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ORIGINAL ARTICLE

Validation of an online risk calculator for the prediction of anastomotic leak after colon cancer surgery and preliminary exploration of artificial intelligence-based analytics

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Abstract
Background Recently published data support the use of a web-based risk calculator (www.anastomoticleak.com) for the prediction of anastomotic leak after colectomy. The aim of this study was to externally validate this calculator on a larger dataset.
Methods Consecutive adult patients undergoing elective or emergency colectomy for colon cancer at a single institution over a 9-year period were identified using the Binational Colorectal Cancer Audit database. Patients with a rectosigmoid cancer, an R2 resection, or a diverting ostomy were excluded. The primary outcome was anastomotic leak within 90 days as defined by previously published criteria. Area under receiver operating characteristic curve (AUROC) was derived and compared with that of the American College of Surgeons National Surgical Quality Improvement Program® (ACS NSQIP) calculator and the colon leakage score (CLS) calculator for left colectomy. Commercially available artificial intelligence-based analytics software was used to further interrogate the prediction algorithm.
Results A total of 626 patients were identified. Four hundred and fifty-six patients met the inclusion criteria, and 402 had complete data available for all the calculator variables (126 had a left colectomy). Laparoscopic surgery was performed in 39.6% and emergency surgery in 14.7%. The anastomotic leak rate was 7.2%, with 31.0% requiring reoperation. The anastomoticleak.com calculator was significantly predictive of leak and performed better than the ACS NSQIP calculator (AUROC 0.73 vs 0.58) and the CLS calculator (AUROC 0.96 vs 0.80) for left colectomy. Artificial intelligence-predictive analysis supported these findings and identified an improved prediction model.
Conclusions The anastomotic leak risk calculator is significantly predictive of anastomotic leak after colon cancer resection. Wider investigation of artificial intelligence-based analytics for risk prediction is warranted.

Keywords Anastomotic leak · Colectomy · Prediction · Risk calculator

Introduction

Anastomotic leak after colectomy is a hazardous complication with significant short- and long-term adverse consequences for patients who experience it [1–3]. The overall incidence of anastomotic leak after colectomy varies from < 4% in retrospective series with a narrow definition which includes only high-grade leaks [1] to approximately 8% in prospective series with more liberal a priori definition criteria [4]. Traditionally, risk factors for anastomotic leak have been categorized as technical and patient specific. Reported technical methods to minimize anastomotic leak include meticulous attention to apposition of the two lumens to be joined, liberal colonic mobilization to reduce tension at the anastomotic site, and care to ensure excellent arterial and venous blood supply to both ends [5]. Intraoperative complications, extended resections, and blood loss also increase the anastomotic leak rate [6, 7]. Recognized patient factors include male gender, obesity, diabetes, immunosuppression, malnutrition, collagen disorders, underling disease, chemotherapy, use of anticoagulants, and smoking [8].

Despite a plethora of published data on risk factors and the general acceptance of these by the surgical and

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scientific community, accurate personalized prediction of anastomotic leak remains notoriously difficult [9, 10]. Currently, the majority of surgeons in clinical practice present the patient with a pragmatic estimate based on a general perception of risk and may quote a range of average risk percentages based on unit experience or published data [11]. This ad hoc estimate has been shown to be highly inaccurate and generally inadequate [12]. Partly as a response to this, there has been a perceptible push to develop risk prediction algorithms and tools to better quantify anastomotic leak risk for individual patients [13, 14]. We recently prospectively investigated one such tool based on the ANACO study group nomogram (www.anastomoticleak.com) and found that not only was it predictive of leak, but significantly more so than the estimate of the primary operating surgeon [15]. This nomogram was chosen chiefly because it was based on the highest quality evidence available on this topic having been developed using a prospective multicentre study of over 3000 patients [16]. It also had the added practical benefit of being simple to perform with only 6 independent variables included.

