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Emergency Laparoscopic Cholecystectomy with Low-Pressure Pneumo-Peritoneum in Cardiopulmonary Risk Patients: Fundus-Calot Cholecystectomy versus Calot First Cholecystectomy. Randomized Controlled Trial

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Abbreviations:
D.M: diabetes mellitus
HTN: hypertension
ICU: intensive care unit

ABSTRACT

Background: Elderly complains of cardiopulmonary diseases, and the incidence of emergent gallbladder diseases increases with age. Laparoscopic cholecystectomy is the usual approach in dealing with cholelithiasis that significantly replaces the open approach even in acute emergency gallbladder diseases. This study aimed to compare between initial Fundus first cholecystectomy followed by Calot dissection vs Calot first cholecystectomy in Emergency laparoscopic cholecystectomy with low-pressure pneumo-peritoneum in cardiopulmonary risk patients regarding intraoperative data and postoperative data complications.
Methods: This prospective randomized controlled study was carried out on 470 cases who underwent emergent laparoscopic cholecystectomy. The patients were divided into Group A: fundus-Calot group (235cases) and Group B (235cases): classical Calot first approach.
Results: Operation time was significantly shorter in the 1st group (p=0.00). Intraoperative cystic artery bleeding, liver bleeding and omental vessel bleeding occurred in 2(0.8%), 0 (0.0%) and 2(0.8%) in group A and 18(7.6%), 16(6.8%) and 6(2.5%) in group B respectively. Iatrogenic bile duct injuries occurred in 2 cases (0.8%) in group A and 11 cases (4.6%) in group B. Liver injury, colonic injury, and duodenal injury occurred in 22(9.3%), 4(1.7%), and 6(2.5%) in group B, respectively. Conversion to open surgery occurred in 9 cases (3.8%) of group A and 34 cases (14%) in group B. Bile leakage, wound infection, intra-abdominal collection, and port site hernia occurred in 4 cases(1.7%),8 cases(3.4%) and 8 cases (3.4%) in group A and 12 cases (5.1%)16 cases(6.8%) and 16 cases(6.8%) in group B respectively. Biliary stricture occurred in 4 cases (1.7%) in group A and 33 cases (14%) in group B.
Conclusion: Laparoscopic initial Fundus first cholecystectomy is an excellent and safe approach.
Key words: acute cholecystitis, laparoscopy, urgent cholecystectomy, fundus first

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INTRODUCTION

The advancement of laparoscopic cholecystectomy had considerably evolved, making laparoscopic cholecystectomy is the commonest operation performed within the field of gastrointestinal tract surgery and almost replaced

open cholecystectomy (1). Many advantages the patients gained as minor operative wounds with minimal postoperative pain and infection and hence rapid discharge from hospital. Other advantages are better cosmetic results, earlier resumption of oral feeding, and rapid restoration of daily activity and work (2).

Many disadvantages emerged as the higher incidence of bile duct injuries that may reach 0.3-0.8%, which may increase acute emergent cases. This may cause mortality in the patients (3). Strasberg gave us the best solution and the way to avoid injury to the biliary tract. (4) Other complications the patients may face after laparoscopic cholecystectomy are organ injury, vascular injury, and obstructive jaundice from missed stones in the common bile duct during the operation (5).

About 30% of patients who undergo laparoscopic cholecystectomy are elderly patients with cardiopulmonary risks. Pneumo-peritoneum with CO_2 causes splinting of the diaphragm, hypercarbia with arrhythmias, compression of central abdominal vasculature (inferior vena cava and abdominal aorta), and stretch of the peritoneal cavity with consequent parasympathetic irritation causing bradycardia (6).

Head up position decreases venous return and hence cardiac output and increases the level of adrenaline in the blood, leading to blood vasoconstriction, which increases peripheral resistance, decreases cardiac output, and increases myocardial load (7).

There is no golden standard initial approach during emergent laparoscopic cholecystectomy surgery for acute gall bladder diseases, which is generally selected by the surgeon's preferences or by local conditions. In this study, we have designed a randomized clinical trial to compare outcomes in patients who underwent emergent laparoscopic cholecystectomy for acute gall bladder diseases either by fundus first approach or Calot first approach. The aim was to compare the incidence of intraoperative complications (time in minutes, bleeding, bile injuries, liver injury, and conversion) and postoperative complications (ICU admission in days, bleeding, biliary leakage, biliary strictures) during and after both techniques.

