International Journal of Research in Medical Sciences
Agrawal P et al. Int J Res Med Sci. 2021 Dec;9(12):3571-3581
www.msjonline.org
pISSN 2320-6071 | eISSN 2320-6012

DOI: https://dx.doi.org/10.18203/2320-6012.ijrms20214462

Original Research Article

Pre-operative predictors of difficult laparoscopic cholecystectomy and its correlation with post-cholecystectomy syndrome and its impact on quality of life in North Indian population

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Received: 19 October 2021
Accepted: 02 November 2021

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ABSTRACT

Background: Laparoscopic cholecystectomy (LC) is the most preferable surgical procedure worldwide. LC is not completely risk-free and 2 to 15% of attempted LC procedures have to be converted to open cholecystectomy. The aim of the study was to assess the predictors of difficult LC procedures and for knowing the impact of difficult LC procedures on post-cholecystectomy syndrome and quality of life of patients.
Methods: A prospective observational study was conducted on patients who underwent LC. Clinical, demographic, radiological and biochemical parameters along with detailed history of patients were documented. Laparoscopic cholecystectomy was then done on patients using standard technique. Level of difficulty in LC procedure was assessed and graded. Occurrence of post-cholecystectomy syndrome was investigated and quality of patient's life was assessed using SF-36 inventory.
Results: The difficulty rate in LC procedure was observed to be 17.4%. The clinical predictors of difficult LC procedures were old age and prior history of abdominal surgery. Contracted gall bladder, peripancreatic fluid and thick gallbladder wall were radiological predictors and presence of adhesions, longer duration of surgery and conversion to open procedures were intraoperative predictors of difficult LC procedures. Early PCS was affected by difficult LC procedures; though with passage of time it reduced. Post-operative quality of life was affected more by PCS incidence than the difficult LC procedure.
Conclusions: The findings of the study would help in anticipating predictors of difficult LC procedures and in understanding the phenomenology and determinants of PCS along with its relationship with operative difficulty and quality of life of patients.

Keywords: Laparoscopic cholecystectomy, Post-cholecystectomy syndrome, Quality of life, Radiological predictors, Clinical predictors, Biochemical predictors

INTRODUCTION

Laparoscopic cholecystectomy (LC) has received worldwide widespread acceptance as surgical procedure for the treatment of gallbladder stones, chronic cholecystitis, symptomatic cholelithiasis, biliary dyskinesia, acalculous cholecystitis, gallstone pancreatitis or other gallbladder disease.[1,2] LC has become the procedure of choice in surgical treatment worldwide because of its benefits of comparatively smaller incision, less intraoperative blood loss, cost-effectiveness, low post-operative pain, rapid recovery, reliability, shorter duration

of hospital stay, cosmetically more elegant, rare occurrence of complications and minimal temporary paralytic ileus.[1-4]

Despite of the above listed benefits LC is not completely risk-free, on an average approximately, 2 to 15% of attempted LC procedures have to be converted to an Open cholecystectomy (OC) procedure due to various challenges encountered like gall bladder malignancy, difficulties in accessing the peritoneal cavity, in difficulty in delineation of the anatomy, late third trimester of pregnancy, extensive adhesions, creating a pneumoperitoneum, multiple previous upper abdominal surgeries, instrument failure, extracting the excised gallbladder, dissecting the gallbladder, after onset of complications or when laparoscopic approach fails.

The term difficult laparoscopic cholecystectomy, is used when there is difficulty in creating pneumoperitoneum, increased intraoperative duration, increased intraoperative blood loss, chances of injury to adjoining structure, increased chance of per-operative complications and increased duration of hospital stay.[3-5] Difficult laparoscopic cholecystectomy may result in conversion to open surgery.[5]

A safe cholecystectomy is one that is safe for both the patient (no bile duct/hollow viscus/vascular injury) as well as for the operating surgeon with no or minimal scope for litigation. Published reports reveal that LC is associated with an overall complication rate of approximately 10% with a higher (0.1%-1.5%) risk of biliary injury in comparison to the open approach (0.1%-0.2%).[6,7] Thus preoperative assessment of complexity factors is required in LC in order ensure an efficient course of surgery. Preoperative complexity estimation can also help the surgeons in deciding whether or not to proceed with LC or to perform an open procedure or to make a referral to a more experienced surgeon.[8] The advantages of predicting difficult LC would be in getting assistance for obtaining quick informed pre-operative consent for conversion into open surgery with improved operating room scheduling and efficiency for management of any possible injury to biliary tree or GI tract and any intra operative blood loss.[9]

Clinical, radiological or biochemical parameters can serve as potential preoperative predictors of difficult laparoscopic cholecystectomy.[7-9] Some of the investigated predictors include age, gender, BMI, presence of other conditions like pancreatitis, hernia, previous per-abdominal surgery, recurrent attacks, distended/contracted gall bladder, peripancreatic fluid, multiple/large gall bladder stones, deranged LFT, elevated serum amylase and cirrhotic liver.[8-10]

