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CASE SERIES

Strategies reducing risk of surgical-site infection following pediatric spinal deformity surgery

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Abstract

Background Identifying beneficial preventive strategies for surgical-site infection (SSI) in individual patients with different clinical and surgical characteristics is challenging. The purpose of this study was to investigate the association between preventive strategies and patient risk of SSI taking into consideration baseline risks and estimating the reduction of SSI probability in individual patients attributed to these strategies.

Methods Pediatric patients who underwent primary, revision, or final fusion for their spinal deformity at 7 institutions between 2004 and 2018 were included. Preventive strategies included the use of topical vancomycin, bone graft, povidone-iodine (PI) irrigations, multilayered closure, impermeable dressing, enrollment in quality improvement (QI) programs, and adherence to antibiotic prophylaxis. The CDC definition of SSI as occurring within 90 days postoperatively was used. Multiple regression modeling was performed following multiple imputation and multicollinearity testing to investigate the effect of preventive strategies on SSI in individual patients adjusted for patient and surgical characteristics.

Results Univariable regressions demonstrated that enrollment in QI programs and PI irrigation were significantly associated, and topical vancomycin, multilayered closure, and correct intraoperative dosing of antibiotics trended toward association with reduction of SSI. In the final prediction model using multiple regression, enrollment in QI programs remained significant and PI irrigation had an effect in decreasing risks of SSI by average of 49% and 18%, respectively, at the individual patient level.

Conclusion Considering baseline patient characteristics and predetermined surgical and hospital factors, enrollment in QI programs and PI irrigation reduce the risk of SSI in individual patients. Multidisciplinary efforts should be made to implement these practices to increase patient safety.

Level of evidence Prognostic level III study.

Keywords Surgical-site infection · Precision prevention · Quality improvement · Risk calculator

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Introduction

Several guidelines for the prevention of surgical-site infection (SSI) have been developed by the Centers for Disease Control and Prevention (CDC) [1, 2] and other agencies [3–5] in the United States. In the field of pediatric spinal deformity care, best practice guidelines for the prevention of SSI were developed based on expert consensus [6, 7]. There are ongoing efforts to build evidence in the field, and a review of recent literature reported that the use of antibiotic prophylaxis regimens, such as gentamicin-impregnated allograft bone and intra-wound vancomycin powder, could be effective in decreasing risk of SSI [8, 9]. However, the complex multi-factorial nature of SSI imposes challenges to identifying which individual patients will best benefit from implementation of specific preventive care factors. Precision prevention [10–12] ensuring that patients, especially those at highest risk, receive appropriate and targeted preventive care is important, particularly in the value-based model of healthcare which balances increasing quality of care and improving population health with decreasing per capita costs [13].

An SSI risk calculator was developed and tested to compute the probability of SSI in individual pediatric patients undergoing spine surgery [14]. The model used patient, surgical and hospital factors which are determined preoperatively are unlikely to be modified [14]. This calculator makes it possible to identify high-risk patients, enhances patient education and shared decision-making, target resources for preoperative optimization, and alerts the perioperative care team in advance. An essential next step is to identify modifiable preventive care measures to reduce the individual patient's probability of SSI. Purposes of this study were to investigate the association between preventive care measures and patient risk of SSI, and to estimate the reduction of SSI probability by these preventive care measures from the baseline probability in individual patients, as calculated by previously identified risk factors [14]. We hypothesized that some preventive care factors would be associated with reduced incidences of SSI within 90 days after spinal surgery in individual patients.

Materials and methods

A multi-center retrospective study was conducted using data from seven institutions in urban hospitals with a broad range in number of surgical procedures (mean = 515, range = 8–1490). Upon IRB approval at each site, pediatric patients (≤ 21 years of age) with spinal deformity who underwent primary, revision, and definitive spinal fusion between 2004 and 2018 with standard perioperative care were included. Trained research personnel at each site reviewed patient charts, and a final audit was conducted by the first author to identify discrepancies or ambiguities in the data. Additional chart reviews were requested at each site for clarity to ensure the quality of the data. The unit of analysis was procedures instead of patients as some patients had more than one procedure and these procedures were different in terms of invasiveness.

Preventive care factors included the use of topical vancomycin in the operative site and/or bone graft, povidone-iodine irrigations, multilayered closure, or impermeable dressing, the enrollment quality improvement (QI) programs, such as the Children's Hospitals' Solutions for Patient Safety (SPS) program [15] (Appendix 1), and adherence to the institutional perioperative antibiotic prophylaxis guideline (Appendix 2). While, the standard closure technique involves conventional fascial, subcutaneous, and skin closure, multilayer closure incorporates the development of myocutaneous flaps and closure of the deep muscles, typically the paraspinous muscles, in a fashion [16]. The technique helps obliterate the peri-hardware dead space and relives tension. The impermeable dressings, such as medical skin adhesive gluing the edges of an incision closed, were waterproof and impermeable to bacteria and contaminants.

The SPS program was designed to prevent patient harms including healthcare-associated infections (HAIs) by employing cultural transformation strategies focusing on in-depth evaluation and change in communication, team dynamics, and leadership. SPS was founded in 2012 and participating hospital enrollment took place from 2012 to 2014. Data regarding adherence to the institutional perioperative antibiotic prophylaxis guideline were collected but were available only from one participating institution. Adherence to the institutional perioperative antibiotic prophylaxis guideline was categorized into incorrect or correct for administration of preoperative, intraoperative, or postoperative dosing or timing (Appendix 2). Patients with suspected infections before surgery who were continued on antibiotics > 24 h after surgery were not categorized as receiving incorrect perioperative prophylaxis.

Data collectors used the Centers for Disease Control and Prevention (CDC) definition of SSI published in 2017 [17] describing SSI as occurring within 90 days after the procedure and involving the skin or subcutaneous tissue of the incision or the fascial and muscle layers below the subcutaneous layer of the incision. In each setting, the treating physicians and surgeons as well as perioperative care team and pediatric infectious disease consults were responsible for closely monitoring wound cultures and readmissions after spine surgery to diagnose and document the occurrence of SSI. If a patient had more than one procedure before an SSI occurrence, the SSI was attributed to the most recent procedure.

