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A Retrospective and Prospective Study to Develop a Pre-operative Difficulty Score for Laparoscopic Cholecystectomy

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Abstract

Background The objectives of this study were to develop a grading system to enable pre-operative prediction of technical difficulty of laparoscopic cholecystectomy using retrospective data and to attempt to validate our scoring system prospectively.

Methods Retrospective analysis was conducted of 100 consecutive patients. Pre-operative variables were collected based on a template devised by the American College of Surgeons. Outcomes were duration of surgery, conversion to open and post-operative complications. Multivariate analysis with subsequent measurement of hazard ratios was used to formulate a weighted grading system. Prospective analysis was performed of 100 consecutive patients who were scored pre-operatively. Outcomes were duration of surgery and length of stay.

Results Retrospective univariate analysis identified four variables associated with an increase in duration of surgery: male gender ($p = 0.023$), age ($p = 0.000$), body mass index (BMI) ($p = 0.000$) and pre-operative endoscopic retrograde cholangiopancreatography (ERCP) ($p = 0.001$). Prospective analysis revealed weak positive correlations between the scoring system and duration of surgery (0.34) and length of stay (0.40).

Conclusion We have identified four pre-operative variables that predicted a longer duration of surgery. Preliminary results suggest a positive correlation between this scoring system and duration of surgery. An adequately powered prospective multi-centre study is needed to validate our findings.

Keywords Cholecystectomy, laparoscopic · Preoperative care · Operative time

Introduction

The prevalence rate of gallstones is about 10–12% population in European populations.[1] Over 20 million people suffer from gallbladder disease in the USA.[2] Laparoscopic cholecystectomy is now considered the gold standard approach in the management of these patients, with improved post-operative morbidity and mortality over open procedures.[3]

Different factors have been associated with increased technical difficulty in laparoscopic cholecystectomy. Male patients have been shown to accumulate more infra-mesocolic perivisceral fat, do not benefit from oestrogen suppression of macrophages and generate a more intense inflammation and fibrosis resulting in a technically more challenging procedure.[4–6] Older patients, often with increasing co-morbidities and potentially longer histories of gallbladder disease, have been shown to have more complicated inflamed or scarred tissue which can be difficult to dissect.[7–9] Patients with a higher body mass index (BMI) introduce technical difficulties such as initial device implantation and obscure anatomy.[8] Patients who have had previous endoscopic retrograde cholangiopancreatography (ERCP) or previous surgery have also been suggested to pose a greater challenge to the operating surgeon.[10–12] These factors increase the risk of injury and impede surgical flow.

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Although these factors, and several others, have been described in the literature, there exists no universal or validated pre-operative scoring system in place to predict the technical difficulty associated with laparoscopic cholecystectomy.[13] Better understanding of these factors would improve patient counselling, optimise surgical planning and allow appropriate selection of cases for trainees based on level of experience.[7,13,14]

The objectives of this study were to develop a preliminary grading system to enable prediction of technical difficulty of surgery as represented by the duration of the operation in patients undergoing elective laparoscopic cholecystectomy using retrospective data. We then attempted to validate our findings using a prospective cohort.

Materials and Methods

Retrospective Data

A retrospective analysis was conducted of consecutive patients who underwent elective laparoscopic cholecystectomy at a single institution. We used the worksheet template devised by the American College of Surgeons (ACS) for its National Service Quality Improvement Programme (NSQIP) and collected over 100 pre-operative variables on each patient included in the study. This provided us with a systematic approach to our data collection, specifically, the pre-operative variables which were of interest to us in this study. Variables included information relating to patient demographics, presentation and course of disease; co-morbidities and surgical risk assessment, operating surgeon grade and pre-operative laboratory data. Pre-operative procedure-specific data was also collected: this included pre-operative radiological findings on ultrasound scanning (USS) and magnetic resonance cholangiopancreatography (MRCP) [thickened gallbladder wall, common bile duct dilatation and hepatic duct dilatation] and information relating to whether pre-operative ERCP was performed.

