A PROSPECTIVE STUDY OF THE INCIDENCE OF CONVERSION OF LAPAROSCOPIC CHOLECYSTECTOMY TO OPEN CHOLECYSTECTOMY IN 100 PATIENTS

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ABSTRACT:

Background: Laparoscopic cholecystectomy is the gold standard treatment for symptomatic gallstones. Conversion to an open procedure is necessary in 5–10% of patients.

The aim of work: The present study was to illustrate the incidence of conversion of laparoscopic cholecystectomy to open cholecystectomy & to validate the efficacy of "CLOC" (Conversion from Laparoscopic to open cholecystectomy) risk scoring system on the patients included in the study.

Patients and methods: The present observational prospective study was conducted in EL-Demerdash Teaching Hospital (January 2019- January 2020). The study included (100) symptomatic cholelithiasis patients. Patients were divided into two groups, firstly those who completed laparoscopic cholecystectomy and secondly those who were converted into open cholecystectomy. Preoperative variables included patient demographics, indications for surgery, ASA grade, admission type, ultrasound findings and preoperative endoscopic retrograde cholangiopancreatography (ERCP). Validation of the "CLOC" scoring system was applied to all patients. Operative data were gathered prospectively, and the difficulty of the procedure was graded using the Nassar scale (grades 1–4).

Results: (24%) of patients recorded difficult total score; open surgery was conducted in (5%). There was statistically significant relation between CLOC risk scoring level and age (p<0.001); indication (p=0.002); ASA (p=0.002); gallbladder wall thickness. (p<0.001) and preoperative ERCP patients (p=0.003). There was statistically significant increase in difficulty in male compared to female. (p=0.019). There was actual conversion according to groups with 'high risk scoring >7 and conversions in the' low risk >6 easy' group below. (p=0.042); highly statistically significant increase of mean in difficult group compared to essay group (p<0.001). The difficult group complications rate was higher than the easy group (75% versus 10.5%); gallbladder rupture was mostly reported in (37.5% and 2.6%) of difficult group and easy group cases, respectively. Receiver operating characteristics (ROC) curve sensitivity was 92%; specificity was 98.7%. Age, gender, indication, ASA, gallbladder wall and Pre-Operative ERCP have a significant effect on the difficulty.

Conclusion: The present study could conclude that parameters as older age, male gender, cholecystitis, ASA, thick wall GB, preoperative ERCP are predictors for difficult LC. Meanwhile these

factors are predictors for conversion to open cholecystectomy. CLOC" risk score may be the most helpful tool in stratifying risks.

Keywords: *Laparoscopic, cholecystectomy, Conversion, CLOC" risk score*

INTRODUCTION:

Laparoscopic cholecystectomy is the gold standard treatment for symptomatic gallstones. Conversion to an open procedure is necessary in 5–10% of patients, and is associated with increased morbidity, prolonged hospitalization and longer recovery in comparison to a laparoscopic approach[1].

Several factors increase the conversion risk to open, including age, male sex, obesity, cholecystitis and previous Endoscopic retrograde cholangiopancreatography[2]. Some experts had been trying to gather predicting factors and incorporate them in form of a scoring model (such as CLOC Conversion from Laparoscopic to open cholecystectomy) score. Risk score for conversion from laparoscopic to open cholecystectomy" (RSCLO) score and the prediction nomogram[3].

Conversion is also associated with complications including death, bile duct injury, bile leak, or bleeding, needing reoperation or transfusion. Identifying risk factors for conversion allowed safer procedures and better surgical planning. A systematic assessment of these factors preoperatively allows determination of whether open surgery should be performed initially, avoiding the potential complications brought through an intraoperative conversion from Laparoscopic cholecystectomy to open cholecystectomy[4].

AIM OF THE WORK:

The aim of the current study was to demonstrate the incidence of conversion of laparoscopic cholecystectomy to open cholecystectomy & to validate the efficacy of "CLOC" risk scoring system on the patients.

PATIENTS AND METHODS

The study was conducted from January 2019 to January 2020 in EL-Demerdash Teaching Hospital. A total of 100 patients with symptomatic cholelithiasis were included; patients were divided into two groups, firstly those subjected to laparoscopic cholecystectomy and secondly those who were converted from laparoscopic to open cholecystectomy. Patients were excluded if they had palpable tender lump in right hypochondrium; portal hypertension; peritonitis; deranged liver function tests; coagulopathy and pregnancy. The study was approved by the medical and Ethical Committee of Ain shams University, Faculty of Medicine and all the patients were informed about the study and a written consent was obtained from all.

