



PREOPERATIVE PREDICTORS OF DIFFICULT LAPAROSCOPIC CHOLECYSTECTOMY: A TWO-YEAR OBSERVATIONAL COHORT STUDY AT AL-HILLA TEACHING HOSPITAL, IRAQ

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Abstract. Laparoscopic cholecystectomy is the gold standard surgical treatment for symptomatic gallstone disease, but a significant minority of procedures are technically challenging and require either conversion to open operation or completion as subtotal cholecystectomy. Reliable preoperative identification of these cases would facilitate operative planning consent, and theatre scheduling. The goal of this study was to investigate the ability of four commonly accessible preoperative variables (i.e., male sex, advanced age, high body mass index [BMI], and history of upper abdominal surgery) as predictors for difficult laparoscopic cholecystectomy in an Iraqi teaching hospital. An observational cohort study was conducted in Al-Hilla Teaching Hospital from June 2010 to June 2012. Methods: The study was a prospective, randomized trial of 120 consecutive patients undergoing laparoscopic cholecystectomy for gallstone disease. Definition of difficult procedure Difficult procedures were defined a priori as requiring conversion to open cholecystectomy or completion as subtotal cholecystectomy. Data on sex, age, BMI and a history of prior upper abdominal surgery were collected pre-operatively. For categorical comparisons, the chi-square test with Yates continuity correction and the Fisher exact test were used—ORs are associated with 95% CI together with absolute risk differences (RD) and post-hoc power. The Holm method was performed for each of the four pairwise comparisons. The significance threshold for the two-sided p value was 35 kg/m² (20/40, 50.0%, vs. 15/80, 18.8%; OR: 4.33; 95% CI : 1.88–10.00; p < 0.001). All three remained significant after Holm adjustment. In men, a complicated surgery was recorded in 20 of 55 (36.4%), and in women in 15 of 65 (23.1%); the difference favored male sex without reaching significance (OR 1.90, 95% CI 0.86–4.23; p = 0.163), with only a post-hoc power of just over 49%. Since the cohort was limited to patients between 30 and 65 years of age, this comparison actually compares patients aged 61–65 with a much younger group rather than comparing the very elderly with everyone else. Advanced age, history of upper abdominal surgery and degree of obesity (class II) were all independently significantly predictive of a difficult laparoscopic cholecystectomy while male sex exhibited a preferential non-significant trend in an underpowered sample size. All four variables are accessible at the bedside within minutes without any imaging or laboratory testing and will provide a defensible one-pass method of preoperative risk stratification in many resources deprived surgical practice. As this was a univariate analysis, the independence of these associations has yet to be determined.

Keywords: Laparoscopic Cholecystectomy, Conversion to Open Surgery, Risk Factors, Preoperative Care, Obesity, Iraq

Introduction

Gallstone disease is one of the most prevalent digestive tract diseases and a major burden on surgical services internationally. Population-based ultrasonographic studies

estimate the prevalence of cholelithiasis to be around 10–15% in adults in Western countries, with lower rates observed throughout much of Asia and sub-Saharan Africa [1, 2]. Abstract Background Gallstones disease has a complicated etiology but female sex, older age, obesity and rapid weight loss as well as hereditary family history of gallstones are consistently identified risk factors, with the global burden likely rising in parallel to the increasing prevalence of obesity and metabolic syndrome [2, 3].

Since the introduction of laparoscopic cholecystectomy (LC) in the late 1980s and its widespread adoption in the following decade, it has become the treatment of choice for symptomatic gallstone disease [4]. The benefits of the laparoscopic route; less postoperative pain, shorter length of stay, earlier return to work and improved cosmesis are well established. However, a percentage of laparoscopic procedures cannot be converted to a surgical procedure as planned. The severe inflammation, extensive adhesions, fibrosis of Calot triangle & distorted biliary anatomy may prohibit safe dissection requiring the surgeon based on his judgement to either convert to an open procedure or complete the operation as a subtotal cholecystectomy.

