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Analysis of a ten step protocol to decrease postoperative spinal wound infections

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Abstract

AIM

To define a ten-step protocol that reduced the incidence of surgical site infection in the spine surgery practice of the senior author and evaluate the support for each step based on current literature.

METHODS

In response to unexplained increased infection rates at our institution following spine surgery, a ten-step protocol was implemented: (1) preoperative glycemic management based on hemoglobin A1c (HbA1c); (2) skin site preoperative preparation with 2% chlorhexidine gluconate disposable cloths; (3) limit operating room traffic; (4) cut the number of personnel in the room to the minimum required; (5) absolutely no flash sterilization of equipment; (6) double-gloving with frequent changing of outer gloves; (7) local application of vancomycin powder; (8) re-dosing antibiotic every 4 h for prolonged procedures and extending postoperative coverage to 72 h for high-risk patients; (9) irrigation of subcutaneous tissue with diluted povidone-iodine solution after deep fascial closure; and (10) use of DuraPrep skin preparation at the end of a case before skin closure. Through an extensive literature review, the current data available for each of the ten steps was evaluated.

RESULTS

Use of vancomycin powder in surgical wounds, routine irrigation of surgical site, and frequent changing of surgical gloves are strongly supported by the literature. Preoperative skin preparation with chlorhexidine wipes is similarly supported. The majority of current literature supports control of HbA1c preoperatively to reduce risk of infection. Limiting the use of flash sterilization is supported, but has not been evaluated in spine-specific surgery. Limiting OR traffic and number of personnel in the OR are supported although without level 1 evidence. Prolonged use of antibiotics postoperatively

is not supported by the literature. Intraoperative use of DuraPrep prior to skin closure is not yet explored.

CONCLUSION

The ten-step protocol defined herein has significantly helped in decreasing surgical site infection rate. Several of the steps have already been shown in the literature to have significant effect on infection rates. As several measures are required to prevent infection, instituting a standard protocol for all the described steps appears beneficial.

Key words: Wound infections; Spine; Ten step protocol; Surgical site infections

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Core tip: The rates of infection following spine surgery have been reported to range from less than 1% to 10.9% depending on the type of case. Several factors have been identified as risk for surgical site infection. In response to an increasing number of surgical site infections at the authors' institution, a new surgical protocol was initiated in an effort to reduce infection rates after an intensive epidemiological investigation failed to reveal a common source. Institution of this bundle returned surgical site infection rates to historic level of < 1%.

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INTRODUCTION

Surgical site infection in spinal surgery is associated with significantly increased morbidity and costs^[1]. Surgical site infections (SSIs) are the most common hospital acquired infections and are usually seen in the early postoperative period^[2]. The rates of infection following spine surgery have been reported to range from less than 1% to 10.9% depending on the type of case^[3].

A variety of measures have been initiated and evaluated in the literature to reduce the occurrence of SSIs. The surgical setting is a multi-faceted environment with numerous variables and control of all risk factors associated with infection can be challenging. In addition to identifying and eliminating known factors, prophylactic treatments are available to help reduce the overall incidence of surgical site infection. Patient risk factors and prophylactic measures have often been evaluated separately, but evaluation of risk factors and interventions as a bundle may be a more appropriate approach given the dynamic environment of the surgical suite.

In response to an increasing number of SSIs at the

authors' institution, a new surgical protocol was initiated in an effort to reduce infection rates after an intensive epidemiological investigation failed to reveal a common source. In addition to standard perioperative intravenous antibiotics (within 1 h preoperative administration with continuation for 24 h) and sterile operating preparation, a new 10 step protocol was instituted after extensive review of surgical and infection control literature as well as consultation with spine, total joint surgeons in the authors' and other institutions in addition to input from division of infection disease. The postoperative SSI rate in the period preceding the implementation of the ten-step protocol climbed to 10%. Institution of this bundle returned SSI rates to historic level of < 1%. The purpose of this paper is to present this protocol with an overview and evaluation of the literature for validity of each of step.

