

IDENTIFICATION OF CLINICAL AND RADIOLOGICAL PARAMETERS TO PREDICT DIFFICULT LAPAROSCOPIC CHOLECYSTECTOMY

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Abstract

Background: Laparoscopic cholecystectomy (LC) is the gold standard treatment for symptomatic cholelithiasis. But there is no clear consensus among the laparoscopic surgeons regarding the parameters predicting the difficult dissection and conversion to open cholecystectomy. The aim is to identify pre-operative clinical and radiological factors that may predict the chances of a difficult laparoscopic cholecystectomy. **Materials and Methods:** 503 patients with symptomatic cholelithiasis who presented to the Dep. Of General Surgery, who met the inclusion and exclusion criteria were studied prospectively for presence or absence of preoperative risk factors as predictors of difficult laparoscopic cholecystectomy. Preoperative risk factors studied were Age, sex, Diabetes mellitus, No. of attacks, Duration of attack, H/o Fever during pain, H/o Jaundice, H/o upper abdominal surgeries, Murphy's sign at the time of presentation. Size of gallbladder, Gallbladder wall thickness, calculus size, number of calculi. The data obtained was analysed using Chi-square tests of significance. **Result:** Multiple calculi was statistically significant (p=0.001); 3.79 times increased risk of having difficult during surgery (Odds ratio= 3.794). Large calculus (≥ 1 cm) was statistically significant (p=0.001). Conversion rate in our study was 1.2% (6 out of 503 patients). Statistical analysis of conversion however was not very relevant due to small sample size and single centre experience. **Conclusion:** Difficult laparoscopic cholecystectomy was found to be significantly associated with increased postoperative stay in hospital.

INTRODUCTION

The origin and development of endoscopic surgery is rooted in man's insatiable curiosity. The brave adventures of many clinicians have laid the ground work for modern day Laparoscopy. The advantages of laparoscopic cholecystectomy over open cholecystectomy were immediately appreciated at that time because of earlier return of bowel functions, less postoperative pain, better cosmesis, shorter length of hospital stay, earlier return to full activity, and decreased overall cost. Laparoscopic surgery is associated with better preservation of immune function and a reduction of the inflammatory response compared with open surgery. The rate of post-operative infection is also significantly lower. Ever since then LC has been accepted and performed by surgeons around the world at an unprecedented rate. The success of LC has made minimal access surgery a revolution that we are presently witnessing.

Laparoscopic cholecystectomy is indeed now the GOLD STANDARD, for treatment of symptomatic cholelithiasis against which newer therapies should be compared.

Today the health system throughout the world and especially in our country is burdened with patients. Cost effectiveness, consumer satisfaction (patient acceptance) and quick treatment are the major criteria for the procedure of choice for any disease. LC scores better than open cholecystectomy (OC) in all these areas. Though instruments and set up are more expensive for LC, the shorter hospital stay and earlier return to work make the procedure more cost effective. Thus performance of LC enables hospitals to treat more patients of gall stone disease at a lower cost, with better patient satisfaction as compared to OC. Many centres now perform LC as a day care operation and almost all centres discharge patients on the first post-operative day.^[1,2]

Several studies have shown the existence of learning curve for surgeons doing LC. Many surgeons especially those in the third world are in early part of the learning curve. In the beginning of laparoscopic cholecystectomy, patients having acute cholecystitis, empyema gall bladder, gangrenous gallbladder, cirrhotic patients and mirizzi's syndrome were contraindications because of high risk of complication and conversion rate. Thus with wider application of laparoscopy for technically difficult and high risk patients it was expected that the complication rates would rise as also the rate of conversion to open cholecystectomy.^[3] However, approximately 2% to 15% of patients require conversion to open surgery for various reasons. Sometimes, the laparoscopic cholecystectomy may pose undue difficulties during access or dissection. These difficulties may be due to anatomical ductal and vascular anomalies or distorted anatomy following acute or chronic inflammation. But irrespective of this morbidity and mortality, statistics do still favour laparoscopic cholecystectomy over open cholecystectomy.^[4]

The difficult gallbladder is the most common 'difficult' laparoscopic surgery being performed by general surgeons all over the world and the potential one that places the patient at significant risk. Difficulty faced during operation may require elective or emergency conversion to open procedure or laparotomy. Patients may have to be kept for longer period than normal for observation after difficult operations. Drains also might have to be kept in place, consequently increasing the hospital stay. Thus, pre-operative prediction of the risk of conversion or difficulty of operation is an important aspect of planning laparoscopic surgery. With the help of accurate prediction, high risk patients may be informed beforehand and they may chance to make arrangements regarding their professional and family commitments. The surgeons may also have to schedule the time and the team for the operation appropriately.

