ASSESMENT OF RISK FACTORS DIAGNOSTIC APPROACH AND MANAGEMENT IN CASES UNDERGOING DIFFICULT CHOLECYSTECTOMIES

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ABSTRACT: BACKGROUND: Laparoscopic cholecystectomy is the standard of care for the treatment of symptomatic gallbladder disease and one of the most common procedures being performed by the general surgeons all over the world. With more and more endeavors being made in the field of laparoscopy, more and more complicated cases which were relatively contraindicated a few years ago, are now being tackled laparoscopically. **AIM:** Aims of this study is assessment of risk factors, diagnostic approach and management of cases undergoing difficult cholecystectomies on basis of clinical, USG, preoperative, intra operative findings, duration of surgery, rate of conversion, post op complications and duration of stay in hospital. MATERIAL & **METHODS:** Prospective study done from June 2012 to Nov. 2014, 192 cases undergoing laproscopic cholecystectomy included in study at tertiary care hospital. **RESULT:** Cholecystitis or pancreatitis and thickened GB wall, PREOP ERCP are found to be significantly associated with increased risk of conversion. Obesity (BMI \geq 30 kg/m²) was significantly associated with difficulty in access to the peritoneal cavity. Various factors. CONCLUSION: clinical factors like male sex, previous acute cholecystitis or pancreatitis and ultrasonographic finding of gall bladder wall thickness ≥ 4 mm can help to predict difficult laparoscopic cholecystectomy and likelihood of conversion of laparoscopic cholecystectomy to open cholecystectomy.

KEYWORDS: Difficult, cholecystectomy, risk factor, management.

INTRODUCTION: Laparoscopic cholecystectomy is the standard of care for the treatment of symptomatic gallbladder disease and one of the most common procedures being performed by the general surgeons all over the world.¹

With more and more endeavors being made in the field of laparoscopy, more and more complicated cases which were relatively contraindicated a few years ago, are now being tackled laparoscopically.

Laparoscopic cholecystectomy decreases postoperative pain, allows earlier oral intake, shortens hospital stay, enhances earlier return to normal activity, and improves cosmetics over open cholecystectomy.^{2,3}

However, approximately 2% to 15% of patients require conversion to open surgery for various reasons.^{2,3} Identifying preoperative variables predicting conversion to open surgery improves patient counseling, planning of convalescence, and postoperative expectations. In addition, the surgeon can appropriately predict operative times while maintaining a lower threshold for conversion when intraoperative difficulties are encountered. These predictive factors for conversion also improve patient safety, minimizes the intraoperative complications.

AIMS AND OBJECTIVES: 1. To study the preoperative Ultrasonographic, Clinical parameters that can predict difficult laparoscopic cholecystectomy. 2. To determine the per operative findings suggestive of difficult laparoscopic cholecystectomy. 3. To establish management approach in term of operative time, conversion rates, per operative and post-operative complications, duration of hospital stay.

MATERIAL AND METHODS:

Study Setting: A Tertiary Care Hospital and Institute draining a large rural population of central India

Study Duration: July 2012 to November 2014.

Study Design: A Hospital based Non Randomized Prospective Study.

All patients undergoing laparoscopic cholecystectomy were included in the study.

Exclusion Criteria:

- 1. Patients unfit for general anesthesia and surgery.
- 2. Patients refusing to undergo surgery.

Criteria for prediction of difficult laparoscopic Cholecystectomy:

CLINICAL	USG BASED	PER-OPERATIVE
 Stocky Male patients 	 Thickened GB wall ≥4mm 	Difficulty in Access
Multiparous female	 Polyp/mass lesion 	• Difficulty in GB
with flabby	Edematous GB	dissection
abdomen	Emphysematous GB	Bleeding
 Pregnancy 	Contracted non-functioning	Abnormal Anatomy
 Liver Cirrhosis 	GB	GB perforation
• Present or previous	 Perforated GB 	Viscus perforation
Acute cholecystitis	 Impacted GB stone 	Intracorporeal suturing
or pancreatitis	• Empyema GB	
·		

TREATMENT:

Surgical:

- (a) Laparoscopic cholecystectomy.
- (b) Laparoscopic cholecystectomy converted to open cholecystectomy.
- (c) Open cholecystectomy.

