**TITLE**: Development of a Risk Severity Score Predicting Surgical Site Infection in Early Onset Scoliosis: Identifying High-Risk Patients

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**SUMMARY:** The RSS will serve as a useful tool to quantify the risk of SSI when considering operative intervention in patients with early onset scoliosis undergoing spinal surgery. The risk severity score included neuromuscular etiology, myelomeningocele, spinal muscular atrophy, endocrine comorbidity, gastrointestinal comorbidity, pulmonary comorbidity, developmental delay, urinary incontinence, and ventriculoperitoneal shunt. The RSS will improve shared decision making with patients and families during preoperative counseling and aid policy makers and administrators in determining reliable and valid risk-adjusted outcome measures.

**ABSTRACT:**

**Introduction:** Surgical site infections (SSI) in children with early onset scoliosis (EOS) have a major impact on quality of life, caretaker burden and healthcare expenditure. This study aims to develop and evaluate a risk severity score (RSS) system based on patients’ preoperative information to predict SSI in EOS patients undergoing spinal surgery.

**Hypothesis:** A risk severity score model utilizing patient characteristics can be developed to predict SSI in patients with early onset scoliosis undergoing spinal surgery.

**Design:** Multicenter retrospective cohort study

**Methods:** Pediatric patients who underwent surgery in 50 academic institutions, between October 2010 and December 2016, were enrolled. Patients undergoing initial implantation or fusion were included. Patient characteristics, preoperative lab values, and clinical data were collected. The CDC’s definition of SSI (infection within 90 days of surgery) was used. In order to develop RSS, multiple logistic regression model was utilized to identify preoperative variables (demographics, characteristics comorbidities) for the prediction of SSI outcome.

**Results:** In total, 1,168 patients were identified and 79 patients (6.8%) obtained SSI. The average age at surgery was 7.7 years and 57% of patients were female. EOS etiology consisted of: 403 (34%) neuromuscular, 289 (24%) idiopathic, 255 (22%) syndromic, and 242 (20%) congenital. The RSS score included neuromuscular etiology (OR: 2.3), myelomeningocele (OR: 1.5), spinal muscular atrophy (OR: 1.4), endocrine comorbidity (OR: 4.3), gastrointestinal comorbidity (OR: 1.3), pulmonary comorbidity (OR: 1.2), developmental delay (OR: 1.4), urinary incontinence (OR: 1.3), and ventriculoperitoneal shunt (OR: 1.5). The model predicted a 3.3% probability of SSI for patients with none of these risk factors, and a 68.4% probability of SSI for patients with myelomeningocele, endocrine comorbidity, gastrointestinal comorbidity, pulmonary comorbidity, developmental delay, urinary incontinence, and ventriculoperitoneal shunt. The RSS had good discrimination in identifying true positives while minimizing false positives (c-statistic = 0.706) and excellent calibration (Hosmer-Lemeshow statistics p<0.05).

**Conclusions:** The RSS was developed using data from two national registries, and it provides empirically derived, patient-specific SSI risks. It can be used as a toll in the shared decision-making process by providing surgeons, patients and caregivers with useful information. It also allows us to prepare for high-risk patients. The RSS can facilitate outcome comparisons between hospitals caring for EOS patients. Further investigations on interactions among high-risk patients and surgical factors and/or perioperative infection prophylaxis are underway.

**INTRODUCTION**:

Despite ongoing efforts, considerable variation in infection prevention practices by surgical teams continues to exist1–3. The risk of surgical site infection (SSI) following pediatric scoliosis surgery since 2000 has been reported to range from 0% to 26.3% in the United States, much of which affects children with early onset scoliosis (EOS)4–21. SSI in this population has a major impact on quality of life, caretaker burden and healthcare expenditure. Treatment of SSI entails long-term antibiotic prophylaxis, multiple surgeries for repeated irrigation and debridement, implant retention, removal, or revision surgery, which often subsequently results in prolonged hospitalization and immense financial cost22,23. This massive burden of SSIs demands our commitment to both define the risk factors associated with SSIs and develop strategies to minimize SSI.

In developing strategies to prevent SSI after scoliosis surgery in pediatric populations, it is essential to create a system to stratify patients by their risk of SSI. A patient-specific risk severity score (RSS) stratification system will allow us to enhance shared decision-making and improve patient care while concomitantly providing fair hospital comparisons, public reporting mechanisms, and reimbursement determinations. This study aims to develop and evaluate a risk severity score (RSS) system based on patients’ preoperative information to predict SSI in EOS patients undergoing spinal surgery.