The rate at which the conversion takes place is reported to differ widely. Meta-analysis of 30 studies involving over 100,000 patients reported a global conversion rate of 5.9% with individual series ranging from 2.5-50%[5]. A later meta-analysis relating to individual preoperative features illustrated an increase in odds of conversion for male sex, age over 60 years, acute cholecystitis, diabetes and the finding of prior upper abdominal surgery [6]. Conversion in itself is not a complication; it often represents an astute intraoperative decision to prevent injury. However, it is associated with longer operative times, increased blood loss, prolonged hospital stay and cost to the health care system due to increased morbidity, and disrupted theatre scheduling in units with limited capacity.

This has led to many attempts at predicting operative difficulty prior to the patient reaching theatre. Randhawa and Pujahari presented a commonly used score involving age, sex, history of hospitalization, BMI, abdominal scars, a palpable gallbladder [7] and Sonographic findings as well as some groups that validated or rewrote it soon after [8, 9]. Kama et al. devised one of the first early risk scores for conversion from simple clinical and radiographic factors [10], but more recently, larger datasets have allowed for more robust statistically-derived instruments: in particular, the CLOC score derived from 8,820 patients in seven centers across the United Kingdom [11] and a preoperative risk score formulated by Nassar et al. against an objective intra-operative difficulty grading scale [12, 13]. For intraoperative grading systems, standardized outcome definitions required for these predictive models have been provided with the Nassar scale and the ten-point G10 score [13, 14] and related tools developed to specifically predict operative duration as part of scheduling processes [15].

While there is a large literature on predictive models, most have been derived in high-income or large tertiary settings and it is unclear how many would generalize to smaller district and teaching hospitals within the Middle East. Studies from Iraq are sparse; a single cross-sectional study based in Baghdad Teaching Hospital found significant

associations between difficult scoring, gender, BMI and method of admission with a difficult laparoscopic cholecystectomy, making it one of the few Iraqi contributions to this body of literature [16]. Although case mix, referral patterns, the proportion of emergency presentations and the availability of preoperative imaging vary substantially from these settings (in which most scoring systems were developed), local data are critical.

Therefore, this study aimed to evaluate four simple and accessible preoperative factors: male sex, age, body mass index (BMI), and a history of previous upper abdominal surgery for the prediction of difficult laparoscopic cholecystectomy in a consecutive series from patients operated at Al-Hilla Teaching Hospital Babil Province Iraq.

Methods

Study design and setting

Methods This was a prospective observational cohort study of patients presented for laparoscopic cholecystectomy in Al-Hilla Teaching Hospital, Babil Province/Iraq during the period from June 2010 to June 2012. Prospectively recorded predictor variables were measured prior to operation, and outcome data at surgery. All procedures were performed by a consultant surgeon experienced in laparoscopic biliary surgery at a public teaching hospital using one of two protocols that had been initiated in the preceding 3 years at our institution and both for an urban-and-rural catchment population. The study is reported in accordance with the STROBE statement for observational research.

Participants

A total of 120 patients were included. Patients underwent laparoscopic cholecystectomy in the hospital were eligibility for admission determined by gallstone disease on abdominal ultrasonography. Patients were excluded if cholecystectomy was planned as an open procedure or as a component of another major abdominal procedure, or if preoperative diagnosis of gallbladder malignancy had been established. Cases where the open procedure was chosen electively prior to surgery were not counted as conversions. No enrolled patients were later excluded, and for all four predictor variables and for the outcome there were no missing values. The cohort ages ranged from 30 to 65 years; no patient younger than 30 or older than 65 years underwent laparoscopic cholecystectomy for gallstone disease during the study period, or fitted into the eligibility criteria applied.

Preoperative assessment and study variables

They all received a uniform preoperative workup comprising history, clinical examination, routine laboratory investigation and transabdominal ultrasonography. Before the operation, four candidate predictor variables were recorded:

Sex, noted as male or female. Age (in completed years, estimated both continuously and dichotomized at 60 years—the most frequently applied cut-off in conversion literature [6]). Body mass index (BMI) which is defined as weight in kilograms divided by the square of height in meters and dichotomized at 35 kg/m², equating to World Health Organization class II obesity History of previous upper abdominal surgery (defined as any previous operation via an upper midline, right subcostal, epigastric or other supraumbilical incision or any prior laparoscopic upper abdominal procedure), obtained from patient record and validated by abdominal scar inspection.