The primary outcome was duration of operation in minutes. Secondary outcomes included conversion to open procedure and post-operative complications. The Dindo-Clavien classification was used to record post-operative complications. Pre-operative variables were tested against the three selected outcome measures in order to identify any significant association.[15]

Thirty-four pre-operative variables were chosen for univariate analysis to examine their effect on duration of operation; the remainder was found to be redundant and included variables such as patient address and anaesthetic type. This was performed using Kaplan-Meier analysis and log-rank test. Variables with greatest significance were entered into a multivariate analysis model. This subsequently allowed for measurement of hazard ratios, which in turn were used to formulate a weighted grading system. Each variable was attached a relevant score based on the strength of association. Upon summing up the total score, procedures could be stratified into three grades: I (General Surgeon), II (Upper Gastrointestinal Surgeon) and III (Hepatobiliary Specialist).

Both age and BMI were analysed individually. Age was divided to either < 49 (group 1) or ≥ 49 (group 2) as this was the median. BMI was categorised into one of four groups based on the World Health Organisation (WHO) BMI (kg/m^2) classification groups: group 1—underweight (BMI < 18.50); group 2—normal (BMI 18.50–24.99); group 3—overweight (BMI 25.00–29.99); and group 4—obese (BMI ≥ 30).

Prospective Data

A prospective analysis was performed of consecutive patients who underwent elective laparoscopic cholecystectomy at two sites.

Factors incorporated into a scoring system based on our retrospective data were collected on these patients (Table 3). These included sex, age, previous ERCP and BMI. Other pre-operative variables collected included most recent white cell count (WCC) (10^9/L) and c-reactive protein (CRP) (mg/L), number of hospital presentations with abdominal pain of suspected biliary source and previous abdominal surgery. Outcome measures collected included duration of operation (minutes) and length of stay in hospital (days).

Duration of surgery was used as a surrogate marker of technical difficulty in our retrospective and prospective cohorts as has been done in previous work.[16] Furthermore, the supervising surgeons were the same for our retrospective and prospective cohorts.

Correlation coefficient and Student's *t* test were used to analyse the data. Correlation strength was described using common nomenclature used in the literature as "weak", "moderate" and "strong".[17]

This study was performed as a service evaluation and no ethical review was required after consultation with our local Research and Development department.

Results

Retrospective Data

A total of 100 patients were included in the retrospective cohort. Seventy-two percent of the patients were females and 28% were males. Age of the patients ranged from 23 to 82 years old with mean age of 51. Mean duration of surgery was 103 min. Three (3%) postoperative complications were noted and 2 (2%) procedures were converted to open.

The variables that demonstrated significant impact on the duration of the operations were male gender ($p = 0.023$), age ($p = 0.000$), BMI ($p = 0.000$), smoking ($p = 0.024$), pre-operative ERCP ($p = 0.001$) and bilirubin levels ($p = 0.005$). Male gender, advancing age, higher BMI and patients who underwent a pre-operative ERCP were all associated with an increased duration of operation (Fig. 1) and thus utilised to design the grading system. Smoking history and higher bilirubin levels were found to be associated with a shorter duration of operation. The rest of the 16 variables, including operating surgeon grade, various co-morbidities and biochemical test results, showed variance amongst patients, but no significant correlation was identified with duration of surgery and hence not included. A summary of univariate analysis of factors influencing duration of operation is found in Table 1.

Gender, age, BMI and previous ERCP were the four variables employed in the multivariate analysis; this was performed using a COX regression model. Hazard ratios of these factors were calculated to measure the contribution of each factor in the overall grade of the scoring system. For example, using age (which demonstrated a hazard ratio of .470), the inverse value obtained was 1/.470 = 2.12. For simplicity, each inverse value calculated was then rounded to the nearest 0.5 figure, giving age a weighted grading of 2. The summary of the hazard ratio scores is found in Table 2.

