ORIGINAL ARTICLE

Evaluation of Pre and Intraoperative Factors for Predicting Difficult Laparoscopic Cholecystectomy

Dr. Rawaa Abdulhassan Jabur Naser[1*] , Professor Dr. Qusay Mohammed Zwain[2]

Author's Information
1. M.B. Ch B
2. M.B.Ch.B. FICMS, Professor of surgery, Faculty of Medicine, University of Kufa, Iraq

Corresponding author:
Rawaa Abdulhassan Jabur Naser
naser_rawaa88@gmail.com

Conflict of interest
None declared by author

ABSTRACT

Background
Laparoscopic cholecystectomy is now considered the gold standard for the treatment of symptomatic GS performed by general surgeon. Preoperative complexity estimation helps deciding whether to proceed with a minimally invasive approach, perform an open procedure or make a referral to a more experienced surgeon.

Objective: To identify and assess the pre- and intra operative parameters that aid in the prediction of the difficult LC.

Patient and Method
A Cross sectional study conducted in the department of surgery of Al sadder medical city, in Al Najaf, during the period from October 2019 to October 2021. A total of 325 patients who underwent elective LC were included. The pre-operative and intraoperative parameters were considered and evaluated

Result;
The significant predictors of difficult LC were Age older than 50 years, obesity, time of surgery >60 minute, intra-peritoneal adhesion, male gender, previous abdominal surgery, previous admission to hospital due to attack of cholecystitis, thickness wall of GB, stone size>10mm, over distended GB, un grasping of GB, however the effect of these parameters varied according to odds ratio, (P. value<0.05). Receiver operating characteristic (ROC) curve revealed that preoperative score of 4.5 or more was significant predictor of difficult LC with good sensitivity, specificity and accuracy

Conclusion
Pre and intraoperative parameters were significant predictor of difficult laparoscopic cholecystectomy and therefore can be useful to take specific measure to overcome the difficult procedures

Keywords: Cholecystectomy , Laparoscopic , difficulty, Evaluation, predictors, risk factor

1. INTRODUCTION

Laparoscopic cholecystectomy is the most common surgery performed by general surgeon for treatment gallstones and other gallbladder conditions (1). In 2011, cholecystectomy consider the eighth most common operating room procedure performed in hospitals in the United States (2). Cholecystectomy is operated either by open or laparoscopic technique (3).

By 2014 laparoscopic cholecystectomy become the gold standard for the treatment of symptomatic gallstones (4). The surgeon must has a good laparoscopic skill to complete the operation with safety and effectiveness (5). Laparoscopic cholecystectomy has many advantage, it decreases postoperative pain, decreases need for postoperative analgesia, shortens the hospital stay, and returns the patient to full activity within 1 week (compared with 1 month after open cholecystectomy) (6,7). Also improved cosmetic and patient satisfaction. The LC has indirect cost saving, due to rapid return to normal daily activity (8). laparoscopic cholecystectomy operated in Day cases and those in inpatient settings recover equally well, indicating that a great proportion of patients can operated in the outpatient modality(9). With preoperative evaluation and understanding the patient factors and disease factor ,the complication of LC decrease and possibly averted (10).

Different research articles have been suggested from time to time using different criteria, for prediction of DLC the predictive factors were broadly described by authors under three categories; clinical parameters - Patient factors and Disease factors, Radiological parameters and Intra operative parameters

Patient's Age is the most important significant risk factor for intraoperative difficulty and conversion. Particularly older than 60 years which has shown to increase the risk (11). Gender was found to be independent risk factor for severity of acute cholecystitis, thus increasing technical difficulty and need for conversion (12). History of previous surgeries with intra-abdominal adhesion between omentum, viscera and abdominal wall have major risk factor for technical difficulty and conversion, however, the effect of previous abdominal surgeries is still controversial. (1,10,13,14).. Higher Body mass index also a significant risk factor for difficult LC (10). Multiple comorbidities such as Diabetes , myocardial infarction, Arterial Hypertension, COPD, Non-Ischemic Heart disease, Previous Pancreatitis, Liver cirrhosis, history of cardiac surgeries was found to have an associations with difficult LC and conversion rates, (11,14–17)

Among disease related factors that associated with difficult LC are history of or clinical sign of cholecystitis which manifested as fever and pain and leukocytosis (acute cholecystitis) or biliary colic and also prior hospitalization for cholecystitis (10,11,18–21).

