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Development and validation of a point-of-care clinical risk score to predict surgical site infection following open spinal fusion

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ABSTRACT

Background: Surgical site infection (SSI) after open spine surgery increases healthcare costs and patient morbidity. Predictive analytics using large databases can be used to develop prediction tools to aid surgeons in identifying high-risk patients and strategies for optimization. The purpose of this study was to develop and validate an SSI risk-assessment score for patients undergoing open spine surgery.

Methods: The Premier Healthcare Database of adult open spine surgery patients (n = 157,664; 2,650 SSIs) was used to create an SSI risk scoring system using mixed effects logistic regression modeling. Full and reduced multilevel logistic regression models were developed using patient, surgery or facility predictors. The full model used 38 predictors and the reduced used 16 predictors. The resulting risk score was the sum of points assigned to 16 predictors.

Results: The reduced model showed good discriminatory capability (C-statistic = 0.75) and good fit of the model ([Pearson Chi-square/DF] = 0.90, CAIC=25,517) compared to the full model (C-statistic = 0.75, [Pearson Chi-square/DF] =0.90, CAIC=25,578). The risk scoring system, based on the reduced model, included the following: female (5 points), hypertension (4), blood disorder (8), peripheral vascular disease (9), chronic pulmonary disease (6), rheumatic disease (16), obesity (12), nicotine dependence (5), Charlson Comorbidity Index (2 per point), revision surgery (14), number of ICD-10 procedures (1 per procedure), operative time (1 per hour), and emergency/urgent surgery (12). A final risk score as the sum of the points for each surgery was validated using a 1,000-surgery random hold-out (independent from the study cohort) sample (C-statistic = 0.77).

Conclusions: The resulting SSI risk score composed of readily obtainable clinical information could serve as a strong prediction tool for SSI in preoperative settings when open spine surgery is considered.

Background

Surgical site infection (SSI) after spine surgery can result in poor patient outcomes and increased healthcare costs [1–3]. The reported SSI rate following spine surgery is highly variable between 1% and 12% [4,5], with an estimated average per patient direct cost of approximately $16,000 per SSI [6,7]. With the increasing rate of spine surgeries being performed, hospitals are to a greater extent forced to absorb the healthcare cost for treatment of these infections. This financial impact has led to a developing focus on preventative strategies and prompted the US Centers for Medicare and Medicaid Services to establish the incidence of SSI as a reportable performance indicator of quality care.

Prevention of SSI is multifactorial owing to a variety of patient and surgery-associated risk factors that may be involved. Risk reduction strategies often target different phases of patient care (pre-operative, intra-operative and post-operative). This has led to the routine practice of infection prevention bundles, which utilize a combination of best practices (surgical hand washing, pre-incisional antibiotic prophylaxis, skin preparation, sterile draping, etc.) [8,9]. Although these measures have been successful in reducing SSI rates, SSIs remain the most common

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Short summary sentence: A surgical site infection risk-assessment tool was developed using readily obtainable clinical information at the point of care to preoperatively identify a risk level continuum for experiencing an SSI among patients undergoing open spine surgery.

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healthcare associated infection and most frequent cause of unplanned surgical hospital admissions [10,11]. This necessitates that a continued effort to prevent SSI remains paramount for all shareholders.

Approximately 1.6 million spinal fusions are performed annually in the United States [12]. While there is a trend toward opting for less invasive surgical strategies to reduce recovery times and chances of complications, traditional open spine surgeries remain prevalent. Open spinal surgery typically involves a midline incision, subperiosteal dissection of muscle tissue, and muscle retraction for longer periods, all of which increase the potential for wound complications. The degree of surgical invasiveness has been shown to be a strong risk factor for SSI [13]. Furthermore, many patients may require a revision surgery which has been shown to have a higher rate of wound complications than the primary index operation [14]. Age, diabetes, obesity, smoker, female sex, dementia, and chronic steroid use have also been identified risk factors for developing an SSI [3,15–20], as have surgical factors such as operative region, procedure duration, posterior approach, and case urgency (elective vs. urgent/emergency) [19,21-24].

Predictive analytics using large databases is an emerging method to develop prediction tools to aid surgeons in better determining outcomes for patients [25–27]. This technology has become a powerful clinical tool to enhance expectation management and shared decision making. Risk scores derived from predictive tools may help stratify overall risk and determine which patients should undergo more extensive evaluation and postoperative care [28].

Although various studies have identified certain independent SSI risk factors for patients undergoing spine surgery [15], clinically meaningful predictive analytic tools to preoperatively determine SSI risk for open spine surgery are lacking in the literature. There is a need for a simplified SSI risk-assessment tool for spinal incisions using available preoperative variables to accurately stratify overall risk. The purpose of this study was to develop and validate a surgical site infection risk assessment tool to minimize uncertainty in predicting SSI rate following open spine surgeries. The goal of this point-of-care clinical tool was to identify a risk level continuum for experiencing an SSI.

Methods

Data source

Data from the all-payer Premier Healthcare Database (PHD) of adult open spine surgery patients (January 1, 2019 to September 30, 2020) were queried for this model. The PHD contains real-world data that has been accruing since 2000 from a large diverse population, reflecting the clinical practices in the general population. Medical records of more than 231 million patients from over 1041 contributing hospitals/healthcare systems are included in the database [29]. This study utilized deidentified data and was exempt from institutional review board review.

