ORIGINAL ARTICLE

VALIDATION OF A SCORING SYSTEM FOR DIFFICULT LAPAROSCOPIC CHOLECYSTECTOMY PREDICTION: PILOT STUDY

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ABSTRACT

Background: Laparoscopic cholecystectomy is excellence of care for the dealing of indicative disease of the gallbladder and commonly repeated operation being carried out by the surgeons. Occasionally done straightforwardly and rapidly and sometimes hard and prolonged. Guess of the situation involving exposure to danger of complication to turning or pitfall of surgery is a key angle for surgeons to setting up of surgery accordingly. But there is no handy scoring tool. The point at a target of our pilot survey is to analyze the feasibility of conducting a large study to validate a scoring tool developed at our institution.

Methods: Eleven patients included, study conducted in general surgery department, Ziauddin University and hospitals. Patient's assessment and surgery done by four experienced Surgeons. The variables such as up in years especially in male sex, past events of cholecystitis, pancreatitis, Overweight, past surgery on abdomen, noticeable gallbladder, gallbladder status and wall thickness, CBD diameter hematological/biochemical appraise in scoring method.

Results: We found that history of cholecystitis/pancreatitis, Significant variables were status and density of the gallbladder for the guess of tough laparoscopic cholecystectomy. P Values of scoring tool were p 0.001 for easy and p 0.001 for difficult case. The turning figure was 1(14.3%) and p 0.388 from conventional to open cholecystectomy.

Conclusion: This preoperative prediction scoring system is accurate, feasible, and inexpensive tool for use in selected clinical trials of gallstone disease. Further studies with large sample size and validation of this new method for assessment of treatment response are warranted.

KEY WORDS: Laparoscopic cholecystectomy, validation study, Pilot study, scoring system

INTRODUCTION

Laparoscopic cholecystectomy is accepted as highly excellence of care for gallstone disease and most frequently performed surgical procedures in the globe. Occasionally done straightforwardly and can be done swiftly and sometimes strenuous and prolonged. So preoperative guess of the danger of complication to turning open or tough operation is a major angle for surgeons to settings of surgery accordingly, detailed planning whether to move with this slant, or move with an open procedure. Scoring method effective to describe the many danger of laparoscopic and open cholecystectomy[1].Preoperative evaluation of complexity factors is required for laparoscopic cholecystectomy in correct condition to keep away complications, delays and to assurance of a well planned course of surgery. An attempt to achieve a goal in the field of laparoscopy, to a greater extent complicated cases which were somewhat contraindicated some years ago, but nowadays being try to cope with laparoscopically[2]. However laparoscopic cholecystectomy has broadly a less extent of morbidity, loss of life and of turning figure to open approach, end result is very extremely influenced by being there of inflammation of gallbladder, up in years, especially male sex and high index of body mass (BMI)[3]. Past surgery of upper abdomen is linked with a dense adhesion, greater risk of surgery complications, high

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conversion rate, lengthy operating time and hospital stay[3,4]. Laparoscopic cholecystectomy less pain after surgery, orally too soon diet permit, less stay in hospital, Prompt back to a routine work, and gives best cosmetic result[5,6]. Laparoscopic cholecystectomy is highly strenuous and lengthy operation time after ERCP (endoscopic retrograde cholangiopancreatography) with stone extraction[(7)]. The key point of our pilot survey was to analyze various variables by using scoring method and to guess tough operation and level of toughness preoperatively. Scoring method has not been validated in clinical trials for application on patients suffering from gallstone disease. The use of scoring tool for preoperative prediction of difficult laparoscopic cholecystectomy is the key for successful preoperative analysis and information of therapeutic response.

METHODS

This pilot validation survey carried out in a tertiary care center, department of General Surgery, Ziauddin university and hospital Karachi Pakistan. Eleven patients reviewed in our pilot validation survey after taking consent previously informed. Survey started after getting Clinical Research Committee confirmation and reviewed from the ethical committee of the organization. Not random in order prospective observational descriptive survey. Patients included with gallstone disease, either gender, age 18 to 70 years. Factors precluding conversion from laparoscopic to open cholecystectomy like instruments or power failure, etc. is exclusion criteria.