Based on the above scoring method, the lowest possible score achievable was 1 (female = 0, age < 49 = 0, no ERCP = 0 and normal BMI = 1). The highest possible score achievable was 11 (male = 2, age ≥ 49 = 2, previous ERCP = 2 and obese BMI = 5). The total score possible was subsequently divided into three groups formulating the three previously outlined categories—grade 1 (General Surgeon) for a score of 1–4, grade 2 (Upper Gastrointestinal Surgeon) for a score of 5–8 and grade 3 (Hepatobiliary Specialist) for any score above 8. The scoring proforma and grading system devised are illustrated in Table 3.

Prospective Data

Data was collected on 100 patients. Analysis revealed weak positive correlations between age and BMI and duration of surgery (0.19 and 0.08, respectively). However, when combined with sex and previous ERCP, a stronger positive correlation was detected (0.34) (Fig. 2). Positive correlations were also identified between WCC, CRP and number of admissions and duration of surgery (0.29, 0.31 and 0.09, respectively). The differences between duration of surgery were statistically

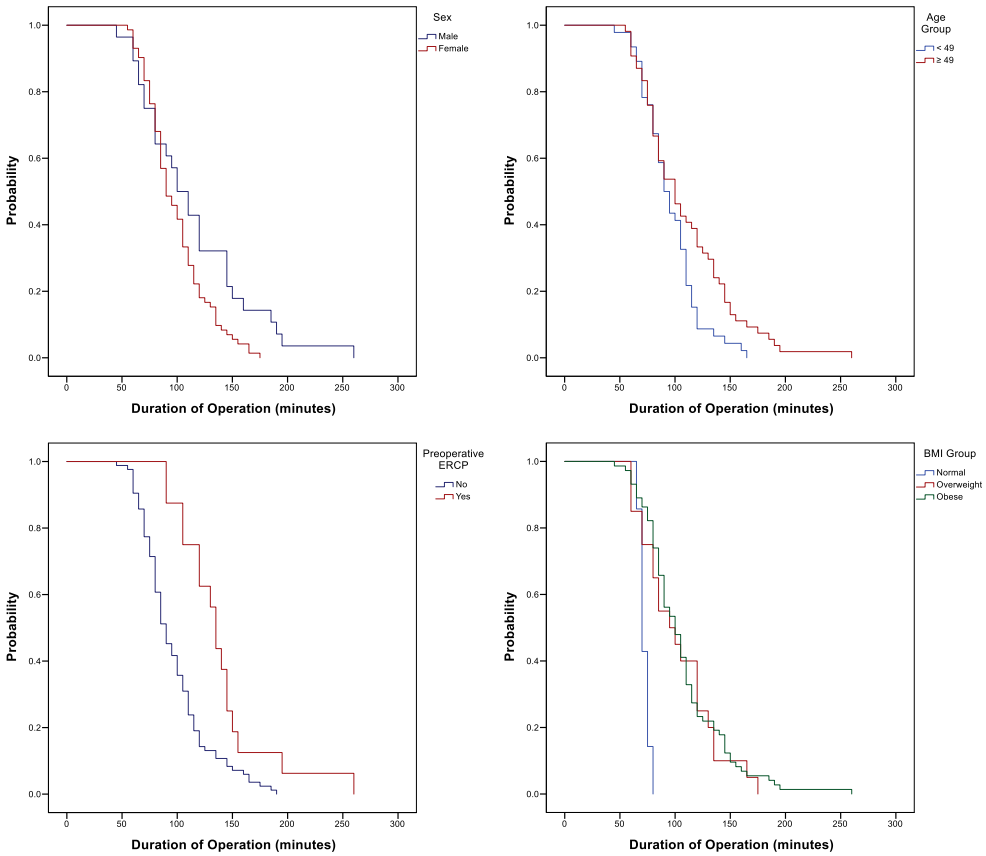

Fig. 1 Kaplan-Meier plot demonstrating duration of operation (minutes) grouped by **a** sex, **b** age, **c** previous ERCP and **d** BMI

Table 1 Univariate analysis of factors influencing duration of operation. Variables in italics were found to be statistically significant (p < 0.05).

