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Accurate Risk Stratification for Development of Organ/Space Surgical Site Infections after Emergent Trauma Laparotomy

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Introduction

Organ/space surgical site infections (OS-SSIs) are a significant problem after trauma laparotomies. OS-SSIs develop in up to 1 out of 5 trauma laparotomies^{1–4} and are associated with significant morbidity, increased healthcare costs, additional procedures, and reduced quality of life.^{5,6} Surgical site infections (SSIs), which include superficial, deep, and OS-SSIs, have been reported to increase patient mortality by 2–11 fold, contribute to an additional 7–11 days of hospitalization, and cost \$3.5 - \$10 billion USD in annual healthcare expenditure.⁷ Surgical Care Improvement Project (SCIP) guidelines aim to reduce the overall incidence of SSIs. Prophylactic measures such as pre-operative antibiotics have been widely adopted for elective surgery. However, despite evidence of benefit, there is still wide variation in use of peri-operative antibiotics after damage control laparotomies.⁸

Furthermore, many evidence-based guidelines to prevent SSIs may not pertain to the trauma population, such as smoking cessation, long-term glucose control, and bowel preparation.⁹

Both general and specialty-specific risk-stratification systems for SSIs have been developed, with perhaps the most well-known system being the National Healthcare Safety Network

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(NHSN) and National Nosocomial Infections Surveillance (NNIS) score. The NHSN/NNIS risk-stratifies surgical patients for SSI development based on 3 variables: the American Society of Anesthesiologist Score, wound classification, and duration of surgery. A disadvantage of this risk-stratification system is its lack of procedure-specificity; for example, it does not take into account risk factors that may play a major role in OS-SSI development in emergent trauma laparotomies. Procedure-specific risk calculators for prediction of SSIs are often derived from a targeted patient population with tailored risk variables and therefore may perform better than general risk models.^{2,10,11} Trauma laparotomy-specific models that have been reported in the literature often include variables that are not available at the completion of the procedure.^{2,8}

Currently, there are no widely accepted models for calculating the risk of OS-SSI after trauma laparotomy at the point of the initial surgical procedure. The ability to accurately stratify trauma laparotomy patients' risk for OS-SSIs early on in their hospital course may allow for modifications in their peri-operative care. Additionally, identifying high-risk patients may allow for more informed clinical trials of post-operative interventions aimed to decrease the rate of OS-SSI. We hypothesized that in trauma patients who undergo emergent laparotomy, probability of OS-SSI can be accurately estimated using patient data available during the index operation.

Methods

Retrospective review was performed of a prospectively maintained database of adult (≥ 16 years) emergent trauma laparotomies from 2011–2016 at a high-volume, level 1 trauma center. OS-SSI was determined by the senior author per the Center for Disease Control as infections occurring within 30 days after emergent trauma laparotomy if no implant was left in place, and the infection appeared to be related to the operation involving any part of the organs and spaces other than the surgical incision.¹² Peri-operative antibiotics administration related to trauma laparotomy was limited to 24 hours post-operatively, and was standardized across all patients in this database. Patient demographics and baseline operating room (OR) variables including age, sex, race/ethnicity, mechanism of injury, Injury Severity Score (ISS) and Abbreviated Abdominal Injury Scale (AIS), body mass index (BMI), intraoperative temperature, intraoperative base excess, and estimated blood loss (EBL) were collected. Potential risk factors for OS-SSIs such as bowel injury, bowel resection, wound class, presence of damage-control laparotomy (DCL), duration of surgery, and red blood cell (RBC) transfusion requirements were collected. The earliest documented case of OS-SSI occurred 5 days after the index laparotomy. Therefore, deaths prior to post-operative day 5 were excluded to avoid death as a competing outcome. Bayesian multilevel logistic regression using regularization was performed to develop the model based on a 70% training sample. Evaluation of model fit using area under the curve (AUC) was performed on a 30% test sample. All variables in the model were selected by the authors based on what has been published in the literature, clinical experience, and whether the variable would be readily available intraoperatively. Hence, it is possible that if certain variables are removed from the final Bayesian model, the coefficients of other variables that remain will change. Therefore, individual variables in the final model are not to be interpreted as independent risk factors in

the development of OS-SSIs, but rather within the context of all variables that together influence the likelihood of OS-SSI development.