All the elective laparoscopic cholecystectomy cases came to Ziauddin University and hospital were included in our study. On admission, one day before to surgery, preoperative points stated on patient's history, examination, hematological (CBC), biochemical (LFTs) with ultrasound result. Preoperative scores up to 5 was sum up as easy, scores 6 – 10 as difficult, 11 – 16 as very difficult. All cases were operated by experienced surgeons having more than 20 years experience in laparoscopic and general surgery. Surgery was done as patient placed in lying face upwards position, surgeons stand on the left side of the patient. Pneumo-peritoneum set up by using CO2 gas with pressure of 10 mm Hg. Made two ports as typical 5 mm and two typical ports of 10 mm. Surgery time was calculated from insertion of first trocar up to the time of the stitch of last trocar opening. Entire per-operative happenings and level of quoted difficulties were estimated by the surgeon, and the level of surgery was interpret at the end of procedure on hospital postoperative notes and labeled as easy, difficult and very difficult by the surgeons on the basis of predetermined risk factors and per-operative duration of surgery, difficult dissection due to distorted calot's triangle anatomy, distended/contracted gallbladder, perforation of the gall bladder, spills or scattered bile/stone, adhesions, damage of duct or artery. The Pre-operative predicted score was estimated in each subject to arrive to end even preoperative guess scoring scale was effective method or not effective method. The survey performed with the help of the software named SPSS version 21. Accepted as statistically significant, and we found significant correlation of preoperative score with per-operative outcome findings.

RESULTS

Survey comprises of eleven patients. Preponderance of the patients was females 9(81.8%). Factors were scrutinized. Intra-operative mean time was 55 minutes (range 45 minutes) with SD 14.31. Gall bladder perforation and spills of bile or leak found in two patients, handle instantly by flushing with saline solution and suction. But not a bit of the patients needs turning as of bleed from cystic artery or spills of bile. Only one conversion in this study all because of perforated gall bladder and thick adhesions at cystohepatic triangle. Analysis of intra-operative conclusion and variables that display four element (History of cholecystitis/pancreatitis, deranged biochemical/hematological parameters, palpable gallbladder, thick wall gall bladder and increase common bile duct diameter) were statistically notably in pre-operative guess of tough laparoscopic cholecystectomy. Pre-operative points 0-5 was 8(72.7%), score 6-10 was 3(27.3%), and none of the patients had 11-16 score. P-values for easy and difficult cases were p 0.001 and p 0.001 respectively. Not a bit of the patient had score11-16 (Table 1). Turning figure from laparoscopic to open cholecystectomy is 1(14.3%). For checking the validity of the pilot data we applied different appropriate statistical testing like chi-square test, fisher exact test, independents sample t-test for scoring, correction test respectively. Also calculate confidence interval 95% and mean of score (3.18) with average. In our study female (n=9) mean scoring $\pm$ SD (3.11$\pm$ 2.66), male (n=2) mean scoring $\pm$ SD (3.5+3.53) with p value 0.862. Fortunately our prediction for difficult laparoscopic cholecystectomy (n=3) mean scoring $\pm$ SD (1.75$\pm$1.03) with significant p value <0.001* and for easy laparoscopic cholecystectomy (n=8) mean scoring 7$\pm$1.0 with p value <0.001*** (Table 2). Chart made ascertain the efficacy of sensitivity, specificity, negative predictive value; positive predictive value and accuracy. Receiver operator characteristics (ROC) will be applied to check the area under the curve of the specific test. If area found more than 0.5 then it will be labeled good validity of the test. That curve produced by apply SAS (Statistical Analysis System) version 9.2. Curve with C statistics applied to construct the magnitude efficacy of between two procedures. C-statistics resolved the Area under curve and most favorable cutoff with a great probability ratio, sensitivity and specificity of every test and support the value of the ROC curves and the predictive competency of every test

(Figure 1). Significant two tailed p value was < 0.05.