Power analysis

An a priori power analysis was conducted to compare the risk of SSI between patients who received each preventive care strategy and those who did not. Given the sample size ($n = 3092$) and a significance level of 5%, more than 90% power would be achieved to detect absolute difference of 2% in area under curves (AUC). To ensure adequate power to add a care factor in the previously developed risk calculator using prediction modeling, the event per variable (EPV) ratio, defined as the number of outcomes divided by the number of risk factors in the model, for more than 10 was sought [18, 19]. There were 3092 procedures and 132 SSI (4.5%) in the database. Therefore, the prediction model up to 13 predictors was adequate to be entered in the prediction modeling at a time. There were ten patient, surgical and hospital factors already determined; therefore, it was appropriate to include up to three preventive care factors in the final prediction model.

Statistical analysis

Missing data in preventive care factors (2.2–8.9%) were addressed using multiple imputation since there was no evidence that the missing data were not random [20–22] (Appendix 3). Simple logistic regression models were first utilized for each preventive care factor to examine its association with the SSI. Significant preventive care factors in the univariable analyses ($p < 0.05$) and patient, surgical, and hospital factors identified in the risk calculator as significant were included: overweight/obese, neuromuscular etiology, American Society of Anesthesiologist Physical Status Classification System (ASA) > 2, non-ambulatory status, abnormal hemoglobin level, revision surgery, presence of pelvic instrumentation, procedure time ≥ 7 h, and 100 spine surgical case per year per institution. The corresponding odds ratio (OR) of SSI in the multiple logistic regression model was obtained for each preventive care factor.

The data were randomly split into training (80%) and testing (20%) cohorts, and five-fold cross-validation was performed with model fit conducted only in the training sets [23]. The AUC plotting sensitivity vs 1-specificity were calculated to evaluate the model's ability to discriminate patients with and without SSI [24]. Discrimination abilities were further assessed by discrimination slopes and box plots comparing average prediction differences in those with and without the observed SSI [25], and by Lorenz estimates and curves depicting the cumulative proportion of patients ranked by predicted probability against the cumulative proportion of patients with SSI [26]. The model calibration was assessed by the Hosmer–Lemeshow (HL) goodness-of-fit test along with the graphic illustration of the fit using calibration plots [27]. Calibration slopes [28], and calibration-in-the-large [29] were also evaluated. Overfitting was calculated by in-sample error over out-sample error comparing the average deviances and Pearson's residuals of training sets and testing sets. To calculate the individual probability of SSI, a risk prediction algorithm was created from coefficients in the final model. Additionally, a smart phone application for the dynamic calculator was developed to facilitate use in clinical settings.

Results

There were 3092 spinal deformity surgical procedures, and a total of 132 SSI within 90 days after surgery were reported (4.5%) (Table 1). Multilayered closure was performed in approximately half of patients followed by topical vancomycin in approximately 40% of patients, povidone-iodine irrigations and QI enrollment in about one-fourth of patients, and impermeable dressing in approximately 15% of patients (Table 2). For the institution with available data regarding adherence to their perioperative antibiotic prophylaxis guideline, there were 1487 surgical procedures and 57 SSI (3.8%) (Table 3). Reported adherence to postoperative dosing of antibiotic prophylaxis had the lowest reported adherence (78.3%) and postoperative timing had the highest (91.5%). Adherence to preoperative and intraoperative dosing and timing was similar, ranging from 87 to 89.5%. Univariable regressions demonstrated that enrollment in QI programs and povidone-iodine (PI) irrigation was significantly associated, and topical vancomycin, multilayered closure, and correct intraoperative dosing of antibiotics were trended toward association with reduction of SSI (Tables 2, 3). When the SPS enrollment alone was in the model, patients whose procedures were performed when sites were enrolled in the programs had 49.4% decrease in SSI (odds ratio [OR] 0.51, [95% CI 0.32; 0.81], $p = 0.005$) and AUC of 0.56 [95% CI 0.52; 0.59].

The final model using multiple regression including povidone-iodine irrigations and the enrollment in SPS as well as the previously identified patient, surgical, and hospital characteristics demonstrated adequate predictive discrimination and calibration abilities in the training and testing sets (Appendix 4). The average discrimination abilities of this model in the training and the testing sets were AUC: 0.78 [95% CI 0.74; 0.83] and 0.77 [95% CI 0.69; 0.85], the discrimination slope of 0.05 [95% CI 0.04; 0.06] and 0.05 [95% CI 0.03;0.06], and Lorenz curve: 2.81%, 12.87%, and 35.65% and 3.52%, 12.19%, and 39.37% at 25%, 50%, and 75% cumulative risk proportions respectively. The average calibration abilities were calibration slope: 1.03 and 0.97, expected/observed ratio: 0.99 and 0.99, calibration-in-the-large: 0.01 and 0.01, HL goodness-of-fit-tests of 0.002 and 0.16. Overfitting was not observed: deviance of 0.99 and