PATIENTS AND METHODS

Study design

This is a prospective randomized controlled clinical study conducted in the hepato-biliary surgical unit of our university hospital from March 2015 to March 2018 performed on 470 patients admitted with the clinical diagnosis of emergent gall bladder diseases. Patients were divided into group A (n=235): patients were subjected to a laparoscopic cholecystectomy with low-pressure pneumo-peritoneum and initial fundus first cholecystectomy then followed by completion Calot triangle dissections and group B (n=235): from the beginning, patients had laparoscopic cholecystectomy with low-pressure pneumo-peritoneum with cholecystectomy starting with dissection of Calot. It is a simple random sample with a balance and based on the operation time difference between conventional and funds first group from previous paper with 80% power of study and 95% confidence interval. Patients were randomly allocated using a random sequence generator. Random allocations were sequentially numbered in sealed opaque envelopes opened during surgery before Carrying out the method of dissection. Patients were blinded to the assigned group until after the study. The registration office does it.

Participant selection criteria

To be eligible for the study, patients had to meet all the following criteria: male and non-pregnant females of any age, patients with controlled cardiopulmonary diseases, patients who diagnosed acute cholecystitis not improving on medical treatment for 48 hours, patients with biliary colic, mucocele of gall bladder and pyocele of the gallbladder. Exclusion criteria were patients who refused surgery, liver disease, previous percutaneous cholecystostomy, and cases not tolerated CO_2 insufflation from the start.

Types of outcome and measurement (study endpoints)

Primary outcomes were the incidence of intraoperative and postoperative complications as regards the biliary leak, conversion rate, including Length of surgery (in minutes), intraoperative blood loss (ml), Vascular/visceral injury at operation, Length of hospital stay (in days), Wound infection at any time point, postoperative pain (on visual analogue score), the recovery time to regular activity (in days), ICU/days (intensive care unit admission) and hospital length of stay (days), and postoperative biliary stricture. The secondary outcome was the overall mortality (within 30 days and 90 days postoperative).

Definitions and measurement of outcomes

The diagnosis of biliary leakage is based on imaging studies and clinical signs, such as fever >38.5°C, leukocytosis, elevated serum C-reactive protein, drainage

of bile in drains or through abdominal wounds or abdominal collections. The diagnosis of biliary stricture is based on clinical signs of abdominal pain and jaundice and imaging studies demonstrating bile duct dilatation. Clavien and Dindo assess postoperative morbidity. Reoperation is defined as re-intervention within 30 days after the primary operation.

Methods

Preoperative workup including laparoscopic surgeons' multidisciplinary interview. Preoperative consultant anesthetist's assessment. Antibiotic prophylaxis: metronidazole 500 mg and ciprofloxacin 400 mg given intravenously 1 hour before surgery. All patients had normal laboratory investigations pre-operatively (serum albumin >3 gm/dl, hemoglobin > 11 gm/dl, well-controlled diabetes). General anesthesia with the protection of the airway from inhalation of vomit. All procedures were performed in mono-center in our unit for two years by three surgeons experienced in laparoscopic cholecystectomy surgery following the principles of laparoscopic surgery. Each surgeon had previous experience of at least 300 laparoscopic cholecystectomy surgeries of a different approach. At least one of three senior surgeons was always present to ensure the same technique and inclusion criteria. A Hasson technique was used through the periumbilical incision, and a trocar was introduced into the abdomen under vision. Pneumoperitoneum was created 8-10 mm Hg. The camera was introduced, and the abdominal cavity was inspected. At epigastrium 5 cm below the xiphoid process, a 10 mm trocar was placed. Only below the right margin was a third 5 mm trocar placed. The 4th trocar is inserted on the anterior axillary line at the umbilical level.

