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ORIGINAL ARTICLE

Preoperative risk factors for conversion from laparoscopic to open cholecystectomy: a validated risk score derived from a prospective U.K. database of 8820 patients

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Abstract

Background: Laparoscopic cholecystectomy is commonly performed, and several factors increase the risk of open conversion, prolonging operating time and hospital stay. Preoperative stratification would improve consent, scheduling and identify appropriate training cases. The aim of this study was to develop a validated risk score for conversion for use in clinical practice.

Patients and methods: Preoperative patient and disease-related variables were identified from a prospective cholecystectomy database (CholeS) of 8820 patients, divided into main and validation sets. Preoperative predictors of conversion were identified by multivariable binary logistic regression. A risk score was developed and validated using a forward stepwise approach.

Results: Some 297 procedures (3.4%) were converted. The risk score was derived from six significant predictors: age ($p = 0.005$), sex ($p < 0.001$), indication for surgery ($p < 0.001$), ASA ($p < 0.001$), thick-walled gallbladder ($p = 0.040$) and CBD diameter ($p = 0.004$). Testing the score on the validation set yielded an AUROC = 0.766 ($p < 0.001$), and a score >6 identified patients at high risk of conversion (7.1% vs. 1.2%).

Conclusion: This validated risk score allows preoperative identification of patients at six-fold increased risk of conversion to open cholecystectomy.

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Introduction

Laparoscopic cholecystectomy is the gold standard treatment for symptomatic gallstones. Conversion to an open procedure is necessary in 5–10% of patients, and is associated with increased morbidity, prolonged hospitalization and longer recovery compared to a laparoscopic approach.[1–4] Common indications for conversion include failure to demonstrate the 'critical view of safety',[1,2,5,6] or the presence of an intraoperative complication, such as intestinal perforation, haemorrhage or bile duct injury. Several factors increase the risk of conversion to open, including age,[4] male sex,[3,7] obesity,[1,2] cholecystitis[2,3,7] and previous ERCP.[8] Conversion to open surgery usually indicates a difficult procedure, and rather than being considered a complication, the decision to convert should be regarded as a sign of good judgement in the presence of adverse conditions.

Preoperative prediction of patients at increased risk of conversion to open cholecystectomy has several potential advantages. Low risk patients could be identified and appropriately scheduled in an ambulatory care facility, and selected as training

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cases for surgical trainees,[9] whilst high risk patients should be appropriately counselled and operated by experienced surgeons. The majority of studies that have evaluated risk factors for conversion to open cholecystectomy are small retrospective series or population-based databases[1–4,6,7,10–14] (Table 1). Several studies have developed risk scores, but their clinical utility is limited by retrospective data, small sample sizes and/or lack of validation. The aim of this study was to develop and validate a preoperative risk score to predict conversion from laparoscopic to open cholecystectomy, using data derived from a large, prospective cholecystectomy database of 8820 patients.[15]

Patients and methods

Data for this study were derived from the CholeS study, a multicentre, prospective population-based cohort study of variation of cholecystectomy.[15] Data was collected from 8820 patients who underwent laparoscopic cholecystectomy in 166 hospitals across the UK, during a two-month period from March to April 2014, and has been found to be 99.2% accurate by independent data validation.[16] Data was collected prospectively by surgical trainees, who formed a network of surgical research collaborative groups across the UK. Data regarding postoperative follow-up was obtained by review of medical records, including outpatient attendances or hospital readmissions up to 30 days postoperatively. Preoperative variables included patient demographics, indications for surgery, ASA grade, admission type, ultrasound findings and preoperative endoscopic retrograde cholangiopancreatography (ERCP). Operative data were also gathered prospectively, and surgeons were asked to grade the difficulty of the procedure using the Nassar scale (grades 1–4).[17] Duration of surgery was calculated from time (minutes) of skin incision to end of skin closure. 30-day follow-up was obtained for all patients and included rates of morbidity and mortality. All cause 30-day morbidity included bile leak, bile duct injury, wound infection, intra-abdominal collection, pancreatitis, bile duct stones, as well as non-surgical complications such as cardiac, respiratory, urinary and other complications. Bile duct injury was defined as any injury to the main biliary tree and was classified using the Stewart-Way classification.[18] Bile leak was defined using a standardized definition from the International Study Group of Liver Surgery.[19]

Perioperative outcomes were compared between those patients who underwent laparoscopic surgery, and those that required conversion to open surgery. Continuous variables were found to be skewed, and so were reported as medians and interquartile ranges, with Mann–Whitney tests used to compare the two groups. Nominal variables were compared between the groups using Fisher's exact test, where this was calculable, or with Chi^2 where this was not possible, whilst Kendall's tau was used to compare ordinal variables.

