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External validation of the Cairns Prediction Model (CPM) to predict conversion from laparoscopic to open cholecystectomy

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Abstract

Background

Valid and user-friendly prediction models for conversion to open cholecystectomy allow for proper planning prior to surgery. The Cairns Prediction Model (CPM) has been in use clinically in the original study site for the past three years, but has not been tested at other sites.

Methods

A retrospective, single-centred study collected ultrasonic measurements and clinical variables alongside with conversion status from consecutive patients who underwent laparoscopic cholecystectomy from 2013 to 2016 in The Townsville Hospital, North Queensland, Australia. An area under the curve (AUC) was calculated to externally validate of the CPM.

Results

Conversion was necessary in 43 (4.2%) out of 1035 patients. External validation showed an area under the curve of 0.87 (95% CI 0.82 – 0.93, $p = 1.1 \times 10^{-14}$).

Conclusions

In comparison with most previously published models, which have an AUC of approximately 0.80 or less, the CPM has the highest AUC of all published prediction models both for internal and external validation.

External validation of the Cairns Prediction Model (CPM) to predict conversion from laparoscopic to open cholecystectomy

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Running head: Validation of Cairns Prediction Model

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Introduction

The benefits of laparoscopic cholecystectomy (LC) have seen it replace the open operation.

(1) Open cholecystectomy (OC) is rarely offered as an initial option, but is imposed on the surgeon either as a strategic conversion to prevent injury or as a reactive conversion to deal with intra-operative injury. (2-4) Conversion occurs in 1% to 15% of all LCs reflecting variations in patient and surgeon related factors. (5-7)

Conversion, is associated with increased risk of bile duct injury, bile leakage, bleeding, and death. (8) Superior tactile feedback, better exposure and movements and minimising the unnecessarily prolonged surgery by limiting the duration of the trial of laparoscopic dissection can be achieved with open surgeries. (9-12)

Being able to pre-operatively identify those patients with an increased risk for conversion, should allow selection and transfer of patients where indicated to specialised units, ensuring competency for OC is at hand or to directly start the procedure as an OC, with the intention of minimising the risk of conversion or injury.

Predictive models for conversion have developed steadily over 20 years. Most are cumbersome and few have been externally validated. (13) The Cairns Prediction Model (CPM) was developed in Cairns Australia, and has attracted the support of surgeons in the region. (14) It is intuitive, easy to use and requires only five variables (three ultrasonic and two clinical) to be collected to provide an immediate estimate of LC to OC conversion risk presented as probability nomograms (Figure 1-4). Internal validation of the CPM showed a very high accuracy represented by an area under the curve (AUC) of 0.97. The aim of this study was to externally validate the CPM in a different patient population from another hospital.

Material and methods

A longitudinal observational design was used to externally validate patients from a different hospital located 350 kilometres away from where the CPM was originally developed. Retrospective data were collected from operation notes, anaesthetic reports, discharge summaries, radiological reports and medical charts. Ethics approval was obtained from the Human Research Ethics Committee from the Townsville Hospital and Health Service (15/QTHS/48) and James Cook University (H5159), Australia.

Patient selection

Consecutive patients from the Townsville Hospital (a level 4 teaching Hospital), Queensland, Australia, who underwent LC between January 2013 and December 2016 were identified from the International Classification of Diseases, 10th revision (ICD10) codes, in the Operating Room Management Information System (ORMIS) database. Patient charts having any of the following codes were retrieved and read: “Cholecystectomy (30443-00)”, “Laparoscopic cholecystectomy (30445-00)”, “Laparoscopic cholecystectomy proceeding to open cholecystectomy (30446-00)”, “Laparoscopic cholecystectomy with exploration of common bile duct via cystic duct (30448-00)”, “Laparoscopic cholecystectomy with exploration of common bile duct via laparoscopic choledochotomy (30449-00)”, “Cholecystectomy with choledochotomy (30454-01)”, and “Cholecystectomy with choledochotomy and biliary intestinal anastomosis (30455-00)”. All patients started as a LC were included in the study. Patients were excluded if their ultrasonic measurements were taken more than 30 days prior to operation, or if any of the variables being part of CPM were lacking. However, no exclusion criteria were applied based on age, sex, indigenous status, pregnancy status, or admission status (elective or emergency).