Calot triangle first dissection: initial laparoscopic view showed distended gall bladder with mucocele and stone in gall bladder neck (*figure 1*). Difficult handling of Hartman due to stone impacted in neck of gall bladder (*figure 2*). Dissection started at the gall bladder neck, which was difficult (*figure 3*). Adhesions to the omentum, colon, duodenum, or stomach are pulled away by blunt and diathermy dissection. Dissection continued very close to the gall bladder wall. Identification of the Calot triangle helped us to recognize the anatomy. Dissected and cut off, and divided are cystic duct and cystic artery. Hazards dissection in the calot first approach may result in bleeding (*figure 4*). Rough retraction of the fundus may result in liver tear (*figure 5*). Then the gall bladder is ruggedly freed from the liver. Hemostasis was

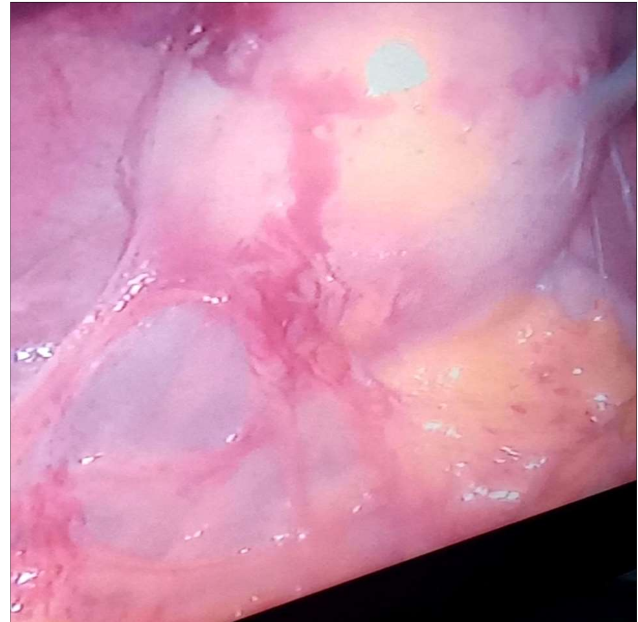

Figure 1 - Laparoscopic view showing distended gall bladder with mucocele and stone in the gall bladder neck

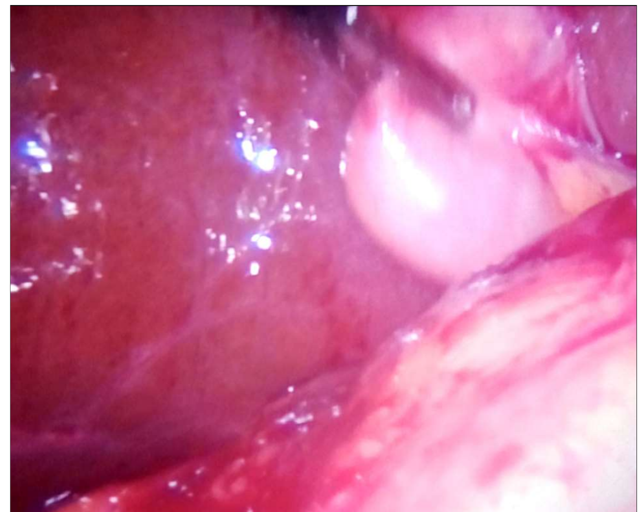

Figure 2 - Difficult handling of Hartman due to stone impacted in neck of gall bladder

inspected on the gallbladder bed, and coagulation was achieved. The gallbladder was removed from the abdomen through the epigastric port. A drain is put in the gall bladder bed.

Fundus first approach initial approach: we start dissection of the peritoneum at the side of gall bladder and perform dissection in inverted U shaped incision in the peritoneum covering the side and fundus of the gallbladder (*figure 6*) then the gall bladder is dissected free from gall bladder bed (*figure 7*). Then the fundus of the gallbladder is retracted easily to the right shoulder and starts the exposure and dissection of the

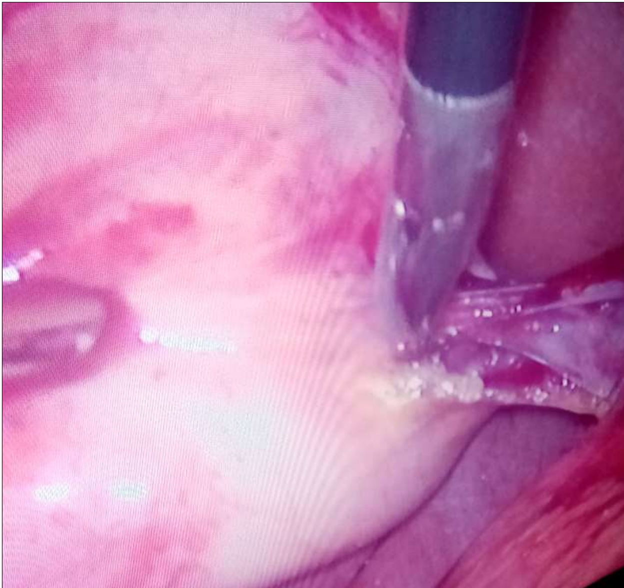

Figure 3 - Difficult dissection of calot triangle inpatient with calot first dissection