Study population

To extract data for the model, a series of 463 pre-identified ICD-10 open procedures were used, describing a traditional open approach for spine surgery. The complete records of 158,664 open spine surgeries were extracted for analysis, of which 2672 (1.7%) were classified as having an SSI. The records represented various payors, including but not limited to Medicare (49.0%), managed care (23.7%), Medicaid (9.1%), commercial (8.8%), and self pay (1.2%). Records of patients under age 18 or patients who used negative pressure therapy over the closed incision were excluded from analysis. A total of 157,664 records (2650 SSIs) used for the main SSI prediction comprised the primary study cohort. A hold-out 1000-case random sample was selected to be the validation cohort.

Measures

Dependent variable

The dependent variable measured in this study was SSIs attributable to the original incisions of open spine procedures. SSI was characterized as any incisional infection occurring during the postoperative inpatient stay, in the outpatient setting, or during readmission within 90 days of surgery. Records that contained one of three pre-identified ICD-10 codes (T81.41, T81.42, T81.43) and/or one of five diagnosis-related group (DRG) codes (856, 857, 858, 862, 863) were classified as having occurrence of an SSI. These ICD-10 and DRG codes were aligned with categories for incisional SSI (superficial [T81.41], deep [T81.42], or organ/space [T81.43]) as defined by the Centers for Disease Control and Prevention. Records that did not contain ICD-10 code "T81.4″ or any of its variates or any of the five aforementioned SSI DRG codes were coded as "No SSI".

Risk factors

Patient-, facility- and procedure-specific risk factors known to be predictors of higher SSI rates after spine surgeries [13,30] were the independent variables measured in this study. Most records did not include weight, body mass index or lab values, and therefore, this data was not extracted for analysis. Patient comorbidities, such as obesity and rheumatic disease, were determined via ICD-10 codes. A surgery's spinal region risk score was calculated as the sum of the points assigned to three different spinal regions (cervical, thoracic or lumbosacral) in which the surgery was performed. Cervical level vertebra/joint/disk was assigned 1 point, thoracic level vertebra/joint/disk was assigned 2 points, and lumbosacral level vertebra/joint was assigned 3 points. Spine surgery invasiveness index [31] was a proximate estimate based on procedure codes listed for each patient.

Statistical analysis

A mixed effects logistic regression model was developed as a foundation for a scoring algorithm of SSI risk. Logistic regression modeling was used to create a risk scoring system from a sample (n = 157,664; 2650 SSIs). First, a full multilevel logistic regression SSI risk model was developed to determine the association between SSI (independent variable) and 38 patient, surgery, or facility predictors (Table 1) originally identified from the PHD dataset. The 38 factors used in the full model are well-known predictors of higher SSI rates in open spine surgery as reported widely in literature [13,30]. Significant variances across facilities were controlled by adding a random effect in the intercept.

A reduced multilevel logistic regression model was developed using 16 of the most significant and strong predictors from the full model of 38 predictors, and the discriminatory capability and goodness of fit were compared between the full and reduced models (Table 2).

A risk-assessment point scoring system was then developed from the 16 predictors in the reduced model to weight each factor according to its effect size in association with SSI. Points were assigned based on relative strength of each factor: the smallest coefficient (0.034) was assigned 1 point, and each other risk factor was assigned a score (rounded to integer) by dividing its β by 0.034 [32]. The resulting risk score was the sum of points assigned to the 16 individual predictors, for a possible score ranging from 0 to 290+, depending on the number of ICD procedures and operative hours.

The discriminatory capability of the two models was assessed by receiver operating characteristic (ROC) curve analysis or C-statistic. Goodness of fit was assessed via a chi-square statistic (Chi-Square/DF). The deviance or Pearson's chi-square divided by its degrees of freedom served as an estimate of the dispersion parameter □, assessing goodness of fit of a given generalized linear model in SAS' PROC GENMOD [33]. ROC of the full model served as a benchmark for comparison to determine whether the reduced model was a comparably strong prediction of SSI. A hold-out sample of 1000 random observations (22 SSIs) was

Table 1
Relationship between SSI risk and 38 risk factors in the *Full Model*.