Definition of a difficult laparoscopic cholecystectomy

Grading of acute inflammation, where present, followed the severity criteria of the Tokyo Guidelines [17, 18]. The primary outcome was a difficult laparoscopic cholecystectomy, defined a priori as a procedure that could not be completed as a standard total laparoscopic cholecystectomy and therefore required either (i) conversion to open cholecystectomy, or (ii) completion as a subtotal (partial) cholecystectomy. Both represent the operative endpoint of a hostile gallbladder in which the critical view of safety could not be attained, and both are recognized bailout strategies intended to avoid bile duct injury rather than technical failures [19, 20, 21].

The two components of the composite outcome were recorded separately and are reported separately in Section 3.1.

Operative technique

Procedure[edit] A standard four-port technique was applied: pneumoperitoneum was achieved by using open (Hasson) access at the umbilicus in cases of previous abdominal scars while otherwise Veress needle. Before dividing any tubular structure, Calot triangle was dissected keeping in mind the critical view of safety [19]. In cases of severe inflammation, fibrosis or adhesions that precluded safe identification of the cystic duct and artery, the operating surgeon advanced with open conversion or subtotal cholecystectomy at his/her discretion.

Statistical analysis

Data were entered into a spreadsheet and analyzed with standard statistical software. For the categorical variables frequencies are shown Absolut in absolute numbers and percentages with Wilson 95% confidence intervals. The associations of each dichotomized predictor with difficult cholecystectomy were evaluated by means of the Pearson chi-square test (with Yates continuity correction); here, since the sizes of some cells in tables for simple contingency were small, confirmatory tests were carried out using Fisher exact test. Effect sizes are expressed as odds ratios with 95% confidence intervals calculated by the Woolf logit method (exact conditional intervals reported alongside for the smaller strata); absolute risk differences are given with normal-approximation intervals. Due to the nature of comparisons, p values were further corrected using Holm step-down for multiple comparisons. For better interpretation of the null result for sex, post-hoc power was calculated at $\alpha = 0.05$ for each comparison. Statistical significance was defined as $p < 0.05$ using all tests being two sided.

No multivariable model was fitted. The dataset would support a four-covariate logistic model with 35 outcome events at about 8.75 events per variable, close to the lower limit of accepted practice; all estimates reported here are therefore unadjusted and this constraint is discussed further in Section 5.

Ethical considerations

All procedures performed were in accordance with the ethical standards of the Helsinki declaration and its later amendments and approved by the ethics committee of Al-Hilla Teaching Hospital (approval number/DATA REQUIRED, date [DATA REQUIRED]). Methods Ethical considerations The study was performed according to the ethical standards of the institutional research committee and declaring Helsinki guidelines (1964, amended in 2000) All individual participants provided clinical informed consent for the operation and anonymized use of their data.

Results

Study population characteristics

For laparoscopic cholecystectomy, the study period involved a total of one hundred and twenty patients. There were 55 (45.8%) males and 65 (54.2%) females, with an approximate ratio of male to female being 1:1.2. Ages varied from 30 to 65 years, meanwhile 40 patients (33.3%) were older than the age of 60 y o. Disease demographics revealed that 40 patients (33.3%) were above a BMI of 35 kg/m², and 25 patients (20.8%) had a prior history of upper abdominal surgery. Table 1 summarizes the baseline characteristics.

Difficult laparoscopic cholecystectomy, either converting to an open operation or completing the laparoscopic surgery as a subtotal cholecystectomy occurred in 35 (29.2%) of the 120 patients; our overall difficult case rate was 29.2% (95% CI 21.8–37.9). Eighty-five patients (70.8%) proceeded to have an uneventful total laparoscopic cholecystectomy.

Table 1. Characteristics of the study population (n=120).

Characteristic	n	%
Total patients	120	100.0
Male	55	45.8
Female	65	54.2
Age range (years)	30–65	—
Age > 60 years	40	33.3
Age ≤ 60 years	80	66.7
BMI > 35 kg/m ²	40	33.3
BMI ≤ 35 kg/m ²	80	66.7
Previous upper abdominal surgery	25	20.8
No previous upper abdominal surgery	95	79.2
Difficult cholecystectomy (overall)	35	29.2
Uncomplicated total laparoscopic cholecystectomy	85	70.8

BMI body mass index. Study period June 2010 to June 2012, Al-Hilla Teaching Hospital, Babil, Iraq.

