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Original Research Article

Development and validation of intraoperative severity score during laparoscopic cholecystectomy- An observational study

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Abstract

Background: Various studies have been carried out to evaluate the risk of pre-operative conversion in laparoscopic cholecystectomy. Different pre-operative scoring techniques have been recommended using different criteria which further add to the controversy.
Materials and Methods: This prospective observational study of 100 patients was conducted for 18 months in the Department of General Surgery at AIIMS Bhubaneswar, Odisha, India to grade the severity of cholecystitis during laparoscopic cholecystectomy using the intraoperative scoring system devised by Michael Sugrue and to evaluate the spectrum of cholecystitis in cases of laparoscopic cholecystectomy at a tertiary centre. Patients excluded from study were cases directly taken for open cholecystectomy, Carcinoma gall bladder, emergency cholecystectomy, Age <18> 75 yrs., Pregnancy, ASA-III & IV and Biliary pancreatitis. All the patients were classified on the basis of severity of grading scale as mild, moderate and severe for degree of intraoperative difficulty.
Results: In this study group of 100 patients, patients having preoperative imaging showing multiple gall bladder stones, thickened gall bladder wall, male patients, high BMI and patients with intraoperative score between 8-10 with degree of difficulty as extreme had more chances of open conversion.
Conclusions: Use of this intra-operative scoring system helped us to provide a trigger for a prompt early conversion to avoid intra-operative complications associated with difficult laparoscopic cholecystectomy.

Keywords: Laparoscopic cholecystectomy, Intraoperative grading system, Severity score

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1. Introduction

In 1987, Professor Mouret of France, performed the 1st laparoscopic cholecystectomy Professor Reddick had defined the classical 4 ports technique of laparoscopic cholecystectomy and it became an accepted technique extensively.

Laparoscopic cholecystectomy achieved its peak since its outset in the early 1990s. In the beginning indication for it was simple gall stone disease. The competence of the surgeon and experience in laparoscopic techniques along with comprehensive knowledge of the risk factors are important determinants for laparoscopic management of gall stone disease in difficult challenging situations.[1]

Usually difficulty faced while performing laparoscopic cholecystectomy are presence of dense adhesions at calot's triangle, contracted gallbladder, an acutely inflammed, gall bladder with gangrenous changes and presence of cholecysto-enteric fistula disease etc. The risk factors for difficult laparoscopic surgery to operate are in old age, male sex, recent attacks of acute cholecystitis, clinically acute cholecystitis and ultrasonographic findings such as thickened gall bladder wall, over distended gall bladder, pericholecystic adhesions and fluid collection, stone impacted in the neck of gall bladder, obese patient, previous abdominal surgery etc.[2,3]

Various studies at different centres have been done for evaluating the risk of pre-operative risk stratification for open conversion. Different scoring techniques and data for scoring

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difficulty level have been recommended using different criteria's which has added more to the controversy.

It is very difficult to preoperatively predict whether it is going to be an easy or difficult surgery. There is no grading or scoring of operative findings during surgery at present, making it difficult to compare the publications citing and outcomes, including the conversion to open surgery although many of pre-operative scoring systems are recorded.[4,5,15]

Michael Sugrue devised a scoring system based upon the intraoperative surgical findings in laparoscopic cholecystectomy. The key aspects of the scoring system include: Access to the gallbladder, body mass index (BMI) of patient, the degree of pericholecystic adhesions and parities and intra-abdominal adhesions in patients who had previous abdominal surgery, total time taken by the surgeon to dissect the critical view of safety with identification of the cystic artery and duct. In this scoring system: score of <2 considered as- Mild, 2 to 4 as Moderate, 5– 7 as Severe and 8 to 10 considered as Extreme.[6,12-14]

The present study has been undertaken to evaluate the role of various factors described above responsible for conversion from laparoscopic to open cholecystectomy based on the intra-operative parameters and challenges faced by the surgeon responsible for conversion in order to make the procedure safer for the patient and to minimize post-operative morbidity, the duration of surgery and to save the resources of operation theatre at a tertiary center in our local demographic area and also to do validation of intra-operative severity scoring system which is devised by Michael Sugrue.[1,6]

2. Materials and Methods

This prospective observational study was done for 18 months from August 2021 to December 2022 in the Department of General Surgery at All India Institute of Medical Sciences, Bhubaneswar, Odisha, India. This study has been done to develop our own intra-operative severity score during laparoscopic cholecystectomy and to validate the grade of scoring system which was devised by Michael Sugrue.[6]

A total of 100 patients have been included in the study after obtaining their informed verbal and written consent. All the confirmed patients of laparoscopic cholecystectomy admitted to wards in the Department of General Surgery were subjected to detailed history, examinations and for scoring of intra-operative findings. All the patients were classified on the basis of severity calculation on grading scale.

