Hernia
https://doi.org/10.1007/s10029-019-02120-6

ORIGINAL ARTICLE

The development and validation of risk-stratification models for short-term outcomes following contaminated complex abdominal wall reconstruction

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Received: 1 October 2019 / Accepted: 30 December 2019

Abstract

Background Short-term outcomes for patients undergoing contaminated complex abdominal wall reconstruction (CCAWR), including risk stratification, have not been studied in sufficiently high numbers. This study aims to develop and validate risk-stratification models for Clavien–Dindo (CD) grade ≥ 3 complications in patients undergoing CCAWR.

Methods A consecutive cohort of patients who underwent CCAWR in two European national intestinal failure centers, from January 2004 to December 2015, was identified. Data were collected retrospectively for short-term outcomes and used to develop risk models using logistic regression. A further cohort, from January 2016 to December 2017, was used to validate the models.

Results The development cohort consisted of 272 procedures performed in 254 patients. The validation cohort consisted of 114 patients. The cohorts were comparable in baseline demographics (mean age 58.0 vs 58.1; sex 58.8% male vs 54.4%, respectively). A multi-variate model including the presence of intestinal failure ($p < 0.01$) and operative time ($p < 0.01$) demonstrated good discrimination and calibration on validation. Models for wound and intra-abdominal complications were also developed, including pre-operative immunosuppression ($p = 0.05$), intestinal failure ($p = 0.02$), increasing operative time ($p = 0.04$), increasing number of anastomoses ($p = 0.01$) and the number of previous abdominal operations ($p = 0.02$). While these models showed reasonable ability to discriminate patients on internal assessment, they were not found to be accurate on external validation.

Conclusion Acceptable short-term outcomes after CCAWR are demonstrated. A robust model for the prediction of CD ≥ grade 3 complications has been developed and validated. This model is available online at www.smbari.co.uk/smjconv2.

Keywords Contaminated · Abdominal wall reconstruction · Risk stratification

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Introduction

Complex abdominal wall reconstruction (CAWR) has emerged rapidly over the last 20 years with improved survival following abdominal catastrophe, advances in surgical techniques and bioprosthetics. The Ventral Hernia Working Group (VHWG) published guidelines in 2010, aiming to risk stratify these patients by comorbidity and underlying wound and operative contamination risk [1]. They grade cases from 1 (clean defects in healthy patients) to 4 (contaminated defects in patients with other comorbidity). It has been suggested by Kanters et al. [2], that combining grades 3 and 4, and stratifying contamination according to the Centre for Disease Control (CDC) classification of wound

Published online: 10 February 2020

contamination scale improves the accuracy of prediction of wound morbidity.

Short-term outcomes in patients undergoing reconstruction of contaminated (modified-VHWG 3) defects have not been sufficiently studied in high numbers. A recently published systematic review demonstrated high overall wound complication rates [pooled-proportion 46% (range 18–85%)], which may be expected in a group of patients with pre-operative active wound infection/contamination [3]. The pooled post-operative mortality rate of 2.3% was acceptably low. There was no standardization of outcome measures reported across the studies and minimal use of the validated Clavien–Dindo (CD) scoring system [4].

A number of studies have attempted to determine risk factors for wound complications in this group of patients. Factors such as active smoking, diabetes mellitus, chronic obstructive pulmonary disease (COPD), number of previous hernia repairs, number of previous abdominal operations, and increasing operative time were found to be significant predictors for wound complications [5–8]. These studies, however, all used small cohorts (range 37–128) and are, therefore, at risk of type one error. No analysis has been performed in modified-VHWG grade 3 (contaminated) to look for risk factors associated with other post-operative comorbidity, such as CD grade or return to theatre.

One previous study has developed a risk-stratification score for prediction of surgical site occurrence (SSO) and surgical site infection (SSI) following ventral hernia repair [9]. They successfully validate the score on an external prospective cohort [10]. The most significant predictor of SSO and SSI in this scoring system is wound contamination and, therefore, of limited use to discriminate risk in patients with modified-VHWG 3 defects. It can be hypothesized that evaluating this cohort in isolation would lead to a more accurate model of risk stratification, therefore, this study aims to develop and validate risk-stratification models for CD grade ≥ 3 post-operative complications for patients with modified-VHWG grade 3 abdominal wall defects.

Methods

A collaboration was set up between St Mark's Hospital, London, UK (SMH) and the Amsterdam University Medical Centres, location AMC, Amsterdam, the Netherlands (AUMC), two national referral centres for complex gastrointestinal surgery and intestinal failure. Ethical approval was granted by the local institutional review board and national ethics committee in both centres (UK: REC ref 16/EE/0348; IRAS 210325). The initial cohort used to develop the model was established from consecutive patients undergoing elective repair of a midline modified-VHWG grade 3 abdominal wall defect [2], between January 2004 and December 2015, through local operative databases. The presence of contamination, to define Grade 3 cases, was taken as the presence of a stoma, concomintant gastrointestinal tract violation, the presence of an infected mesh, septic dehiscence or enterocutaneous fistula. To validate the models, an independent cohort of consecutive patients was identified from January 2016 to December 2017. At both centres, data were collected via as retrospective review of prospectively collected clinical databases.