Sex and operative difficulty

Severe procedure occurred in twenty of fifty-five males with post-menopausal bleeding (36.4%; 95% CI 24.9–49.6) compared to fifteen female patients (23.1%; 95% CI 14.5–34.6). Hence, although the proportion of male patients in the study cohort was only 45.8%, they represented 20 (57.1%) of the 35 difficult cases. The absolute risk difference was 13.3 percentage points (95% CI –3.0 to 29.6), the relative risk 1.58 and the odds ratio 1.90 (95% CI 0.86–4.23; exact conditional CI 0.80–4.58). While the direction of association was in line with published literature, this difference did not reach statistical significance in this sample ($\chi^2 = 1.94$ with Yates correction, $p=0.163$; Fisher exact $p=0.158$). The post-hoc power for this comparison was 36%, indicating that the study had about a one-in-three likelihood of detecting an effect of the size observed, even if it were real. The results are summarized in Table 2.

Table 2. Operative difficulty gender table

Sex	Total (n)	Difficult (n)	Difficult (%)	Not difficult (n)
Male	55	20	36.4	35
Female	65	15	23.1	50
Total	120	35	29.2	85

Odds ratio 1.90 (95% CI 0.86–4.23); risk difference +13.3 percentage points (95% CI –3.0 to 29.6); $\chi^2 = 1.94$ (Yates corrected), $p = 0.163$; Fisher exact $p = 0.158$; post-hoc power 36%.

Age and operative difficulty

Of the 120 patients, 40 (33.3%) were older than 60 years old. Of these, 25 (62.5%; 95% CI 47.0–75.8) were difficult laparoscopic cholecystectomy, compared with ten of the patients aged 60 years or younger (12.5%; 95% CI 6.9–21.5). Age greater than 60 years was the most robust single predictor identified in this cohort, with an absolute risk difference (presumed attributable risk) of 50.0% (95% CI 33.3–66.7), a relative risk of 5.00 and odds ratio of 11.67 (95% CI 4.64–29.31; exact conditional CI: 4.26 to 32.73). Such an association was very strong ($\chi^2 = 29.89$ with Yates correction, $p < 0.001$; Fisher exact $p < 0.001$). Older patients comprised a third of the cohort, yet they accounted for 25 of the 35 difficult cases (71.4%). Of these 25 frail elderly cases, 15 were men and 10 women both sexes carrying the excess risk of older age.

And finally, one aspect of the cohort limits what this estimate can tell us and must be remembered whenever considering the odds ratio of 11.67: since no patient was older than 65 years, patients aged 61–65 years were compared with a group aged 30–60 years; that is, not between frail elderly and all others. Thus the estimate describes not the risk itself but how that risk is distributed across early old age in this population. The results are presented in table 3.

Table 3. Operative Difficulty according to Age

Age group	Total (n)	Difficult (n)	Difficult (%)	Not difficult (n)
> 60 years	40	25	62.5	15
≤ 60 years	80	10	12.5	70
Total	120	35	29.2	85

Odds ratio 11.67 (95% CI 4.64–29.31); risk difference +50.0 percentage points (95% CI 33.3–66.7); $\chi^2 = 29.89$ (Yates corrected), $p < 0.001$; Fisher exact $p < 0.001$. Of the 25 difficult cases aged over 60 years, 15 were men and 10 were women.

Body mass index and surgical difficulty

Forty patients (33.3%) had a BMI > 35 kg/m² which is Class II obesity based on World Health Organization classification system. Of these 40 patients with a BMI of greater than 35 kg/m² and who had difficult or complicated operations, twenty (50.0%; 95% CI 35.2–64.8) experienced a difficult operation compared to fifteen of the eighty patients having a BMI of 35 kg/m² or less (18.8%; 95% CI 11.7–28.7). The absolute risk difference was 31.2 percentage points (95% CI 13.6–48.9), the relative risk 2.67 and odds ratio 4.33 (95% CI 1.88–10.00; exact conditional CI 1.73–10.88), a statistically significant association ($\chi^2 = 11.14$ with Yates correction, $p < 0.001$; Fisher exact $p < 0.001$). Fifty percent of the 20 most challenging difficult cases of the severely obese were men and fifty percent women. Results are given in Table 4.