	Chi^2	*df*	Sig.
Surgical setting	–	–	–
1st Surgeon	1.244	2	.537
2nd Surgeon	1.595	4	.810
Sex	*5.152*	*1*	*.023*
Age	*86.902*	*42*	*.000*
Age group	*4.725*	*1*	*.030*
BMI	*77.143*	*29*	*.000*
BMI group	*19.613*	*2*	*.000*
Diabetes	.476	1	.490
Smoking	*5.103*	*1*	*.024*
Hypertension	.449	1	.503
Renal failure	–	–	–
COPD	–	–	–
Pregnancy	–	–	–
Prior operation	–	–	–
Alcohol	–	–	–
Hb	.306	1	.580
WCC	2.547	1	.110
Platelet	4.616	2	.099
Neutrophils	.810	1	.368
Sodium	–	–	–
Potassium	–	–	–
Urea	.166	1	.684
Creatinine	.049	1	.825
Total protein	3.411	1	.065
Albumin	.170	2	.919
Bilirubin	*8.047*	*1*	*.005*
ALP	.551	1	.458
ALT	.003	1	.959
PT	–	–	–
APTT	–	–	–
Thickened GB wall	.053	1	.819
CBD dilatation	–	–	–
HD dilatation	–	–	–
Pre-op ERCP	*11.850*	*1*	*.001*
ASA grade	.096	2	.953

Table 2 Multivariate analysis of factors influencing duration of operation

	Hazard ratio		95% CI	*p* value
Age	.470	.261	.848	.012
Sex	1.755	1.062	2.901	.028
ERCP	.434	.242	.779	.005
BMI				
Normal		Reference group		
Overweight	.245	.095	.631	.004
Obese	.201	.085	.480	.000

Table 3 Pre-operative grading system for laparoscopic cholecystectomy

		Score
Sex	Female	0
	Male	2
Age	< 49	0
	> 49	2
Previous ERCP	No	0
	Yes	2
BMI	18.50–24.99	1
	25–29.99	4
	≥ 30	5
Scoring classification	Grade 1 = 1–4	
	Grade 2 = 5–8	
	Grade 3 = > 8	

significant between males and females (mean: 109.21 and 76.17 min, respectively, $p = < 0.01$), but not between those with previous ERCP ($p = 0.58$) or previous abdominal surgery ($p = 0.82$). Finally, there was a positive correlation between our scoring system and length of stay (0.40).

Data was analysed on all 100 patients for each of the above parameters except for CRP which was carried out for 70 patients as the remainder of the patients did not have a pre-operative CRP. Furthermore, one patient was excluded from analysis who had 17 admissions to hospital; this was considered an outlier.

Discussion

Our results have shown that male gender, advancing age, high BMI and previous ERCP are significantly associated with increased duration of operation. Patients who smoke and those with high bilirubin levels were found to be significantly associated with a shorter duration of operation. There was no

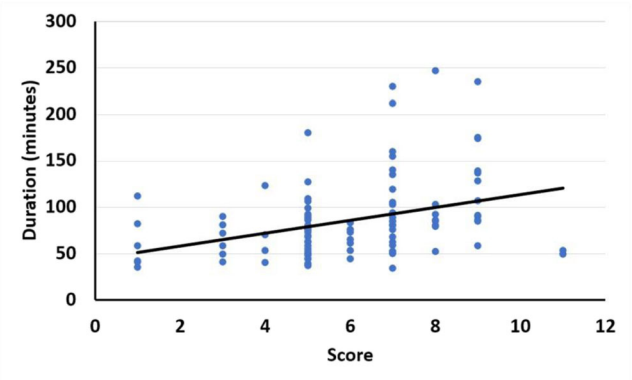

Fig. 2 Correlation between calculated score (based on sex, age, previous ERCP and BMI) and duration

significant association found between any of the remaining collated 28 pre-operative variables. The multivariate analysis using a COX regression model has shown that these six variables demonstrate strong associations in a multivariate model. The identification of hazard ratios for each variable has allowed for the proposal of a simple to use preliminary grading system.