Nevertheless, the rate of difficulties in LC is also dependent on the skill-level and experience of the operating surgeon, employed techniques and instruments; still identification of such preoperative predictors in the dynamically changing environment could help in giving momentum to development of strategies to counter them.[11]

Moreover, predictors of difficult laparoscopic cholecystectomy would also help in assessing as to how the intraoperative difficulties could play a role in determining the post-operative experience and satisfaction of patients.[12]

Post-cholecystectomy syndrome (PCS) is a condition identified by persistence of biliary colic or right upper quadrant abdominal pain. PCS include heterogeneous gastrointestinal symptoms like fatty food intolerance, nausea, flatulence, indigestion, vomiting, heart burn, jaundice, diarrhoea, and intermittent episodes of abdominal pain.[13,14] PCS is termed as early if occurs in the post-operative period and late if it manifests after months or years. Usually symptoms of PCS occur after few weeks of surgery or may reoccur after months/years of symptom free duration. PCS symptoms are reported to be observed in 5 to 40% of patients who undergo LC and PCS symptoms can be persistent or lifelong.[15]

Post-cholecystectomy syndrome is a problem that is encountered in a substantial number of patients during the early post-operative period and is one of the major reasons affecting the patient experience, satisfaction and quality of life in general.[16] LC is expected to substantially improve quality of life of patients but may adversely affect the same if it causes post cholecystectomy syndrome.[15,16] The aim of the study was to predict difficulties encountered during the laparoscopic procedures and knowing its impact on the post-cholecystectomy syndrome and to assess the relationship of difficulty in LC procedures and PCS as well as their impact on post-operative quality of life of patients for formulating better management strategies.

Aim and objectives

The aim of the study was to identify the preoperative predictors of difficult LC procedure; to correlate graded LC procedures with early PCS and to study impact of early PCS on quality of patient's life. The primary objective of this study was to find out varied clinical, radiological and biochemical factors for prediction of difficult LC. Clinical predictors that were considered in current study were age, gender, BMI, presence of other indications like pancreatitis, hernia, previous per-abdominal surgery, recurrent attacks.

Radiological predictors investigated in current study were distended/contracted gall bladder, peripancreatic fluid, multiple/large gall bladder stones. Biochemical parameters assessed in current study were deranged LFT, elevated serum amylase and cirrhotic liver.

The secondary objectives of this study were to assess the prevalence of early post-cholecystectomy syndrome and its relationship with difficulty experienced during the

procedure and to study the appearance of early PCS and its impact on quality of life of patients.

METHODS

Study design, location, population and duration

Current study was a prospective observational study, conducted at department of surgery, K. K. Hospital, Lucknow, Uttar Pradesh on all the patients admitted for elective laparoscopic cholecystectomy, for a period of one year from January 2020 to December 2020.

Sample size

The sample size considered in the current study was based on published literature that reported the prevalence of post-cholecystectomy syndrome to be 10%. In present study, similar prevalence was assumed. The sample size was calculated using the following formula proposed by Snedecor and Cochrane.[22]

$$N = Z^2[p \times (1-p)]/e^2$$

Where p is the targeted prevalence i.e. 10% or 0.1, and e is the absolute error which is as 5% or 0.05, z is a constant with a value of 1.96 at 95% confidence and 80% power. The calculated sample size was n=138, considering 10% contingency, the sample taken in current study were 150. However, during the course of study, a total of 11 patients were lost to follow-up and finally the study was completed in 139 patients. Thus, the final sample size of the study was 139.

Inclusion criteria

Inclusion criteria for current study were; all patients selected for elective laparoscopic cholecystectomy and patients with ultrasonographically proved cholelithiasis.

Exclusion criteria

Exclusion criteria for current study were; patients with significant co-morbid illness which may prolong the hospital stay and patients not fit for creation of pneumoperitoneum.

Procedure

Detailed surgical procedure was explained to the patients and informed consent was obtained. During enrolment demographic details like age and sex were documented. Height and weight of patients was measured and body mass index was calculated.

Details regarding prior medical and surgical history were documented. All the patients were enquired regarding presenting complaints followed by complete hematological, biochemical, immune and urinary investigations.

Chest X-ray of all the patients was obtained. All the patients were then subjected to USG whole abdomen assessment and the findings were documented. Subsequent to demographic, clinical, laboratory and radiological investigations, all the patients were assessed for quality of life using SF-36 inventory.

LC was then done on all the patients using standard technique. Prior to surgery, each patient was screened in pre-anesthetic clinic and length of procedure was documented considering skin incision as initial point and skin closure as final point. Conversion to open procedure was noted. Adhesion to the gall bladder region was graded subjectively as absent, mild, moderate, and severe by the operating surgeon. Other complications and difficulties faced during the procedure were also recorded.

