Original Resear	Volume-9 Issue-3 March-2019 PRINT ISSN - 2249-555X General Surgery PRE OPERATIVE PREDICTORS OF DIFFICULT LAPAROSCOPIC CHOLECYSTECTOMY	
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KEYWORDS :		

INTRODUCTION

Gallstones represent a sizeable problem for the contemporary health care system in both developed and developing countries alike. Gallstone disease is the major indication for cholecystectomy worldwide. National Institute of Health consensus development stated that laparoscopic cholecystectomy "provides a safe and effective treatment for most patients with symptomatic gallstones" and "provides distinct advantages over open cholecystectomy" but that "the outcome of laparoscopic cholecystectomy is influenced greatly by the training, experience, skill, and judgment of the surgeon performing the procedure"¹

Yet around 2-15 percent of attempted laparoscopic cholecystectomies are converted to open procedure due to difficulties faced in laparoscopic approach. The main difficulties faced are at three levels, the step during application of ports, the step at dissection of callot's triangle and extracting the excised gallbladder. Various factors contribute to the difficulty in the surgery.

In this study various parameters that affect the procedure making laparoscopic approach difficult are studied. The factors considered in this study are age, sex and body mass index of the patient, history of hospitalization with acute cholecystitis, clinical palpability of GB and those based on USG assessment are GB wall thickness, site of GB stone, pericholecystic fluid collection. Such assessment allows the surgeon and the patient to be well aware of the outcome of surgery and risk of conversion of the laparoscopic approach to open procedure.

AIM OF THE STUDY

 To determine preoperatively the factors based on clinical and radiological evaluation that can predict the outcome in terms of difficulty in laparoscopic cholecystectomy.

OBJECTIVES OF THE STUDY

- 1) To assess the clinical risk factors based on history and physical examination of the patient.
- To assess ultrasonographycally the risk factors pertaining to gall bladder wall thickness, position of gallstones and pericholecystic fluid collection
- To predict the intraoperative risk based on the above clinicoradiological findings using a scoring system preoperatively
- To stratify the patients post operatively based on intra-operative findings
- 5) The data obtained will be analyzed to establish if any significant correlation exists between the factor analyzed and the event of difficult LC and to find effectiveness of the scoring system in predicting difficult LC

PATIENTS AND METHODS

Study area: Department Of General Surgery, Government General Hospital, Kurnool

Study population: Total of 50 patients with symptomatic gall stone disease admitted for Laparoscopic Cholecystectomy

Selection of patients: In the study patients of all age groups and both sex admitted in government general hospital, kurnool with symptomatic gallstone disease were included in the study.

Inclusion criteria

All cases of Symptomatic Gall Stone Disease of 20yrs and above age

Exclusion criteria

- 1) Patients below the age of 20yrs.
- 2) LC performed with other laparoscopic intervention in the same setting
- 3) Patients requiring CBD exploration
- Absolute contraindications for LC like cardiovascular, pulmonary diseases, coagulopathies, and end stage liver disease and other medical comorbidities
- 5) Patients with features of obstructive jaundice

Study period: A period of 2 years from November 2016 to November 2018 during which patients meeting the inclusion criteria were included in the study.

Study design: It was a Hospital based Prospective Study

Methodology

- All patients satisfying the inclusion criteria were included in the study
- 2) Written informed consent is obtained from all patients included in the study.

Pre-operative Work Up: After enrolling the patients the following work up is to be done

- 1) Clinical history and Physical examination
- Hematological investigations within the govt. general hospital Kurnool with the coordination of the department of radiology, pathology, microbiology and biochemistry.
- 3) Investigations to assess fitness of the patient for anesthesia:
- 4) Ultra-sonography is to be done on the previous day of the proposed procedure taking into account the parameters such as site of GB stone (impacted at the neck or free in the lumen), GB wall thickness, Peri-cholecystitic fluid.

Patients are to be given a score pre-operatively based on the scoring system for clinical and radiological evaluation to predict difficulty in procedure.