SSI Risk Full Model	β	SE	P Value	Odds Ratio (95% CI)	All Open Spine Surgeries (n = 157,664)	No SSI (n = 155,014)	SSI (n = 2650)
Demographics							
Age	−0.01	0.002	<0.0001	1.0 (1.0,1.0)	60.8 ± 13.5	60.8 ± 13.5	60.9 ± 12.9
Sex: F	0.2	0.04	0.0002	1.2 (1.1,1.3)	79,889 (50.7%)	78,452 (50.6%)	1437 (54.2%)
Sex: M	Ref	Ref	Ref	Ref	77,775 (49.3%)	76,562 (49.4%)	1213 (45.8%)
Patient-related risk factors							
Asthma	−0.2	0.1	0.0378	0.8 (0.7,1.0)	14,377 (9.1%)	14,074 (9.1%)	303 (11.4%)
Blood Disorder[a]	0.2	0.05	<0.0001	1.3 (1.2,1.4)	39,160 (24.8%)	38,144 (24.6%)	1016 (38.3%)
Myocardial Infarction	−0.2	0.1	0.031	0.8 (0.7,1.0)	9575 (6.1%)	9326 (6.0%)	249 (9.4%)
Para/Hemiplegia	−0.1	0.1	0.2062	0.9 (0.7,1.1)	9678 (6.1%)	9342 (6.0%)	336 (12.7%)
Renal Disease	−0.2	0.1	0.0709	0.8 (0.7,1.0)	15,078 (9.6%)	14,618 (9.4%)	460 (17.4%)
Cancer	−0.4	0.1	0.0029	0.7 (0.6,0.9)	6783 (4.3%)	6585 (4.2%)	198 (7.5%)
Metastatic Carcinoma	−1.1	0.2	<0.0001	0.3 (0.2,0.5)	3034 (1.9%)	2920 (1.9%)	114 (4.3%)
AIDS/HIV	−1.1	0.4	0.006	0.3 (0.1,0.7)	312 (0.2%)	304 (0.2%)	8 (0.3%)
Congestive Heart Failure	0.1	0.1	0.4919	1.1 (0.9,1.2)	11,056 (7.0%)	10,673 (6.9%)	383 (14.5%)
PVD	0.2	0.1	0.0281	1.2 (1.0,1.4)	10,266 (6.5%)	9935 (6.4%)	331 (12.5%)
Cerebrovascular Disease	−0.3	0.1	0.0003	0.7 (0.6,0.9)	7116 (4.5%)	6935 (4.5%)	181 (6.8%)
Dementia	0.2	0.1	0.0603	1.2 (1.0,1.5)	2995 (1.9%)	2884 (1.9%)	111 (4.2%)
Chronic Pulmonary Disease	0.3	0.1	0.0008	1.3 (1.1,1.5)	34,821 (22.1%)	33,966 (21.9%)	855 (32.3%)
Rheumatic Disease	0.4	0.1	<0.0001	1.5 (1.3,1.7)	7959 (5.0%)	7688 (5.0%)	271 (10.2%)
Peptic Ulcer Disease	−0.3	0.2	0.0506	0.7 (0.5,1.0)	1541 (1.0%)	1501 (1.0%)	40 (1.5%)
COPD	−0.4	0.1	<0.0001	0.7 (0.6,0.8)	13,798 (8.8%)	13,481 (8.7%)	317 (12.0%)
Hypertension	0.3	0.05	<0.0001	1.3 (1.2,1.4)	80,961 (51.4%)	79,519 (51.3%)	1442 (54.4%)
Diabetes	−0.02	0.1	0.7845	1.0 (0.8,1.1)	41,456 (26.3%)	40,405 (26.1%)	1051 (39.7%)
Liver Disease	0.1	0.1	0.255	1.1 (0.9,1.3)	6574 (4.2%)	6335 (4.1%)	239 (9.0%)
Obesity	0.3	0.04	<0.0001	1.4 (1.3,1.5)	38,439 (24.4%)	37,528 (24.2%)	911 (34.4%)
Charlson Comorbid. Index	0.2	0.03	<0.0001	1.2 (1.2,1.3)	1.6 ± 2.2 (SD = 2.2)	1.5 ± 2.2	2.9 ± 3.0
Alcohol Disorder	0.2	0.1	0.1203	1.2 (1.0,1.5)	3857 (2.4%)	3760 (2.4%)	97 (3.7%)
Cocaine Disorder	−0.5	0.3	0.1534	0.6 (0.3,1.2)	581 (0.4%)	571 (0.4%)	10 (0.4%)
Nicotine Dependence	0.1	0.1	0.0069	1.2 (1.0,1.3)	24,887 (15.8%)	24,374 (15.7%)	513 (19.4%)
Surgery-related risk factors (open spine procedure)							
Surgical Category: Revision	0.5	0.05	<0.0001	1.6 (1.5,1.8)	31,843 (20.2%)	30,984 (20.0%)	859 (32.4%)
Surgical Category: Primary	Ref	Ref	Ref	Ref	125,821 (79.8%)	124,030 (80.0%)	1791 (67.6%)
Blood Transfusion	0.2	0.1	0.0042	1.2 (1.1,1.4)	7454 (4.7%)	7176 (4.6%)	278 (10.5%)
Spinal Region Risk Score	0.02	0.01	0.0665	1.0 (1.0,1.0)	3.9 ± 2.2	3.9 ± 2.2	4.2 ± 2.4
No. ICD-10 Procedures	0.01	0.01	0.3328	1.0 (1.0,1.0)	4.1 ± 2.4	4.1 ± 2.4	4.6 ± 3.0
Type: Emergency/Urgent	0.4	0.05	<0.0001	1.5 (1.3,1.6)	29,926 (19.0%)	29,058 (18.7%)	868 (32.8%)
Operative Time (Hours)	0.03	0.01	<0.0001	1.0 (1.0,1.0)	4.2 ± 2.3 (SD = 2.3)	4.2 ± 2.3	4.7 ± 2.4
Invasiveness Index	0.02	0.01	0.0012	1.0 (1.0,1.0)	4.4 ± 3.9	4.4 ± 3.9	5.1 ± 5.1
Facility-related risk factors							
100–199 Beds	0.3	0.2	0.0625	1.4 (1.0,2.0)	17,912 (11.4%)	17,663 (11.4%)	249 (9.4%)
200–299 Beds	0.4	0.2	0.0211	1.5 (1.1,2.1)	22,970 (14.6%)	22,582 (14.6%)	388 (14.6%)
300–399 Beds	0.3	0.2	0.0726	1.4 (1.0,2.0)	26,337 (16.7%)	25,915 (16.7%)	422 (15.9%)
400–499 Beds	0.4	0.2	0.0353	1.5 (1.0,2.1)	20,120 (12.8%)	19,785 (12.8%)	335 (12.6%)
500+ Beds	0.4	0.2	0.031	1.5 (1.0,2.1)	64,287 (40.8%)	63,091 (40.7%)	1196 (45.1%)
000–099 Beds	Ref	Ref	Ref	Ref	6038 (3.8%)	5978 (3.9%)	60 (2.3%)
Cost Type: Procedural	−0.01	0.07	0.93	1.0 (0.9,1.1)	110,508 (70.1%)	108,588 (70.1%)	1920 (72.5%)
Cost Type: RCC	Ref	Ref	Ref	Ref	47,156 (29.9%)	46,426 (29.9%)	730 (27.5%)
Region Midwest Provider	0.2	0.1	0.0825	1.2 (1.0,1.5)	37,012 (23.5%)	36,401 (23.5%)	611 (23.1%)
Region South Provider	0.3	0.1	0.0066	1.3 (1.1,1.6)	74,794 (47.4%)	73,468 (47.4%)	1326 (50.0%)
Region West Provider	0.4	0.1	0.0004	1.5 (1.2,2.0)	18,261 (11.6%)	17,906 (11.6%)	355 (13.4%)
Region Northeast Provider	Ref	Ref	Ref	Ref	27,597 (17.5%)	27,239 (17.6%)	358 (13.5%)
Rural Location Provider	0.004	0.1	0.9726	1.0 (0.8,1.2)	13,186 (8.4%)	12,976 (8.4%)	210 (7.9%)
Urban Location Provider	Ref	Ref	Ref	Ref	144,478 (91.6%)	142,038 (91.6%)	2440 (92.1%)
Teaching Hospital	0.1	0.1	0.3495	1.1 (0.9,1.2)	86,771 (55.0%)	85,230 (55.0%)	1541 (58.2%)