A number of preoperative clinical and radiological parameters can help to predict these difficult situations. A statistically proven positive correlation with one or more of these variables may be helpful in assigning them as possible predictive risk factor for "Difficult Laparoscopic Cholecystectomy." Preoperative prediction of possible difficulties will help a surgeon in the preparation for surgery, counselling of the patient about it, thereby reducing the morbidity, complication, rate of conversion and overall cost of therapy.

Keeping in mind these controversies and the benefits of accurate pre-operative prediction of difficulties expected to be faced during LC, this prospective study was designed. Though many of these factors have already been studied, the objective of this study was to establish the significance or otherwise of these factors in the Indian scenario. While most of the previous studies in the literature were retrospective and evaluated various risk factors in terms of

conversion to OC, ours is a prospective study analysing these risk factors as pre-operative predictors not only for anticipating difficulties in LC but also for conversion of LC to OC.

MATERIALS AND METHODS

A prospective, descriptive study done in 503 patients who underwent Laparoscopic cholecystectomy in the Department of General Surgery in Dr. B. L. Kapur Memorial Hospital from January 2015 to June 2016.

Inclusion Criteria

All patients aged >18 years underwent Laparoscopic cholecystectomy in Department of General Surgery at Dr. B. L. Kapur Memorial Hospital were included in this study.

Exclusion Criteria

Patients diagnosed as acute cholecystitis, Suspicion of carcinoma gallbladder.

A total of 500 patients underwent laparoscopic cholecystectomy and met the above mentioned criteria between January 2015 and June 2016 were included in the study. Informed written consent was taken from all the patients to enrol in the study. All patients were examined and the history and findings were noted in a pre-structured proforma. The patients underwent preoperative ultra-sonographic assessment of the gall bladder and findings were noted. Laparoscopic cholecystectomy was performed under general anaesthesia. Intra operative parameters were noted according to the pre-structured proforma. Every patient included in the study was assessed, which are regarded as risk factors for Difficult Laparoscopic Cholecystectomy.

Patients' characteristics as Gender Age, Pre-operative clinical parameters, Diabetes mellitus, No. of attacks, Duration of attack are noted

Abdominal ultrasound will include the following parameters as Size of gallbladder: contracted or distended, Gallbladder wall thickness (thick > 3 mm vs. normal ≤ 3 mm). The calculus size (small <1 cm vs. large ≥1 cm) Largest calculus in case of multiple gall stones. The number of calculi (single vs. multiple). Operative parameters as Difficult Intra peritoneal access, Difficult Calot's triangle dissection, Excessive Bleeding during surgery, Difficult Gallbladder bed dissection and Conversion to Open Cholecystectomy.

RESULTS

In our study, 201 patients (40%) were in the age group of 31-50 years followed by 196 patients (39%) in the age group of 51-70 years. Our study group had only 26 patients (5.2%) with age >70 years. 80 patients (15.9%) out of 503 patients with age <30yrs. Mean age of study group was 47.32 yrs. [Table 1] 327 out of 503 patients in our study group were females followed by 176 males. 154 out of 503 patients in the study group had h/o diabetes mellitus (30.6%). In our study 442 patients (87.9%) out of 503

had more than 1 attack before presented to the OPD in our hospital. In our study 468 patients (93.0%) had attack that was lasted for less than 24hrs. Rest of the 35 patients had attack lasted for more than 24 hrs. 48 out of 503 patients had h/o fever when patient was having pain. It consists of only 9.5% in our study. [Table 2]

Only 19 patients (3.8%) had previous h/o jaundice in our study group. In our study 125 patients (24.9%) had murphy's sign positive at the time of operation. Only 4 patients had h/o previous upper abdominal surgery. Among these patients one had sleeve gastrectomy. In our study group 104 patients (20.7%) out of 503 had GB wall thickness >3mm on pre-operative ultrasound.