Level of difficulty was assessed by the operating surgeon and was graded (Table 1). Subsequent binary differentiation was done as follows; duration of post-operative stay at hospital was noted along with any post-operative complications. All the patients were followed-upto three months. Recurrence of symptoms existing prior to cholecystectomy for more than consecutive 24 hours or more was considered as PCS. Nature and type of these symptoms was noted.

Table 1: Grading criteria as per the level of difficulty.

Level of difficulty	Inference	Grading
No difficulty	Operation performed routinely.	No difficult+ slightly difficult =easy
Slightly difficult	Procedure done with minor complications.	
Difficult	Procedure done with multiple complications leading to contemplated conversion to open procedure.	difficult+ extremely difficult = difficult
Extremely difficult	Multiple uncontrollable complications leading to contemplation to open procedure.	

Post-operative follow-up

The results of preoperative prediction of difficult LC were documented immediately after surgery. All the patients were followed-up for early detection of PCS for atleast 12 weeks. Quality of life (QOL) of patients was measured using SF-36 inventory at time intervals of 2 weeks, 1 month and 3 months post-cholecystectomy operation.

The outcomes determined were rate of difficult procedures, preoperative predictors of difficulty, rate of post-cholecystectomy syndrome, quality of life change following laparoscopic cholecystectomy and difference in quality of life of patients with and without post-

cholecystectomy syndrome. All the relevant data collected as was subjected to analysis.

Data collection method and tools

The data was collected through a semi-structured questionnaire. Records of all the test reports were maintained and representative photographic record were made. All observations were made under direct supervision of the supervisor.

PCS was defined as simultaneous presence of two or more of the following symptoms persisting unresolved for one-continuous week or more during the follow-up interval gaps: pain abdomen, vomiting, nausea, diarrhoea, fever and bloating/indigestion. Quality of life assessment was done using SF-36 QOL scale which is a 36-item inventory that measures quality of life on eight domains: Physical functioning (PF), Role physical (RP), bodily pain (BP), general health (GH), vitality (VT), social functioning (SF), role emotional (RE), and Mental health (MH). In current study each-domain was scored on a 100 points scale and scores were then transformed into percentages of maximum score.

Finally, average of all the eight domains to nearest rounded off value was considered in order to represent the overall transformed SF-36 quality of life score. Domain-wise study of scores was done and only final SF-36 scores were reported. Interpretation of data was as; a score of 0 was represented as worst score while 100 was represented as the best score. The data so collected was fed into computer using MS excel 2013 and subjected to analysis.

Statistical analysis

The statistical analysis was done using SPSS (statistical package for social sciences) version 21.0. The values were represented as; number (%) and mean±SD. Chi-square test, t-test and analysis of variance were used for comparison of data.

RESULTS

Current investigation was done on 150 patients fulfilling inclusion and exclusion criteria; who underwent laparoscopic cholecystectomy. In current study operating surgeon grading criteria was used for assessment of difficulty in procedure.

Demographic data of study participants revealed that age of the enrolled patients ranged from 20 to 70 years with a mean age of 47.76±12 years (Table 2). Majority of patients were females (71.3%) while 43 (28.7%) of study participants were males.

Time length assessing the duration of patient's complaints ranged from 0.5 to 6 months with a mean duration of 2.27±1.24 months. At enrolment the transformed mean SF-36 score was observed to be 69.15±9.47.

Distribution of investigational participants according to grade of difficulty in performing laparoscopic cholecystectomy procedure; revealed that majority of participants (N=94; 62.7%) were not considered to be falling in difficult grade (Table 3). Slight difficult grade laparoscopic cholecystectomy procedure was observed in 30 (20%) participants; while 19 (12.7%) participants exhibited difficult and 7 (4.7%) extremely difficult grade laparoscopic cholecystectomy procedure (Table 3). Thus according to the mentioned grading criteria a total of 26 (17.4%) participants (difficult+extremely difficult) were graded to have difficult laparoscopic cholecystectomy procedure.

The results of current investigation revealed that difficult laparoscopic cholecystectomy procedure was significantly associated with a higher mean age (52.15±9.41 years) and with patients having previous history of abdominal surgery (26.9%). Comparatively easy grade laparoscopic cholecystectomy procedure was observed in participants of 46.84±12.31 years of mean age and in patients with no previous history of abdominal surgery. No significant association of gender and other medical history factors was observed with difficulty grading ($p>0.05$) (Table 4). It was observed in current investigation through radiological predictors that difficult grade of laparoscopic cholecystectomy procedure was more prevalent in patients with presence of multiple large stones (2 or more stones with size >10 mm), distended and contracted gall bladder, peripancreatic fluid and thick gall bladder. Although patients with above mentioned complications were more associated with difficult grade LC procedure; however, it was observed that significant association of difficult grade was established only with patients of contracted gall bladder, peripancreatic fluid and thick gall bladder wall (Table 4).