Reasons Continuous variables (Age, Duration of surgery) were presented as Mean± SD. Continuous variables were compared by performing unpaired t-test.Categorical variables were compared by chi-square statistics. For small numbers, fisher exact test was applied wherever applicable.

RESULT:

NO. OF PATI	ENTS	MALE	FEMALE		
EASY	130	40	90		
DIFFICULT	62	36	26		
TOTAL	192	76	116		
TABLE NO. 1					

AGE IN YEARS	TOTAL	DIFFICULT (n=62)			
11-20	7	4	6.45%		
21-30	09	08	12.90%		
31-40	51	16	25.80%		
41-50	61	15	24.19%		
51-60	40	12	19.35%		
61-70	23	06	9.67%		
71-80	01	01	1.61%		
TOTAL	192	62	100%		
TABLE NO. 2: AGE DISTRIBUTION OF THE PATIENTS					

PRESENTATION	NO. OF CASES	PERCENTAGE
Chronic Calculus Cholecystitis	13	20.96
Chronic Calculus Cholecystitis With		
Choledocholithiasis With Pre-Operative	14	22.58
ERCP Guided Clearance Done		
Acute Cholecystitis	5	8.06
Sickle Cell Disease/Thalessemia	12	19.35.
Empyema Gallbladder	8	12.9
Gallbladder Polyp	1	01.61
Cholelithiasis With Pancreatitis	5	8.06
TABLE NO. 3: DIFFERENT PRESEN	TATION OF DIFFIC	CULT CASES

DISEASE	TOTAL		DIFFICULT CASES		P-VALUE
DISEASE	NUBMER	%	NUBMER	%	
Pure Gall Bladder Disease	158	82.29	37	23.41	-
Gall Stone With CBD Pathology	15	7.81	14	93.33	<0.001 (HS)
Gall Stone With Pancreatic Pathology	5	2.6	5	100	<0.001 (HS)

Gall Stone with Systemic Disease	14	7.29	8	57.14	0.039 (S)
TABLE NO. 4: RELATION BETWEEN BILIO-PANCREATIC AND					

SYSTEMIC DISEASES WITH DIFFICULT CHOLECYSTECTOMY

PRE OPEARTIVE RISK			ACCESS	ACCESS			
FACTOR		NUMBER	DIFFICULT	EASY	P-VALUE		
BMI	OBESE	46	11	35	<0.001,		
	NONOBESE	146	1	145	(HS)		
PREVIOUS ABDOMINAL	PRESENT	24	1	23	0.652 (NS)		
SURGERY	NONE	168	11	157	0.032, (113)		
TABLE NO. 5: ACCESS TO THE PERITONEAL CAVITY ACCORDING							
TO PRESENCE A	TO PRESENCE AND ABSENCE OF PRE-OPERATIVE RISK FACTORS						

			GB BED DISS	SECTION		
		NUMBER	DIFFICULT	Easy	p-value	
FACTOR			N=44	N=153		
Local Signs Of	Present	32	19	13	0.001 (S)	
Cholecystitis	Absent	160	25	135	0.001, (3)	
	Single	38	6	32		
No. Of Stones	Multiple	149	38	111	0.208, (NS)	
	NO	5	0	5		
CB Wall Thicknoss	≥4	32	15	17	<0.001 (HS)	
	<4	160	29	131	<0.001, (113)	
Liver	Normal	139	33	106	<0.6	
	Fatty	53	11	42	(NS)	
Droop EDCD	Done	17	7	10		
Preop ERCP	Not Done	175	37	138	<0.001 (HS)	
TABLE NO. 6: GB BED DISSECTION ACCORDING TO						
PRESENCE AND ABSENCE OF PREOPERATIVE RISK FACTOR						

			ADHE		
		NUMBER	PRESENT	ABSENT	P-VALUE
FACTOR			N=30	N=150	
Local Signs Of Chologystitis	Present	32	12	20	0.001
	Absent	160	21	139	(HS)
Bro On EPCP	Done	18	7	11	0.01,
	Not Done	174	26	14	(S)