**METHODS:**

***Study Patients***

 This study identified patients who underwent surgical procedures to correct spinal deformity from October 2010 to December 2016 entered into the Children’s Spine Study Group registry and the Growing Spine Study Group registry from 15 different academic medical institutions. All patients underwent initial implantation with growth friendly instrumentation (magnetically-controlled growing rods (MCGR), the traditional growing rod (TGR), Vertical Expandable Prosthetic Titanium Rib (VEPTR) or Shilla) or received posterior instrumentation and fusion for spinal deformity correction. Inclusion criteria included patients who were diagnosed with early onset scoliosis (before 10 years of age), had follow up between 90 days and 7.5 years, and were between 0 and 21 years of age on the day of the surgery. All patients received standard preoperative evaluations during routine office visits.

***Data Collection***

Investigators at each site reviewed the charts of eligible patients. The data collection sheet included patient characteristics: age on the date of surgery, gender, height, weight, etiology and type of spine deformity, type of spinal surgery, the presence of fused ribs, medical comorbidities (cardiac comorbidities, such as valve disorders or congenital defects; developmental delay, such as cognitive slowing, attention deficit hyperactivity disorder; endocrine comorbidity, such as diabetes, hypothyroidism; gastrointestinal comorbidity, such as gastrointestinal reflux disease, hiatal hernia; immunologic comorbidity, such as eczema, allergies; musculoskeletal comorbidities, such as myopathies; neurologic comorbidities, such as myelomeningocele, seizures; nutritional comorbidities, such as failure to thrive; Crohn’s disease; pulmonary comorbidities, such as asthma, restrictive airway disease; urinary incontinence), ambulatory status, presence of a feeding tube, presence of a ventriculoperitoneal shunt, respiratory status, and the Cobb angle of the major curve and kyphosis. Preoperative laboratory data included hemoglobin, hematocrit, white blood cell count and preoperative urinalysis or culture (within 90 days of surgery). Each of the eligible medical records was reviewed to evaluate for the development of a SSI. All de-identified data was reviewed and verified at the main institution by orthopaedic surgeons and an epidemiologist. Any discrepancy or ambiguity of data was sent back to each institution for audit.

***Predicting Factors***

All continuous and categorical variables were classified into binary variables. Body mass index (BMI) was calculated using the Center for Disease Control and Prevention (CDC) BMI calculator and BMI percentile calculator for children and teenagers (21). Children with a BMI in the 5th percentile or less were classified as underweight, children with a BMI in the 5th-85th percentile were classified as normal, and children with a BMI in the 85th percentile or greater were classified as overweight or obese according to CDC classifications(22). BMI classification was used to create several binary variables for this analysis, specifically underweight versus not underweight, overweight versus not overweight, obese versus not obese, and abnormal BMI (underweight or overweight) versus normal BMI. The spinal deformity etiology was categorized into neuromuscular, syndromic, congenital, or idiopathic as per c-EOS classification. The neuromuscular etiology was further classified into binary variables based on the presence versus absence of cerebral palsy (CP), spinal muscular atrophy (SMA), or myelomeningocele. Ambulatory status was defined as ambulatory (including patients who required an assistive device) versus non-ambulatory. The continuous variable of degrees of the major curve was converted to a binary variable of Cobb ≥90 degrees versus <90 degrees based on a clinically meaningful value. Kyphosis was categorized into normal versus abnormal (hypokyphosis or hyperkyphosis). Comorbidities and other medical or surgical record data (assistive device use, fused ribs) were tallied as either present or absent in binary form. Instrumentation was divided into either fusion or initial growing implantation and made binary by that categorization.

***Surgical Site Infections***

SSI was defined according to the Center for Disease Control and Prevention (CDC) definitions of superficial and deep SSI published in 201524,25. Superficial SSI occurs within 30 days after the procedure and involves only the skin or subcutaneous tissue of the incision. A deep SSI occurs within 90 days after surgery if an implant remains in place and involves the fascial and muscle layers deep to the subcutaneous layer of the incision. The diagnosis of both types of SSI is made either clinically by the surgeon using signs such as purulent drainage, erythema, pain or tenderness and erythema or by pathogen isolation from an aseptically obtained wound specimen.

