INTRODUCTION

Cholelithiasis is a common disease throughout the world. The prevalence among adults is approximately 10-20% in West and 4.3% in India.[1] Majority of subjects (approximately 80%) with gallstones are asymptomatic.[2] Serious symptoms appear in 1-2% annually among persons with asymptomatic gallbladder stones.[1] Gallstone disease may lead to complications which include: acute and chronic cholecystitis, cholecystolithiasis, cholangitis, cholecystoenteric fistula, gallstone ileus, gallstone pancreatitis and rarely gallbladder carcinoma.[4] Gallstones are frequent in those belonging to high socioeconomic status and multiparous females.[3] The frequency of gallstones increases with age, escalating markedly after age 40 to become 4 to 10 times more likely in older individuals.[6] Obesity is a well-established risk factor for gallstone disease.[7]

After the first documented laparoscopic cholecystectomy (LC) was performed by Erich Mühe in Germany in 1985. The laparoscopic approach was declared the gold standard in 1993 by the National Institutes of Health (NIH) consensus conference.[8] Cholecystectomy is associated with mortality of 0.45 to 6% depending on severity of gallbladder disease.[9] The reasons for poor outcomes and postoperative complications after laparoscopic cholecystectomy is multifactorial in origin. It relates to severity of disease, clinical presentation, surgical experience, available instrumentation, patient body habitus and associated comorbidity etc. An important intraoperative...
consideration during laparoscopic cholecystectomy is the intraoperative difficulty encountered which may subsequently lead to conversion to laparotomy (Open Cholecystectomy). Most common reason for conversion to laparotomy is the inability to identify important anatomic structures during surgery. Other potential causes for conversion are: distorted anatomy from previous surgeries, inflammation, anatomic anomalies / variations and intraoperative complications (vascular, bowel or bile duct injury). Risk of conversion for uncomplicated gallstone disease is less than 1% and for patients with acute cholecystitis or history of that, may be as high as 20%. [19]

The need for conversion from laparoscopic to open cholecystectomy (OC) is an attempt to avoid complications and should not be considered either as a failure or complication of the laparoscopic procedure. It would be very helpful to predict the operative difficulty expected preoperatively. [11] This may allow the patients to be better prepared for the surgery and to plan their absence from work accordingly. [12] In addition, such prediction may allow a surgeon to be better prepared, to take extra precautions to reduce intra-operative complications and to convert from LC to OC at an appropriate stage. Many surgeons have tried to preoperatively identify such potential candidates depending on some preoperative variables like patient’s history, clinical findings, ultrasonography findings or early in the course of laparoscopic approach based on the operative findings. With this background, this study was conducted with an aim to determine preoperative variables that are associated with difficult laparoscopic cholecystectomy (DLC as determined by consultant operating surgeon using intraoperative scoring system decided by the study). This would then enable patients suspected to be having DLC to be handled by senior surgeon with low threshold for conversion to open cholecystectomy (OC).

MATERIALS AND METHODS
The study was conducted on 150 consecutive patients with gall stones posted for elective laparoscopic cholecystectomy performed by senior surgeon with experience of >100 laparoscopic cholecystectomy (LC) using a standard laparoscopic American set (karl storz) under General Anaesthesia (GA) at tertiary care service hospital.

Inclusion criteria
- All (symptomatic and asymptomatic) gall stone disease (GSD) patients scheduled to undergo elective laparoscopic cholecystectomy.
- Age group of 18 – 70 yrs.
- Patients giving valid informed consent and willing for follow up for 06months post-op.
- ASA grade 1 and 2 patients.

Exclusion criteria
- Patient refused to give consent.
- Patients belonging to ASA grade 3 and grade 4.
- Patients unwilling/unfit for laparoscopic surgery.

Following preoperative variables were used to predict DLC
1. Preoperative history included Age, sex of the patient, comorbidity, any history of previous abdominal surgeries and previous hospitalizations for pancreatice-biliary disease.
2. Preoperative clinical examination included patients’ body mass index, palpation of gall bladder per abdomen and tenderness in right hypochondrium.
3. Preoperative transabdominal sonography included gall bladder wall thickness, impacted gall stones (confirmed with dynamic USG noting the mobility of stone with the change in position of the patient), the number of gall stones in gall bladder, contracted or distended (mucocele) gall bladder and evidence of any pericholecystic collection.

Operative Scoring System for DLC used in this study as adopted from Michael Sugrue et al study [15]

- **Gallbladder appearance**
  - Adhesions < 50% of GB
  - Adhesions burying GB

- **Access**
  - BMI >30
  - Adhesions from previous surgery limiting access

- **Severe Sepsis/Complications**
  - Bile or Pus outside GB
  - Time to identify cystic artery and duct
    - >90 minutes

- **Total Max 10**
  - Degree of difficulty
  - Mild < 2; Moderate 2–4; Severe 5–7; Extreme 8–10

The score of 5 or more was taken as DLC and the various preoperative variables (history, clinical and USG) were correlated to find which of the preoperative variables are significantly associated with a DLC.