Briefly, this "Ten Step" surgical bundle is as follow: (1) preoperative glycemic management based on hemoglobin A1c (HbA1c); (2) skin site preoperative preparation the night before surgery and in the preoperative suite with disposable cloths moistened with 2% chlorhexidine gluconate (CHG) antiseptic solution; (3) limitation of operating room traffic by closure of the front door of the room with tape once the patient is in the room and until wound closure. The door through the sterile core remains available if needed; (4) decreasing the number of personnel in the room to the minimum required; (5) absolutely no flash sterilization of equipment; (6) double-gloving with frequent changing of outer gloves for the surgeon, assistant and scrub nurse throughout the case and after any step that may contaminate the gloves; (7) vancomycin powder mixed in with bone graft and applied locally to the wound after fascial closing; (8) antibiotic re-dosing every 4 h for prolonged procedures and extending postoperative coverage to 72 h for high-risk patients; (9) irrigation of the wound with diluted povidone-iodine solution; and (10) use of DuraPrep skin preparation at the end of a case to clean the skin before skin closure.

MATERIALS AND METHODS

A systematic computerized Medline literature search was performed using Pubmed. The electronic databases were searched from 1990 to October 2014. Searches were performed using the terms "surgical site infection" in conjunction with each of the following sets of terms; "spine," "hemoglobin A1c," "glycemic control," "skin preparation," "DuraPrep," "chlorhexidine cloths," "operating room traffic," "door opening," "flash sterilization," "double gloving," "glove exchange," "vancomycin powder," "postoperative antibiotics," and "wound irrigation." Abstracts were reviewed for content. Articles that included the use of one of the 10 aforementioned steps with associated outcomes for SSIs were included in the review. Where substantial information was available for a specific protocol step, only articles following outcomes for spine specific

surgeries were included. If no results for spine surgery were available on a topic, the available literature across surgical specialties was reviewed. Each manuscript was evaluated for level of evidence, number of patients included, outcome and, statistical significance.

RESULTS

Preoperative glycemic management based on HbA1c

Decreasing postoperative infection rates begins during the preoperative evaluation with the identification of patients at increased risk for infection. Diabetes mellitus is a well-known independent risk factor for SSIs. Approximately 25% of patients with diabetes are unaware that they have diabetes, which highlights the need for careful preoperative testing^[4]. HbA1c provides a good marker of a patient overall glucose management over a 2-3 mo period. An elevation in HbA1c identifies those patients with more chronic hyperglycemia and is an important indicator of poor glucose control. If HbA1c is related to risk of infection, it may represent a modifiable factor prior to proceeding with elective surgery.

The initial reports on the effects of elevated HbA1c were in the field of urology. In 1992, Bishop *et al*^[5] prospectively evaluated the influence of HbA1c on SSIs in 90 patients receiving penile implants. They found a significantly increased rate of SSI in diabetics with HbA1c greater than 11.5%. The authors recommended denying elective surgery to patients with HbA1c > 11.5% which was subsequently adopted as the standard of care. However, Wilson *et al*^[6] refuted the findings in 1998 after following 389 patients with the same surgery in which they failed to find a significant increase in infection rates with elevated HbA1c.

Since that time, there has been only slight variability in the surgical literature. Although Latham *et al*^[7] found no association between SSI and HbA1c, several other studies have found a significantly increased risk of SSIs with elevated preoperative HbA1c^[8-13]. Still others found an increased rate of infection with high HbA1c but were unable to achieve significance. Rawlins *et al*^[14] evaluated diabetics undergoing Roux-en-Y gastric bypass and Knapik *et al*^[15] looked at those having coronary artery surgery. Both found elevated rates of infection with HbA1c $\geq 7.0\%$ but did not reach statistical significance.