The admission sheet was utilized to collect data about: the patients" characteristics (Gender, Age, Weight and height for Body mass index calculation). Detailed Clinical examination of the patient was done. Ultrasonography was performed for all patients following standardized protocol with assessment of gallbladder size and shape, Pericholycystic collection, gallbladder wall thickness, the size and number of calculi, and preoperative endoscopic retrograde cholangiopancreatography (ERCP).

Prophylactic antibiotics were given intravenously in a single preoperative dose within one hour of skin incision and re-dosed when the procedure is more than 4 hours long, NPO for at least 6 hours,

abdomen and groin area shower and cleaning with mild antibacterial soap, Deep Venous Thrombosis Prophylaxis in patients with two or more risk factors. Surgical procedure of LC was performed on the standard 4-ports technique, Post operatively the nasogastric tube was removed at the end of operation, the drain, if inserted, was removed in the following day if there is no bile in it and minimal blood loss has occurred and Majority of patients were discharged on the following day.

Validation of the "CLOC" scoring system was applied to all patients. A CLOC score equal or more than 6 was considered a high risk patient for conversion. A CLOC score below 6 was considered a low risk patient for conversion[2].

Operative data were also gathered prospectively, and the difficulty of the procedure was graded using the Nassar scale (grades 1–4).

Statistical analysis:

Recorded data were analyzed using the statistical package for social sciences, version 20.0 (SPSS Inc., Chicago, Illinois, USA). Quantitative data were expressed as mean± standard deviation (SD). Qualitative data were expressed as frequency and percentage.

- Chi-square (x2) test of significance was used in order to compare proportions between qualitative parameters.

- Binary logistic regression: was used to predict the outcome of categorical variable based on one or more predictor variables.

- The confidence interval was set to 95% and the margin of error accepted was set to 5%. So, the p-value was considered significant as the following:

- Probability (P-value):
  - P-value <0.05 was considered significant.
  - P-value <0.001 was considered as highly significant.
  - P-value >0.05 was considered insignificant.

RESULTS

In the current study; (29%) of the study group were <30 years; (36%) were 30-39 years; (29%) were 40-69 years and (6%) were over 70 years old. **Diagram (1)**: (60%) of the study group were females while male represented (40%). Cholecystitis was the most reported indication (76%); while the colic/pancreatitis represented (24%) of indications.

Table (1) showed that (68%) of the study group recorded ASA I, (32%) ASA II and (0%) ASA III+. **Diagram (2)** shows that (61%) of the study cases had normal gallbladder wall; while (39%) had thick wall.

Table (2) showed that (95%) of the study cases had normal CBD diameter while preoperative ERCP was done in (5%).

According to CLOC risk scoring system (76%) of the study cases recorded easy total score; while (24%) recorded difficult total score. Laparoscopic cholecystectomy (LC) was conducted in (95%) of the study cases; while open surgery was conducted in (5%) of the study cases.
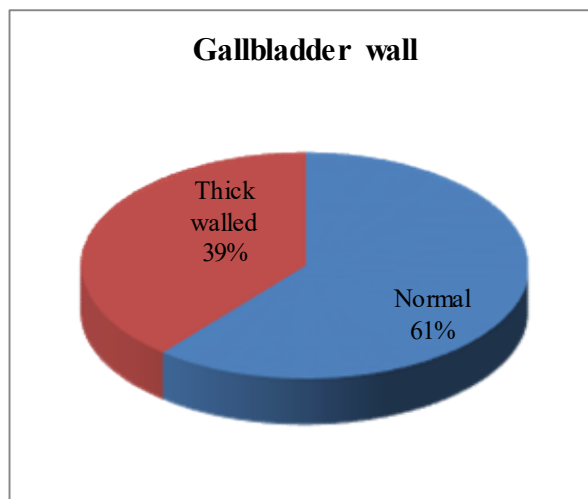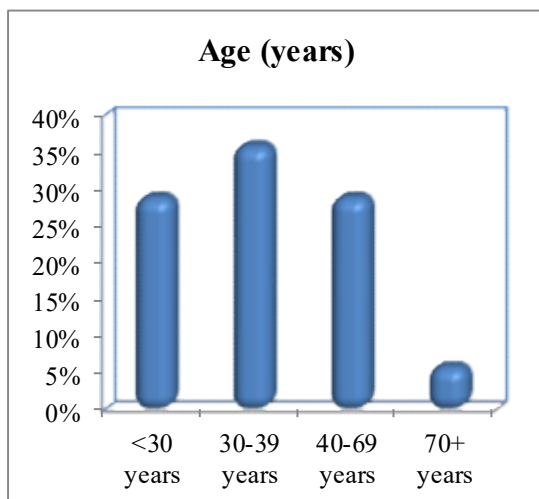
Diagram (1): Age (years) distribution

