A risk score to predict the difficulty of elective laparoscopic cholecystectomy

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Abstract

Introduction: *Several preoperative scoring systems have been proposed to predict the difficulty of laparoscopic cholecystectomy in order to optimize the results of surgical treatment by either selection of patients for the procedure or providing an adequately experienced surgical team for a given patient. Nevertheless, none of them has achieved significant penetration into everyday practice.*
Aim: *To propose and validate a novel risk score based on the patient's history, physical examination and abdominal ultrasonography parameters.*
Material and methods: *The risk score was defined by the presence of the following risk factors: male sex, biliary colic within the last 3 weeks prior to surgery, history of acute cholecystitis treated conservatively, previous upper abdominal surgery, right upper quadrant pain, rigidity in right upper abdomen and ultrasonographic parameters – thickening of the gallbladder wall ≥ 4 mm, hydropic gallbladder (diameter exceeding 4.5 cm) and shrunken gallbladder. One point was allocated for each risk factor, except for previous upper abdominal surgery, which scored two. Difficulty of the surgery was assessed by operating time (OT) and the postoperative subjective evaluation score (PSES).*
Results: *Five hundred and eighty-six consecutive patients were enrolled in the prospective observational study. A significant linear correlation was observed between the risk score and measures of difficulty employed. Five levels of difficulty were defined (score 0, 1, 2, 3, ≥ 4) with significant differences in OT, PSES and conversion rates ($p < 0.001$).*
Conclusions: *The suggested risk score is designed as a simple and reliable predictive model, possibly effective to overcome the negative effect of the individual proficiency gain curve and/or to select 'easy' cases for day surgery, single incision laparoscopic surgery or natural orifice translumenal endoscopic surgery procedures.*

Key words: *laparoscopic surgery, cholecystectomy, conversion, one-day surgery, single incision laparoscopic surgery, natural orifice translumenal endoscopic surgery.*

Introduction

Since its introduction, laparoscopic cholecystectomy has aimed at improving the results of traditional surgical treatment. Compared to its open counterpart, the laparoscopic procedure provides several significant advantages, generally based on the reduced surgical access trauma. Obviously, if conversion is necessary for whatever reason, the benefit of the minimal access concept is lost. Therefore, every effort should be made to increase the probability of successful completion of the laparoscopic procedure to be attempted.

The outcome of surgical treatment itself depends on the relation between the difficulty of the given task and the ability of the operating team to accomplish it. As such, two fundamental strategies are available to optimize the results – either selection of

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the patient for a given procedure or selection of the surgical team for a given patient. While selection of the patient for laparoscopic or open surgery helps to overcome limited experience with the procedure at the institutional level, selection of the surgical team allows one to address the issue of the individual proficiency gain curve. Successful prediction of difficulty of elective laparoscopic cholecystectomy could therefore be an important factor making it possible to achieve optimal therapeutic results.

Any selection process is dependent on the assumption that the difficulty of the procedure can be assessed preoperatively with high accuracy. Such assessment should ideally be simple to perform, reliable, reproducible and cost-effective. Although several predictive scoring systems have been proposed by different authors, none of them has gained significant acceptance within the general surgical community so far [1–7].

Aim

The aim of the study is to validate a newly proposed preoperative scoring system predicting difficulty of elective laparoscopic cholecystectomy based on the patient's history, physical examination and abdominal ultrasonography parameters.

Material and methods

All consecutive patients undergoing elective laparoscopic cholecystectomy due to symptomatic or complicated gallstone disease in a tertiary center over a 2-year period were enrolled in the prospective observational study. Patients scheduled for acute laparoscopic cholecystectomy for acute cholecystitis or indicated for a primary open procedure were not included.

The standardized 3-port technique (2 × 10 mm, 1 × 5 mm) of laparoscopic cholecystectomy was executed, with optional insertion of a fourth port (5 mm) in order to facilitate achieving the critical view of safety concept, the patient and operating team being positioned in the American style. Monopolar electrocautery was used as the hemostatic modality. The cystic duct and cystic artery were divided sharply with scissors in between the clips. Intraoperative cholangiography as well as subhepatic space drainage was performed on a selective basis.