***Statistical Methods***

Differences in patient demographics and preoperative characteristics between patients who developed a SSI and patients who did not were examined by χ2 tests. The variables with clinical importance and a trend toward significant association with SSI (p≤0.25) in simple regression analysis were then entered into a multiple logistic regression model. Model performance was evaluated using the c-statistic and the Hosmer-Lemeshow (HL) statistic. The c-statistic, also referred to as the area under the receiver operating characteristic (ROC) curve (the plot of sensitivity and 1-specificity), indicates how well the model does in predicting the binary response such as SSI outcome (presence or absence of SSI) and takes values from 0.5 to 1.0, with 0.5 being no better than chance and 1.0 being perfect prediction. In general, models with a c-statistic greater than 0.7 are considered to be good models. Although useful, c-statistic alone is not the best in evaluating model performance, as it does not directly assess the accuracy of the prediction and it struggles when a population is homogenous. Therefore, the HL statistic was used to measure calibration, detecting bias in predicting risk over the range of risk. The data are ordered by predicted risk and then divided into risk groups of equal size. The HL statistic will be statistically significant (p<0.05) if there is a tendency for the model to overestimate or underestimate risk based on the risk group. Thus, a good model which neither overestimates or underestimates the data generates a “non-significant” p-value. Since the HL statistic varies based on the number of groups the data are divided into and finds smaller deviations to be statistically significant when the sample size becomes large, graphic representation fit are also presented in which the mean predicted probability is plotted against the mean observed probability for each of the risk groups.

**RESULTS:**

***Patient Characteristics***

 In total, 1,189 patients with EOS were identified in the registries meeting inclusion criteria. The average age at surgery was 7.7 years (0.5-19.4 years, ± 3.31) and 57% of patients were female. Of the 1,189 patients, 403 (34%) had neuromuscular, 289 (24%) had idiopathic, 255 (22%) had syndromic, and 242 had (20%) congenital etiologies. Of those patients with neuromuscular etiologies, 74 (6.2%) had Spinal Muscular Atrophy (SMA), and 66 (5.6%) had Spina Bifida (including myelomengingocele). The average Cobb angle for the major curve at the time of exam was 70 degrees (range 0.3-154°, SD: 23°), and the average maximum measurable kyphosis was 51 degrees (range: -116-180°, SD: 27°). Five patients had endocrine comorbidities (0.4%), 201 had gastrointestinal comorbidities (16.9%), 267 had pulmonary comorbidities (22.5%), and 294 had developmental delay (24.7%). Urinary incontinence affected 118 patients (9.9%) and 45 patients were in possession of a VP shunt (3.8%).

***Surgical Site Infection***

Of 1,189 patients, 80 patients (6.9%) developed SSI. Sixteen (21%) of the SSIs were superficial and 60 (79%) were deep. Risk of SSI differed by specific demographics and preoperative characteristics as shown in Table 1. Of note, etiology was found to predispose a starkly different risk for SSI. Specifically, neuromuscular EOS patients were at the highest risk for SSI (11.9%, p<0.01), as compared to non-neuromuscular etiologies such as congenital (3.7%, p=0.036), idiopathic (3.8%, p=0.024), and syndromic (4.7%, p=0.14). Subtypes of neuromuscular etiology also differ in their risk, though not significantly: Spina Bifida had 16.7% risk, SMA had 12.2% risk, and CP had a 10.3% risk.

***Development of Risk Stratification Score***

 A final model yielding risk stratification score include the presence of neuromuscular etiology, myelomeningocele, SMA, endocrine comorbidity, gastrointestinal comorbidity, pulmonary comorbidity, developmental delay, urinary incontinence, and ventriculoperitoneal (VP) shunt (Table 2). The probability of SSI for individual patients can be calculated using the beta-values yielded from the final model by substituting 1 (presence) or 0 (absence) into the following equation: [exp [-3.365 + 0.828(neuromuscular etiology) + 0.376(Spina Bifida) + 0.304 (SMA) + 0.287 (Urinary Incontinence)+ 0.387(VP Shunt) + 0.347(Developmental Delay) + 1.449 (Endocrine Comorbidity) + 0.276(GI Comorbidity)+ 0.19(Pulmonary Comorbidity)] ]/ [1 + exp [-3.365 +0.828(neuromuscular etiology) + 0.376(Spina Bifida) + 0.304 (SMA) + 0.287 (Urinary Incontinence)+ 0.387(VP Shunt) + 0.347(Developmental Delay) + 1.449 (Endocrine Comorbidity) + 0.276(GI Comorbidity)+ 0.19(Pulmonary Comorbidity)]]. For example, the model predicted 3.3% probability of SSI for patients with none of these risk factors, and 68.4% probability for patients with myelomeningocele, GI, endocrine, and pulmonary comorbidities, developmental delay, urinary incontinence, and ventriculoperitoneal shunt.