Provious Abdominal Surgary	Present	24	1	23	0.071 (NS)	
Frevious Abdominal Surgery	None	168	32	136	0.071, (113)	
CB Wall Thickness	Thick (≥4)	32	10	22	0.021	
	Normal	160	23	137	(S)	
	Fatty	53	11	42	0.410 (NS)	
	Normal	139	22	117	0.419 (103)	
H/o Acute	Present	8	4	4	0.012	
cholecystitis/pancreatitis	Absent	184	29	155	(S)	
TABLE NO. 7: DENSE ADHESIONS ACCORDING TO PRESENCE						
OR ABSENCE OF PREOPERATIVE RISK FACTORS						

DIFFICULTY	NUMBER	PERCENT		
Dense Adhesions At Calots	32	94.11		
Cholecystoduodenal Fistula	01	2.94		
Anatomical Variation	01	2.94		
TABLE NO. 8: OPERATIVE DIFFICULTIES				

PRE OPEARTIVE		NO	BLEED	DING		
RISK FACTOR		NO.	PRESENT	ABSENT	P-VALUE	
BMI	Obese	46	4	42	0.432, (NS)	
	Non Obese	146	8	138		
Lower Abdominal Surgery	Present	24	1	23	0.652 (NS)	
	None	168	11	157	0.052, (115)	
GB Wall Thickness	Thick (≥4)	32	6	26	<0.001 (HS)	
GB Wall Thickness	Normal	160	6	154	<0.001, (113)	
Liver	Fatty	53	1	52	0 123 (NS)	
Livei	Normal	139	11	128	0.125, (115)	
Acute Cholecystitis/	Present	8	3	5	<0.002.(HS)	
AcutePancreatitis	Absent	184	10	174	(113)	
TABLE NO. 9: BLEEDING DURING SURGERY ACCORDING TO PRESENCE AND ABSENCE OF PREOPERATIVE RISK FACTOR						

PRE OPERATIVE RISK FACTOR		NUMBER	DURATION OF SURGERY	P-VALUE	
Local Signs Of Chologystitis	Present	32	76.09 ±22.71	<0.0001 (HS)	
	Absent	160	59.42 ±27.25	<0.0001, (113)	
No. Of Stopos	Single	38	56.26 ±16.92	0.124 NS	
No. Of Stoffes	Multiple	149	63.97 ±29.47	0.124, NS	
CR Wall Thickness	≥4	32	84.34 ±43.23	0.0001, (HS)	
GB Wall Thickness	<4	160	57.78 ±20.18		
Livor	Fatty	53	58.91 ±25.31	0.30, NS	
Livei	Normal	139	63.46 ±27.34		
	DONE	18	81 ±19.63	0.002	
PREOF ERCP	ND	174	60 ±27.19	(S)	
	Present	8	84.38 ±4.95	0.018	
	Absent	184	61.24 ±27.38	(S)	
TABLE NO. 10: DURATION OF SURGERY IN THE PRESENCE AND ABSENCE OF PRE-OPERATIVE RISK FACTORS					

COMPLICATION	NUMBER	PERCENT	
Bleeding	12	46.15	
GB Perforation	08	30.76	
Duodenal Perforation	01	03.84	
Stone Spillage	05	19.23	
TABLE NO. 11: INTRAOPERATIVE COMPLICATIONS			

COMPLICATION	NUMBER	PERCENT		
Fever	03	30		
Wound Infection	4	40		
Delayed Bleeding	02	20		
Delayed Bile Leak	1	10		
TABLE NO.12: POST OPERATIVE COMPLICATIONS				

REASON FOR CONVERSION	NUMBER	PERCENT
Difficult GB Dissection	10	58.82
Intra Operative Bleeding	04	23.52

GB Perforation	02	18.18		
Duodenal Perforation	01	5.88		
TABLE NO. 13: CONVERSION TO OPEN				