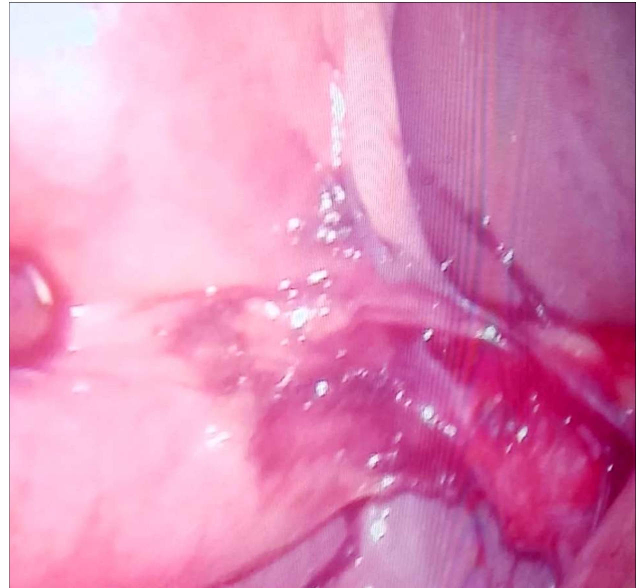

Figure 4 - Hazards dissection in calot first approach may result in bleeding

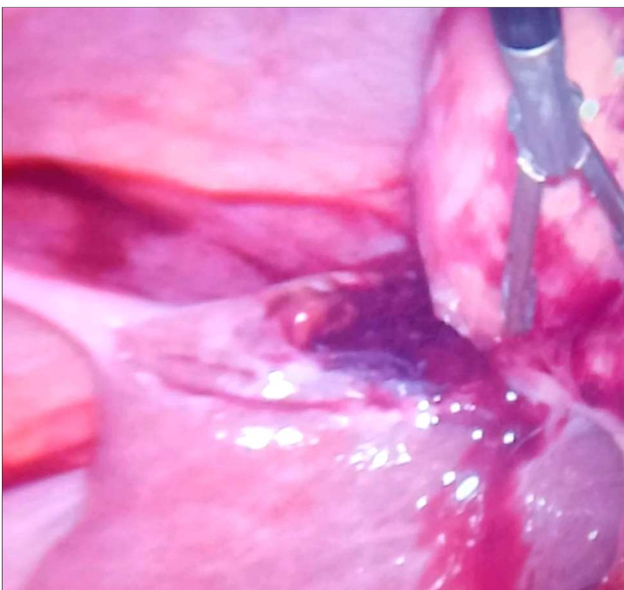

Figure 5 - Rough retraction of the fundus may result in liver tear

Calot triangle. In this way, dissection of the Calot triangle becomes very easy. Sometimes aspiration of the gall bladder contents helped us to grasp the fundus. Patients were allowed clear fluid as soon as they tolerated it. Usually introduced from the second post-operative day. Antibiotic prophylaxis was continued for 24 hours after the operation. All patients received metronidazole (500 mg three times daily for three days) and ciprofloxacin (400 mg twice daily for three days). The patient was encouraged for ambulation. When the drain was normal, the drainage tube was removed. All patients were followed for one week, one month, three

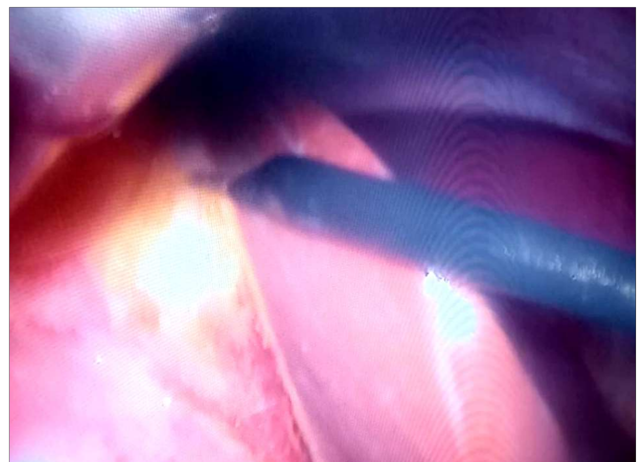

Figure 6 - Fundus-calot dissection started by opening the peritoneum at the side of the gall bladder

