but are not advised in children in view of side effect profile and short-term effectiveness.<sup>10–13</sup> Endoscopic injections of botulinum toxin at LES are also reported in children without long-lasting effectiveness. Its use described as a bridge to EBD/HM or in cases where later not possible. Endoscopic balloon dilatation has been described in children for long with initial data showing favorable results. Various studies reveal good short-term results in older children. However, it is found to be technically difficult in younger (<7 years) children.<sup>14</sup> The risk of recurrence reaches 100% during long-term follow-up, and young age at presentation is an independent predictive factor for the need for repeated treatment.<sup>2,15</sup> The recent and majority of data reveal recurrent symptoms in majority requiring re-interventions.

Schoenberg et al. in his meta-analysis demonstrated superiority of myotomy over EBD in both short and long-term efficacy.<sup>16</sup> Heller's myotomy (lap/open) is an established procedure in adults with proven superiority to other means of treatment. With increasing experience, LHM is increasingly being performed in children as well compared to open HM. The data suggest success rate of more than 80% for surgical repair in long term studies in adults. For pediatric achalasia, long term permanent success rate is highest with myotomy compared to other means of treatment but these are based on small studies.<sup>2,11</sup> However, the data also reveal intervention in up to 28% patient in follow-up.<sup>17</sup> The most

common cause of failure or recurrence of symptoms is believed to be incomplete myotomy.<sup>18</sup> The role of fundoplication in pediatric AC is controversial. However, majority of studies support fundoplication.

Of late, POEM is considered to be a novel approach in adults with few case series reported in children as well with good short-term results. It can be considered to be a potential approach in future but its role in pediatric patients is not established at present.<sup>19</sup> Further long-term studies required to establish its status. In spite of drawbacks associated with LHM, it is the current surgical treatment of choice in pediatric achalasia cardia.<sup>19</sup>

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# Staged Management for Impacted Denture with Esophageal Perforation: Minimally Invasive Esophagectomy and Retrosternal Gastric Pull-up

Chaitra K Bhat<sup>1</sup>, Murugappan Nachiappan<sup>2</sup>, Jayanth Reddy<sup>3</sup>, Srikanth Gadiyaram<sup>4</sup>

## ABSTRACT

**Aim:** This case report aims to show the feasibility of minimally invasive surgery in the management of impacted denture in the esophagus complicated with perforation and mediastinitis.

**Background:** Foreign body impaction in the esophagus due to accidental or intentional swallowing is a rare but serious gastrointestinal emergency. Dentures are among the common causes of esophageal foreign body impaction in elderly, merely due to the presence of sharp clasp at the edges and their sheer size. The surgical intervention in these situations is rare but may be required following failed endoscopic extraction and for management of underlying esophageal perforation.

**Case description:** A 54-year-old lady presented to us within 24 hours following repeated attempts at endoscopic extraction of an accidentally swallowed denture. She had developed esophageal perforation with mediastinitis. Computed tomography (CT) showed a denture impacted 4 cm above the gastroesophageal junction with esophageal perforation, minimal mediastinal contamination, and extensive subcutaneous emphysema. After hemodynamic stabilization, the patient underwent an emergency laparoscopic transhiatal esophagectomy with end cervical esophagostomy and feeding jejunostomy. Elective reconstruction was performed after six weeks. A laparoscopic retrosternal gastric pull-up with cervical esophagogastric anastomosis was performed.

**Conclusion:** Laparoscopic transhiatal esophagectomy in the emergency setting is feasible when carried out in stable patients who are not amenable for primary repair and is associated with all the advantages of minimal access surgery. Minimally invasive reconstruction is feasible at a later date using a gastric conduit and the retrosternal route.

**Clinical significance:** This case emphasizes that multiple attempts at endoscopic retrieval should be avoided in patients with an impacted foreign body as it carries the risk of multiple perforations, precluding a primary repair at surgery, necessitating a major undertaking of a staged esophagectomy and gastric conduit reconstruction.

**Keywords:** Denture, Esophagus, Esophageal perforation, Foreign body, Minimally invasive esophagectomy.

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## INTRODUCTION

Foreign body impaction in the esophagus due to accidental or intentional swallowing is a rare but serious gastrointestinal emergency.<sup>1,2</sup> In adults, this is seen in the background of pre-existing esophageal pathology and in those with underlying psychiatric illness or mental retardation.<sup>3</sup> Dentures are among the common causes of esophageal foreign body impaction in elderly, merely due to the presence of sharp clasp at the edges and their sheer size.<sup>4,5</sup> The surgical intervention in these situations is rare but may be required following failed endoscopic extraction and for management of underlying esophageal perforation.<sup>6</sup> This report describes successful use of minimally invasive esophagectomy followed by staged esophageal replacement in the management of denture induced esophageal perforation.

## CASE DESCRIPTION

A 54-year-old lady presented to us within 24 hours following repeated attempts at endoscopic extraction of an accidentally swallowed denture. Following the endoscopic procedure, she had developed progressively worsening chest pain and dyspnea. She was in circulatory shock (pulse rate, 110/min; blood pressure, 90/60 mm Hg) and had extensive subcutaneous emphysema over the face, neck, chest, and upper abdomen. An esophageal perforation was suspected and a multidetector contrast enhanced computed

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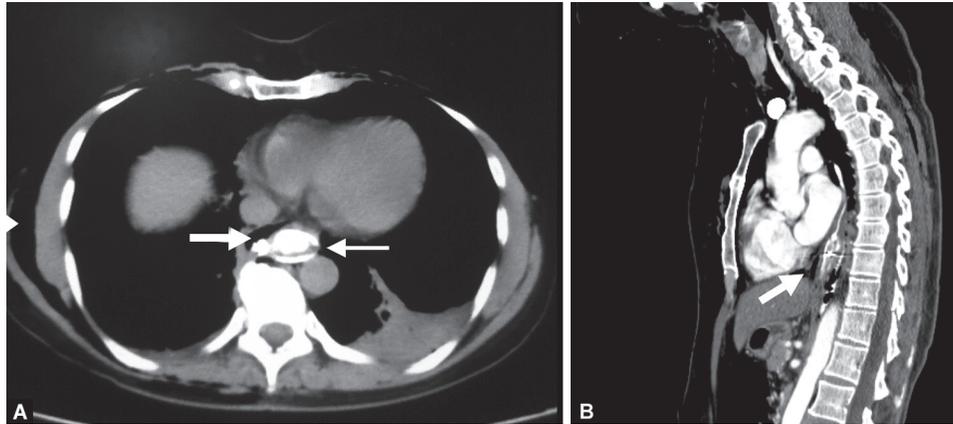
**Source of support:** Nil

**Conflict of interest:** None

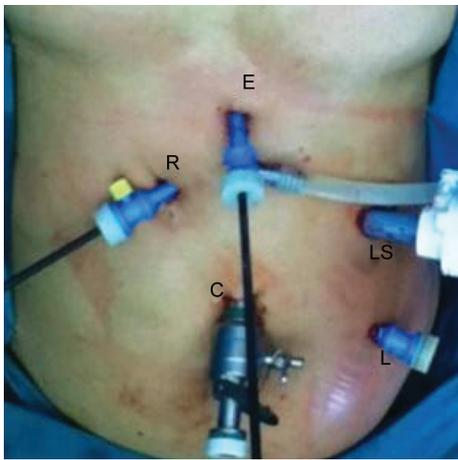
tomography (MDCT) was done after aggressive fluid resuscitation. The report of MDCT showed a denture impacted 4 cm above the gastroesophageal junction with esophageal perforation, minimal mediastinal contamination, and extensive subcutaneous emphysema (Fig. 1). After hemodynamic stabilization the patient underwent an emergency laparoscopic transhiatal esophagectomy with end cervical esophagostomy and feeding jejunostomy.

