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Original research

A risk-stratification algorithm to reduce superficial surgical site complications in primary hip and knee arthroplasty

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A B S T R A C T

Background: Surgical site complications (SSCs) are the most common cause for readmission after total joint arthroplasty (TJA), increasing costs while predisposing to inferior long-term outcomes. Prophylactic use of closed-incision negative pressure therapy (ciNPT) may lower the risk of these complications, especially in high-risk populations, but appropriate-use guidelines are lacking for patients undergoing primary TJA. We sought to develop a risk-stratification algorithm to guide use of ciNPT dressings and test its use in normalizing the rate of superficial SSCs among high-risk groups.
Methods: We reviewed 323 consecutive primary TJAs, where 38% of those patients considered at elevated risk were risk-stratified to receive ciNPT dressings. An individual risk score was developed, assigning points based on patient-specific risk factors. We identified a historical control population of 643 patients who all received the same postoperative dressing to test the impact of this risk score.
Results: Compared with historical controls, we observed a modest but significant improvement in superficial SSCs after implementation of risk-stratification (12.0% vs 6.8%; $P = .013$). Among high-risk patients, there was a marked improvement in SSCs when treated prophylactically with ciNPT dressings as compared with historical controls (26.2% vs 7.3%; $P < .001$). Low-risk patients, who continued to be treated with standard postoperative dressings, demonstrated no significant improvement (8.6% vs 6.5%; $P = .344$).
Conclusions: ciNPT dressings are effective at reducing and normalizing risks of superficial SSCs among high-risk primary arthroplasty patients. The proposed risk-stratification algorithm may help identify those patients who benefit most from these dressings.

Introduction

Surgical site complications (SSCs) are common after primary hip and knee arthroplasty. Orthopedic surgeons will inevitably deal with these postoperative complications, which are typically superficial and include delayed wound healing, prolonged wound drainage, seromas and hematomas, stitch abscesses, and occasionally surgical site infection (SSI). Historical data report the rate of these complications as high as 14.3% [1], but more recent large cohort studies suggest the incidence ranges to be between 5.5% and 11.5%, depending on how strictly they are defined. Their incidence clearly increases with certain patient-specific risk factors, such as diabetes and obesity. [2-4]

Although often considered benign, SSCs play an underappreciated role in postoperative recovery. They are the leading cause of unplanned early readmission after total hip arthroplasty (THA) and total knee arthroplasty (TKA). [5,6] In addition, patients with superficial SSCs are significantly more likely to develop a subsequent deep periprosthetic joint infection. [7-10] Even noninfectious wound complications can have long-term implications that result in lower functional scores and higher rates of pain. [11] Furthermore, these persistent wound issues delay return to work, increase postoperative resource utilization, and cause distress to both the patient and surgeon.

Closed-incision negative pressure therapy (ciNPT) dressings have been shown in multiple studies to decrease SSCs in arthroplasty

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patients. [4,12-14] Although there is evidence these dressings may be cost-effective when used in all patients undergoing primary arthroplasty, [15] their increased cost relative to standard postoperative dressings can be substantial. The following were the goals of this study: (1) to develop a risk-stratification algorithm to guide use of ciNPT dressings for patients undergoing primary hip and knee arthroplasty and (2) to subsequently test its use in normalizing the rate of incisional complications among high-risk groups.

Material and methods

This study was designed as a retrospective comparative cohort study using a historical control population to assess change from baseline. Institutional review board approval was obtained before any data collection or data analysis being performed.

Study population

The study group consisted of 323 consecutive patients who underwent primary joint arthroplasty by a single fellowship-trained arthroplasty surgeon at an urban, academic medical center from January 2017 through March 2018 (Table 1). At the beginning of the study period, the surgeon had a mature 3-year experience in using ciNPT dressings frequently in revision and subsequently primary hip and knee arthroplasty patients [12,13]. Over the study period, patients were risk-stratified into two subgroups based on their perceived risk of developing a postoperative SSC (Table 2). One hundred twenty-three patients (38%) were placed into a high-risk subgroup (*study HIGH*) and were treated with a ciNPT dressing (PREVENA; Kinetic Concepts, Inc, San Antonio, TX) after the surgical incision was primarily closed at the conclusion of surgery. The remaining 200 patients (72%) were placed into the low-risk subgroup (*study LOW*) and were treated with a standard postoperative dressing that did not use negative pressure (AQUACEL Ag; Convatec, Greensboro, NC, or Dermabond Prineo; Ethicon, Somerville, NJ).