It was observed in current investigation that adhesions were seen in 13 (50.0%) of difficult graded laparoscopic cholecystectomy procedure and 10 (8.1%) of easy graded procedures. Statistically, this difference was significant ($p<0.001$) (Table 5).

There were 7 (26.9%) conversions to open procedure in difficult graded laparoscopic cholecystectomy procedures. Mean duration of surgery was observed to be 49.42±6.05 minutes in difficult grade procedures as compared to 27.26±10.50 minutes in easy grade procedures; revealing a significant difference between two groups ($p<0.001$) (Table 5).

It was observed that for all the biochemical parameters, the difference between two graded groups were not statistically significant ($p>0.05$) (Table 6). Owing to conversion to open procedure, a total of 3 cases were

excluded from the post-operative assessment. Hence the further assessment was limited to 147 cases only.

Post-cholecystectomy syndrome

The incidence of PCS at 2 weeks, 1 month and 3 months follow-up intervals was observed to be 14%, 10.5% and 9.1% respectively (Figure 1). Overall cumulative incidence of early PCS (upto 3 months) was observed to be 28.0%. Current investigation results also revealed that incidence of PCS were 42.1%, 21.1% and 15.8% respectively at 2 weeks, 1 month and 3 months follow-up intervals in difficult graded LC procedures as compared to 9.7%, 8.9% and 8.1% respectively in easy graded LC procedures (Table 7), however, the difference between two groups was observed to be statistically significant only at 2 weeks interval ($p<0.001$).

Overall incidence of early PCS was 63.2% in difficult graded LC procedures and 22.6% in easy graded LC procedures. Statistically, this difference was significant ($p<0.001$). Pre-operative, mean QOL scores were 69.42±9.45 depicting a gap of 30.58% from the maximum achievable QOL scores. Postoperatively, at 2 weeks, 1 month and 3 months follow-up intervals QOL scores were 73.33±10.89, 77.07±10.34 and 81.27±8.51 respectively, depicting a significant and consistent increment with the passage of time ($p<0.001$) (Figure 2). At all the follow-up intervals mean QOL scores were lower in difficult LC procedures as compared to that in easy LC procedures, however, at none of the time intervals, the difference between two groups was significant ($p>0.05$) (Table 8). At 2 weeks, 1 month and 3 months follow-up intervals, mean QOL scores in patients with PCS were 63.55±5.55, 66.93±6.22 and 67.00±5.34 respectively as compared to 74.92±10.72, 78.26±10.09 and 82.69±7.39 respectively at the same corresponding time intervals in patients not having PCS. At all the time intervals, mean values were significantly higher in cases without PCS as compared to those having PCS ($p<0.001$) (Table 8).

Table 2: Demographic details of patients enrolled in the study.

Characteristics	Statistic
Mean age±SD (years) (range)	47.76±12.00 (20-70)
Gender	
Female	107 (71.3)
Male	43 (28.7)
Mean BMI±SD (kg/m^2) (range)	25.38±2.45 (19.6-30.0)
Mean duration of complaints±SD (months) (range)	2.27±1.24 (0.5-6)
Mean SF-36 scores±SD (transformed)	69.15±9.47

Table 3: Distribution of cases according to grade of difficulty (n=150).

Difficulty grade	N	%
Not difficult	94	62.7
Slightly difficult	30	20.0
Difficult	19	12.7
Extremely difficult	7	4.7

Table 4: Clinical and radiological predictors of difficulty.

Characteristics	Difficult (n=26)		Easy (n=124)		Statistical significance
	N	%	N	%	
Clinical predictors					
Mean age±SD (range) in years	52.15±9.41 (37-68)		46.84±12.31 (20-70)		t=2.077; p=0.040
Sex N (%)					
Male	5	19.2	38	30.6	t=1.369; p=0.242
Female	21	80.8	85	69.4	
Medical conditions N (%)					
Diabetes	3	11.5	16	12.9	t=0.036; p=0.849
Hypertension	5	19.2	14	11.3	t=1.225; p=0.268
Respiratory disease	0	0	8	6.5	t=1.772; p=0.183
Hypothyroidism	2	7.7	22	17.7	t=1.615; p=0.204
Pancreatitis	0	0	0	0	-
Hernia	0	0	0	0	-
Previous-abdominal surgery	7	26.9	12	9.7	t=5.779; p=0.016
Recurrent attacks	0	0	0	0	-

Continued.

Characteristics	Difficult (n=26)		Easy (n=124)		Statistical significance
	N	%	N	%	
Radiological predictors					
Multiple large stones	3	-	11.5	-	t=2.399; p=0.121
Distended gall bladder	1	-	3.8	-	t=1.510; p=0.219
Contracted gall bladder	4	-	15.4	-	t=8.121; p=0.004
Peripancreatic fluid	7	-	26.9	-	t=17.76; p<0.001
Thick gall bladder wall	4	-	15.4	-	t=8.121; p=0.004

Table 5: Association of difficulty with adhesions seen during surgery, duration of surgery and conversion to open procedure.