Table 1 Descriptive Statistics for baseline characteristics

Candidate predictor variables		Descriptive analyses		
		All patients ($N=3092$)	Patients without SSI ($N=2960$)	Patients with SSI ($N=132$)
Preoperative patient characteristics				
Age in years, mean ± SD [95% CI]		13.0 ± 4.1	13.0 ± 4.1	12.9 ± 4.6
Gender	Male	1207 (39.0%)	1136 (94.1%)	71 (5.9%)
	Female	1885 (61.0%)	1825 (96.8%)	60 (3.2%)
Height, mean ± SD (range)		144.4 ± 25.0	144.7 ± 25.4	137.6 ± 131.5
Weight, mean ± SD (range)		44.7 ± 20.6	44.8 ± 20.9	43.8 ± 120.7
BMI	Underweight	426 (13.8%)	400 (93.9%)	26 (6.1%)
	Healthy weight	1874 (60.6%)	1810 (96.6%)	64 (3.4%)
	Overweight/obese	792 (25.6%)	750 (94.7%)	42 (5.3%)
Etiology	Idiopathic	1511 (48.8%)	1482 (98.1%)	29 (1.9%)
	Congenital	474 (15.3%)	459 (96.8%)	15 (3.2%)
	Neuromuscular	806 (26.1%)	729 (90.5%)	77 (9.5%)
	Syndromic	284 (9.2%)	273 (96.1%)	11 (3.9%)
	Other	17 (0.6%)	17 (100%)	0 (0%)
Major Coronal Curve, mean ± SD (range)		60.5 ± 24.0	60.3 ± 24.3	63.3 ± 136.4
Sagittal Curve	Hypo-kyphosis	504 (16.3%)	479 (95.0%)	25 (5.0%)
	Hyper-kyphosis	875 (28.3%)	837 (95.7%)	38 (4.3%)
	Normo-kyphosis	1713 (55.4%)	1644 (96.0%)	69 (4.0%)
ASA	1	653 (21.1%)	647 (99.1%)	6 (0.9%)
	2	1249 (40.4%)	1214 (97.2%)	35 (2.8%)
	3	1042 (33.7%)	961 (92.2%)	81 (7.8%)
	4	68 (2.2%)	62 (90.8%)	6 (9.2%)
	5	80 (2.6%)	77 (96.6%)	3 (3.4%)
Pulmonary comorbidity	Present	600 (19.4%)	559 (93.2%)	41 (6.8%)
	Absent	2492 (80.6%)	2400 (96.3%)	92 (3.7%)
Cardiac comorbidity	Present	232 (7.5%)	218 (93.9%)	14 (6.1%)
	Absent	2860 (92.5%)	2743 (95.9%)	117 (4.1%)
Behavioral comorbidity	Present	538 (17.4%)	502 (93.4%)	36 (6.6%)
	Absent	2554 (82.6%)	2457 (96.2%)	97 (3.8%)
Endo comorbidity	Present	136 (4.4%)	131 (96.2%)	5 (3.8%)
	Absent	2956 (95.6%)	2829 (95.7%)	127 (4.3%)
GI comorbidity	Present	390 (12.6%)	361 (92.5%)	29 (7.5%)
	Absent	2702 (87.4%)	2599 (96.2%)	103 (3.8%)
Immunology comorbidity	Present	37 (1.2%)	35 (94.5%)	2 (5.5%)
	Absent	3055 (98.8%)	2924 (95.7%)	131 (4.3%)
Nutritional comorbidity	Present	136 (4.4%)	129 (94.5%)	7 (5.5%)
	Absent	2956 (95.6%)	2832 (95.8%)	124 (4.2%)
MSK comorbidity	Present	442 (14.3%)	411 (92.9%)	31 (7.1%)
	Absent	2650 (85.7%)	2549 (96.2%)	101 (3.8%)
Neurologic comorbidity	Present	708 (22.9%)	651 (92.0%)	57 (8.0%)
	Absent	2384 (77.1%)	2308 (96.8%)	76 (3.2%)
G-Tube	Present	368 (11.9%)	337 (91.5%)	31 (8.5%)
	Absent	2724 (88.1%)	2623 (96.3%)	101 (3.7%)
VP shunt	Present	102 (3.3%)	90 (88.5%)	12 (11.5%)
	Absent	2990 (96.7%)	2870 (96.0%)	120 (4.0%)
Neural axis	Present	272 (8.8%)	257 (94.4%)	15 (5.6%)
	Absent	2820 (91.2%)	2704 (95.9%)	116 (4.1%)

Table 1 (continued)

Candidate predictor variables		Descriptive analyses		
		All patients ($N=3092$)	Patients without SSI ($N=2960$)	Patients with SSI ($N=132$)
Ambulatory status	Non-ambulatory	735 (23.8%)	659 (89.7%)	76 (10.3%)
	Ambulatory	2357 (76.2%)	2301 (97.6%)	56 (2.4%)
Diaper dependence	Dependent	701 (22.7%)	631 (90.0%)	70 (10.0%)
	Independent	2391 (77.3%)	2329 (97.4%)	62 (2.6%)
HGB in g/dl	Abnormal < 10 or > 14	959 (31.0%)	902 (94.1%)	57 (5.9%)
	Normal 10–14	2133 (69.0%)	2056 (96.4%)	77 (3.6%)
HCT in %	Abnormal < 31 or > 48	155 (5.0%)	149 (95.9%)	6 (4.1%)
	Normal 31–48	2937 (95.0%)	2811 (95.7%)	126 (4.3%)
WBC in #/ul	Abnormal < 3.5 or > 12	402 (13.0%)	384 (95.5%)	18 (4.5%)
	Normal 3.5–12	2690 (87.0%)	2577 (95.8%)	113 (4.2%)
Hospitalization within 2 years	Yes	2412 (78.0%)	2274 (94.3%)	138 (5.7%)
	No	680 (22.0%)	653 (96.1%)	27 (3.9%)
Prior SSI	Yes	2956 (95.6%)	2,752 (93.1%)	204 (6.9%)
	No	136 (4.4%)	130 (95.9%)	6 (4.1%)
Prior spine SSI	Yes	102 (3.3%)	95 (93.2%)	7 (6.8%)
	No	2990 (96.7%)	2864 (95.8%)	126 (4.2%)
Prior spine surgery	Yes	710 (23.0%)	670 (94.4%)	40 (5.6%)
	No	2382 (77.0%)	2,290 (96.1%)	92 (3.9%)
Preoperative halo traction	Yes	143 (4.6%)	136 (95.1%)	7 (4.9%)
	No	2949 (95.4%)	2824 (95.8%)	125 (4.2%)
Surgical factors				
Type of surgery	Primary instrumentation	1437 (46.5%)	1389 (96.9%)	45 (3.1%)
	Definitive fusion	1220 (39.5%)	1165 (95.5%)	55 (4.5%)
	Revision	427 (13.8%)	395 (92.5%)	32 (7.5%)
	Stapling	8 (0.2%)	11 (100%)	0 (0%)
Type of surgery	Revision	427 (13.8%)	395 (92.5%)	32 (7.5%)
	Not revision	2665 (86.2%)	2565 (96.2%)	100 (3.8%)
Surgical approach	Combined	130 (4.2%)	120 (92.2%)	10 (7.8%)
	Posterior	2929 (94.4%)	2806 (95.8%)	123 (4.2%)
	Anterior	43 (1.4%)	43 (100%)	0 (0%)
Pelvic instrumentation	Yes	637 (20.6%)	573 (90.0%)	64 (10.0%)
	No	2455 (79.4%)	2387 (97.2%)	68 (2.8%)
Intraoperative skeletal traction	Yes	263 (8.5%)	248 (94.2%)	15 (5.8%)
	No	2829 (91.5%)	2713 (95.9%)	116 (4.1%)
Instrumented levels in #, mean ± SD (range)		10.9 ± 4.8	11.0 ± 5.0	12.8 ± 25.8
Type of instrumentation	Screw and hook	931 (30.1%)	879 (94.4%)	52 (5.6%)
	Screws only	2161 (69.9%)	2081 (96.3%)	80 (3.7%)
Spinal osteotomies	Yes	1125 (36.4%)	1080 (96.0%)	45 (4.0%)
	No	1967 (63.6%)	1880 (95.6%)	87 (4.4%)
VCR	Yes	108 (3.5%)	107 (98.9%)	1 (1.1%)
	No	2984 (96.5%)	2853 (95.6%)	131 (4.4%)
Transfusion	Yes	1132 (36.6%)	1069 (94.4%)	63 (5.6%)
	No	1960 (63.4%)	1891 (96.5%)	69 (3.5%)
Cell saver	Yes	1592 (51.5%)	1524 (95.7%)	68 (4.3%)
	No	1500 (48.5%)	1437 (95.8%)	63 (4.2%)
Staples skin closure	Yes	12 (0.4%)	12 (100%)	0 (0%)
	No	3078 (99.6%)	2946 (95.7%)	132 (4.3%)