Skin closure procedure before dressing application was the same in both the groups, using a monofilament subcuticular suture without using skin glue. All dressings were applied under sterile conditions in the operating room at the conclusion of the surgical procedure. Both the groups were instructed to keep the original postoperative dressing in place for a minimum of 7 days without the need for dressing changes (unless saturated), and both groups were given instructions that allowed them to shower with the dressings in place.

Historical control population

A historical control group was extracted from a previously published data set. [2] This historical group consisted of 643 patients undergoing primary arthroplasty from January 2012 through December 2014 (Table 1) before utilization of ciNPT dressings by the senior author for primary arthroplasty patients. All patients in the historical group were treated with a standard postoperative dressing (AQUACEL Ag); these patients had been given the same instructions for dressing removal and showering as the patients in the study group. This historical control group was retrospectively divided into two subgroups (Table 2) using the risk-stratification algorithm described in the following sections. Using these criteria, 122 patients (19%) were considered high risk (*historical HIGH*), whereas 521 patients (81%) were considered low risk (*historical LOW*).

Table 1
Baseline patient demographics in the study group and historical control group.

Variable	Study group (n = 323)	Historical controls (n = 643)	*P* value
Age	64.6 ± 14.0	65.5 ± 12.8	.33
BMI (kg/m^2)	28.4 ± 5.3	27.0 ± 5.5	<.001
Risk factors			
Diabetes mellitus (%)	40 (12.4%)	48 (7.5%)	.013[a]
Immunodeficiency (%)	31 (9.6%)	44 (6.8%)	.131[a]
Active smoking (%)	11 (3.4%)	25 (3.9%)	.709[a]
Non-ASA anticoagulation (%)	25 (7.7%)	84 (13.0%)	.014[a]
Prior surgery (%)	22 (6.8%)	13 (2.0%)	<.001[a]

BMI, body mass index.
[a] Chi-square test.

Table 2
Baseline patient demographics in the low-risk and high-risk subgroups.

Variable	Study group		Historical controls	
	study LOW	*study HIGH*	*historical LOW*	*historical HIGH*
	$n = 200$ (72%)	$n = 123$ (38%)	$n = 521$ (81%)	$n = 122$ (19%)
Age	63.3 ± 13.3	64.7 ± 15.2	65.2 ± 12.8	66.8 ± 12.7
BMI (kg/m^2)	27.0 ± 4.4	30.7 ± 5.8	25.5 ± 3.9	32.2 ± 7.5
Risk factors				
Diabetes mellitus (%)	10 (5.0)	30 (24.4)	0 (0.0)	48 (39.3)
Immunodeficiency (%)	0 (0.0)	31 (25.2)	15 (2.8)	20 (16.4)
Active smoking (%)	5 (2.5)	6 (4.9)	15 (2.8)	10 (8.2)
Non-ASA anticoagulation (%)	5 (2.5)	20 (16.3)	43 (8.3)	41 (33.6)
Prior surgery (%)	12 (6.0)	10 (8.1)	16 (3.1)	8 (6.6)

BMI, body mass index.

Risk-stratification algorithm

Comorbidities assessed in the risk-stratification algorithm included many of those demonstrated in prior studies to lead to a higher risk of wound healing complications and SSIs. Specifically, we included body mass index [7,16-19], diabetes mellitus, [17-19] immunodeficiency (including immunosuppressive disorders and immunosuppressive medications), [17,18,20-23] active smoking status, [17,18,24,25] postoperative chemoprophylaxis other than aspirin, [7,26-28] and prior open surgery on the joint [2,29] (Table 1). Using data from the historical control group [2], these comorbid conditions were weighted to create a risk score for each patient (Table 3) which was predictive of developing superficial SSCs.

Outcome measures

Our primary outcome measure was any postoperative SSC that required intervention during the initial 90-day postoperative period. We used an inclusive and broad definition of superficial SSCs, consistent with prior published work [2,12,13]. These were defined as any dehiscence, suture granuloma, drainage occurring beyond postoperative day 5, significant hematoma formation, or SSI as defined by the CDC [30] that required unplanned postoperative interventions such as additional office visits to examine the incision, topical application of antibiotic ointment, superficial wound debridement in the office, aspiration and drainage of a hematoma or seroma, prescription of oral antibiotics, and reoperation.