## Surgical Procedure

- Under general anesthesia, with the patient placed in supine leg split position. Pneumoperitoneum up to 14 mm Hg was created and five laparoscopic ports were inserted as shown in Figure 2.



**Figs 1A and B:** (A) Non-contrast CT image showing the impacted denture in the esophagus (line arrow), extraluminal air (block arrow) and extensive subcutaneous emphysema (arrowhead) are also noted. There is minimal infiltration seen in the left pleural cavity; (B) Contrast-enhanced CT sagittal image showing the denture and the extraluminal air



**Fig. 2:** Laparoscopic port positions. C, camera port; R, right mid-clavicular line which serves as the left-hand working port; LS, left mid-clavicular line which serves as the right-hand working and stapler port; E, epigastric port; L, assistant retraction port

- At laparoscopy, she had a hugely dilated stomach necessitating gastrostomy and decompression as pre-operative placement of a nasogastric (NG) tube was not feasible
- The gastroesophageal junction (GEJ) and lower esophagus were defined and short gastric vessels divided. A ribbon tape loop placed around the GEJ facilitated traction for further dissection.
- An impacted denture was visualized perforating the esophagus in the lower one-third at two sites (measuring 2 cm at 3 o'clock and 4 cm at 9 o'clock positions) (Fig. 3).
- Transhiatal mobilization of the esophagus was carried up to the carina. This step was performed using 5-mm harmonic shears (Ethicon Endosurgery, Cincinnati, USA).
- The denture causing perforation was retrieved through the esophageal perforation site and extracted through an endobag (Fig. 3).
- As there were two large perforations with adjacent mediastinal contamination not amenable to primary closure a decision to proceed with esophagectomy was taken.
- Esophagus just proximal to the GEJ was divided with Endo GIA™ Universal 60-mm linear stapler (United States Surg Corp. Norwalk, Conn.)

- Cervical esophagus was looped through a left hockey stick cervical incision along the anterior border of the left sternocleidomastoid muscle. Blunt digital mobilization of the upper esophagus was done keeping close to the esophagus up to the level of carina.
- Specimen was delivered out in the neck and an end esophagostomy fashioned on the left side (Fig. 4).
- Feeding jejunostomy was constructed and tube drains were inserted transhiatally into the mediastinum

Postoperative recovery was uneventful. She was discharged on postoperative day 7 on jejunostomy feeds.

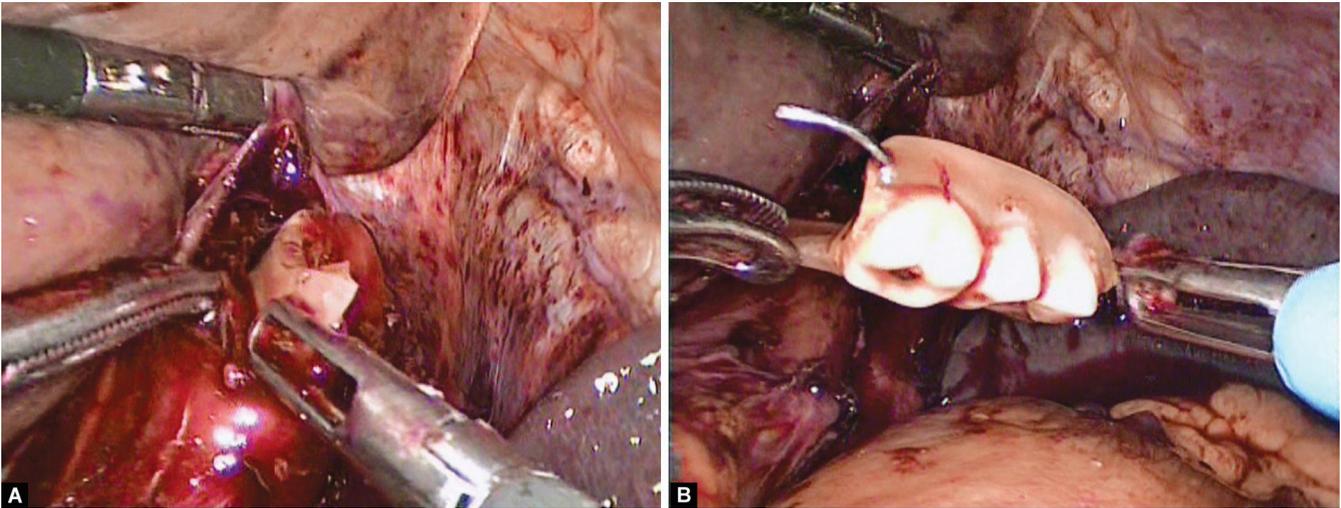
Elective reconstruction was performed after 6 weeks. A laparoscopic retrosternal gastric pull-up with cervical esophago-gastric anastomosis was performed in the following steps:

- Standard foregut ports as illustrated earlier (Fig. 2)
- Laparoscopic adhesiolysis and gastric conduit preparation based on the right gastroepiploic arcade.
- Creation of retrosternal tunnel.
- Cervical exploration, take down of the cervical esophagostomy and completion of the upper part of retrosternal tunnel.
- Nasogastric tube passed from the neck via the retrosternal tunnel into the abdomen. Tip of the NG hitched to the fundus of the gastric conduit. Rail roading of the gastric conduit into the neck by steady traction on the NG tube.
- Cervical esophago-gastric anastomosis was performed using an Endo GIA™ universal 60-mm stapler (United States Surg Corp. Norwalk, Conn.). Neck wound was closed in layers after placing a corrugated drain.

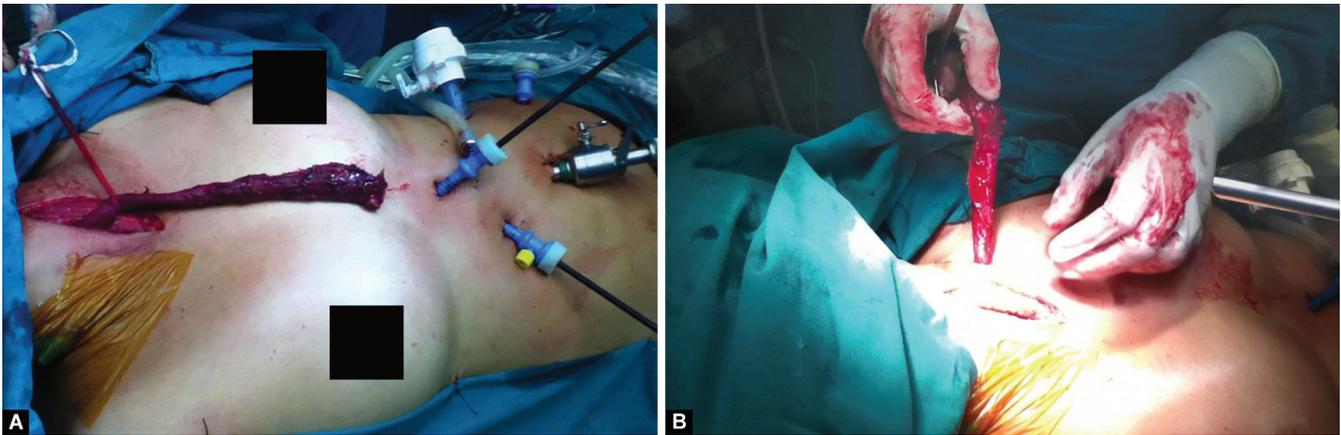
Postoperative recovery was uneventful except for left pleural effusion which settled with a single-time image guided aspiration. Contrast study on day 5 did not show any evidence of anastomotic leak (Fig. 5) and she was discharged on day 7. She is doing well at 8 years follow-up.