PRE OPEARTIVE		NO	CONVERSIO	D_VALUE		
RISK FACTOR		NO.	COMPLETED	CONVERTED	F-VALUE	
Condor	Male	76	64	12	0.006 (HC)	
Genuel	Female	116	111	5	0.000, (113)	
DMI	Obese	46	40	6		
BMI	Non Obese	146	135	11	0.251, (NS)	
Lower Abdominal Surgery	Present	24	23	1	0.207 (NC)	
	None	168	152	16	0.367, (113)	
	Thick	32	22	10	~0.001 (HS)	
	Normal	160	153	7		
History of Acute	Present	08	5	3	0.01, (S)	
Cholecystitis / Pancreatitis	Absent	184	169	15		
	DONE	18	4	14	0.036(5)	
	ND	174	13	161	0.030(3)	
TABLE NO. 14: CONVERSION TO OPEN ACCORDING TO PRESENCE AND ABSENCE OF PRE OPERATIVE RISK FACTOR						

	DI	FFICULT	EASY	
NUMBER OF DATS	NO. PERCENT		NO.	PERCENT
2-4	15	24.19	105	80.76
5-7	35	56.45	25	19.23
8-10	12	19.35	00	00
TOTAL	62	100	130	100
TABLE NO. 15: POST OPERATIVE HOSPITAL STAY				

	NUMBER	PERCENT	
DIFFICULT CHOLECYSTECTOMY	17	26.56	
OVERALL	17	8.85	
TABLE NO. 16: CONVERSION RATE			

DISCUSSION: Total 192 patients underwent laparoscopic cholecystectomy during this period and 62 cases which were considered as difficult were studied in detail.

The observations were as follows:

1. Sex: In present study, 76 patients were males and 116 patients were females. (Table no 1).The male: female ratio in this study is 1: 1.53.

2. Age: The age group (Table no 2) in this study ranged from 14 years to 71 years. Mean age incidence in the present study was 45.77 years whereas mean age in difficult group was 43.52 years. Palanivelu C et al $(2007)^4$ in their study over 9864 patients found that the mean age of patients was 40.4 yrs.

3. Relation between Biliopancreatic diseases and systemic diseases with difficult laparoscopic cholecystectomy:

In this study, (Table no.4) 14 out of 15 patients having CBD pathology in whom Preoperative ERCP was done, had difficulty in laparoscopic cholecystectomy which was statistically significant (p<0.001), 5 out 5 patients with pancreatitis had difficult laparoscopic cholecystectomy which is statistically significant (p<0.001) and 8 out of 14 patients with systemic disease had difficult laparoscopic cholecystectomy which is also statistically significant (p<0.03).

Akoglu M et.al (2010) in their study, performed preoperative ERCP was done in 32.5% patients and according to their study preoperative ERCP appeared to be related to scleroatrophic gall bladder and that that scleroatrophic gallbladders present more difficulties for laparoscopic cholecystectomy and are associated with a higher conversion rate.

Costantini R et.al. (2011).⁵ The execution of ERCP before surgery proved to be significantly associated with the risk of conversion (p<0.01) and hence the difficulty of procedure.

4. In this study, two variables were analyzed in relation to difficulty in access which were obesity and history of previous abdominal surgery. (Table no.5)

In this study it was found that obese patients had significantly higher difficulty in access as compared to non-obese patients. (p<0.001).

Similar finding has been noted in many other studies.

Jagadish Nachnani et.al. $(2005)^6$ in his study concluded that difficulty in access was encountered significantly more often in obese patients (p<0.05) and patients with past history of upper abdominal surgery. (p<0.01).

5. In our study, Difficulty in GB dissection was studied in relation to 4 variables that were presence or absence of local signs of cholecystitis, number of stones, GB wall thickness and status of liver, preoperative ERCP. (Table no.6).

Out of these, cases with local signs of cholecystitis, GB wall thickness 4 mm or more and those in which preoperative ERCP was done had significantly higher difficulty in GB dissection (p<0.001), (p<0.001) and (p<0.001) respectively.

Jagadish Nachnani et. al. $(2005)^6$ in his study concluded that dissection of GB bed was more difficult in patients with past history of acute cholecystitis/pancreatitis (p<0.01) and in those with GB wall thickness exceeding 3mm(p<0.05).

6. In our study, presence of dense adhesions during surgery was correlated with various variables (Table No. 7) out of which history of local sign of cholecystitis was significantly associated with presence of dense adhesions(p<0.001). Preoperative ERCP, past history of acute cholecystitis or acute pancreatitis and GB wall thickness 4mm or more were also positively associated with presence of dense adhesions intra operatively, (p<0.003, p<0.012and p<0.021 respectively).