Data collection

Factors included in the CPM were variables found to be significant after multi-variate analysis from Goonawardena et. al. (14), three ultrasound parameters (gallbladder wall width in millimetres, visible choledocholithiasis, and impacted stone at the neck of gallbladder) and two clinical variables (previous upper abdominal surgery and obesity). Clinical data were collected from anaesthetic report, medical charts and discharge summaries. Consistent with Goonawardena et.al. (14), upper abdominal surgery was defined as any previous abdominal surgery through a midline or paramedian incision above the level of the umbilicus. This included laparoscopic upper abdominal procedures, sleeve gastrectomy, gastric band, and laparoscopic cholecystostomy as was used in the description of Goonawardena et.al.'s study(15). Obesity was defined as having a body mass index (BMI) greater than 30 kg/m². Furthermore, age and gender were retrieved for the completion of descriptive statistics. All ultrasonic measurements were obtained from radiologists and sonographers' reports extracted from Picture Archiving and Communication System (PACS). All data were extracted by one author (AH) and another author (POD) counter-checked. All discrepancies were resolved by discussing with a third author (AdeC).

Statistical analysis

A probability for conversion was calculated for each patient using the relative weighting of factors as described in the CPM (14). For the variables: history of previous upper abdominal surgery, visible choledocholithiasis on ultrasound, obesity, impacted stone at the gallbladder neck, and gallbladder wall width, the regression coefficients in CPM were +4.56, +2.98, +2.51, +1.77, and +0.735 respectively. The intercept was -9.36.

A receiver operator curve (ROC) was used to compare the model's calculated probability for conversion with the true status of conversion to calculate an area under the curve (AUC) with

95% confidence interval. SPSS software version 23.0 (IBM Corp, Armonk, NY) was used in the statistical analyses.

Sample size calculation

The required sample size was estimated by assuming a ROC curve analysis, the total proportion of patient needing conversion at 5%, a power of 0.90 and an alpha value of 0.05. PASS version 11 was used. Based on these suppositions, a sample size of at least 23 and 460 were needed in the conversion group and non-conversion group respectively.

Results

Data from 1072 patients were retrieved, with nearly 70% being women, and ages ranged from six to 94 years old. Thirty-seven patients were excluded: 27 patients had ultrasonic investigation performed more than 30 days prior to operation, nine (0.84%) were missing data from ultrasonic measurements, and one cancelled procedure due to anaesthetic complications. Consequently, 1035 patients were included in this study, with 43 (4.2%) patients needing conversion.

Conversion

The conversion rates were 4.1%, 6.3%, 3.8% and 2.7% for 2013, 2014, 2015, and 2016 respectively over the course of the study. Ninety-three percent (40/43) of the conversions were strategic to avoid injury or manage bile duct stones while seven percent (3/43) were reactive conversions to sort out actual injury occurring intraoperatively.

Factors predicting conversion

As predicted by the CPM converted cases were more likely to be obese, have a thicker gall bladder wall, impacted stone on US, choledocolithiasis and have had previous upper abdominal surgery (Table 1). Out of the 25 patients who had a previous history of upper abdominal surgery. Nine had previous laparoscopic cholecystostomy, while nine of them had histories of sleeve gastrectomies.

Other histories include previous laparotomies, Roux-en-Y intestinal-biliary bypass and a history of previous laparoscopic gastric banding, accounting for four, two and one patients respectively.

External validation of CPM

The CPM accurately predicted conversion with an area under the curve of 0.87 (95% CI 0.82 – 0.93, $p = 1.1 \times 10^{-14}$).

Discussion

Whilst scoring systems for difficult laparoscopic cholecystectomies intraoperatively (16, 17) can be useful in comparing outcomes, pre-operative scoring systems, such as the CPM, allow for a more practical utility to serve as a surrogate for difficult dissection, allowing for selection of patients for appropriate referrals. This study has successfully validated the CPM showing an AUC of 0.87, supporting its use in current clinical practice.