Table 1: Correlations of preoperative scores and surgery conclusion

Score	Straightforward	Tough	Highly tough	Sum
0-5 (Easy)	8(72.7%)	0(0%)	0(0%)	s8
6-10 (Difficult)	0(0%)	3(27.3%)	0(0%)	3
11-16 (Very difficult)	0(0%)	0(0%)	0(0%)	0
Total	8(72.7%)	3(27.3%)	0(0%)	11

P value for easy laparoscopic cholecystectomy is 0.001(significant), P value for difficult laparoscopic cholecystectomy 0.001*(Significant).

Table 2: Check the validity of prediction of Easy and difficult laparoscopic cholecystectomy

Gender	Scoring Mean + SD	P-VALUE
Female (n=9)	3.11±2.66	0.862
Male (n=2)	3.5±3.53	
Difficult lap chole (n=3)	1.75±1.03	<0.001*
Easy lap chole (n=8)	7±1.0	

Independent sample t-test for scoring

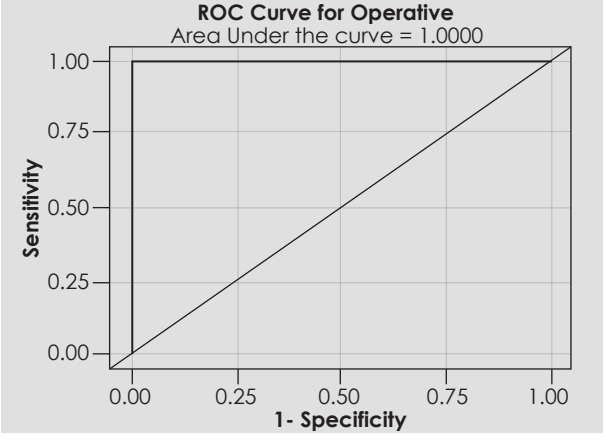

Figure 1: ROC curve and its area under curve for anticipate the operative conclusion depend on pre-operative points
Area under ROC curve = 1.00
ROC= Receiving operating characteristic

DISCUSSION

In this study total 11 patients underwent for elective laparoscopic cholecystectomy, during this period three cases were observed as difficult cases according to our preoperative predicting scale. We analyzed different preoperative guess of danger variables for tough laparoscopic cholecystectomy. Up in years, especially male sex, past events of cholecystitis/pancreatitis, Co-morbidities (DM, HTN, IHD), Obesity, past surgery on abdomen, noticeable gallbladder/lump, ultrasound result like gallbladder status and dense wall, fluid collection around gallbladder, considered as preoperative predictive danger variables in our pilot survey. Many risk factors are given, like increasing age makes surgery difficult[8] and turning figure is higher with up in years[9]. Considered one point if age between 40-60 years, and we found it significant. Male gender can make surgery difficult with high conversion rate[10]. As conversion rate and high mortality reported in males[11], but in our study is non-significant (p 0.425) because our study sample is too low. Preoperative assessment/diagnosis of acute cholecystitis/chronic cholecystitis/cholangitis of patient going for laparoscopic cholecystectomy can make surgery difficult or conversion. One study showed acute cholecystitis in obese is highly significant factor for conversion. Some studies reported top figure of bleed, damage of duct and subsequently turning in acute attacks[8, 9, 12, 13]. We scored one, if BMI is =>30 but we did not have patients with BMI =>30 in this study, as it's a small sample pilot study. BMI =>30 as obese group reported high chances of difficult access and conversion rate[12]. History of previous attacks of cholecystitis/pancreatitis can increase the chances of difficulty and conversion.