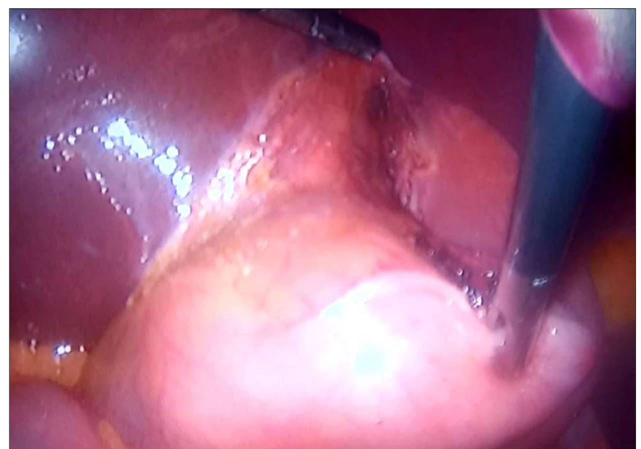

Figure 7 - Inverted u-shaped incision in the peritoneum around fundus of the gall bladder that helps retraction of the bladder neck and also prevents difficult final step of gall bladder removal

months, six months, 12, and 24 months after hospital discharge. After discharge, patients were communicated by phone and follow up visit at an outpatient clinic. Methods of follow-up included clinical examination, full laboratory examination, and imaging in patients who developed symptoms of biliary stricture as magnetic resonance cholangiopancreatography. No patients were lost during the follow-up period.

Statistical analysis

We performed an intention-to-treat analysis whenever possible. Data entered and analyzed using (SPSS version 20.0) software for analysis. According to the type of data qualitative represented as number and percentage, quantitative continues group represented by mean ± SD, the following tests were used to test differences for significance. Difference and association of qualitative variable by Chi-square test (χ^2) or Fisher's exact. Differences between quantitative independent groups by t-test. P-value was set at <0.05 for significant results & <0.001 for high significant result.

RESULTS

The study involved 470 patients. They were subdivided into groups: group A: (n = 235): Low-pressure pneumoperitoneum laparoscopic cholecystectomy and initial fundus of the first cholecystectomy, and group B: (n=235): Patients underwent low-pressure pneumoperitoneum laparoscopic cholecystectomy and first Calot dissection from the beginning.

Preoperative data

No statistically significant difference between both groups as regards all preoperative variables. Age was distributed as 56.8±16.87 years and 53.6±17.95 years respectively between group A & group B. Females were majority in both groups Most cases of both groups were in ASA III (270 /470). Previous upper abdominal surgery occurred in 30 (13%) in group A and 14 (6%) in group B. Persistent biliary colic was the commonest preoperative diagnosis in group A [87 cases (37%)], and pyocele was the commonest preoperative diagnosis in group B [75 cases (32%)] (*table 1*).

Table 1 - Demographic and preoperative data

	Group A (n=235)	Group B (n=235)	χ^2/t	p
Age (years)				
<40 years	40(17%)	54(23%)		
40-59	131(55.7%)	110(47%)	4.22	0.11
>60	64(27.3%)	70(30%)		
Mean ±SD	56.8±16.87	53.6±17.95	t=1.69	P=0.081
Sex				
Female	177(75.3%)	190 (80.8%)	2.11	0.14
Male	58(29%)	45(19.2%)		
Co-morbidities				
D.M	87(37%)	99(42%)	0.31	0.57
HTN	56(24%)	77(33%)	1.42	0.23
Respiratory diseases (Bronchial Asthma-C.O.P.D)	87(37%)	59(25%)	2.32	0.12
Coronary disease (angina-MI)	134(57%)	80(34%)	5.81	0.015*
Valvular diseases	14(6%)	96(41%)	26.06	0.00**
Obesity	87(37%)	106(45%)	0.78	0.37
American society of anesthesiologist score				
II	59(25%)	54(22.9%)		
III	141(60%)	129(55%)	4.07	0.13
IV	35(15%)	52 (22.1%)		
Previous upper abdominal surgery	30(13%)	14(6%)	2.57	0.11
Preoperative diagnosis				
Acute calcular cholecystitis	23(10%)	37(16%)		
Acute non calcular cholecystitis	16(6.8%)	7(2.9%)	27.19	0.00**
Biliary colic	87(37%)	45(19%)		
Mucocele	61(26%)	70(30%)		
pyocele	47(20%)	75(32%)		