***Evaluation of Model Performance***

 The RSS had a good discrimination, identifying true positives while minimizing false positives (c-statistic = 0.706). It also had an excellent calibration (Hosmer-Lemeshow statistics: p=0.149) with p-value greater than 0.05. The fit was also excellent when portrayed graphically (Figure 1). Plots of mean observed probabilities of SSI versus mean predicted probabilities of SSI for 7 risk groups were close to the diagonal line which shows perfect prediction (mean predicted risk = mean observed risk). The graphical representation of fit suggests that the model provides predictions that are consistent with the observed values.

**DISCUSSION**

 This study is the first to our knowledge to develop and evaluate RSS for EOS patients with all etiologies undergoing all surgical procedures for their correction of spinal deformity. This study demonstrated that the developed RSS has the ability to identify true positives while minimizing false positives and producing predictions that are consistent with the observed values.

 The RSS for the prediction of SSI included the presence of neuromuscular etiology, myelomeningocele, SMA, endocrine comorbidity, gastrointestinal comorbidity, pulmonary comorbidity, developmental delay, urinary incontinence, and VP shunt. Including neuromuscular etiology as a predictive variable in the RSS is a theme consistent with most of literature investigating the association between etiology and SSI and including pediatric patients (younger than 21 years of age) undergoing surgery for scoliosis performed after 2000 in the United States. These studies reported that patients with non-idiopathic etiologies especially patients with neuromuscular etiology have increased risk of SSI4,11,14,15. Studies investigating associations between comorbidities, urinary incontinence and VP shunt have disagreements in their findings. The majority of the studies available in the literature has not been able to examine associations between various comorbidities, urinary incontinence and/or VP shunt and SSI, possibly due to small sample size in single-center approaches and lack of comorbidity data in studies using administrative national datasets. Additionally, previous studies often included spine surgeries performed in the 1980s and 1990s, surgeries other than spinal deformity, patients of older age (e.g. 0-28), and define SSI as occurring beyond 90 days, all of which have inherent faults and limit their credibility for use in analysis. While associations between various risk factors and SSI from previous studies are useful, variables used to estimate these associations do not need to be the same for variables used in the prediction model. In contrast to research investigating causal inference, causality is neither a primary aim nor a requirement for predictor inclusions in predictive research26. Evaluations of prediction models depend upon models’ ability to make accurate predictions utilizing measures such as overall model performance and discriminating, calibrating, and reclassifying abilities27.

 A prediction model such as the RSS is important for several reasons. First, the individualized probability of SSI yielded from the RSS would enhance informed counseling and shared decision-making with patients and families. In the past decade, there have been national initiatives to promote shared decision-making such as the 2007 Washington State legislation incentivizing shared decision-making as an alternative to the traditional informed consent process notifying patients and their families the decision made by healthcare providers (Washington State Legislature. RCW 7.70.060). The Journal of the American Medical Association issued an article encouraging decision aids with high quality evidence to be disseminated and implemented in support of the shared decision-making process28. Since the RSS demonstrates high predictive probability for SSI after scoliosis surgery, it would serve as useful aids for patients and their families to share in decision-making with their healthcare providers in terms of the best individualized scoliosis management. Second, knowledge of the risk of SSI for individual patients likely improves patient care in the clinical setting. A high probability of SSI yielded from the RSS in a certain pre-operative patient would likely facilitate communication among healthcare providers and improve their teamwork in caring for this patient. Studies have shown a positive correlation between communication and teamwork and positive surgical outcomes29, including SSI after colorectal procedures30. Third, individualized risk probability of SSI could be used as a tool for risk adjustment. The Centers for Medicare & Medicaid Services (CMS) use incidence of readmission as a publicly reported quality metric and plan to decrease reimbursement to hospitals with high incidence of readmission31. However, if reimbursements are based on the incidence of readmission alone and are not adjusted properly for patient-specific risk, no hospital will provide service to high-risk patients. SSI is one of the most common causes for hospital readmission18,32,33 and the risk prediction model for SSI can be a useful risk adjustment tool to calculate incidence of readmission with standardized risk. This risk-standardized readmission then can be used for hospital comparison, public reporting, and reimbursement determinations.

