OPERATIVE OUTCOMES BASED ON CLINICO RADIOLOGICAL ASSESSMENT FOR PREDICTORS OF DIFFICULT LAPAROSCOPIC CHOLECYSTECTOMY IN SYMPTOMATIC GALL STONE DISEASE

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ABSTRACT

Background- Laparoscopic cholecystectomy (LC) being the gold standard in the treatment of cholelithiasis, with raising incidence in India, associated with increase in the number of difficult LC. This study is conducted to predict difficult LC pre-operatively which can help the patient as well as the surgeon prepare better for the intra-operative risk and the risk of conversion to open cholecystectomy.

Methods: A one and half year (November 2018 to April 2020) prospective observational study was conducted on 50 patients who underwent LC in the Department of General Surgery at Dr. B. R. AMCH, who's clinical, sonological and operative details were analysed.

Results: Of the total participants (n=50), 13 (26%) were males and 37 (74%) were females, showing higher incidence in females. Majority of the participants belonged to 31 – 40 years age group (28%). Obesity showed strong co-relation between BMI >30 kg/m2 and difficult surgery. USG parameters had significant correlation with prediction of difficult LC i.e., Contracted GB (n=9) had significant correlation with gall bladder bed dissection (p= 0.002) and difficult GB extraction (p=0.014). Thickened GB wall showed good correlation with moderate bleeding during surgery (p < 0.001), GB bed dissection (p=0.031). Multiple calculi had an evident correlation with difficult bed dissection (p=0.04). Impacted stone (n=5) also had a moderate correlation with bleeding during surgery (p=0.042). Stone size greater than 1 cm (n= 20) was significantly associated with difficulty in extraction of gall bladder (p<0.001). 5 patients had deranged LFT, out of these 2 had difficult surgery due to bleeding, but the data was not statistically significant

Conclusion: From our study we conclude that the obesity and sonological parameters like thickened gall bladder wall, contracted gall bladder, stone size >1 cm and to some extent multiple stones and immobile/impacted gall stones were significantly correlated with difficult laparoscopic cholecystectomy.

Key words: Laparoscopic Cholecystectomy, Conversion to Open Cholecystectomy, Pre-Operative Indicators

INTRODUCTION

Cholelithiasis is the major cause of abdominal morbidity and mortality globally which was once considered as the disease of the affluent. With at least 10% of the adults have gallstones with a recent rise in the incidence due to change in the dietary factors. The condition affects 10-15% of the world population. In India, the proportion of cholelithiasis ranges from 10 to 20% in and commonly seen in North India than South India.[1]

Changing incidence in India is mainly attributed to urbanization, westernization, socioeconomic changes and change in dietary habits. Majority of the individuals are asymptomatic but around 1 to 2 %[2] of the patients will develop symptoms and require surgery and hence cholecystectomy was one of the most common procedure performed by general surgeons. The incidence of gall stones increases as age increases especially after 40 years of age and reaches its peak in 5th and 6th decade. Women were more commonly affected than men. Open cholecystectomy was the procedure of choice for surgical removal of the gallbladder. The classical open cholecystectomy (OC) and the minimally invasive laparoscopic cholecystectomy (LC) are the two procedures for cholecystectomy.

Though the Laparoscopic cholecystectomy was introduced in 1985, it became the gold standard treatment modality of gall bladder stones. This rising popularity was based on many outcomes, earlier return to bowel functions, less postoperative pain, less postoperative surgical site infection, short hospital stays, earlier resume of the daily routine activities and reduced total cost of the procedure.[3,4]

Laparoscopic cholecystectomy is associated a reduction of the inflammatory response as compared to open surgery.[6] It has improved patient satisfaction in terms of both primary and secondary outcome measures. Although it showed early promising results, recent trials show an increase in the incidence of operative complications, especially common bile duct injury.[7] The limitations of minimally invasive technique are expensive instruments, specialized training and long learning curve. The conservative methods for the treatment of gallstones like oral bile acid (chenodexycholic acid and ursodexycholic acid) therapy and Extracorporeal Shock Wave Lithotripsy (ESWL) have not shown encouraging results.