Our previous study had several limitations, however, resulting in our conclusion that the Frasson nomogram and online calculator still required further validation. Firstly, the number of patients included was small, with a correspondingly low anastomotic leak event rate. Secondly, we did not test the calculator against other established and commonly used risk prediction tools such as American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP) surgical risk calculator and the colon leakage score (CLS) which both include a leak risk estimate for colectomy [17–19]. Finally, we performed predictive testing based on the standard area under the receiver operating characteristic (AUROC) analysis method which is commonly used in studies evaluating the predictive value of a nomogram. With the recent advent of artificial intelligence and natural language processing technology, it is now possible to analyze a large number of variables using cognitive computing and predictive analytics to identify patterns in data that may otherwise be missed [20]. Other features include semantic recognition of data concepts, agnostic recommendation of starting points for analysis and targets for prediction, and interaction in natural language [21]. It is quite possible that these aids may complement traditional statistical methods and represent a novel opportunity to gain deeper and unselected insights into the relationship between risk factors and outcomes [22].

The aim of this study was to validate the anastomotic leak risk calculator on a larger dataset and test its performance against the ACS NSQIP and CLS calculators for the prediction of anastomotic leak. We also sought to explore the utility of artificial intelligence analytics to further interrogate predictive algorithms in the dataset.

Materials and methods

Patients

The study group consisted of consecutive patients who underwent colon cancer resection at Royal Adelaide Hospital in Adelaide, Australia, over an 8-year period between January 1, 2008 and January 1, 2016. Patients were identified using the Binational Colorectal Cancer Audit (BCCA) database [23, 24] and were all treated and managed in a tertiary care setting with established specialized colorectal and oncology services. Inclusion criteria were: all patients with colon cancer (defined as a distal edge located at more than 15 cm from the anal verge, measured by rigid proctoscopy) treated with elective or emergent surgery, with local curative intent, in whom primary anastomosis with no protective stoma was performed. The exclusion criteria were patients younger than 18 years, R2 cancer resection, patients with tumor classified as "rectosigmoid" with no height given, and patients with missing information such that the calculator variables could not be determined.

Data collected

Baseline patient characteristics, preoperative, operative, and postoperative variables were collected prospectively using the BCCA database [23, 24]. Additional retrospective review of patient records was required to collect additional data on body mass index (BMI), comorbidities, anticoagulation use, and intraoperative complications, and to ensure that no anastomotic leak events were missed. Comorbidity variables were coded as required by the ACS NSQIP surgical risk calculator [17, 18]. Anticoagulation use was defined as: the use of any known antiplatelet or antithrombotic agent that was still active at the time of surgery (i.e., had not been stopped preoperatively with enough time to be metabolized). Intraoperative complications were defined as per Frasson et al. for the purposes of the calculator: unexpected surgical adverse events that occurred in the operating room during surgery. These included iatrogenic injury of bowel or other organs, bleeding, stapling device malfunction, refashioning of the anastomosis due to technical problems, and others [16]. Postoperative complications and mortality up to 60 days after surgery were recorded prospectively. All complications were then graded as per the Clavien–Dindo classification [25, 26]. Anastomotic leak was defined as per the definition by Frasson et al. [16]: leak of luminal contents from a surgical join between two hollow viscera diagnosed by any of the following methods:

- Radiologically (radiographic enema with hydrosoluble contrast or by computerized tomography) with the pres-

ence of intra-abdominal collection adjacent to the anastomosis.
- Clinically (evidence of extravasation of bowel content or gas through a wound or drain).
- Endoscopically.
- Intraoperatively.

No radiological examinations were made in asymptomatic patients. Anastomotic leaks were also classified as grade A: requiring no invasive intervention (diagnosed radiologically, antibiotics only), grade B: requiring active radiological intervention but manageable without surgical reintervention, and grade C: requiring surgical reintervention [4, 9].

Calculator details

The anastomoticleak.com calculator was accessed online at www.anastomoticleak.com [15]. The 6 variables included in the calculator are: (1) gender (male or female), (2) BMI > 30 kg/m^2 (yes or no), (3) oral anticoagulants (yes or no, referring to patients considered therapeutic intraoperatively, and antiplatelet agents were included), (4) serum total protein (preoperative value of 4.0–8.0 g/dL, in increments of 0.5 g/dL), (5) number of hospital beds (100–1500 in increments of 100 beds; in the current study this was fixed at 700 beds), (6) intraoperative complication (yes or no, as defined above) [16]. The online calculator was used to derive the percentage risk of anastomotic leak for each patient.