Characteristics	Difficult (N=26)		Easy (N=124)		Statistical significance	
	N	%	N	%	t value	P value
Adhesions	13	50.0	10	8.1	29.115	<0.001
Conversion to open procedure	7	26.9	0	0	35.019	<0.001
Mean duration of surgery±SD (min) (range)	49.42±6.05 (40-60)		27.26±10.50 (15-55)		t=10.39; p<0.001	

Table 6: Comparison of biochemical and hematological parameters between difficult and easy cases.

Parameters	Difficult (N=26)		Easy (N=124)		Statistical significance	
	Mean	SD	Mean	SD	t value	P value
Serum bilirubin (mg/dl)	0.93	0.18	0.93	0.17	-0.089	0.929
SGPT (U/l)	32.42	6.87	32.46	7.41	-0.023	0.982
SGOT (U/l)	34.35	7.13	33.51	7.24	0.538	0.591
Serum alkaline phosphatase	83.73	16.12	85.65	15.15	-0.579	0.563
Blood urea (mg/dl)	32.12	6.49	30.28	6.10	1.378	0.170
Serum creatinine (mg/dl)	0.85	0.14	0.87	0.17	-0.594	0.554
Hb (g/dl)	11.99	1.36	12.29	1.38	-0.989	0.324
TLC (‘000/mm^3)	6.68	1.19	6.29	0.91	1.869	0.064

Table 7: Association of incidence of early PCS with difficulty status at different follow-up intervals.

Follow-up intervals	PCS incidence in				Statistical significance	
	Difficult (N=19)*		Easy (N=124)			
	N	%	N	%	t value	P value
2 weeks (N=20)	8	42.1	12	9.7	14.40	<0.001
1 month (N=15)	4	21.1	11	8.9	2.604	0.107
3-months (N=13)	3	15.8	10	8.1	1.190	0.275
Total incidence (N=40)	12	63.2	28	22.6	13.46	<0.001

Note: *7 difficult graded cases were excluded owing to conversion to open procedure.

Table 8: Association of difficulty status and PCS incidence with post-operative SF-36 QOL scores at different follow-up intervals.

Difficulty status						
Follow-up intervals	Post-operative SF-36 QOL scores				Statistical significance	
	Difficult (N=19)*		Easy (N=124)			
	N	%	N	%	t value	P value
2 weeks	70.63	9.59	73.74	11.05	1.161	0.248
1 month	73.53	10.70	77.61	10.22	1.613	0.109
3 months	80.26	9.61	81.42	8.36	0.550	0.583
PCS incidence	**PCS**		**No PCS**			
	Mean	**SD**	**Mean**	**SD**	**t value**	**P value**
2 weeks	63.55 (N=20)	5.55	74.92 (N=123)	10.72	4.632	<0.001

Continued.

Difficulty status						
1 month	66.93 (N=15)	6.22	78.26 (N=132)	10.09	4.247	<0.001
3 months	67.00 (N=13)	5.34	82.69 (N=134)	7.39	7.458	<0.001

Note: *7 difficult graded cases were excluded owing to conversion to open procedure.

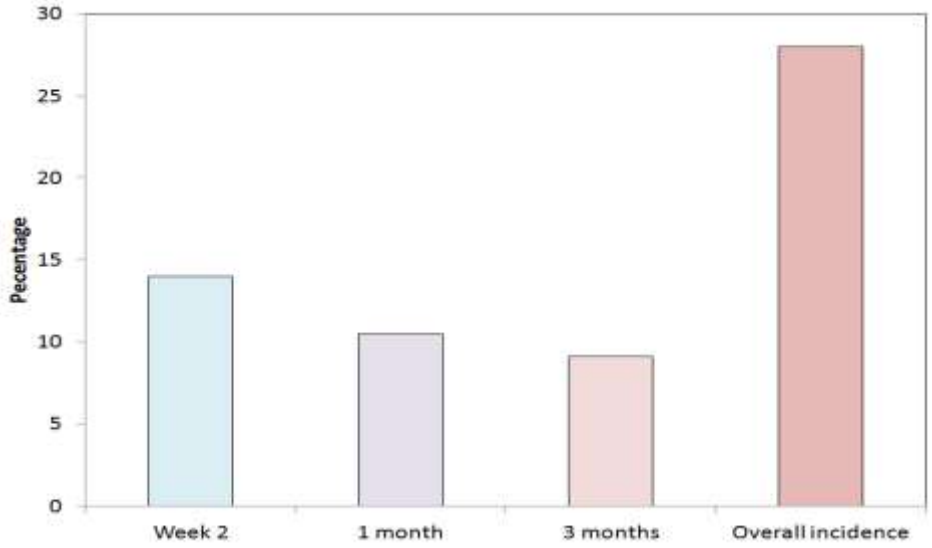

Figure 1: Incidence of post-cholecystectomy syndrome at different follow-up periods.