Diagram (2): Gallbladder wall distribution

Table (1): ASA distribution of the study group

ASA	No.	%
I	68	68
II	32	32
III+	0	0
Total	100	100

ASA: American Society of Anesthesiologists physical status classification system

Table (2): ERCP distribution of the study group

ERCP	No.	%
NO	95	95
PRE- OP ERCP	5	5
Total	100	100

ERCP: **Endoscopic retrograde cholangiopancreatography:**

Diagram (3) showed highly statistically significant relation between level of CLOC risk scoring system and age (years). (p<0.001); Diagram (4) shows statistically significant increase in difficulty in male compared to female. (p<0.019); Table (3) showed statistically significant relation between levels of CLOC risk scoring system and indication (p=0.002). Table (4) showed statistically significant relation between levels of CLOC risk scoring system and ASA (p=0.002). **Table (5)** showed highly statistically significant relation between levels of CLOC risk scoring system and ASA (p<0.001).
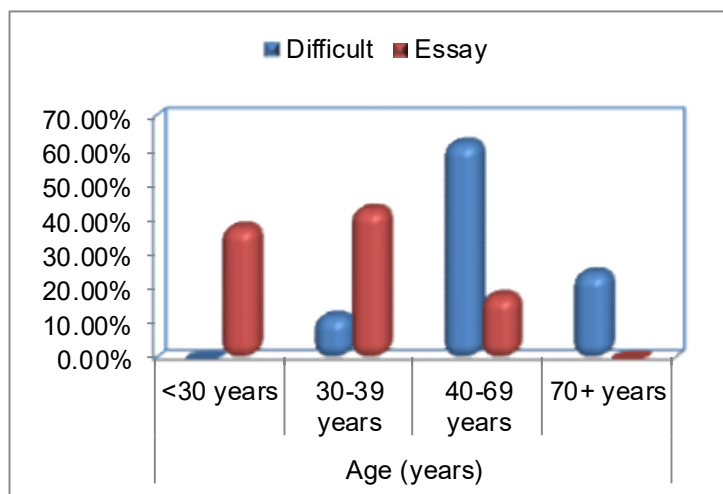
Diagram (3): Relation between levels of CLOC risk scoring system according to age (years).
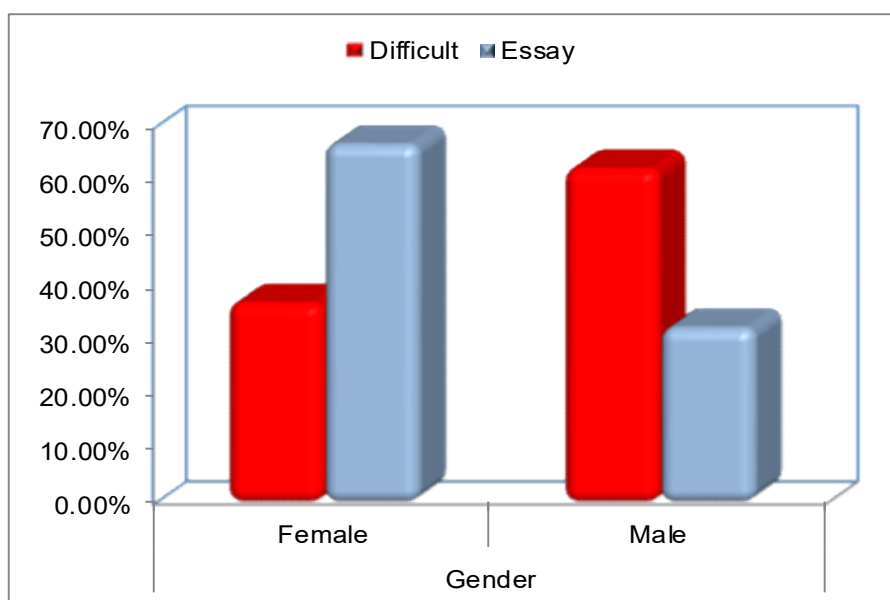

Diagram (4): Relation between levels of CLOC risk scoring system and gender.