Table 1 (continued)

Candidate predictor variables		Descriptive analyses		
		All patients ($N=3092$)	Patients without SSI ($N=2960$)	Patients with SSI ($N=132$)
Procedure time in hours, mean ± SD [95% CI]		5.8 ± 2.6	5.8 ± 2.6	6.8 ± 14.8
Hospital characteristics				
Geographic region	West	746 (24.1%)	708 (94.9%)	38 (5.1%)
	Northeast	2346 (75.9%)	2252 (96.0%)	94 (4.0%)
Area	Urban	3092 (100%)	2960 (95.7%)	132 (4.3%)
	Rural	0 (0%)	0 (0%)	0 (0%)
Academic health center	Yes	3084 (99.7%)	2952 (95.7%)	132 (4.3%)
	No	8 (0.3%)	8 (100%)	0 (0%)
Surgical volume/year, mean ± SD (range)		73.8 ± 74.0 (1.6; 220)	74.4 ± 74.4 [71.8; 77.1]	58.9 ± 62.5 [48.2; 69.7]

Table 2 Descriptive statistics for preventive care factors in all patients

Preventive care factors		Descriptive analyses			Univariable regression	
		All patients ($N=3092$)	Patients without SSI ($N=2960$)	Patients with SSI ($N=132$)	Coefficient [95% CI]	*p* value
Topical vancomycin	Performed	1292 (41.8%)	1248 (96.6%)	44 (3.4%)	− 0.36 [− 0.73; 0.01]	0.056
	Not performed	1800 (58.2%)	1712 (95.1%)	88 (4.9%)		
Povidone-iodine irrigations	Performed	773 (25.0%)	751 (97.1%)	22 (2.9%)	− 0.50 [− 0.97; − 0.03]	0.037
	Not performed	2319 (75.0%)	2210 (95.3%)	109 (4.7%)		
Multi-layer closure	Performed	1614 (52.2%)	1535 (95.1%)	79 (4.9%)	0.31[− 0.04; 0 0.67]	0.086
	Not performed	1478 (47.8%)	1425 (96.4%)	53 (3.6%)		
Dressing	Impermeable	461 (14.9%)	437 (94.9%)	24 (5.1%)	− 0.21 [− 0.68; 0.25]	0.366
	Permeable	2631 (85.1%)	2523 (95.9%)	108 (4.1%)		
SPS enrollment	Enrolled	829 (26.8%)	808 (97.5%)	21 (2.5%)	− 0.68 [− 1.15; -0.21]	0.005
	Not enrolled	2263 (73.2%)	2152 (95.1%)	111 (4.9%)		

Table 3 Descriptive statistics for adherence to IV antibiotics in the subgroup

Adherence to IV antibiotics		Descriptive analyses			Univariable regression	
		All patients ($N=1487$)	Patients without SSI ($N=1430$)	Patients with SSI ($N=57$)	Coefficient [95% CI]	*p* value
Preoperative dosing	Incorrect	156 (10.5%)	151 (96.8%)	5 (3.2%)	0.21 [− 0.71; 1.14]	0.666
	Correct	1331 (89.5%)	1279 (96.1%)	52 (3.9%)		
Preoperative timing	Incorrect	178 (12.0%)	173 (97.2%)	5 (2.8%)	0.36 [− 0.57; 1.29]	0.45
	Correct	1309 (88.0%)	1257 (96.0%)	52 (4.0%)		
Intraoperative dosing	Incorrect	193 (13.0%)	181 (93.8%)	12 (6.2%)	− 0.61 [− 1.27; 0.05]	0.068
	Correct	1294 (87.0%)	1249 (96.5%)	45 (3.5%)		
Intraoperative timing	Incorrect	172 (11.6%)	162 (94.2%)	10 (5.8%)	− 0.51 [− 1.21; 0.19]	0.154
	Correct	1315 (88.4%)	1268 (96.4%)	47 (3.6%)		
Postoperative dosing	Incorrect	323 (21.7%)	310 (96.0%)	13 (4.0%)	− 0.07 [− 0.70; 0.57]	0.839
	Correct	1164 (78.3%)	1120 (96.2%)	44 (3.8%)		
Postoperative timing	Incorrect	126 (8.5%)	120 (95.2%)	6 (4.8%)	− 0.25 [− 1.12; 0.62]	0.571
	Correct	1361 (91.5%)	1310 (96.3%)	51 (3.8%)		