Strength and weaknesses

The validation was carried out in a location distant enough to have a distinct demographic. The data collected were all objective measurements, and all but one dichotomous, making the

retrospective design acceptable. Missing data were minimal, suggesting that these variables are already part of routine medical care.

The original study by Goonawardena et al. (14) addressed the question of Endoscopic Retrograde Cholangiopancreatography(ERCP) but was insufficiently powered to deal with this, and it remains that ERCP may be an additional predictive factor that may enhance the CPM. However, the CPM is, without considering preoperative ERCP, already the prediction model with the highest AUC.

Anomalies of cystic duct, right hepatic artery truncation and the cystic artery could in theory be factors increasing predictive ability of the CPM. However, reliable information about duct and vessel anomalies are rarely available preoperatively.

Clinical value of a prediction model

As gall bladder surgery has evolved, difficulties and consequences predicted a generation ago(18) have been realised. The dearth of opportunities to learn and teach open cholecystectomy are widely acknowledged. Younger surgeons, particularly when not supported by the infrastructure of a major teaching hospital, are faced with difficulties when deciding to convert from LC to OC. A lack of familiarity with OC may lead to futile and dangerous persistence with LC, and unfamiliarity when converted. Prediction, then, has a central role in risk stratification. This study uses conversion as a reasonably reliable surrogate measure for difficult dissection. The benefits of early on identifying increased risk for difficult dissection are

- 1) A careful and ethical consent process (19)
- 2) The transfer of patients at high risk to specialist units where appropriate (9, 20, 21)
- 3) The selection of patients for registrar or resident operation (21, 22)
- 4) Planning for conversion, by ensuring the presence of senior surgeons expert at doing what are likely to be difficult open cholecystectomies (3, 23)

- 5) Planned open cholecystectomies performed by experienced surgeons, with a commitment to teaching the open operation

Comparison between validated prediction models

The clinical usefulness of different prediction models can be compared using various measurements. Sensitivity, specificity and predictive values assume the introduction of a cut-off while AUC provides an estimate of performance over an infinite number of cut-offs. The latter is preferred since a high AUC indicates the prediction model can be used with different cut-offs in diverse settings.

While several prediction models have been described using AUC for internal validation (3, 9, 14, 24-27) (Table 2), only two have reported AUC in an external validation. (14, 24)

In comparison to other models, Goonawardena et.al. (14) evaluated 40 variables to develop the CPM, more than any other study. Variables which were considered significant and included in models from other studies, such as acute cholecystitis (3); elevated white cell counts, low albumin and diabetes (26) and ASA (American Society of Anaesthesiologist) physical classification (24) were also evaluated by Goonawardena, but found to not be significant enough via multivariate analysis to be included in the CPM.

There are some similarities across various models. Thick-wall gallbladder has been consistently included in all the models. This is in contrast to the variable, male gender, which is not included in CPM but included in most other models. (3, 24, 26) Randhawa et al.'s (27) model included BMI or more than 27.5kg/m^2 as a measure instead of the standard definition of obesity, BMI of more than 30kg/m^2 to be included in their model.

Kama et. al's study (3) has been externally validated. (28, 29) However, an AUC was not reported by those validation studies because a cut-off was chosen. The CPM has the highest AUC of any models evaluated (Table 2).

The CPM uses nomograms (Figure 1-4), which are currently in use in urology(30, 31), oncology (32, 33), and other areas of medicine. (34, 35) Nomograms are superior in terms of ease of use and practicality over risk group stratification (25, 36), tables (9, 21, 26, 37), and artificial neural networks (6, 38). CPM has been applied clinically for the past three years by surgeons in Cairns Hospital and Cairns Private Hospital, Australia, and has proved practical and useful.

A cut-off score was deliberately not suggested in the CPM as the threshold should be decided locally by the treating surgeons, surgical departments or hospitals. Thus, a more flexible yet accurate application with continuous probability can be achieved by balancing risks predicted by CPM while considering factors such as availability of hospital resources, time pressure, and surgeons' experience.