Table 2 - Intraoperative data

	Group A (n=235)	Group B (n=235)	χ^2/t	p
Duration of operation(skin incision to closure)				
< 60 min	35(14.8%)	17(7.2%)		
60-90	141(60%)	87(37%)	47.15	0.00**
>90 min	59(25.2%)	131(55.8%)		
Mean ±SD	75.85±27.5	98.63±27.6	21.36	0.00**
Intra-operative bleeding				
Cystic artery bleeding	2(0.8%)	18(7.6%)	4.55	0.03*
Liver bleeding	0 (0.0%)	16(6.8%)	Fisher exact=4.95	0.021*
Omental vessel bleeding	2(0.8%)	6(2.5%)	0.98	0.31
Iatrogenic injury				
Bile duct injury	2(0.8%)	11(4.6%)	2.67	0.101
Liver injury	0%	22(9.3%)	Fisher exact=7.46	0.006*
Colonic injury	0%	4(1.7%)	Fisher exact=0.22	0.63
Duodenal injury	0%	6(2.5%)	Fisher exact=0.92	0.34
Conversion to open	9(3.8%)	34(14%)	5.84	0.015*
Causes of conversion				
Obscure anatomy	3 (1.2%)	8(3.4%)	1.05	0.31
Difficult dissection in Callot triangle	3 (1.2%)	7(2.9%)	0.77	0.4
Uncontrolled bleeding from cystic artery	3(1.2%)	11(5%)	2.32	0.12
Colonic injury	0	2(0.8%)	Fisher exact=0.05	0.82
Duodenal injury	0	2(0.8%)	Fisher exact=0.05	0.82
Bile duct injury	0	4(1.7%)	Fisher exact=0.28	0.59

Intraoperative data

The duration of operation in group A [141 cases (60%)] mainly was between 60-90 min and >90 min in group B with mean operative time 75.85±27.5 min and 98.63±27.6 min between group A and group B, respectively. Operation time was significantly shorter in the 1st group (p=0.00). Regarding intraoperative bleeding, There is a statistically significantly higher in Group B regarding cystic artery bleeding (p=0.03) and liver bleeding (p=0.021). There is no statistically significant difference between both groups as regard Iatrogenic bile duct injuries (p=0.101). Liver injury, colonic injury, and duodenal injury don not occurred in group A and occurred in 22 (9.3%), 4 (1.7%), and 6 (2.5%) in group B, respectively. There is a statistically significant difference regarding liver injury (p=0.006) but no statistically significant difference regarding colonic injury and duodenal injury (p=0.63 and p=0.34, respectively). Conversion to open surgery occurred in 9 cases (3.8%) of group A and 34 cases (14%) in group B. There is a statistically significant difference between both groups (p=0.015) (*table 2*).

Postoperative data

ICU admission occurred in 8 cases (3.4%) in group A and 33 cases (14%) in group B. There is a statistically significant difference between both groups (p=0.011). Postoperative bleeding occurred in 6 cases (2.5%) in group A and 26 cases (11%), and there is a statistically significant difference between both groups (p=0.02). There is no statistically significant difference between groups regarding Bile leakage, wound infection, intra-abdominal collection, and port site hernia (p=0.19, p=0.19, p=0.28, and p=0.28, respectively). Re-exploration occurred in 7 cases in group A (2.8%) and 16 cases (6.6%) in group B. There was no statistically significant difference between both groups regarding re-exploration. Biliary stricture occurred in 4 cases (1.7%) in group A and 33 cases (14%) in group B. There is a statistically significant difference between both groups (p=0.001) (*table 3*).