The data were then randomly divided 3:1 into a main and validation set. Within the main set, univariable analyses were used to compare the conversion rates across the preoperative variables being considered, using Chi^2 tests or Kendall's tau for nominal and ordinal factors, respectively. A multivariate binary logistic regression model was then produced using a forward stepwise approach. The coefficients of the model were multiplied by two, and rounded to the nearest integer, in order to produce a

Table 1 Preoperative risk factors for conversion from laparoscopic to open cholecystectomy

Reference	N	Conversions (%)	Design	Risk score	Patient-related	Disease-related
[a]Sippey (2015)[10]	7242	6.0	Retrospective	No	Age, sex, BMI Comorbidity	
Goonawardena (2015)[1]	732	6.4	Retrospective	Yes	BMI Previous surgery	CBD stone, GB wall thickness
Vivek (2014)[11]	323	7.5	Prospective	No	Age, sex, BMI Previous surgery	ERCP
Stanisic (2013)[12]	369	2.7	Prospective	No	BMI	Cholecystitis, GB wall thickness, WCC
Kaafarani (2010)[13]	9530	9.0	Retrospective	No	Age, sex Previous surgery	
Randhawa (2009)[14]	228	1.3	Retrospective	Yes	BMI	Cholecystitis, GB wall thickness
Ballal (2009)[4]	43,821	5.2	Retrospective	No	Age, sex	
Lipman (2007)[3]	1377	8.1	Retrospective	Yes	Age, sex, diabetes	Cholecystitis
Ishizaki (2006)[6]	1179	7.5	Retrospective	No	Sex	Cholecystitis, CBD stone, GB wall thickness, ERCP
Rosen (2002)[2]	1347	5.3	Retrospective	No	Age, BMI	Cholecystitis, GB wall thickness
Kama (2001)[7]	1000	4.8	Retrospective	Yes	Age, sex Previous surgery	GB wall thickness Abdominal tenderness

GB = gallbladder; CBD = common bile duct; BMI = body mass index; ERCP = endoscopic retrograde cholangiopancreatography; WCC = white cell count.
[a] Included patients with cholecystitis only.

simplified risk score. Receiver operating characteristic (ROC) curves were then produced for this score in both sets of data to determine accuracy. All analyses were performed using IBM SPSS Statistics 22 (IBM Corp. Armonk, NY). Missing data were excluded on a per-analysis basis, and $p < 0.05$ was considered to be statistically significant.

Results

Overall, 297 out of 8820 (3.4%) laparoscopic cholecystectomies were converted to open. Mean patient age was 51 ± 17 years and 73.9% were female. Procedural difficulty was graded 3–4 in 94% of converted procedures compared to only 27% of laparoscopic procedures ($p < 0.001$; Fisher's exact test). Compared to laparoscopic procedures, converted procedures took significantly longer, and were associated with longer hospital stay, as well as increased morbidity and mortality (Table 2). Although the specific indications for conversion were not collected prospectively in the CholeS study protocol, bile duct injury (N = 7), bowel injury (N = 12) and bleeding (N = 64) were observed in 83 out of 297 (28%) converted patients. Of the remainder, operative difficulty was graded 3 or 4 in 170 (57%), and 35 patients (12%) underwent bile duct exploration. The reason for conversion was unclear in 9 patients (3%).

Of 8523 patients who successfully underwent laparoscopic cholecystectomy without conversion, the operating time was longer than 2 h in 544 patients (6.4%). However, a prolonged laparoscopic procedure (>2 h) was associated with increased overall complications (17.5% vs. 9.3%; $p < 0.001$), bile leak (3.7% vs. 0.8%; $p < 0.001$), bile duct injury (1.8% vs. 0.13%; $p < 0.001$) and longer median hospital stay (2 vs. 1 days; $p < 0.001$) compared to shorter laparoscopic procedures (less than 2 h). Thirty three percentage of patients who underwent a prolonged laparoscopic cholecystectomy had a postoperative length of stay ≥5 days. The morbidity (18% vs. 33%; $p < 0.001$) and median length of hospital stay (2 vs. 6 days; $p < 0.001$) after a prolonged laparoscopic cholecystectomy were significantly less than after converted cholecystectomy.