Pearson's residuals of 0.99. Coefficient and odds ratios with 95% confidence intervals (CIs) for preventive care factors in the final prediction model are presented in Table 4. Patients from institutions enrolled in the SPS programs had an average 48.9% lower in SSI compared with patients from non-enrolled sites [odds ratio: 0.51, (95% CI 0.30; 0.86), $p = 0.01$]. Although not statistically significant, patients who received povidone-iodine irrigations had an average 18.3% decrease in SSI compared with patients without the irrigations [odds ratio: 0.81, (95% CI 0.44; 1.48), $p = 0.494$]. Accumulative AUCs are presented in Appendix 5.

The equation and the smartphone application to calculate the reduction of the predicted risk of SSI in individual patients from the final model are presented in Figs. 1 and 2 respectively. Some likely cases are described in Table 5. For example, Case 2 shows the predicted risk of SSI in patients with neuromuscular etiology, ASA = 2, and non-ambulatory status, who underwent pelvic instrumentation and had ≥ 7-h surgical procedure. The predicted risk was reduced from 13.4% to 11.1% with povidone-iodine irrigations, to 7.3% with SPS enrollment, and to 6.0% with both strategies.

Discussion

The goal of this study was to identify preventive care factors associated with a reduction in SSI incidence within 90 days of pediatric spinal deformity surgery. The previously developed risk calculator used prediction modeling to identify the probability of SSI in individual patients based on preoperative factors and intraoperative factors, which are determined and planned preoperatively and unlikely to be modified in many cases. In this study, we attempted to identify modifiable preventive care factors in individual patients, taking the baseline risk of these patients into account as calculated by the previously developed clinical risk model [14].

This study demonstrated that enrollment in SPS was most significantly associated with a reduced risk of SSI. SPS, focusing on teamwork, communication, and leadership, was designed to prevent patient harms by facilitating organizational improvements and employing cultural transformation. This finding was consistent with existing literature reporting the benefit of QI programs in reducing SSI in various surgical specialties among both adult and pediatric populations [30–33]. This suggests that the socio-adaptive aspects of care were especially important in reducing the risk of SSI. Quality improvement requires orchestrated efforts including

Table 4 Odds ratio and coefficients for SSI in the final prediction model

	Coefficient	Odds ratio	95% confidence interval	*p* value
Overweight/obese	0.40	1.49	1.00; 2.20	0.048
Neuromuscular etiology	0.51	1.67	1.19; 2.74	0.043
ASA > 2	0.34	1.40	0.86; 2.30	0.179
Non-ambulatory status	0.66	1.93	1.11; 3.35	0.020
HGB < 10 g/dL or > 14 g/dL	0.31	1.36	0.94; 1.98	0.106
Revision surgery	0.70	2.01	1.29; 3.12	0.002
Pelvic instrumentation	0.39	1.48	0.92; 2.35	0.106
Procedure duration ≥ 7 h	0.66	1.93	1.28; 2.90	0.002
Surgical volume < 100	0.18	1.20	0.74; 1.94	0.473
Povidone-iodine irrigations	− 0.21	0.81	0.44; 1.48	0.494
SPS enrollment	− 0.67	0.51	0.30; 0.86	0.011

Fig. 1 Equation calculating the reduction of individual probability of SSI by preventive care factors

$$\text{Probability of SSI} = \frac{\exp[-4.42 + 0.40(\text{overweight/obese}) + 0.51(\text{neuromuscular}) + 0.34(\text{ASA}>2) + 0.66(\text{non-ambulatory}) + 0.31(\text{HGB}<10\text{g/dL or} >14\text{g/dL}) + 0.70(\text{revision}) + 0.39(\text{pelvic instrumentation}) + 0.66(\text{procedure} \geq 7\text{ hours}) + 0.18(\text{surgical volume}<100) - 0.21(\text{povidone-iodine irrigations}) - 0.67(\text{SPS enrollment})]}{1 + \exp[-4.42 + 0.40(\text{overweight/obese}) + 0.51(\text{neuromuscular}) + 0.34(\text{ASA}>2) + 0.66(\text{non-ambulatory}) + 0.31(\text{HGB}<10\text{g/dL or} >14\text{g/dL}) + 0.70(\text{revision}) + 0.39(\text{pelvic instrumentation}) + 0.66(\text{procedure} \geq 7\text{ hours}) + 0.18(\text{surgical volume}<100) - 0.21(\text{povidone-iodine irrigations}) - 0.67(\text{SPS enrollment})]}$$