Elevation of liver enzyme and bilirubin also found to have a significant impact in prediction of difficulty, where it had been found that raised amylase level was a warning sign of a difficult LC (2). ERCP before surgery and emergency LC increase the difficulty and rate of conversion to open surgery(10,11). A palpable gallbladder found by to be a significant predictor of intra operative difficulty (20). Regarding the radiological parameters, ultrasound found to be the most sensitive investigation by all authors. The sonographic features of Gallbladder which predict a risky procedure are the shape and state of GB, the wall thickness of gall bladder, size of gall stones >3mm, impacted stone in the cystic duct and the presence of pericholecystitic fluid (11,17,19–25). Intra operative parameters such as adhesions at the Calot's triangle and anomaly of the anatomy (25) (14) in addition to the surgeon's experience are important factors in difficult LC (16,17).

There are different scoring system used for grading the difficult LC, Randhawa and Pujahari score is the commonly used; which categorizes the difficulty according to a score from 0 to 15 where a score up to 5 considered easy, 6-10 as difficult and 11 – 15 as very difficult (20). More detailed scoring was adopted by Vivek et al. where a score of more than 9 considered as difficult and the score was directly associated with the degree of difficulty (10,24)

2. METHODOLOGY

A Cross sectional prospective study performed in the department of surgery in AL- Sadder medical City in Al- Najaf , from 1st October 2019 to 1st October 2021. The 325 patients presented with symptomatic GB stones diagnosed by history ,clinical examination, investigation and abdominal ultrasound and then electively operated by different laparoscopic surgeons working in the AL-Sadder Medical City . full informed consent taken from all patients to participate in this study. The protocol of this study has been approved by the relevant ethical committee related to our institution.

The study included patient with symptomatic GB stones underwent elective LC with informed consent for operative intervention during the research period .

Eligible patients included in this study were subjected to following parameters ,which were by history include age, sex, duration of illness ,previous (history of ERCP, admission to hospital

for acute cholecystitis , history of pancreatitis , abdomen surgery ,, attack of biliary colic) and co morbidity. Clinical examination included abdominal examination for previous abdominal scar , presence of palpable GB and body mass index (BMI).

Routine preoperative investigation(CBC,LFT,RFT) and abdominal US., finding (GB wall thickness, size of GB, size of stones , number of stones). All the patients were electively operated under GA ,events of surgery were documented in terms of the -Duration(in minute)of surgery must be recorded, included from insertion of first port until closure of last port site , adhesion at calots triangle , funds state , state and grasping ability of GB .

Statistical analysis

The statistical package for social sciences (SPSS) version 27 used in analysis of data, Appropriate statistical tests and procedures were applied accordingly. Cohen's kappa statistic used to assess the agreement between scoring systems.. Receiver operating characteristics (ROC) curve used to assess the validity of pre-operative scores as predictor of difficulty of laparoscopic Cholecystectomy. Binary regression analysis used to find the significant predictors of difficult LC. Level of significance set at 0.05