Statistical Analysis

Baseline characteristics and patient outcomes between the two groups were compared using Wilcoxon rank-sum test, Pearson's Chi-squared, and Fisher's Exact test, for continuous, binary, and sparse binary outcomes, respectively. Preliminary data analyses characterized the sample in demographic and baseline clinical variables using point estimates and 95% confidence intervals. All univariate statistical calculations were performed using STATA statistical software (version 14.0, Stata Corp; College Station, Texas).

The OS-SSI predictive model adopted a Bayesian perspective because it offered several advantages over traditional frequentist approaches: 1) Bayesian methods such as regularization can be used to develop predictive models where the ratio of predictor variables to events is low, and allows for inclusion of more variables in the predictive model without overfitting,¹³ 2) a Bayesian framework can account for clustering within attending physician,^{13,14} 3) Bayesian approaches allow calculation of predictive probabilities even when there is low conventional statistical power,¹⁶ and 4) the Bayesian approach allows one to iteratively refine the model as future data accrues.

The use of Bayesian regularization differs from frequentist approaches to model development (such as purposeful selection). Of note, the univariate analyses described above did not drive development of the OS-SSI predictive model. Variable selection incorporated in the model were based on theoretically important factors known/suspected to influence SSIs and are available during the operation. The data analytic strategy applied Bayesian regularization to generalized linear multilevel modeling using random intercepts to account for clustering by primary surgeon (R v. 3.4 and Stan v. 2.16).^{16–18} Regularization is the use of a shrinkage approach to render model estimates more likely replicable outside of the current sample by avoiding over-fitting on the current data set. Regularization shrinks variable coefficients towards zero, which decreases the likelihood that predictor variables will be strongly associated with the outcome variable based on idiosyncrasies of the sample and increases the likelihood that there is a true association (Appendix A). Model fitting used posterior predictive checking.¹⁹ Given that Bayesian regularization allows for inclusion of more variables without overfitting the data, all variables initially selected to be in the predictive model remains in the model in contrast to purposeful selection where variables are dropped given a pre-specified p-value in the univariate analysis. These advantages of Bayesian regularization over traditional multiple regression approaches render the model more likely replicable outside of the current data sample.

Results

Between January, 2011 and December, 2016, there were 28,726 total adult trauma admissions and 1,309 emergent trauma laparotomies. After excluding these early deaths, 1,171 trauma laparotomies were included (868 definitive laparotomies [abdominal fascia closed during index operation] and 303 damage control laparotomies [DCL; abdominal

fascia left open during index operation]). OS-SSI developed in 172 patients (15%), of whom 32 also developed superficial SSIs (Figure 1).

Patients were predominantly male (77%); they had a median age of 33 years and a median BMI of 26 (Table 1). On univariate analysis, patients who developed OS-SSIs were more likely to have had a penetrating mechanism of injury. On presentation to the emergency department (ED), patients who developed OS-SSIs were more severely injured and physiologically deranged as demonstrated by lower systolic blood pressures, higher serum lactate levels, lower base excess, and higher ISS and AIS scores (refer to Appendix B – Table 1 for AIS scores). They spent a shorter time in the ED prior to proceeding to the OR. Similarly, patients who developed OS-SSIs were more likely to be bleeding, reflected by greater EBL, receipt of more blood products, and a higher proportion undergoing DCL. Patients who developed OS-SSIs also endured longer OR times and appeared to be less hemodynamically stable and more coagulopathic post-operatively (refer to Appendix B – Table 2 for post-operative vitals and labs). Patient injuries discovered upon trauma laparotomy revealed a high proportion of solid organ, hollow viscus, and abdominal vascular injuries in patients who developed OS-SSIs (refer to Appendix B – Table 3 for injuries and surgical procedures).

Patient outcomes were worse in those who developed OS-SSIs as highlighted by increased post-operative morbidity, longer length of intensive care and hospitalization, and a significantly higher proportion of OS-SSI patients requiring skilled nursing care after hospital discharge (Table 3). There were no significant differences in in-hospital death rate or cause of death between the two groups.

The final model reflects a surgeon's perspective in the OR, using variables available to him/her near the conclusion of a trauma laparotomy. The model includes the following patient variables: age, sex, race/ethnicity, BMI, mechanism of injury (penetrating versus blunt), first intraoperative base excess, first intraoperative temperature, units of RBCs transfused, open small bowel injury, small bowel resection, open large bowel injury, large bowel resection, performance of DCL, wound class, and duration of surgery. Individual variables in the model are not to be interpreted as independent risk factors in the development of OS-SSIs, but rather within the context of all variables that together influence the likelihood of OS-SSI development. The two variables that contributed most to OS-SSIs were DCL and colon resection (Table 2). The AUC of the predictive model validated on the test sample was 0.78 (95% CI 0.71–0.85) (Figure 2), which decreased by 0.07 from training model's AUC of 0.854 (95% CI 0.81 – 0.89).