Statistical analysis

Descriptive statistics including mean, range, and standard deviation were performed to report patient demographics. Paired *t*-tests were used for continuous variables to determine statistical significance between groups, whereas chi-square tests were used

Table 3
Scoring system used for the risk-stratification algorithm.

Risk factor	Weight
BMI	
<18.5 kg/m^2	1
18.5-29.9 kg/m^2	0
30-34.9 kg/m^2	1
35-39.9 kg/m^2	2
>40 kg/m^2	3
Diabetes mellitus	2
Immunodeficiency	1.5
Active smoking	1
Non-ASA anticoagulation	1
Prior surgery	2

BMI, body mass index.

for categorical variables. Data analyses were performed using SPSS for Windows statistical software (version 18.0; SPSS, Chicago, IL). *P* values of less than 0.05 were considered statistically significant.

Results

Overall data set

We observed 22 superficial SSCs in the study population and 77 in the historical control population for an overall incidence of 10.2% across the entire sample (Table 4). With implementation of a risk-stratification system, there was a significant improvement in the rate of SSCs over time from the historical control population to the study population compared with the historical control population (12.0% vs 6.8%; $P = .013$).

Historical control population

Patients were considered to be at low risk if their retrospectively calculated risk score was <2 and were considered high risk if their risk score was ≥2. The mean risk score in the 122 patients in the *historical HIGH* subgroup was 2.86 ± 1.17 (range, 2-8.5), whereas the mean risk score in the 521 patients in the *historical* LOW subgroup was 0.34 ± 0.50 (range, 0-1.5) (Table 4). There was a significantly higher rate of superficial SSCs observed in the *historical HIGH* subgroup (26.2%) than those in the *historical LOW* subgroup (8.6%) ($P < .001$).

Study population

The mean risk score in the 123 patients in the *study HIGH* subgroup that was risk-stratified to receive a ciNPT dressing was 2.08 ± 1.60 (range, 0-7), whereas the mean risk score in the 200 patients in the *study LOW* subgroup that was risk-stratified to receive a standard dressing was 0.55 ± 0.88 (range, 0-4) (Table 4). We observed no significant difference in the incidence of superficial SSCs between the low-risk and high-risk subgroups (6.5% vs 7.3%; $P = .82$). Two patients (0.6%) required a reoperation for incisional or infectious complications; one patient in the *study LOW* subgroup treated with an AQUACEL Ag underwent superficial wound debridement with reclosure for a wound dehiscence, whereas another in the *study HIGH* subgroup treated with ciNPT developed deep infection requiring subsequent two-stage exchange. Reoperation rates were not significant between subgroups.

Table 4
Risk score and incidence of wound complications.

Group	n	Mean risk score	Wound complication (%)
Study group	323	1.13	6.8
study LOW	200	0.55	6.5
study HIGH	123	2.08	7.3
Historical control group	643	0.82	12.0
historical LOW	521	0.34	8.6
historical HIGH	122	2.86	26.2
Overall population	966	0.92	10.2

Risk-stratification algorithm

Among patients stratified as low risk for developing SSCs, we observed no difference in their occurrence between the historical control group and the study group (8.6% vs 6.5%; $P = .334$). However, among patients stratified as high risk for developing SSCs, we observed a significant improvement in their occurrence (26.2% vs 7.3%; $P < .001$) after changing the postoperative dressing protocol from a standard antimicrobial dressing to one that used ciNPT.

Discussion

Hip and knee arthroplasty procedures are among the most common and most successful operations performed in modern medicine. They account for one of the largest health-care expenditures in the United States, and as a result, there is much discussion around both appropriate utilization of these procedures and preoperative patient optimization. Orthopedic surgeons recognize there can be significant variability in the risk of postoperative complications based on individual patient characteristics and comorbidities. For instance, Tan et al. demonstrated that the risk of developing a postoperative periprosthetic joint infection can vary from as little as 0.56% to greater than 20.63% depending on individual patient's risk factors. [31] Several excellent risk calculators and risk-stratification algorithms exist which attempt to quantify individual surgical risk for many different postoperative complications. [31-37] One practical risk calculator examines individual patient characteristics, with the goal of guiding orthopedic surgeons to select the most appropriate medication for chemoprophylaxis against venous thromboembolic disease. [37] Several other risk calculators predict risk of SSI or SSCs, [31,34-36] yet none make specific recommendations that might reduce this elevated risk in at-risk populations.