Surgical technique

Both centres have a long-standing history of treating patients with contaminated abdominal wall defects and intestinal failure. All procedures were performed in the elective setting and, therefore, patients received pre-operative medical optimisation, including weight loss and diabetic control. Operative strategies were comparable between the centres and consistent with published guidelines and consensus at the time of operation. Briefly, according to consensus on the management of patients with intestinal failure [11], enterocutaneous fistulas were resected and a primary hand sewn anastomosis was usually performed. Proximal diverting stomas were used when necessary. The primary aim of repair of the abdominal wall defect was tension-free fascial closure with reinforcing retro-rectus or intra-abdominal mesh whenever possible. Open component separation techniques (CST) were used if appropriate and possible. Plastic and reconstructive surgeons were consulted and performed reconstructions where deemed appropriate.

Fascial closure was typically performed using a looped monofilament polydioxanone (PDS) suture. If fascial closure was not achievable, the defect was bridged using an intra-peritoneal onlay mesh or retro-muscular (sublay) mesh. Passive intra-abdominal drains were used where deemed appropriate but not routinely, and active/closed suction subcutaneous drains were used routinely. AUMC preferred interrupted polyester Mersilene sutures (Ethicon, Johnson and Johnson, Belgium), whereas SMH tended to use surgical clips or interrupted prolene sutures for skin closure.

Patient demographics and outcomes

Data were collected for baseline patient demographics including sex, age and body mass index (BMI) at time of surgery, comorbidity, number of previous abdominal operations and previous hernia repairs. Previous open abdomen was defined as long-term management with laparostomy. Operative details including operative time, technique of abdominal wall reconstruction and concurrent procedures were recorded. The validated CD grade of surgical complications was used as the primary short-term outcome measure [4]. Wound morbidity was divided into any wound

complication, and the wound intervention required to treat the complication (conservative/bedside measures vs radiological or surgical intervention) was recorded. Similarly, intra-abdominal septic complications (IASC) (anastomotic leak, intra-abdominal collection and recurrent fistula) were separately defined by their occurrence and required intervention to treat the complication (conservative/bedside measures vs radiological or surgical intervention). This is consistent with recent recommendations in outcome reporting in this cohort [12].

Statistical analysis

Baseline characteristics are presented as proportions and compared between cohorts using the Mann–Whitney test. Uni-variate binary logistic regression analysis was used to identify factors associated with CD ≥ 3, wound intervention and IASC intervention within the development cohort. Multi-variate binary logistic regression, using a backward selection process, was then undertaken on factors of significance to determine a risk-stratification model, with inclusion significance level set at a p value of ≤ 0.05. The logit-p equation was used to determine predicted probabilities for each outcome using factors retained in multi-variate analysis [$\log(p/1-p) = y = \text{constant} + \text{risk factor } A$ (regression coefficient) + risk factor B (regression coefficient) + ⋯], with the probability of complication being defined as $P = (e^y/1 + e^y)$). Receiver operating characteristics (ROC) curves were analysed to assess the predictive ability of the models.

Using the validation cohort, model discrimination was tested by examining the difference in predictive probability of a complication when it occurred compared to when it did not. The predicted probabilities were non-parametric and compared using the Mann–Whitney test. Discrimination was then further evaluated using the c-statistic with a 95% confidence interval. Model calibration was evaluated using the Hosmer–Lemeshow test to compare the predicted and observed number of adverse events. Differences between these groups were assessed using a Chi-squared test with one degree of freedom. Both discrimination and calibration were evaluated together by dividing patients into three categories. These categories were based on the predicted risk of an outcome parameter, and by comparing the observed percentage of an outcome with the predicted risk.

Results

Development cohort: baseline patient demographics and outcomes

The development cohort consisted of 269 consecutive patients who underwent 287 procedures. Fifteen patients who had incomplete or missing records were excluded from the analysis. This resulted in 272 procedures in 254 patients included in the final analysis. The mean age was 58.0 (SD 13.6 years) and 58.8% were male (Table 1).

The median post-operative length of stay was 18 days (IQR 10–31). Eighty-four percent of patients had a post-operative complication on the CD scale, of which 43.8% were of grade 3 or higher. A wound complication was recorded in 58.5% and an intra-abdominal septic complication (see "Methods") in 18.8% (Table 2).

Validation cohort: baseline demographics and outcomes

The validation cohort consisted of 112 consecutive patients who underwent 114 procedures. The mean age was 58.1 (SD 12.6 years) and 54.4% were male (Table 1). No significant differences were seen between the pre-operative demographics of the validation and development cohorts, with the exception of the number of patients with a history of treatment with an open abdomen ($p = 0.01$) and the number where fascial closure was achieved ($p = 0.01$).

The average length of stay was 19 days (IQR 10–37), which was comparable to the development cohort. Any complication on the CD scale was seen in 80.7% of patients, with 40.2% having a complication of grade 3 or higher. A wound complication was recorded in 50.9% and an IASC in 23.7% (Table 2).