The final model can be used to calculate individual probabilities of OS-SSI development. For example, suppose an 18-year old male with a penetrating injury has small and large intestinal injuries, undergoes small and large intestinal resection, receives 9 units of RBC transfusion, and undergoes a 140-minute operation requiring DCL. This patient's posterior predictive probability of OS-SSI development is 73% based on the model. Conversely, a 26-year old male with blunt injury without intestinal perforation or resection undergoes an 84-minute definitive laparotomy requiring no blood transfusion has a 3% posterior predictive probability of OS-SSI development.

Discussion

A traumatically injured patient's risk of OS-SSI can be accurately predicted by a model using patient variables available to the surgeon during the index trauma laparotomy. Although multiple variables impact the likelihood of OS-SSI, DCL and colon resection have the strongest influence on development of OS-SSIs.

DCL was the most contributory variable in the OS-SSI predictive model. DCL was first described in the early 1990's, and is an abbreviated, staged laparotomy that allows resuscitation of unstable patients in the intensive care unit prior to return to the operating room.²⁰ Despite its life-saving potential, DCL is thought to be fraught with complications such as OS-SSI, entero-atmospheric fistulae, and ventral hernias.^{21–23} Even after adjusting for differences, such as injury severity, physiologic derangement, and resuscitation volumes, DCL has still been associated with the development of OS-SSI.^{24,25}

However, there are conflicting results regarding this association between DCL and OS-SSIs. Goldberg et al examined 121 trauma laparotomy patients and did not identify an association between DCL and intra-abdominal infection.⁸ At this point, it is unclear if the DCL itself or some unknown confounding factor is responsible for the association between DCL and OS-SSI. A recent single-center quality improvement project successfully reducing the use of DCL was not accompanied by a concurrent reduction in the incidence of OS-SSI.²¹ Thus, it is unknown whether there is a causal relationship between DCL and OS-SSI. An ongoing randomized, controlled trial ([NCT02706041](#)) is specifically addressing this question.

Other factors not included in our final model have been reported to influence the development of an OS-SSI in DCL patients. Increase time to delayed primary fascial closure, increased number of take backs prior to fascial closure, failure to achieve delayed primary fascial closure, and higher ISS have all been associated with intra-abdominal complications, such as OS-SSI.^{1,24–26,28,29,31} We chose not to include those variables in this model as they are not readily available to the surgeon at the time of primary laparotomy in order to calculate a probability of OS-SSI.

The model also identified colon resection as a major contributor to OS-SSI development. Multiple prior studies have also demonstrated this association.^{25,29,30} While interventions exist to decrease OS-SSI in elective colorectal resections, such as bowel preparation, these interventions are not possible in trauma patients who require emergency surgery.⁹ Additionally, risk factors that may be modifiable prior to elective procedures, such as smoking and obesity, are not modifiable in emergency conditions.

Since trauma surgeons are unable to address patient-specific modifiable risk factors, provide pre-operative interventions to decrease the risk of OS-SSI, and always avoid DCL, which is sometimes necessary, accurate risk-stratification of trauma laparotomy patients could better direct testing of promising interventions for decreasing OS-SSI rates. We plan to conduct trials of promising or controversial interventions in patients at higher risk for OS-SSI. For example, direct peritoneal resuscitation (DPR) involves continuously irrigating the abdominal cavity with 2.5% hypertonic glucose-based peritoneal dialysis solution during the time between the index operation and re-exploration. A single-center, open-labeled,

randomized, controlled trial in 103 DCL patients found a significant reduction in the incidence of OS-SSI in patients receiving DPR (3% v 14%, $p<0.05$).²⁶ Although promising, DPR has not yet been demonstrated to be effective in multi-center trials, and has not been tested in patients undergoing definitive laparotomy at the initial operation. Additionally, the role of pre-operative antibiotic prophylaxis and the indications for intra-operative re-dosing of antibiotics remains unknown.^{8,27,28} Given that prolonged post-operative antibiotics could cause serious complications, such as *Clostridium difficile* colitis, we would not subject patients at low risk of OS-SSI to this intervention.

