

ORIGINAL RESEARCH PAPER

General Surgery

PREDICTING DIFFICULT LAPAROSCOPIC CHOLECYSTECTOMY BASED ON CLINICORADIOLOGICAL ASSESSMENT

KEY WORDS:

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1. INTRODUCTION

Gallstone disease is one of the most common and costly of all digestive diseases. The third National Health and Nutrition Examination Survey estimated that 6.3 million men and 14.2 million women aged 20 to 74 in the United States had gallbladder disease.(1)

As a general rule, there appears to be higher rates of cholelithiasis in western Caucasian, Hispanic, and Native American populations and lower rates in eastern European, African American, and Japanese populations. (2-4) In India the prevalence of cholelithiasis is estimated to be around 4%.

Chronic cholecystitis is the term used by the pathologist to describe chronic inflammatory cell infiltration of the gallbladder seen on histopathology. It is almost invariably associated with the presence of gallstones and is thought to be the result of mechanical irritation or recurrent attacks of acute cholecystitis leading to fibrosis and thickening of the gallbladder.(5-7)

Over the past two decades, a great deal has been learned about the epidemiology of and risk factors for gallstones. Ultrasonography has played a major role in this process, providing a rapid, risk-free method of screening large populations. Prior to the availability of ultrasound, most studies relied on highly selective autopsy data and limited oral cholecystography.

In the late 1980s after the first successful laparoscopic cholecystectomy in Europe, this revolutionary minimally invasive surgery rapidly became the accepted technique for the treatment of gallbladder disease all over the world. The rapid acceptance of this new technique by the medical profession and the public was related to the obvious advantages of reduced cost, decreased hospital length of stay, and increased patient satisfaction. In 1992,

The National Institute of Health (NIH) consensus development conference stated that laparoscopic cholecystectomy "provides a safe and effective treatment for most patients with symptomatic gallstones." The advantages of laparoscopic cholecystectomy over open cholecystectomy are earlier return of bowel functions, less postoperative pain, cosmesis, shorter length of hospital stay, earlier return to full activity and decreased overall cost.(8-10) # Email addresses: deepak.kilroy@gmail.com(DeepakKumar)

Laparoscopic cholecystectomy is associated with better preservation of immune function and a reduction of the inflammatory response compared with open surgery. The rate of postoperative infections seems to be lower. (11) Laparoscopic cholecystectomy has become the gold standard in the treatment of cholelithiasis and has replaced open cholecystectomy. Laparoscopic cholecystectomy is the standard of care for patients with cholelithiasis. Several randomized controlled trials and systematic reviews have demonstrated the effectiveness and safety of laparoscopic cholecystectomy for the treatment of symptomatic

cholelithiasis.(12-15) The rapid acceptance of laparoscopic cholecystectomy as the standard of care for patients with gallstones has been attributed to several benefits including decreased patient morbidity, faster recovery, and shorter hospital stay when compared to open cholecystectomy.(16,17)

Serious complications that occur with laparoscopic cholecystectomy, including bile duct injury, bile leaks, bleeding and bowel injury result in part from patient selection, surgical inexperience, and the technical constraints that are inherent to the minimally invasive approach.(18-22) The rate of conversion from laparoscopic cholecystectomy to open cholecystectomy is 5 to 10%. Hence it is necessary to study the predictive factors for difficult laparoscopic cholecystectomy.

2. MATERIALS AND METHOD

The present study is an observational cross sectional study and was carried out in a tertiary care teaching hospital in New Delhi. The hospital is a referral centre for personnel in the armed forces service, retired personnel and their dependent families.

The Patients presenting to the hospital who were eligible for laparoscopic cholecystectomy based on predetermined inclusion and exclusion criteria comprised the study population.

The minimum required sample size was calculated to be 73 based on the prevalence of difficult laparoscopic cholecystectomy in the study by Nidoni R et al (23) (24.4%), with the relative precision of 10%. However, 120 patients were included in the study. The study was carried out for a period of 02 years.