Pre-operative scoring system

Difficulty	Score
Easy	0-5
Difficult	6-10
Very difficult	11-15

PATIENT PREPARATION

All cases were admitted two days prior to surgery. Detailed history, findings in general and systemic examination, through investigations reports were obtained for each patient.Patients were counseled on the surgical procedure. They will be informed of the probable risk of being converted to open procedure based on complications encountered intra-operatively. Patient willing to undergo surgery and his or her relative were required to sign in the form for consent for the procedure as well as in the form for open conversion of LC.Proper preparation of the patient was done the night before surgery and all the patients are made to take scrub bath on the morning of surgery. A single dose of a broad spectrum inject able antibiotic was given routinely immediately before application of first port.

INDIAN JOURNAL OF APPLIED RESEARCH

5

All the cases were done under general anesthesia and lap cholecystectomy was performed. In difficult cases converted to open cholecystectomy. The operative parameters need to be recorded for the patients undergoing LC are time taken for the surgery, bile spillage/stone spillage, injury to CBD or cystic artery and conversion to open cholecystectomy. Based on these observations post-operative outcome of LC is to be grouped into easy, difficult and very difficult as follows and evaluated.

Intra-operative grading with criteria

	CRITERIA
EASY	Time taken <60 min.
	No bile spillage
	No injury to duct or artery
DIFFICLUT	Time taken >60 min <120 min
	Bile or stone spillage
	Injury to duct
	No conversion to open
VERY DIFFICULT	Time taken >120 min
	Conversion to open

PLAN OF STATISTICAL DATA ANALYSIS:

Statistical analysis is done using Fischer's test for qualitative data and unpaired t test for quantitative data. Percentages and proportions is calculated wherever appropriate. Percentage value is rounded off to first decimal digit. Suitable graphs and pie charts have been made to enhance visual appeal. A p value of <0.05 is considered significant

OBSERVATIONS AND RESULTS

The mean age of the study group was 46.02 ± 14.42 (SD) years with minimum age being 21 years and maximum being 75. Of 50 patients in the study, 30 patients were < 50 years and 20 patients were >50 years. 20 patients were male (40%) and 30 were females (60%).

Mean BMI of the patients included in the study group was 24.565 ± 3.14 (SD) kg/m2 while the least was 19.5 and highest was 32.45. In 50 cases, 32 cases had BMI <25, 10 cases had between 25.1-27.5 and 8 cases had >27.5

The history of hospital admission for acute cholecystitis was considered as a major risk factor and of the 50 patients under study, 12 patients had a history of hospital admission for acute cholecystitis. Of the 50 cases, only three cases had a palpable gallbladder on clinical examination. The swelling in rt hypochondrium, globular and cystic with movement with respiration and continuous with liver dullness.No patient of the study had a previous history of upper abdominal surgery.

Ultrasound was done to detect whether the gall stones were freely mobile in the GB lumen or impacted at the neck of the GB. Out of 50 cases,43 cases had free stones in GB and 7 cases had stone impacted at neck. GB wall thickness was assessed and the findings were grouped into three categories: GB wall thickness of \leq 4mm, >4mm are taken as parameters. 12 patients were found to have GB wall thickness of more than 4mm. Of all the cases 4 cases had a pericholecystic fluid collection on USG, indicating the presence of acute inflammation ongoing in the gallbladder probably an episode on ongoing acute cholecystitis.