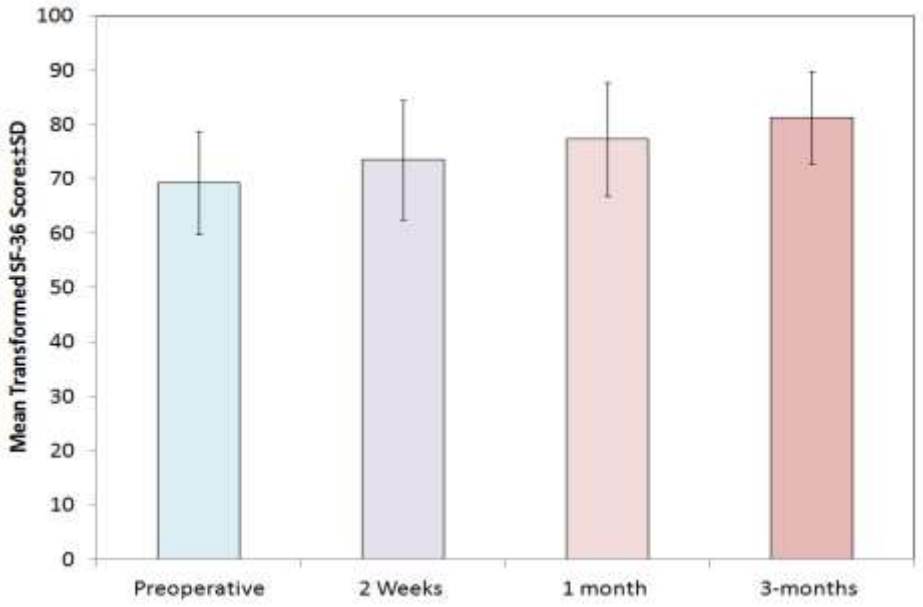

Figure 2: Quality of life status in patients undergoing laparoscopic cholecystectomy at different follow-up intervals (t values were observed to be 3.220,6.41 and 11.13 for time intervals of 2 weeks, 1 month and 3 months respectively and p value for all three times intervals was observed to be <0.001).

DISCUSSION

Current study was carried out to assess the preoperative predictors to identify difficult LC and to correlate it with early PCS and to study impact of early PCS on quality of life of patients. Results of the current study revealed that among preoperative clinical and radiological preditors, older mean age and previous history of abdominal surgery were found to be significant predictors of difficult procedures whereas among radiological predictors, contracted gall bladder, peripancreatic fluid and thick gall bladder wall were found to be significant predictors of difficulty. Serkan et al and Philip et al in their published reports recognized advanced age, male gender, previous upper abdominal surgery, preoperative diagnosis of acute cholecystitis, and gallbladder wall thickness as the predictors of difficulty in LC procedure.

Hussain et al also revealed male sex, increased age, acute and thick wall chronic cholecystitis, wide and short cystic duct, cholecystodigestive fistula, previous upper abdominal surgery, obesity, liver cirrhosis, anatomic variation, cholangiocarcinoma, and low surgeon's caseload as the predictors for difficulty assessment.[17,18] Gupta et al in their reported palpable gall bladder, impacted stone and gall bladder wall thickness as the predictors of difficulty.[19] Among different other studies, age, gender, BMI, presence of other conditions like pancreatitis, hernia, previous per-abdominal surgery, recurrent attacks, distended/contracted gall bladder, peripancreatic fluid, multiple/large gall bladder stones, deranged LFT, elevated serum amylase and cirrhotic liver have been recognized as the predictors of difficulty/conversion.[10-13,19] Since in present study there were no obese patients (BMI >30 kg/m^2), or patients with abnormal liver functions and liver cirrhosis and also since majority of participants were women (71.3%) thus these factors failed to emerge as significant predictors of difficulty/conversion rate. Previously published literatures have reported intraoperative findings such as inflammation (35%), adhesions (28%), and anatomic difficulty (22%) to be associated with difficulty.[11,12] In present study too it was observed that, adhesions was an intraoperative finding more common in difficult cases, however, presence of such conditions is what makes the procedure difficult and they cannot be considered as pre-operative predictors.

Although a number of other studies have highlighted the role of other factors like C-reactive protein and TLC as preoperative predictors of difficulty, however, in present study, all the patients had TLC levels within normal ranged and assessment of C-reactive protein was not part of our routine investigations.[20] It was observed through current study findings that patients were clinically and biochemically much stabilized and thus had a lower difficulty and conversion rate. No role of other biochemical parameters in procedural difficulty was observed or encountered.