Inclusion criteria:

Patients who require cholecystectomy for reasons like

- Symptomatic cholelithiasis
- Acalculus cholecystiti
- · Cholecystitis due to GB polyps

Exclusion criteria:

- Acute cholecystitis
- Common bile duct stone
- · Jaundice or abnormal liver function test
- Known carcinoma gall bladder
- Peritonitis
- · Cholangitis and biliary enteric fistula
- Portal hypertension and
- Contraindication to laparoscopic surgery
- · History of pancreatitis
- Any previous biliary procedures such as stenting and ERCP

Variables used to define difficult laparoscopic cholecystectomy:

· Difficult intraperitoneal access where the creation of

pneumoperitoneum is considered risky

- Difficult calot's triangle dissection with extensive adhesions requiring over 30 minutes to dissect or requiring additional ports along with frozen calot's triangle or difficult dissection as perceived by surgeon
- Excessive bleeding during surgery of > 100ml as measured in suction or as perceived by the operating surgeon
- Difficult gall bladder bed dissection
- Spillage of bile / stone
- Conversion to Open Cholecystectomy for reasons other than equipment related issues

Four parameters were assessed to predict the difficult LC:

- Number of attacks of pain in the right hypochondriac region due to gall bladder pathologies like cholelithiasis, acalculus cholecystitis & cholecystitis due to GB polyps.
- Total leucocyte count done during the last attack of pain
- Gallbladder wall thickness on ultrasound done during the last attack of pain
- Pericholecystic fluid collection on ultrasound done during the last attack of pain

AGE DISTRIBUTION						
Age (in years)	Frequency	Percent				
18-30	18	15.0				
31-45	50	41.7				
46-60	37	30.8				
>60	15	12.5				
Total	120	100.0				

The study was conducted on the patient's admission for surgery and the surgery was done by a qualified Laparoscopic surgeon to ensure validation of the procedure.

Statistical analysis: Data entry was done by using MS Excel 2013 and analysis was done by using the software SPSS version 22. Means and proportions were calculated for continuous and categorical variables respectively. Chi square test was applied to test statistically significant difference in proportions. Independent sample t test was applied to test statistical difference in means. A p value less than 0.05 was considered statistically significant.

Institute ethical committee clearance was sought and obtained before the study was begun. Written informed written consent was obtained from all the study before including them in the study. Implications of the study were explained to the patients in detail before obtaining written informed consent.

DIFFICULTY IN LAPAROSCOPIC CHOLECYSTECTOMY					
Difficulty Frequency Percent					
Easy	89	74.2			
Difficult	25	20.8			
Converted to open Cholecystectomy	6	5.0			
Total	120	100.0			

3. RESULTS

During the period of 02 years, 192 laparoscopic cholecystectomy were done at our centre out of which 52 did not meet inclusion criteria because of common bile duct stone or presence of jaundice or abnormal liver function test or underwent previous biliary procedures such as stenting or

ERCP procedure. 2 patients denied consent and data was unavailable for 18 patients. The study was stopped when a total of 120 patients data was collected who met the eligible criteria and gave consent for the study.

The age of the study participants ranged from 19 years to 82 years with a mean of 45 ± 13.9 years.

GENDER		
Gender	Frequency	Percent
Male	40	33.3
Female	80	66.7
Total	120	100.0

Majority of the study participants were women (66.7%), while 33.3% of them were male.

DURATION OF SYMPTOMS					
Duration of symptoms	Percent				
< 6 months	30	25			
6 months – 1 year	45	37.5			
1-5 years	43	35.8			
> 5 years	2	1.7			
Total	120	100.0			

Majority of the study participants were having symptoms for a period ranging from 6 months to 1 year (37.5 %). DIFFICULTYINLAPAROSCOPIC CHOLECYSTECTOMYDIFFICULTYFrequencyPercentEasy8974. 2 Difficult 2520.8 Converted to open Cholecystectomy 65.0 Total 120100.0 Difficult cholecystectomy was encountered among 25.8% of the study participants of whom 19.3% had to undergo open cholecystectomy.