Statistical Analysis
Data analysis was done by using SPSS (Statistical Package for Social Sciences) package version 20.0. Qualitative Data variable was expressed by using frequency and percentage. The Chi-square test was used to find the association between intra operative difficulty with various preoperative variables. A p value of < 0.05 was considered as statistically significant.
RESULT

1. Intraoperative Difficulty Score

Table 1: A total of 38 patients (25.3%) who had an intraoperative score of 5 or more, constituting them as Difficult Laparoscopic Cholecystectomy (DLC).

<table>
<thead>
<tr>
<th>Intra-op difficulty score</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 5</td>
<td>112</td>
<td>74.7</td>
</tr>
<tr>
<td>≥5 (DLC)</td>
<td>38</td>
<td>25.3</td>
</tr>
<tr>
<td>Total</td>
<td>150</td>
<td>100</td>
</tr>
</tbody>
</table>

2. Conversion to Open Surgery

Table 2: A total of 03 patient (2%) where laparoscopic surgery couldn’t progressed satisfactorily and converted to open approach which includes patients who had intra-op bleed, unclear anatomy and failure to proceed by lap cholecystectomy.

<table>
<thead>
<tr>
<th>Conversion to open</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>No</td>
<td>147</td>
<td>98</td>
</tr>
<tr>
<td>Total</td>
<td>150</td>
<td>100</td>
</tr>
</tbody>
</table>

3. Correlation between Preoperative variables (history, clinical and USG) and DLC (intraop score =>5)

In our study, the age group of patients were ranged from 18 years to 69 years, maximum operated patients were from age group 30-40 yrs and increasing age was statistically significantly associated with a DLC (p value 0.035).

Based on sex, males were 28(18.7%) and females were 122 (81.3%) which shows that gall stone disease has a higher frequency in females as compared to males. Although, the males Percentage were higher than females [39% (11/28) vs 22% (27/122) respectively] for DLC. However, sex of the patients was not statistically significant for a DLC (p value 0.06).

According to BMI, 84 (56%) patients had a Body mass Index of less than 25 Kg/m2, 61 (40.6%) patients had a BMI range between 25 to 30 Kg/m2 and 05 (3.4%) patients had a BMI of or more than 30 Kg/m2. However, Preobese individuals (BMI 25-30Kg/m²) had DLC rather than Obesity (BMI>30Kg/m²) which was statistically significant with p value 0.003.

Based on comorbidities, only 7(4.7%) patients had diabetes mellitus (DM) and 6 (4%) patients had HTN. However, Comorbidities (DM or HTN) were not statistically significantly associated with a DLC (p value 0.498).

Out of 150 patients, only 27(18%) patients had undergone previous lower abdominal surgeries which includes both minimal invasive and open surgeries like tubectomy, appendectomy and hysterectomy. However, none of the patients in our study had prior upper abdominal surgery and Lower abdominal surgery was not statistically significant with a DLC (p value 0.369). Preoperative history of hospitalization, palpable GB and preoperative tenderness on clinical examination were found to be statistically significantly associated with a DLC (P- value < 0.001).

Based on preoperative USG findings, DLC was associated with thickness of GB > 4mm, impacted stone, multiple stones and contracted/distended GB (P- value <0.003)

DISCUSSION

Cholecystectomy is the treatment for Symptomatic Cholelithiasis and laparoscopic Cholecystectomy is the gold standard procedure. In some patients, the laparoscopic approach for cholecystectomy may be technically difficult due to various factors. If these factors can be identified pre operatively or early during the surgery, it can reduce the incidence of certain avoidable intra operative complications associated with the surgery.

In our study, we had included a total of 150 patients of symptomatic cholelithiasis who underwent elective laparoscopic cholecystectomy by experienced surgeons after thorough preoperative evaluation and workup. The DLC was opined by the operating surgeon using the intraoperative difficulty scoring system as enumerated above. The various preoperative factors were correlated with the DLC. There was a total of 38 cases (25.3%) which had a DLC with a conversion rate of 2% which is almost similar to Volkan Genc et al[31] study where overall conversion rate from lap chole to open chole was 3.16%.

In our study, 30-40yrs age group were most underwent laparoscopic cholecystectomy which was similar to Basim Rassam Ghadhban[28] study. However, when preoperative variables correlated with DLC in our study, there was an increasing trend observed for difficult cases with advancing age which was statistically significant with a P value of 0.035. Although females were more than males (122 vs 28) which was similar to Torres et al[20] study but males percentage were higher than females [39% (11/28) vs 22% (27/122)] for DLC and which was similar to Prem Chand et al[14] study where surgeon faced difficulty while performing lap cholecystectomy in men. It was also collaborated from other studies[11,15,16,17,18,19] as well where they also encountered difficulty while operating male patients compared to female patients. However, Gupta N et al and Lie U et al[20] did not find a statistically significant correlation between sex and the difficulty level.