The ACS NSQIP calculator was accessed online at: http://riskcalculator.facs.org [17, 18]. Individual risk determination for anastomotic leak was made using the following 20 variables for each patient: procedure, age group, sex, functional status, emergency case, American Society of Anesthesiologists (ASA) class, steroid use, ascites, systemic sepsis, ventilator dependence, disseminated cancer, diabetes, hypertension requiring medication, congestive heart failure, dyspnea, current smoker (within 1 year), severe chronic obstructive pulmonary disease (COPD), dialysis, acute renal failure, and BMI. Post hoc surgeon adjustment of risk was not performed.

The CLS calculator result was derived using the method outlined by the authors [19]. Only left-sided resections were included in this analysis (n = 126) since the calculator was only designed to include these (defined by the authors as left colectomy, sigmoid resection, or rectal resection). The 11 variables in the CLS calculator are age, gender, ASA, BMI, intoxication (smoking, alcoholism, present use of steroids excluding inhalers), neoadjuvant therapy, emergency surgery, distance of anastomosis to anal verge (cm), additional procedures, blood loss/transfusion, and duration of operation (allocated a value of 2 as this was not routinely recorded). All patients were allocated a value of 0 for “distance of anastomosis from anal verge” field since no rectal cancers were included in our dataset.

Statistical analysis

Results were analyzed using IBM SPSS Statistics for Windows® version 23.0.0.0 (SPSS, Chicago, IL, USA). AUROC analysis was derived for all three calculators and compared (only left-sided resections for CLS calculator). Youden’s index was used to calculate the statistical optimal cutoff value if a calculator was predictive [27]. AUROC curves were compared directly using MedCalc version 17.6 (MedCalc Software, Ostend, Belgium). Continuous variable distribution was tested using the Kolmogorov–Smirnov test. Groups were compared using the Fisher’s exact or Chi-square test for categorical variables, the nonparametric Mann–Whitney U test for continuous normally distributed variables, and the parametric t test for normally distributed continuous variables. Correlations between continuous variables were assessed using nonparametric Spearman’s rho. Statistical significance was accepted at the 0.05 level.

Artificial intelligence analytics

An anonymized dataset was analyzed using IBM Watson Analytics (Armonk, NY, USA: IBM Corp). This dataset included all the variables in both anastomoticleak.com and ACS NSQIP calculators, as well as a binary variable coding for the outcome of anastomotic leak. Guidelines for data entry and analysis were followed as recommended by the software developer. Dataset quality was automatically assessed by the software program and available for each analysis. The query “What predicts anastomotic leak?” was used to identify a predictive model. The query was not restricted to any specific number of variables allowing maximum sensitivity in the analysis.

Results

A total of 626 patients who underwent colectomy for cancer were identified in the BCCA database, of whom 402 were ultimately included in the analysis (Fig. 1).

Clinical data

Baseline patient characteristics are shown in Table 1. The overall anastomotic leak rate was 7.2% (N = 29) with 27.6%