Model 1: Clavien–Dindo complication grade 3 or more

Uni-variate analysis identified a number of factors associated with CD ≥ 3. Patient factors included cardiac comorbidity, previous treatment with open abdomen, presence of intestinal failure and presence of an enterocutaneous fistula. Operative factors were operative time, number of bowel anastomoses, the need for component separation techniques and the inability to obtain fascial closure (Table 3).

The factors found to have a significant effect on the likelihood of a CD ≥ 3 complication were entered into a backward stepwise multi-variate logistic regression model. In the multi-variate model, the presence of intestinal failure ($p < 0.01$) and total operative time ($p < 0.01$) remained significant and were included in the final risk model (Table 4). Evaluation of the model using receiver operating characteristics (ROC) revealed a c-statistic of 0.72 (95% CI 0.66–0.79), suggesting a reasonable ability of the model to discriminate between high- and low-risk patients.

Assessment of the models discriminative ability was performed on the validation cohort. A comparison of the predictive percentage of the model revealed a p value of < 0.0001, suggesting that the model is able to discriminate between

Table 1 Baseline demographics of the development and validation cohorts

	Development cohort 272 procedures in 254 patients	Validation cohort 114 procedures in 112 patients	*p* value
Patient characteristics			
Age, mean (SD)	58.0 (13.6)	58.1 (12.6)	0.94
Sex male, *n* (%)	160 (58.8)	62 (54.4)	0.42
BMI, median (IQR)	26.0 (22.6–29.6)	26.0 (22.9–30.5)	0.59
ASA classification, mean (SD)	2.43 (0.5)	2.45 (0.6)	0.70
1	0 (0)	3 (2.6)	
2	162 (59.6)	61 (53.5)	
3	103 (37.9)	46 (40.4)	
4	7 (2.6)	4 (3.5)	
Active smoker, *n* (%)	62 (22.8)	16 (14.0)	0.06
Diabetes, *n* (%)	50 (18.4)	16 (14.0)	0.43
Immunosuppression, *n* (%)	21 (7.7)	9 (7.9)	0.96
Cardiac comorbidity, *n* (%)	63 (23.2)	28 (24.6)	0.77
Pulmonary comorbidity, *n* (%)	55 (20.2)	34 (29.8)	0.04
COPD, *n* (%)	29 (10.7)	11 (9.6)	0.75
Hypertension, *n* (%)	83 (30.5)	34 (29.8)	0.89
Abdominal malignancy, *n* (%)	50 (18.4)	31 (27.2)	0.06
IBD, *n* (%)	39 (14.3)	24 (21.1)	0.06
Intestinal failure, *n* (%)	129 (47.1)	48 (42.1)	0.47
History of open abdomen, *n* (%)	128 (47.1)	38 (33.3)	**0.01**
Presence of intestinal fistula, *n* (%)	159 (58.1)	60 (52.6)	0.42
Operative characteristics			
Number of previous abdominal surgeries, median (IQR)	4 (2–5)	3 (2–5)	0.18
Undergone previous hernia repair/s, *n* (%)	119 (43.8)	49 (43.0)	0.90
Anastomosis constructed, *n* (%)	200 (73.5)	84 (73.7)	
Mesh removal, *n* (%)	59 (21.7)	23 (20.2)	0.74
Open component separation technique performed, *n* (%)	183 (67.3)	85 (74.6)	0.20
Mesh used, *n* (%)	182 (66.9)	77 (67.5)	0.90
Fascial closure achieved, *n* (%)	197 (72.5)	99 (86.8)	**0.01**

Differences between the cohorts have been evaluated using the Mann–Whitney test ($\alpha = 0.05$)

BMI body mass index, *ASA* American Society of Anaesthesiology, *COPD* chronic obstructive pulmonary disease, *IBD* inflammatory bowel disease *SD* standard deviation, *IQR* inter-quartile range

patients. ROC assessment of the model on the validation cohort demonstrated a *c*-statistic of 0.73 (95% CI 0.63–0.82) (Fig. 1). Analysis of the model calibration revealed evidence of good calibration as the predicted and observed complication rates were comparable Examination of this using the Hosmer–Lemeshow test showed a *p* value of 0.12, consistent with good calibration of the model for this outcome (Table 5).

Model 2: wound intervention

Uni-variate analysis demonstrated patient factors including the presence of intestinal failure, previous treatment with an open abdomen and the number of previous abdominal operations ≥ 3 as associated with the requirement for wound intervention. Operative factors were also significantly associated with wound intervention, such as increasing operative time, the number of anastomoses and the use of component separation techniques (Table 3).

Multi-variate analysis retained pre-operative immunosuppression ($p = 0.05$), intestinal failure ($p = 0.02$), increasing operative time ($p = 0.04$) and increasing number of anastomoses ($p = 0.01$) in the final model. ROC demonstrated a reasonable ability of the model to discriminate between high- and low-risk patients ($c = 0.76$; 95% CI 0.68–0.83) (Table 4).