383 patients (76.1%) had >1 cm (largest one in case of multiple stones) size of stone on pre-operative ultrasound report and 119 patients (23.7%) had ≤1 cm (largest one in case of multiple stones) size of stone. Only one patient had biliary sludge on pre-operative ultrasound. 446 patients (88.7%) had multiple GB calculi on pre-operative ultrasound report and 56 patients (11.1%) had single calculus. Only patient had biliary sludge on pre-operative ultrasound. [Table 3]

Only 6 patients (1.2%) out of 503 had contracted GB on pre-operative ultrasound examinations which was done after 4 hrs of fasting period.

Difficulty was assessed by intra-operative parameters like difficulty in intra peritoneal access, difficult calot's triangle dissection, excessive intra operative bleeding, difficult gall bladder bed dissection and conversion to open cholecystectomy. Operations having the presence of any of these factors were labelled as difficult. 134 out of 503 patients in the study group had one or more of these difficulties during laparoscopic cholecystectomy. 6 out of these 134 patients required conversion to open

cholecystectomy. Thus we had 26.6% of difficulty rate while the conversion rate was 1.2%.

For the purpose of statistical analysis patients in the study were divided into 2 groups, namely, the difficult group and the non-difficult group. In each group, patients were divided according to the presence or absence of each risk factor. The proportions of patients according to this division in each group were compared by Chi-square tests of significance. Relative risk and odd's ratio were calculated for those parameters found to be significant. [Table 4]

Diabetes Mellitus was found to be a significant factor predicting difficult LC (p=0.009). 126 (94%) out of 134 patients in difficult Laparoscopic cholecystectomy group had >1 attacks before presenting to our OPD. No. of attacks was statistically significant (p=0.011). Patients who had more than one attack were found to have 2.64 times increased chance of having difficult LC.

In our study group 20 (41.7%) out 48 patients who had h/o fever during pain were faced difficult LC. In our statistical analysis H/o fever during pain was found to significant factor to predict difficult LC (p=0.013). Patients having h/o fever during pain had 1.9 times of increased risk of having difficult LC compared to the patients who had no h/o fever during pain. [Table 5]

Statistically h/o jaundice was not found to be a significant factor to predict difficult LC (p=0.620). Murphy's sign positive at the time of surgery as compared to 47 out of 369 patients had murphy's sign positive in non-difficult group at the time of surgery (58.2% Vs. 12.7%) which was statistically significant (p=0.001); they also had 9.54 times increased risk of having difficult laparoscopic cholecystectomy than patients without positive murphy's sign at the time of surgery. [Table 6]

Table 1: Demographic details of the patients

Age Groups	Frequency	%
<30 yrs	80	15.9%
31-50 yrs	201	40.0%
51-70 yrs	196	39.0%
>70 yrs	26	5.2%
Total	503	100%
Mean ± SD	47.32 ± 14.47	
Min - Max	9 - 82	
Gender		
Female	327	65.0%
Male	176	35.0%
Diabetic mellitus		
No	349	69.4%
Yes	154	30.6%
No. of attacks		
1	61	12.1%
>1	442	87.9%
Duration of Attack		
<24 hrs	468	93.0%
>24 hrs	35	7.0%

Table 2: Clinical evaluation of patients

H/O fever during pain	Frequency	%
No	455	90.5%
Yes	48	9.5%

History of Jaundice		
No	484	96.2%
Yes	19	3.8%
Murphy's Sign		
Negative	378	75.1%
Positive	125	24.9%
H/O Upper Abdominal Surgery		
Absent	499	99.2%
Present	4	0.8%

Table 3: Ultrasound and surgical evaluation of patients

	Frequency	%
GB Wall Thickened		
NO (≤ 3 mm)	399	79.3%
YES (> 3 mm)	104	20.7%
STONE SIZE(Cm)		
< 1	119	23.7%
> 1	383	76.1%
SLUDGE	1	0.2%
No. of Stones		
Multiple	446	88.7%
Single	56	11.1%
Sludge	1	0.2%
GB size		
Contracted	6	1.2%
Distended	497	98.8%
Laparoscopic Cholecystectomy		
Non Difficult	369	73.4%
Difficult	134	26.6%