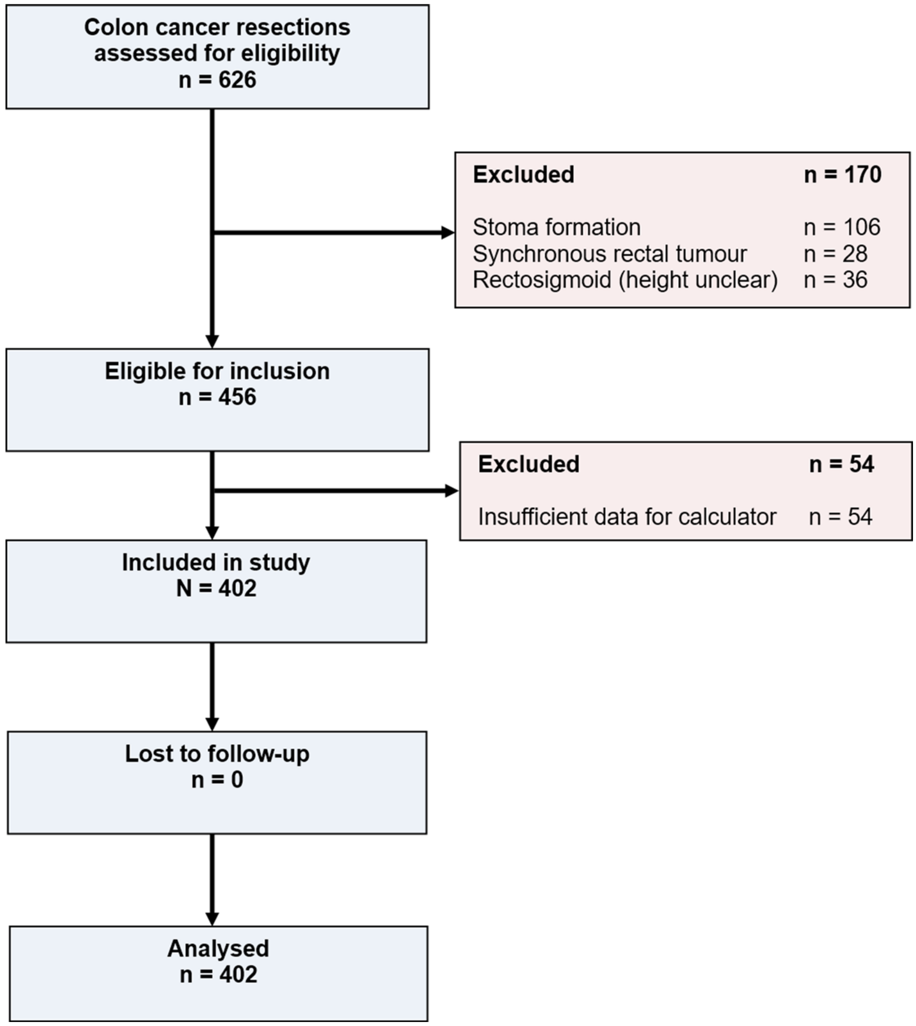

Fig. 1 Patient flow diagram

($N = 8$) being grade A, 27.6% ($N = 8$) grade B, and 44.8% ($N = 13$) grade C. Day stay, complication rate and severity, and mortality were significantly higher in patients who had an anastomotic leak versus those who did not (Table 2). Eight patients (27.6%) died as a consequence of anastomotic leak, although 4 of these patients elected not to undergo operative reintervention despite high-grade leak due to age and/or premorbid disease and were managed in a palliative fashion.

AUROC analysis

With all resections included, the anastomoticleak.com calculator was significantly predictive of anastomotic leak (AUROC 0.73, $p < 0.0001$), whereas the ACS NSQIP calculator was not predictive (AUROC 0.58, $p = 0.144$), (Table 3 and Fig. 2). The statistical optimal cutoff value for the calculator estimate was 12.5% (likelihood ratio 3.44, sensitivity 0.62, specificity 0.82, positive predictive value 0.21, and negative predictive value 0.97).

Subset analysis of left-sided resections only for the purposes of evaluating the CLS score was performed. Both the anastomoticleak.com and CLS calculator were predictive in this group, but the anastomoticleak.com calculator performed better with an AUROC 0.96, $p < 0.0001$ versus AUROC 0.80, p 0.023, respectively (Table 3, Fig. 3). The NSQIP calculator was again not significantly predictive in this subset despite an improved AUROC result (0.72, p 0.094).

On direct comparison, the differences in the AUROC did not reach statistical significance.

Artificial intelligence analytics

The quality of the inputted dataset was rated as “Good” by the analytics software (Fig. 4). Of all the variables evaluated by the software, only the anastomoticleak.com calculator result and patient age were identified as independent predictors and included in a decision tree model for anastomotic leak. Cutoff values were determined at 14% for the calculator