 This study had a number of strengths including the large number of patients, multiple participating sites, and utilization of two national registries known to have participation in number of surgeons who treat patients with EOS. It allowed us to investigate the predictive effect of a number of variables relating to SSI including wide range of comorbidities. However, one limitation of this study includes reliance of registry data, which may be subject to misclassifications of explored variables and SSI status due to its nature of being entered by individual sites. Data entry at each participating site requires retrospective review of the patient charts by research personnel at all levels. If assessment of variables and their data entry were performed at the time of SSI occurrence, differential misclassification may occur and lead to information bias. For example, given the presence of SSI, research personnel may rigorously search for comorbidities whereas they may not do so in the absence of SSI. Selection bias due to loss to follow up should not be an issue in this study as the time of SSI to occur is within 90 days. The developed RSS identifies the high-risk patients, who possess etiologies and comorbidities that are not able to be manipulated. Therefore the important next step in minimizing SSI in these high risk patients is to create a RSS including surgical procedures and perioperative managements including antibiotic prophylaxis regimen.

             Overall, this study provides a means for predicting SSI in high-risk patients with EOS using preoperatively-known characteristics. By basing patient-specific RSS on preoperatively-known characteristics, we sought to be able to use it as a means of educating patients and families about their risk of SSI at the time of preoperative counseling and use it as a guide for shared decision making. Given the shifting insurance landscape and implementation of pay-for-performance policies, the ability to compare risk of SSI in different hospitals will be necessary. The development of RSS with high predictive performance and a focus on ease of implementation thus deserves our collective attention.

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**Table 1: Preoperative Characteristics of Early Onset Scoliosis Patients Undergoing Spinal Surgery and Their Risk of Surgical Site Infection (SSI) as Compared to the SSI Risk of Patients Without these Characteristics.**

|  |  |  |
| --- | --- | --- |
| **Risk Factor** | **SSI N(%)** | **p-value** |
| *Gender* Male Female | 36 (7.1%)44 (6.4%) | 0.641 |
| *Etiology* Neuromuscular* Spina Bifida
* Spinal Muscular Atrophy
* Cerebral Palsy

 Congenital Syndromic Idiopathic | 48 (11.9%)11 (16.7%)9 (12.2%)11 (10.3%)9 (3.7%)12 (4.7%)11 (3.8%) | <0.0001\*0.3510.036\*0.1410.024\* |
| Cobb Angle > 90 | 13 (7.5%) | 0.655 |
| *Kyphosis Status* Abnormal Kyphosis Hypokyphosis Hyperkyphosis | 26 (5.3%)1 (1.2%)25 (6.2%) | 0.047\*0.0840.464 |
| Non-Ambulatory | 57 (11.7%) | <0.0001\* |
| *Comorbidities* Cardiac Developmental Delay Endocrine Gastrointestinal Immunologic Musculoskeletal Neurologic Nutritional Pulmonary Urinary Incontinence | 9 (5.0%)31 (10.5%)1 (20.0%)25 (12.4%)0 (0.0%)13 (7.9%)14 (8.2%)0 (0.0%)24 (9.0%)17 (14.4%) | 0.3150.003\*0.2380.0004\*0.5080.5380.4220.4450.0990.0005\* |
| *Assistive Devices* Gastric Tube Respiratory Assistance Ventriculoperitoneal shunt | 21 (12.1%)53 (5.8%)9 (6.2%) | 0.003\*0.023\*0.0003\* |
| Fused Ribs | 4 (4.0%) | 0.255 |
| Fusion Procedure | 11 (6.0%) | 0.644 |

**Table 2: Surgical Site Infection Predictive Model.**

|  |  |  |  |
| --- | --- | --- | --- |
| **Variables** | **Beta** | **95% CI for Beta** | **OR** |
| **Lower** | **Upper** |
| Neuromuscular Etiology | 0.828 | 0.148 | 1.508 | 2.289 |
| Myelomeningocele (Spina Bifida) | 0.376 | -0.727 | 1.479 | 1.456 |
| Spinal Muscular Atrophy | 0.304 | -0.778 | 1.386 | 1.355 |
| Urinary Incontinence | 0.287 | -0.354 | 0.928 | 1.332 |
| VP Shunt | 0.387 | -0.240 | 1.014 | 1.473 |
| Developmental Delay | 0.347 | -0.198 | 0.892 | 1.415 |
| Endocrine Comorbidity | 1.449 | 0.881 | 2.017 | 4.259 |
| Gastrointestinal Comorbidity | 0.276 | -0.273 | 0.825 | 1.318 |
| Pulmonary Comorbidity | 0.19 | -0.398 | 0.778 | 1.209 |

OR: Odds Ratio; CI: Confidence Interval; VP = Ventriculoperitoneal

**Figure 1: Mean observed versus mean predicted probabilities for 7 risk groups.**