Analysis of available literature data along with the primary research published previously [8] was used to identify relevant preoperative risk factors increasing the difficulty of elective laparoscopic cholecystectomy, yielding 9 parameters: male sex, biliary colic within the last 3 weeks prior to surgery, history of acute cholecystitis treated conservatively, previous upper abdominal surgery, right upper quadrant pain, rigidity in right upper abdomen and selected ultrasonographic parameters – thickening of the gallbladder wall ≥ 4 mm, hydropic gallbladder (diameter exceeding 4.5 cm) and shrunken gallbladder. Consequently, the risk score of difficulty was calculated for every particular patient by simple allocation of points according to the presence of the given risk factors (Table I). All the data were collected and stored by an independent researcher prior to surgery to avoid possible bias.

In order to assess the difficulty of the procedure, objective and subjective measures were employed. Operating time, defined as the time interval from skin incision to skin suture, was selected as an objective measure and recorded in minutes by an observer independent from the surgical team. Postoperative subjective evaluation score, defined as an integral value from 0 (no problems) to 4 (conversion), was defined as a subjective measure and recorded by the operating surgeon, blinded to the risk score of difficulty value.

Statistical analysis

All the data were subsequently statistically analyzed to detect a possible significant correlation between the risk score of difficulty value and ob-

Table I. Calculation of the risk score of difficulty

Parameter	Points
Patient's history:	
Male sex	1
Biliary colic within last 3 weeks	1
History of acute cholecystitis in the past	1
Previous upper abdominal surgery	2
Physical examination:	
Right upper quadrant pain	1
Rigidity in the right upper abdomen	1
Abdominal ultrasound:	
Gallbladder wall thickening ≥ 4 mm	1
Hydropic gallbladder (diameter > 4.5 cm)	1
Shrunken gallbladder	1

jective/subjective measures employed to assess the difficulty of the procedure. Statistical methods used included simple linear regression, analysis of variance and the Tukey-Kramer method.

Results

Five hundred and eighty-six patients underwent elective laparoscopic cholecystectomy during the study period, 430 females (73.37%) and 156 males (26.63%) with mean age 50.31 ±13.07 (19–85) years. Mean operating time was 59.87 ±24.61 (20–205) min. Conversion was necessary in 3.41% (20 cases). The mean postoperative subjective evaluation score was 0.93 ±1.02 (0–4), and the mean risk score of difficulty was 0.92 ±0.97 (0–5).

Simple linear regression analysis confirmed a strong linear correlation between operating time and postoperative subjective evaluation score ($p < 0.01$, $r = 0.837$), postoperative subjective evaluation score and risk score of difficulty ($p < 0.001$, $r = 0.915$) and operating time and risk score of difficulty ($p < 0.01$, $r = 0.757$). As such, both objective and subjective measures of difficulty correlated with each other as well as with the proposed predictive risk score of difficulty.

Furthermore, analysis of variance and the Tukey-Kramer method revealed a strong correlation between the integral values of the risk score of difficulty and operating time, postoperative subjective evaluation score and conversion rate (Table II). Therefore, the predictive value of the risk score of difficulty was validated (Table III).

Table II. Validation of the risk score of difficulty

Risk score	Operating time [min]	Postop. subjective evaluation score	Conversion (%)
0 ($n = 237$)	44.19 ±11.17	0.04 ±0.24	0
1 ($n = 214$)	58.15 ±13.59	1.0 ±0.45	0.47
2 ($n = 91$)	80.44 ±21.53	2.08 ±0.52	5.49
3 ($n = 36$)	107.9 ±30.36	2.86 ±0.68	16.67
≥ 4 ($n = 8$)	120 ±12.25	4.0 ±0.00	100
Value of p	< 0.001	< 0.001	< 0.001

Table III. Predictive value of the risk score of difficulty

Value	Description of difficulty of the procedure
0	Easy surgery, no problems
1	Some minor problems, not serious
2	Difficult operation, serious problems
3	Very difficult surgery, close to conversion
≥ 4	Conversion

Discussion

During the early era of minimal access surgery, laparoscopic cholecystectomy would be indicated for selected group of patients as a result of limited institutional and individual experience with the procedure. Nevertheless, similar to any newly introduced effective therapeutic option, there was a trend towards broadening of the indications over time. The vast experience with laparoscopic surgery nowadays, along with the substantial technological progress, has made laparoscopic cholecystectomy the current gold standard, with exceptionally good results and almost universal indication, even in very complex cases [9, 10]. Therefore, the issue of predicting the difficulty of the procedure to serve as the basis for the selection process may seem irrelevant. No doubt, such an assumption can be considered true with respect to institutional experience, but the problem of individual experience still persists. The risk of a negative impact of the proficiency gain curve on therapeutic results remains real despite the possibility to modify its influence at the individual level by modern simulation and training modalities [11]. Hence, the possibility to select an adequately experienced surgical team for a given patient may still play an important role. Furthermore, even the selection at the institutional level is becoming more and more relevant again due to introduction of new surgical access strategies such as single incision laparoscopic surgery (SILS) and/or natural orifice translumenal endoscopic surgery (NOTES) techniques [12].