Laparoscopic cholecystectomy has become the gold standard in the treatment of cholelithiasis and is replacing open cholecystectomy. The rate of conversion from laparoscopic cholecystectomy to open cholecystectomy is 5 to 10%.[8] In developing countries like India the laparoscopic cholecystectomy becomes more challenging it should have good acceptance rate with the procedure cost at the barest minimum and the disease pattern also shared a major role as people in lower socio economic status had a greater tolerance for pain and suffering, fear of hospital all tend to present themselves at the later stages. Hence there is a need to study the predictive factors for difficult laparoscopic cholecystectomy and so the current study was planned in the tertiary care hospital in Bengaluru

METHODOLOGY

Source of data

All the eligible patients admitted in Dr. B. R. Ambedkar Medical College and Hospital, Bengaluru, who undergone Laparoscopic Cholecystectomy during the period of study were included.

Sample Size - 50 Patients

Data collection and evaluation

It's a hospital based prospective observational study. All the eligible patients who were admitted to Dr B. R. Ambedkar Medical College and Hospital, diagnosed to have cholelithiasis, symptomatic and posted for laparoscopic cholecystectomy were evaluated.

Written informed consent of the patient/attender was obtained. A detailed clinical history, physical examination and relevant investigations required for the study were done.

Study Design: Prospective and observational study.

Study Procedure

The method for the study included screening of patients who presented with upper abdominal pain or vomiting or dyspepsia or jaundice. Such patients were studied in detail clinically and investigated as per the proforma detailed below. Routinehematological and biochemical investigations were done. LFT and PT INR were done in all patients. Ultrasonogram of the abdomen is done after a 12 hour fast. The patients confirmed by USG examination were evaluated with following factors: age, sex, h/o previous hospitalization, BMI wt (kg)/ ht (mt2), abdominal scar, supraumbilical or infraumbilical, sonographic findings- wall thickness, GB size, number of stones, mobility of stones, stone size.

Intra operative evaluations were done for the patients subjected to laparoscopic cholecystectomy and time taken for surgery and conversion were noted. All the patients were operated by experienced surgeons. Post operatively cases were followed up for any complication. Suture removal was done on 8th post OP day. All cases were followed up for any recurrent

symptoms.
Inclusion criteria
All patients admitted to DR B R Ambedkar Medical College Hospital, Bengaluru undergoing Laparoscopic cholecystectomy during the study period
Age: 18yrs - 65yrs
Exclusion criteria
Pregnant women, Common Bile Duct Stone, Jaundice, Cholangitis,
Patients who are not fit for general anesthesia, Patient who did not give consent to participate in the study.

Statistical methods: Radiological predictors were considered as primary outcome of interest. Descriptive analysis was carried out by mean and standard deviation for quantitative variables, frequency and proportion for categorical variables. Data was also represented using appropriate diagrams like bar diagram, pie diagram and box plots. The association between categorical explanatory variables and quantitative outcome was assessed by comparing the mean values. The mean differences along with their 95% CI were presented. Independent sample t-test/ ANOVA was used to assess statistical significance. The association between explanatory variables and categorical outcomes was assessed by cross tabulation and comparison of percentages. Odds ratio along with 95% CI is presented. Chi square test/ Fishers was used to test statistical significance. Univariate Binary logistic regression analysis was performed to test the association between the explanatory variables and outcome variables. Unadjusted Odds ratio along with 95% CI is presented. Variables with statistical significance in univariate analysis were used to compute multivariate regression analysis. Adjusted odds ratio along with their 95% CI is presented. P value < 0.05 will be considered statistically significant.

RESULTS
A total of 50 patients who underwent laparoscopic cholecystectomy during the study period in the hospital were included in our study. Observation and analysis were done as follows. Of the total participants about 13 (26%) were males and the remaining 37 (74%) were females. Majority of the participants belonged to 31 – 40 years age group (28%), followed by 41 – 50 years (26%) and 21 – 30 years (22%). About 22% of the study subjects were aged more than 50 years of ageOf the total 50 subjects, about 10 (20%) of the patients were obese (BMI>30 Kg/m^2). The remaining 80% (n=40) had BMI lower than 30. Out of 50 subjects, 30 subjects (60%) had sub-costal angle less than 90°. 9 out of 50(18%) people had a contracted gall bladder. 14 (28%) people had thickened gall bladder wall. 35 out 50 people were found to have multiple gall bladder stones. 5(10%) people had immobile gall stones. 20 (40%) people were found to have stone size greater than 1cm. Out of the 50 subjects, 16 (32%) had a difficult calot's dissection. LC in one female patient was converted to open cholecystectomy due to this difficulty. Duration of surgery was prolonged (>60 mins) in 24 of the 50 patients who underwent LC. Difficulty in accessing the peritoneal cavity was encountered in 15 patients. One patient was converted to open cholecystectomy due to difficulty in adhesiolysis. Out of the 50 subjects, surgeons encountered difficult gall bladder bed dissection in 17 subjects. Difficulty in extraction of the Gall Bladder out of the abdominal cavity was observed in 16 patients. 4 patients needed extension of the port incision for extraction while rest of the patients required removal of stones using forceps followed by extraction.
Of the 50 patients, moderate bleeding was encountered in 5 patients and one of the patients had severe bleeding. Only 2 patients required conversion to open cholecystectomy.
One was a Male patient with previous history of upper abdominal surgery where the surgeon had difficulty due to dense adhesions.
Second case was a 32-year-old female with thickened gall bladder wall and multiple calculi. It was converted to open due to difficulty in calot's dissection.
Correlation coefficient and p value of correlation between risk factor and type of difficulty encountered intraoperatively is shown in table 2. Thickened Gall bladder wall was associated with longer duration of surgery, difficult bed dissection, difficulty in GB extraction and moderate bleeding. Contracted gall bladder was associated with difficulty in bed dissection and GB extraction. Stone size >1 cm significantly was associated with difficulty in GB extraction.