[a] Blood disorder: coagulation defects, purpura and other hemorrhagic conditions

SE: standard error; Ref: reference; PVD: peripheral vascular disease; COPD: chronic obstructive pulmonary disease; No: number; RCC: ratio of costs-to-charges (to pay hospitals for services exempt from DRG payment).

independent from the primary study cohort for validation of our final prediction model. A prediction model with the risk score as the only predictor in the primary study cohort was fitted to examine the risk score's predictive power.

Results

Descriptive statistics

The primary study cohort comprised a large number of cases with SSIs (n = 2650; 1.7%) as well as cases with no SSIs (n = 155,014; 98.3%) (Table 1). The average age of open spine surgery patients at the time of initial surgery was 60.8 (range: 18–89) years old and 50.7% of the study cohort were female. A relatively high proportion of the cohort was obese (24.4%) and/or hypertensive (51.4%); blood disorders affected 24.8% of the population, 15.8% were current smokers, and 22.1% had chronic pulmonary disease. A total of 29,926 (19.0%) cases were emergency/urgent. Twenty percent of patients underwent revision surgeries, and 79.8% primary surgeries, which were composed of 78.7% primary fusion, 8.8% revision fusion, 0.8% primary non-fusion, and 11.7% revision non-fusion surgeries. The average operative time was 4.2 h (SD=2.3) and average Charlson comorbidity score was 1.6 (SD=2.2). A higher percentage of risk factors was reported in SSI cases, compared to non-SSI cases, especially with respect to obesity (34.4% vs 24.2%), blood disorder (38.3% vs 24.6%), and rheumatic disease (10.2% vs 5.0%).

Table 2
Relationship between SSI risk and 16 risk factors in the *Reduced Model*.

SSI Risk Reduced Model	β	SE	P Value	Odds Ratio (95% CI)	Score
Patient-related risk factors					
Female Sex[a]	0.15	0.04	0.0002	1.2 (1.1, 1.3)	5
Hypertension	0.15	0.04	0.0004	1.2 (1.1, 1.3)	4
Blood Disorder[b]	0.27	0.05	<0.0001	1.3 (1.2, 1.4)	8
PVD	0.29	0.07	<0.0001	1.3 (1.2, 1.5)	9
Chronic Pulmonary Disease	0.21	0.05	<0.0001	1.2 (1.1, 1.3)	6
Rheumatic Disease	0.54	0.07	<0.0001	1.7 (1.5, 2.0)	16
Obesity	0.39	0.04	<0.0001	1.5 (1.4, 1.6)	12
Diabetes	0.24	0.05	<0.0001	1.3 (1.2, 1.4)	7
Liver Disease	0.34	0.07	<0.0001	1.4 (1.2, 1.6)	10
Dementia	0.28	0.10	0.0068	1.3 (1.1, 1.6)	8
Nicotine Dependence	0.18	0.05	0.0004	1.2 (1.1, 1.3)	5
Charlson Comorbidity Index	0.08	0.01	<0.0001	1.1 (1.1, 1.1)	2
Surgery-related risk factors (open spine procedure)					
Surgical Category: Revision[c]	0.49	0.04	<0.0001	1.6 (1.5, 1.8)	14
Number of ICD-10 Procedures	0.03	0.01	<0.0001	1.0 (1.0, 1.1)	1
Operative Time (Hours)	0.04	0.01	<0.0001	1.0 (1.0, 1.1)	1
Type: Emergency/Urgent	0.41	0.05	<0.0001	1.5 (1.4, 1.7)	12
SSI Risk Score Model					
SSI Risk Score	0.03	0.001	<0.0001	1.04 (1.03, 1.04)	

[a] Female = 1, all else = 0.