On assessment of the model using the validation cohort, poor discrimination of the model was demonstrated (Fig. 1).

Table 2 Short-term post-operative outcomes from the development and validation cohorts

Outcome	Development ($N=272$)	Validation ($N=114$)
Length of stay (median days, IQR)	18 (10–31)	19 (10–37)
Clavien–Dindo complication, *n* (%)		
0	41 (15.1)	22 (19.3)
1	47 (17.3)	14 (12.3)
2	65 (23.9)	33 (28.9)
3a	38 (14.0)	15 (13.2)
3b	19 (7.0)	8 (7.0)
4a	44 (16.2)	9 (7.9)
4b	11 (4.0)	11 (9.6)
5	6 (2.6)	3 (2.6)
Post-operative wound complication, *n* (%)	159 (58.5)	58 (50.9)
Wound intervention required (interventional radiology or surgery), *n* (%)	71 (26.1)	14 (12.3)
Intra-abdominal septic complication, *n* (%)	51 (18.8)	27 (23.7)
Intra-abdominal septic complication intervention, *n* (%)	42 (15.4)	22 (19.3)
Return to theatre, *n* (%)	33 (12.1)	12 (10.5)
Re-admission within 30 days of discharge, *n* (%)	35 (12.9)	6 (5.3)
Recurrent enterocutaneous fistula, *n* (%)	20 (7.4)	4 (3.5)

IQR inter-quartile range

The predicted percentages of patients with and without a wound intervention were not significantly different on Mann–Whitney testing ($p=0.61$), and evaluation of this data with the *c*-statistic revealed a value of 0.54 (95% CI 0.36–0.73). Calibration testing also did not demonstrate adequate calibration of the model with poor correlation between predicted and observed interventions and a significant difference between the observed numbers and the predicted values ($p<0.001$) (Table 5).

Model 3: intra-abdominal septic complications

Analysis with uni-variate regression revealed only five factors to be associated with an IASC: pre-operative immunosuppression; pre-operative intestinal failure; previous treatment with an open abdomen; presence of an enterocutaneous fistula and a number of previous abdominal operations of three or more (Table 3). These factors were, therefore, entered into multi-variate analysis. Pre-operative immunosuppression ($p=0.04$), pre-operative intestinal failure ($p=0.02$) and the number of previous abdominal operations ($p=0.02$) remained in the final model. ROC revealed a reasonable ability of the model to predict this outcome ($c=0.72$; 95% CI 0.64–0.80) (Table 4).

Assessment of the model using the validation cohort revealed no significant difference in the predicted percentage of intervention versus no intervention ($p=0.62$) (Fig. 1). Evaluation of this result using the *c*-statistic revealed a value of 0.47 (95% CI 0.32–0.61) suggesting poor ability of the model to discriminate between low- and high-risk patients. On assessment of the calibration of the model, there was no observed consistent pattern between the observed and predicted rate of intervention in each group. This revealed that the model significantly under-estimated the rate of intervention in the low-risk group. Hosmer–Lemeshow testing showed a significant difference between the observed and predicted number of interventions ($p<0.001$) suggesting poor calibration of the model to predict this outcome (Table 5). The significant difference observed suggests poor calibration.

Discussion

This study aimed to evaluate short-term outcomes, and to risk stratify patients undergoing contaminated (VHWG grade 3) complex abdominal wall reconstruction. Development and validation of a risk-stratification model for predicting CD complications of grade 3 or more in CCAWR has been demonstrated. This is an inherently heterogeneous and complex group of patients as illustrated by the extensive number of comorbidities, high mean ASA grade, high number of previous abdominal operations and inherent surgical site contamination. Nevertheless, good short-term outcomes with acceptable rates of wound complication and post-operative enterocutaneous fistula recurrence were found. While the total number of patients who experienced any complication (84.9%) and the median length of stay are high, most

Table 3 Uni-variate analysis demonstrating significant factors associated with three key outcomes