Conclusion

The CPM is a validated, flexible, user friendly model to predict the conversion from LC to OC. The often-quoted aphorism that "conversion should not be seen as a failure, but as an exercise in good judgement" may have served its purpose, and should now be tempered by the availability of reliable predictive science.

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Conflict of interest

The authors declare no conflict of interest.

ACCEPTED MANUSCRIPT

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Table 1 – Patient characteristics

	No conversion	Conversion	Total
	N= 992	N= 43	N= 1035
Women (%)	707 (71%)	19 (44%)	724 (67%)
Mean age in years (SD, range)	47 (17, 6 - 94)	61 (15, 31 - 84)	47 (17, 6 - 94)
Mean gallbladder wall width in mm (SD, range)	3.2 (2.1, 0.9 – 15)	5.2 (3.1, 1.2 – 19)	3.3 (2.2, 0.9 – 19)
Previous upper abdominal surgery (%)	25 (2.5%)	4 (9.3%)	29 (2.8%)
Obesity/BMI>30 (%)	481 (48%)	27 (63%)	508 (49%)
Visible choledocholithiasis on ultrasound (%)	69 (6.9%)	21 (49%)	90 (8.7%)
Impacted stone at gallbladder neck on ultrasound (%)	137 (14%)	28 (65%)	165 (16%)

Table 2 – Prediction models presenting AUC in validation of their models

Author, year	Internal validation			External validation		
	n	AUC (CI)	P value	n	AUC (CI)	P value
Sutcliffe, 2016 (24)	6,615	0.81 (0.79- 0.84)	<0.001	2,205	0.77 (0.71- 0.82)	<0.001
Goonawardena, 2015 (14)	732	0.97		1,035	0.87 (0.82 – 0.93)	1.1 x 10 ⁻¹⁴
Randhawa, 2009(27)	228	0.82				
Lipman, 2007 (26)	1,377	0.83				
Kama, 2001 (25)	1,000	0.83				
Random allocation		0.50			0.50	