Jagadish Nachnani et.al. (2005)⁶ in his study commented that past history of abdominal surgery, past history of acute cholecystitis/pancreatitis and thickened GB wall were associated with difficulty in defining the anatomy

7. Significant intra operative bleeding was correlated with various variables (Table No.9) out of which there was significant correlation observed between thickened GB wall and bleeding(p<0.001) and presence of acute cholecystitis/pancreatitis and bleeding (p<0.025).

Jagadish Nachnani et.al. $(2005)^6$ concluded that bleeding occurred more commonly in patients with having GB wall thickened (p<0.01) and those with history of acute cholecystitis/pancreatitis (p<0.01).

Abdel Baki et. al. (2006)⁷ in their study demonstrated that patients with thickened GB wall had high incidence of bleeding resulting in significant increase in duration of surgery.

8. Operative time (Table no. 10) mean operative time required for laparoscopic cholecystectomy is 62.2min; while mean time required for difficult cases is 90.56 minutes whereas mean operating time for converted procedures is 121.58 min which is significantly higher as compared to non-converted cases.

9. In our study, in presence of local signs of cholecystitis and thickened GB wall \geq 4mm, pre op ercp, duration of surgery was significantly higher. (p<0.001).

Abdel Baki et. al. $(2006)^7$ in their study commented that patients with local signs of cholecystitis, single impacted stones, thickened GB wall and liver fibrosis had significantly higher operative time (p<0.05).

10. The present study, (Table No. 13) the reasons for conversion were as follows – dense adhesions (10 cases), bleeding (4 cases), GB perforation (2 cases), and Duodenal perforation (1 case).

Duca S et al (2003)⁸ in their study over 9542 patients found following results - The rate of conversion was 1.9%. The causes of conversion were - CBD injury was the cause of conversion in 11 cases, right hepatic duct injury in 2 cases, bleeding in 9 cases, pericholecystitis in 124 cases, perforated GB in 2 cases, adhesions of previous laparotomy in 6 cases and instrument failure in 5 cases.

Jagadish Nachnani et.al. (2005)⁶ in their study found that 12 patients (11.4%) required conversion because of the following reasons: inability to delineate anatomy (66.7%), bleeding (25%), suspected CBD injury (8.3%).

The common reasons for conversions are dense adhesions, bleeding which hamper surgeons visibility other factors like viscus injury, aberrant anatomy, instrument failure also play role.

11. In our study, (Table No.14) a gallbladder wall thickness of 4mm or more was significantly associated with difficult surgical preparation leading to conversion and with the histopathologic report of chronic or acute inflammation (p value <0.001).

Avinash Supe et al (2005)⁶ inferred that preoperative predictive factors significantly associated with conversion to OC are: obesity, patient gender, past history of acute cholecystitis or acute pancreatitis, past history of upper abdominal surgery, and GB wall thickness >3 mm.

N.A. Kama et al(2001),⁹ B J Ammori et al(2001)¹⁰ found following factors as significant predictors of conversion male sex, past history of upper abdominal surgery, thickened GB wall(>4mm), age>60 years, clinical diagnosis of acute cholecystitis or previous attacks of acute cholecystitis.

12. In present series we found significant association with male sex and conversion to open cholecystectomy (p value 0.006). Table No.14

The c Avinash Supe et al (2005)⁶ found significant association between male sex, obesity, past history of acute cholecystitis or acute pancreatitis, past history of upper abdominal surgery, and GB wall thickness >3 mm.

ommon reasons for conversion in males were adhesions, moderate bleeding.

13. In study conducted by Raad S. Al-Saffar et.al.(2010),¹¹ it was seen that conversion rate declined as the number of cases progressed and concluded that LC is preferred method even in the difficult cases and as the number of surgery increases, the learning curve of surgeons increases and the difficult cases become less difficult.

Similar results are drawn from our study as well.

In present series of 192 patients; 192 patients had undergone laparoscopic cholecystectomy, 17 (8.85%) cases required conversion to open cholecystectomy (Table no. 16).