Risk factor	Clavien–Dindo Grade ≥ 3 (OR (95% CI))	Wound intervention (OR (95% CI))	Intra-abdominal septic complication (IASC) intervention (OR (95% CI))
Age	1.01 (0.99–1.03)	0.99 (0.97–1.01)	1.00 (0.97–1.02)
Sex (female)	1.10 (0.67–1.79)	1.24 (0.72–2.14)	0.97 (0.50–1.89)
Obese	0.92 (0.51–1.65)	0.93 (0.48–1.78)	0.77 (0.33–1.77)
Smoker	0.61 (0.33–1.11)	0.61 (0.30–1.23)	0.52 (0.21–1.30)
Diabetes	1.02 (0.55–1.91)	0.76 (0.37–1.58)	1.48 (0.68–3.26)
Immunosuppression	1.31 (0.54–3.19)	**2.29 (0.92–5.68)**	**3.09 (1.16–8.18)**
Cardiac comorbidity	**2.29 (1.29–4.05)**	0.76 (0.39–1.49)	1.22 (0.57–2.58)
Pulmonary comorbidity	1.61 (0.89–2.92)	0.85 (0.43–1.69)	1.09 (0.49–2.44)
COPD	1.59 (0.73–3.43)	0.89 (0.36–2.18)	1.16 (0.42–3.23)
IBD	**0.44 (0.20–0.93)**	0.83 (0.37–1.84)	0.78 (0.29–2.12)
Intestinal Failure	**2.59 (1.58–4.25)**	**2.05 (1.18–3.57)**	**2.90 (1.43–5.87)**
Pre-op resistant bacteria	1.43 (0.67–3.06)	0.83 (0.34–2.02)	1.09 (0.39–3.02)
N. previous abdominal surgeries ≥ 3	**2.31 (1.27–4.19)**	**3.00 (1.39–6.42)**	**5.27 (1.57–17.67)**
N. previous hernia surgeries			
1	1.41 (0.81–2.47)	0.86 (0.47–1.61)	0.97 (0.47–2.01)
≥ 2	0.61 (0.30–1.26)	0.38 (0.15–0.95)	0.22 (0.05–0.97)
Recurrent hernia	0.95 (0.58–1.55)	0.57 (0.32–1.00)	0.64 (0.32–1.28)
Previous component separation	1.48 (0.59–3.69)	0.95 (0.33–2.72)	0.60 (0.13–2.69)
Previous open abdomen	**1.71 (1.05–2.79)**	**1.94 (1.12–3.36)**	**2.30 (1.16–4.55)**
Wound classification			
Contaminated	1.85 (1.04–3.30)	**2.18 (1.13–4.24)**	3.57 (1.49–8.57)
Dirty	1.41 (0.72–2.76)	0.92 (0.40–2.10)	0.69 (0.19–2.47)
ECF	**1.76 (1.06–2.90)**	1.69 (0.96–2.99)	**2.60 (1.22–5.53)**
Stoma	1.14 (0.70–1.90)	0.84 (0.48–1.46)	1.33 (0.66–2.70)
Time from last operation	1.78(0.75–4.23)	2.16 (0.72–6.49)	2.44 (0.56–10.71)
Operation time			
3.5–5.5 h	**0.93 (0.43–2.03)**	**0.91 (0.37–2.26)**	0.66 (0.17–2.59)
5.5–7.5 h	**2.02 (0.95–4.26)**	**2.13 (0.93–4.92)**	3.40 (1.16–9.97)
≥ 7.5 h	**9.15 (3.62–23.1)**	**4.48 (1.73–10.1)**	4.85 (1.59–14.81)
Mesh removal	0.96 (0.53–1.72)	0.58 (0.28–1.20)	0.69 (0.29–1.63)
Number of anastomosis			
1	**1.58 (0.78–3.21)**	**3.22 (1.07–9.65)**	1.77 (0.57–5.50)
≥ 2	**3.46 (1.55–7.69)**	**10.0 (3.21–31.2)**	4.40 (1.38–14.04)
Stoma takedown/relocation	1.42 (0.87–2.31)	1.40 (0.82–2.42)	1.46 (0.75–2.82)
Anterior component separation	**1.85 (1.08–3.18)**	**2.79 (1.41–5.54)**	2.15 (0.95–4.87)
Drain use	1.71 (0.86–3.39)	1.29 (0.60–2.75)	4.60 (1.07–19.77)
S/C drain	1.90 (1.00–3.62)	1.48 (0.72–3.07)	2.00 (0.75–5.37)
IA drain	1.20 (0.74–1.94)	1.26 (0.74–2.17)	1.56 (0.80–3.03)
Fascial closure	**1.83 (1.06–3.17)**	1.58 (0.87–2.87)	1.72 (0.85–3.48)

Bold highlighted factors demonstrate a p value of ≤ 0.05 and were used in multi-variate analysis

COPD chronic obstructive pulmonary disease, *IBD* inflammatory bowel disease, *ECF* enterocutaneous fistula, *S/C* subcutaneous, *IA* intra-abdominal

complications were of low grade (CD1/2) and, therefore, this is something that can be expected from such a complex type of surgery [3, 13, 14].

The model for CD outcome appears to have good predictive ability, both in discrimination and calibration tests. This is the first risk-stratification tool designed and validated for use in contaminated ventral hernia surgery, and the first that predicts the risk of a validated outcome measure (Clavien–Dindo grade). Models predicting other short-term outcomes (wound and IASC interventions)

Table 4 Risk-stratification models for Clavien–Dindo complications ≥ 3, wound intervention, IASC intervention and further hernia surgery developed using multi-variate backward selection logistic regression