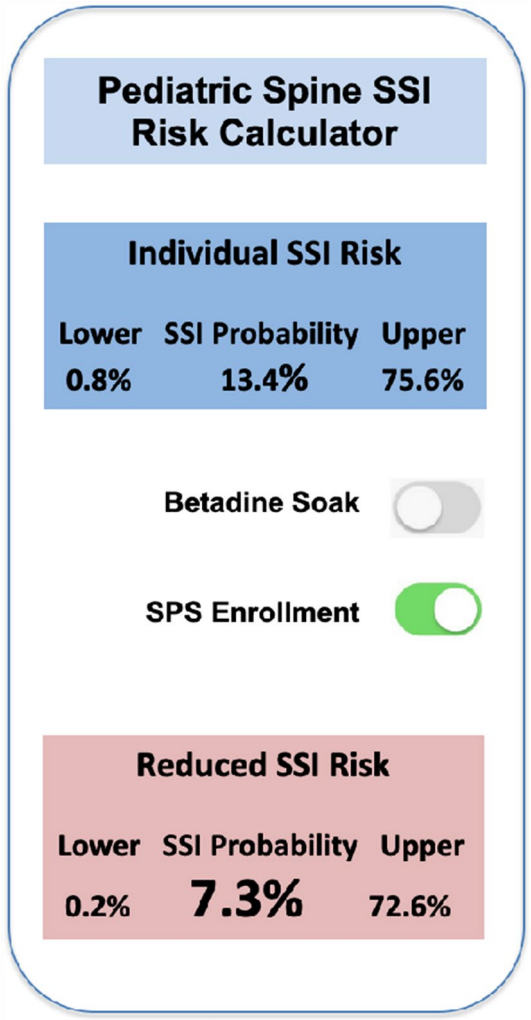


Fig. 2 App for the dynamic risk calculator producing reduction of individual probabilities of SSI by preventive care factor

robust leadership and commitment of the entire care team along with an understanding of health care delivery and human behavior [34, 35]. Hence, reviewing and investing in socio-adaptive aspects of care delivery may be a crucial step along with seeking other technical approaches. Additionally, SPS is a multimodal QI program that may improve the administration and adherence to other preventative strategies examined, such as antibiotic timing.

On the technical side, this study showed that povidone-iodine irrigations might have been associated with a reduced risk of SSI. Although it was not statistically significant, on average, the calculated probability of SSI at the individual level produced by the equation was still reduced when povidone-iodine irrigations were performed. The impact of the povidone-iodine irrigations found in our study was not as great as in a previous study reporting an approximately 20 percent reduction [36]. This may be because our sample size was too small, or the previous study only included patients with adolescent idiopathic scoliosis (AIS) while this study had patients with AIS as well as younger patients and patients with more involved etiologies and complex comorbidities.

This study is important in several ways. First, identifying potentially modifiable preventive care factors is valuable in the clinical setting. Although it is not possible to modify some risk factors, such as neuromuscular etiology, changing modifiable factors can reduce the incidence of SSI. Targeting preventive care strategies for children undergoing surgery for spinal deformities, and focusing on those identified to be at the highest risk for SSI, is important and may enable simultaneous improvements in the quality of care while minimizing per capita costs [13]. Second, results of this study can provide insights into potential causal mechanisms of SSI. Although risk prediction and investigation of causal inference differ in principle and methodology, prediction

Table 5 Predicted risk of SSI with preventive strategies

Factors	Case 1	Case 2	Case 3
BMI overweight/obese			X
Neuromuscular etiology	X	X	
ASA > 2	X	X	
Non-ambulatory	X	X	
HGB < 10 g/dL or > 14 g/dL	X		
Revision surgery			
Pelvic instrumentation	X	X	
Procedure duration ≥ 7 h	X	X	X
Surgical volume < 100	X		X
Predicted risk of SSI	20.1%	13.4%	4.0%
Predicted risk of SSI with povidone-iodine irrigations	16.9%	11.1%	3.2%
Predicted risk of SSI with SPS enrollment	11.4%	7.3%	2.1%
Predicted risk of SSI with both povidone-iodine irrigations and SPS enrollment	9.4%	6.0%	1.7%

modeling identifies exposures significantly associated with outcomes. Therefore, preventive care factors identified in this research warrant further study to advance our understanding of potential strategies to reduce SSI. Third, this study defined SSI using the standard CDC definition which is also used by Center for Medicare and Medicaid Services to determine penalties for surgical readmission.

There were several limitations in this study. First, misdiagnosis or variations in defining SSI might have occurred across sites as SSI ranged from 0 to 5.3%. Although each site agreed to use the CDC definition of SSI and was asked to validate the SSI data in patient charts, the accuracy of the data was dependent on research personnel at each site. Despite providing each site with a standardized definition, variations in reporting may also have occurred for multilevel closure due to differences in surgical technique. Second, an SSI could have been treated at an outside hospital not contributing to the database and not reported to a performing surgeon. However, this was unlikely due to the seriousness of spinal surgery and SSI. Next, some preventive care factors may have been misclassified or not recorded. If recording errors of the outcome and/or exposures were different, information bias and inaccurate prediction are possible. An important next step in the research is to validate the reduction effect of preventive care factors tested in this study in multiple data sets across different times and settings. Finally, the SPS program is specific to the United States and may not be generalizable to other countries. SPS focuses on the socio-adaptive aspects of care management, facilitated organizational improvements and cultural transformation, but may not be appropriate in different cultures and customs. Therefore, future studies which investigate causal pathways (mediator effects) between quality programs and the decreased risk of SSI are needed to identify potential interventions to replace culturally specific programs that improve human behavior and reduce the risk of SSI in other countries. Additionally, future studies could investigate how the level of site involvement in QI programs interacts with SSI risk.

Conclusion

In conclusion, this study presents the first-time evaluation of the potential effects of preventive care factors on SSI risk in individual patients, considering individual patients' baseline characteristics and predetermined surgical and hospital factors, which are difficult to modify and can confound the results. The final model encompassing preventive care factors and patient, surgical and hospital factors has adequate predictive accuracy for 90-day SSI after surgery in pediatric patients with spinal deformity. SSI incidence was most significantly associated with quality improvement program enrollment, further supporting the use of multimodal, multidisciplinary teams to improve patient safety. The results of this study add new information to enhance personalized care in clinical practice by identifying factors, which could reduce the risk of SSI for specific patients.