All the patients parameters are recorded and then categorized into three categories based on the preoperative scoring system described earlier. They are divided into easy, difficult and very difficult categories

Distribution of	patients based of	n total pre-o	perative score
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Total Preoperative score	Number of patients	Percentage	
0 - 5 (easy)	40	80%	
6 – 10 (difficult)	9	18%	
11 - 15 (very difficult)	1	2%	
TOTAL	50	100%	

INTRA OPERATIVE OUTCOME:

Time taken for surgery was divided into three categories and time taken for surgery if less than 60 min was considered easy, 38 patients (76%) fell into this category, and time taken from 60-120 is considered as difficult and 12 patients (20%) fell into this category and time taken more than 120 min fell into very difficult category. No patients were in this group. There were 4 cases where there was either bile spillage or stone spillage either due to injury to cystic duct or due to perforation of the GB.Of all the cases 2 (4%) cases were converted to open procedure

due to difficulties faced intraoperatively. CBD was not injured in any of the cases studied

Intraoperative outcome of the cases:



We observed a positive predictive value (PPV) of 92.5% for our scoring system for cases predicted to be easy or Negative Predictive Value (NPV) of the scoring system is 92.31%. For cases predicted to be difficult we registered a positive predictive value (PPV) of 77.78% for the scoring system and negative predictive value of 71.4%. Only one patient was labelled as very difficult and found to be very difficult. For the ease of calculations for individual predictor, the very difficult category has been included in the difficult category to make the calculations easy and comparable and to make the p value significant.

Correlation between individual predictor and outcome:

Postoperative outcome was correlated with the each factor included in the scoring system and data analysed to assess the significance of each factor. The distribution of each risk factor in the study population was analysed and the significance of each factor on the outcome was by using fishers exact test and the p value obtained is analysed. A p value of less than 0.05 is considered to be significant and the predictors with a p value less than 0.05 are considered to assess the operative outcome based on their presence or absence in the patient requiring the surgical intervention. The individual factor assessment is depicted in graphs and tables to quick analyse the statistical significance.

correlation between gender and outcome











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Correlation between acute cholecystitis and outcome



Correlation between palpable gallbladder and outcome



Correlation between GB wall thickness on USG and outcome



Correlation between gallstone impaction and outcome



Correlation between pericholecystic fluid collection and outcome



DISCUSSION

Laparoscopic Cholecystectomy (LC) is one of the most commonly performed surgeries world over and is undergoing regular improvements with growing technology in order to make it safer, cosmetically acceptable and cost effective. This prospective observational study was carried out in Department of General Surgery, Government general hospital, kurnool. The study period was from November 2016 to October 2018.

Getting access to the peritoneal cavity, creating pneumoperitoneum, dissecting the GB and extracting the excised GB may pose problems while performing LC. Various clinical and ultrasonological parameters that may help predict the difficulty level preoperatively were analysed in the present study. The clinical factors that were considered included age, sex, history of hospitalisation due to acute cholecystitis, BMI and palpability of GB and those based on ultrasonological assessment were site of GB stone (impacted at neck or free in the lumen), GB wall thickness and pericholecystic collection.

Each of the above risk factors was graded on a scale of 0 to 4. Based on

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the sum total of this score an attempt was made to predict the difficulty level of the surgery preoperatively. The scores were categorised into 3 categories; easy, difficult, very difficult with scores of 0-5, 6-10, 11-15 respectively.

The difficulty level so assessed was correlated with the surgical outcome as easy, difficult and very difficult in terms of time taken to perform the procedure bile/stone spillage, injury to arteries or common bile duct and conversion to open cholecystectomy.

A similar study with similar parameters was done by jaskiran s. randhawa and aswin k. pujara² with a study sample of size 228 cases at command hospital, Bangalore, Karnataka, india published in the Indian journal of surgery july-august, 2009. The current study is being compared to this study as a whole and individual parameters are compared to other world studies.

In studies done world-wide, male sex has been described to be associated with difficult LC. In a study of population of 564 patients, Kanaan et al, reported a conversion rate of 4% among patients undergoing elective LC, the rate being higher in males. In a series of 1804 patients found male sex to be one of the factors attributing to a difficult surgery in terms of time taken for the procedure (p value < 0.01) and the conversion to open cholecystectomy.³ Age as a risk factor for difficult GB surgery. Kanaan et al had a difficult procedure in 33 patients who had to be converted to open surgery. In his series 60% (20 out of 33)patients were aged more than 50 years.³. In the study by jaskiran et al, also age was not statistically significant.