[b] Blood Disorder: coagulation defects, purpura and other hemorrhagic conditions.

[c] Primary surgeries as the reference

PVD: peripheral vascular disease.

Full model

The full prediction model with all 38 predictors had good discriminatory capability (C-statistic = 0.75) and model fit ([Chi-Square/DF] = 0.90). The effect size, significance, and odds ratio of each predictor are listed in Table 1. All 38 predictors are preoperative except “blood transfusion” which was not selected for the reduced model. Revision surgery (OR, 1.6; 95% CI, 1.5 to 1.8), rheumatic disease (OR, 1.5; 95% CI, 1.3 to 1.7), obesity (OR, 1.4; 95% CI, 1.3 to 1.5), and emergency/urgent surgery (OR, 1.5; 95% CI, 1.3 to 1.6) were among the most influential risk factors for SSI.

Reduced model and SSI risk score

A reduced model was successfully developed by selecting the 16 strongest predictors (Table 2). Patients who had rheumatic disease (OR, 1.7; 95% CI, 1.5 to 2.0) and obesity (OR, 1.5; 95% CI, 1.4 to 1.6) at baseline, and underwent revision surgery (OR, 1.6; 95% CI, 1.5 to 1.8) were more likely to develop SSI. Emergency/urgent surgery (OR, 1.5; 95% CI, 1.4 to 1.7), liver disease (OR, 1.4; 95% CI, 1.2 to 1.6), peripheral vascular disease (OR, 1.3; 95% CI, 1.2 to 1.5), diabetes (OR, 1.3; 95% CI, 1.2 to 1.4), blood disorder (OR, 1.3; 95% CI, 1.2 to 1.4), and dementia (OR, 1.3; 95% CI, 1.1 to 1.6), considerably increased the probability of SSI as well.

The reduced model showed good discriminatory capability (C-statistic = 0.75) (Fig. 1**A**) compared to the full model (C-statistic = 0.75) (Fig. 1**B**), and good fit of the model ([Pearson Chi-square/DF] = 0.90). An indicator that the reduced model was better fitted than the full model was demonstrated in the calculated CAIC (consistent Akaike information criterion [34]), an estimator of prediction error and of statistical model quality. The CAIC was slightly lower in the reduced model versus the full model (25517.2 vs 25578.4, respectively).

Risk factor variables and their weights derived from the reduced model were the following: female (5), hypertension (4), blood disorder (8), peripheral vascular disease (9), chronic pulmonary disease (6), rheumatic disease (16), obesity (12), diabetes (12), liver disease (10), dementia (8), nicotine dependence (5), Charlson Comorbidity Index (2 per point), revision/primary surgery (14), number of ICD-10 procedures (1 per code), estimated operative time (1 per hour), and emergency/urgent surgery (12). As an example, a female (5 points), obese (12 points), hypertensive (4 points) patient with a blood disorder (8 points) and CCI = 3 (6 points) who underwent a non-urgent 4-hour (4 points) revision surgery (14 points) that was coded as 12 ICD-10 procedures (12 points) would have a total SSI risk score of 65 points (Table 2) and an estimated probability of SSI of 7.3% (Table 3).

The total SSI risk score, as the sum of the weights assigned to the planned procedure and all baseline comorbidities, had a score distribution from 2 to 293 in our primary study cohort. Most surgery cases had a relatively low estimated risk of SSI; the risk score of 99% of cases was <100; only 3 cases were at a markedly elevated risk with a risk score >150. The SSI risk score model (C-statistic = 0.75) suggested that for each additional point in the SSI risk score, the estimated probability of SSI increased 4% (odds ratio=1.04, p <0.0001) (Table 2 and Fig. 1**C**). Distribution of the risk scores for this primary study cohort is shown in Fig. 2**A**. The probability of risk mirrored this distribution: 88.7% of the population displayed a lower than 3% SSI risk and 0.8% displayed a high SSI risk (>9%) (Table 4 and Fig. 2**B**). Validation of the SSI risk score using the 1000-case random hold-out sample (composed of 80.8% primary fusion, 8.3% revision fusion, 0.9% primary non-fusion, and 10.0% revision non-fusion surgeries) demonstrated that the risk score maintained good discriminatory capability (C-statistic = 0.77) (Fig. 3) and calibration ([Pearson Chi-square/DF] = 0.88).

When varying the score value as a cutoff to stratify surgery cases by their SSI risk, a medium risk score such as 30 demonstrated 76.0% sensitivity and 52.2% specificity while a high risk score such as 90 was associated with higher specificity (99.6%) and low sensitivity (2.1%) (Table 3); using a cutoff score of 30 captured a larger number of true SSIs than a cutoff score of 90, but at the cost of flagging more false SSIs.