Table (3): Relation between levels of CLOC risk scoring system and indication

Indication	Level of CLOC risk scoring system				x2	p-value
	Difficult		Essay			
	No.	%	No.	%		
Colic/ Pancreatitis	0	0.0%	24	31.6%	9.972	0.002*
Cholecystitis	24	100.0%	52	68.4%		
Total	24	100.0%	76	100.0%		

x2: Chi-square test; *p-value <0.05 S;

Table (4): Relation between levels of CLOC risk scoring system and ASA

ASA	Level of CLOC risk scoring system				x2	p-value
	Difficult		Essay			
	No.	%	No.	%		
I	10	41.7%	58	76.3%	10.064	0.002*
II	14	58.3%	18	23.7%		
Total	24	100.0%	76	100.0%		

x2: Chi-square test; *p-value <0.05 S;

Table (5): Relation between levels of CLOC risk scoring system and gallbladder wall thickness

Gallbladder wall	Level of CLOC risk scoring system				x2	p-value
	Difficult		Essay			
	No.	%	No.	%		
Normal	8	33.3%	53	69.7%	10.161	<0.001**
Thick walled	16	66.7%	23	30.3%		
Total	24	100.0%	76	100.0%		

x2: Chi-square test; **p-value <0.001 HS

Table (6) showed statistically significant relation between levels of CLOC risk scoring system and preoperative ERCP patients. (p=0.003). Table (7) showed statistically significant relation between observations and level of CLOC risk scoring. There was actual conversion according to groups with 'high risk scoring >7 and conversions in the' low risk >6 easy' group below. (p=0.042).

Table (6): Relation between levels of CLOC risk scoring system and preoperative ERCP patients

ERCP	Level of CLOC risk scoring system				x2	p-value
	Difficult		Essay			
	No.	%	No.	%		
No	20	83.3%	75	98.7%	9.049	0.003*
Yes	4	16.7%	1	1.3%		
Total	24	100.0%	76	100.0%		

x2: Chi-square test; *p-value <0.05 S;

Table (7): Relation between researcher observation and level of CLOC risk scoring

Level of CLOC risk scoring system	Conversions						r	p-value
	Open		Laparoscopy		Total			
	No.	%	No.	%	No.	%		
Difficult	3	60%	21	22.1%	24	24%	0.396	0.042*
Easy	2	40%	74	77.9%	76	76%		
Total	5	100%	95	100%	100	100%		

r: Spearman's Correlation Coefficient; **p-value <0.001 HS

Diagram (5) showed highly statistically significant increase of mean in difficult group compared to essay group according to duration of surgery. (p<0.001); Diagram (6) show highly statistically significant increase of mean in difficult group compared to essay group according to POD (days). (p<0.001)
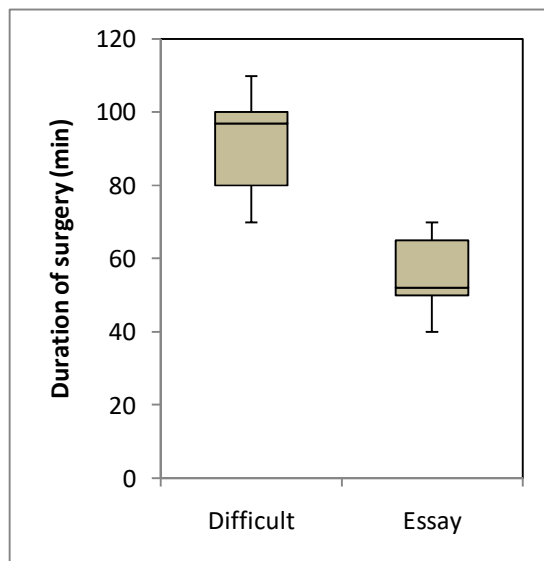
Diagram (5): Box plot between easy & difficult according to surgery duration
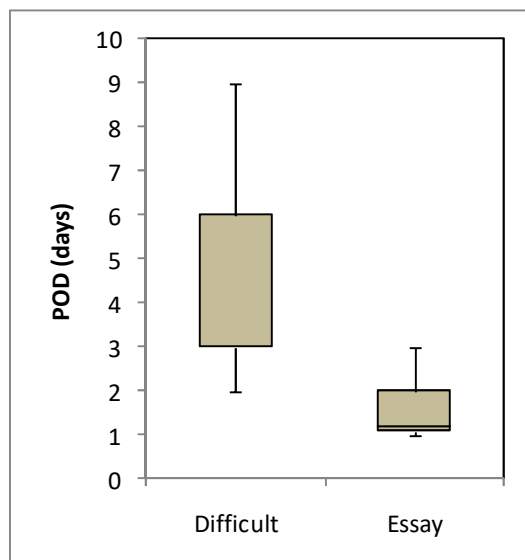