The data were then divided into two random groups, a main set (N = 6615; 3.3% converted to open), which could be used to produce a risk score, and a validation set (N = 2205; 3.4% converted to open) to validate the resulting score. Within the main set, the association between preoperative variables and conversion was evaluated by univariable analysis of a range of patient and surgical factors (Table 3). Several patient-related (age, gender, ASA) and disease-related factors (gallbladder wall thickness, bile duct diameter, indication for surgery, previous ERCP) were found to be significantly associated with conversion to open surgery. Body mass index was not found to be a risk factor for conversion in this analysis. On multivariable analysis, six factors (age, gender, ASA, indication, gallbladder wall thickness and bile duct diameter) were identified as significant independent predictors of conversion, whilst type of admission ($p = 0.225$) and previous ERCP ($p = 0.141$) were no longer significant (Table 4).

The model's accuracy was tested using ROC analysis, and returned an area under the curve (AUROC) of 0.811 (SE = 0.013; $p < 0.001$). The model was then transformed into a Conversion from Laparoscopic to Open Cholecystectomy risk score (CLOC score), by rounding the coefficients to the nearest integer, after multiplying by two to minimize the effect of rounding errors. The resulting 'points' scores for each of the factors in the model are reported in Table 5. In order to generate a CLOC score for a patient, the number of points for each of the factors is looked up

Table 2 Perioperative outcomes after laparoscopic cholecystectomy

	Laparoscopic (n = 8523)	Converted (n = 297)	p-Value
Procedural difficulty[a]			<0.001*
1	3535 (42%)	7 (2%)	
2	2618 (31%)	12 (4%)	
3	1724 (20%)	65 (22%)	
4	572 (7%)	212 (71%)	
Median operating time (min)	60 (45–88)	120 (90–160)	<0.001*
Median time to conversion (min)	–	34 (20–60)	–
Median hospital stay (days)	1 (0–2)	6 (4–10)	<0.001*
Morbidity (30 day)			
All	840 (10%)	99 (33%)	<0.001*
Bile leak	92 (1%)	25 (8%)	<0.001*
Bile duct injury	23 (0.3%)	6 (2%)	<0.001*
Mortality (30 day)	8 (0.1%)	2 (0.7%)	0.043*

Data reported as medians and interquartile ranges, with p-values from Mann–Whitney tests, or numbers and column percentages, with p-values from Fisher's exact tests, as applicable.
*Significant at $p < 0.05$.
[a] Nassar scale (Ref. 17), with p-value from Kendall's tau.

Table 3 Univariable analysis of preoperative variables (main dataset)

	N (n = 6615)	Converted (n = 221)	p-Value
Age#			<0.001#*
<30	803	3 (0.4%)	
30–39	983	11 (1.1%)	
40–49	1255	28 (2.2%)	
50–59	1365	57 (4.2%)	
60–69	1234	54 (4.4%)	
70+	970	68 (7.0%)	
Gender			<0.001*
Female	4889	111 (2.3%)	
Male	1726	110 (6.4%)	
BMI#			0.667#
<25	1318	42 (3.2%)	
25–30	2261	76 (3.4%)	
31–35	1536	50 (3.3%)	
>35	1198	43 (3.6%)	
ASA#			<0.001#*
1	2505	28 (1.1%)	
2	3340	131 (3.9%)	
3+	712	57 (8.0%)	
Primary indication			<0.001*
Colic	3647	45 (1.2%)	
CBD stone	429	39 (9.1%)	
Cholecystitis	1912	124 (6.5%)	
Pancreatitis	623	13 (2.1%)	
Gallbladder wall			<0.001*
Normal	4363	90 (2.1%)	
Thick walled	2094	122 (5.8%)	
CBD diameter			<0.001*
Normal	5449	145 (2.7%)	
Dilated	1011	66 (6.5%)	
Admission type			<0.001*
Elective	3125	52 (1.7%)	
Delayed	2450	111 (4.5%)	
Acute	1040	58 (5.6%)	
Preoperative ERCP			<0.001*
No	5848	160 (2.7%)	
Yes	692	58 (8.4%)	