2.1. Sampling method

The study done by Bulbuller et al,[7] observed that sensitivity and specificity of RSCLO (Risk Score for Conversion of Laparoscopic to Open Cholecystectomy) score for predicting conversion rate was 100% and 96% respectively. Taking these values as reference, the minimum required sample size with desired precision of 10%, 95% power of study and 5% level of significance is 92 patients. To reduce margin of error, total sample size taken is 100.

❖ **OPERATIVE GRADING SYSTEM FOR CHOLECYSTITIS SEVERITY**

Gallbladder appearance	Ref.Score	Operative Score
Adhesions < 50% of GB	1	
Adhesions burying GB	3	
Max	3	
Distension/Contraction		
Distended GB (or contracted shrivelled GB)	1	
Unable to grasp with atraumatic laparoscopic forceps	1	
Stone ≥1 cm impacted in Hartman's Pouch	1	
Access		
BMI >30	1	
Adhesions from previous surgery limiting access	1	
Severe Sepsis/Complications		
Bile or Pus outside GB	1	
Time to identify cystic artery and duct >90 minutes	1	
Total Max	10	

Figure 1: Operative grading factors for cholecystitis severity

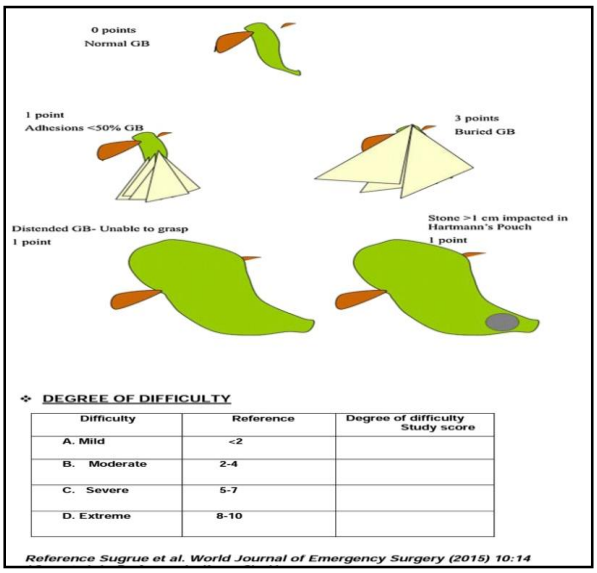


Figure 2: Intra operative degree of difficulty for cholecystitis severity

2.2. Statistical analysis

Variables have been presented categorically in number and percentage (%), continuous variables were presented as mean ± SD and median. Normality of data was tested by Kolmogorov Smirnov test.

Statistical tests were applied as follows -

1. Quantitative variables were analysed using ANOVA/Kruskal Wallis test (when the data sets were not normally distributed) with grading of severity.
2. Qualitative variables were analysed using Chi-Square test /Fisher's exact test.
3. Receiver operating characteristic curve was used to find out cut off point of RSCLO score for predicting conversion rate. Sensitivity, specificity, PPV and NPV were calculated.

A p-value of <0.05 was considered as statistically significant.

The data was entered in MS EXCEL spreadsheet and analysis has done using Statistical Package for Social Sciences (SPSS) version 21.0.

2.3. Inclusion criteria

1. All cases posted for laparoscopic cholecystectomy on selective basis.

2.4. Exclusion criteria

1. Cases that are directly taken for open cholecystectomy.
2. Carcinoma gall bladder.
3. Age <18 and > 75 yrs.
4. Pregnancy.
5. ASA- III & IV.
6. Biliary pancreatitis
7. Emergency laparoscopic cholecystectomy

3. Results

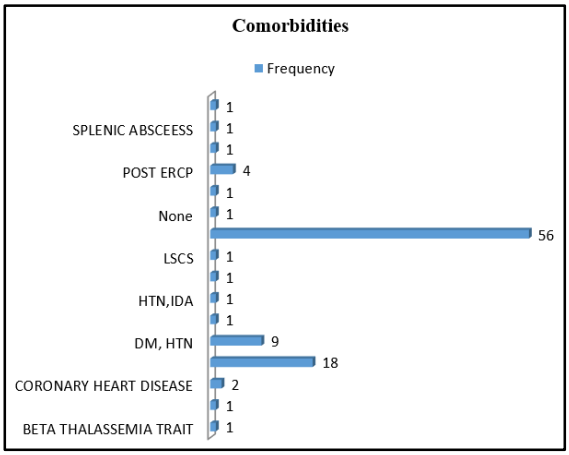
This prospective study conducted from August 2021 to December 2022 in the department of General Surgery, All India Institute of Medical sciences, Bhubaneswar, Odisha, India. Total 100 number of patients were included in the study.