Sr. No.	Series	Rate of conversion
1	Avinash Supe et al (2005) ⁶	11.4%
2	Sajid Randhawa(2014) ¹²	11 %
3	Kumar A et al (1996) ¹³	14.3%.
4	Samir shrestha et al (2014) ¹⁴	11.14 %.
5	Pradeepanand Vaidya et al (2015) ¹⁵	7%.
6	S K Sahu et al (2007) ¹⁶	6%
7	Shamiyeh A et al (2007) ¹⁷	5.4%
8	Present series	8.85%

Study Name	Voor	Diaco	No.	Conversion
of Author	rear	Place	of Cases	Rate
Fletcher et al	1992	AUSTRALIA	186	3%(11% in different cases)
Perissat J.	1993	FRANCE	6110	3%(8% in different cases)
Lee FT et al	1994	USA	587	6%
Sanabria et al ¹⁸	1994	CANADA	628	5%(10% in different cases)
Margret et al	1995	UK	443	10%
Vecchio et al	1998	USA	114005	2.2%
Thompson et al	2003	ITALY	1360	1.8%
Kologlu ot al	2004	TUDKEV	1000	3.2% (4.8% in
Kologiu et al	2004	TURKLI	1000	different cases)
Gauraya et al	2004	SAUDI ARABIA	549	2.9%
Nachnani et al ⁶	2005	INDIA	105	11.4%
Kuldip et al	2005		6147	0.36%(1.66%
	2005	INDIA	0147	in different cases)
Tarcoveanu	2005	ROMANIA	6985	3.2%
Lim et al	2006	SINGAPORE	149	11.5%
Burr et al	2006	LAHORE	300	4%
Jabizalii at al	2006		1170	5.3%(10.6%
ISHIZAKI EL AI	2006	JAPAN	11/9	in different cases)
Bakos et al	2008	SLOVAKIA	1535	5.7%
Waseem et al	2008	PAKISTAN	216	4%
Rosita et al	2009	IRAN	793	9%

Rate of conversion in various studies is 2 to 15 %.

Table taken from Raad S. Al-Saffar et. al. (2010)¹⁰ for comparison.

Conversion rate (8.85%) is comparable with other studies whereas conversion rate in difficult cases (26.58%) is slightly higher in our study which is considerable on the basis of fact that this is an institutional study.

CONCLUSION: Mean age of difficult laparoscopic cholecystectomy was highest in the age group of 31-40 years, showing incidence of 23.5%. The mean age incidence undergoing difficult laparoscopic cholecystectomy in present study was 43.6 years. Chronic calculus cholecystitis is the commonest mode of presentation in this study. In clinical factors, male gender, previous acute cholecystitis or pancreatitis and thickened GB wall are found to be significantly associated with increased risk of conversion. Preoperative ultrasonographic finding of gall bladder wall thickness \geq 4mm is significantly associated with increased risk conversion.

Preoperative ERCP significantly increases the number of difficult cases and increases the risk of conversion to open & can help to predict difficult laparoscopic cholecystectomy. Obesity (BMI≥30 kg/m²) was significantly associated with difficulty in access to the peritoneal cavity. Various factors like thickened GB wall, presence of local signs of cholecystitis and preoperative ERCP were significantly associated with difficulty in GB dissection and dense adhesions causing difficulty in performing laparoscopic cholecystectomy.

In present series, mean operative time required for difficult laparoscopic cholecystectomy is 89.92 min; while mean time required for converted procedures is 121.58 min which is highly significant as compared to operative time for non-converted cases which is 68.75 minutes. Significant bleeding occurred more often in patients with past history of acute cholecystitis or pancreatitis and those patients having gall bladder wall thickness \geq 4m. The common reasons for conversion in present study were as follows-dense adhesions (57.9%), bleeding (21.1%), GB perforation (10.5%) and intra operative viscus perforation (10.5%).As more and more number of cases were performed laparoscopic cholecystectomy to open cholecystectomy is 9.64% overall and 29.69 % in difficult cases which is slightly higher in our study and can be explained on the basis of less experience in difficult cases, early phase of learning curve and lack of technological advances.

Patients with a high predicted risk of conversion could be operated on either by or under the supervision of a more experienced surgeon. Also, a high predicted risk of conversion may allow the surgeon to take an early decision to convert to OC when difficulty is encountered during dissection; this may significantly shorten the duration of surgery and decrease the associated morbidity.

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