Table 4. Operative difficulty based on body mass index

Body mass index	Total (n)	Difficult (n)	Difficult (%)	Not difficult (n)
> 35 kg/m ²	40	20	50.0	20
≤ 35 kg/m ²	80	15	18.8	65
Total	120	35	29.2	85

Odds ratio 4.33 (95% CI 1.88–10.00); risk difference +31.2 percentage points (95% CI 13.6–48.9); $\chi^2 = 11.14$ (Yates corrected), $p < 0.001$; Fisher exact $p < 0.001$. Of the 20 difficult cases with a BMI above 35 kg/m², 10 were men and 10 were women.

Past upper abdominal surgery and surgical complexity

A total of 25/120 patients (20.8%) had a history of upper abdominal surgery. Difficult laparoscopic cholecystectomy had a prior history in 15 of these 25 patients (60.0%; 95% CI 40.7–76.6) than in the other, easy group containing only 20 of the remaining 95 patients with such a working past value as that (21.1%; 95% CI:14.1–30.3). This uses an absolute risk difference of 38.9 percentage points (95% CI 18.1–59.8), a relative risk of 2 and an odds ratio of 5.62 (95% CI 2.20–14.40; exact conditional CI 1.99–16.11). The association was highly statistically significant ($\chi^2 = 12.71$ with Yates correction, $p < 0.001$; Fisher exact $p < 0.001$). Almost half (15 of the 35 difficult cases; 42.9%) were related to previous upper abdominal surgery, despite treating patients with previous upper abdominal surgery comprising only one-fifth of the cohort. Results are contained in Table 5.

Table 5. Operative difficulty by prior upper abdominal surgery

Previous upper abdominal surgery	Total (n)	Difficult (n)	Difficult (%)	Not difficult (n)
Yes	25	15	60.0	10
No	95	20	21.1	75
Total	120	35	29.2	85

Odds ratio 5.62 (95% CI 2.20–14.40); risk difference +38.9 percentage points (95% CI 18.1–59.8); $\chi^2 = 12.71$ (Yates corrected), $p < 0.001$; Fisher exact $p < 0.001$.

Summary of predictors

The performance of the four candidate predictors are summarized in Table6 and Figure 7. 1 displays them graphically. Of the four (age > 60 years, previous upper abdominal surgery and a BMI >35 kg/m²), three were independently significantly associated with operative difficulty — age having by far the largest effect size — all remained significant after Holm adjustment for the four comparisons. Male sex demonstrated a consistently directional trend in the same with the published literature but lacked statistical significance at this sample size.

Table 6. Association of Preoperative Factors for the Prediction of Difficult Laparoscopic Cholecystectomy.

Predictor	Difficult rate	Odds ratio (95% CI)	p value	Holm-adjusted p	Power
Age > 60 years	62.5% vs 12.5%	11.67 (4.64–29.31)	< 0.001	< 0.001	100%

Previous upper abdominal surgery	60.0% vs 21.1%	5.62 (2.20–14.40)	< 0.001	0.001	95%
BMI > 35 kg/m ²	50.0% vs 18.8%	4.33 (1.88–10.00)	< 0.001	0.002	94%
Male sex	36.4% vs 23.1%	1.90 (0.86–4.23)	0.163	0.163	36%

CI confidence interval, BMI body mass index. Predictors are ordered by effect size. Unadjusted p values are from the chi-square test with Yates continuity correction; Holm-adjusted values account for the four primary comparisons. Power is post-hoc power at $\alpha = 0.05$ given the observed proportions and group sizes. Absolute risk differences with 95% confidence intervals are: age +50.0 percentage points (33.3 to 66.7); previous upper abdominal surgery +38.9 (18.1 to 59.8); BMI +31.2 (13.6 to 48.9); male sex +13.3 (−3.0 to 29.6). All estimates are univariate and unadjusted for one another.