Age (in years)	Laparoscopic Cholecystectomy		Totaln (%)	
	Difficult n (%)	Easy n (%)		
18-30	2(11.1)	16(88.9)	18(100.0)	0.148
31-45	18(36.0)	32(64.0)	50(100.0)	
46-60	8(21.6)	29(78.4)	37(100.0)	
>60	3(20.0)	12(80.0)	15(100.0)	
Total	31(25.8)	89(74.2)	120(100.0)	

* Chi Square test was applied to test statistical difference in proportions

No significant association was observed between age and difficulty in laparoscopic cholecystectomy.

Gender	Laparoscopio	C	Total n (%)	p value*
	Cholecystec	tomy		
	Difficult Easy			
	n (%)			
Male	8(20.0)	32(80.0)	40(100.0)	0.302
Female	23(28.8)	57(71.3)	80(100.0)	
Total	31(25.8)	89(74.2)	120(100.0)	

 $\ensuremath{^{*}}$ Chi Square test was applied to test statistical difference in proportions

No significant association was observed between gender and difficulty in laparoscopic cholecystectomy.

Duration of symptoms	Laparoscopic Cholecystecto		Total n (%)	
	Difficult Easy n (%) Easy			
<6 months	9(30.0)	21(70.0)	30(100.0)	0.798
6 months – 1 year	11(24.4)	34(75.6)	45(100.0)	
1-5 years	11(25.6)	32(74.4)	43(100.0)	

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> 5 years	0(0.0)	2(100.0)	2(100.0)	
Total	31(25.8)	89(74.2)	120(100.0)	

* Chi Square test was applied to test statistical difference in proportions

No significant association was observed between duration of symptom and difficulty in laparoscopic cholecystectomy

TLC COUNT								
	Total	lt	Easy		Difference in	p value*		
		y (n = 31)		(n = 89)		mean		
	te Count	Mean	SD	Mean	SD	(95% CI)		
		8652	2529	8702	2194	50(-893-993)	0.917	

^{*}Student t test was applied for comparison of means

No significant difference was observed in mean TLC count between the participants with easy and difficult laparoscopic cholecystectomy.

pain	T T		Total n (%)	p value*
attacks	Difficult n (%)	Easy n (%)		
1	9(21.4)	33(78.6)	42(100.0)	0.680
2	18(29.0)	44(71.0)	62(100.0)	
3	4(28.6)	10(71.4)	14(100.0)	
4	0(0.0)	2(100.0)	2(100.0)	
Total	31(25.8)	89(74.2)	120(100.0)	

^{*}Chi Square test was applied to test statistical difference in proportions

No significant association was observed between number of right hypochondrial pain attacks and difficulty in laparoscopic cholecystectomy.

GALL BLADDER WALL THICKNESS						
Gall Difficult Easy Difference p value						
bladder	(n = 31)		(n = 89))	in mean	
wall thickness	Mean	SD	Mean	SD	(95% CI)	
tnickness	3.34	0.60	2.95	0.39	0.39(0.14 – 0.09)	

^{*}Student t test was applied for comparison of means

GALL BLADDER WALL THICKNESS						
Gall Bladder	lder Laparoscopic cholecystectomy					
wall thickness	Difficult Easy Total					
Raised (>3)	22	35	57 (47.5%)			
Normal (≤3)	9	54	63 (52.5%)			
Total	31 (25.8%)	89 (74.2%)	120 (100.0%)			

*Chi Square Value = 9.231; p-value =0.002; Odds Ratio = 3.8 (95% C.I.:1.5-9.1)

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Statistic	Value	95% CI
Sensitivity	70.97%	51.96% to 85.78%
Specificity	60.67 %	49.75% to 70.87%
Positive Predictive Value	38.60%	30.86% to 46.96%
Negative Predictive Value	85.71%	77.15% to 91.43%
Accuracy	63.33%	54.05% to 71.94%

Sensitivity and specificity of raised gall bladder wall thickness in predicting difficult cholecystectomy was 70.97% and 60.67% respectively.