Table 4: Comparison of difficult group and the non-difficult group on demographic details

Age Groups	Laparoscopic Cholecystectomy				p-value
	Non Difficult		Difficult		
	Frequency	%	Frequency	%	
< 30 yrs	59	16.0%	21	15.7%	0.136
31-50 yrs	143	38.8%	58	43.3%	
51-70 yrs	152	41.2%	44	32.8%	
> 70 yrs	15	4.1%	11	8.2%	
Total	369	100%	134	100%	
Gender					0.060
Female	231	62.6%	96	71.6%	
Male	138	37.4%	38	28.4%	
Diabetes Mellitus					
No	268	72.6%	81	60.4%	0.009
Yes	101	27.4%	53	39.6%	
No. of Attacks					
1	53	14.4%	8	6.0%	0.011
> 1	316	85.6%	126	94.0%	
Duration of Attack					
< 24 hrs.	343	93.0%	125	93.3%	0.898
> 24 hrs.	26	7.0%	9	6.7%	

Table 5: Comparison of difficult group and the non-difficult group on clinical evaluation

H/O Fever During Pain	Laparoscopic Cholecystectomy				p- value
	Non Difficult		Difficult		
	Frequency	%	Frequency	%	
No	341	92.4%	114	85.1%	0.013
Yes	28	7.6%	20	14.9%	
H/O Jaundice					
No	356	96.5%	128	95.5%	0.620
Yes	13	3.5%	6	4.5%	
Murphy s sign					
Negative	322	87.3%	56	41.8%	0.001
Positive	47	12.7%	78	58.2%	
H/O Upper Abdominal Surgery					
Absent	367	99.5%	132	98.5%	0.289
Present	2	0.5%	2	1.5%	

Table 6: Comparison of difficult group and the non-difficult group on ultrasound and surgical findings.

GB Wall Thickened	Laparoscopic Cholecystectomy				p- value
	Non-Difficult		Difficult		
	Frequency	%	Frequency	%	
No (≤ 3 mm)	364	98.6%	35	26.1%	0.001
Yes (> 3 mm)	5	1.4%	99	73.9%	
GB Size					
Contracted	2	0.5%	4	3.0%	0.046
Distended	367	99.5%	130	97.0%	
No. of Stones					
Multiple	342	92.7%	104	77.6%	0.001
Single	26	7.0%	30	22.4%	
Sludge	1	0.3%	0	0.0%	
Stone Size(cm)					
<1	61	16.5%	58	43.3%	0.001
>1	307	83.2%	76	56.7%	
SLUDGE	1	0.3%	0	0.0%	

In our study, thickened gallbladder wall was found to be a significant factor of difficulty in LC ($p=0.001$). 99 out of 104 patients (95.1%) with thickened gallbladder wall on ultrasound had difficult LC. Such patients were found to have 205.92 times increased risk of having difficult LC. 4 out of 6 patients who were converted to OC had thickened wall on ultrasound.

Contracted gallbladder was found to be significant factor predicting difficult LC ($p=0.046$). 4 out of 6 patients (92%) with contracted gallbladder had difficult LC. Such patients were found to have 5.64 times increased risk of having difficulties during surgery (Odds ratio= 5.64). 3 out of 6 patients who were converted to OC had contracted gallbladder and the rest 3 had normally distended on ultrasound.

In our study group 104 (77.6%) out of 134 patients had multiple calculi on pre- operative ultrasound report. Multiple calculi was statistically significant ($p=0.001$); they also had 3.79 times increased risk of having difficult during surgery (Odds ratio= 3.794).

Large calculus (≥ 1 cm) was statistically significant ($p=0.001$). 76 patients out of 134 patients in difficult laparoscopic cholecystectomy had large stone on pre-operative ultrasound report. They also had 3.84 times increased risk of having difficult LC (Odds ratio = 3.794)

DISCUSSION

In our hospital, fresh preoperative admissions are usually taken on the day of surgery. Admissions and operation theatre list can be appropriately planned in the light of information regarding expected hospital stay of patients after LC. Patients expected to have difficult surgery can thus be planned for longer hospital stay and more intensive postoperative facilities. This exercise streamlines the cost effectiveness of hospital administration.