DISCUSSION

Laparoscopic cholecystectomy is increasing in old age; however, a problem emerging that most old age is complaining of low cardiopulmonary reserve that makes insufflation of the abdomen with 14 mmHg pressure pneumo-peritoneum most probably affect the base of lung and the cardiac action. We faced the fact that low pressure hinders good visualization of the Calot triangle from starting dissection of critical view of safety. In this study, we performed laparoscopic cholecystectomy with low-pressure pneumoperitoneum ten mmHg, but we started with fundus dissection; first, that enabled us to push the gallbladder over the liver and help clear visualization of the Calot triangle

Yong et al. declared that bradycardia might develop

Table 3 - Postoperative data and outcomes

	Group A	Group B	X2	P
ICU admission	8 (3.4%)	33 (14%)	6.45	0.011*
Postoperative bleeding	6 (2.5%)	26 (11%)	5.35	0.02*
Bile leakage	4 (1.7%)	12 (5.1%)	1.81	0.19
Wound infection	4 (1.7%)	12 (5.1%)	1.81	0.19
Intra-abdominal collection	8 (3.4%)	16 (6.8%)	1.13	0.28
Re-exploration				
Cystic artery stump leakage	3 (1.2%)	5 (2.1%)	0.24	0.62
Port site bleeding	1 (0.4%)	2 (0.8%)	0.13	0.71
Omental bleeding	0 (0.0%)	1 (0.4%)	0.91	0.34
Missed intestinal injury	0 (0.0%)	5 (2.1%)	0.57	0.43
Biliary fistula	3(1.2%)	3 (1.2%)	0.0	1.0
Biliary stricture	4(1.7%)	33(14%)	9.63	0.001**
port site hernia	8(3.4%)	16(6.8%)	1.13	0.28
mortality	4(1.7%)	21(8.9%)	4.89	0.026*

with induction of pneumo-peritoneum due to distension of the peritoneum with parasympathetic irritation. If occurred, immediately deflate the abdomen (8). In the present study, we started with eight mmHg intra-peritoneal pressure and gradually increased to 10 mmHg, not more. Only 5 cases showed hypoxia and bradycardia. We deflated the abdomen and re-insufflated again with no problem developed.

Neri et al. stated that the duration of laparoscopic cholecystectomy was shorter in the fundus first approach than classical Calot first dissection (70 min and 90 min respectively), and difficult cases of Calot first dissection were converted into open approach without any attempts for fundus first approach (9). This is similar to our results that concluded that fundus first initial approach has a shorter operative time than classic initial Calot dissection and most cases of the fundus first approach took up to 90 minutes in Group A, while in Group B, most cases took more than 90 minutes (55%). This is attributed to the low pressure of intraperitoneal making the retracted fundus hits the anterior abdominal wall making exposure of the Calot triangle very difficult, but it is not in cases of the initial fundus first approach.

Bleeding during operation may be either minor bleeding from cystic artery stump slippage and omental vessels bleeding or significant bleeding from torn liver and significant vascular injuries. The portal vein or hepatic artery bleeding may account for 0.03–10% of cases and is responsible for the second cause of death after complications related to anesthesia (10). In our experience, intraoperative bleeding occurred in Group A in 2% of cases from cystic artery bleeding (1%) and omental blood vessel bleeding (1%). Both cases were controlled laparoscopically. in Group B, most bleeding occurred from liver tear during extensive fundus traction in the hope to expose Calot triangle (7%) that was controlled laparoscopically by electrocoagulation, cystic artery stump bleeding (7%), and omental vessels bleeding (3%) that controlled laparoscopically by ligation. Seven cases of bleeding cystic artery were controlled laparoscopically, and eleven cases of cystic artery slippage bleeding cannot be controlled laparoscopy and required open exploration to control bleeding. No cases of significant blood vessels injury occurred in both groups.

Hussain, in his study, stated that fundus first cholecystectomy decreases the rate of complications (11) while other studies stated the opposite (12). In our series, the fundus first approach much decreased the complication rate. Dissection of the fundus first allows traction of the fundus easy in the condition of low intraperitoneal pressure that helps expose of Calot trade then we start dissection in the Calot triade to get a critical view of safety and adequate envision cystic duct, common duct of bile, hence decrease the incidence of biliary injury. Intraoperative bile duct injury occurred in 1% of cases in Group A, and it was minor common bile duct injury that repaired laparoscopy while the incidence was 5% of cases with Calot first dissection. Seven cases were minor common bile duct injuries repaired laparoscopically; two cases were transected common bile duct that necessitated open exploration and hepaticojejunostomy; two cases were an injury to the right hepatic duct that necessitated exploration and repaired over T-tube drainage. Intraoperative bile duct injury is detected by staining the operative field with bile. Intraoperative colonic and duodenal injuries occurred in group B only, and they were discovered intraoperatively. Four cases of colonic

injuries occurred, and 2 of them were minor perforations controlled by laparoscopy, while the other 2 cases required exploration and repair in one case and simple loop colostomy in the other case that was closed after two months. Duodenal injuries occurred in 6 cases; 4 cases were minute perforation repaired laparoscopically by repair over the omental patch, while 2 cases required exploration and repair of the big tear with suture over the omental patch gastrojejunostomy.