Pericholecystic fluid	Peri	cholect	ystic	fluid
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	Laparoscopic cholecystectomy		
fluid	Difficult	Easy	Total
Present	23	45	68 (56.7%)
Absent	8	44	52 (43.3%)
Total	31 (25.8%)	89 (74.2%)	120 (100.0%)

Chi Square Value = 5.229; p-value =0.022; Odds Ratio = 2.8 (95% C.I.:1.1-6.9)

Statistic	Value	95% CI
Sensitivity	74.19%	55.39% to 88.14%
Specificity	49.44 %	38.67% to 60.25%
Positive Predictive Value	33.82%	27.62% to 40.63%
Negative Predictive Value	84.62%	74.50% to 91.19%
Accuracy	55.83%	46.48% to 64.89%

Sensitivity and specificity of presence of pericholecystic fluid on USG in predicting difficult cholecystectomy was 74.19% and 49.44% respectively.

- Difficult intraperitoneal access was encountered among 4
 (3.3%) of the entire study participant among whom 2
 (50%) were converted to open cholecystectomy.
- Difficult calot's triangle dissection was noted among 25
 (20.8%) of all the study participants among whom 6 (24%)
 were converted to open cholecystectomy.
- Excessive bleeding was observed among 9 (7.5%) of all the study participants among whom 5 (55.55%) were converted to open cholecystectomy.
- Difficult gall bladder dissection was observed among 5 (4.2%) of all the study participants among whom none were converted to open cholecystectomy.
- Spillage of bile stone was observed among 19(15.8%) of all the study participants among whom 3 were converted to open cholecystectomy.

DISCUSSION

The present study was carried out with an aim to predict difficult laparoscopic cholecystectomy by clinical and radiological assessment and help in pre-operative preparedness towards early intra operative decision of conversion.

In the present study most of the study participants were in the age group of 31-45 years (41.7%) The mean age of the study participants was observed to be 45 ± 13.9 years. Most of the study participants were females (66.7%), while 33.3% of them were males. Most of the study participants were having symptoms for a period ranging from 6 months to 1 year (37.5).

The study participants who had gall bladder wall thickness >3mm and presence of pericholecystic fluid collection on ultrasound findings had a significant p value of 0.002 and 0.022 with sensitivity of 70.97% and 74.19% and specificity of 60.67% and 49.44% respectively.

Gall bladder wall thickness > 3 mm was noted in 57 (47.5%) of all the study participant among whom 22 (38.5%) had difficult laparoscopic cholecystectomy and 6 (10.5%) were converted to open cholecystectomy. Pericholecystic fluid collection was noted in 68 (56.7%) of all the study participant among whom 23 (33.82%) had difficult laparoscopic cholecystectomy and 4 (5.8%) were converted to open cholecystectomy.

Raised TLC count was noted in 21 (17.5%) of all the study participants among whom 5 (23.8%) had difficult laparoscopic cholecystectomy and 5 (23.8%) were converted to open cholecystectomy. Number of previous pain attacks >2

was noted in 16 (13.3%) among whom 4 (25%) had difficult laparoscopic cholecystectomy and 4 (25%) were converted to open cholecystectomy.

Nidoni R et al (23) reported that majority of the patients in the present series were in the age group of 31-50 years of age. Out of total 180 patients 115 were females and 65 were males. It was found that patients with gall bladder wall thickness >3 mm had significantly high rates of difficulty (21.71% vs 75%, p = 0.01). The sensitivity, specificity, positive predictive value and negative predictive value of gall bladder wall thickness >3 mm in predicting conversion of laparoscopic cholecystectomy to open surgery are 70%, 87.64%, 25% and 98% respectively. It was found that patients with pericholecystic collection had significant high rates of difficulty (23.27% vs 80.95%, p = 0.01, 95% confidence interval) and conversion (1.88% vs 33.33%, p = 0.02,). The sensitivity, specificity, positive predictive value and negative predictive value of pericholecystic collection in predicting conversion of laparoscopic cholecystectomy to open surgery are 70%, 91.76%, 33.33% and 98.11% respectively which are similar to that of the present study.

Agarwal N et al(24) in their study noted that of the 30 patients included in the study, 6 patients were male (20%) and 24 were females (80%). The mean age group of the study was 39.47 \pm 12.008 years. Charan S et al(26) reported that mean age of the study participants was 33 years. The age group of the patients ranged from 16 years to 60 years. Out of which only 6 of the patient were males rest 45 were female patient. These findings with respect to demographic characteristics were similar to that of the present study participant characteristics.