Similarly, better informed surgeons can preoperatively prepare themselves mentally for a challenging surgery ahead. They can be prepared for an early decision of conversion to OC in high-risk patients. Early conversion in such patients is proved to decrease postoperative morbidity. Difficult surgery can also be scheduled early on that day. Such

patients should be operated by experienced surgical team. These patients are not fit for resident training. Also surgeons in the early phase of their learning curve should refer such patients to more experienced surgeons. Several risk factors have previously been implicated as predictors of conversion to OC. Of the factors evaluated in our study, factors namely, Diabetes Mellitus, No. of attacks, H/o Fever during pain, Murphy's sign at the time of presentation, thickened gallbladder wall, contracted gallbladder, No. of calculi and size of calculus on preoperative ultrasound were found to be significant.^[5]

Among 134 patients who had difficult surgery, 58 were in 31-50 yrs age group, 44 were in 51-70 yrs age group, 21 were in <30 yrs age group and 11 were in >70 yrs age group. Most of our patients in study group were distributed between 30-70yrs. In >70 yrs 11 out of 26 patients had difficult LC. On statistical analysis definite age was not found to be significant factor to predict difficult LC ($p=0.136$).

38 out of 176 male patients in the study had difficult surgery (21.6%) while 96 out of 327 (29.4%) female patients had difficult LC. Sex was not found to be a significant factor in predicting difficulty in surgery ($P=0.06$).

In our study 53 (34.4%) out of 154 diabetic patients had difficult LC. Diabetic patients had 1.4 times increased chance of having difficulties during surgery. Diabetes Mellitus was found to be a significant factor predicting difficult LC ($p=0.009$).

This was in agreement with the studies of Simopoulos et al,^[6] and Lipman et al.^[7] But most of studies like Kanaan et al,^[8] Yetim et al,^[9] etc. ruled out Diabetes mellitus as a significant predictor of difficult LC. Majority of these patients had acute cholecystitis in the past (72.7%) and all of them had thickened gallbladder wall. This implies increased chance of inflammation in diabetic patients which lead to increased difficult LC. Only 1 out of 11 diabetic patients required conversion to OC (9.09%). 126 (94%) out of 134 patients in difficult cholecystectomy group had >1 attacks before presenting to our OPD in Dep. Of General surgery. No. of attacks was statistically significant (0.011): they also had 2.64 times increased risk with increase in the no. of attacks. Nidoni, et al,^[10] conversion were

significant when patients had >2 attacks and faced high rates of p=vs 20%, p = 0.03, 95% confidence interval) compared to patients with less than 2 attacks.

In our study group 20 (41.7%) out 48 patients who had h/o fever during pain were faced difficult LC. In our statistical analysis H/o fever during pain was found to significant factor to predict difficult LC (p=0.013). They also had 1.97 times of increased risk compared to the patients who had no h/o fever during pain.

Only 35 patients had attacks that were lasted for more than 24 hrs. Rest of the patients had attacks, lasted for less than 24 hrs. In our study, Statistically, Duration of attack was not found to be a significant factor to predict difficult LC (p=0.898)

In our study 78 (58.2%) out of 134 patients in difficult laparoscopic cholecystectomy group had murphy's sign positive at the time of surgery as compared to 47 out of 369 patients had murphy's sign positive in non-difficult group at the time of surgery (58.2% Vs. 12.7%) which was statistically significant (p=0.001); they also had 9.54 times increased risk of having difficult laparoscopic cholecystectomy than patients without positive murphy's sign at the time of surgery. In their study, Kama et al,^[11] found upper abdominal tenderness at the time of surgery as a significant factor in predicting difficult laparoscopic cholecystectomy (p=0.007) and had conversion rate of 6.3% as compared to 2.5% in patients with no upper abdominal tenderness at the time of surgery. Surprisingly all of these patients had thickened GB wall, history of cholecystitis in the past and 6 patients had contracted GB. Upper abdominal tenderness at the time surgery in these patients may be explained by ongoing chronic cholecystitis which is suggested by the above-mentioned associations. 5 out of 8 of these patients (62.5%) required conversion to OC, 2 among these was due to perforated GB with spillage of stones, 2 was due to dense adhesions and increased bleeding and one was due to dense adhesions which rendered Calot's triangle unclear even after dissection.