Several studies have been published in the orthopaedic literature since 2009 evaluating the effect of HbA1c on surgical outcomes (Table 1)^[16-23]. Many of these studies focus on total joint arthroplasty. Marchant *et al*^[16] performed the largest study by utilizing the Nationwide Inpatient Sample (NIS) database in which glycemic control and outcomes after total joint arthroplasty for over 1 million patients was evaluated. The sheer population size gave the study the power to detect small differences. Among other findings, they found a significantly increased rate of postoperative infections in diabetics with HbA1c $\geq 7.0\%$ compared

to either patients without diabetes or diabetics with HbA1c < 7.0%. Iorio *et al*^[17] and Jämsen *et al*^[18] came to a similar conclusion using a smaller group. Myers *et al*^[19] also found increased rates of infection with HbA1c > 7 in patients undergoing ankle and hindfoot fusions. Lamloum *et al*^[20] retrospectively reviewed all orthopaedic procedures in their hospital and found a slightly increased infection rate without statistical significance with HbA1c $\geq 7.0\%$. Adams *et al*^[21] and Harris *et al*^[22] similarly evaluated HbA1c and infection rate in total joint arthroplasty and found no significant association, although Harris did find an increased overall rate of complications in patients with uncontrolled diabetes.

Specific to effects of HbA1c in spine surgery, Hikata *et al*^[23] retrospectively reviewed the results of elective posterior instrumented thoracic and lumbar arthrodesis in 345 consecutive patients. Thirty-six of these patients had preexisting diabetes with preoperative HbA1c values available. In these patients, the presence of diabetes and diabetics with HbA1c ≥ 7.0 were both independent risk factors for surgical site infection. Although not looking specifically at infections, Takahashi *et al*^[24] reviewed functional results after lumbar surgery in patients and found that patients with HbA1c $\geq 6.5\%$ showed poor improvement in low back pain.

Preoperative skin preparation with CHG cloths

During the preoperative clinic appointment, each patient is given a preoperative skin preparation kit and written instructions for use. The skin preparation is done with disposable cloths moistened with a rinse-free, 2% CHG antiseptic solution. The patient is instructed to shower one hour prior to prepping, then wash with the cloths. The skin is then prepped again with a second set of cloths in the preoperative holding area. The goal of the preoperative preparation is to decrease bacterial colonization.

It has been shown that preoperative cleansing the night before surgery and the morning of with CHG decreases the bacterial colonization on the skin. Murray *et al*^[25] found that 66% of patients were colonized with microbes after prepping with CHG compared to 94% for those who showered alone preoperatively.

The data supporting the effectiveness of CHG preparation is based heavily on cohort studies. Johnson *et al*^[26] performed a cohort study comparing infection rates in patients who performed CHG preoperative prepping the night before surgery and in the preoperative area, and those who were noncompliant with prepping. They found no infections in the compliant CHG group, and 14 (1.6%) infections in the non-compliant group. Similarly, Zywił *et al*^[27] compared compliant, partially compliant, and non-compliant patients with regard to CHG preparation. They found no infections in the group that appropriately prepared with CHG, 1 (1.5%) infections in the partial compliance group, and 21 (3%) in the noncompliant group.

Table 1 Studies from orthopedic literature evaluating preoperative hemoglobin A1c and surgical site infections