## DISCUSSION

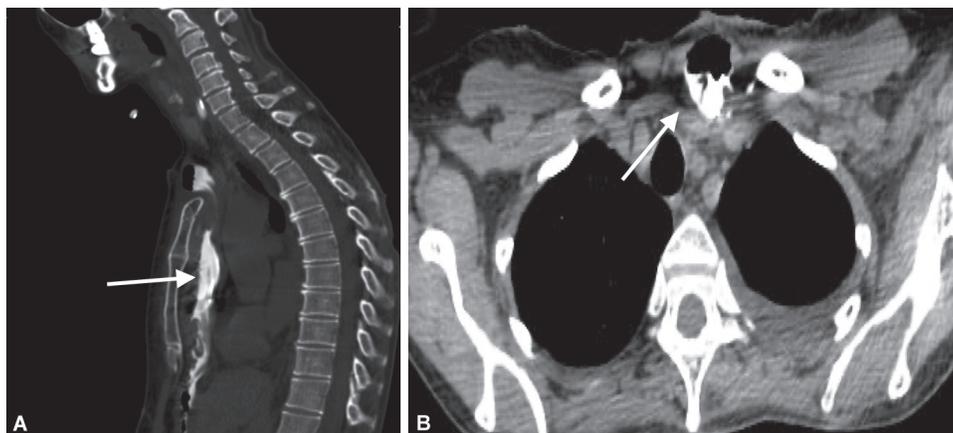
Foreign body ingestion with resulting impaction proximal to the site of narrowing in the esophagus is a rare but serious surgical emergency in adults.<sup>2</sup> Multidetector contrast enhanced computed tomography is preferred over conventional radiography for the diagnosis, recognition of resulting complications, and planning the



**Figs 3A and B:** (A) Retrieval of the impacted denture; (B) Retrieved denture with the sharp metal clasp



**Figs 4A and B:** (A) Extraction of transected and mobilized esophagus through cervical incision; (B) Esophagus taken out through a separate neck incision for creation of cervical esophagostomy



**Figs 5A and B:** Oral contrast study of the retrosternal gastric conduit (line arrow). (A) Sagittal view; (B) CT axial view

treatment strategy in case of impacted foreign body.<sup>7</sup> Although endoscopic extraction of an impacted foreign body is the most commonly used treatment modality, it is of limited utility for impacted dentures. A study from China evaluating the efficacy of flexible endoscopy in the management of esophageal foreign

bodies showed that impacted dentures were the most difficult to remove, resulting in more complications with 35% of these patients requiring further surgical intervention.<sup>8</sup> A previous report describing the use of the thoracoscopic technique for the removal of an impacted denture in the esophagus has also highlighted the

problem associated with endoscopic extraction.<sup>6</sup> These reports together with those published earlier emphasize the fact that surgical removal of an impacted denture is safer as compared to endoscopic extraction.<sup>9,10</sup> This is mainly due to the large size and presence of metal clasps in the denture which frequently get embedded in the esophageal wall making endoscopic extraction difficult. Prolonged impaction of dentures leads to underlying mucosal ischemia resulting in esophageal perforation. Although uncommon in comparison to iatrogenic and spontaneous esophageal perforation, foreign body induced perforation is a grave condition which if not recognized early and treated aggressively, is associated with high morbidity and mortality.<sup>11</sup> Aggressive surgical intervention for esophageal perforation was the management of choice for the predominant part of the twentieth century.<sup>12</sup> With advances in endoscopic techniques over the years, endoscopic therapy is being used more commonly in the management of esophageal perforations.<sup>13</sup> Surgical intervention is still necessary in the following scenarios: Failure of endoscopic therapy, presence of underlying esophageal pathology or in the event of gross mediastinal contamination.<sup>14</sup> Choice of surgical procedure is dictated by the time elapsed since perforation, hemodynamic stability of the patient, degree of mediastinal contamination, length and location of perforation, and condition of the underlying esophageal wall.<sup>15</sup> Esophagectomy is indicated in the presence of underlying esophageal pathology and in perforations not amenable for primary repair.<sup>15</sup> Richardson et al. reported the successful use of aggressive surgical management with which they were able to salvage 14 of the 64 patients of esophageal perforation who underwent esophageal resection.<sup>16</sup> Conventional method of esophagectomy and/or esophageal exclusion for the management of thoracic esophageal perforations performed *via* a thoracotomy/laparotomy in the emergency setting is however associated with high morbidity and delayed recovery.<sup>17</sup> The advantages of the use of minimally invasive surgery in the management esophageal perforation have been well documented in recent literature in terms of shorter operative time, lesser requirement of postoperative ventilation, faster recovery, early return to work, and thereby reduced overall cost.<sup>6,18</sup>

Although our patient presented within 24 hours of the onset of symptoms, the perforation was not amenable for primary repair due to the presence of multiple perforations probably secondary to attempted endoscopic extraction. Reconstruction of the alimentary tract in the staged setting was the next concern in this patient as the native tract was obliterated due to extensive posterior mediastinal adhesions. Therefore, we chose the retrosternal route for the gastric conduit placement. Literature review has shown that minimally invasive techniques in the management of foreign body induced esophageal perforation have mostly been used for extraction of the foreign body followed by primary repair.<sup>6,18</sup> Following an extensive MEDLINE search, we did not come across any report of the use of laparoscopic transhiatal esophagectomy followed by staged minimally invasive reconstruction for management of a foreign body induced esophageal perforation.

## CONCLUSION

Esophageal perforation secondary to denture impaction is an uncommon but serious surgical emergency. Repeated attempts at endoscopic extraction of an impacted denture carries the risk

of esophageal perforation and further mediastinal contamination and thereby should be avoided. Laparoscopic transhiatal esophagectomy in the emergency setting is feasible when carried out in stable patients who are not amenable for primary repair and is associated with all the advantages of minimal access surgery. This benefit can also be extended during restoration of the alimentary tract continuity at a later date by performing a laparoscopic retrosternal gastric transposition.

## CLINICAL SIGNIFIANCE

This case emphasizes that multiple attempts at endoscopic retrieval should be avoided in patients with an impacted foreign body as it carries the risk of multiple perforations, precluding a primary repair at surgery, necessitating a major undertaking of an esophagectomy and gastric conduit reconstruction. Successful management of an esophageal perforation in a case of attempted removal of the impacted denture in the esophagus with a minimally invasive approach.

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# Laparoscopic Revision of Benign Hepaticojejunostomy Stricture Following Previous Open Pancreaticoduodenectomy

Ravi Kiran Thota<sup>1</sup>, Srikanth Gadiyaram<sup>2</sup>

## ABSTRACT

Post-pancreaticoduodenectomy (PD) benign hepaticojejunostomy stricture (PDHJS) is an infrequent long-term complication. The therapeutic options in these patients are endoscopic or percutaneous balloon dilatation and surgical revision of the anastomosis. We herein describe the preoperative diagnosis and operative steps of laparoscopic revision hepaticojejunostomy (LRHJ) in an elderly male presenting with a hepaticojejunostomy stricture (HJS) 12 years post-open PD who had a failed percutaneous intervention.

**Keywords:** Benign hepaticojejunostomy stricture, Laparoscopic revision hepaticojejunostomy, Pancreaticoduodenectomy, Post-pancreaticoduodenectomy hepaticojejunostomy stricture.