Designing reliable models predicting the difficulty of laparoscopic surgical procedures is a complicated process that often fails to achieve satisfactory results [13]. Although the reasons are multifactorial, one of the key issues is proper identification of the independent risk factors to be considered. This process is significantly influenced by definition of the primary end-point. Several authors based their scores on conversion as the predicted value [3, 4],

probably under the impression that converted cases are those that indicate room for improvement. Conversion, however, is relatively infrequent, only defined in a binary fashion (yes/no) and confounded by several parameters other than difficulty of the procedure. Therefore, it seems more appropriate to use difficulty of the surgery as a reference since it is defined as a continuous parameter with a given value for every patient [1, 2, 5–7]. The second issue is the scope of the predictive model, because laparoscopic cholecystectomy can be indicated for a heterogeneous group of pathologies, including some very different entities – for example an elective procedure due to symptomatic gallstones versus acute cholecystectomy due to acute calculous cholecystitis [1]. Last but not least is the nature of the risk factors to be used in the model, which may be easily confounded (e.g. fever, white blood cell count, obesity, age) [1–7], difficult to assess (e.g. cystic duct length, intraperitoneal adhesions) [2, 7] or obsolete (e.g. preoperative cholangiography) [1].

To overcome the above-mentioned problematic issues of the previously published predictive systems, a novel risk score was suggested to predict the difficulty of elective laparoscopic cholecystectomy, based on 9 preoperative variables derived from the patient's history, physical examination and abdominal ultrasonography. Such a simple construction offers the anticipated advantage of universal applicability, reproducibility and cost-effectiveness. Some criticism may be raised to a certain extent with regards to objectivity of assessment of certain parameters (e.g. right upper quadrant pain, rigidity in the right upper abdomen), but this kind of possible bias is almost unavoidable in healthcare.

The proposed risk score of difficulty proved to be in significant correlation with the difficulty of the procedure. With an increasing score, surgery was perceived as more difficult by the operating surgeon and took longer, with a higher risk of conversion. Based on the statistical analysis of the data, five degrees of difficulty of elective laparoscopic cholecystectomy were defined, with a similar impact on selection of an adequately skilled surgical team, as described by Schrenk *et al.* [1]. Cases scoring 0 or 1 can be predicted as 'easy', with the conversion rate close to zero, and as such, ideal whenever an uneventful procedure is desirable (e.g. inexperienced surgeon, day surgery, SILS or NOTES techniques). On the other hand, a risk score of 4 or more suggests a conversion rate close to 100% and therefore may be the reason for primary open surgery or postponing the procedure if any of the positive risk factors are modifiable with time. Also of note, the risk score could only predict 40% of conversions in our series, which supports the opinion that conversion as an end-point is not the best available measure for predictive models.

Application of the risk score also appears to offer much more precise information about the risk of conversion compared to mean values. While the mean conversion rate for the whole series was 3.41%, for risk scores of 0, 1, 2, 3 and 4 it appeared to be 0, 0.47, 5.49, 16.67 and 100%, respectively. Based on these data, it can be concluded that the mean conversion rate has low accuracy for a particular patient. Similar conclusions apply to the length of operating time. Linear correlation between the risk score of difficulty and operating time allows calculation of the expected length of surgery according to the formula: operating time (min) = 19.28 × risk score + 42.19, which may have implications for operating room time planning.

As for the limitations of the study, it should be pointed out that external validity of the score is yet to be confirmed. Larger patient sample sizes in the multicenter prospective design are necessary to validate the suggested predictive model within the external environment. Also of note, the score is not valid for acute cholecystitis.

Conclusions

The suggested novel risk score to predict the difficulty of elective laparoscopic cholecystectomy is designed as a simple and reliable model based on fundamental parameters derived from the patient's history, physical examination and abdominal ultrasonography. Based on the score, five levels of difficulty can be defined that correlate with the subjective perception of difficulty by the operating surgeon, length of the procedure and conversion rate. This is particularly useful in situations when either ensuring an adequately experienced surgical team or selection of the appropriate patient is necessary. Therefore, the score seems to be an effective tool to overcome the negative effect of the individual proficiency gain curve and/or to select the most suitable patients for day surgery, SILS or NOTES procedures.

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