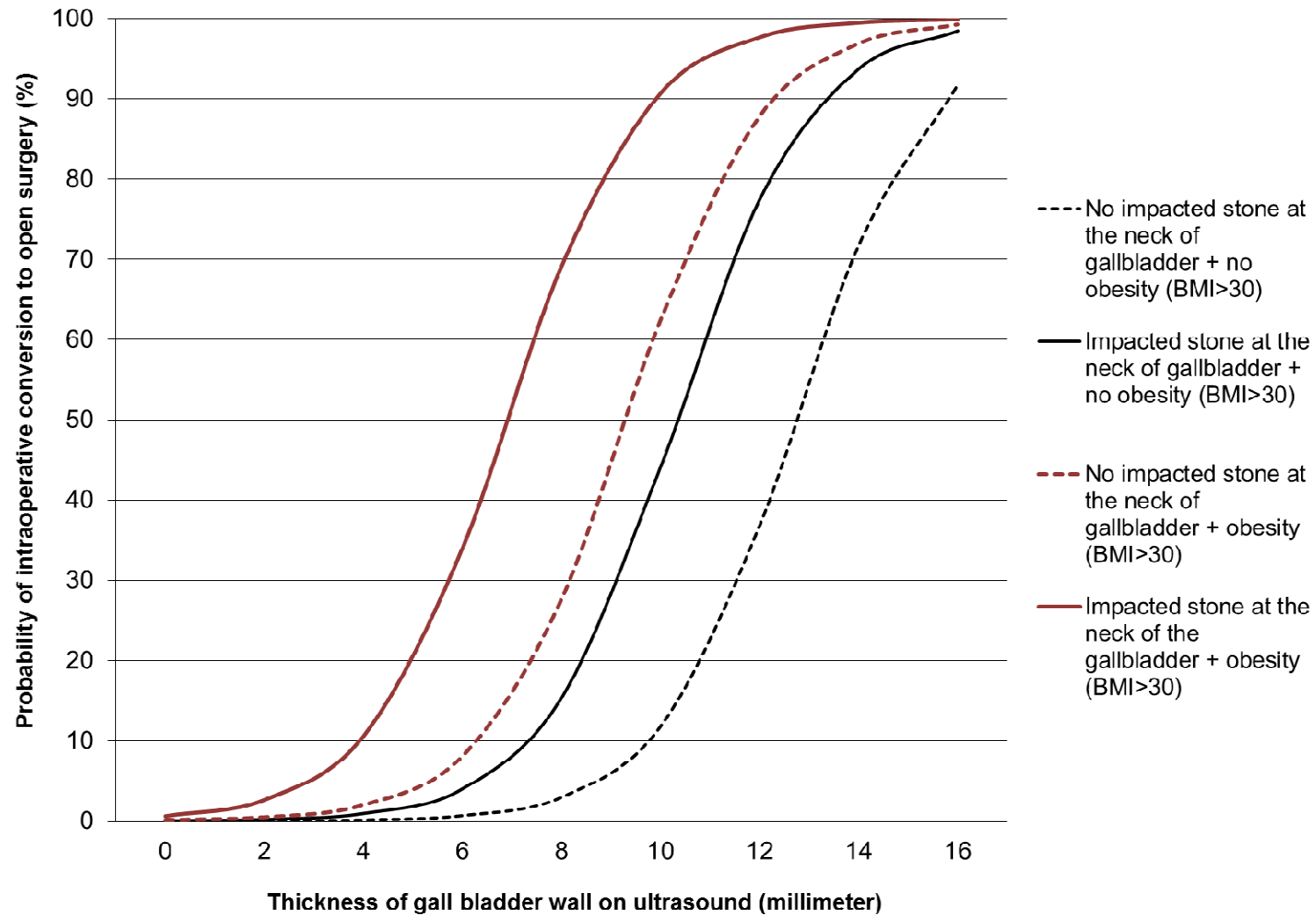


Figure 1 – Probability for conversion in patients with no previous abdominal surgery and no choledocholithiasis
Adapted from The American Journal of Surgery¹⁰ with kind permission from Elsevier (licence no. 4183111486535)