The limitations of this OS-SSI predictive model include a lack of prospective validation. A prospective observation study is underway to evaluate our predictive model on trauma laparotomy patients from our institution. Furthermore, the model was created using the data of a single center, bringing into question generalizability. One of the advantages of Bayesian statistics is the ability to iteratively the model. Although the AUC of 0.78 is fair (not excellent), the model is designed to stratify patients based on risk of OS-SSI at the time of index laparotomy in order to identify patients in whom additional interventions aimed at reducing OS-SSIs may be of benefit. One-hundred percent accuracy is not necessary for this purpose. Furthermore, while the AUC of the test sample decreases by 0.06 from the AUC of the training sample, the credible intervals for each estimate overlap. This is likely due our use of Bayesian regularization to decrease the degree of over-fitting the data in the training sample, which yields a more realistic picture of performance of the predictive model in future sample estimations. We plan to update our model using data from a prospective, multicenter laparotomy study. Finally, the model is complex. To address this, a web application is under development to provide a user-friendly interface for OS-SSI probability calculations based on our predictive model.

Conclusion

Using a combination of factors available to surgeons during an emergent laparotomy, the probability of OS-SSI could be accurately estimated using this predictive model. A web-based calculator is under design to allow the real-time estimation of probability of OS-SSI intraoperatively. The calculator could be used to improve intra- or post-operative management of moderate and high-risk patients. Prospective validation of its generalizability to other trauma cohorts and of its utility at the point-of-care is required.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Figure 1:
Patient selection flow diagram.

Figure 2: Receiver Operating Characteristics (ROC) curve for OS-SSI prediction model on test sample set. Area under the curve (AUC) = 0.78 (95% CI 0.71–0.85).

Table 1:

Patient Demographics

	No OS-SSI (n=999)	Yes OS-SSI (n=172)	p-value
Age, years (median IQR)	33 (24 – 46)	33 (22 – 47)	0.554
Sex			
Female	240 (24%)	30 (17%)	0.058
Male	759 (76%)	141 (83%)	
Race/Ethnicity			
White	400 (40%)	54 (31%)	0.053
Black	232 (23%)	50 (29%)	
Hispanic	334 (33%)	58 (34%)	
Other	32 (3%)	10 (6%)	
Mechanism of Injury			
Blunt	562 (56%)	69 (40%)	<0.001
Penetrating	437 (44%)	103 (60%)	
Injury Severity Score	18 (10, 29)	22 (13, 34)	0.006
Type of Laparotomy			
Definitive	799 (80%)	69 (40%)	<0.001
Damage control	200 (20%)	103 (60%)	
Body Mass Index (median IQR)	26 (23 – 30)	27 (24 – 30)	0.607
Emergency Department (ED) Vital Signs, Labs, and Fluids			
Temperature, F	97.8 (97.0, 98.4)	97.5 (96.8, 98.2)	0.017
Systolic Blood Pressure, mmHg	118 (98, 134)	101 (82, 125)	<0.001
Heart Rate, beats/min	98 (82, 114)	100 (84, 120)	0.169
Glasgow Coma Score	15 (14, 15)	15 (9, 15)	0.022
Lactate, mg/dL	3.0 (2.0, 4.6)	4.0 (2.5, 6.6)	<0.001
Base Excess, mmol/L	–3 (–6, –1)	–5 (–8, –2)	<0.001
Hematocrit, %	39.3 (35.1, 42.7)	38.6 (35.2, 42.7)	0.881
Platelet Count	231 (198, 275)	229 (201, 278)	0.937
Crystalloid, mL	0 (0, 0)	0 (0, 0)	0.057
Red Blood Cells, units	0 (0, 1)	0 (0, 1)	0.033
Fresh Frozen Plasma, units	0 (0, 1)	0 (0, 1)	0.325