Discussion

We developed and validated a simplified point-of-care preoperative SSI risk scoring system for open spine surgery patients from a large, comprehensive electronic healthcare database. A reduced model, utilizing 16 clinical predictors, was further developed without compromising accuracy. This allows for less cumbersome utilization and increased applicability to a surgeon’s practice. Results of the model showed that spine surgery patients with a risk score ≥ 50 represented 15.1% of all

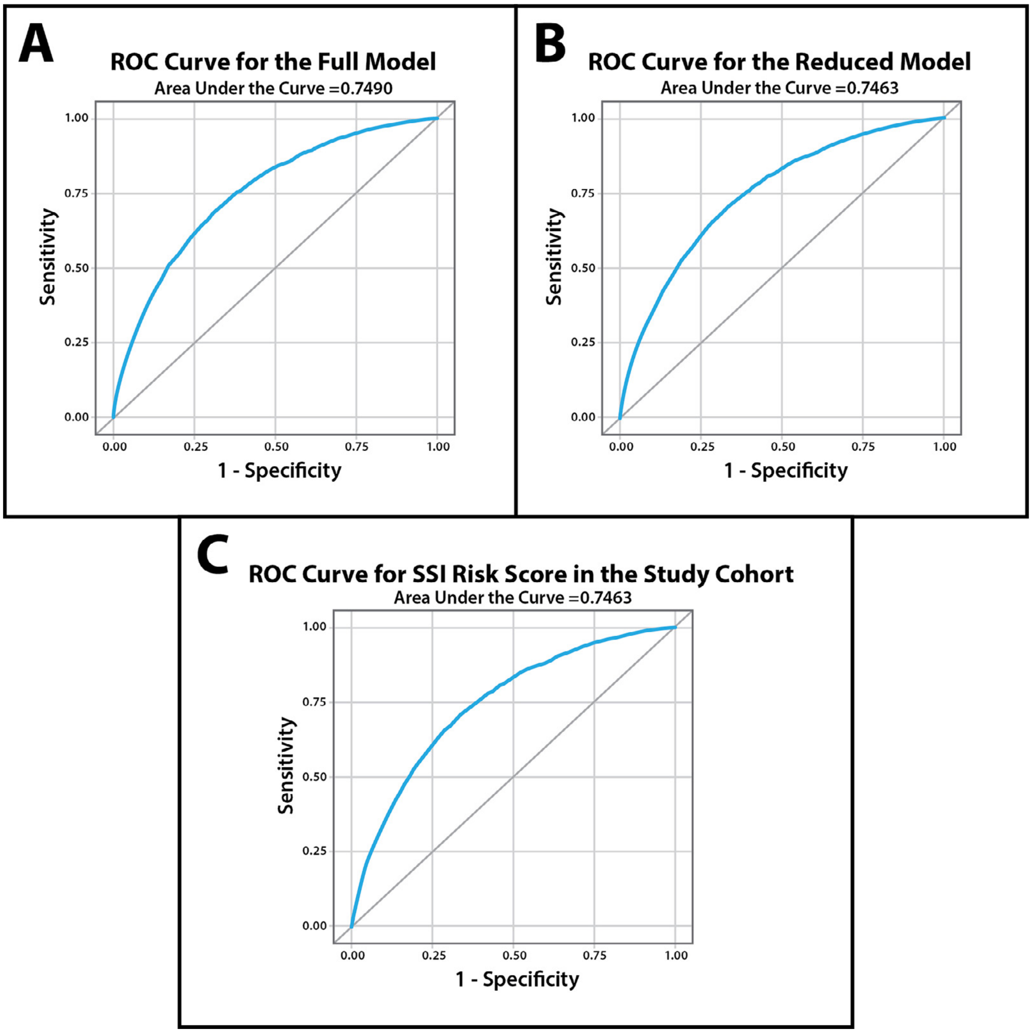

Fig. 1. Prediction model ROC curve analysis. The discriminatory capability was similar between the full model (C-statistic = 0.75) (A), and the reduced model (C-statistic = 0.75) (B). The risk score had strong predictive power (C-statistic = 0.75) in the study cohort (C).

Table 3
Cutoff values and risk score performance.

Risk Score as a Cutoff	Probability of SSI (%)	% Surgeries	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
0	1.7	100.0	100.0	0.0	1.7	–
10	1.7	93.7	98.3	6.3	1.8	99.6
20	2.0	72.6	90.8	27.7	2.1	99.4
30	2.5	48.3	76.0	52.2	2.6	99.2
40	3.2	28.3	57.4	72.2	3.4	99.0
50	4.2	15.1	39.1	85.3	4.3	98.8
60	5.5	7.3	22.8	93.0	5.2	98.6
70	7.3	3.3	11.4	96.9	5.9	98.5
80	9.6	1.3	5.4	98.7	6.9	98.4
90	12.9	0.5	2.1	99.6	7.7	98.3
100	17.8	0.1	0.7	99.9	8.9	98.3
110	25.0	0.0	0.2	100.0	8.2	98.3
120	43.9	0.0	0.1	100.0	14.3	98.3
130	54.0	0.0	0.0	100.0	11.1	98.3

PPV: positive predictive value; NPV: negative predictive value.

surgeries but 39.1% of all SSIs. Such risk score cut-off levels that contain a high density of SSIs can be used clinically as a marker for when to employ more aggressive measures to mitigate SSI occurrence, such as advanced incisional management strategies.