3. RESULTS

A total of 325 patients were enrolled in this study, all were operated on for cholecystectomy. The mean age of the patients was 39.2 ± 13.8 (range: 18 – 85) years. Baseline characteristics of the studied group are shown in (**Table 1**). The descriptive statistics of laboratory parameters of the studied group are shown in (**Table 2**). Ultrasonography (U/S) examination showed abnormal (over distended, distended and contracted) gall bladder in majority of patients, (89.2%) . Thickened gall bladder wall > 4 mm in 31 (9.5%). A median total gall stone of 4 stones with a size ranged from < 5 mm to > 20 mm , (**Table 3**). In majority of the patients, (92.6%), 4 ports were used. Direct method of first port insertion after Veress needle insertion and insufflations in 129 (39.7%), Direct without insufflation in 193 (59.4%) while open method in only 3 patients (0.9%). Intraoperatively, it had been found that most of fundus was out of liver edge in 22.2% of cases, slightly out of liver edge in 64.6%, slightly below liver edge in 10.2% and it was more than 3 cm below liver edge in 10 cases (3.1%). Regarding grasping ability of gall bladder, it was easily graspable in majority of cases (88.3%). Gall bladder was looked normal in 92.3% of cases, Chronic cholecystitis in 5.2%, Empyema in only 3 cases, Acute cholecystitis in 3 cases and contracted in only 2 cases. Filmy omental adhesions

reported in 71.4% of cases. CBD stenting performed in 12 cases while drain inserted in 96.9% of cases. The time of surgery was < 60 minutes in 225 patients (69.2%), 60-120 minutes in 98 (30.2%) while it was > 120 minutes in 2 patients. Vast majority of the patients discharged from hospital within 24 hour, however, only 4 patients hospitalized for 2-3 days (**Table 4**). According to Pre-operative scoring system used in the study, 283 patients had a score of 0-5 and were assigned as easy while 42 patients had a score of 6-10 (difficult), none of the patients had a score of > 10 so none assigned as very difficult. Intra-operative difficulty levels of LC revealed that 223 (68.6%) easy LC, 95 (29.2%) difficult and 7 (2.2%) very difficult. The cross-tabulation and agreement between preoperative and intraoperative difficulty scoring revealed a good agreement between preoperative and intraoperative difficulty scoring, i.e. preoperative difficulty scoring can predict the intraoperative difficulty. Cohen's kappa value (K) = 0.71 which is substantial agreement giving a percent agreement of 79.4% (good agreement level), (**Table 5**). Furthermore, the Receiver Operating Characteristic (ROC) curve analysis (**Figure 1**), showed that preoperative scoring was significant valid predictor of intraoperative difficulty, with an area under the curve (AUC) of 0.918. At a cutoff point of preoperative scoring of 4.5, it produced sensitivity 72.2%, specificity 94.6%, accuracy 84.3%, positive predictive value (PPV) 93.0% and negative predictive value (NPV) of 77.3%.

Results of bivariate correlation analysis for the correlation of difficulty of LC with laboratory parameters, revealed no significant correlation, (P. value > 0.05), indicated that these parameters were not predictors of difficulty of LC, (**Table 6**). Regarding the significant predictors of difficult LC it had been found that age older than 50 years (OR= 4.06), obesity (OR = 3.32), conversion to open (OR =3.10), time of surgery > 60 minutes (OR =2.72), massive intra-peritoneal adhesions (OR =2.46), male gender (OR =2.39), previous abdominal surgery (OR =2.28), previous attacks of biliary colic (OR =2.20), chronic cholecystitis/ Empyema (OR =1.65), previous attacks of pancreatitis (OR =1.53), over distended /contracted Gall bladder (OR =1.52), thicker GB wall (>4 mm) (OR =1.45), need deflation/Ungraspable GB (OR =1.42) and larger stone size > 10 mm (OR = 1.26), were significant predictors of difficult LC, (P. value <0.05), (**Table 7**).

Table 1. Baseline characteristics of the studied group

Variable		No.	%
Age (year)	≤ 50	260	80.0
	> 50	65	20.0
Gender	Male	33	10.2
	Female	292	89.8
BMI (kg/m²)	< 25	61	18.8
	25 - 27.5	93	28.6
	> 27.5	171	52.6
Associated comorbidity		93	28.6
Previous abdominal surgery		157	48.3
Previous attacks of biliary colic	Once	44	13.5
	Twice	277	85.2
	≥ 3	4	1.2
Previous acute or chronic cholecystitis	Once	32	9.8
	≥ 2	287	88.4
	None	6	1.8
Previous attacks of pancreatitis		15	4.6