Diagram (6): Box plot between easy & difficult According to POD

Diagram (7): Receiver-operating characteristic (ROC) curve for prediction of difficult surgery using the CLOC risk scoring system.

Sensitivity	Specificity	PPV	NPV	AUC
92.0%	98.7%	95.8%	97.4%	0.970

Table (8) shows highly statistically significant higher complication in difficult group compared to essay group (p<0.001); Table (9) shows that age, gender, indication, ASA, gallbladder wall and Pre-Operative ERCP have a significant effect on the difficulty.
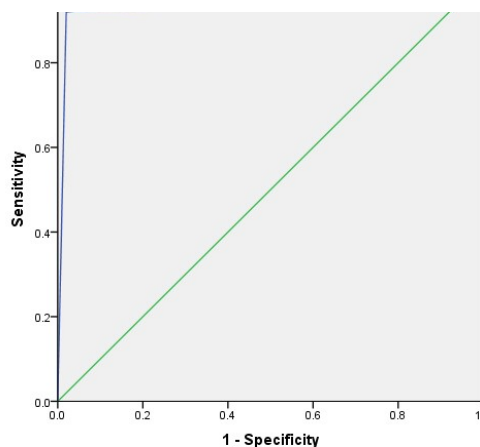
Table (8): Comparison between difficult and essay according to complications (n=100).

Complications	Level of CLOC risk scoring system				x2	p-value
	Difficult		Essay			
	No.	%	No.	%		
No	6	25.0%	68	89.5%	43.401	<0.001**
Yes	18	75.0%	8	10.5%		
Gallbladder rupture	*9*	*37.5%*	*3*	*2.6%*		
DVT	*3*	*12.5%*	*1*	*1.3%*		
Cystic duct avulsion	*1*	*4.2%*	*0*	*0.0%*		
CBD injury	*2*	*8.3%*	*0*	*0.0%*		
Postoperative ERCP	*2*	*8.3%*	*0*	*1.3%*		
Intra-operative heamorrage	*5*	*5.0%*	*2*	*2.6%*		
Biloma	*1*	*4.2%*	*0*	*0.0%*		
post cholecystectomy syndrome	*0*	*0.0%*	*2*	*2.6%*		
Total	24	100.0%	76	100.0%		

x^2-Chi-square test; **p-value <0.001 HS **(DVT): deep vein thrombosis**

Table (9): Multivariable binary logistic regression model analysis using the difficulty vs. patients as the dependent variable and the age, gender, indication, ASA, Gallbladder wall and ERCP as the independent variable in patients group

Parameters	Co-efficient	Odds ratio	95% C.I.		p-value
			Lower	Upper	
Age (years)					
<30 years	--	--	--	--	--
30-39 years	1.936	6.933	1.173	22.981	0.033*
40-69 years	2.686	4.667	2.178	18.777	0.006*
70+ years	1.442	3.556	0.289	12.379	0.017*
Gender					
Female	--	--	--	--	--
Male	-1.539	0.983	0.231	3.473	0.028*
Indication					
Colic/ Pancreatitis	--	--	--	--	--
Cholec-ystitis	-0.418	0.658	0.365	1.186	0.016*
ASA					
I	--	--	--	--	--
II	-0.753	0.471	0.290	0.764	0.011*
Gallbladder wall					
Normal	--	--	--	--	--
Thick walled	-1.528	0.217	0.081	0.578	0.006*
ERCP CBD diameter					
Normal	--	--	--	--	--
Dilated	-2.708	0.067	0.007	0.630	0.018*