Table 1: Correlation between risk factor and type of intraoperative difficulty

		Duration of surgery >60 mins	Difficult Umbilical port entry	Difficult Gall bladder bed dissection	Difficult Gall bladder extraction	Bleeding present
H/O Past Surgery	Correlation coeff.	0.08	0.06	0.27	-.15	0.15
	p Value	0.266	0.312	0.057	0.597	0.254

Deranged LFT	Correlation coeff.	0.09	0.31	0.03	0.05	0.11
	p Value	0.131	0.010	0.196	0.157	0.042
GB Wall Thickness	Correlation coeff.	0.413	0.05	0.27	0.317	0.477
	p Value	<0.001	0.891	0.031	0.017	<0.001
Stone Size	Correlation coeff.	0.21	-0.17	-0.08	0.548	0.389
	p Value	0.049	0.529	0.465	<0.001	0.004
Obesity	Correlation coeff.	0.14	0.189	0.15	-0.17	0.03
	p Value	0.396	0.123	0.232	0.544	0.828
Contracted GB	Correlation coeff.	0.105	0.04	0.368	0.310	0.171
	p Value	0.216	0.810	0.002	0.014	0.297
No. Of stones	Correlation coeff.	0.21	0.01	0.306	0.19	0.12
	p Value	0.174	0.736	0.043	0.234	0.447
Stone mobility	Correlation coeff.	0.05	0.298	0.135	0.16	0.299
	p Value	0.131	0.010	0.196	0.157	0.042

Correlation coefficient significance >0.3 weak, >0.5 moderate, >0.7 strong, P value <0.05 Significant. Nonsignificant values i.e. correlation coefficient <0.3 and p value >0.05.

DISCUSSION

Laparoscopic Cholecystectomy has become the gold standard treatment for symptomatic cholelithiasis with failure rates between 2 to 15 %. The conversion to open surgery does not strictly mean failure or a complication; it is seen as a measure to prevent further complication during the surgery.

In this study of 50 patients undergoing LC, we have evaluated the factors, both clinical and sonological, which can be used to predict the difficulty in LC pre- operatively so that it can result in accurate planning of surgery and also proper counselling of the patient.

Of the total participants about 13 (26%) were males and the remaining 37 (74%) were females. Majority of the participants belonged to 31 – 40 years age group (28%), followed by 41 – 50 years (26%) and 21 – 30 years (22%). About 22% of the study subjects were aged more than 50 years of age. Some studies have reported old age as a significant risk[25], but in present study age had no significant effect on intraoperative difficulty factor for difficult laparoscopic cholecystectomy. This finding is consistent with Gupta N and Acharya A.[9,10,11].