In the present study difficult cholecystectomy was encountered among 25.8% of the study participants of whom 5% had to go undergo open cholecystectomy. Nidoni R et al(23) observed in their study that 70% were easy, 24.44% were difficult and 5.56% patients required conversion to open cholecystectomy. Out of total 51 cases, 7(13.72%) cases were converted to open procedure in the study by Charan S et al.(26) The research work by Randhawa JS et al (27) scored one hundred and seventy-eight (78%) as easy and 50 (21.9%) were difficult. Arumugam R et al(28) study stated that eight patients of 80 were converted to open cholecystectomy. These observations of the discussed studies were comparable to that of the present study findings.

In the present study no significant association was observed between age, gender, duration of symptoms, number of pain attacks and TLC was associated with difficulty in laparoscopic cholecystectomy. Nidoni R et al(23) study noted that out of 180 patients, 65 patients had history of similar cholecystitis attacks in the past and 115 patients had no such attacks previously. But patients with >2 attacks had significant high rates of difficulty (21.29% vs 84%, p value <0.01). Also, It was found that patients with TLC >11000/cu mm had significant high rates of difficulty (18% vs 77.77%, p = 0.02, 95% confidence interval) and conversion (1.38% vs 22.22%, p = 0.03). Agarwal N et al(24) in their study observed that the factors like previous history of hospitalization (P - 0.004), clinically palpable gallbladder (GB) (P - 0.009), impacted GB stone (P - 0.001), pericholecystic collection (P - 0.04), and abdominal scar due to previous abdominal surgery (P - 0.009) were found statistically significant in predicting difficult laparoscopic cholecystectomy. The above findings were in contracts to that of the present study results.

Gupta AK et al (25) observed that age >50yrs, Male gender, radiological predictors (Thickened gall bladder wall, small contracted gall bladder, Single large impacted stone) and deranged LFT did not show significant predictive value. These findings were concurrent to that of the present study observations.

Arumugam R et al (28) in their study among 80 patients, there was difficulty in access to peritoneal cavity for 22 (27.5%) patients, difficult GB bed dissection in 21 (26.3%) patients, abnormal bleeding in 20 (25%) patients and difficulty in extraction of gall bladder in 19 (23.8%) patients. These observations were identical to that of the ones observed in the present study.

1. CONCLUSION

The present study was carried out with an aim to predict difficult laparoscopic cholecystectomy by clinical and radiological assessment and help in pre-operative preparedness to early intra operative decision of conversion. The surgery was done by a qualified Laparoscopic surgeon to ensure validation of the procedure among 120 patients presenting to the hospital who were eligible for laparoscopic cholecystectomy based on predetermined inclusion and exclusion criteria.

Maximum of the study participants were in the age group of 31-45 years (41.7%) The mean age of the study participants was observed to be 45 ± 13.9 years. Most of the study participants were females (66.7%), while 33.3% of them were males. Most of the study participants were having symptoms for a period ranging from 6 months to 1 year (37.5).

Difficult cholecystectomy was encountered among 25.8% of the study participants of whom 5% had to undergo open cholecystectomy. Significant association was observed with gall bladder wall thickness >3mm and the presence of pericholecystic fluid collection on ultrasound findings with significant p value of 0.002 and 0.022 with sensitivity of 70.97% and 74.19% and specificity of 60.67% and 49.44% respectively. No significant association was observed between age, gender, duration of symptoms, number of pain attacks, TLC and difficulty in laparoscopic cholecystectomy. Sensitivity and specificity of raised TLC count in predicting difficult cholecystectomy was 82% and 16% respectively.

Sensitivity and specificity of number of pain attacks > 2 in predicting difficult cholecystectomy was 86% and 12.9% respectively.

Hence, evaluation of the factors that lead to difficult Laparoscopic cholecystectomy is extremely important before the surgery , which is instrumental pre-op patient counselling, making them understand their medical condition better and getting them on the same platform in present world of medical allegations.

It prepares the surgeon pre-operatively for the probable Intra-operative and immediate post-operative complications and better preparedness results in better surgery and in-turn good patient outcome.

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