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## INTRODUCTION

Post-pancreaticoduodenectomy benign hepaticojejunostomy stricture is reported in 2.6% of patients.<sup>1</sup> We herein report a case of HJS masquerading as hilar cholangiocarcinoma who underwent LRHJ.

## CASE DESCRIPTION

A 70-year-old male patient who had undergone a Whipple PD for ampullary carcinoma and adjuvant chemotherapy 12 years before presented now with low-grade cholangitis and was evaluated at another hospital. The diagnosis of hilar cholangiocarcinoma with left duct extension was made based on imaging, namely, multi-detector computed tomography (MDCT) (Fig. 1A), magnetic resonance cholangiopancreatography (MRCP) (Fig. 1B), and positron emission tomography with computed tomography (PET-CT) (Fig. 1C). A left hepatectomy/caudate resection had been advised there, and he was subsequently reviewed by us. After the review of LFT (total Bilirubin 0.36 mg/dL and ALP, GGT 89, 87 U/L, Serum albumin 3.34 gm/dL) and imaging, a possibility of benign HJS with hepatolithiasis was considered. The percutaneous transhepatic cholangiogram (PTC) (Fig. 1D) showed filling defects at hilar bile duct, left hepatic duct, and a non-dilatatable tight biliary stricture with only a streak of contrast entering the jejunum. Percutaneous transhepatic biliary drainage (PTBD) was left as an interno-external drain. Two weeks later, he underwent an LRHJ under general anesthesia (GA) in a supine/leg split position. The operative steps were as follows:

- Step I: Port-placement: Illustrated in Figure 2.
- Step II: Adhesiolysis: Adhesions were lysed from anterior abdominal wall and subhepatic regions. Hepatic flexure was taken down and further adhesiolysis was done with harmonic shears to define the HJS.
- Step III: Exposure of common hepatic duct (CHD): HJS site was looped with umbilical tape (Fig. 3A). Traction on umbilical tape helped further dissection, exposure of CHD up to biliary confluence.

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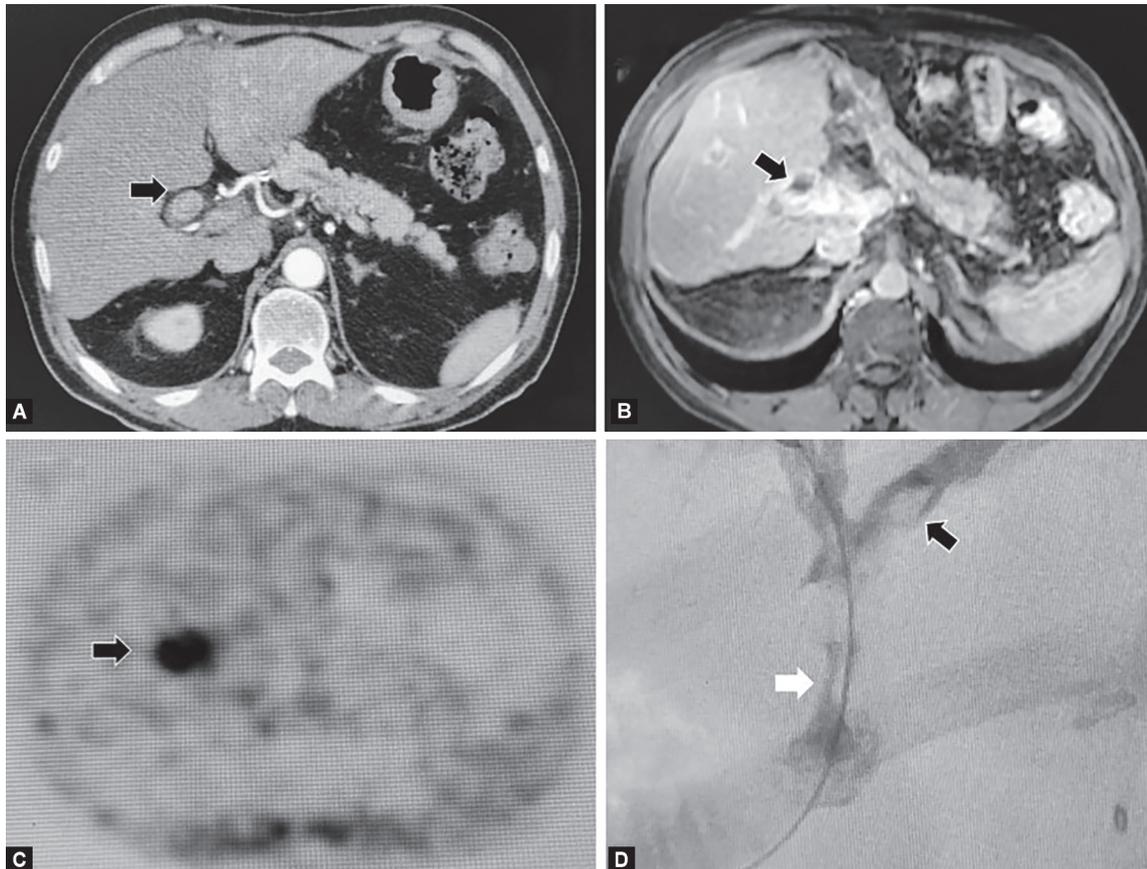
- Step IV: Jejunostomy, choledochotomy, and choledochoscopy: A jejunostomy (Fig. 3B) was made below HJS and across HJS into the normal CHD. The PTBD catheter was flushed and cleared of sludge and stones. Choledochoscopy (Fig. 3C) revealed no residual calculi and normal intra hepatic biliary mucosa.
- Step V: Revision HJ: The vertically aligned hepaticojejunostomy was closed horizontally with V-lock 3–0 suture in a continuous manner (Fig. 3D). Check PTBD-gram showed no leak from suture line.
- Step VI: Peritoneal lavage and subhepatic drains was placed. Sheath at 10-mm port sites were closed and skin with staples.

He made an uneventful recovery; subhepatic drain was removed on postoperative day (POD3) and he was discharged on POD6.

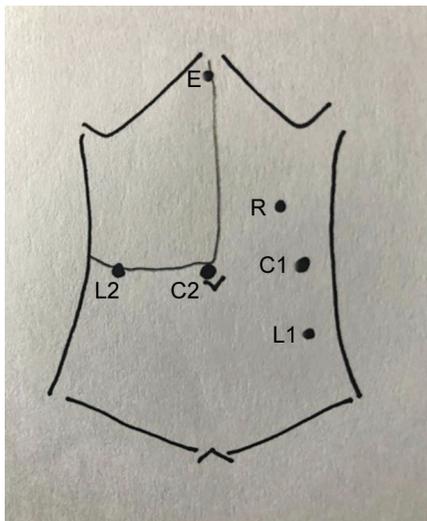
Furthermore, PTBD-gram done after 3 weeks showed free flow of contrast across HJ with no evidence of leak, and it was removed. At 12-months follow-up, he remains asymptomatic with normal LFT and no biliary dilatation on ultrasonography (USG).