Concerning predictor selection, the number of ICD-10 procedures and duration of surgery as indices of surgery complexity were chosen over other similar surgery-related measures (e.g., invasiveness index and spinal region risk score) to be included in our reduced model because they had more predictive power. The Charlson Comorbidity Index was used as a summary comorbidity measure for this model based on its proven utility as a substitute for the use of individual comorbidity variables in health care research [35]. Emergency/urgent surgery elicited a higher risk score versus pre-planned surgery in our model, which is consistent with the lack of preoperative ability to modify risks. This has

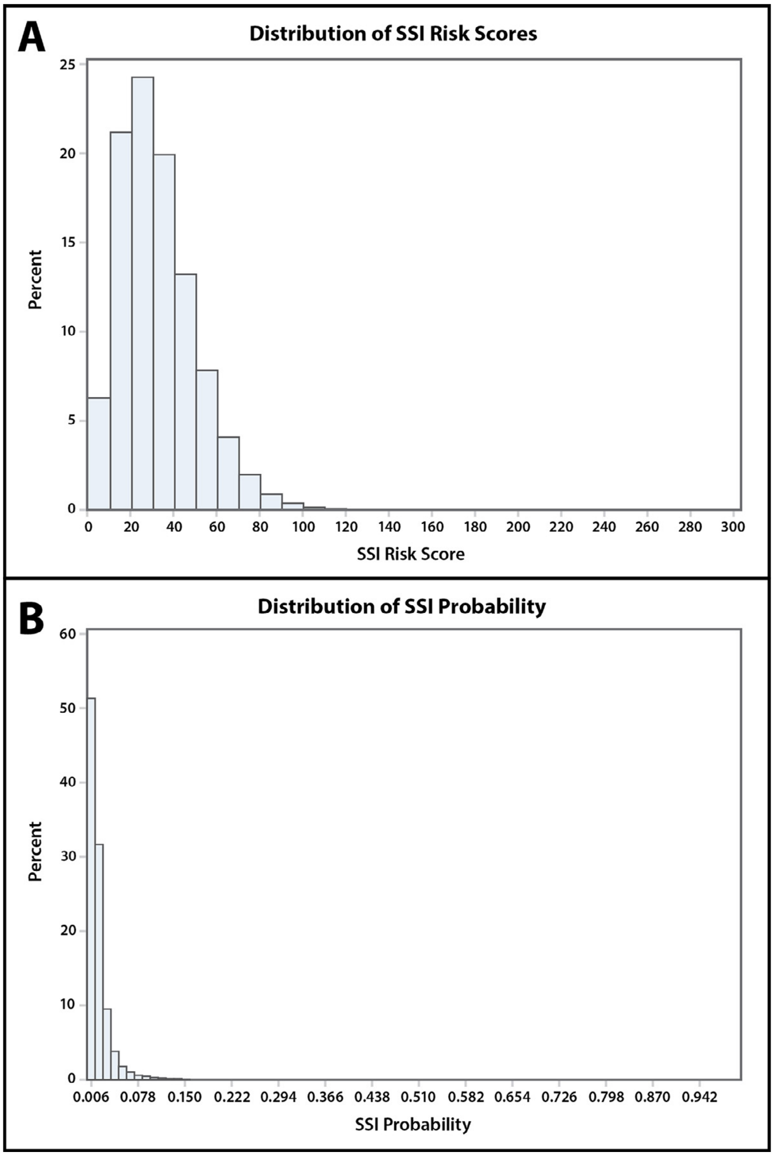

Fig. 2. Distribution of SSI risk scores (A) and SSI probability (B).

Table 4
Actual SSI rate vs. predicted SSI rate with model predictors.

Predicted Percent SSI Risk	Number (%) of Surgeries	Number of SSIs Predicted	Actual Number of SSIs (%)	% Total SSIs (n = 2650)
<3%	139,918 (88.7)	1714	1686 (1.2)	63.6
3%–6.9%	15,285 (9.7)	644	751 (4.9)	28.3
7.0%–8.9%	1253 (0.8)	99	106 (8.5)	4.0
9.0%–12.9%	870 (0.6)	91	72 (8.3)	2.7
13.0%–17.9%	245 (0.2)	37	25 (10.2)	0.9
18.0%–27.9%	79 (0.1)	17	7 (8.9)	0.3
28.0%–37.9%	6 (0.0)	2	1 (16.7)	0.0
>=38.0%	8 (0.0)	5	2 (25.0)	0.1

been demonstrated in studies involving decompression alone as well as fusion studies [36,37].

The predictors in our reduced model are consistent with risk factors reported in literature. Studies have associated a higher number of fusion levels, obesity, variables describing the complexity and/or duration of surgery, and more complex pathologies with increased SSI rates [38–41]. In a retrospective analysis of 5761 patients who underwent orthopedic spine surgery, the Charlson Comorbidity Index, the duration of the operation, obesity, and posterior surgical approach were all independently associated with a higher risk of infection for each of the three CDC classifications of SSI [40]. History of hypertension, prolonged hospitalization, longer operative time, blood transfusion, and higher ASA score have also been found to be risk factors for SSI in other spine surgery study populations [42–44].

In a collaborative effort to improve spine care outcomes, the first orthopedic/neurologic spine registry (American Spine Registry [45]) was recently established by the American Association of Neurological Surgeons and the American Academy of Orthopaedic Surgeons to facilitate the participation of all US-based spine surgeons in a shared, data-collection platform. This American Spine Registry collects procedural