DISCUSSION:

In the present study, cholecystitis was the most reported indication. This agreed with[6&7] and didn't match with[8]. The majority of our patients recorded ASA. That had been detected by[9] and while[10] showed the opposite view. The majority of our patients had normal gall bladder wall; this disagrees with[10]; where (46/50) of patients had thick wall.

The results showed that (95%) of the study cases had normal CBD diameter while preoperative ERCP was done in (5%). Recently, in[11], ERCP was done in (8%) cases. The majority of the study group recorded easy total score (76%); similar findings were obtained by [12]; [13]; [14]. Open surgery was conducted in (5%) of the study cases; this agrees with[9].

The current studied showed a statistically significant relation between CLOC risk scoring system levels and indication. (p=0.002); ASA (p=0.002); preoperative ERCP patients. (p=0.003) and highly statistically significant relation with gallbladder wall thickness. (p<0.001).

Increased risk of conversion with statistical significance was found for acute cholecystitis in[15] study and[16] study confirmed that ASA score; pre-operative ERCP; a thick-walled gallbladder and a dilated CBD were significant predictors of difficult surgery

We could demonstrate statistically significant relation between observations and level of CLOC risk scoring. There was actual conversion according to groups with 'high risk scoring >7 and conversions in the' low risk >6 easy' group below. (p=0.042)

In the validation set in[3], the risk of conversion to open for low (CLOC ≤ 6) and high risk (CLOC > 6) patients was 1.2% and 7.1%, respectively. Hence, patients identified as high risk had a near six-fold

higher rate of conversion than low risk patients. The CLOC score might help to identify high risk patients, in whom an early decision to convert would avoid a lengthy laparoscopic procedure.

In the present work, there was highly statistically significant increase of mean in difficult group compared to essay group according to duration of surgery, (p<0.001) and according to POD (days), (p<0.001)

According to[17] conversion to open surgery was significantly associated with longer operating time[18]. Results showed that in conversion group there was increase in duration of total hospital stay by more than 24 hours in about (90.1%) of patients.

The results of the current study had observed highly statistically significant higher complication in difficult group compared to essay group, (p<0.001). The rate of complications was (75% versus 10.5%)

Receiver operating characteristics (ROC) curve was used to define the sensitivity of 92% specificity of 98.7% positive predictive value of 95.8%, negative predictive value of 97.4% with diagnostic AUC of 0.970%.

As for predicting the risk of conversion from laparoscopic to open surgery in [19], the scoring system had 73% sensitivity and 87% specificity with P = 0.001 making it a highly significant association. The preoperative prediction scoring system used in[12] study for prediction of difficult laparoscopic cholecystectomy with sensitivity and specificity of their scoring system for prediction of easy or difficult laparoscopic cholecystectomy were 93.75% and 52.94% respectively.

The current study results showed that age, gender, indication, ASA, gallbladder wall and Pre-Operative ERCP have a significant effect on the difficulty.

Similar findings were obtained in different investigations;[20] study found that advanced age, presentation with acute cholecystitis, and choledocholithiasis affected difficulty. LC was technically difficult when performed later than 96 h after symptom onset in patients with grade II AC. Moreover, male sex also affects difficulty in[21] study. Previous history of hospitalization for acute cholecystitis and wall thickness of GB (in both univariate and multivariate analysis), along with age, sex, palpable GB, and impacted stone (in univariate analysis) were found to be statistically significant to predict difficult LC in[22&23] study conducted in Aswan University Hospital.

Conclusion: Parameters like older age, male gender, cholecystitis, ASA, thick wall GB, preoperative ERCP were predictors for difficult LC. These were risk factors and predictors for conversion to open cholecystectomy. CLOC" risk score may be the most helpful tool in stratifying risks

Recommendations:

Proper preparation of patients preoperatively is needed. Predictive factors could be used to plan the intervention. More attention should be given to demographic data, history and clinical examination to predict the difficult LC. Adequate training and experience of the surgeon, proper execution of appropriate technique and accurate identification of the anatomy are essential guidelines for prevention of complications.