Mean duration since last attack of acute cholecystitis: 16.3 ±4.2 (range: 1 – 120) days

Table 2. Descriptive statistics of laboratory parameters of the studied group

Parameter	Mean	SD	Range
WBC count (x10³)	7.11	3.01	0.39 – 17.5
neutrophil count (x10³)	2.64	2.45	0.04 – 14.1
Lymphocyte count (x10³)	1.62	1.6	0.03 – 11.0
Total serum bilirubin	0.66	0.3	0.20 – 2.3
Direct bilirubin	0.54	0.69	0.10 – 1.9
ALT U/L	24.34	12.37	12.0 – 77
AST U/L	26.36	17.24	14.0 – 179.0
ALP IU/L	101.21	51.06	42.0 – 454.0

SD: standard deviation of the mean

Table 3. Findings of ultrasonography examination of gall bladder

Variable		No.	%
Gall bladder size by U/S	Distended	202	62.2
	Over distended	72	22.2
	Contracted	16	4.9
	Normal	35	10.8
Gall bladder wall thickness	> 4 mm	31	9.5
	< 4 mm	294	90.5
Size of stones (mm)	< 5	19	5.8
	5 – 10	62	19.1
	11 - 20	66	20.3
	> 20	34	10.5
	Variable	144	44.3
Total		325	100

Table 4. Operative parameters and findings of the studied group

Variable		No.	%
Ports number	3	24	7.4
	4	301	92.6
Method of first port insertion	Veress needle insufflations	129	39.7
	Direct without insufflation	193	59.4
	Open method (HASSON)	3	0.9
Intraoperative fundus state	Most of it out of liver edge	72	22.2
	Slightly out of liver edge	210	64.6
	Slightly below liver edge	33	10.2
	More than 3 cm below liver edge	10	3.1
Grasping ability of gall bladder	Need deflation	8	2.5
	Ungraspable	5	1.5
	Frequent re-grasping	25	7.7
	Easily graspable	287	88.3
State of GB	Chronic cholecystitis	17	5.2
	Empyema	3	0.90
	Acute cholecystitis	3	0.90
	Contracted	2	0.60
	Normal appearing	300	92.3
Intraoperative adhesions	Filmy omental adhesions	232	71.4
	Edematous thick omental adhesions	40	12.3
	Massive intra-peritoneal adhesions	10	3.1
	None	43	13.2
CBD stenting		12	3.7
Drain inserted		315	96.9
Time of surgery	< 60 minutes	225	69.2
	60 – 120 minutes	98	30.2
	> 120 minutes	2	0.60
Hospital stay (day)	One	321	98.8
	2 – 3	4	1.2
Total		325	100.0

Table 5. Cross-tabulation and agreement between preoperative and intraoperative difficulty scoring

Intraoperative Difficulty (outcome)	Preoperative Difficulty score				Total	
	Easy (0 - 5)		Difficult (6 - 10)			
	No.	%	No.	%	No.	%
Easy	**223**	78.8	0	0.00	223	68.6
Difficult	60	21.2	**35**	83.3	95	29.2
Very difficult	0	0.0	7	16.7	7	2.2
Total	283	100.0	42	100.0	325	100.0