Outcome	Variable	Category	Odds ratio (95% CI)	Regression coefficient	p-value	c-statistic
Clavien Dindo ≥ 3 Significance 0.05 Removal 0.05 Inclusion 0.05	Constant	–	–	− 1.80	–	0.72 (0.66–0.79)
	Intestinal Failure	No	1		< 0.01	
		Yes	3.08 (1.56–6.06)	1.12		
	Operation time	≤ 3.5 h	1		< 0.01	
		3.5–5.5 h	1.34 (0.53–3.35)	0.29		
		5.5–7.5 h	3.53 (1.46–8.52)	1.26		
		> 7.5 h	11.39 (3.92–33.16)	2.43		
Wound Intervention Significance 0.05 Removal 0.05 Inclusion 0.05	Constant	–	–	− 3.02	–	0.76 (0.68–0.83)
	Immuno-suppression	No	1		0.05	
		Yes	3.02 (0.98–9.29)	1.11		
	Intestinal Failure	No	1		0.02	
		Yes	2.20 (1.11–4.37)	0.79		
	Operation time	≤ 3.5 h	1		0.04	
		3.5–5.5 h	0.88 (0.29–2.72)	− 0.12		
		5.5–7.5 h	2.20 (0.78–6.24)	0.79		
		> 7.5 h	3.17 (1.06–9.43)	1.15		
	Number of anastomosis	0	1		0.01	
		1	2.41 (0.63–9.21)	0.88		
		2+	6.04 (1.46–25.0)	1.80		
IASC Intervention Significance 0.05 Removal 0.05 Inclusion 0.10	Constant	–	–	− 3.60	–	0.72 (0.64–0.80)
	Immuno-suppression	No	1		0.04	
		Yes	2.86 (1.03–7.90)	1.05		
	N. previous abdominal surgeries	≤ 2	1		0.02	
		3+	4.36 (1.28–14.83)	1.47		
	Intestinal Failure	No	1		0.01	
		Yes	2.61 (1.26–5.41)	0.96		

c-statistics derived using receiver-operating characteristic demonstrate values all greater than 0.70 suggesting a moderate discriminatory ability of all models

IASC intra-abdominal septic complication

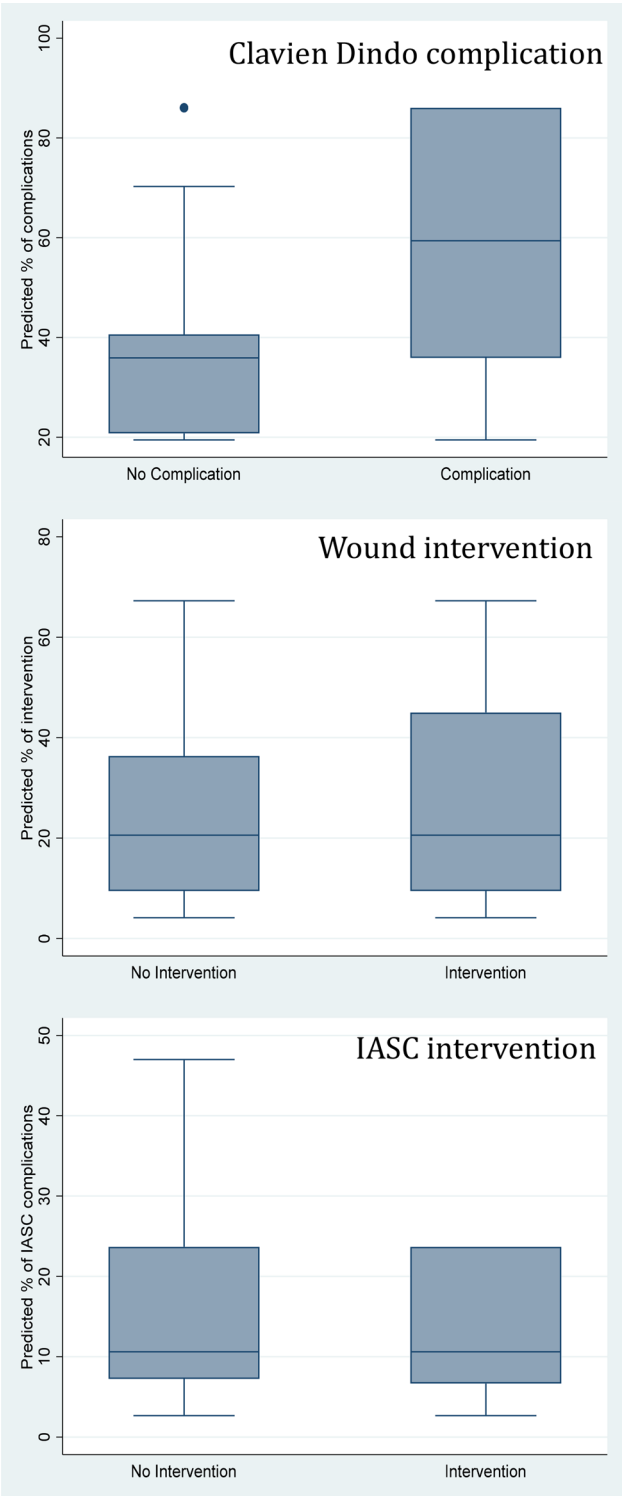

Fig. 1 Evaluation of the discriminative ability of the models using predictive probability of a given outcome. A significant difference was seen between predicted groups when using the Clavien–Dindo model suggesting the model has a moderate ability to discriminate between patients. The other two models did no demonstrate a significant difference