In our study group 4 patients had previous h/o upper abdominal surgery. They were equally distributed in difficult and no difficult group. In statistical analysis h/o upper abdominal surgery was not found to be a significant factor to predict difficult LC (p= 0.289). Our study analysis is correlated with studies for difficult LC. In contrast to meta-analysis of Yang TF, et al,^[12] previous upper.

19 (7%) out of 503 patients had h/o jaundice before presenting to our OPD. Only 6 patients (4.5%) in difficult LC group had h/o jaundice. Statistically h/o jaundice was not found to be a significant factor to predict difficult LC (p=0.620).

In our study, thickened gallbladder wall was found to be a significant factor of difficulty in LC (p=0.001). 99 out of 104 patients (95.1%) with thickened gallbladder wall on ultrasound had difficult LC. Such patients were found to have 205.92 times increased risk of having difficult LC. 4 out of 6 patients who

were converted to OC had thickened wall on ultrasound. According to Fried et al⁸, patients with thickened gallbladder wall had increased chances of conversion and they associated thickened gallbladder wall with difficulties in exposure of biliary anatomy. Most of the studies like Kama et al,^[11] Alponat et al,^[13] Lal et al.^[14]

Daradkeh et al,^[15] Tayeb et al,^[16] etc. have associated thickened gallbladder wall on ultrasound with difficult laparoscopic cholecystectomy.

Contracted gallbladder was found to be significant factor predicting difficult LC (p=0.046). 4 out of 6 patients (92%) with contracted gallbladder had difficult LC. Such patients were found to have 5.64 times increased risk of having difficulties during surgery (Odds ratio= 5.64). 3 out of 6 patients who were converted to OC had contracted gallbladder and the rest 3 had normally distended on ultrasound. Most of the studies had similar results.^[12]

In our study group 104 (77.6%) out of 134 patients had multiple calculi on pre-operative ultrasound report. Multiple calculi was statistically significant (p=0.001); they also had 3.79 times increased risk of having difficult during surgery (Odds ratio= 3.794). This is comparable to Abdel baki,^[17] and Nachnani et al.^[10] Abdel baki et al,^[17] study showed 57.5%. Similarly, Nachnani et al,^[10] study showed 63.8% multiple stones. Large calculus (≥ 1 cm) was statistically significant (p=0.001). 76 patients out of 134 patients in difficult laparoscopic cholecystectomy had large calculus on pre-operative ultrasound report. However there were no such studies to compare our statistical analysis.

In our study 6 patients required conversion to open cholecystectomy. Thus conversion rate of 1.2% was observed. 4 out of 6 patients had h/o diabetes mellitus. 5 patients had more than 1 attacks. 3 had h/o fever during pain. 4 patients had attack that was lasted for >24 hrs. 3 patients had jaundice before presenting to our OPD. All patients had murphy's sign positive at the time of operation. None of them had previous h/o upper abdominal surgery. 4 patients had thickened gallbladder wall on pre-operative ultrasound. 4 patients had calculus size measuring >1cm (largest). All the patients had multiple gall stones. 3 patients had contracted gall bladder. Only one patient had all those factors statistically significant in our study. All the patients were electively converted to open cholecystectomy. 3 were due to gallbladder perforation with stone spillage and dense adhesions and the other 3 conversions were due to dense adhesions around gallbladder, unclear anatomy of Calot's triangle and increased bleeding during dissection.

CONCLUSION

Our study analysis shows Diabetes mellitus, No. of attacks, H/o Fever during pain, Murphy's sign positive at the time of surgery, thickened gallbladder wall, contracted gallbladder, number of calculi,

Calculus size >1cm are associated with increased chances of encountering difficulties during laparoscopic cholecystectomy. Majority of such patients have dense adhesions which make Calot's triangle unclear and pose difficulties during dissection and also have increased bleeding during dissection. This consequently increases operating time in such patients. Patients with difficult laparoscopic cholecystectomy also have increased postoperative hospital stay.

Our study design should however be applied to a larger group of patients to further evaluate the validity of our results. This can contribute to the quest for surgical excellence and better patient care for one of the most commonly performed surgery in the world.

Recommendations

A study of bigger sample size and involving multiple centres would be more authentic to improve the power and statistical significance of the data. The predictive factors in this study needs to be validated by further studies before being implemented in routine clinical practice.

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