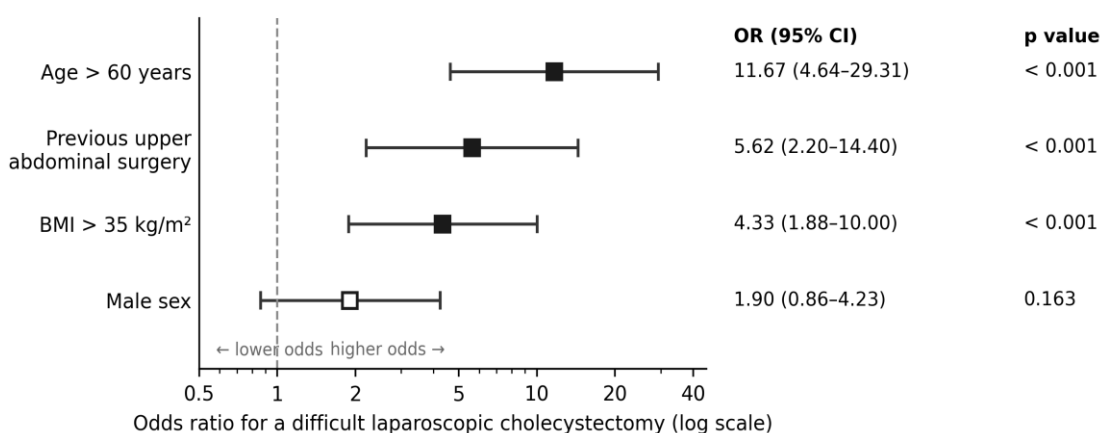


Figure 1. Preoperative predictors of a difficult laparoscopic cholecystectomy (n = 120, 35 events) Solid squares represent confidence intervals that do not include null; the empty square represents male sex, whose interval crosses unity.

Discussion

In this consecutive series of 120 patients undergoing surgery at an Iraqi teaching hospital, essentially three-in-ten laparoscopic cholecystectomies were difficult enough to require conversion to an open procedure or completion as a subtotal cholecystectomy. Three of the four preoperative factors evaluated demonstrated a statistically significant association with degree of operative difficulty. Age over 60 years was nearly twelve times and previous upper abdominal surgery greater than five times, while class II obesity increased the odds of an onerous operation by more than fourfold. Male sex was consistently but not statistically significantly associated with an increased difficulty rate (resulting in a wider confidence interval), compared with the larger literature.

Overall difficulty rate

The meta-analysis by Chin and colleagues [5] showed a pooled conversion rate of 5.9%, which is significantly lower than the more favorable overall difficulty rate of 29.2% here, but

comparisons must be made cautiously. The definition of review eventually only included conversion to open surgery in that study whereas present definitions also included subtotal cholecystectomy, a bailout maneuver which has been gaining attention as converting to open is known to increase morbidity [20, 21]. This cohort reported a conversion-only rate of [DATA REQUIRED]% patient, not 29.2%, which is directly comparable with the pooled estimate from our systematic review.

In fact, series defining difficulty by intraoperative grading rather than by conversion alone report figures much closer to ours, and studies applying the Nassar grading scale have classified a large minority of operations as grade 3 or more [12, 13]. Using a preoperative scoring system in the Ghadhban series, 58% of patients scored within the difficult range, and 7% at very difficult [16], close to what one would expect for complex biliary disease presented for surgical management in Iraq. This study also carried particular relevance given that it was performed between 2010 and 2012; a time during which institutional experience with laparoscopic biliary surgery was still early, thresholds for conversion were relatively low.

Age

In this cohort, the best predictor was age >60 years which had a large effect size — older patients were difficult to operate on in 62.5% of cases compared with 12.5% in younger patients (odds ratio = 11.67). This is greater than the pooled estimate of 4.32 from the meta-analysis by Magnano San Lio and colleagues [6] and the approximately twofold to threefold increases summarized by analyses of elderly cohorts [22, 23]. Some of this difference is definitional, as the current outcome encompasses subtotal cholecystectomy with conversion; some reflects the age structure of the cohort which faced an upper limit of 65 years, meaning that patients in their early sixties were compared to a substantially younger group rather than the very elderly and everyone else, emphasized further in Section 3.3 as it limits transportability of the estimate.