Ref.	Study design (level of evidence)	Surgery performed	Groups	Main outcome	Significance
Hikata <i>et al</i> ^[23] (2013)	Retrospective cohort (IV)	Adult elective posterior instrumented thoracic and lumbar spinal arthrodesis	Non-diabetics ($n = 309$), Controlled diabetics ($\text{HbA1c} < 7.0$; $n = 19$), Uncontrolled diabetics ($\text{HbA1c} \geq 7.0$; $n = 17$)	10 (3.2%) SSI in non-diabetic group, No SSI in controlled diabetic group, 6 (35.3%) SSIs in uncontrolled diabetic group	Diabetes was an independent risk factor for SSI ($P = 0.0005$), Significantly higher rate of infection in diabetics with $\text{HbA1c} \geq 7.0$ ($P = 0.006$)
Adams <i>et al</i> ^[21] (2013)	Retrospective cohort (II)	Primary total knee arthroplasty	Non-diabetics ($n = 32924$), Controlled diabetics ($\text{HbA1c} < 7.0$; $n = 5042$), Uncontrolled diabetics ($\text{HbA1c} \geq 7.0$; $n = 2525$)	216 (0.7%) deep infections in non-diabetics, 58 (1.2%) in controlled diabetics, and 13 (0.5%) in uncontrolled diabetics	No significant association between HbA1c level and deep infection
Harris <i>et al</i> ^[22] (2013)	Retrospective cohort (IV)	Total joint arthroplasty	Controlled diabetics ($\text{HbA1c} < 7.0$; $n = 3961$), Uncontrolled diabetics ($\text{HbA1c} \geq 7.0$; $n = 2127$)	Identical percentage of patients in both groups developed superficial and deep infections	Significant increase in overall complications ($P = 0.028$), but not infections, for diabetics with $\text{HbA1c} \geq 7.0$
Iorio <i>et al</i> ^[17] (2012)	Retrospective cohort (IV)	Primary or revision total hip or knee arthroplasty	Controlled diabetics ($\text{HbA1c} < 7.0$; $n = 191$), Uncontrolled diabetics ($\text{HbA1c} \geq 7.0$; $n = 85$)	5 (2.6%) infections in controlled diabetics, 5 (5.9%) infections in uncontrolled diabetics	Increased rate of infections in uncontrolled diabetics without statistical significance ($P = 0.293$)
Myers <i>et al</i> ^[19] (2012)	Retrospective cohort (III)	Ankle and hindfoot fusions	Non-diabetics ($n = 74$), Controlled diabetics ($\text{HbA1c} < 7.0$; $n = 30$), Uncontrolled diabetics ($\text{HbA1c} \geq 7.0$; $n = 44$)	1 (1.4%) SSI in non-diabetics, 2 (6.7%) SSI in controlled diabetics, 12 (27.3%) SSI in uncontrolled diabetics	Significantly higher rate of SSI in uncontrolled vs controlled diabetics ($P < 0.05$)
Jämsen <i>et al</i> ^[18] (2010)	Retrospective cohort (IV)	Primary total knee arthroplasty	Patients with $\text{HbA1c} < 6.5$ ($n = 205$), Patients with $\text{HbA1c} \geq 6.5$ ($n = 176$)	No infections in patients with $\text{HbA1c} < 6.5$, 5 infections in patients with $\text{HbA1c} \geq 6.5$ (2.84%)	Significant increase in infection rate in patients with $\text{HbA1c} \geq 6.5$ ($P = 0.015$)
Lamloum <i>et al</i> ^[20] (2009)	Retrospective cohort (IV)	Any orthopaedic surgical procedure	Controlled diabetics ($\text{HbA1c} < 7.0$; $n = 80$), Uncontrolled diabetics ($\text{HbA1c} \geq 7.0$; $n = 238$)	10 SSIs in controlled diabetics (12.5%), 33 SSIs in uncontrolled diabetics (13.9%)	No significant difference in SSI occurrence between the two groups ($P > 0.05$)
Marchant <i>et al</i> ^[16] (2009)	Retrospective cohort (III)	Total joint arthroplasty	Non-diabetics ($n = 92055$), Controlled diabetics ($\text{HbA1c} < 7.0$; $n = 105485$), Uncontrolled diabetics ($\text{HbA1c} \geq 7.0$; $n = 3973$)	3807 (0.41%) non-diabetics with infection, 405 (0.38%) controlled diabetics with infection, 47 (1.18%) uncontrolled diabetics with infection	Uncontrolled diabetics had a statistically significant increased rate of infection compared to patients without or with controlled diabetes ($P = 0.002$)

HbA1c: Hemoglobin A1C; SSI: Surgical site infections.