have not demonstrated good predictive ability on validation. Previous studies in smaller cohorts have demonstrated some of the factors identified in these models to also be significant. The choice of wound and abdominal intervention as outcome measures has been selected based on giving the maximal clinical ability to counsel patients pre-operatively. For example, the ability to predict and inform a patient they have high risk for a wound complication in a cohort of patients was a 50% chance of having a wound complication is of limited use [3]. The aim of these models is to aid in discrimination by defining a risk for a given patient of requiring surgical or radiological intervention for wound complications compared to simple measures, such as oral antibiotics. It is unclear why these models proved less effective on validation in the present study. However, it is possibly due to the smaller size of the validation cohort or related to changes in practice patterns, such as the introduction of closed incision negative pressure wound therapy, which potentially reduced the rate of wound infection [15]. This was necessary to include patients and to mount sufficient numbers due to the available length of follow-up. Attempts were undertaken to validate the models, however, additional centres with adequate volume and a similar case mix could not be identified. As the prevalence of these cases at our two institutions has increased in recent years, a further 2–3 years of data collection should provide the evidence to validate or redevelop the current models.

The Ventral Hernia Risk Score (VHRS) is currently the best attempt to risk stratify patients undergoing ventral hernia surgery [9]. This score also includes contaminated wound class as an independent predictor. However, if a patient has a contaminated wound, this immediately places them into the highest risk bracket, as defined by the score, despite the presence or absence of any other risk factor. This, therefore, limits its ability to discriminate in our cohort of patients. The currently developed models aim to fill this gap.

The principle limitation of this study is the retrospective nature of the majority of the data, particularly in the development cohort. Every effort has been made to ensure the robustness of the data collection including cross-checking case notes and clinic letters, review by independent data collectors and discussion with patients when they attended for prospective follow-up. The age of some of this data also limits effectiveness.

The inherently heterogeneous nature of clinical factors within this cohort of patients, such as the range of reasons for underlying contamination, range of patient comorbidity, variety of repair techniques, mesh used and changing practice patterns over time also limits the analysis. Designing a prospective study, controlling for all of these factors and generating sufficient patient numbers for this analysis would be impractical. We have attempted to control for as much of

Table 5 A table demonstrating calibration of the models using Hosmer–Lemeshow and Chi-squared tests

Model/risk group	Number of patients	Observed number of complications (%)	Predicted number of complications (%)	Chi-squared statistic (*p* value)
Clavien–Dindo ≥ 3				
≤ 25%	42	10 (23.8)	8.5 (20.4)	2.5 (0.12)
26–50%	35	12 (34.3)	13.5 (38.5)	
≥ 50%	36	23 (63.9)	26.6 (74.0)	
Wound intervention				
≤ 15%	43	5 (11.6)	3.4 (8.0)	19.7 (< 0.001)
16–30%	39	5 (12.8)	8.4 (21.4)	
≥ 30%	31	4 (12.9)	15.5 (50.1)	
IASC intervention				
≤ 10%	34	9 (26.5)	1.6 (4.6)	37.2 (< 0.001)
11–20%	41	4 (9.8)	4.2 (10.8)	
≥ 20%	39	9 (23.1)	9.6 (24.5)	

the inherent difference as possible by standardising inclusion criteria and repair decisions based on the best available current guidelines.

Another limitation lies within the use of regression analysis and is affected by the paucity of previous analysis of risk factors in this cohort. The ideal methodology for regression analysis would use previously identified risk factors and perform multi-variate analysis to identify the overall effect of each factor, as well as analysis of factors that should be included in the risk model. To avoid over-fitting the model, a factor can only be included in the multi-variate analysis for every ten events for that outcome occurring in the dataset. Due to the lack of previous analysis of risk factors in this cohort, we have used uni-variate analysis to identify significant variables to include