Nonetheless, the mechanisms are described well. Chronic fibrosis, a contracted thick-walled gallbladder and obliteration of the tissue planes in Calot triangle is produced by repeated subclinical attacks of cholecystitis over a lifetime; comorbidity limits many from tolerating prolonged pneumoperitoneum; and older patients more often present acutely rather than electively. The dominance of males (15/25) in the elderly difficult cases is in agreement with the high-risk profile associated with acute cholecystitis by Chin et al [5], but cannot indicate whether age and gender are independent.

Previous upper abdominal surgery

Operative difficulty was associated with a history of previous upper abdominal surgery (OR 5.62; p 70% had adhesions based on laparoscopic findings; moreover after previous upper abdominal surgery, 46.6% the subsequent conversion rate was 19% versus only 5.4% in those without prior operations, and more than 75% required adhesiolysis [24].

This finding needs the right context. So a high odds ratio for difficulty is not an argument to deny patients laparoscopic access. By comparing 277 patients with or without past upper abdominal surgery, Katar and Ersoy found substantial increases in operative times and adhesion density in the previous-surgery group but a similar rate of complications, conversion to open surgery, and length of stay versus no serious burden from prior surgical history that should not be considered a contraindication [25]. It is preparation, not exclusion: open (Hasson) access, modified port placement, sufficient operative time and the presence of a surgeon skilled in adhesiolysis and bailout techniques. The same argument can be made for

patients who have had a preoperative endoscopic retrograde cholangiography, where the subsequent cholecystectomy is demonstrably more challenging [26].

Body mass index

Body mass index more than 35 kg/m² were identified in 50.0% of the cohort as "difficult" compared with only 18.8% of rest of the group (odds ratio 4.33; $p < 0.001$). Obesity is an inherently intuitive cause of technical challenge: increased intra-abdominal and omental fat obscures anatomy, hepatomegaly and a fatty liver mitigate fundus retraction, the thickness of abdominal wall limits instrument working length and angulation; exposure of Calot triangle is thus harder to achieve and maintain. But the published proof, though, is right down the middle. Obesity has been found to have increased odds for conversion [6] and BMI forms part of the Randhawa and Pujahari scoring system [7] as well as several validated scores [8, 27]. In contradiction to this, several large series have recently been published demonstrating that increasing BMI significantly increased operative time without increasing conversion or complication rates and concluded that obesity alone should not be considered a contraindication to laparoscopic access [28, 29].

Two characteristics of the current analysis may explain why a positive association appeared in this case. T1:34 kg/m² threshold is also high compared with 25–27.5 kg/m² cut-offs in multiple accepted scoring systems, meaning that this analysis compares a severely obese subgroup to the remainder of cohort rather than performs a general test for impact; many studies failing to find an effect often dichotomies at 30 kg/m². Second, the endpoint a subtotal cholecystectomy and exposure difficulty may lead to retention of the posterior gallbladder wall in point without conversion to open. The result thus should be interpreted as showing that extreme obesity is a risk factor for the technical challenges of the operation, but not worse outcome.

Male sex

In this cohort men comprised over the half of difficult operations to a much greater extent (57.1% of difficult cases from 45.8% of population). The lack of this difference even approaching conventional significance is optimally interpreted as a ceiling on statistical power rather than evidence for null effects: post-hoc power to discern an effect of the observed size with 55 men and 65 women was 36%. Most recently, the meta-analysis by Magnano San Lio et al. presented a pooled odds ratio for conversion of 1.91 in men [6] — almost exactly coinciding with the point estimate obtained here (1.90) and, similarly to systematic reviews of Chin et al. The authors also recognized male sex as an important preoperative risk factor [5]. Several explanations have been offered. Men have later presentation with more advanced disease; evidence suggests gallbladder inflammation is worse in men at the time of presentation [30]; and denser adhesions, as well as greater anatomical difficulty had been documented intra-operatively in male patients [22]. Not all series agree, however. In a single-surgeon series, Al-Mulhim found no difference between sexes in conversion rate, complication rate or operative time; however postoperative stay was longer in males [31]. Our data are consistent with a genuinely present but modest male bias in operative difficulty that possesses inadequate power to empirically establish based on a study of this size.