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دراسة مستقبلية لوقوع تحويل استئصال المرارة بالمنظار لفتح استئصال المرارة في مائة مريض

الخلفية: استئصال المرارة بالمنظار هو العلاج القياسي الذهبي لحصوات المرارة المصحوبة بأعراض التحويل إلى إجراء مفتوح ضروري في ٥-١٠٪ من المرضى.

الهدف من العمل: كانت الدراسة الحالية لتوضيح حدوث تحويل استئصال المرارة بالمنظار لفتح استئصال المرارة والتحقق من فعالية نظام "CLOC" (التحويل من المنظار إلى استئصال المرارة المفتوح) على المرضى المشمولين بالدراسة.

المرضى والطرق: أجريت الدراسة الاستطلاعية الحالية في مستشفى الدمرداش التعليمي (يناير ٢٠١٩ - يناير ٢٠٢٠). اشتملت الدراسة على (١٠٠) مريض مصاب بأعراض تحص صفراوي. تم تقسيم المرضى إلى مجموعتين ، أولاً أولئك الذين أكملوا استئصال المرارة بالمنظار وثانيًا أولئك الذين تم تحويلهم إلى استئصال المرارة المفتوح. تضمنت المتغيرات قبل الجراحة التركيبة السكانية للمرضى ، ومؤشرات الجراحة ، ودرجة ASA ، ونوع القبول ، ونتائج الموجات فوق الصوتية ، وتصوير البنكرياس والقنوات الصفراوية بالمنظار قبل الجراحة (ERCP). تم تطبيق التحقق من صحة نظام التسجيل المسمى "CLOC" على جميع المرضى. تم جمع البيانات العملية بأثر رجعي ، وتم تصنيف صعوبة الإجراء باستخدام مقياس نصار (الصفوف ١-٤).

النتائج: (٢٤٪) من المرضى سجلوا درجات إجمالية صعبة. أجريت الجراحة المفتوحة بنسبة (٥٪). كانت هناك علاقة ذات دلالة إحصائية بين مستوى تسجيل مخاطر CLOC والعمر (0.001> P) ؛ دلالة (ع = ٠.٠٠٢) ؛ ASA (ع = ٠.٠٠٢) ؛ سمك جدار المرارة. (0.001 >P) ومرضى ERCP قبل الجراحة (ع = ٠.٠٠٣). كانت هناك زيادة ذات دلالة إحصائية في الصعوبة عند الذكور مقارنة بالإناث. (ع = ٠.٠١٩). كان هناك تحويل فعلي وفقًا للمجموعات ذات "نقاط المخاطرة العالية> ٧ والتحويلات في المجموعة" منخفضة المخاطر> ٦ سهلة "أدناه. (ع = ٠.٠٤٢) ؛ زيادة ذات دلالة إحصائية عالية في المتوسط في المجموعة الصعبة مقارنة بمجموعة المقالات (P <0.001). كان معدل مضاعفات المجموعة الصعبة أعلى من المجموعة السهلة (٧٥٪ مقابل ١٠.٥٪) ؛ تم الإبلاغ عن تمزق المرارة في الغالب في (٣٧.٥ و ٢.٦٪) من المجموعة الصعبة وحالات المجموعة السهلة ، على التوالي. كانت حساسية منحنى خصائص تشغيل جهاز الاستقبال 92٪ (ROC) ؛ كانت الخصوصية ٩٨.٧٪. العمر والجنس والإشارة و ASA وجدار المرارة و ERCP قبل الجراحة لها تأثير كبير على الصعوبة.

الخلاصة: يمكن أن تستنتج الدراسة الحالية أن العلامات مثل العمر الأكبر ، جنس الذكور ، التهاب المرارة ، ASA ، جدار سميك للمرارة ، ERCP قبل الجراحة تنبئ بصعوبة المنظار. وفي الوقت نفسه ، تعد هذه العوامل تنبؤًا بالتحويل إلى استئصال المرارة المفتوح. قد تكون درجة مخاطر CLOC "هي الأداة الأكثر فائدة في تصنيف المخاطر إلى طبقات.