Table 1 Baseline characteristics

	Patients (n = 402)
Median age in years (IQR)	73 (17)
Sex	
Male	162 (40.3%)
Female	240 (59.7%)
Median BMI in kg/m^2 (IQR)	27 (7)
Mean total protein in g/dL (SD)	7.1 (0.70)
Anticoagulation	
None	249 (61.9%)
Stopped preoperatively	96 (23.9%)
Anticoagulated at surgery	57 (14.2%)
Intraoperative complication	11 (2.7%)
ASA Score	
I	9 (2.3%)
II	152 (38.0%)
III	212 (53.0%)
IV	27 (6.8%)
Comorbidity	
Diabetes	79 (19.7%)
Hypertension	161 (40.0%)
Congestive health failure	37 (9.2%)
Smoker	33 (8.2%)
Chronic obstructive airway disease	49 (12.2%)
Chronic renal failure	11 (2.7%)
Steroids (long term)	8 (2.0%)
Ascites	1 (0.2%)
Operation	
Right hemicolectomy	185 (46.0%)
Extended right hemicolectomy	66 (16.4%)
High anterior resection	126 (31.3%)
Total colectomy	24 (6.0%)
Transverse colectomy	1 (0.2%)
Access	
Open	242 (60.2%)
Laparoscopic	138 (34.3%)
Laparoscopic converted	22 (5.5%)
Urgency	
Elective	343 (85.3%)
Emergency	59 (14.7%)
AJCC stage	
I	55 (13.7%)
II	157 (39.1%)
III	116 (28.9%)
IV	74 (18.4%)
Median predicted leak risk (IQR)	
Online calculator	9.0% (5.0)
NSQIP calculator	2.5% (1.6)

ASA American Society of Anesthesiologists, *AJCC* American Joint Committee on Cancer, *NSIQP* National Surgical Quality Improvement Program, *SD* standard deviation, *IQR* interquartile range

result and 65 years for age. In the group of patients with a calculator result ≤ 14%, the anastomotic leak rate was 0% if patient were aged ≤ 65 years and 5% for those older than 65 years. If the calculator result was > 14%, then the leak rate in that group was 24% (age had no effect).

The anastmoticleak.com calculator was recalibrated with this new information, and the resulting modification was re-tested with AUROC analysis. The resulting AUROC increased from 0.73 to 0.75, $p < 0.0001$. The statistical optimal cutoff value for the modified calculator estimate was 10.0% (likelihood ratio 3.44, sensitivity 0.59, specificity 0.85, positive predictive value 0.25, and negative predictive value 0.96).

Discussion

We conducted a validation study for the anastomoticleak.com risk prediction calculator using BCCA registry and retrospective data. The results confirm that the anastomoticleak.com calculator is significantly predictive of anastomotic leak and performs better than both the ACS NSQIP and CLS calculators in terms of the absolute value of the AUROC analysis. However, we were not able to quantify statistically significant differences in AUROC comparisons. In addition, the utility of artificial intelligence-based analytics was demonstrated with the analysis supporting the predictive value of the anastomoticleak.com calculator and the identification of age as an additional risk stratifier in the lower end of the calculator range. When the calculator was adjusted with this information, a minor improvement in performance was observed.

The ANACO study group nomogram was first published by Frasson et al. [16] and was based on a high-quality large multicentre prospective study which identified 6 independent predictive variables from total of 27 variables which were evaluated. Our group subsequently converted this nomogram into an online web-based format for ease of use, and tested this in a prospective study which confirmed that it was predictive with an AUROC of 0.84 (p=0.002) [15]. Importantly, and somewhat surprisingly, we noted that the risk estimate of the primary surgeon who was blinded to the calculator result was not predictive [15]. While the AUROC in the current retrospective dataset is somewhat lower at 0.73, this may be due to somewhat lower-quality data collection given that registry and retrospective medical record review was used. Nevertheless, the calculator was again shown to be predictive, thus supporting the external validation of the calculator in a Western population.

The CLS nomogram was also predictive in the subset of patients undergoing left-sided resection, although it did not seem to perform as well. This nomogram was designed by systematic review of the literature to identify risk variables,

Table 2 Postoperative recovery and predicted leak rates

	No leak (*n* = 373)	Leak (*n* = 29)	*p* value
Median hospital day stay, days (range)	7 (5)	12.5 (12)	< 0.0001**
Complication grade			< 0.0001*
No complication	168 (45.0%)	0	
I	10 (2.7%)	0	
II	159 (42.6%)	7 (24.1%)	
III	20 (5.4%)	7 (24.1%)	
IV	12 (3.2%)	7 (24.1%)	
V	4 (1.1%)	8 (27.6%)	
Mortality	4 (1.1%)	8 (27.6%)	< 0.0001*
Median predicted leak risk (IQR)			
Anastomoticleak.com calculator	9.0% (4.0)	17.0% (13.0)	< 0.0001**
NSQIP calculator	2.4% (1.5)	2.7% (1.4)	0.144**
CLS calculator score (left colectomy only)[a]	8 (7)	13 (4)	0.022