## DISCUSSION

Post-pancreaticoduodenectomy benign hepaticojejunostomy stricture is due to a recurrence of cancer, benign HJ stricture or a second primary malignancy. A hilar cholangiocarcinoma following PD is most often seen in patients who had a distal common bile duct (CBD) cholangiocarcinoma to start with.<sup>1</sup> Imaging modalities



**Figs 1A to D:** (A) Depiction of MDCT showing soft tissue lesion filling hilar bile duct; (B) MRCP showing filling defect; (C) PET-CT increased uptake at hilum; (D) PTC demonstrating calculi in CHD and left hepatic duct. Black arrows show the lesions and calculi; white arrow shows HJS



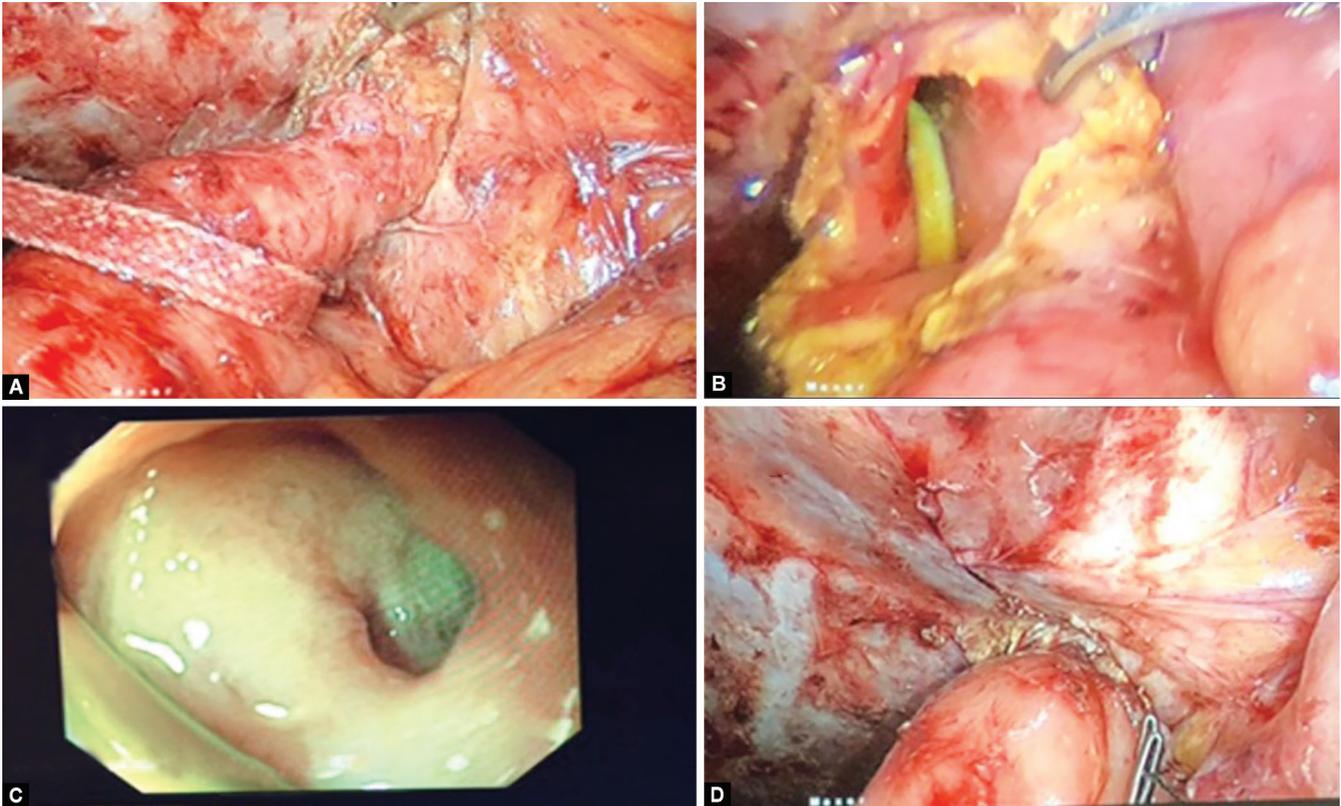
**Fig. 2:** Illustration of port sites; C1, camera port during initial adhesiolysis; C2, camera port during later part of procedure; R, right-hand working port; L1, left-hand working port during the initial part of the procedure; L2, left-hand working port during the later part of procedure; E, epigastric retraction port

used for diagnosis of HJS are MDCT, MRCP, and PTC which help in characterizing the lesion as benign or malignant.<sup>2</sup> Although the initial evaluation elsewhere had suggested hilar malignancy in the

present case, clinical course, findings on PTC/PTBD led us to a higher suspicion of benign stricture with hepatolithiasis. The higher uptake on PET-CT seems to be because of inflammation at stricture and associated cholangitis corroborated later at surgery and mistaken to be a second primary at initial evaluation.

Therapeutic options for PDHJS are percutaneous or endoscopic dilatation of the HJS, and surgical revision of the anastomosis.<sup>3</sup> The percutaneous and endoscopic approaches usually require multiple sittings to achieve satisfactory dilatation of HJS and are generally preferred over a surgical revision which is often accomplished by an open operation. There seemed to be a little merit in considering an endoscopic approach in a patient with "non-dilatable" HJS by percutaneous approach and we elected to do a minimally invasive surgical repair.

Zayne B et al. reported feasibility of robotic revision HJ.<sup>4</sup> By planning port placement for the initial adhesiolysis, and with patient dissection, the HJS could be clearly delineated. Also, the jejunostomy permitted choledochoscopy which confirmed normal biliary mucosa, thereby permitting us to proceed with the revision surgery. We feel, the previous open pancreaticoduodenectomy alone should not be a contraindication for repair of PDHJS, among groups with experience in minimally invasive hepatobiliary surgery. The laparoscopic approach brings with it the advantages of lesser pain; shorter hospital stay; fewer wound-related complications and can be achieved at a lesser overall cost than a robotic repair. To our knowledge, this is the first report of laparoscopic revision HJ for HJS following open PD.



**Figs 3A to D:** (A) Looping of HJS with ribbon tape; (B) Hepaticojejunostomy and PTBD catheter seen *in situ*; (C) Choledochoscopy showing normal mucosa; (D) Suture line after revision hepaticojejunostomy

## CONCLUSION

Laparoscopic repair of PDHJS stricture following a previous open PD is safe and feasible, and brings with it all the short-term benefits of minimal access surgery.

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# Laparoscopic Reversal of Hartmann's Procedure as a Primary Treatment Modality: A Single-center Experience

Leesa Misra<sup>1</sup>, Jyotirmaya Nayak<sup>2</sup>, Manash Ranjan Sahoo<sup>3</sup>, Soumya Bharati Rout<sup>4</sup>

## ABSTRACT

**Aim:** The aim of this study is to evaluate the results of laparoscopic reversal of Hartmann's procedure assisted by transanal circular stapler as a primary treatment modality.

**Materials and methods:** About 32 patients presenting with an end colostomy due to various elective and emergency surgical, gynecological, and obstetric indications were selected for this study, from April 2010 to March 2016. All the patients were subjected to ultrasonography of the abdomen and pelvis, a colostogram and contrast enema, and colonoscopy. Patients selected for the study were subjected to all routine workup. Pre-anesthetic evaluation was done. Parameters such as operative time, conversion rates, intraoperative blood loss, postoperative complications, return of bowel movements, starting on oral feed, anastomotic leak, port-site infection, and hospital stay were studied.

**Results:** About 32 patients, including both male (12) and female (20), were included in the study. The age ranged between 30 years and 65 years (mean 47.5 years). The mean operative time was  $150.6 \pm 20.4$  minutes. Four cases were converted to open. Oral feeds were started on  $2 \pm 1$  postoperative day. Patients tolerated solid soft diet 96 hours after surgery. Postoperative hospital stay was 7 days (range 6–8 days). No patients had anastomotic leak or required revision surgery. Three patients had port-site infections.