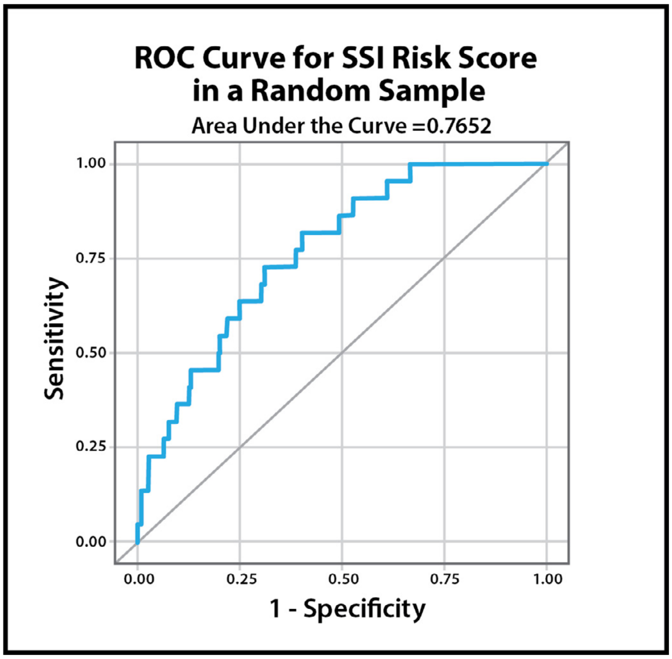

Fig. 3. ROC curve for SSI risk score model in the random sample.

data, post-operative data, and patient-reported outcome measurement data. Providing computational tools to analyze large data sets and generate hypotheses has been the focus of a growing number of projects such as the National Surgical Quality Improvement Program (NSQIP) risk calculator published by the American College of Surgeons [46], which incorporates data from hundreds of institutions to deliver an individualized risk profile. However, such calculators can easily miss important factors specifically related to spine procedures and be inaccurate predictors of spine surgery outcomes [47]. Consequently, there has been a push to develop disease- and surgery-specific predictive tools for spine surgery patients [25,26].

Predictive analytic modeling in spine surgery is in the beginning stages and has included development via machine learning, statistical modeling, and other techniques. Within adult spinal deformity surgery, use of predictive analytics has been used to predict patient-reported outcomes, hospital length of stay, need for blood transfusion, pseudoarthrosis, complications, and cost [27,48–51]. Predictive models have also been used to predict patient satisfaction after decompression for lumbar stenosis, functional outcomes after surgery for cervical spondylotic myelopathy and recurrent lumbar disk herniation [52–55], and outcomes following elective degenerative spine surgery [26].

Predictive analytics are meant to combat growing healthcare costs and improve value in the healthcare system. Recently, the European Spine Study Group developed the Adult Deformity Surgery Complexity Index (ADSCI) to help quantify the invasiveness of posterior adult spinal deformity surgery and determine which patients may experience a postoperative complication [28]. Implementing this risk score model into clinical practice assists surgeons in identifying high-risk patients for which counseling and perioperative optimization protocols are needed to reduce the risk of experiencing costly complications. As these complications are ultimately being linked to quality metrics that determine prospective payments, the present model may offer an improvement in value-based care by helping to guide decision-making for risk modification around open spine procedures.

The present risk score model developed using a spinal fusion-dominant (87.5%) population is the first tool to be specifically developed for the preoperative assessment of SSI risk in open spine surgery, particularly involving fusion procedures. Furthermore, we were able to externally validate this model utilizing a large healthcare database. The model allows for practitioners to obtain a bedside risk profile on a patient's potential risk for developing an SSI after open spine surgery. This treatment measure allows for surgeons to tailor perioperative risk management strategies to individualized patient risk. For example, 15.1% of the cases had a risk score of 50 or above; these cases accounted for 39.1% of total SSIs following an open spine surgery. Applying a 50-point cutoff would have enabled 15.1% of the surgeries to adopt preoperative SSI intervention targeting 39.1% of SSIs (Table 3).

We used risk score cut-off levels of 10-point intervals to illustrate how prediction would vary for each 10-point increase. Table 3 is meant to be used as a reference for surgeons to determine the levels that best fit their needs. An economic model could be developed to inform future studies regarding risk score cut-off levels that would provide positive returns for a surgeon, given the cost of intervention, SSI rate, and SSI cost.

While data analytics are increasingly being applied by surgeons, health-policy makers, and public health scientists to better understand shortfalls in care, each model has its own limitations. An inherent limitation of any model is the quality of data from which the model was generated. This present model does not account for the complete patient pathology or certain distinctions in comorbidities. We have limited knowledge about the severity of comorbidities for each patient, such as duration, acute/chronic status, controllability, etc. Likewise, information was unavailable to determine the purpose or history of a spine surgery. We categorized the spine surgeries by screening each of the documented ICD-10 procedures to determine if a surgery had decisive codes for fusion or revision (e.g., removal of an existing internal fixation device). Surgeries with no defining procedures of fusion or revision were assigned to non-fusion or primary categories. The present study thus provides a more conservative estimate of the impact of surgical category on SSI. Additionally, this new SSI prediction tool was developed and validated using a population made up of almost 90% spinal fusions. Future research is needed to examine how well the risk score functions in more diverse spine surgery populations.

Conclusions

Risk scores for predicting health outcomes are quickly becoming powerful, essential tools to inform perioperative management. The ability to accurately predict infection risk based on preoperative factors is an important step toward reducing SSI rates and improving value-based care in open spine surgery. We developed and externally validated a point-of-care SSI risk prediction tool for open spine surgery. The resulting SSI risk score composed of readily obtainable clinical information could serve as a strong prediction tool for SSI in preoperative settings when open spine surgery is considered.

Declaration of Competing Interest

One or more authors declare potential competing financial interests or personal relationships as specified on required ICMJE-NASSJ Disclosure Forms.

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