SD standard deviation, *IQR* interquartile range, *CLS* colon leakage score, *NSQIP* National Surgical Quality Improvement Program

[a]The CLS calculator outputs a number score not a leak risk percentage

*Fisher's exact test; **Mann–Whitney *U* test

Table 3 ROC curve analysis

Test	AUROC	SE	*p* value	95% CI
All cases (*n* = 402)				
Anastomoticleak.com calculator	**0.732**	0.057	**< 0.0001**	0.621–0.843
NSQIP calculator	0.581	0.051	0.144	0.482–0.681
Difference between areas	0.151	0.078	0.055	− 0.003–0.304
Left colectomy only (*n* = 126)				
Anastomoticleak.com calculator	**0.961**	0.018	**<0.0001**	0.925–0.997
NSQIP calculator	0.721	0.147	0.094	0.434–1.000
CLS calculator	**0.800**	0.093	**0.023**	0.618–0.982
Difference between areas				
Anastomoticleak.com vs NSQIP	0.240	0.171	0.161	− 0.096–0.575
Anastomoticleak.com vs CLS	0.161	0.111	0.148	− 0.057–0.379
NSQIP vs CLS	0.079	0.153	0.608	− 0.221–0.378

Results in bold are statistically significant

CI confidence interval, *ROC* receiver operating characteristic curve, *AUROC* area under receiver operating characteristic curve, *CLS* colon leakage score, *NSQIP* National Surgical Quality Improvement Program

p Value indicates comparison between AUROC and 0.5 value (non-predictive curve/null hypothesis)

but ultimately the variables included were somewhat subjectively chosen by "ease of accessibility," and weighted by the collective expertise of three dedicated colorectal surgeons using the Delphi method [19]. The CLS has only been tested in a retrospective fashion for left-sided resections, including patients who had a defunctioning stoma [19, 28]. The method of variable selection and the un-blinded retrospective nature of the validation analysis introduce significant bias, and it remains unclear if this contributed to the very high AUROC values seen in the original studies (in excess of 0.95) [19, 28]. Nevertheless, the results so far for the CLS nomogram for left-sided colon and rectal resections have been promising, and further validation of this score in a prospective fashion is the next logical step, perhaps in rectal cancer patients for whom the anastomoticeak.com calculator does not cater [9, 29]. The NSQIP surgical risk calculator on the other hand was not predictive of anastomotic leak and grossly underestimated the overall risk. While the calculator itself may be underperforming, there are several other possible reasons for this. For example, while the NSQIP calculator does include a post hoc "surgeon adjustment of risk" modifier which increases the risk prediction value across all complications, this could not be used in this study. In addition, the recording of anastomotic leak data in the NSQIP database may be skewed toward grade

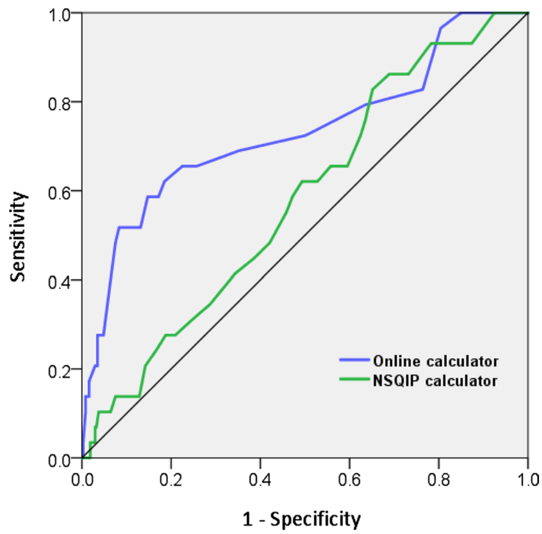

Fig. 2 Receiver operating characteristic curves for the anastomoticleak.com calculator and the ACS NSQIP calculator ($n = 402$). *ACS NSQIP* American College of Surgeons National Surgical Quality Improvement Program