Jaskiran² et al in the series of 228 cases divided patients into 3 groups based on BMI and found a BMI of> 27.5 kg/m² to be associated with difficult surgery. In their series 43% of patients with a BMI of >27.5 kg/m² had a difficult operation compared to 28% in those with a BMI of <27.5kg/m². In the study by jaskiran et al, palpable gallbladder was found to be significant risk factor with p value of<0.001

Table : operative outcome of study by jaskiran and aswin k pujahara

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Risk factor	Level	Preoperat	P value	
		Difficult	easy	
Age	≤50	22 (68.8%)	57 (69.5%)	0.937
	>50	10(31.3%)	25 (30.5%)	
Sex	Female	20 (62.5%)	54 (65.9%)	0.736
	Male	12 (37.5%)	28 (34.1%)	
BMI	≤25	9 (28.1%)	42 (51.2%)	0.227
	25.1-27.5	9 (28.1%)	22 (26.8%)	0.010
	>27.5	14 (43.8%)	18 (21.9%)	
Previous	Nil	25 (78.1%)	63 (76.8%)	0.882
surgery	Yes	7 (21.9%)	19 (23.2%)	
Hospitalisation	Nil	14 (43.8%)	73 (89.0%)	< 0.001
	Yes	18 (56.3%)	9 (10.9%)	
Gallbladder	NP	24 (75.0%)	76 (92.7%)	0.022
palpable	Yes	8 (25.0%)	6 (7.3%)	
GB wall	Normal	27 (84.4%)	79 (96.3%)	0.038
thickness	Thickened	5 (15.6%)	3 (3.6%)	
Impacted stone	Nil	30 (93.8%)	81 (98.8%)	0.190
	Yes	2 (6.3%)	1 (1.2%)	
Pericholcystic	Nil	32 (100.0%)	81 (98.8%)	0.999
colletion	Yes	_	1 (1.2%)	
total		32	82	

Five prospective randomized trials^{4,9} have evaluated the outcome of patients with acute cholecystitis undergoing early versus late laparoscopic cholecystectomy. Although a significant increase in operation time was experienced for those undergoing early compared with delayed cholecystecomy (P = .002), the results of these trials uniformly showed no significant difference in postoperative morbidity or mortality, including common bile duct injury, when surgery is performed early.

Jaskiran et al² found a wall thickness >4mm to be a significant factor predicting a difficult LC. 25.5% of their cases who had a GB wall thickness of <4mm had a difficult procedure while 62.5% of patients with a GB wall thickness of > 4mm encountered difficulties in the surgery. Fred et al¹⁰ also reported similar findings.

7

INDIAN JOURNAL OF APPLIED RESEARCH

Stone impacted at GB neck on ultrasonography was found to be statistically significant factor in predicting the difficulty of the procedure in our study. This is also supported by a study on 210 patients conducted by Gupta N et al in Ram Manohar Lohia hospital, Delhi. But in jaskiran et al study, the factor had no significant correlation.

Pericholecystic fluid collection was found to be a significant risk factor in various studies, But in the study of jaskiran et al, the factor was not found to be significant probably due to low study group with only three patients compared to 223 cases of study population, with pericholecystic fluid collection.

In the current study 0f the 50 cases, 40 cases were predicted to be easy based on the scoring system. Of these 40 cases, 37 cases turned out to be easy with a positive predictive value of 92.5%. and 3 cases were found to be difficult. The negative predictive value of the score was 92.31. most of the time the difficulty was due to dense adhesions between gallbladder with omentum and bowel. In the cases predicted to be difficult, of the 9 cases predicted to be difficult, 7 were found to be difficult with a positive predictive value of 77.78%. and 1 case predicted to be difficult turned out to be easy and one case very difficult. The negative predictive value of the scoring system is 71.4%. The difficulty in majority of cases is for the releasing of adhesions. dissection of callots triangle, and dissection of gallbladder. Only one case was scored to be very difficult and 2 cases turned out to be very difficult. Positive predictive value is 100%, negative predictive value of 50%. Preoperative scoring system was found to have significant correlation with actual level of difficulty and thus it could be a significant predictor of difficult LC.