Out of 100 patients of gall stone disease 68% were female and 32% were male as distribution (**Table 1**).

Table 1: Distribution of gender among study subjects

Sex	Frequency	Percent
Female	68	68.0
Male	32	32.0
Total	100	100.0

Only 44% of total study subjects had comorbidities, out of which maximum were of Diabetes Mellitus (18%) followed by Diabetes Mellitus & Hypertension as 9%. Below given chart with mentioned data showing co morbidities of patients of Gall stone disease posted for laparoscopic cholecystectomy in **Graph 1**.



Graph 1: Distribution of Comorbidities among study subjects

Laparoscopic Cholecystectomy was done in maximum patients i.e. 99% of our study subjects, out of 100 patients posted for laparoscopic cholecystectomy only 1 was converted to open having severity score as 'extreme' (**Table 2**).

Table 2 Distribution of types of surgery among study subjects

Types of surgery	Frequency	Percent
Lap converted open cholecystectomy	1	1.0
Laparoscopic Cholecystectomy	99	99.0
Total	100	100.0

On the basis of preoperative ultrasonographic assessment and histopathological follow up of patients posted for laparoscopic cholecystectomy 100% were diagnosed as chronic cholecystitis (**Table 3**).

In our result of 100 patients posted for laparoscopic cholecystectomy the degree of difficulties faced as mild in 1%, moderate in 74%, severe in 21% and extreme in 4% cases, of these 4%, 1% patient converted to open surgery as details given in **Table 4** and bar graph below.

Table 3: Distribution of Diagnosis among study subjects on ultrasonography and histo pathological follow up

Diagnosis	Frequency	Percent
Chronic Calculous Cholecystitis	100	100.0
Total	100	100.0

Table 4: Distribution of Degree of Difficulty among study subjects.

Degree of difficulty	Score	Frequency	Percent
Extreme	8-10	4	4.0
Mild	<2	1	1.0
Moderate	2-4	74	74.0
Severe	5-7	21	21.0
Total		100	100.0

Table 5: Mean difference of various variables among study subjects with respect to gender

Variables Name	Sex	N	Mean	Std. Deviation	95% Confidence Interval		p-value
					Lower	Upper	
Age (years)	Male	32	43.91	11.300	-3.374	6.922	0.496
	Female	68	42.13	12.453			
BMI (KG/M2)	Male	32	25.72	4.342	-19.695	6.632	.327
	Female	68	32.25	37.306			
Gallbladder wall thickness	Male	32	3.03	.740	-.268	.301	.908
	Female	68	3.01	.635			
Study score	Male	32	3.63	1.963	-.590	.870	.026
	Female	68	3.49	1.588			
CBD Diametr	Male	32	5.38	1.431	-.385	.870	.004
	Female	68	5.13	1.495			

Table 6: Mean difference of various variables among study subjects with respect to number of stones.

Variables Name	No. of stones	N	Mean	Std. Deviation	95% Confidence Interval		p-value
					Lower	Upper	
Age (years)	Multiple	85	43.19	12.401	-3.454	9.964	.338
	Single	15	39.93	9.874			
BMI (KG/M2)	Multiple	85	30.75	33.517	-13.310	21.216	.651
	Single	15	26.80	3.707			
Gallbladder wall thickness	Multiple	85	3.06	.679	-.110	.627	.167
	Single	15	2.80	.561			
Study score	Multiple	85	3.66	1.777	-.080	1.797	.013
	Single	15	2.80	1.014			
CBD diametr	Multiple	85	5.25	1.580	-.574	1.068	.022
	Single	15	5.00	.535			

Table 7: Pearson Correlation of various variables among study subjects

Variables	Statistics	Degree of difficulty	Study score
Age (years)	Pearson Correlation	.148	.300**
	p-value	.145	.002
BMI (KG/M2)	Pearson Correlation	-.039	.011
	p-value	.702	.911
Gallbladder wall thickness	Pearson Correlation	-.146	-.054
	p-value	.151	.595
CBD Diametr	Pearson Correlation	.264**	.216*
	p-value	.009	.031
Degree of difficulty	Pearson Correlation	1	.588**
	p-value		.001
Study score	Pearson Correlation	.588**	1
	p-value	.001	

Mean age of patients in this study who underwent laparoscopic approach of cholecystectomy was 42.70 years with the variation as 12.06, mean BMI level of 30.16. The average gallbladder wall thickness was 3.02 with standard deviation of 0.666. The mean CBD diameter was 5.21 with 1.47 as standard deviation. The average study scores 3.53 with the variation of 1.708.