Mahmud stated in his series that the conversion rate with the fundus first approach might be as low as 1.2% (13). While other studies reported higher conversion rate 50%, 20%, 18.5%, 23% and 50% respectively (14-16). In this study, the lower incidence in the fundus first group (4%) while higher in the Calot first approach (14%).

Postoperative bleeding occurred in 3% of Group A and 11% of Group B cases. Postoperatively these patients developed hypotension, tachycardia, and continuous fresh bleeding from the drain. Initially, these patients underwent conservative treatment in the form of fresh blood transfusion and intravenous fluid. Two cases in group A continued to bleed and required re-exploration and revealed cystic artery clip slippage controlled by ligation, and the other cases were due to post-site bleeding controlled by trans fixation suture. In Group B, eight cases continue to bleed. Five cases due to slippage of cystic artery clip that was controlled by careful identification of the stump and ligation by suture. Two cases were due to port site bleeding controlled by trans fixation sutures. The last case was due to more significant omental portal arteries that are big enough that required ligation.

In the literature, no bile duct injuries occurred after laparoscopic fundus first cholecystectomy (17). Other literature described incidence up to 3% (18). In the present study, postoperative biliary leakage is noted in 2% of Group A and 6% in group B. The condition is diagnosed postoperatively by abdominal pain, fever, sonar evidence of gall bladder bed collection that revealed bile by aspiration and bile drainage from the intra-abdominal drain. Most cases were found in 2-3 days after surgery. Cases of drying less than 200 mL (n=10) of the bile have undergone conservative treatment in the form of nothing in the oral, cephalosporin, and spasmolytic in the third generation, with sonar catheter drainage of the collections. With plastic stenting, three cases draining more than 500 ml of bile per day underwent urgent endoscopic retrograde cholangiopancreatography. Most cases were slipped cystic duct stump clips, and others were minor common bile duct injuries. These cases improved immediately with no bile drainage from the drain. Three cases showed a complete cut of the right hepatic duct in two cases and transaction common bile duct in one case with dye extravasation on ERCP and treated with re-exploration and hepaticojejunostomy. A study stated that surgical site infection is common in emergent cholecystectomy (19). In this study, 2% of cases in Group A and 5% in Group B.

Postoperative biliary strictures developed in 2 % of group A and 14 % in group B. mainly discovered after 10th months postoperatively. Patients present with abdominal pain, slight jaundice, and elevated liver enzyme. All cases underwent ERCP with balloon dilatation and stenting.

However, our work was not without limitations. The choice of patients operated at night may have been affected by a selection bias. This might have favored our analysis of the risk factor.

CONCLUSIONS

The fundus first approach is a safe and excellent approach to such patients as this enables rapid operation, adequate fundus retraction in low-pressure pneumoperitoneum, and excellent exposure of Calot triangle to complete safe cholecystectomy. Also, low CO_2 pressure had a favorable effect on the heart and lungs. We state that low-pressure pneumoperitoneum with fundus first approach adds safety to the patients during surgery, especially in ASA grade III. Laparoscopic cholecystectomy is not more contraindicated in high-risk cardiopulmonary patients.

Consent to participate & consent for publication

All involved persons gave their informed written consent to participate and for publication.

Authors' contributions

All authors shared important intellectual content in study design, data analysis, writing, and critical review of the manuscript. They participated in the final approval of the submitted version.

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Availability of data and materials

The datasets used and analyzed during the current study available from the corresponding author on reasonable request

Competing interests

The authors declare that they have no competing financial or non-financial competing interests.

Ethical approval

Our Faculty of Medical Ethical Committee, Zagazig University, gave all the ethical approval. The described work has been carried out for human experiments following the World Medical Association's Code of Ethics (Helsinki Declaration). Registration Criteria for registering on the quality control review protocol on clinicaltrials.gov protocol: NCT04368611 registered on 28/04/2020.

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