This study introduced an individual risk assessment of patients undergoing primary total joint replacement for the purpose of reducing SSCs through selection of the most appropriate postoperative dressing. The scope of this risk assessment is narrow compared with those described by the American Joint Replacement Registry [36] and the American College of Surgeons [34,35], focused just on superficial SSCs, yet it is practical that it provides a specific and tangible recommendation that improved postoperative outcomes in our hands. We found that despite an inherently elevated risk, when “high-risk” patients were risk-stratified to receive ciNPT dressings, their rate of superficial SSCs returned to the baseline rate of their healthy counterparts. It is likely that the reduction in superficial SSC rates we observed across the overall population from the historical control period to the study period (12.0% to 6.8%) was due in large part to a large risk reduction in the high-risk subgroup (26.2% to 7.3%) as we observed no significant change in the superficial SSC rate among low-risk patients (Fig. 1). No other specific SSC-reduction interventions were added to the high-risk subgroup during the study period.

ciNPT dressings are a powerful tool at reducing superficial SSCs in high-risk patients and with high-risk surgical procedures, with demonstrated utility over a range of different surgical subspecialties [38-43]. Specific to patients undergoing THA and TKA, their use has been associated with significantly lower rates of SSCs and SSIs after revision arthroplasty [12,14], as well as after lower extremity periprosthetic fracture surgery [13]. Among patients undergoing primary arthroplasty, a recent prospective study of 592 patients demonstrated significantly lower rates of SSIs (1.0% vs 3.5%) and SSCs (1.5% vs 5.5%) when ciNPT was used than when using gauze dressings. [4] A subsequent decision analytic modeling analysis of primary THA and TKA patients found ciNPT dressings to be cost-effective in the general population, with a cost savings of approximately $1600 per patient. [15] These cost savings increased in specific high-risk cohorts, including $10,293 per patient cost savings in patients with an ASA ≥ $3 and $11,296 per patient with a body mass index ≥ 35 kg/m^2, supporting our findings that these dressings are most useful in high-risk subgroups.

Superficial SSCs remain relatively common after joint arthroplasty. Even with techniques intended to reduce the occurrence of incisional problems among high-risk patients, 6.8% of our study group still developed superficial SSCs. The vast majority of these were minor and resolved with nonoperative treatment, but 0.6% of patients required a return to the operating room. Our results are consistent with other reports from the literature, as several studies have reported similar rates of superficial SSCs rates ranging from 5.5% to 14.3%, [1-4] with relatively low rates of reoperation (0.2% to 3.8%) needed to address these wound complications. [2,9,44,45] Our historical control population demonstrates that the rate of superficial SSCs can be much higher in patients with certain risk factors. The previous publication from which the historical data set was extracted identified obesity, diabetes, and prior surgery on the involved joint to be independent risk factors for superficial SSCs and reoperation. [2] Other studies have similarly found these risk factors to predispose toward higher rates of SSCs or SSIs. [18,45-47]

Potential implications of this study are quite large. Superficial SSCs are by far the leading cause for readmission in the early postoperative period after primary THA and TKA, accounting for approximately 50% of unplanned readmissions when combining infectious and noninfectious causes. [5,6] Reduction in these SSCs would not only lead to system-wide benefits, such as long-term cost savings and improvements in quality-adjusted life years, [15] but also potentially improve institutional performance metrics in alternative payment models under which health-care providers may have to bear the costs of early postoperative complications and readmissions. Although several prior reports have described successful strategies for dealing with superficial SSCs after they occur, [48,49] there is no question that the best possible treatment is prevention. The type of practical, risk-based approach described here appears to normalize some of the postoperative risks inherent in caring for certain high-risk subgroups of patients, such as those with obesity or diabetes.