In present study, assessment of difficulty was done by the operating surgeon in terms of level of discomfort and prospect of conversion of the procedure to open cholecystectomy. Majority of procedures, were not considered to be difficult. On the basis of intent or actual conversion to open surgery procedure, a total of 26 procedures were considered as difficult after ruling out the slightly difficult procedures in view of absence of intent or actual conversion to open procedure. In present study, conversion rate to open procedure was only 4.7%. The rate of difficult procedures and conversion to open surgery has shown a considerable variability in contemporary literature owing to difference in definition of difficult procedures. In current study, difficult procedures were defined on the basis of operator's own assessment of difficulty and both intent and actual conversion to open procedures, however, some published literature have considered difficult procedures as only those procedures that have been converted to open procedure.[21] Hence, this difference in subjective interpretation of difficulty has led to difference in reporting the difficulty rate in different studies. Conversion rate was reported to vary from 0.18% and 30% in earlier published reports however in present study, it was restricted to only 4.7%.[21] One of the reasons for this could be that the patients were primarily non-obese (BMI <30 kg/m^2) and did not have biochemical risk factors like derangement of liver functions, elevated serum amylase and cirrhotic liver. Moreover, the operating team was led by a surgeon having almost four-decades of experience of laparoscopic procedures in different environments in India and abroad.

Patients having a good physical and biochemical profile along with a highly skilled operating surgeon could have a deterministic role in reducing the conversion rate substantially. Similar to present study, Le et al who performed 3371 laparoscopic cholecystectomy over two years reported the conversion rate to open procedure as 2.6% only.[21] The results in present study are in agreement with the observation of Al Ghamdi et al who termed 17.3% of their procedures as difficult and reported a conversion rate of 1.67% only.[22] Rashid et al reported both difficulty rate (35%) as well as conversion to open procedure (6%) to be higher than that encountered in present study.[23] In present study, not only the definition of difficult procedure was more objective in nature but also the patient profile was more favourable owing to inclusion of only ASA I/II patients having a much stable clinical picture. Yajima et al also reported the conversion rate to be 11.6% which is much higher than that found in present study and could be attributed primarily to the fact that their series included a high proportion of acute cholecystitis period who underwent intervention in the acute and hot phase itself.[24] In present study, none of the patients underwent the procedure before 15 days of onset of symptoms.

In fact, mean duration of symptoms was 2.27 months. Yajima et al.[41] identified acute presentation as one of the significant factors affecting the conversion rate.[24] Gupta et al reported the difficulty rate to be as high as 48%, however, obese (BMI>30 kg/m^2) as well as acute patients were not excluded in their study as in current study.[19] The high prevalence of complicated/difficult procedures could be owing to a different definition of complication based on intraoperative grading system. Comparison of findings of published reports with present study revealed that careful selection of patients, time for making surgical intervention and relatively better patient physical profile could not only minimize the risk of difficulties but also reduces the risk of conversion to open procedures.[21-24]

Hence, it is essential that in all the elective LC cases, the pre-surgical focus should be on improving the physical and biochemical profile of patients in order to ensure a better success rate. Similar conclusions were also drawn by Ahmed et al who stated that proper case selection, good laparoscopic skill and adequate experience of the surgeon are the prerequisites for safe laparoscopic cholecystectomy and thereby reducing conversion rate.[25] Study of incidence of early PCS and post-operative quality of life and their

mutual relationship was also investigated in the present study. In present study, criteria to define PCS were presence of any two of the six listed biliary and dyspeptic symptoms continuously for at least one-week duration as the indicator of PCS. Cumulative incidence of PCS by 3 months postoperative interval was found to be 28%. Latenstein et al described the prevalence of these symptoms at 6 weeks post-operative period as 27.8% and 57.3%.[14] Results of present study also revealed gradual declining trend in incidence of symptoms starting from 2 weeks post-operative interval to 3 months.

Yueh et al also reported a decline in incidence of diarrhoea from at 1 week after LC to 3 months of LC.[26] Dey et al evaluated persistence of preoperative symptoms at 6 months after the LC and found them to be present in 8.6% of patients.[27] In present study, preoperative symptoms rate was found to be 9.1% at 3 months interval, probably owing to the fact that the patients in present study had a much favourable physical and biochemical profile. The time of observation is a key factor for calculating PCS rates which are quite high in early post-operative period. Arora et al reported PCS incidence to be 58% at day 7, 39.1% at day 30, 23.2% at 3 months and 13% at 6 months follow-up.[28] In present study, though such declining trends were seen with passage of time but the incidence of PCS at any time was not that higher as compared to earlier published reports.