**Conclusion:** We conclude that transanal stapler-assisted laparoscopic Hartmann reversal can be considered as a primary modality of treatment in the hands of an experienced surgeon though having a steeper learning curve and a higher difficulty score compared with other laparoscopic colorectal surgeries with benefits of lesser intraoperative time, early return of bowel movements, faster initiation of oral solid feeds, decreased incidence of anastomosis leak, and lesser hospital stay.

**Keywords:** Covidien EEA 31 mm circular stapler, Laparoscopic Hartmann reversal, Primary treatment modality.

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## INTRODUCTION

Hartmann's procedure refers to a colon or rectal resection without an anastomosis in which a colostomy is created, and the distal colon or rectum is left as a blind pouch. The term is typically used when the left or sigmoid colon is resected and the closed-off rectum is left in the pelvis.<sup>1</sup> It is usually performed as a temporary procedure with the intent to reverse it. A colostomy is known to impact negatively on a patient's quality of life. Hence, attempts to close colostomies are of vital importance for the comfort of patients. Surgical approaches to Hartmann's reversal include conventional open surgery and transanal stapler-assisted laparoscopic surgery. In this study, we present our single-center experience over 6 years in transanal stapler-assisted laparoscopic Hartmann's reversal as a primary treatment modality.

## MATERIALS AND METHODS

About 32 patients presenting with an end colostomy due to various elective and emergency surgical, gynecological, and obstetric indications were selected for this study, from the period April 2010 to March 2016. In 32 patients included in the study, Hartmann's procedure was performed for recurrent diverticulitis, colovesical fistula, volvulus with gangrenous bowel, colonic diverticular perforation, traumatic rupture of left colon and rectum, MTP complications, and gynecological operation complications. All the patients had their Hartmann's procedure performed by conventional laparotomy. The study included both males (12 patients) and females (20 patients). Age ranged between 30 years and 65 years (mean 47.5 years). With an interval of

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minimum 130 days (range 130–400 days), the following Hartmann's procedure was taken as the criteria. All the patients were subjected to ultrasonography of the abdomen and pelvis. A colostogram and contrast enema were done to check the patency of the bowels and the status of the rectal stump. Colonoscopy was done to rule out any residual pathology. Patients selected for the study were subjected to all routine workup. Patients with high comorbid conditions, undergoing radiotherapy and chemotherapy, and patients with any intra-abdominal malignancy were excluded from the study. Pre-anesthetic evaluation was done. The proximal bowel and the rectal stump were prepared prior to surgery. The patients were subjected to laparoscopic Hartmann's reversal assisted by transanal tension-free intracorporeal stapler. Parameters such as operative time, intraoperative complications, blood loss, conversion rates, postoperative complications, return of bowel movements, starting



Fig. 1: Laparoscopic ports were given as shown in the image

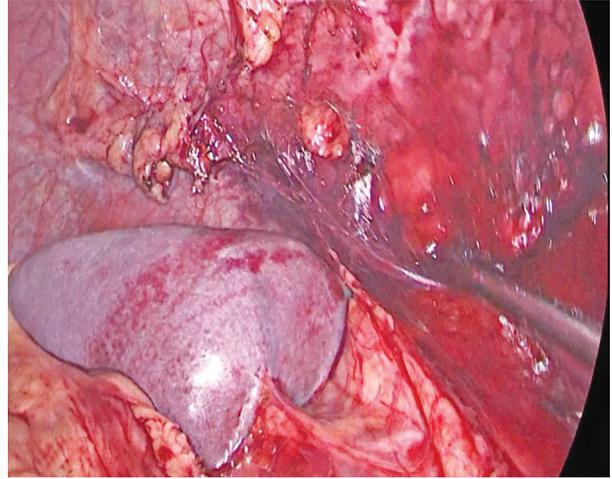


Fig. 3: Mobilization of splenic flexure done

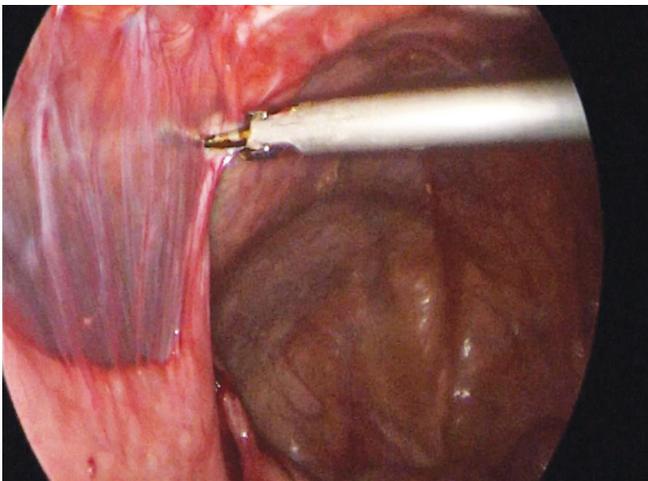


Fig. 2: Adhesiolysis done

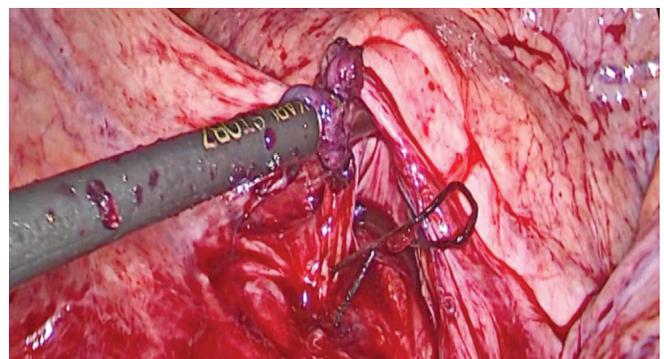


Fig. 4: Rectal stump identified by non-absorbable sutures and dissection done

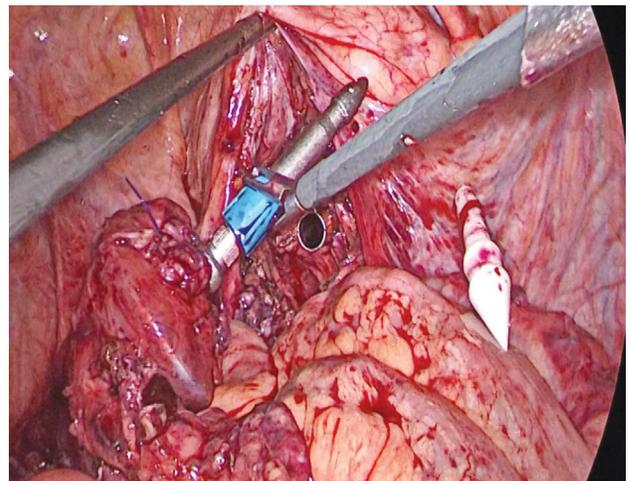


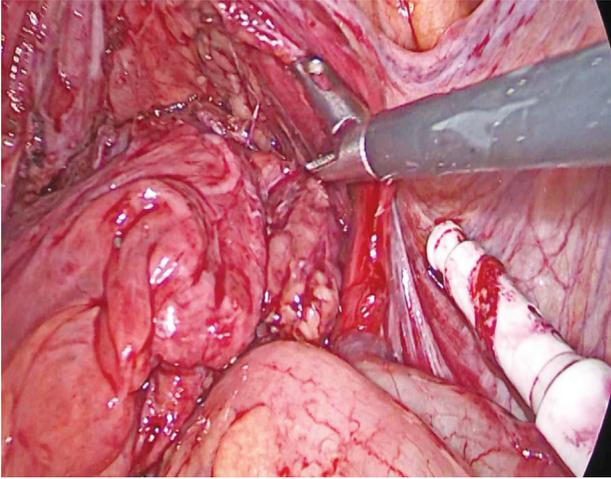
Fig. 5: Anvil of the stapler fixed to the proximal colon by purse-string sutures

on oral feed, postoperative hospital stay, port-site infections, and anastomotic leak were studied. All the patients postoperatively were reviewed and followed up for a minimum period of 1 year.