On evaluation in study subjects it was concluded that male patients and patients having more gall bladder wall thickness and multiple gall bladder stones has more intraoperative severity score and difficulty compared to female patients and patients with gall bladder wall thickness less and single gall bladder stone as details of comparison given in **Table 5** and **Table 6**.

It was found that on comparing the mean difference between age, BMI, gallbladder wall thickness, CBD diameter, Study score with Gender. Age, BMI and Gallbladder wall thickness was found statistically insignificant (p-value>0.05), while CBD diameter and study score was found statistically significant (p-value<0.05) with gender (**Table 5**).

It was found that on comparing the mean difference between age, BMI, Gallbladder wall thickness, CBD diameter, study score with number of stones i.e. Multiple and single stones. Age, BMI and Gallbladder wall thickness was found statistically insignificant (p-value>0.05), while CBD diameter and study score was found statistically significant (p-value<0.05) with number of stones (**Table 6**).

While correlating the relationship between Age, BMI, Gallbladder wall thickness, CBD diameter, Study score with Degree of Difficulty, it was found that CBD diameter and study score was positively correlated and statistically significant (p-value<0.05). Also, Age, BMI, Gallbladder wall thickness, CBD diameter with study score, it was found that age, CBD diameter and Degree of difficulty was positively correlated and statistically significant (p-value<0.05) among patients. (**Table 7**)

4. Discussion

The development and validation of an intraoperative severity score during laparoscopic cholecystectomy is an important tool that can help surgeons to assess the severity of complications, predict post-operative outcomes and safe point for open conversion. In this study, we have developed and validated an intraoperative severity score devised by Michel Sugrue**[6]** based on the data collected from 100 patients undergoing laparoscopic cholecystectomy at All India Institute of Medical Sciences, Bhubaneswar, Odisha, India..

The score followed in this study here for intraoperative severity scoring devised by Michel Sugrue[6] has a range of 0-10, in our study of 100 patients we got a median score of 4. Where out of 100 cases, 1% classified as mild, 74% cases are moderate, 21% cases are severe and 4% cases as extreme in severity. Among these 4 extreme cases 1 case required conversion to open cholecystectomy. The score has excellent internal consistency with a Cronbach's alpha coefficient of 0.87. This indicates that the score is reliable and consistent.[8]

In this study we found a significant correlation between preoperatively assessed CBD diameter, multiple gall bladder stone, male patients and high BMI with degree of difficulty and intraoperative scoring system.

The study also found a significant association between the severity score and chances of intra operative difficulty and conversion to open surgery along with post-operative outcome. Higher scores were associated with a higher chance of difficulties and chances of open conversion. These finding are consistent with previous studies that have shown that intraoperative complications can have a significant impact on post-operative outcomes.[9,10] The developed intraoperative severity score can provide surgeons with an objective tool to assess intraoperative severity and predict time and minimum threshold for open conversion and to minimize morbidity along with better post-operative outcome. The scoring system can also be used to identify patients who may require additional monitoring or intervention during post-operative period.

However, this study has few limitations. Like, the study was conducted in a single centre, which may limit the generalizability of the result. Secondly, the study had a small sample size of 100 patients.

Further validation studies with a larger sample sizes and in different settings are needed to validate the generalizability of the developed intraoperative severity score.

5. Conclusion

This observational study developed and validated an intraoperative severity score of Michel Sugrue[6,**Error! Reference source not found.**] during laparoscopic cholecystectomy in 100 patients at AIIMS Bhubaneswar. The developed scoring system can provide objective criteria assess intraoperative severity and predict the correct required threshold for open conversion if degree of difficulty is high. The score guides the management of patients undergoing laparoscopic cholecystectomy and help to improve patient's outcome by minimizing post-operative morbidity and complications as well as it can minimize operative time and burden to the operation theatre resources.

Overall, the developed intraoperative severity score can be a useful tool for surgeon to guide, assess intraoperative degree of difficulty, correct time for open conversion and to minimize complications to the patients undergoing laparoscopic cholecystectomy thus it can improve the quality of care provided to patients and contribute to better clinical outcome.

6. Source of Funding

None.

7. Conflict of Interest

None.

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