ASA – American Society of Anesthesiologists physical status classification system.
BMI – body mass index; CBD – common bile duct.
ERCP – Endoscopic Retrograde Cholangio-Pancreatography.
p-Values from Chi^2 test, unless stated otherwise.
#p-Value from Kendall's tau.
*Significant at $p < 0.05$.

in the table, and added together, giving a score in the range of 0–14. The simplification of the logistic regression model into the CLOC score had minimal impact on its accuracy (AUROC 0.802; SE = 0.013; p < 0.001). The score was then applied to the validation set of patients, resulting in an AUROC of 0.766 (SE = 0.027; p < 0.001). The performance of the risk score for both sets of data is shown graphically in Fig. 1. The ROC curve from the validation set was then used to identify the best cut off from the risk score (Fig. 1). Based on the Youden's J statistic, the optimal grouping was to classify patients with scores >6 as high risk, which yielded a sensitivity of 77.1% and a specificity of 65.4%. In the validation set, the risk of conversion to open for low (CLOC $\leq$ 6) and high risk (CLOC > 6) patients was 1.2% and 7.1%, respectively. Hence, patients identified as high risk have a near six-fold higher rate of conversion than low risk patients.

Table 4 Multivariable binary logistic regression model (main dataset)

	Coefficient#	Odds ratio (95% CI)	p-Value
Age			0.005*
<30	–	–	–
30–39	0.88	2.41 (0.66–8.72)	0.181
40–49	1.26	3.53 (1.05–11.94)	0.042*
59–59	1.74	5.72 (1.75–18.69)	0.004*
60–69	1.48	4.41 (1.33–14.59)	0.015*
70+	1.77	5.88 (1.78–19.40)	0.004*
Gender			<0.001*
Female	–	–	–
Male	0.57	1.76 (1.30–2.39)	<0.001*
Indication			<0.001*
Biliary colic	–	–	–
CBD stone	1.26	3.54 (2.06–6.08)	<0.001*
Cholecystitis	1.12	3.05 (2.01–4.65)	<0.001*
Pancreatitis	−0.24	0.79 (0.38–1.62)	0.517
ASA			<0.001*
1	–	–	–
2	0.81	2.26 (1.44–3.53)	<0.001*
3+	1.38	3.97 (2.37–6.67)	<0.001*
Gallbladder wall			0.040*
Normal	–	–	–
Thick walled	0.36	1.43 (1.02–2.01)	0.040*
CBD diameter			0.004*
Normal	–	–	–
Dilated	0.53	1.70 (1.18–2.45)	0.004*

ASA – American Society of Anesthesiologists physical status classification system.
CBD – common bile duct.
Factors not in the final model: BMI (p = 0.466), Admission Type (p = 0.225).
Preoperative ERCP (p = 0.141).
#Log_e-odds.
*Significant at $p < 0.05$.

The CLOC score was found to be significantly associated with the intraoperative assessment of operative difficulty (Spearman's

Table 5 Conversion from laparoscopic to open cholecystectomy (CLOC) risk score

	Points
Age	
<30	0
30–39	2
40–69	3
70+	5
Gender	
Female	0
Male	1
Indication	
Colic/Pancreatitis	0
Cholecystitis	2
CBD Stone	3
ASA	
1	0
2	2
3+	3
Gallbladder wall	
Normal	0
Thick walled	1
CBD diameter	
Normal	0
Dilated	1

ASA – American Society of Anesthesiologists physical status classification system.
CBD – common bile duct.

rho = 0.386; $p < 0.001$), and also correlated with bile duct injury, whether diagnosed intra- ($p = 0.032$) or postoperatively ($p = 0.035$) (see Table 6).