One of the reasons for this could be the fact that in present study determination of PCS was done using a stricter-criteria that defined combined presence of two or more symptoms that remained unresolved for a continuous one week. Thus, mere presence of a single symptom as well as presence of an incidental symptom showing no syndromal nature was excluded from the definition of PCS thus helping to understand the problem in a more objective way and studying the actual burden of post-cholecystectomy symptoms in terms of a syndromal nature. Using well-defined criteria for PCS assessment have shown a relatively lower incidence rate of PCS as also observed by Shirah et al who found it to be 17.64% patients in patients having a follow-up period ranging from 3 to 10 months, however, in their study they did not mention whether the incidence rate reported by them was recorded at the end-point of follow-up or was an accumulated incidence as reported in present study.[29]

In present study, a significant association of procedural difficulty with PCS incidence at immediate-post-operative, 2 weeks and overall cumulative incidence time was observed; but significant association was not observed at 1- and 3-months evaluation. These findings show that difficulty in procedure has only short-term post-operative impact. In most of the studies on PCS, significant association with difficulty of procedure has either been evaluated or being reported. Among factors associated with PCS incidence in different studies are presence of pre-operative dyspeptic symptoms, notably bad taste and flatulence, a low-fat diet and a high score on a preoperative diarrhoea scale, Shorter duration of preoperative UAP (occurring within 24 h before admission), less frequency of postoperative UAP (<1 episode per day) and administration of choleretic medication, preoperative flatulence, nonspecific preoperative symptoms and patients' poor preoperative awareness.

In fact, some studies have found the PCS incidence to be highly unpredictable independent of age, sex, BMI, ASA classification, preoperative ERCP stone removal, gall bladder stones, combined comorbid disease, single port cholecystectomy, difficulty, post-operative complications, acute/chronic nature, postoperative Rowachol treatment and operative time.[14-25] In present study too, though the operative time was significantly longer in difficult procedures, however, difficulty of procedure was shown to have most pronounced impact on immediate post-operative assessment for PCS (at 2 weeks) only. Shin et al too reported that except for medical history of digestive system disease no other demographic, anthropometric, medical history, dieting and physical activity, personal habits (smoking/drinking), fatty liver and CBD diameter factors were found to be significantly associated with PCS.[30]

In present study, a significant and gradual improvement in SF-36 QOL was observed in patients throughout the study period. Interestingly while PCS incidence showed a declining trend with the passage of time, QOL scores showed a significant increasing trend with passage of time thus implying that symptomatic relief was significantly associated with an improvement in quality of life of patients. On the other hand, at none of the time intervals surgical difficulty showed a significant association with quality of life of patients, thus implying that while surgical difficulty was a one-time inconvenience for the patient and the treating physician yet it did not accompany long-term impact on physical well-being and quality of life of patients.

In current study owing to a low conversion rate to open procedure (2%), the more physical complications that could interfere with the post-operative quality of life of patients were less pronounced and hence surgical difficulty as such did not show a significant impact on PCS symptoms in second and third follow-ups. Moreover, it did not interfere with the quality of life. A significant improvement in post-LC quality of life of patients was also reported extensively in literature with associated symptomatic improvement.[31] The present study also highlighted the dependence of QOL improvement on symptomatic relief rather than surgical difficulty. Improvement in quality of life of patients is one of the ultimate objectives of LC and a substantial improvement in quality of life has been reported in a number of studies, however, there are limited studies on evaluating the determinants of change in QOL.[31,32] Thus findings in present study were interesting and pioneering to some extent as till date no study has evaluated the mutual relationship of surgical difficulty, PCS and post-

cholecystectomy quality of life. The present study findings also depicted that surgical difficulty (with low conversion rate) has only a short-term impact on PCS occurrence but did not have a significant association with post-cholecystectomy quality of life which is mainly governed by symptomatic relief and is hence affected by PCS rather than difficulty in procedure.

Limitations

Limitations of the current study were the small sample size of the study group was not adequate to make concrete recommendations. Follow up investigations, for a longer duration could have aided to establish more significant correlations between the investigated parameters.

CONCLUSION

It was concluded on the basis of current study findings that the difficulty rate in LC procedure as per criteria used in present study was 17.4%. The clinical predictors of difficult LC procedures identified were older age and prior history of abdominal surgery. Contracted gall bladder, peripancreatic fluid and thick gall bladder wall were radiological predictors and presence of adhesions, longer duration of surgery and conversion to open procedures were intraoperative predictors of difficult LC procedure. Early PCS affected nearly one-quarter of patients and was affected by more by difficult LC procedures in immediate post-operative assessments. With passage of time difficult LC procedures started to have a less dominant role in determining the PCS incidence. Following cholecystectomy there was a significant improvement in quality of life of patients. Post-operative quality of life was affected more by PCS incidence than the difficult LC procedure. Thus, the findings of the study would help in understanding the phenomenology and determinants of PCS and its relationship with operative difficulty and quality of life of patients.

Recommendations

Further studies to understand this relationship are recommended in order to describe the different aspects of problem and to formulate appropriate management strategies for reduction of conversion, PCS and to enhance the post-operative quality of life of patients.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Agrawal P, AlamM, Pratap D, Singh KK, Gupta L, Tripathi U. Pre-operative predictors of difficult laparoscopic cholecystectomy and its correlation with post-cholecystectomy syndrome and its impact on quality of life in North Indian population Int J Res Med Sci 2021;9:3571-81.