Cohen's kappa value (*K*)= 0.71 substantial agreement, Percent agreement (**223+35/325**)= **79.4%**
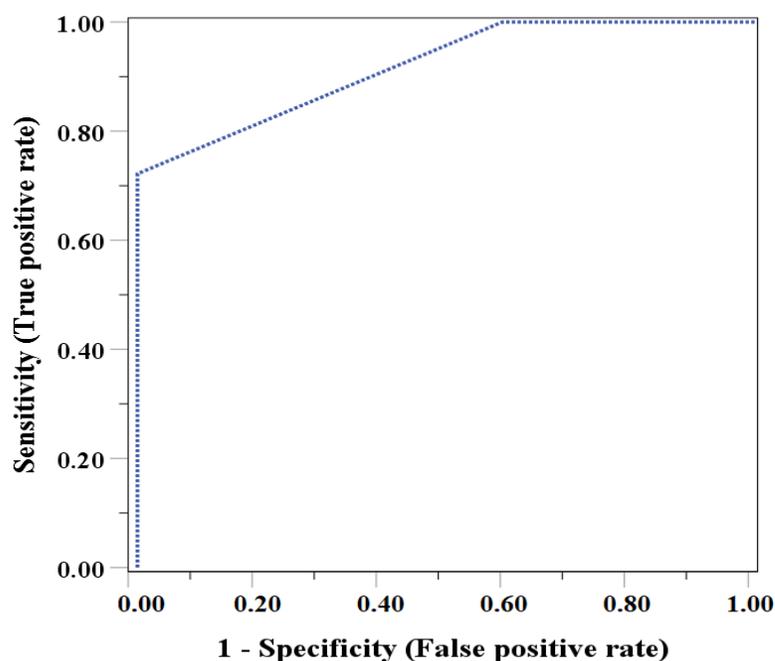P. value = 0.001

Figure 1. Receiver Operating Characteristic (ROC) curve for the validity of preoperative scoring in prediction of intraoperative difficulty level. [at an Optimal Cutoff point of 4.5, area under the ROC curve (AUC) = 0.918, Sensitivity: 72.2%, Specificity: 94.6%, Accuracy: 84.3%, positive predictive value (PPV): 93.0% and Negative predictive value (NPV): 77.3%]

Table 6. Results of bivariate correlation analysis for the correlation of difficulty of LC with laboratory parameters

Parameter	Intraoperative difficulty of LC	
	R	P. value
WBC count (x10³)	0.066	0.149
neutrophil count (x10³)	0.077	0.090
Lymphocyte count (x10³)	0.008	0.856
Total serum bilirubin	0.082	0.110
Direct bilirubin	0.234	0.537
Alanine amino-transaminase	0.029	0.590
Aspartate amino-transaminase	0.029	0.582
Alkaline phosphatase	0.036	0.467

R: correlation coefficient of the bivariate analysis

Table 7. Results of regression analysis for the predictors of difficult LC

Variable	OR	95%CI of OR	P. value
Age older than 50 year	4.06	1.88 - 6.39	0.001
Obesity	3.32	1.28 - 5.17	0.001
Conversion to open	3.10	1.41-4.92	0.001
Time of surgery > 60 minutes	2.72	1.11 - 4.27	0.011
Massive intra-peritoneal adhesions	2.46	1.22 - 4.42	0.018
Male gender	2.39	1.09 - 4.33	0.022
Previous abdominal surgery	2.28	1.11 - 3.88	0.027
Previous attacks of biliary colic	2.20	1.12 - 4.08	0.025
Chronic cholecystitis/ Empyema	1.65	1.10 - 2.89	0.033
Previous attacks of pancreatitis and ERCP	1.53	1.07 - 3.10	0.039
Over distended /contracted Gall bladder	1.52	1.03 - 2.49	0.041
Thicker wall Gall bladder	1.45	1.21 - 3.17	0.042
Need deflation/Ungraspable GB	1.42	1.09 - 2.11	0.044
Larger stone size > 10 mm	1.26	1.12 - 1.86	0.031

OR: odds ratio, CI: confidence interval

4. DISCUSSION

Laparoscopic cholecystectomy (LC) is the golden standard of treatment GB stones and other GB conditions ,it can be difficult in many conditions such as dense adhesion ,empyema of GB ,acute inflammation of GB and contracted GB (26), DLC can be defined (according to Randhawa et al. difficult criteria) when time of surgery (60-120 minute),injury to duct, bile\stone spillage ,bleeding, risk of conversion. In the first years of laparoscopic surgery, there is higher rate of complication of LC and conversion to open surgery but with development of technique   and experience of surgeon ,the rate become low at 2.0-6.0% (27). Many times, LC is challenging and the surgeon has to face the difficulty that might lead to injury to adjacent structures leading to an increase in morbidity. Therefore, the preoperative estimate of a difficult LC is essential to predict the difficulty as well as for a better surgical plan. It also help the surgeon in being better prepared to anticipate the intra operative difficulty (28).