### Operative Technique

The patient was placed in supine position. The colostomy was mobilized and adequate bowel was freed from the surrounding tissue and sheath. Colostomy site was closed temporarily. One 12-mm port was given in the right hypochondrium and three 5-mm ports were given—one in the epigastrium, one in the left hypochondrium, and one in the right lumbar region (Fig. 1). Pneumoperitoneum was created, and diagnostic laparoscopy was done. Adhesiolysis was done with a harmonic scalpel (Fig. 2). The left colon was mobilized and left colonic vessels mobilized up to the splenic flexure to allow tension-free anastomosis (Fig. 3). The rectal stump was identified by non-absorbable monofilament sutures, and adequate length was mobilized for anastomosis (Fig. 4). The proximal bowel was taken out through the colostomy opening anvil of the circular stapler that was inserted into the proximal colon and purse-string suture given following which the colon was returned to the abdominal cavity (Fig. 5). Pneumoperitoneum recreated. The shaft of the circular stapler (COVIDIEN 31 mm STAPLER) was inserted through the rectal stump and docked into the anvil in the proximal

colon. An end-to-end intracorporeal anastomosis was performed by circular stapler (Fig. 6). Underwater leak test was done by filling the abdominal cavity with normal saline and insulating the rectum with air checking for air bubbles in the anastomosis site. Intra-abdominal drain was given. All ports were closed with port closure, and the colostomy site was closed in layers.



**Fig. 6:** An end-to-end intracorporeal anastomosis done by circular stapler

## RESULTS

During the study period between April 2010 and March 2016, 32 patients, including both male (12 patients) and female (20 patients) of age-groups ranging between 30 years and 65 years (mean 47.5 years) were enrolled in the study. All 32 cases were posted for transanal-assisted laparoscopic Hartmann's reversal. Mean operative time was  $150.6 \pm 20.4$  minutes. Four cases (12.5%) were converted to open, 2 cases were due to difficulty in identification of rectal stump, and 2 cases were due to extensive adhesions. Intraoperative bleeding was minimal, no patient required blood transfusion. Oral feeds were started on  $2 \pm 1$  postoperative day. Patients were started on oral solid diet after 96 hours of surgery. Postoperative hospital stay was 7 days (range 6–8 days). Three patients had port-site infections, which were treated. No patients had anastomotic leak or required revision surgery.

## DISCUSSION

Hartmann's procedure refers to a colon or rectal resection without an anastomosis in which a colostomy is created and the distal colon or rectum is left as a blind pouch.<sup>1</sup> It is usually performed as a temporary procedure with the intent to reverse it. Hartmann's reversal carries a high amount of operative morbidity and mortality. Surgical approaches to Hartmann's reversal include conventional open surgery and transanal stapler-assisted laparoscopic surgery. Many studies have been published regarding the feasibility, comparison of laparoscopic and open Hartmann reversals, and case selection for Hartmann's reversal. Laparoscopic Hartmann's reversal procedure remains a technically challenging procedure associated with relatively high open-conversion rates reported even from high-volume centers, with less than 20% of cases attempted laparoscopically.<sup>2</sup> In the present study, 32 patients who had

undergone Hartmann's procedure for various reasons, including both elective and emergency conditions, were included. The timing between the initial procedure and reversal is controversial.<sup>3</sup> Longer intervals will result in atrophy of the distal stump. A minimum period of 130 days from Hartmann's procedure to laparoscopic Hartmann's reversal was taken as the criteria in our study. This allowed in the maturation of scar tissue and adhesions. Mean operative time was  $150.6 \pm 20.4$  minutes. Four cases (12.5%) could not be continued laparoscopically and were converted to open Hartmann reversal and completed. Two cases were due to extensive adhesions, and 2 cases were due to difficulty in accessing the rectal stump. Laparoscopic Hartmann's reversal resulted in minimal blood loss intraoperatively, and no patient required blood transfusion during surgery. All the patients were started on oral liquid diet on the 2nd postoperative day. Patients tolerated solid diet 96 hours postoperatively. Postoperative pain was less due to small incisions. In our previous experience, using the colostomy site as a laparoscopic port showed increased incidence in port-site infection and difficulty in approximating the external oblique to be used as a port site, hence, the colostomy site was closed temporarily and another 5-mm port was made. Three patients had port-site infections that were treated. None of the patients had anastomotic dehiscence.

In the advent of technological advancement and transanal-assisted circular stapler reducing intraoperative time and reducing incidence in anastomotic leaks, transanal stapler-assisted laparoscopic Hartmann's reversal can be considered as primary modality of treatment in the hands of an experienced surgeon though having a steeper learning curve and a higher difficulty score compared with other laparoscopic colorectal surgeries.

## CONCLUSION

This study demonstrates that transanal stapler-assisted laparoscopic Hartmann's reversal can be a primary treatment modality in reversal of end colostomy in the hands of experienced surgeons, with benefits of lesser intraoperative time, early return of bowel movements, faster initiation of oral solid feeds, decreased incidence of anastomotic leak, and reduced postoperative hospital stay.

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# Laparoscopic Mesh Hernioplasty: A Novel Method of Extraperitoneal Space Creation

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## ABSTRACT

**Introduction:** In the era of laparoscopic surgery, total extraperitoneal (TEP) hernia repair has become the standard procedure for treatment of inguinal hernias. While balloon is used to create extraperitoneal space in most Western countries, the financial burden of buying a balloon in a developing country like India is overwhelming. So, we present a case series of extraperitoneal space creation using a zero-degree telescope to reduce the cost of the surgery to a few thousand rupees (less than 100 dollars).

**Context:** Laparoscopic total extraperitoneal inguinal hernia repair.

**Aims:** To study the feasibility of creation of extraperitoneal space using a zero-degree telescope in laparoscopic total extraperitoneal hernia repair.

**Materials and methods:** It is a case series of 500 patients from June 2011 to July 2021. Furthermore, it is a single-surgeon experience.

**Results:** A Total of 500 laparoscopic TEP hernia surgeries were performed over a period of 10 years. Out of these, 485 patients were male and 15 patients were female. The age of patients ranged from 5 years to 85 years. Out of these, 50 patients (10%) were converted to transabdominal preperitoneal (TAPP) hernia repair. During the follow-up period, no hernia recurrence was found. No major complication was noted in any patients during this period. Seroma formation was noted in 25 patients (5%). Retention of urine was noted in 25 patients (5%). All patients returned to normal routine work within 2 weeks.

**Conclusion:** Zero-degree telescope is a feasible method of creating extraperitoneal space in laparoscopic total extraperitoneal repair.

**Key messages:** Slight changes in advanced laparoscopic methods can make these costly procedures accessible to a vast population of poor people in the world.

**Keywords:** Extraperitoneal space creation, Laparoscopic, Laparoscopic hernioplasty, Mesh hernioplasty, Total extraperitoneal repair.