Preliminary results from our prospective multi-site study suggest a positive correlation between this scoring system (incorporating age, sex, BMI and ERCP) and duration of surgery, a surrogate marker used to predict the difficulty of the laparoscopic cholecystectomy. Furthermore, previously observed differences in duration of surgery between male and female patients have been validated.

Such an understanding of pre-operative difficulty is essential in providing the surgeon with accurate information thus improving informed consent to patients at highest risk, predicting those who may need conversion to open surgery, selecting appropriate cases for trainees based on grade, planning of service delivery and overall improving patient outcomes and safety.[7,13,16,18,19]

Our study validates those findings in previous work that sex, age, previous ERCP and BMI are associated with increased technical difficulty of laparoscopic cholecystectomies. Operating on male patients, the surgeon may encounter increased inflammation and fibrosis resulting in a more difficult anatomical dissection.[4] Elderly patients are more likely to have longstanding disease with a higher likelihood of complicated biliary tract disease, coupled with several co-morbidities, making the procedure more difficult to perform.[8,9] A higher BMI has been suggested to cause difficulty due to troublesome manipulation of surgical instruments in a thicker abdominal wall and excessive intraperitoneal fat making optimal access more problematic.[8] Although ERCP in itself does not cause any technical difficulty, it has been suggested that the primary pathology of these patients and more complex biliary tract disease may contribute to a difficult procedure.[12] Smoking history and higher bilirubin levels in our study were oddly found to be associated with a shorter duration of operation which could not be logically explained and excluded from the scoring system.

Numerous studies have attempted to design tools to predict difficulty of laparoscopic cholecystectomy. Despite this, there is currently no validated scoring system that is universally accepted or in common use among surgeons. Fried et al. suggested incorporating age, sex, acute cholecystitis, obesity and thickened gallbladder wall as predictors of conversion.[7] Whereas *Kama* et al. suggested that as well as these factors (excluding obesity), previous abdominal surgery is a further parameter that would be useful in predicting conversion.[4] Other studies have included biochemical markers in their scoring systems including WCC, CRP and fibrinogen.[13,16,20] Our results are in agreement with several of these factors. Our scoring system may benefit from adjustments based on our prospective pilot work. This may include the removal of previous ERCP and the addition of WCC and CRP. This would need to be assessed in a further prospective study with a larger sample size.

We recognise the various limitations to our study namely being a small sample size of 100 patients in each of the cohorts. The decision to analyse 100 patients in each cohort was purely pragmatic to explore the possibility of devising such a system in the shortest period accepting the limitation imposed by the small number of cases included. This may explain the finding that raised bilirubin and smoking both decreased the duration of operation; an adequately powered study would need to be performed to eliminate both type I and type II errors. And although the principle surgeon and assistant surgeon were identified for all procedures, one could argue that cases that appeared difficult may have been immediately taken over by the most senior surgeon and hence may have contaminated our findings. The ACS NSQIP worksheet is designed for use in a database system for which information is collected on a population-based scale. Thus, the majority of variables collected ultimately became redundant when applied to our patients undergoing laparoscopic cholecystectomy. Our scoring system does not differentiate between patients who score similarly but in different categories, for instance, would a female patient under the age of 49, with no previous ERCP and a BMI of 37 (total score = 5) be considered as difficult as a male patient aged 45 with previous ERCP and BMI of 23 (total score = 5)?

Conclusion

Our retrospective work has identified four pre-operative variables that predicted a longer duration of surgery and presumed to reflect a more difficult procedure. Preliminary results from our prospective multi-site study suggest a positive correlation between this scoring system (incorporating age, sex, BMI and ERCP) and duration of surgery. Modifications to our current scoring system have been suggested based on these results and these would need to be validated in an adequately powered prospective multi-site study. This would become an essential tool in planning service delivery and improving patient outcomes.

Author's Contribution We can confirm that all authors have been involved in:

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND- Drafting the work or revising it critically for important intellectual content; AND- Final approval of the version to be published; AND- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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