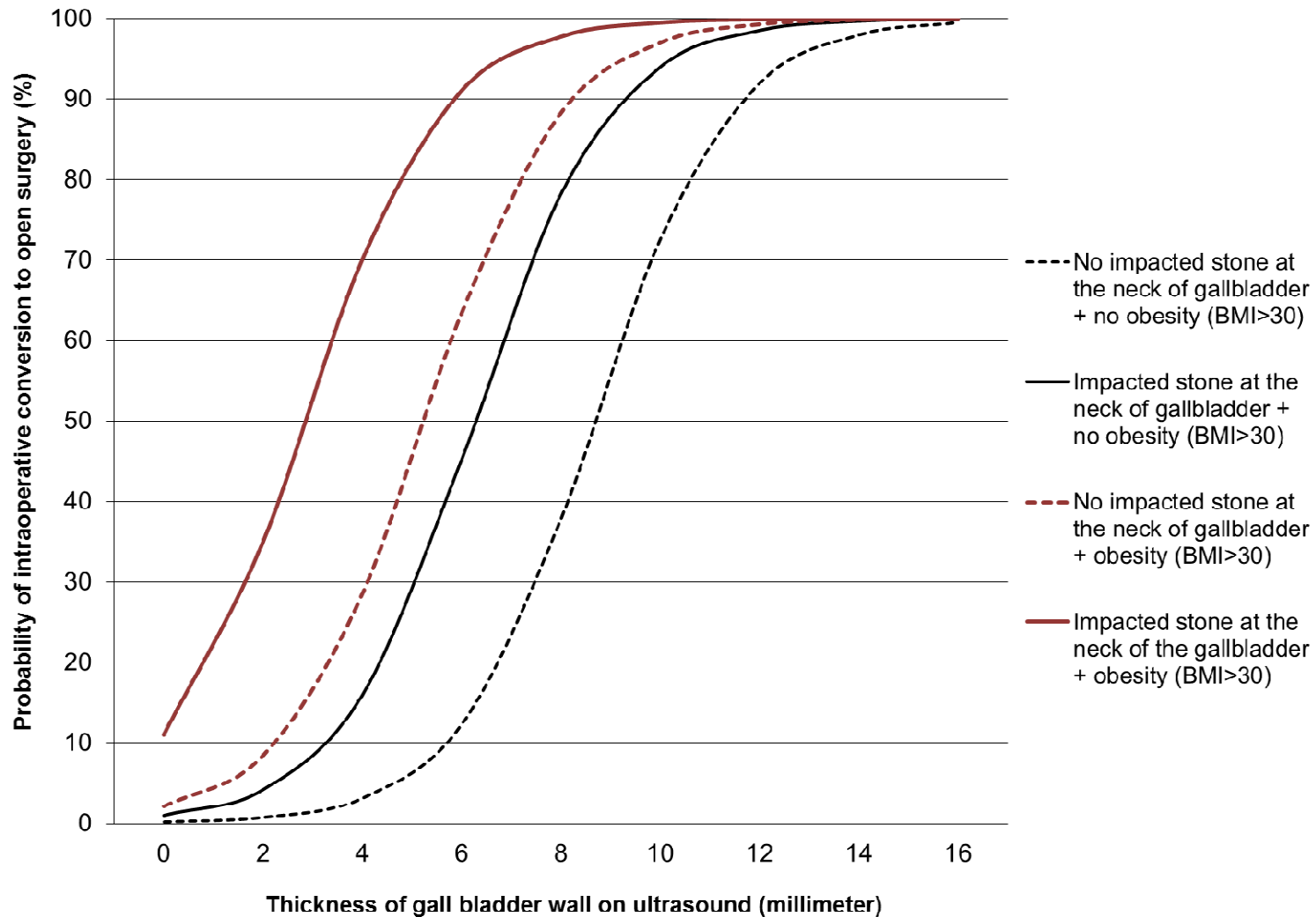


Figure 2 – Probability for conversion in patients with no previous abdominal surgery having choledocholithiasis

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Validation of Cairns Prediction Model