Discussion

In this study, a risk score has been developed and validated using a large prospective cholecystectomy database, and accurately predicts the risk of conversion from laparoscopic to open cholecystectomy ("CLOC score"). The CLOC score correlated with indicators of operative difficulty, such as the Nassar scale and bile duct injury, and could therefore potentially be used pre-operatively to predict difficult cases. The score has several potential applications, including consent, training and resource utilization. Low risk patients (CLOC score ≤ 6) may be selected for ambulatory care facilities, and are suitable training cases for surgical registrars in the early phase of training. High risk patients (CLOC score > 6) should be operated by experienced surgeons in an inpatient facility. Depending on the availability of local expertise and resources, consideration should be given to referring very high risk patients to a specialist unit. Several risk scores have been published previously,[1,3,8,20–22] but all have failed to be incorporated into routine clinical practice. Early scores have been derived from small, retrospective series using subjective variables and included data from the learning curve of the laparoscopic era.[7,20–22] Recently, Goonawardena *et al.* developed a predictive nomogram from a retrospective series of 732 patients.[1] Similar variables were found to be significant predictors of conversion in this and the present report.[1]

Laparoscopic cholecystectomy has been the standard approach for symptomatic gallstones for more than two decades, and is

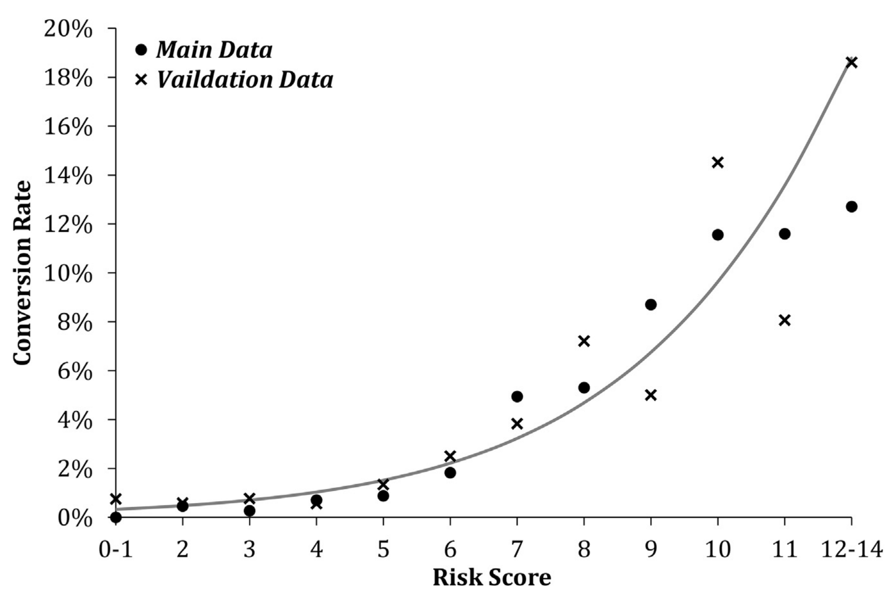

Figure 1 Relationship between conversion risk score and conversion rates. Reference line is based on a binary logistic model using the combination of the two datasets, with the risk score as a covariate

Table 6 Correlation between conversion risk score and operative difficulty (entire cohort)

	N	Risk score	p-Value
Operative difficulty			<0.001#*
1	3404	4.5 ± 2.6	
2	2547	5.6 ± 2.6	
3	1726	6.7 ± 2.6	
4	742	8.2 ± 2.4	
Bile duct injury (intraoperative diagnosis)			0.032*
No	8333	5.6 ± 2.8	
Yes	23	6.9 ± 2.8	
Bile duct injury (delayed diagnosis)			
No	8481	5.6 ± 2.8	0.035*
Yes	7	7.9 ± 3.0	

Data reported as mean ± SD, with p-values from t-tests, unless stated otherwise.
#p-Value from Spearman's rho − correlation coefficient = 0.386.
*Significant at $p < 0.05$.