	No OS-SSI (n=999)	Yes OS-SSI (n=172)	p-value
Operating Room Vital Signs, Labs, and Fluids			
First Temperature, F	96.8 (95.9, 97.9)	96.8 (95.4, 97.5)	0.009
First Systolic Blood Pressure, mmHg	123 (104, 140)	115 (93, 138)	0.003
First Heart Rate, beats/min	97 (83, 110)	101 (87, 118)	0.051
First pH	7.32 (7.25, 7.37)	7.28 (7.22, 7.36)	0.002
First Base Excess, mmol/L	-4 (-7, -1)	-5 (-9, -2)	0.002
First Lactate, mg/dL	2.5 (1.6, 3.8)	3.2 (2.2, 5.0)	<0.001
First Hematocrit, %	35 (30, 39)	35 (30, 39)	0.670
Time from ED to Surgical Start (min)	84 (47, 170)	51 (32, 91)	<0.001
Operating Room Time (min)	120 (83, 178)	146 (109, 216)	<0.001
Crystalloid, mL	1400 (900, 2000)	1200 (800, 2000)	0.254
Colloid, mL	500 (0, 1000)	500 (0, 1000)	0.050
Red Blood Cells, units	0 (0, 3)	3 (0, 9)	<0.001
Fresh Frozen Plasma, units	0 (0, 2)	3 (0, 8)	<0.001
Platelets, units	0 (0, 0)	0 (0, 6)	<0.001
Cryoprecipitate, units	0 (0, 0)	0 (0, 0)	0.006
Estimated Blood Loss, mL	300 (100, 800)	750 (300, 2000)	<0.001

Table 2:

Predictive Model for OS-SSI Development

Variable	Odds Ratio [95% CI]
Delayed-closure laparotomy (DCL)	4.67 [2.58 – 8.44]
Colon resection	3.34 [1.53 – 6.85]
Mechanism of injury (penetrating versus blunt) *	1.62 [0.94 – 3.29]
Small bowel resection	1.61 [0.95 – 3.13]
Open colon injury	1.42 [0.85 – 3.33]
Red blood cell transfusion (units)	1.26 [0.97 – 1.71]
Base excess	1.20 [0.98 – 1.85]
Surgery Duration (minutes)	1.20 [0.96 – 1.57]
Sex (female is reference category)	1.17 [0.81 – 2.12]
Open small bowel injury	1.12 [0.71 – 2.08]
Age (years)	1.09 [0.91 – 1.39]
Wound class	1.05 [0.78 – 1.47]
temperature (degrees Fahrenheit)	0.99 [0.77 – 1.28]
Body Mass Index (BMI)	0.94 [0.74 – 1.12]
Race/Ethnicity = White (reference race)	-
Race/Ethnicity = Black	0.99 [0.65 – 1.45]
Race/Ethnicity = Hispanic	1.07 [0.78 – 1.66]
Race/Ethnicity = Other	0.91 [0.35 – 1.74]
Area under the curve (AUC)	0.78 [0.71 – 0.85]
Intercept	0.03 [0.02 – 0.07]

* blunt is the reference category

Table 3:

Patient Outcomes

	No OS-SSI (n=999)	Yes OS-SSI (n=172)	p-value
Mortality			
Death	48 (5%)	5 (3%)	0.325
Disposition			0.008
Home	775 (78%)	119 (70%)	
SNF	50 (5%)	11 (6%)	
LTAC	37 (4%)	17 (10%)	
Rehab	73 (7%)	18 (11%)	
Other	15 (2%)	2 (1%)	
Morgue	48 (5%)	5 (3%)	
Cause of Death			0.674
Hemorrhage	1 (2%)	0 (0%)	
TBI	16 (33%)	1 (20%)	
Cardiopulmonary Arrest	2 (4%)	0 (0%)	
Respiratory Failure	2 (4%)	0 (0%)	
Stroke	3 (5%)	1 (20%)	
MOF/Sepsis	24 (50%)	3 (60%)	
Morbidity			
Ileus	169 (17%)	75 (44%)	<0.001
Enteric Suture Line Failure	4 (0%)	33 (19%)	<0.001
Bacteremia	26 (3%)	37 (22%)	<0.001
Sepsis	123 (12%)	110 (64%)	<0.001
Enterocutaneous Fistula	4 (0%)	21 (12%)	<0.001
Pancreatic Leak	21 (2%)	25 (15%)	<0.001
Fascial Dehiscence	30 (3%)	56 (33%)	<0.001
Acute Kidney Injury	86 (9%)	50 (29%)	<0.001
Lengths of Stay (median, IQR)			
Hospital-free days	20 (11, 25)	0 (0, 13)	<0.001
ICU-free days	28 (23, 30)	22 (11, 27)	<0.001
Ventilator-free days	30 (27, 30)	27 (20, 29)	<0.001

SNF = skilled nursing facility, LTAC = long-term acute care facility, TBI = traumatic brain injury, MOF = multi-organ failure