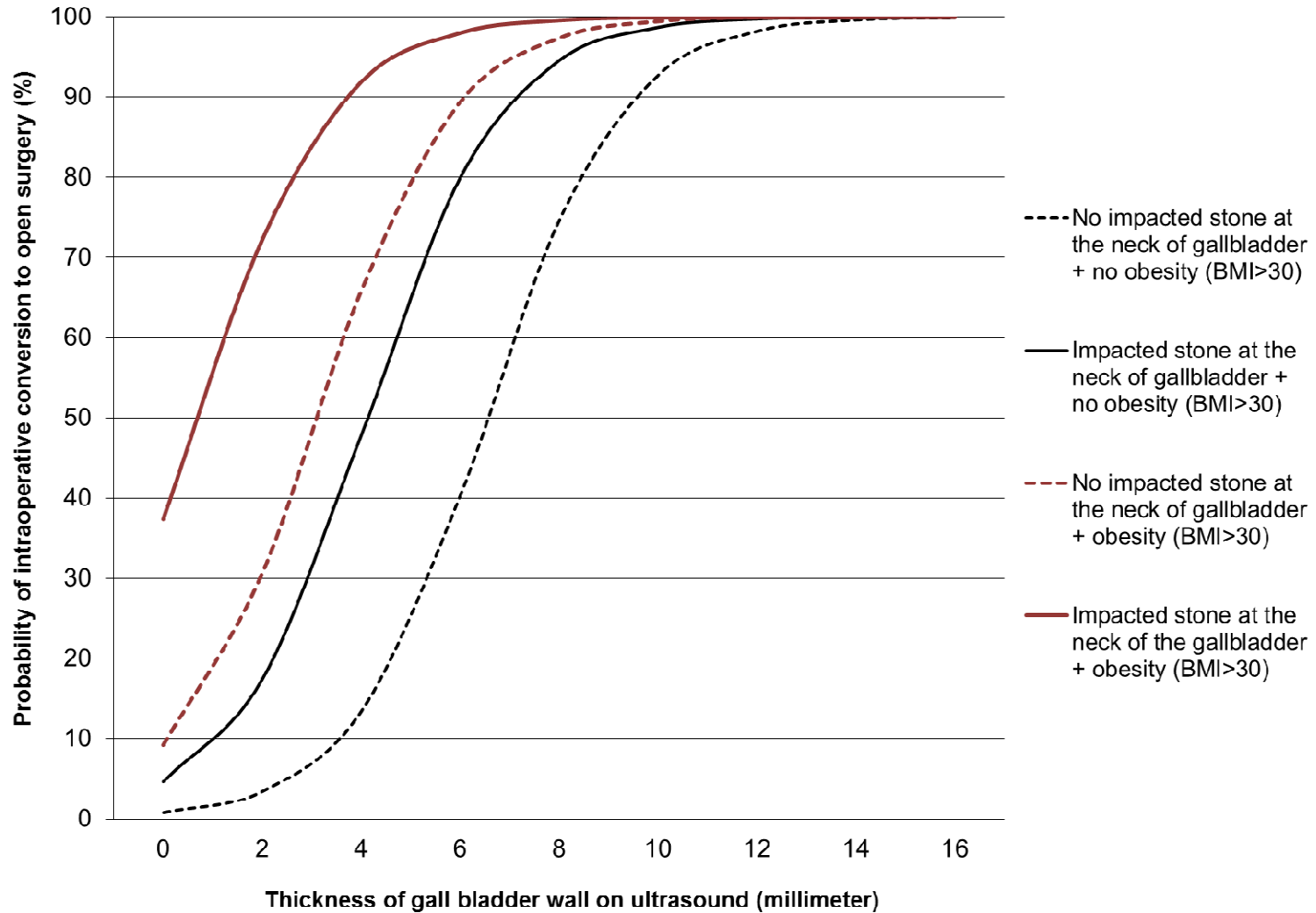


Figure 3 – Probability for conversion in patients with previous abdominal surgery and no choledocholithiasis
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Validation of Cairns Prediction Model