We note several limitations to our methodology. The study population represents the experience of a single arthroplasty surgeon over a relatively short period of time; although the magnitude of the differences we observed was large, it is possible these may not generalize to other practice settings. Notable also is the fact that this surgeon reports a financial conflict of interest with the manufacturer of the product discussed in this article. Second, we acknowledge the inherent limitations of the study's retrospective methodology. Third, although both the cohorts consisted of primary hip and knee arthroplasty patients, the study and historical cohorts exhibited some baseline differences in comorbidities, which is likely reflective of the senior author's move from private practice into an academic tertiary referral center where the proportion of "high-risk" patients increased from 19% to 38%. This highlights that idea that individual surgeons may find ciNPT dressings helpful to varying degrees depending on their individual

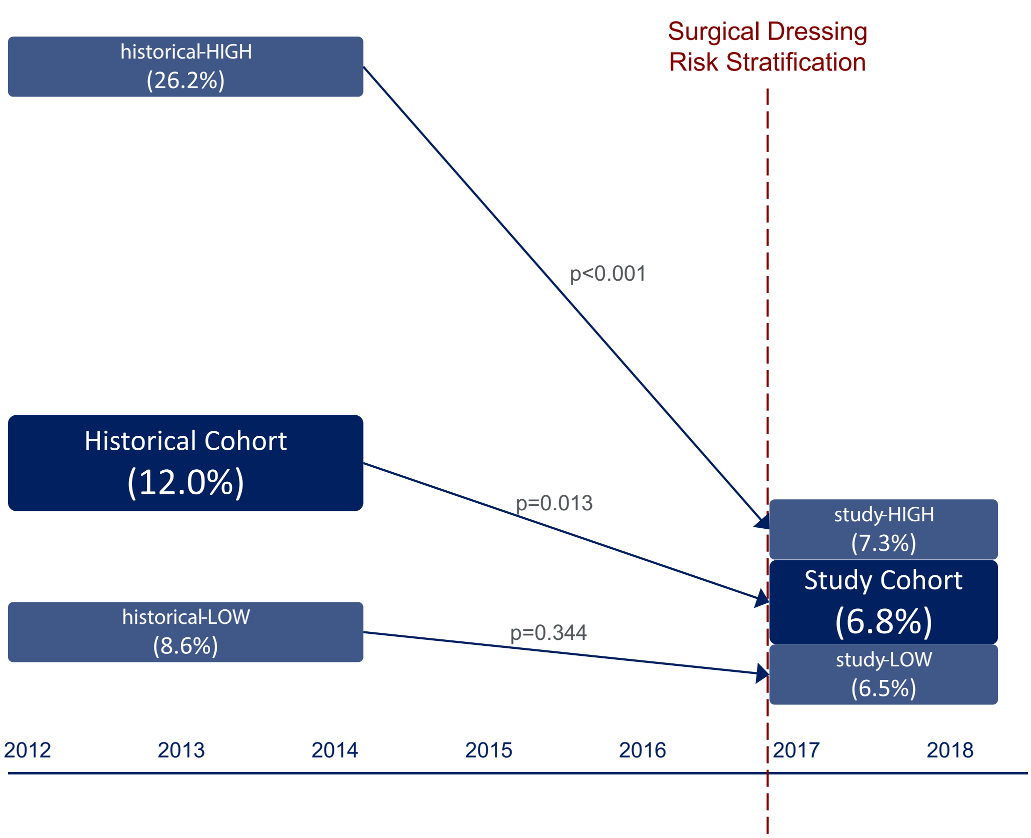

Figure 1. Rates of superficial surgical site complications in the historical cohort (2012-2014) where all patients received the same dressing compared with the rates of superficial SSCs in the study cohort (2017-2018) when patients were risk-stratified to standard vs negative pressure dressings based on risk factors. The two cohorts were divided into high-risk and low-risk subgroups based on risk stratification.

practice patterns. Finally, our retrospective methodology did not allow for a more nuanced examination of risk factors, such as the level of glycemic control for diabetic patients, [50] and also did not allow our model to account for other known risk factors such as renal insuffiency, malnutrition, peripheral vascular disease, anemia, and prior radiation among others [17,18]. Although our risk-scoring system was clearly helpful, it was likely not comprehensive in selecting which patients were most likely to benefit from ciNPT, and surgeons may wish to consider additional factors when selecting the optimal postoperative dressing.

Conclusions

ciNPT dressings can be effective at reducing and normalizing the rate of superficial SSCs in high-risk primary arthroplasty patients. The proposed risk-stratification algorithm may help identify those patients who benefit most from these advanced surgical dressings. We plan to continue using such a practical risk-stratification algorithm to reduce the SSC risk in this subgroup of patients who are at elevated risk. Future directions of focus would be to include additional patient data that may allow the predictive modeling to be more robust and to consider expanding potential therapeutic interventions for high-risk patients to other ideas beyond postoperative dressing selection.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.artd.2018.09.004

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