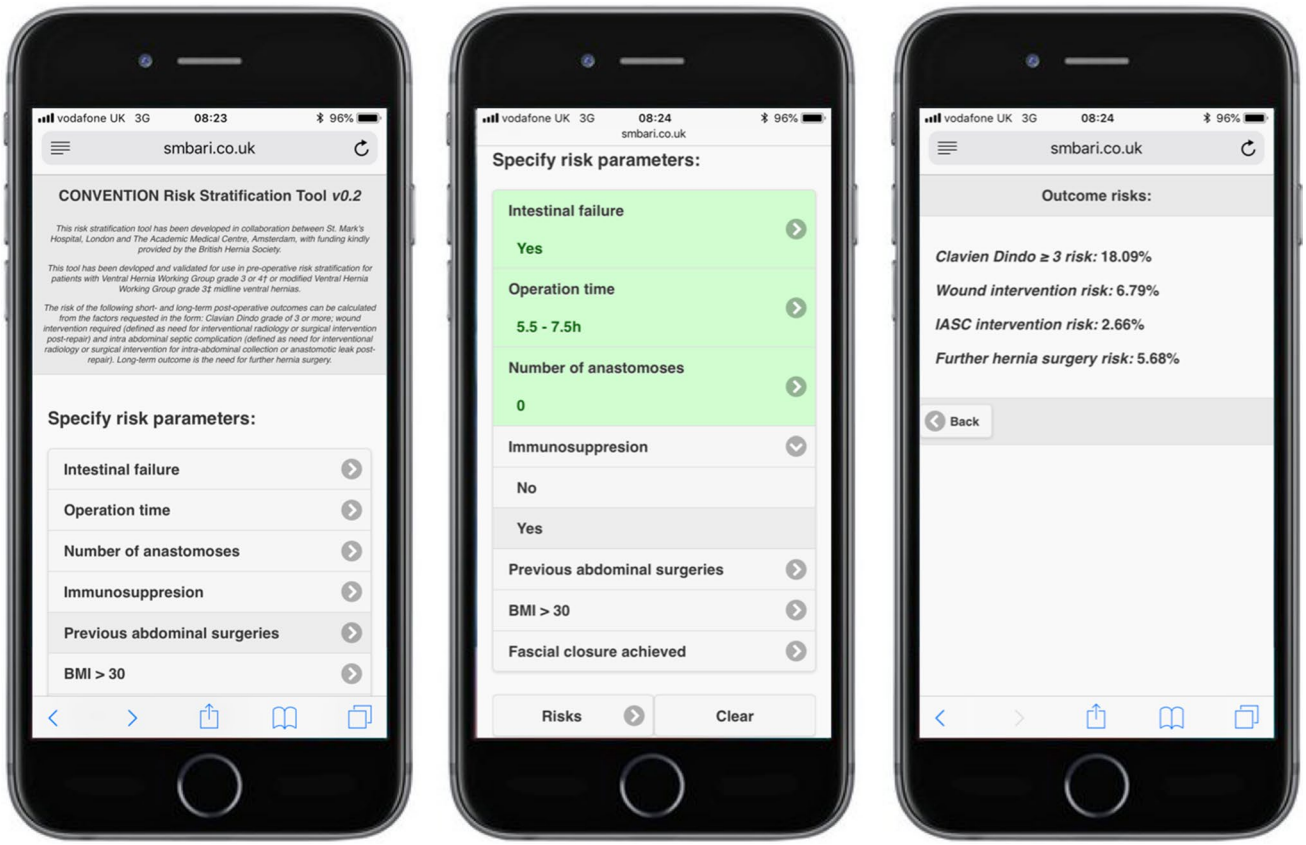

Fig. 2 An example of the Convention webtool in use

in the multi-variate analysis, which puts the model at risk of over-fitting. However, the use of subsequent backward selection and good area under the curve minimise this and improve the chances of model validation. This is demonstrated in the successful validation of the model for CD ≥ 3.

Acceptable short-term outcomes have been demonstrated in this large cohort of contaminated complex abdominal wall reconstructions. The reported model provides the ability to accurately predict the likelihood of a CD ≥ 3 outcome in these patients. While a number of these risk factors have been identified previously and would be discussed with patients, this tool will likely improve the ability of the surgeon to counsel patients pre-operatively, by increasing the accuracy of the strength of the effect of each risk factor and more precisely determining a specific patients risk in an inherently heterogenous cohort. The tool could also improve a patients' outcome by better facilitation of resource planning for the surgery, and checking of the availability of high-dependence post-operative care for high-risk patients. This model is available online at www.smbari.co.uk/smjconv2 for use by clinicians (Fig. 2).

Given the rarity of the condition, the only way to prospectively evaluate short- and long-term outcomes is through collaboration and national/international database development. The identification of significant risk factors in this study could provide the basis of what factors should be stored in such a database.

Acknowledgements The authors would like to acknowledge Mr Paul Bassett, of StatsConsultancy, for his help and support with statistical analysis and model development. The authors would like to thanks Mr Victor Lesk for his work in developing the Convention webtool.

Funding A research award from the British Hernia Society kindly funded the development and creation of the model webtool calculator.

Compliance with ethical standards

Conflict of interest JDH, FEEdV, JJMC, CAL, YM, OvR, OL, MCO, PJT, WAB, JC, GBH and JW declare no conflict of interest directly related to the current work; MAB declares no conflict of interest directly related to the current work and reports institutional research grants from Baxter, Mylan, Ipsen, Acelity/KCI, Bard, LifeCell and Johnson & Johnson/Ethicon and New Compliance; and is a speaker or advisory board member for Acelity/KCI, Bard, LifeCell/Allergan, Gore, Bard, Smith&Nephew and Johnson & Johnson / Ethicon; CJV declares no conflict of interest directly related to the current work and declares consultancy advisor to Acelity and paid lecture for Allergan.

Ethical approval This study was performed in accordance with the ethical standards of the institutional and national research committee (East of England REC ref 16/EE/0348; IRAS 210325) and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. Ethical approval for the study was given by local and national bodies in both centres as stated in the manuscript.

Human and animal rights This retrospective study involving human participants was in accordance with the ethical standards of the institutional and national research committee.

Informed consent Data were obtained from records obtained for clinical purposes.

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