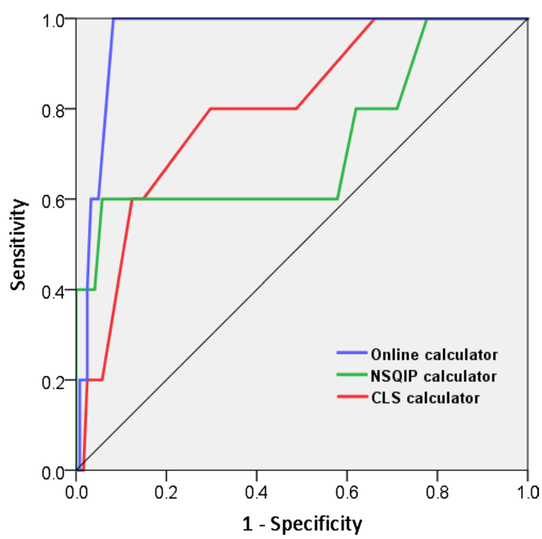

Fig. 3 Receiver operating characteristic curves for the anastomoticleak.com calculator, the ACS NSQIP calculator, and the CLS calculator (left-sided colectomy only, $n = 126$). *CLS* Colon leakage score, *ACS NSQIP* American College of Surgeons National Surgical Quality Improvement Program

C leaks, and not capture grades A and B leaks as accurately since they may be coded as organ/deep space surgical site infection. This is evidenced by the lower-than-expected leak rate reported in prior studies [1, 30].

There is one other published anastomotic leak risk prediction tool in colorectal surgery, called the prognostic colorectal leakage (PROCOLE) index [14]. Similar to the colon leakage score, the PROCOLE index was developed by systematic review including 68 studies published between 2002 and 2012 [14]. Based on the results of these studies, 28 variables were identified as risk factors and a weight assigned to each of these based on published hazard ratios to create a nomogram. The same nomogram is used for all colectomy and proctectomy operations, which may be an issue since there are disparate considerations both in terms of surgical technique/stoma formation and risk factors (such as neoadjuvant chemoradiation). Secondly, the quality of the data on which the nomogram is based on is quite poor and there was not enough high-quality data on which to base a meta-analysis (as acknowledged by the authors). This is likely to significantly confound the results. Thirdly, the nomogram was only tested on data from a small case–control study, and unfortunately, the details of this study were not made available by the authors and so the validity of this approach is unclear. To our knowledge, there are no further publications investigating the PROCOLE index with the exception of a duplicate publication published in the same year [31]. Given the lack of good data, and the large number of variables in this index, we elected not to include it in the present analysis.

While it is clear that further work is needed to further refine and improve these tools, the clinical benefits are obvious. A significant improvement in the accuracy and a reduction in the variation of operative risk judgement by surgeons is seen even with the addition of relatively simple risk assessment aids [12, 32]. The use of artificial intelligence and machine learning to automate and continually improve risk prediction algorithms with updated datasets has the potential to considerably progress the gains already being achieved. To our knowledge, ours is the first study to utilize artificial intelligence analytics in this setting, although the method has shown promise in other areas of healthcare research [33, 34]. Our results demonstrate that new insights can be gained above and beyond the usually employed targeted traditional statistics for risk prediction. Indeed, risk prediction data appear to be an ideal target for this kind of cognitive computing, given the potential size and complexity of the dataset, and the simplicity of the clinical questions which commonly have a binary outcome variable. In the present use case, the analytics software identified patient age as being relevant in the bottom end of the calculator prediction. However, while the modification to the calculator as a result of the analytics data did improve in the AUROC result slightly, the relevance of this is unclear, and whether this warrants an addition of a seventh variable (age < or > 65 years) to the anastomoticleak.com calculator is debatable.

Our study has some limitations. While the BCCA data were collected prospectively, the database is mainly designed as a clinical audit tool and some relevant fields had to be collected retrospectively as a result. In addition, there

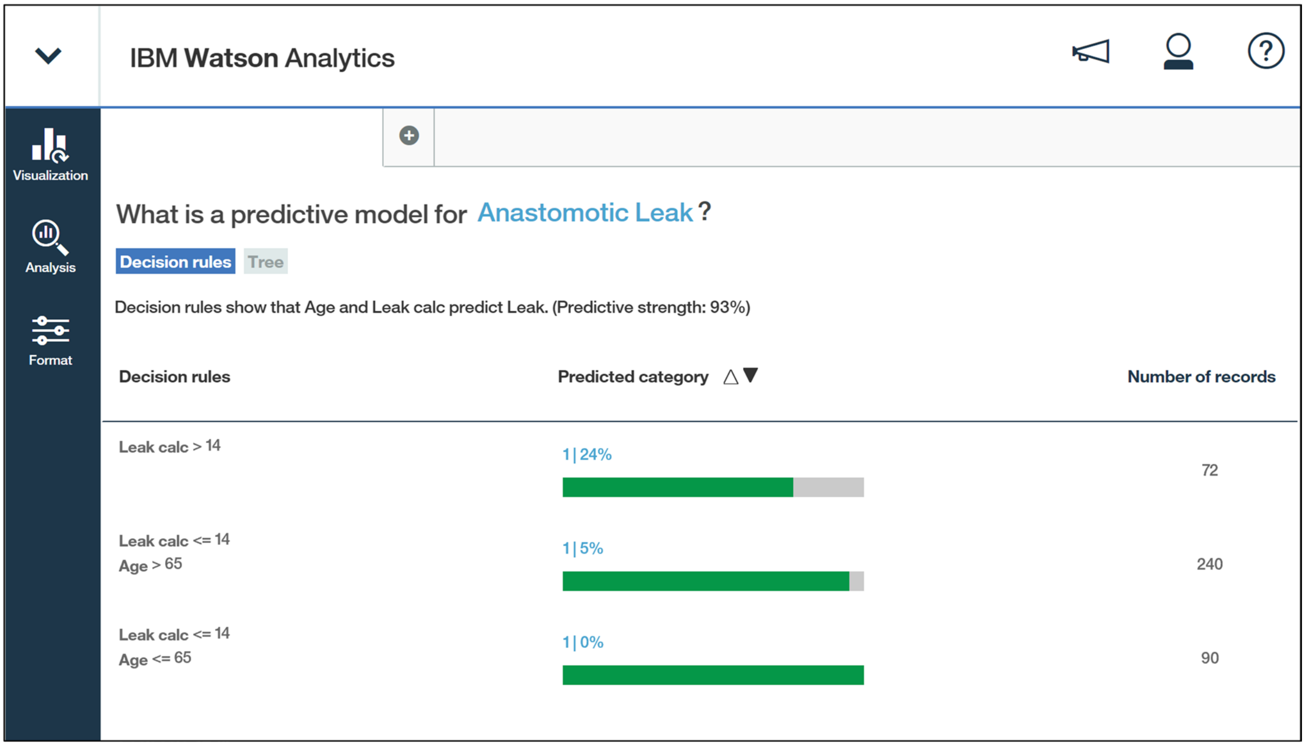

Fig. 4 Predictive model analysis using IBM Watson analytics

were a moderate number of patients (11.8%) with missing data points in the records such that the calculator could not be used and they had to be excluded. Another limitation is that the CLS calculator was used in subset analysis of left-sided colectomy with relatively small numbers only. The artificial intelligence analytics results presented are considered exploratory in nature, since there has been little validation of this novel technique. The Watson analytics platform also does not publish detailed statistical methods presumably because of the complexity of the underlying analysis and natural language processing involved in combination with protected patents on these. Further work is necessary to confirm and define the role of this kind of analysis in clinical research.

Conclusions

The anastomoticleak.com risk calculator is significantly predictive of anastomotic leak after colon cancer resection. Wider investigation of artificial intelligence-based analytics for risk prediction is warranted.

Author's contributions All authors made substantial contributions to the conception, design, acquisition, analysis, and interpretation of data; drafting the article; and revising it critically for important intellectual content and also gave final approval of the version to be published.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval Ethics approval was granted by the Royal Adelaide Hospital Human Research Ethics Committee (reference number: HREC/15/RAH/186, RAH Protocol No: 150524).

Informed consent No informed consent was necessary for the study.

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