Many   literature   has mentioned different predictors for difficult LC such   as age 60 or more, male gender, co morbid condition, past history of acute cholecystitis, previous abdominal surgery, gall bladder wall thickness ≥4–5 mm, contracted gall bladder (19).

In this study, LC was performed in 325 patient ,it's had different pre and intra operative parameters for DLC, were analysis the prediction of difficulty, found that old age(age > 50 years) had significant correlation with difficulty and conversion to open. Some studies found that age was the most important risk factor for difficult LC and conversion (29,30).   While other authors did not (31,32). Regarding obesity ,LC is difficult in obese patient due to multiple factor such as introduction of port insertion   take more time because of thickness of abdominal wall, due to excessive intra-abdominal fat cause obscure of anatomy of Calot's triangle so the dissection is more difficult. Also there is difficulty in manipulation of many instrument because of thickness of abdominal wall (33–36).

In this study ,larger BMI was significant risk factor for difficulty of LC, this consistent with previous studies (10,20,21). Difficulty also present   when adhesion between omentum ,viscera and abdominal wall due to previous surgery, given a big chance of injury to these structure when insertion first port and risk of conversion to open become high (37,38). Patient who complain from multiple attack of inflammation of GB have greater risk for

difficulty and conversion to open due to adhesion of calot triangle (39).These required more time for dissection of Calots triangle and dissection of GB from liver bed (23). In our study we found the time of surgery (more than 60 minutes) and previous abdominal surgery were significantly associated with DLC. Male gender also consider risk factor for difficulty in LC (34,40). In male sex, there is high rate of conversion and mortality rate (37). According to Yol S et al. (41), men with symptomatic gall bladder are more prone to inflammation and fibrosis with the thus leading to difficulty in dissection as is reflected in this study. We found that male sex is one of the significant risk factors for difficulty LC .

The GB wall thickness when increase make the dissection of Calot's triangle very difficult ,also difficult in grasping and manipulation of GB and cause limitation in define the anatomy (42).The gall bladder wall thickness had significant impact, similarly, Jansen et al. (42) found contracted gall bladder increases the risk of conversion , we found contracted GB is significant (p.value0.041) (OR 1.52). Many authors found the size of stones associated with conversion (40,43).   in this study also found the same, but Jansen et al. (42) found that stone size >20 mm was associated with risk of difficulty and conversion to open . In this study, found stone size >10 cm(p.value0.031)(1.26) is significant.

Other pre and intra operative parameter that found in Vivek's and Randhawa's scoring show important significance in predicting difficulty of laparoscopic cholecystectomy, like stone size and history of acute pancreatitis and ERCP (10,20).

As mentioned in result there is a good agreement between pre and intraoperative scoring in predicting difficult LC ,but not so in easy case, because preoperative predicting factor show about 90.2% easy while intraoperative score show only 68.6% are easy ,also preoperative score show 9.8% difficult and no case very difficult , on the other hand intraoperative scoring show29.2% difficult and 2.2% very difficult(including the case that converted to open).

5. CONCLUSIONS

Age more than 50, obesity, time of surgery more than 60-minute, male gender, adhesion, previous admission to hospital due to acute cholecystitis, abdominal ultra sound finding (state of GB, thick wall of GB, over distended of GB, size of stone) are significant factors in

prediction of difficult LC and must be considered for every patient admitted for elective LC. Solving of these risk factors depend on experience of the surgeon. we believe that equipped and experience surgeon can face these factors and proceed with this procedure. Therefore, pre and intra-operative predicting parameter for DLC are helpful and useful for surgeon in planning for surgery

Ethical Approval:

All ethical issues were approved by the author. Data collection and patients enrollment were in accordance with Declaration of Helsinki of World Medical Association , 2013 for the ethical principles of researches involving human. Signed informed consent was obtained from each participant and data were kept confidentially.

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