Veiga *et al*^[28] conducted a randomized controlled trial to assess the effect of preoperative chlorhexidine showers on skin colonization and postoperative infection rates associated with plastic surgical procedures involving the trunk. Chlorhexidine showers were effective in reducing skin colonization with coagulase-negative staphylococci and yeasts, but there was no difference in postoperative infection rates. Two systematic reviews evaluated the clinical effectiveness of preoperative skin antiseptic preparations and the prevention of SSIs^[29,30]. Kamel *et al*^[29] reviewed 20 studies and concluded that the evidence suggests that preoperative antiseptic showers reduce bacterial colonization and may be effective at preventing SSIs. Webster and Osborne^[30] additionally reviewed 3 studies that included 7791 participants comparing CHG cloth bathing vs placebo. In their systemic review, they concluded that there is no

statistically significant benefit for preoperative showering or bathing with chlorhexidine over other wash products to reduce surgical site infection.

Limiting operative room traffic

One of the strategies implemented in this bundle to decrease SSIs involved limiting traffic in the operating room. In order to achieve this, the front door to the operating room is taped off once the patient is in the room. Only necessary door openings were performed, all of which occurred through the sterile core rather than the main operating room door.

An operating room is an isolated environment designed to recirculate air through filtered ventilation ducts. Frequent opening of the operating room door has been shown to disrupt this airflow system^[31,32]. Scaltriti *et al*^[32] studied the air quality in the operating room and

compared this with multiple parameters. They found that increased door openings and personnel changes were a positive predictor of raised bacterial counts in a room. Ritter similarly found a correlation between number of operating door openings and increased colony forming unit (CFU) counts in the operating room^[33].

In addition to affecting the air quality, door openings and increased traffic have been identified as major surgical distractors. Using an observational tool to record distraction and interruption in the operating room, Healey *et al.*^[34] found that interference levels significantly correlated with frequency of door openings. In addition unwanted distractions may lead to mistakes beyond just SSIs.

In response to an unexplained increase in SSIs at one institution, Lynch *et al.*^[35] studied operating room foot traffic. They found that their spinal fusion cases had the highest rate of door openings at 50 per hour. Additionally, when investigating the reasons for door openings, they found the most common reason for door openings was to request information from outside the room, which could feasibly be done *via* telephone or other electronic means.

In an attempt to evaluate the risk to the patient, Young and O'Reagan^[36] performed a prospective cross-sectional study in forty-six consecutive cardiac operations. An electronic door counter calculated the frequencies and rates of door openings during each surgery. Everyone was blinded to the counters except the practicing surgeons. They showed a trend toward an increased frequency of door openings per case in those patients that developed a surgical site infection vs those who had not. However, the difference did not achieve statistical significance. Additionally, there was a positive correlation between length of case and frequency of door opening.

Limit number of personnel in the operative room

Spine surgery, much like any other surgery, requires a multidisciplinary effort. In light of that fact, there is often a considerable number of people in the operating room at any given time, the attending surgeon, resident or surgical assistant, anesthesia team, surgical scrub technician, circulating nurse, radiology technician, technician for neurological monitoring, and oftentimes an equipment representative. At a teaching hospital, there is the potential for a student in the room at any of these positions as well.

Pryor *et al.*^[37] attempted to find an association between surgical site infection and increased number of personnel in the operating room. Although there was an association of increased surgical site infection with the number of people in the OR, the results were not statistically significant. The increased number of people was also associated with length of the case.

In a prognostic level III evidence study, Olsen *et al.*^[38] found that one of the factors that was significantly associated with an increased risk of surgical site in-

fection during spinal operations was the participation by two or more surgical residents. As suggested by the author, this was likely a proxy for the duration and complexity of the procedure rather than a direct cause for infection.

Although not yet clearly demonstrated, an increasing number of people present in the operating room may increase the risk of contamination and subsequently increased surgical site infection. With that in mind the authors have made efforts to limit the number of people in the operating room to the minimum. The minimum staff present includes the attending surgeon and assistant, surgical technician, anesthesiologist, nurse circulator, radiology technician, equipment representative, and spinal cord monitoring technician. In a teaching hospital reducing the number of the students in the room can be a challenge. However, in the authors' current protocol, no more than one student of any kind (medical, nursing, radiologist, or anesthesia) is allowed in the room. These practices require further evaluation for their effectiveness.

No flash sterilization of surgical equipment

Instrument reprocessing technique plays a vital role in maintaining a sterile surgery. Flash sterilization has often been utilized in order to turn over equipment quickly when additional sterile equipment is unavailable. As part of our policy, absolutely no flash sterilization may be used in spine surgery. An adequate number of sterile surgical trays are on the shelf prior to surgery to avoid any flash sterilization.

From the International Conference on Healthcare-Associated Infections, Lopansri *et al.*^[39] demonstrated their experience with SSIs and sterilization techniques. They identified 14 cases of surgical site infection after arthroscopy over a 21 mo span. Thirteen of the infections were from an individual surgeon, representing a 2.4% infection rate, while 8 other surgeons had a total of 1 infection in the same span, representing an infection rate of 0.06%. The surgeon with the larger infection rate was the only one whose equipment underwent flash sterilization. Additionally, this same surgeon operated at a separate facility that did not use flash sterilization and experienced an infection rate of 0.3% over a 4-year span. This represented a relative risk for infection after arthroscopy of 6.7 for this individual surgeon while working at a facility that used flash sterilization as opposed to one that did not.

Tosh *et al.*^[40] explored an outbreak of pseudomonas aeruginosa SSIs after arthroscopic procedures. In this retrospective case-control study, there were 7 patients with surgical site infection after arthroscopy with isolates that were indistinguishable from each other. On endoscopic examination of equipment that was flash sterilized during these cases, residual tissue was seen in the lumens of the arthroscopic equipment.

Although available literature on flash sterilization and the primary outcome of surgical site infection is

limited, it can be identified as a possible avoidable cause of infection. To our knowledge, there is no literature available evaluating the use of flash sterilization in spine surgery. Additional investigations as to the benefit of reducing utilization of flash sterilization may be of benefit.

Frequent changing of surgical gloves

It is vital to attempt to maintain a completely sterile environment in the surgical field. An important factor in surgery, which can easily transmit bacteria, is the surgical glove. Instituting a policy of double gloving with frequent changes of the outer gloves may assist in decreasing surgical infection rates. In the authors' current protocol, the surgeon, assistant, and scrub nurse change their outer gloves after steps that may contaminate the gloves such as after draping the patient and using the surgical microscope. The policy also includes changing the outer gloves prior to instrumentation and before closure.

Ritter *et al.*^[41] reported that contamination of outer gloves is common among all scrubbed personnel and occurs at a rate of 33%. It has been shown by McCue^[42] in a study evaluating frequent outer glove changes in total hip arthroplasties that gloves used at draping were the most frequently contaminated. This highlighted the draping portion as an important step for glove changes.

Ward *et al.*^[43] performed an experiment to determine risk of bacterial contamination associated with changing gloves with 251 prospectively randomized surgical team members in 142 cases in which all members were double gloved. Cultures were taken from the dominant palms at 1 h into the case at which time selected randomized individuals changed their outer gloves. A repeat culture was taken from the dominant palm 15 min later. They found a significant decrease in the number of positive cultures for the group exchanging their gloves ($P = 0.0419$). This represented nearly 2 times greater odds of being contaminated if gloves were not exchanged. However, they did not assess subsequent infection rates.

Although several studies have been published on various double gloving techniques and rates of perforation, there is very little literature on changing of gloves and the primary outcome, SSIs. Rehman *et al.*^[44] in a retrospective cohort study, compared infection rates in two groups undergoing lumbar spine fusion. The control group of 179 patients underwent surgery with the standard surgical protocol and the treatment group of 210 patients, after double gloving, the outer gloves were removed prior to instrumentation. They found a significantly decreased infection rate at 1 year postoperatively when outer gloves were removed in this manner (3.35% in control vs 0.48% in treatment; $P = 0.0369$). