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Development of Risk Scoring Tool to Predict Surgical Site Infections

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Abstract

Surgical site infections (SSIs) are common complications following surgery that can extend hospital stay and increase direct health care costs, the risk of morbidity and mortality. Due to the high emergence of resistant bacteria, more attention is required preoperatively and intraoperatively to prevent SSIs. Assessment of the individual patient's risk for developing an SSI may identify those that require more aggressive prophylaxis. This will increase the efficiency of these interventions. Furthermore, standardized SSI risk assessment can facilitate comparison of SSI rates between institutions and at different times. The objective of the study was to develop a user-friendly tool quantifying SSI risk.

The data for this study were obtained from the National Surgical Quality Improvement Program (NSQIP) database at the Jewish General Hospital (JGH) in Montreal. The study cohort included 2907 patients undergoing surgery between November 2009 and December 2011. Bivariate analysis and stepwise multivariate logistic regression were used to identify risk factors that were independently associated with SSI risk. Logistic regression models with ROC curve analysis were used for the development of an SSI risk scoring tool.

Out of 2907 patients treated, 268 (9.2%) developed an SSI [148 (5.2%) superficial incisional SSI; 9 (0.3%) deep incisional SSI; 111 (3.9%) organ/space SSI]. Of the 37 risk factors assessed, five were significantly associated with SSI development and were included in the SSI-risk scoring tool: male gender (OR = 1.854, p = 0.005), inpatient status (OR = 9.491, p < 0.001), hypertension (OR = 2.464, p < 0.001), corticosteroid use (OR = 2.485, p = 0.042) and caregiver dependence for everyday activities prior to surgery (OR = 2.577, p = 0.047). The ROC curve has an area under the curve of 0.660 (95% CI: 0.628-0.692; p < 0.001) and scores range from 0 to 100. Scores of the SSI risk tool below 43.17, between 43.17 and 63.40 and above 63.40 indicate a low, moderate and high risk for SSI development, respectively. Compared to low-risk patients, moderate-risk patients had a relative risk of 3.963 (95% CI: 2.58-6.08, p < 0.001) and high-risk patients had a relative risk of 6.48 (95% CI: 4.16-10.10, p < 0.001) of developing an SSI. Overall, 2.8% of low-risk patients, 10.3% of moderate-risk patients and 15.8% of high-risk patients developed an SSI.

The JSS-SSI Risk Scoring Tool is a promising user-friendly tool for quantifying SSI risk. Further validation of the tool will be subsequently conducted.

Keywords: Surgical site infection; Risk assessment; Scoring tool; Infection prevention

Introduction

Surgical site infections (SSIs) are the second most frequent surgical complication causing 25% of the annual 1.8 million healthcare-associated infections, as reported by the CDC [1]. The National Nosocomial Infections Surveillance (NNIS) has further reported that SSIs represent 38% of nosocomial infections among surgical patients [2]. In Canada, two million surgeries are performed per year, resulting in 50,000 SSIs. SSIs increase the length of the hospital stay and resources utilized to drive hospital costs to rise. They further increase morbidity, disability and mortality rates [2,3]. Overall, 77% of all surgical patient deaths are related to infections [1]. SSIs are also associated with an increased risk of mortality, Intensive Care Unit (ICU) stay and hospital readmission after discharge [4].

SSIs are typically treated by wound debridement and/or by the administration of intravenous antibiotics, depending on the severity of the case [5,6]. Nonetheless, treatment is difficult if the infection is caused by resistant bacteria such as MRSA (Methicillin-resistant *Staphylococcus aureus*) or VRE (Vancomycin-resistant *Enterococci*), two of the most common resistant bacteria causing SSIs. Many beta-lactam-based antibiotics, such as cephalosporins and penicillins, are ineffective in the treatment of many infections caused by resistant strains of bacteria. In 1987, close to 20% of the *S. aureus* strains were MRSA and this rate climbed to 59% in 2004 [7-9]. This rise of bacterial resistance is not showing any signs of stabilizing or declining [7,10]. For the above reasons, additional effort must be focused on SSI prevention and the risk factors associated with SSI development.

Several risk factors have been identified as significant SSI predictors in the literature such as male sex [11-15], obesity [16], diabetes [17-20], tobacco use [21], hypertension [22,23] and corticosteroid use [24]. The development of an SSI may be due to a combination of these factors, some of which are dependent on the surgical staff and hospital settings while others are patient-centric including comorbidities such as hypertension and corticosteroid use [2]. SSIs can occur following any type of surgery, although the risk of acquiring an SSI is strongly correlated with the procedure's level of contamination and incision size. Class I clean, class II clean-contaminated, class III contaminated and class IV

dirty/infected surgeries are associated with incidence SSI rates of < 2%, 5-15%, 15-30% and > 30%, respectively [1,3]. Moreover, as increased levels of pathogenic bacteria enter the organism during surgeries with larger incisions, laparoscopic surgeries are associated with a decreased amount of SSIs. Boni et al. observed that 1.1% and 4% of patients who underwent cholecystectomies laparoscopically and with open surgery, respectively, developed SSI [25]. Furthermore, McCoy et al. showed that patients who underwent emergent surgeries had an increased OR (95% CI) risk of SSI of 3.15 (2.69, 3.68) ($p < 0.001$) of developing an organ/space SSI following surgery when compared to patients who underwent elective procedures [26].

There is a need for a quantitative tool to measure the risk of SSI to improve the management of surgical patients and SSI prevention. Indeed, the classification of surgical patients according to their SSI risk will allow the proper management of SSI prophylactic measures, therefore, increasing the effectiveness of preventive interventions. As high-risk SSI patients may require additional care while certain precautions may be omitted for low-risk SSI patients, an individualized approach will provide an adequate prophylactic SSI care to all surgical patients while possibly controlling costs as a minority of patients possess a high SSI risk. The aim of the current study was to develop a user-friendly quantitative tool for classifying surgical patients according to their SSI risk.

Methods

Data Acquisition

This was a retrospective study using data obtained from the 'NSQIP' database of the Jewish General Hospital in Montreal, Canada. No review board approval was required due to the retrospective nature of the study. NSQIP was created in 2009 and prospectively includes valid and comprehensive information on all patients who underwent surgery at the Jewish General Hospital. The NSQIP database contains information on gender, patient status, emergent surgery status, transfer origin, anesthesia technique, surgical subspecialty, body mass index, diabetes, smoking status, alcohol abuse, dyspnea, caregiver dependence prior to surgery, ventilator usage, COPD, pneumonia, congestive heart failure, myocardial infarction, history of angina, hypertension, PVD, gangrene, renal failure, dialysis, disseminated cancer, open wound, steroid use, weight loss, bleeding disorders, preoperative transfusion, chemotherapy, radiotherapy, sepsis, level of resident, wound classification, ASA class, other procedures and concurrent procedures.

Study Population

The patients who underwent surgery at the Jewish General Hospital from November 2009 to December 2011 were identified from the NSQIP database. Patients who underwent procedures with no incision and those whose hospital stay did not exceed 24 hours were excluded from the study cohort, the latter to exclude day surgery. No patients were excluded due to incomplete data.

Outcome

The outcome was the development of any type of SSI. SSIs were also classified into superficial incisional, deep incisional and organ/space infections as per the CDC SSI guidelines by Mangram et al. [1] (Table 1).

Risk Factors

All thirty-seven variables included in the NSQIP were considered as potential risk factors that could predispose a patient to an SSI and were therefore evaluated in order to assess their association with SSIs. The risk factors with continuous scales were dichotomized for statistical purposes. The BMI abnormality original classification included underweight (< 18.5), overweight (25-30), class I obese (30-35), class II obese (35-40) and class III obese (> 40) groups as per pre-defined NSQIP BMI ranges. The altered classification classified BMI levels below 18.5 and above 25 as abnormal (under/overweight) and those between 18.5 and 25 as normal [27]. Moreover, residents' experience was classified by the year of residency: groups comprised residents between 0 and 4 as well as between 5 and 8 years of residency. Furthermore, patients who required additional procedures were classified as such (yes vs. no) regardless of the number of procedures performed (Table 2).

Statistical Analyses

Bivariate logistic regression analysis and Chi-Square tests were performed to identify all potential significant risk factors for developing any type of SSI, superficial incisional SSI, deep incisional SSI and organ/space SSI. All results with p-values less than 0.05 were considered potentially significant SSI predictors. The variables that were significantly associated with the risk of an SSI in the multivariate logistic regression analysis were retained to develop the SSI risk score. The weight of each variable was a function of the logistic regression parameter estimate. The total score has a range between 0 and 100 points.

Each patient was assigned an SSI score based on the sum of the weight for present risk factors. To establish the cutoff values defining low, moderate and high-risk patients, Receiver Operating Characteristic (ROC) curve analysis were performed.

All statistical analysis was performed using the Statistical Packages for Social Sciences v 16.0 (SPSS).

Results

Two thousand nine hundred and seven patients were included in the study cohort. There were 1468 (50.5%) males and the mean (SD, range) patient age was 61.6 (17.74, 18.2-95.7) years. A total of 260 different types of surgeries were reported. Overall, 1188 surgeries (40.9%) were emergent procedures. The most frequent surgeries (> 3%) were laparoscopic cholecystectomy (254 surgeries, 8.8%), partial colectomy (244 surgeries, 8.4%), partial mastectomy (167 surgeries, 5.8%), laparoscopic appendectomy (166 surgeries, 5.7%) and open appendectomy (102 surgeries, 3.5%).

Out of the 2907 patients, 148 (5.2%) developed a superficial incisional SSI, 9 (0.3%) acquired a deep incisional SSI and 111 (3.9%) of patients developed an organ/space SSI. Overall, 9.2% (n = 268) of the 2907 patients developed an SSI.

Table 1: Classification and Criteria of Diagnosis of Surgical Site Infections [1,3,39].

Type of SSI	Characteristics of the infection
Superficial incisional	Infection involves only the skin or subcutaneous tissue. Also presents with one or more of the following characteristics:
	- Purulent drainage from superficial incision (with or without laboratory confirmation).
	- Isolated organisms from a culture of fluid or tissue from the superficial incision obtained aseptically.
	- At least one of the symptoms of infection: pain or tenderness, localized swelling, redness, or heat *and* superficial incision have been opened by the surgeon intentionally.
	- The diagnosis of a superficial incisional SSI may be made by a surgeon or attending physician.
Deep incisional	Infection involves deep soft tissues (such as the fascial and muscle layers) of the incision. Also presents with one or more of the following characteristics:
	- Purulent drainage from deep incision of the surgical site (not from the organ/space).
	- Deep incision spontaneously dehisces or is intentionally opened by the surgeon when the patient has at minimum one of the following signs or symptoms: fever (> 38°C), localized pain, or tenderness.
	- The diagnosis of a deep incisional SSI may be made by a surgeon or attending physician.
Organ/ space	Involves any part of the anatomy (such as organs or spaces), other than the incision, which has been opened or manipulated during surgery. Must also present with at least one of the following criteria:
	- Purulent drainage from a drain placed through a stab wound into the organ/space.
	- Organisms have been isolated aseptically from a culture of fluid or tissue which is in the organ/space.
	- An abscess or other evidence of a present infection involving the organ/space of the surgical site is found on direct examination, during reoperation, or by histopathologic or radiologic examination.
	- The diagnosis of an organ/space SSI may be made by a surgeon or attending physician.

Table 2: Assessed Risk Factors Including Alterations to Dichotomous Classifications.

Criteria	Original Classification	Altered Classification
Gender	Male; Female	No modification made
Patient status	Inpatient; Outpatient	No modification made
Emergent surgery status	Elective; Emergent	No modification made
Transfer origin	1. Not transferred, admitted directly from home 2. Acute care hospital (inpatient) 3. Nursing home/ chronic care facility/ intermediate care unit 4. Transfer from other 5. Transfer from outside Emergency Department	Not transferred, admitted directly from home; Transfer from other or inpatient
Anesthesia technique	1. General 2. Epidural 3. Spinal 4. Regional 5. Local 6. Monitored anesthesia care (MAC) 7. Other 8. None	General; Spinal, local, epidural, regional or MAC
Surgical subspecialty	Vascular; General	No modification made
BMI	1. Underweight (< 18.5) 2. Normal weight (18.5-25) 3. Overweight (25-30) 4. Class I obese (30-35) 5. Class II obese (35-40) 6. Class III obese (> 40)	Normal (BMI 18.5-25); Under/overweight (< 18.5 or > 25)
Diabetes	1. Non-diabetic 2. Diabetic requiring therapy with a non-insulin anti-diabetic agent 3. Diabetic requiring insulin therapy	Non-diabetic; Diabetic (type I or II)
Smoker	No; Yes	No modification made

Criteria	Original Classification	Altered Classification
Alcohol abuse	No; Yes	No modification made
Dyspnea	1. No dyspnea 2. Dyspnea upon moderate exertion 3. Dyspnea at rest	No; Yes (upon moderate exertion or at rest)
Caregiver dependence prior to surgery	1. Independent 2. Partially dependent 3. Totally dependent	Independent; Partially or totally dependent
Ventilator usage	No; Yes	No modification made
COPD	No; Yes	No modification made
Pneumonia[1]	No; Yes	No modification made
Congestive heart failure[2]	No; Yes	No modification made
Myocardial infarction[3]	No; Yes	No modification made
History of angina[2]	No; Yes	No modification made
Hypertension[4]	No; Yes	No modification made
PVD[5]	No; Yes	No modification made
Gangrene[6]	No; Yes	No modification made
Renal failure[7]	No; Yes	No modification made
Dialysis[8]	No; Yes	No modification made
Disseminated cancer	No; Yes	No modification made
Open wound[9]	No; Yes	No modification made
Steroid use[10]	No; Yes	No modification made
Weight loss > 10%[11]	No; Yes	No modification made
Bleeding disorders	No; Yes	No modification made
Preoperative transfusion[12]	No; Yes	No modification made
Chemotherapy[13]	No; Yes	No modification made
Radiotherapy[13]	No; Yes	No modification made
Sepsis[14]	1. No sepsis 2. SIRS 3. Sepsis 4. Septic shock	No; Yes (SIRS, sepsis or septic shock)
Highest level of resident	In numerical values (each year is equivalent to 1)	5 to 8 years of residency; 0 to 4 years of residency
Wound classification[15]	1. Class I clean 2. Class II clean-contaminated 3. Class III contaminated 4. Class IV dirty/infected	Class I or II (clean or clean-contaminated); Class III or IV (contaminated or dirty/infected)
ASA class[16]	1. ASA 1 (no disturb) 2. ASA 2 (mild disturb) 3. ASA 3 (severe disturb) 4. ASA 4 (life threat)	ASA 1 or 2 (no disturb or mild disturb); ASA 3 or 4 (severe disturb or life threat)
Other procedures[17]	In numerical values (for example, if two procedures were performed: the value of 2 was noted)	No; Yes
Concurrent procedures[18]	No; Yes	No modification made

1 Patient must be on current antibiotic treatment at the time he/she is brought to the OR; must meet specific radiologic and symptomatic criteria. Radiologic diagnosis: Patient must have presented with at least one of the following criteria: new or progressive and persistent infiltrate; consolidation or opacity; cavitation. Symptomatic diagnosis: Patient must have presented with at least one of the following criteria: fever (> 38°C or 100.4°F) with no other recognized cause, leukopenia (< 4000 white blood cells/mm^3) or leukocytosis (≥ 12,000 white blood cells/mm^3), for adults ≥ 70 years old, altered mental status with no other recognized cause; and at least one of the following criteria: 5% bronchoalveolar lavage, positive growth in blood culture not related to another source of infection, positive growth in culture of pleural fluid, positive quantitative culture from minimally contaminated lower respiratory tract specimen, or at least two of the following criteria: new onset of purulent sputum or change in character of sputum or increased respiratory secretions or increased suctioning requirement, or new onset or worsening cough or dyspnea or tachypnea, or rales or rhonchi, or worsening gas exchange.

2 Within 30 days prior to surgery.

3 Within 6 months prior to surgery.

4 Patient has persistent elevation of systolic blood pressure > 140 mmHg or a diastolic pressure > 90mmHg or requires an antihypertensive treatment at the time the patient is being considered as a candidate for surgery.
5 A history of any type of angioplasty or revascularization procedure for atherosclerotic PVD or a patient who has had any type of amputation procedure for PVD.
6 Rest pain or gangrene. Includes patients with ischemic ulceration and/or tissue loss related to peripheral vascular disease. Does not include Fournier's gangrene.
7 Elevated levels of BUN and creatinine (the latter above 3 mg/dl).
8 Currently requiring or on dialysis.
9 With or without infection. The wound must communicate to the air by direct exposure.
10 Patient has required the regular administration of oral or parenteral corticosteroid medications in the 30 days prior to surgery for a chronic medical condition.
11 Within 6 months prior to surgery. Patients who have intentionally lost weight are excluded.
12 Preoperative blood loss necessitating any transfusion (minimum of 1 unit) of whole blood/packed red cells transfused during the 72 hours prior to surgery.
13 Within 90 days prior to surgery.
14 Within 48 hours prior to surgery. Includes any case of SIRS, sepsis or septic shock. SIRS diagnosis: Patient must have at least two of the following criteria: temperature > 38°C (100.4°F) or < 36°C (96.8°F), heart rate > 90 bpm, respiratory rate > 20 breaths/min or PaCO2 < 32 mmHg (< 4.3 kPa), white blood cell > 12,000 cells/mm^3 or < 4000 cells/mm^3 or > 10% immature (band) forms, anion gap acidosis. Sepsis diagnosis: Patient must have SIRS diagnosis and at least one of the following criteria: positive blood culture, clinical documentation of purulence or positive culture from any site thought to be causative. Septic shock diagnosis: Patient must have sepsis diagnosis and documented organ and/or circulatory dysfunction.
15 Class I Clean: uninfected operative wound in which the respiratory, gastrointestinal and genitourinary tracts were not entered; including incisional surgery due to blunt trauma; Class II clean-contaminated: enters the respiratory, gastrointestinal and/or urinary tracts however no unusual contamination has occurred; Class III contaminated: procedure on an open wound with major breaks in sterile technique; Class IV dirty/infected: surgery on an old wound with dead tissue or involved existing infection or perforated bowel; the pathogens that cause SSI were present at the site before the operation [1].
16 No patients had an ASA of 5 (moribund person who is not expected to survive without the operation).
17 An additional operative procedure performed by the same surgical team under the same anesthetic which has a CPT code different from that of the Principal Operative Procedure.
18 An additional operative procedure performed by a different surgical team under the same anesthetic which has a CPT code different from that of the Principal Operative Procedure.

Table 3A reports the odds ratios (ORs) of every risk factor that was found to be significantly ($p < 0.05$) associated with the development of any type of SSI based on bivariate analysis. Among the 14 risk factors found to predict SSIs, the seven most influential (OR > 2.0) were preoperative pneumonia (OR = 6.332; $p = 0.004$), inpatient status (OR = 4.736; $p < 0.001$), caregiver dependence for everyday activities prior to surgery (OR = 2.644, $p < 0.001$), open wound (OR = 2.266; $p = 0.001$), preoperative sepsis (OR = 2.112; $p < 0.001$), disseminated cancer (OR = 2.083; $p = 0.005$) and class III or IV wound (contaminated or dirty/infected) (OR = 2.066; $p < 0.001$).

The significantly independent predictors for any type of SSI, superficial incisional and organ/space SSIs ($p < 0.05$) identified with multivariate logistic regression analysis are presented in Table 3B. The five significant risk factors found to independently predict SSIs which were subsequently selected and included in the risk-scoring tool were male gender (OR = 1.854; $p = 0.005$), inpatient status (OR = 9.491; $p < 0.001$), hypertension (OR = 2.464; $p < 0.001$), steroid use (OR = 2.485; $p = 0.042$) and caregiver dependence for everyday activities prior to surgery (OR = 2.477; $p = 0.047$).

Table 4 presents the specific relative weights and scoring values that were calculated and assigned to each risk factor included in the JSS-SSI Risk Scoring Tool. Inpatient status, caregiver dependence for everyday activities, hypertension, steroid use and male gender add 50, 14, 13, 13 and 10 points to the patients' SSI score, respectively. Total score ranges between 0 and 100 with a higher score indicating a higher risk of developing an SSI.

Based on ROC curve analysis, a sensitivity of 75.5% and a specificity of 49.8% for the JSS-SSI Risk-Scoring Tool along with the false positive rate of 50.2% and false negative rate of 24.5% were selected to estimate the development of an SSI in surgical patients in the study cohort since these represented the best combination of highest sensitivity (true positive rate) and lowest 1- specificity (false positive rate).

The ROC curve (Figure 1) has an area under the curve of 0.660 (95% CI: 0.628-0.692; $p < 0.001$). Optimal cutoff values of 43.17 and 63.40 for SSI risk classification were determined based on the optimal balance of sensitivity and specificity. Therefore, patients with an individual SSI score below 43.17, between 43.171 and 63.40 and above 63.401 had a low, moderate and high risk of developing an SSI, respectively. With respect to the established cutoff values, 31.8% (n = 925), 46.2% (n = 1342) and 22.0% (n = 640) of the surgical patients had a low, moderate and high risk of developing any type of SSI, respectively of which 2.8%, 10.3% and 15.8% actually developed any type of SSI postoperatively, respectively (Table 5). More specifically, 2.1%, 5.7% and 8.4%

Table 3A: Significant SSI Risk Factors Identified with Bivariate Analyses.

Risk factor	OR any type of SSI	p-value	OR superficial incisional SSI	p-value	OR organ/ space SSI	p-value	Incidence rate of any type of SSI (%)[1]
Male gender (n = 1468)	1.376	0.014	-	NS	1.839	0.002	10.4
Inpatient status (n = 1982)	4.736	< 0.001	3.343	< 0.001	7.846	< 0.001	12.1
Preoperative pneumonia (n = 13)	6.332	0.004	-	NS	7.184	0.014	38.5
Disseminated cancer (n = 132)	2.083	0.005	-	NS	2.244	0.021	16.7
Open wound (n = 147)	2.266	0.001	3.647	< 0.001	-	NS	17.7
Preoperative weight loss > 10% (n = 123)	1.884	0.023	-	NS	2.704	0.004	15.4
Caregiver dependence (n = 141)	2.644	< 0.001	2.736	0.001	2.549	0.007	19.9
Level of resident from 0 to 4 years (n = 2200)	1.474	0.021	-	NS	-	NS	9.9
Class III or IV wound (n = 592)	2.066	< 0.001	-	NS	3.599	< 0.001	14.7
ASA class of 3 or 4 (n = 1109)	1.648	< 0.001	2.133	< 0.001	-	NS	11.8
Preoperative sepsis (n = 283)	2.112	< 0.001	-	NS	3.194	< 0.001	15.2
General anesthesia (n = 233)	1.531	0.031	-	NS	2.555	0.004	9.6
General surgery (n = 226)	1.496	0.024	-	NS	-	NS	9.7
Other procedures (n = 1353)	1.617	0.001	1.538	0.019	1.744	0.008	10.5
Diabetes (n = 455)	-	NS	1.849	0.003	-	NS	11.4
Alcohol abuse (n = 34)	-	NS	-	NS	3.198	0.048	17.6

1 Among patients with a positive risk factor.
OR: Odds ratio; NS: not significant (p > 0.05)
No statistically significant risk factors were identified for deep incisional SSI.
Emergent surgeries, transfer origin, BMI, smoking, dyspnea, ventilator usage, COPD, congestive heart failure, myocardial infarction, history of angina, hypertension, PVD, gangrene, renal failure, dialysis, steroid use, bleeding disorders, preoperative transfusion, chemotherapy, radiotherapy and concurrent procedures were not found to be statistically significant risk factors predisposing patients to any SSI, superficial incisional SSI or organ/space SSI.

Table 3B Significant SSI Risk Factors Identified with Logistic Regression Analysis.

Risk factor	OR any type of SSI	p-value	95% CI	OR superficial incisional SSI	p-value	95% CI	OR organ/ space SSI	p-value	95% CI	Incidence rate of any type of SSI (%)[1]
Male gender (n = 1468)	1.854	0.005	1.199 – 2.864	-	NS	NS	2.097	0.015	1.157 – 3.799	10.4
Inpatient status (n = 1982)	9.491	< 0.001	3.360 – 26.810	6.592	0.002	1.958 – 22.193	15.067	0.009	1.992 – 113.983	12.1
Hypertension (n = 1264)	2.464	< 0.001	1.571 – 3.864	2.098	0.017	1.140 – 3.861	2.597	0.002	1.412 – 4.778	10.1
Steroid use (n = 92)	2.485	0.042	1.034 – 5.970	2.971	0.049	1.004 – 8.791	-	NS	NS	15.2
Caregiver dependence (n = 141)	2.577	0.047	1.012 – 6.564	3.703	0.031	1.126 – 12.175	-	NS	NS	19.9
Preoperative weight loss > 10% (n = 123)	-	NS	NS	-	NS	NS	3.057	0.013	1.270 – 7.361	15.4
Class III or IV wound (n = 592)	-	NS	NS	-	NS	NS	2.637	0.006	1.328 – 5.236	14.7

1 Among patients with a positive risk factor.
CI: confidence interval; OR: odds ratio; NS: not significant (p > 0.05)
No statistically significant risk factors were identified for deep incisional SSI
All risk factors were included in the multivariate logistic regression analysis

Table 4 Variables and SSI Weights in the JSS-SSI Risk Scoring Tool.

Variables	Negative (reference)	Positive (risk factor)	Odds Ratio	Relative SSI weight	Variable score value
Gender	Female	Male	1.854	0.0982	10
Patient status	Outpatient	Inpatient	9.491	0.5029	50
Hypertension	No	Yes	2.464	0.1306	13
Steroid use	No	Yes	2.485	0.1317	13
Caregiver dependence	Independent	Partially or totally dependent	2.577	0.1366	14
Total			18.871	1	100

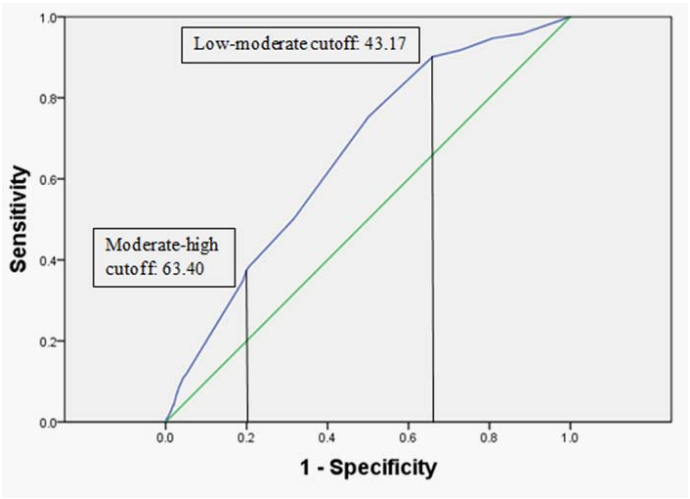

Figure 1: Receiver Operating Characteristic (ROC) Curve of the JSS-SSI Risk Scoring Tool.

of low-risk, moderate-risk and high-risk patients developed a superficial incisional SSI, respectively (Table 5). Moreover, 0.8%, 4.6% and 7.8% of low-risk, moderate-risk and high-risk patients developed an organ/space SSI, respectively (Table 5).

When applying the JSS-SSI Risk Scoring Tool, the patients classified in the moderate-risk group were 4, 2.8 and 6.5 times more likely to develop any type of SSI, superficial incisional SSI and organ/space SSI than patients included in the low-risk group, respectively, while the patients identified to be at high-risk were 6.5, 4.3 and 11.1 times more likely to develop any type of SSI, superficial incisional SSI and organ/space SSI than low-risk patients, respectively (Table 5).

Discussion

SSIs are a common surgical complication causing a significant burden of illness due to increased hospital stay, morbidity, mortality and healthcare costs [4]. Due to the increasing prevalence of resistant bacteria increasing the difficulty of SSI treatments, focus must be shifted from postoperative therapy to preoperative prophylactic SSI care, particularly as pathogenic bacteria may develop resistance against new antibiotics over time [7]. Given limited financial resources, the implementation of an SSI risk-scoring tool in a focused and cost-efficient manner may reduce the economic burden associated with SSIs as it allows the identification of high-risk patients for whom more intensive and aggressive prevention measures should be applied as well as of low-risk patients for whom a decreased level of SSI preoperative care is required.

In the current study, the JSS-SSI Risk Scoring Tool, a quantitative and user-friendly SSI risk tool was developed. The model includes the following risk factors found to independently predict SSIs: male gender, inpatient status, hypertension, preoperative corticosteroid use and caregiver dependence for everyday activities prior to surgery. Our results concur with those reported in the literature. It has been reported that male gender is a significant predictor of SSIs [11-15]. Although there is no consensus regarding the reason why males are predisposed to SSIs, bacterial skin colonization may be accountable as differences between males and females have been found concerning skin pH, serum production and skin thickness [12]. There is little evidence of a direct association between inpatient status and SSI development. However, Hennessey et al. reported that the duration of inpatient stay was negatively correlated with preoperative albumin levels which is an independent risk factor for SSI [28]. Conversely, it can be presumed that a preoperative hospital stay has several effects on the patient. Firstly, it has been shown that preoperative mobility decreases the risk of postoperative complications [29-31]. Secondly, a longer

Table 5: SSI Development According to JSS-SSI Risk Classification.

		Low SSI Risk	Moderate SSI Risk	P-value*	High SSI Risk	P-value*
N of patients		925	1342	-	640	-
Any type of SSI	**OR (95% CI)**	-	3.963 (2.584 – 6.079)	< 0.001	6.479 (4.156-10.101)	< 0.001
	n (%)	26 (2.8%)	138 (10.3%)	-	101 (15.8%)	-
Superficial incisional SSI	**OR (95% CI)**	-	2.863 (1.719-4.767)	< 0.001	4.394 (2.579-7.488)	< 0.001
	n (%)	19 (2.1%)	76 (5.7%)	-	54 (8.4%)	-
Organ/space SSI	**OR (95% CI)**	-	6.352 (2.854-13.942)	< 0.001	11.114 (5.005-24.677)	< 0.001
	n (%)	7 (0.8%)	62 (4.6%)	-	50 (7.8%)	-

CI, confidence interval; OR, odds ratio; SSI, surgical site infection
*Compared with low SSI risk group.

preoperative stay may increase the risk of acquiring nosocomial bacteria uncommonly in the patient's flora [32].

Similarly with the current study, some data has shown that hypertension is an independent risk factor for developing SSI. Hypertension was found to increase SSI risk among women undergoing a cesarean section (RR = 2.47; 95% CI: 1.21-5.04) and breast surgery (OR = 1.69, 95% CI: 1.34-2.14) [22,23] although the precise mechanism has not been demonstrated. Cardoso Del Monte et al. presume that the "chronic alteration in peripheral blood supply as a result of increased vascular resistance" could explain the increased infection rates among hypertensive surgical patients [22].

Corticosteroid use in the 30 days prior to surgery predisposes surgical patients for SSIs as their mechanism of action diminishes patients' immune function, therefore, increasing the risk of opportunistic infections, including SSI. The results presented by Lee et al. concur with our findings as they reported that steroid use is an independent risk factor for SSI development with OR = 2.65 (95% CI: 1.08 - 6.54) [24].

The link between caregiver dependence prior to surgery and the risk of SSI has not yet been established and this is a new finding for this analysis. This association could be due to reduced mobility in dependent patients with lower functional status. Anderson et al. reported that a partially or totally dependent patient prior to surgery has an increased risk of developing an SSI caused by MRSA, but this has not been proven for any other type of pathogenic microorganism [33].

While some risk factors evaluated in this study have not been previously assessed, such as inpatient status and caregiver dependence for everyday activities prior to surgery, certain other risk factors known to independently predict SSIs were not found to be significant predictors of SSI in this study, more specifically, BMI, diabetes mellitus and tobacco use. Obesity was found to independently predict postoperative SSI by Giles et al. (OR = 1.7, 95% CI: 1.4-2.1) [16]. In addition, it has been reported that diabetes predisposes patients for SSI as the glucose level in the blood diminishes immune function [17,19,20]. The study conducted by Ferrazzi et al. showed that, of the patients who underwent CABG surgery (coronary artery bypass graft), 35% to 50% of patients with complications (including SSI) had diabetes [18]. Moreover, smoking has been identified to independently predict SSIs. Data suggested that past smokers had an increased risk of SSI (adjusted OR = 1.46, CI 95%: 1.02 - 2.09). However, as this association was not observed with current smokers, confounding by disease severity or disease duration may have been introduced in the study as previous smokers may have been more likely to cease smoking due to worsening symptoms over time. Case-mix and patient profile differences between studies and patient populations may further explain why these risk factors were not found to be significant predictors of SSI in the current study.

In contrast with other studies [26], emergent surgery was not found to be a significant risk factor in our study cohort. This could be explained by the differences in patient profiles as well as by divergence in the surgical patient population characterized by the deserving hospital, its settings and surgical management protocols and policies.

The user-friendliness of the SSI risk-scoring tool and simple score interpretation will help facilitate the adoption of this tool in surgical settings. The total score varies between 0 and 100 points with higher values indicating greater SSI risk. The final patient score classifies patients in one of three groups: low-risk, moderate-risk or high-risk of developing any type of SSI. The decision whether additional or more aggressive prophylactic care (preoperative and intra operative) is to be administered to patients should be assessed according to the overall risk-benefit ratio; measures should only be undertaken in cases when the overall benefits outweigh the risks. In general, high-risk patients would receive additional infection prophylactic care. The surgical staff may advise at their discretion whether additional care is warranted in the prophylactic SSI care of moderate-risk patients. This decision would have an important financial and resource utilization implication since the majority of surgical patients (46.2%) have a moderate risk of developing an SSI.

The increase of SSI incidence from the low-risk to the high-risk SSI category is similar for superficial incisional SSI, organ/space SSI and all types of SSI. Approximately the same percentage of high-risk patients develop superficial incisional and organ/space SSIs although the ORs vary considerably. High-risk patients possess an increased risk of 4.394 (95% CI: 2.579-7.488) for superficial incisional SSI development whereas the same group of patients has an OR of 11.114 (95% CI: 5.005-24.677) for organ/space SSI. As superficial incisional SSIs typically have an increased incidence rate when compared to organ/space SSIs, the increased OR rate for the latter type of infection among high-risk patients explains the similar incidence rate observed in the study.

An important strength of the study is the absence of selection bias as all patients in the NSQIP database who underwent surgery between November 2009 and December 2011 were included in the study cohort. Furthermore, the scoring tool is generalizable to numerous surgical settings beyond high-volume university hospitals. Also, as the surgical patient's medical history is typically collected prior to surgery, the assessment of the five risk factors included in the risk scoring tool as well as the patient's classification of SSI risk would require minimal additional effort by the surgical staff. In addition, the user-friendliness of the risk scoring tool is ensured by the calculation of the SSI score merely requiring the addition of whole integers according to the presence of only five risk factors included in the model and by the simple classification of patients in low, moderate and high SSI risk groups.

However, the usage of a database is associated with inherent limitations such as the retrospective nature of the study, missing data, variations among the healthcare personnel in the documentation of information and incorrect or imprecise coding of outcome and exposure possibly introducing information bias in the analysis [34]. Moreover, certain SSI predictors reported in the literature, such as age, *S. aureus* colonization, use of medical device, length of preoperative stay and surgery duration [35], were not captured in the NSQIP database and therefore, were not assessed in this analysis. Albeit, the study aim to create a user-friendly risk scoring tool may have been hindered by the inclusion of many variables. Nonetheless, the JSS-SSI Risk Scoring Tool includes the five most influential risk factors that were significantly associated with SSI development, therefore leading to a suitable quantification of SSI risk. Furthermore, the AUC under the ROC curve of 0.660 was of moderate predictive value. Validation of this risk scoring tool will be necessary to ensure its predictive accuracy. The follow-up duration represents an additional limitation as this information was missing for all patients. This may be due to several factors, such as the addition of the variable following the database implementation or differences pertaining to data collection during the hospital stay and the post-discharge period. This variable may have impacted the results as a short follow-up duration may lead to an underestimation of SSI cases as up to 50% of SSIs develop following discharge [36].

As no exclusion was performed based on the type of surgical procedure and wide demographic profile of the patient population, the generalizability of the JSS-SSI Risk Scoring Tool simultaneously represents a strength and limitation of its future use. Its potential use following various surgical fields increases the adaptability of the tool therefore, having significant clinical and economic impact in these subspecialties. Nonetheless, risk tools specific to the surgical subspecialty and patient demographics may allow identification of SSI predictors which may not have been identified in the present analysis due to case mix and patient profile differences. This would subsequently allow an optimal classification of patients according to SSI risk in each surgical subspecialty. Similarly to the Physiological and Operative Severity Score for the enumeration of Mortality and Morbidity (POSSUM) tool development and adaptation to several specialty-driven tools [37,38], this may warrant further investigation and alteration of the JSS-SSI Risk Scoring Tool in future studies.

In summary, the development of the JSS-SSI Risk Scoring Tool will have an important clinical impact as it quantifies SSI risk among surgical patients subsequently allowing the individualization of SSI prophylactic care according to SSI risk. As the utilization of the JSS-SSI Risk Scoring Tool may be associated with decreased resource utilization among low-risk SSI patients, this could have an important economic impact. Further validation in other populations is required preferably utilizing surgical populations from diverse hospital settings such as urban, rural and university-based hospitals as several differences exist between these locations. Regardless, the JSS-SSI Risk Scoring Tool is a promising user-friendly tool for quantifying SSI risk.

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