associated with improved recovery and lower morbidity.[23] Conversion to open surgery may be necessary to prevent injury (e.g. bile duct injury), treat an intraoperative complication (e.g. bleeding, bowel injury, bile duct injury) or due to failure to progress.[1,2,6] In this analysis, the precise indication for conversion was not collected prospectively, since it was not part of the CholeS dataset. It was assumed that the presence of a bile duct injury, bowel injury or bleeding was the reason for conversion. Although it is feasible that an intraoperative complication occurred *after* conversion to open in some or all patients, this was considered unlikely. Nonetheless this is a potential weakness of the present study. Of the converted patients without intra-operative complications (N = 214), conversion was due to procedural difficulty (Nassar grade 3–4 or bile duct exploration) in the majority of cases (96%). In patients with significant inflammation and/or fibrosis in the region of Calot's triangle, accurate identification of anatomical landmarks may prove difficult or impossible using a laparoscopic approach. In this scenario, conversion to open surgery permits assessment by palpation and is an essential step if the critical view of safety has not been achieved. In patients in whom the critical view of safety cannot be obtained at open surgery, dissection in this region should be avoided and a subtotal cholecystectomy should be performed. Importantly, there were no cases of delayed diagnosis of bile duct injury in converted patients in this series. A third of converted patients in this study developed a postoperative complication, including bile leak in 8% and mortality (Table 2). This is in part due to selection bias, and these findings are compatible with previously published reports.[1–4]

The threshold for conversion is likely to vary between surgeons, and may relate to several factors, such as experience, procedural difficulty (e.g. bile duct exploration) and possibly logistic issues (e.g. time pressures and inpatient bed availability). Such variation in threshold may explain the range of times to conversion observed in this study (up to 4 h). The CLOC score may help to identify high risk patients, in whom an early decision to convert may avoid a lengthy laparoscopic procedure.

Conversion from laparoscopic to open cholecystectomy is a strategy to prevent and/or treat bile duct injuries. In this study, the incidence of bile duct injury in the entire cohort was 0.33% (29 patients). 23 out of 29 (79%) bile duct injuries were diagnosed intraoperatively, of which 16 were managed laparoscopically and 7 were converted to open. The remaining six bile duct injuries were diagnosed postoperatively. It is important to note that patients who were diagnosed with iatrogenic bile duct injury after thirty days (e.g. ischaemic biliary stricture) would not be included in this analysis, and this may underestimate the true incidence of iatrogenic bile duct injury after cholecystectomy. 18 out of 29 (62%) bile duct injuries were in high risk patients based on a CLOC score > 6, including 4 of 6 (67%) bile duct injuries that were diagnosed postoperatively. Although a high CLOC score may alert the surgeon to a potentially difficult cholecystectomy, a significant proportion of bile duct injuries developed in 'low risk' cases in this cohort, and a high degree of suspicion is needed both intra- and post-operatively. The critical view of safety (CVS) was described more than twenty years ago to prevent bile duct injury during laparoscopic cholecystectomy.[5] However, the incidence of bile duct injuries has failed to reduce in the intervening period.[3] The reasons for this are unclear, although it is possible that the CVS is either not being routinely used or is being applied incorrectly. The 'infundibular technique', which is flawed and may predispose to bile duct injury, cannot be recommended.[24] In a recent single centre series of over 1000 patients, the CVS was associated with a zero incidence of bile duct injury.[25] Information regarding the use of CVS in our cohort was not collected, and it is therefore not possible to comment on the aetiology of bile duct injury in this series, but it is hypothesised that bile duct injuries in low risk patients (CLOC score ≤ 6) occurred due to improper or failure to use CVS. Other strategies designed to reduce bile duct injuries, including the use of the anatomical landmark Rouvière's sulcus or a cholecystectomy checklist, have not been rigorously tested.[26,27]

This study has some limitations. The primary aim of the CholeS study was to assess the variation in practice of cholecystectomy in the UK and was not designed to develop a risk score to predict conversion. Consequently, several variables potentially of interest were not included in the original dataset, such as history of previous surgery, comorbidity, reason for conversion and use of the critical view of safety. It is unclear whether history of previous surgery independently predicts conversion, since previous reports are conflicting.[1–3] Although correlation between the risk score and operative difficulty was demonstrated in this study, the threshold for conversion to open is variable as outlined above, and the optimal time to convert cannot be deduced from this study. Interestingly, body mass index did not independently predict conversion in this study, in contrast to data from other series.[1,2,10–12] The reasons for this discrepancy are unclear, but given the large sample size and number of variables included in this multivariable analysis, it may indicate that important confounding factors could have been omitted from other studies.

In summary, this is the first validated risk score to predict conversion from laparoscopic to open cholecystectomy, and is based on a large prospective, contemporary database. Stratifying patients according to the risk of conversion has several potential clinical applications.

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Conflict of interest

None declared.

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