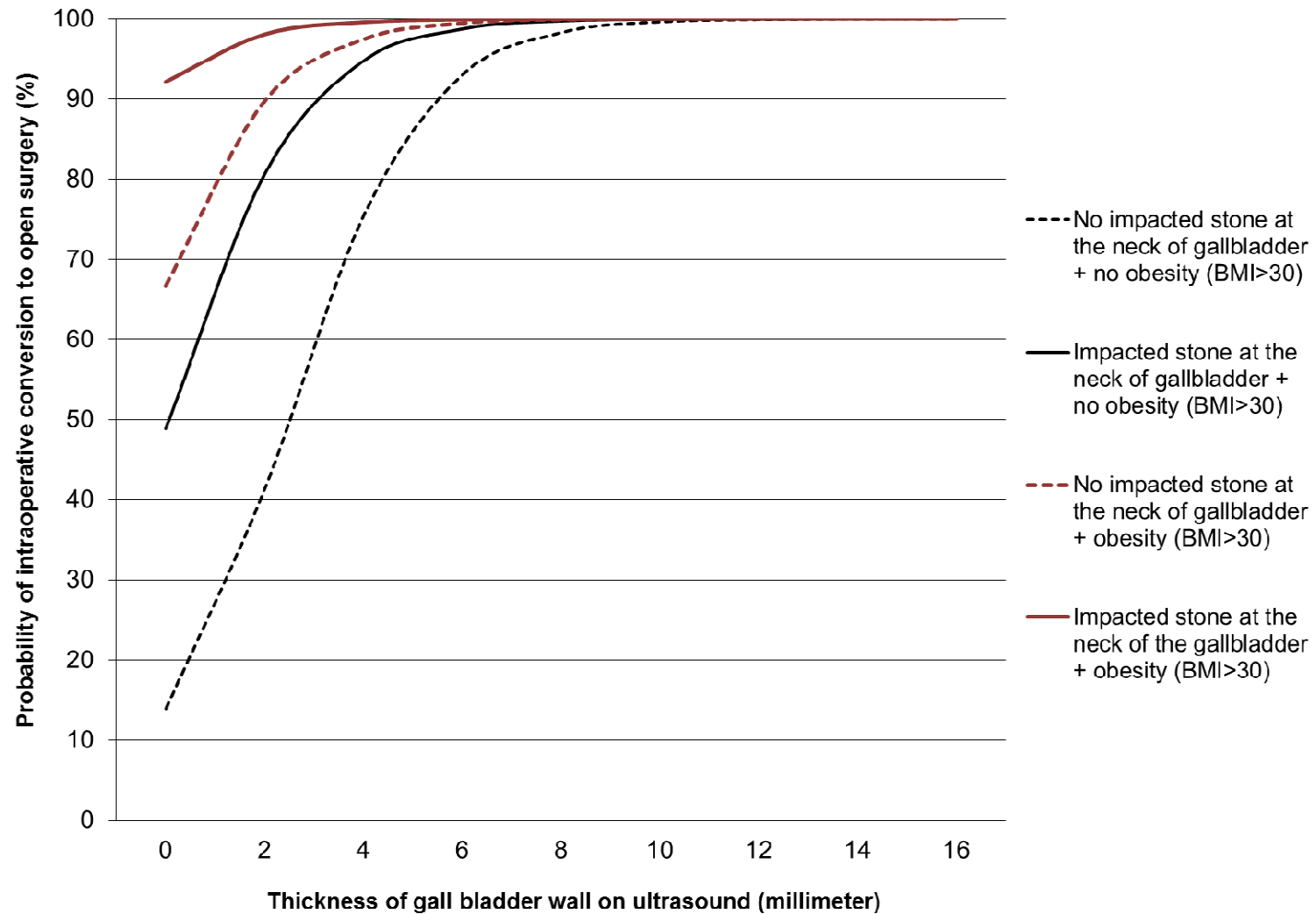


Figure 4 – Probability for conversion in patients with previous abdominal surgery having choledocholithiasis

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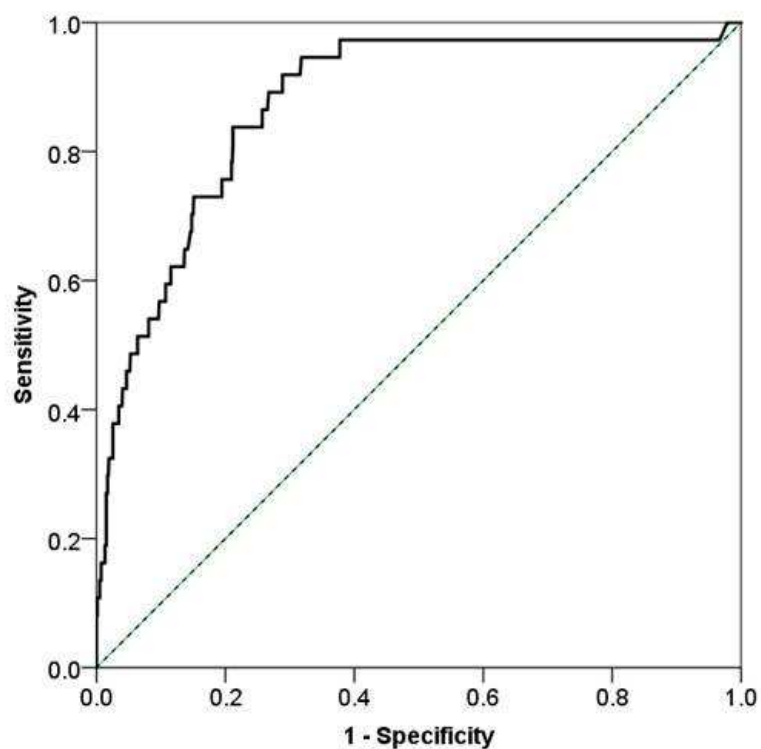


Figure 5 – External validation for the Cairns Prediction Model (CPM)

Highlights

- Conversion at laparoscopic to open cholecystectomy is associated with adverse outcomes
- Cairns Prediction Model (CPM) used to predict the conversion, which achieved an area under the curve (AUC) of 0.97, has been in use clinically in the original study site for the past three years, but has not been tested at other sites
- External validation of the model was performed and showed an AUC of 0.87
- The CPM has the highest AUC of all published models for both internal and external validation