Appendix 1 Preventive care factors

Type of preventive care factors	Measures
Topical vancomycin	Dichotomous (yes or no)
Povidone-iodine irrigations	Dichotomous (yes or no)
Multi-layer closure	Dichotomous (performed or not performed)
Dressing	Dichotomous (permeable or impermeable)
Children's hospitals' solutions for patient safety or comprehensive unit-based safety program enrollment	Dichotomous (yes or no)
Preoperative dosing of any IV antibiotics	Dichotomous (correct or incorrect)
Preoperative timing of any IV antibiotics	Dichotomous (correct or incorrect)
Intraoperative dosing of any IV antibiotics	Dichotomous (correct or incorrect)
Intraoperative timing of any IV antibiotics	Dichotomous (correct or incorrect)
Postoperative dosing of any IV antibiotics	Dichotomous (correct or incorrect)
Postoperative timing of any IV antibiotics	Dichotomous (correct or incorrect)

Appendix 2 perioperative antibiotic prophylaxis regimen for spine surgery, pediatric orthopedic spine service

Drugs	Dosage	Timing	Intraoperative antibiotic prophylaxis guidelines	Antibiotic prophylaxis re-dosing guidelines
IV Cefazolin (if no b-lactam antibiotic allergy and not colonized with MRSA)	30 mg/kg ± 10%	15 to 60 min prior to incision	Eligible for re-dosing if surgery duration ≥ 4 h after first antibiotic dose. Timing of intraoperative re-dosing: 4 h ± 30 min from previous dose OR	Discontinuation of antibiotics within 24 h of surgery end time. Postoperative re-dosing interval: every 8 h
IV Vancomycin (if b-lactam antibiotic allergy or MRSA colonization)	15 mg/kg ± 10%	15 to 60 min prior to incision	Eligible for re-dosing if surgery duration ≥ 8 h after first antibiotic dose. Timing of intraoperative re-dosing: 8 h ± 30 min from previous dose AND	Discontinuation of antibiotics within 24 h of surgery end time. Postoperative re-dosing interval: every 8 h
IV Tobramycin (If tobramycin antibiotic allergy, Gram-negative coverage selected on a case-by-case basis)	2.5 mg/kg ± 10%	15 to 60 min prior to incision	Eligible for re-dosing if surgery duration ≥ 8 h after first antibiotic dose. Timing of intraoperative re-dosing: 8 h ± 30 min from previous dose AND	Discontinuation of antibiotics within 24 h of surgery end time. Postoperative re-dosing interval: every 8 h
Topical vancomycin	1 g	After the spine muscle exposure	Powder rubbed into spinal muscles	
Povidone-iodine	3%	After instrumentation	Irrigations for 3 min	
Topical vancomycin	1 g	Before wound closure	Powder rubbed into spinal muscles	

Appendix 3 Number (%) of missing values per candidate predictor variables, and distribution of predictors among subjects without and with missing values (100%: *N* = 3092)

Candidate predictor variables		No missing *N* (%)	Missing *N* (%)	Before imputation	After imputation *N* = 3092	Patterns of missing data	Variables used to impute	# Of imputed datasets
Topical Vancomycin	Performed Not performed	2816 (91.1%)	276 (8.9%)	1270 (45.1%) 1546 (54.9%)	1292 (41.8%) 1800 (58.2%)	Arbitrary	Age, gender, etiology, ambulatory status, diaper dependence, prior spine surgery, type of surgery, pelvic instrumentation, region, surgical volume, SSI	20
Betacaine Irrigations	Performed Not performed	2816 (91.1%)	276 (8.9%)	748 (26.6%) 2068 (73.4%)	773 (25.0%) 2319 (75.0%)	Arbitrary	Age, etiology, halo traction, type of surgery, pelvic instrumentation, region, surgical volume, SSI	20

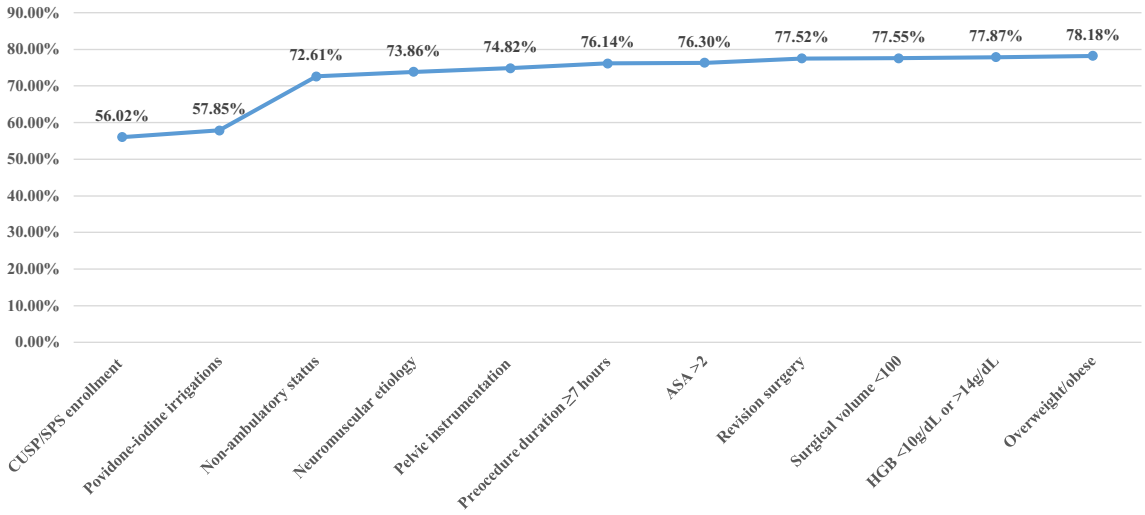
Candidate predictor variables		No missing *N* (%)	Missing *N* (%)	Before imputation	After imputation *N* = 3092	Patterns of missing data	Variables used to impute	# Of imputed datasets
Multi-layer Closure	Performed Not performed	2816 (91.1%)	276 (8.9%)	1487 (52.8%) 1329 (47.2%)	1614 (52.2%) 1478 (47.8%)	Arbitrary	Age, etiology, diaper dependence, prior spine surgery, halo traction, type of surgery, pelvic instrumentation, region, surgical volume, SSI	20
Dressing	Permeable Impermeable	2818 (91.1%)	274 (8.9%)	404 (14.3%) 2414 (85.7%)	2631 (85.1%) 461 (14.9%)	Arbitrary	Etiology, prior spine surgery, halo traction, type of surgery, pelvic instrumentation, region, surgical volume, SSI	20
SPS	Enrolled Not enrolled	3024 (97.8%)	68 (2.2%)	823 (27.2%) 2201(72.8%)	829 (26.8%) 2263 (73.2%)	Arbitrary	Age, gender, etiology, ambulatory status, diaper dependence, prior spine surgery, halo traction, type of surgery, pelvic instrumentation, region, surgical volume, SSI	20