Clinical implications

The importance of preoperative prediction is that we do not need to avoid difficult operations but to prepare for them. In a patient with one or more of the recognized risk factors detailed here — particularly in this cohort, where elderly/phlegmatic/severely obese/upper abdominal scar all coincide — some practical considerations arise. The case must be given to an

experienced surgeon (and not a training case) and booked for realistic operative time rather than at the end of a busy list [15, 32]. The issue of conversion or subtotal cholecystectomy should be specifically dealt with in the consent document, as a discussion that occurs pre-operatively is much better than an explanation postoperatively. The surgical team should plan to give-up the critical view of safety Find a method or behavior early rather than late, and that failure of finding the critical View are predictable in advance from preop variables [33] [34]. Timely conversion to subtotal cholecystectomy will greatly reduce bile duct injury risk at the cost of only modest increase in bile leak / reoperation rate [20] 21}} Lastly, at centers where index-admission laparoscopic cholecystectomy is being incorporated as a service for biliary emergencies, risk stratification of this type is paramount to the safe design of services [35]. There is a specific attraction for a hospital in a resource-poor environment with the variables investigated here: sex, age, BMI and previous upper abdominal surgery can be assessed directly at bed-side, within minutes of obtaining imaging or laboratory testing or scoring calculator. While they cannot supplant standardized instruments like the Randhawa and Pujahari score [7] or CLOC score [11] that include demonstrated value sonographic variables, they offer an justifiable first-pass triage in settings where such workup is not regularly performed.

Limitations

Several limitations must be acknowledged

The sample of 120 patients is small, and the study was therefore underpowered for associations of the magnitude published elsewhere in males; post-hoc power for that comparison was 36% and all four odds ratios are surrounded by wide confidence intervals. Second, this was a single-center study and its results may not generalize to institutions with different case mix or surgical experience.

Third, multivariable analysis was not performed and independence of observed effects cannot be established. This wonkery has a material constraint—there is clearly clustering of risk factors: 15 of 25 elderly difficult cases were men, and univariate testing cannot disentangle the relative contributions of age, sex, obesity and previous surgery. The model would therefore need to be a logistic regression including all four variables, and the present sample of 35 events (8.75 events per variable) is at or below the lower limit on what such a model supports; penalized (Firth) estimation would be appropriate.

Fourth, we did not ascertain whether each operation was elective or done on an acute admission. Acute presentation is one of the strongest predictors for operative difficulty and also correlated highly with age and sex, so its omission may explain at least some of the associations described here.

Fifth, a number of variables had established predictive value but were not collected including gallbladder wall thickness on ultrasonography, pericholecystic fluid, an impacted stone in Hartmann pouch, previous hospitalization for acute cholecystitis and C-reactive protein—all with strong emphasis in validated scoring systems [7, 11, 28, 36].

Sixth, no standardized intraoperative difficulty grading scale was utilized; the binary outcome of conversion or subtotal cholecystectomy is a crude proxy for a graded construct and further work at this institution should adopt the Nassar or G10 scoring systems to facilitate direct comparison with global literature [13, 14]. Data were recorded on the two components of the composite outcome, but they were not analyzed separately and predictors for conversion to open surgery and subtotal cholecystectomy may differ.

Finally, the study period (2010 to 2012) is now in the past. The four exposures examined are patient characteristics that are time-invariant; their biological relationship to operative difficulty is unlikely to have changed, and the cohort holds documentary value as a record of practice at the wavefront of institutional adoption of laparoscopic biliary surgery. However, the timeframe predates the recognition of subtotal cholecystectomy as a formal bailout strategy [20, 37], and current conversion thresholds (at this and other institutions) will be distinct; thus the absolute difficulty rate reported herein should not be interpreted as a contemporary benchmark.

Conclusion

Sonographic variables, multivariable modelling and a formal intraoperative difficulty grading scale are needed in larger prospective studies to develop and validate an applicable predictive score locally.

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