We observed non-significant (Cholecystitis/Pancreatitis) in this study (p 0.179). Co-morbidities like diabetes and hypertension/ischemic heart disease are other risk factors can make difficult laparoscopic cholecystectomy and we found non-significant (p 0.086). History of previous abdominal surgery especially upper abdominal Surgery, can make difficulty in surgery, associated with a higher rate of adhesions at calot's triangle and around gallbladder, with high risk of complications, conversion and increase operating time[14,15]. In this study, conversion is less often seen, because it was done by highly experienced laparoscopic surgeon (p 0.521). Post-operative adhesions can make difficult dissection, needs additional hours for separation of the gallbladder (>60 min)[14] .

Clinically palpable gallbladder seen in mucocele or empyema with distended gallbladder. Per-operatively hard to grasp bloated gallbladder fundus, needs decompression as often drawn contents by suction from gallbladder. It takes more time with high possibility of spills of bile. Single research has correlation of clinically preoperative palpable gallbladder with significant per-operative difficulty [16]. Single palpable gallbladder found in this pilot survey. Conclusion of this pilot survey was (p 0.087) found non-significant component in multivariate study. Deranged hematological (CBC) and biochemical (LFTs) factors are also associated with per-operative difficulty in surgery[17]. In this study ultrasonography finding of acute cholecystitis is thick walled gall bladder had significant (p 0.007).

In previous studies it was a significant factor[18,19]. One study displayed a preoperative dense walled gallbladder with stones as in ultrasound finding in indicative cholecystitis, is a caution for surgeon for tough laparoscopic cholecystectomy and may need to turning in open cholecystectomy[19]. In

another study in 1994, come to the conclusion they said it's a small efficacy to decide preoperatively on the basis of ultrasound finding for tough laparoscopic cholecystectomy, showed no association of preoperative ultrasound finding with tough or easy laparoscopic cholecystectomy[20]. We found only one thick wall gallbladder, significant by chi-square test (p 0.035). Furthermore logistic regression study determined the importance of this preoperative guess. Diameter of common bile duct is significant factor for preoperative difficulty in surgery[21]. Contracted gallbladder, it's a preoperative ultrasound finding greatly associated with surgical difficulty[22]. Peri-cholecystic fluid collection suggested an acute cholecystitis as in ultrasound. Not significant variable in this survey (p 0.011). Result of our survey in agreement with the observation of this study. For prediction of difficult laparoscopic cholecystectomy a scoring method applied in this survey. Previous study calculated sensitivity 75% and specificity 90.24%, PPV for easy laparoscopic cholecystectomy 88.8% and for difficult laparoscopic cholecystectomy 92.2%, ROC curve 0.82. As a consequence scoring method found highly effective in our survey not found in last study. However, PPV was not as much for tough type in comparison in previous study[16]. Reported turning figure in past studies was 7 to 35% [22]. Turn to open is a significant variable in this study, while it is low in our study as surgeries tackle by skilled surgeons[16].

All included cases in this study, were performed by highly experienced surgeons. Turn to open by reason of artery bleed[23]. In this study, none of the cases converted from artery damage, little bleeding found in one case, it was not turned to open, bleed ceased by putting clip. One study reported conversion from spillage of stones [24]. This study showed conversion rate is 11% [25]. In our survey none of the case found turning to open on this basis. In our study perforation of gall bladder and bile leak from gallbladder was present in 2 cases, but intra-operative time was less than 60 minutes, one case labeled as tough because of spills of bile. All were properly handled with experienced hands by washing, no turning case found. This survey showed one case out of eleven was turned because of perforated gallbladder and hard adhesions around gallbladder distorted cystohepatic anatomy.

CONCLUSION

Little can be safely deduced from these figures preoperative prediction by scoring method appraised in this pilot survey, suggested as a clinically and statistically, authentic and effective archetype to guess preoperative difficulties in laparoscopic cholecystectomy. Although mini size of data could be a hindrance in obtain a full statistical authenticity. So we put forward a relatively great size study to check and prove the accuracy of the scoring method and initiate intended result. Because preoperative knowledge of these factors can help in patient's safety with involvement of experienced laparoscopic surgeon who could better anticipate difficulties during surgery.

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