Appendix 4 Predictive discrimination and calibration abilities in the training and testing sets in the five-fold cross-validation

Model with preventive care factors							
Training sample ($N=2474$)				Testing sample ($N=618$)			
Discrimination			Calibration	Discrimination			Calibration
ROC curve	Slope and box plot	Lorenz curve	Calibration plot	ROC curve	Slope and box plot	Lorenz curve	Calibration plot
Experiment 1							
AUC 0.80 SE 0.02 95% CI 0.76; 0. 84	Slope 0.06 SE 0.01	p25 2.22% p50 11.32% P75 32.08%	E:O = 0.99 HL GOF 0.01 CITL 0.01 Slope 1.03	AUC 0.70 SE 0.04	Slope 0.03 SE 0.01 95% CI 0.0`; 0.04	p25 3.85% p50 19.23% *p* 57.69%	E:O = 0.99 HL GOF < 0.001 CITL 0.02 Slope 0.60
Experiment 2							
AUC 0.79 SE 0.02 95% CI 0.75; 0.83	Slope 0.06 SE 0.01 95% CI 0.05; 0.06	p25 2.95% p:50 11.43% p75 34.29%	E: O = 0.99 HL GOF 0.001 CITL: 0.01 Slope: 1.03	AUC 0.75 SE 0.05 95% CI 0.66;0.84	Slope 0.04 SE 0.01 95% CI 0.03; 0.06	p25 3.70% p50 14.81% p75 40.74%	E:O = 0.91 HL GOF 0.176 CITL 0.10 Slope 0.87
Experiment 3							
AUC 0.77 SE 0.02 95% CI 0.73; 0.81	Slope 0.05 SE 0.004 95% CI 0.04; 0.05	p25 3.22% p50 12.26%	HL GOF 0.002 CITL: 0.01 Slope: 1.03	AUC 0.81 SE 0.04		p25 2.90% p50 11.54% p75 31.41%	E:O = 1.00 HL GOF 0.29 CITL − 0.01 Slope 1.40

Model with preventive care factors							
Training sample ($N=2474$)				Testing sample ($N=618$)			
Discrimination			Calibration	Discrimination			Calibration
ROC curve	Slope and box plot	Lorenz curve	Calibration plot	ROC curve	Slope and box plot	Lorenz curve	Calibration plot
Experiment 4							
AUC 0.78 SE:0.02	Slope 0.05 SE 0.01	p25 3.85% p50 14.24% p75 37.36%	E:O = 0.99 HL GOF < 0.001 CITL: 0.01 Slope 1.02	AUC 0.80 SE 0.03 95% CI 0.73; 0.86	Slope 0.05 SE 0.01 95% CI 0.03; 0.07	p25 0% p50 3.81% p75 33.33%	E:O = 1.03 HL GOF 0.01 CITL − 0.04 Slope 0.91
Experiment 5							
AUC 0.78 SE 0.02 95% CI 0.74; 0.82	Slope 0.05 SE 0.01 95% CI 0.04; 0.06	p25 1.82% p50 15.09%	E:O = 0.99 HL GOF 0.001 CITL: 0.01 Slope: 1.04	AUC 0.78 SE 0.04 95% CI; 0.70; 0.87	Slope 0.05 SE 0.01 95% CI 0.03; 0.07	p25 7.13% p50 11.54%	E:O = 1.03 HL GOF 0.20 CITL − 0.03 Slope 1.05
Average of five experiments							
AUC 0.78 SE 0.02 795% CI 0.74; 0.83	Slope 0.05 SE 0.005 95% CI 0.05; 0.06	p25 2.81% p50 12.87% p75 35.65%	E:O = 0.99 HL GOF 0.002 CITL 0.01 Slope 1.03	AUC 0.77 SE 0.04 95% CI 0.69; 0.85	Slope 0.05 SE 0.01 95% CI 0.03; 0.06	p25 3.52% p50 12.19% p75 39.37%	E:O = 0.99 HL GOF 0.16 CITL 0.01 Slope 0.97

Appendix 5 Accumulative AUC for predictive model including preventive factors and risk factors



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Availability of data and material The data that support the findings of this study are available from the corresponding author, HM, upon reasonable request.

Code availability Not applicable.

Declarations

Conflict of interest Dr. Lenke reports personal fees from Medtronic, non-financial support from Broadwater, grants and non-financial support from Scoliosis Research Society, grants from EOS, grants from Setting Scoliosis Straight Foundation, other from Evans Family Donation, other from Fox Family Foundation, grants and non-financial support from AOSpine, personal fees from Abryx, personal fees from EOS Technologies, personal fees from Acuity Surgical. Dr. Vitale reports grants from POSNA, during the conduct of the study; grants from Setting Scoliosis Straight Foundation, grants and other from Children's Spine Foundation, grants from Orthopaedic Scientific Research Foundation, grants and other from POSNA, other from OMeGA, personal fees from Stryker, personal fees from Biomet, personal fees from NuVasive, and other from IPOS outside of the submitted work. Dr. Roye reports grants from POSNA, during the conduct of the study; grants from Orthopaedic Scientific Research Foundation, grants from POSNA, other from OMeGA, outside the submitted work. The other authors have no example conflicts of interest to disclose.

Ethics approval This study was approved by the participating sites and by the Columbia University Institutional Review Board under protocol AAAD9701. It was performed in accordance with the ethical standards of the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.

Consent to participate Informed consent was obtained from all participants included in this study upon enrollment into the registry.

Consent for publication No patient identifying information is included in the article. Not applicable.

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