Seventy four percent (37/50) of patients in present study were females. Higher incidence of gallstone in females has been suggested due to the effect of estrogen and progesterone on biliary cholesterol level and gallbladder motility[12-13]. A correlation of male gender with only bleeding and difficult GB bed dissection was observed but overall, it was not evident as a significant risk. This is in contrast to previous studies where male sex significantly predicted the conversion of laparoscopic cholecystectomy and also found male sex to be a significant predictor of severity[14-15]. The observed disparity may be due to the lesser number of males in the present study (26%). It is consistent with observations of Schrenk P *et al.* and others.[16,-18]

Obesity was a significant factor in the study. The results showed correlation between persons with BMI >30 kg/m^2 and difficulty port entry and duration of surgery. This is comparable to observation by Rosen *et al.*[19] but is not consistent with studies by Simopoulos C *et al.* and others who found no significant correlation between obesity and intraoperative difficulty.[20]

History of previous abdominal surgery did not have significant correlation with difficulties faced during LC which is in contrary to the observations by previous studies[9,21,-24]. This can be explained on the basis that most of the patients had undergone lower abdominal surgery with only one having undergone upper abdominal surgery. However, the one patient who had undergone upper abdominal surgery (Epigastric hernia) had to be converted to open due to dense adhesion. But Kanaan *et al.* and Lipman *et al.* did not find prior abdominal surgery as a significant risk factor for conversion or prediction of difficult laparoscopic cholecystectomy[25-26].

Ultra-sonological parameters had significant correlation with prediction of difficult cholecystectomy with each having

influenced specific part of a surgery. In our study, Contracted gall bladder (n=9) had significant correlation with gall bladder bed dissection (p= 0.002) and difficult gall bladder extraction (p=0.014). Thickened gall bladder wall (n= 14) proved to be a significant predictor of difficult surgery by having a good correlation with moderate bleeding during surgery (p < 0.001), gall bladder bed dissection (p=0.031) and which subsequently prolonged the surgery more than 60 mins (p<0.001). This can be explained by the fact that thick-walled gall bladder and contracted gall bladder occurs most commonly in chronic cholecystitis which would have produced inflammation and fibrosis. This is consistent with previous literature[21,27]. Thickened GB wall was also found to be most important predictor of difficulty in studies by Supe *et al.* and Fried *et al.* observations of which are comparable to our study [27-30].

Multiple calculi had an evident correlation with difficult bed dissection (p=0.04). Impacted stone (n=5) also had a moderate correlation with bleeding during surgery (p=0.042) reason being fibrosis and inflammation in gall bladder due to impaction. Stone size greater than

1 cm (n= 20) was significantly associated with difficulty in extraction of gall bladder (p<0.001) which is coherent with previous study by Lal *et al.* stating that large calculus at neck region is associated with distention of gall bladder and multiple stones are associated with difficulty in gall bladder extraction through small incision of LC and hence may lead to perforation of gall bladder with spillage of bile and gall stones[29].

Out of the 50 patients involved in the study, 5 had deranged LFT. Out of these 5, 2 had difficult surgery due to bleeding. But the data was not statistically significant to show a relation between deranged LFT and difficulty during calot's dissection. This is comparable to previous study by Gupta *et al.*[12] which found no significance (p-0.181) between deranged LFT and difficulty during surgery and is in contrast to the study by Murthy AK *et al.* and Alphonat *et al.* who found that deranged LFT and elevated amylase is a factor for prediction of difficult laparoscopic cholecystectomy.[30,31]

In our study, Thickened Gall bladder wall, contracted gall bladder, Stone size >1 cm significantly predicted the difficulty in Laparoscopic cholecystectomy. Other factors which also played role were Multiple stones and immobile stones. Fried *et al.*'s prospective study of 1,676 patients has similar observations except that our study had two extra parameters that were significant namely contracted gall bladder and stone size >1cm.[27]

CONCLUSION

From our study we can conclude that various pre-operative predictors of difficult LC are present which influence various stages of the surgery which cumulatively or as a single factor make the surgery difficult for even the experienced laparoscopic surgeons.

The parameters that significantly correlate with the difficult surgery were thickened gall bladder wall, contracted gall bladder, stone size >1 cm and to some extent multiples stones and immobile stones.

Ultrasonological parameters play an upper hand in predicting the course of the surgery than by the clinical parameters. Hence a detailed Abdominal USG to look for these parameters would surely help in predicting the difficult surgery beforehand.

To conclude, prediction of difficult LC or conversion to open surgery will be helpful to both the patients and surgeons. For the patients, pre-op mental preparation can drastically reduce the post-operative stress and morbidity. From surgeon's point of view, patients with high risk for difficult LC could be operated by an experienced surgeon. Surgeons in the early phase of their training can mentally prepare for a difficult surgery there by negating intra- operative panic or can performs the LC under supervision of experienced surgeon.

On knowing the chances of difficult surgery or possibility of conversion to open prior to LC itself can enable the surgeon to convert to open cholecystectomy early if faced by any difficulties which can help in reducing the duration of surgery and subsequently the post- operative morbidity.

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