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## INTRODUCTION

Inguinal hernioplasty has progressed from tissue-based repair of Bassini and mesh repair of Lichtenstein to laparoscopic hernia repair today which was reportedly first performed by Ger.<sup>1</sup> Initially, surgeons used the TAPP method for hernia repair.<sup>2</sup> But it was soon found out that entering peritoneal cavity for hernia repair has its own disadvantages such as inadequate closure of the peritoneum and injury to viscera from trocars and needles. To overcome these complications, total extraperitoneal (TEP) approach was developed. Total extraperitoneal approach eliminates complications related to entry into the peritoneal cavity and reduces operative time in bilateral hernias.<sup>2,3</sup>

Extraperitoneal space creation is most commonly done by balloon dissector as it simplifies the process.<sup>4</sup> The space creation can also be done without using balloon dissector. In this case, a zero-degree telescope (10 mm) is used to create the space by sweeping down fibrofatty tissues to the sides. But this may be difficult and time-consuming for inexperienced surgeons. Moreover, the surgeon may tear the peritoneum inadvertently leading to conversion of TEP to TAPP. So here we present a case series of TEP approach of laparoscopic hernia repair in which extraperitoneal space creation is done using a zero-degree telescope, thus reducing the cost of hernia surgery.

## MATERIALS AND METHODS

This is a case series of 500 patients from June 2011 to July 2021 with a follow-up period of at least 1 year. This study is a single surgeon

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experience which has been done in a premiere Government Institute in Eastern India.

All patients had to undergo pre-anesthesia checkup and fit patients were taken up for surgery. All patients were catheterized during the procedure, and the catheter was removed within few hours after surgery. A 10 mm incision was given just below the umbilicus. Anterior rectus sheath was identified and incised to expose rectus muscle. Two right-angled retractors were used to retract rectus muscle laterally to expose the posterior rectus sheath. A 10 mm trocar is pushed through the posterior rectus sheath to enter the extraperitoneal space. A zero-degree telescope is then introduced, and the space creation is done with gentle vertical and horizontal motion and plane achieved by identification of Cooper's ligament. Two 5 mm ports are created under vision, one



Fig. 1: 10 mm trocar being placed behind the rectus muscle

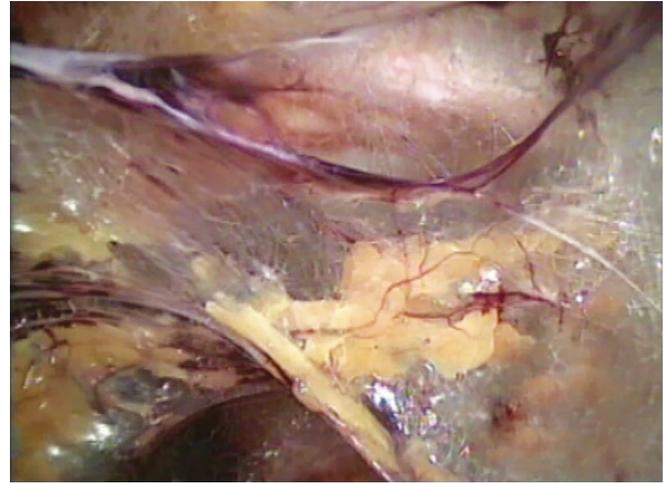


Fig. 3: Extraperitoneal space creation being done with zero-degree telescope

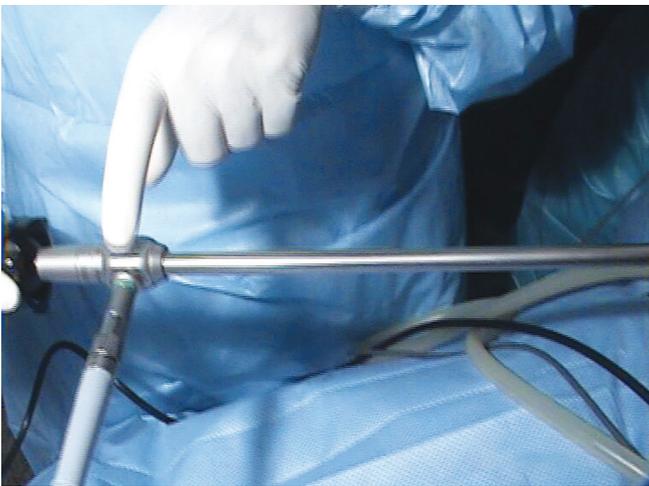


Fig. 2: Zero-degree telescope being used

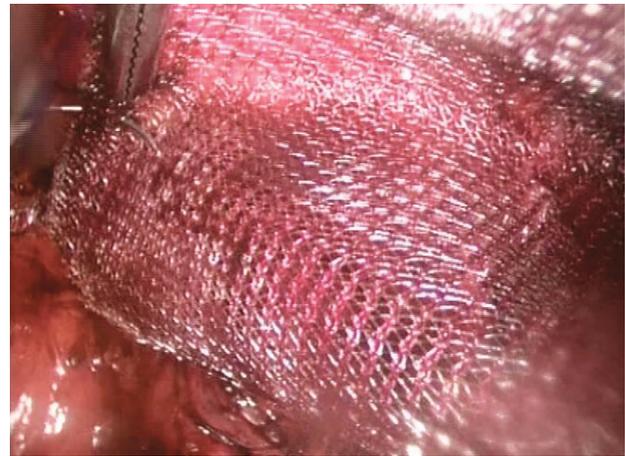


Fig. 4: Mesh being sutured to Cooper's ligament

4–5 cm above the pubis and another in the middle. Hernial sac is identified, separated from cord structures, and pushed cephalad. The edge of the peritoneum is freed from vas deferens and testicular vessels and pushed downward. Now, a 15 × 15 cm prolene mesh is introduced through the 10 mm port and is positioned medially to overlap the pubic bone and laterally 2 cm beyond the deep ring. The mesh is fixed using prolene suture to the Cooper's ligament using single intracorporeal prolene suture. The abdomen is deflated under vision, so as to ensure no wrinkling of the mesh. All ports are closed and pressure bandage is given over the deep ring. All patients were given intravenous antibiotics for 1 day and analgesics for 2 days. Patients were discharged on the third day and follow-up was done after 1 month. Subsequent follow-up was done on yearly basis (Figs 1 to 4).

## RESULTS

A total of 500 laparoscopic TEP hernia surgeries were performed over a period of 10 years. The follow-up period was minimum of 1 year. Out of these, 485 patients (97%) were male and 15 patients (3%) were female. All patients had undergone pre-anesthetic checkup, and only fit patients were included in the study. Age of patients ranged from 5 years to 85 years. All patients were operated

laparoscopically with no conversion. Out of these, 50 patients (10%) were converted to TAPP due to either the inability to create a space due to previous surgery or due to inadvertent creation of bigger-size rent in the peritoneum. During the follow-up period, no hernia recurrence was found. No major complication was noted in any patients during this period. Few minor complications were noted. Seroma formation was noted in 25 patients (5%), which got resolved within 6 months with conservative treatment. Retention of urine was noted in 25 patients (5%). In these patients, recatheterization was done. No other complications were noted. All patients returned to normal routine work within 2 weeks.

## DISCUSSION

This single-surgeon experience supports extraperitoneal space creation using a zero-degree telescope to reduce the cost of laparoscopic hernia surgery in developing countries like India. Most commonly, balloons are used to create the extraperitoneal space. The cost of a balloon in India is around 20,000 rupees (~300 dollars), which is almost five times the total cost of hernia surgery. Also, intracorporeal suturing eliminates the need of tacker, which saves another 25,000 rupees (~400 dollars). The incidence of seroma formation in TEP is reported to be around 7%<sup>5</sup> in other

studies as compared with 5% in this study. Using only zero-degree telescope resulted in conversion to TAPP in 10% patients, which is an acceptable rate, keeping in mind the reduction of economic load on poor patients.

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