Summarizing based on the above observations and at the same time keeping into account our findings it can be concluded that adhesions are one of the most important factors deciding the difficulty level of the surgery. Availability of a radiological investigation that can accurately diagnose these adhesions preoperatively can allow the addition of adhesions as a factor for preoperative prediction of a difficult LC. This could give us a better and more accurate scoring system that will have a better predictive value. This observation was also demonstrated by retrospective study on 1000 patients by Nuri Aydin Kama et al 11, who found a conversion rate of 4.8% (48 patients). Rosen et al ¹² reported that conversion from laparoscopic to open cholecystectomy was required in 5.3% of their patients.

Finally another important factor that plays a role in the time requirement for the procedure is the surgical expertise of the operating surgeon. The same was reported by Takegami et al13 who had a conversion rate of 13% in LC performed by general surgeons and 2% in LC performed by specialized surgeons, suggesting that the skill of the operator has a large influence on the time taken to perform LC.

CONCLUSION

The following conclusions were drawn on the basis of evaluation of 60 patients who underwent LC:

Male sex had difficulty intra-operatively in view of dissection and separation of gallbladder but the results found were statistically insignificant. Higher BMI has difficulty in ports insertion and extraction of gallbladder and ports closure but the results were not statistically significant. Age >50 years was not a statistically significant risk factor. GB wall thickness > 4mm was found to be a very strong and significant predictor of difficult LC in terms of increased mean duration of LC. Impacted GB stone was a significant risk factor. pericholecystic fluid collection was a strong and significant risk factor

Adhesions were found to be the important cause for difficulty encountered in LC and these cannot be assessed by routine USG examination for cholelithiasis. Positive Predictive Value (PPV) of the scoring system laid down in patients preoperatively were found to be 77.78% and 92.5% in difficult and easy cases respectively.

SUMMARY

This prospective observational study was carried out in Department of General Surgery, Kurnool General Hospital, Kurnool .The study period started from November 2016 to November 2018. Data form was prepared for each patient satisfying the inclusion criteria. Patients with any one of the exclusion criteria were not considered for the study.

The preoperative factors considered were age, sex, history of hospital admission for acute cholecystitis, BMI, palpability of GB and those

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based on US assessment were pericholecystic fluid collection, site of GB stone, GB wall thickness. Each of the above risk factors was graded on a scale of 0 to 4. Based on the sum total of this score an attempt was made to preoperatively predict the difficulty level of the surgery. The scores were categorised into 3 categories; easy, difficult, and very difficult with scores of 0-5,6-10, 11-15 respectively. The difficulty level so assessed was correlated with the surgical outcome as easy, difficult and very difficult in terms of time taken to perform the procedure, bile and stone spillage and conversion to open cholecystectomy.

In our study we observed that male cases were found to have denser adhesions during surgery and age is not a significant risk factor. Obese patients in our series (BMI >25kg/m²) were associated with difficult port placement, difficult extraction of gallbladder may be due to thick abdominal wall. But the results were statistically insignificant

In our series, patients with GB wall thickness >4mm were found to be significant risk factor Patients with impacted GB stone was found to be a significant predictor of difficult LC. The patients with pericholecystic fluid collection on USG had been found to be a statistically significant risk factor.

In most of the patients, where the procedure turned out to be difficult although predicted easy, adhesions were the main reason for difficult LC. At present it is difficult to preoperatively assess these adhesions on ultrasound, which is readily available to us. Availability of a radiological investigation that can accurately diagnose these adhesions preoperatively can allow the addition of adhesions as a factor for preoperative prediction of a difficult LC. This could give us a better and more accurate scoring system that will have a better predictive value.

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8