Our study data analysis revealed, that there was significant high risk of difficulty encountered while performing lap chole in patients with BMI of less than 30 with a statistically significant P- value of 0.003 and which was similar to Lee et al[21] study where non-obese male patients had higher incidence of severe cholecystitis and surgeons encountered difficulty while performing
lap chole. Whereas, Jaskiran Randhawa[22], Bouarfa et al[23] and Supe et al demonstrated a significant correlation between increased BMI and intra operative difficulty level. However, It could be explained on the fact that, our study population belongs to the services and usually have BMI <30 (although exceptions are there every-where) who were usually posted at far-flung peripheral remotest areas with limited access to the surgical procedure on time and might have encountered multiple attacks of acute cholecystitis before they could get operated at this tertiary hospital which results in development of adhesions and inflammation around GB.

In our study, there was no statistically significant correlation observed between the history of previous lower abdominal surgeries (P- value 0.369) and DLC which is in contrast to study by Salleh Ibrahim et at. Supe et al and Kama et al where, they found a significant correlation between the history of previous upper abdominal surgery and intra operative difficulty level. However, it can be explained easily by the fact that, there was no case of previous upper abdomen surgeries in our study population group.

However, based on previous hospitalization, there were 13 patients in our study who had previous history of hospitalization in past 3 months for pancreatoco-biliary disease, out of which 12 patients (92.3%) had a DLC. There was an increased intra operative difficulty encountered with previous history of hospitalization which was statistically significant with p value <0.001. The reason could be due to dense GB adhesions and inflammation of operated site which was also enumerated in other studies.[22,24]

In our study, who were presented with palpable GB (04 patients) and preoperative tenderness on clinical examination (05 patients) had encountered 100% DLC intra-op with statistically significant p-value <0.001. which was similar to Teixeira J.P. et al study, where they had mentioned that palpable gallbladder and abdominal tenderness were predictors of a difficult procedure for cholecystectomy.[25]

Ultrasonographic findings in our study, which statistically significant with p-value <0.003 to predict DLC were thickness of GB > 4mm, impacted stone, multiple stones and contracted/distended GB. It was also similar to other studies[28,29,30,31,32,33] where, they also found similar preoperative USG diagnosed etiologies to predict DLC. It is also imperative to mention that none of the patients in our study had pericholecystic collection, however, it is associated with a difficult laparoscopic surgery which is in concordance with findings by Stanisic et al[44] and Kim MS et al in their study. There are several studies who agreed on the role of preoperative USG to predict difficulty and/or surgical conversion. Some authors even considered, that radiologists should specify the risk of conversion to open in their USG report.[35,36]

CONCLUSION
An important intraoperative consideration during laparoscopic cholecystectomy is the intraoperative difficulty encountered which may subsequently lead to conversion to laparotomy. The subset of patients who may end up with difficult laparoscopic cholecystectomy may be assessed preoperatively for the difficulty level based on various preoperative parameters. This would help the surgeon in anticipating the difficulty level and prepare accordingly to deal appropriately with avoidable complications. This also helps to inform the patient accordingly.

In this study using the intraoperative difficulty assessment scoring system we described the patients as DLC if score was =>5 out of 10. These patients were then retrospectively assessed to see if DLC could be predicted preoperatively using patient’s history, clinical and USG findings.

The Conclusions drawn from the study are
1. The incidence of gallstone disease is more among females as compared to males.
2. It is possible to predict DLC using epidemiological, clinical and USG findings.
3. Historically, the pre-operative prediction of surgery as difficult is significantly higher in patients aged more than 50 years and previous history of hospitalization for pancreatico-biliary disease in past. The gender, obesity (BMI>30Kg/m2) and comorbidity do not show much statistical significance in predicting a difficult surgery.
4. Clinically a positive finding in the form of palpable GB or right hypochondrium tenderness strongly signifies a DLC.
5. The intra operative difficulty level is higher in patients with a thickened gall bladder wall, impacted gallstone, multiple stones and presence of contracted/overdistended GB on ultrasonographic examination.

Recommendations
1. All the patients requiring cholecystectomy (if fit for GA) can safely undergo LC. In good hands, the only complication is a conversion.
2. Using clinical and epidemiological data with USG findings, it is possible to predict DLC.
3. Those predicted to have DLC should be operated upon by an experienced team and the threshold for conversion should be low.

Limitation of study
1. The pneumo-peritoneum was achieved in some patients with an open technique compared to the closed technique in the remaining patients which would have had a bearing on the overall time taken for the surgery.
2. The steps of surgery and the technique of dissection were at surgeon’s discretion and there was no pre-defined protocol set for the same in the study. This
would have affected the difficulty level in terms of overall time consumed and the difficulty encountered in dissection.
3. The males represented a small number in the study.
4. GB dissection was performed using different energy sources; diathermy/harmonic.
5. The time to identify cystic duct and artery used in operative scoring system is too high (90min).
6. In mucocele GB, some GB were aspirated by the surgeon while others did not.
7. Further studies with a greater number of patients and long follow up will increase the accuracy.

REFERENCES
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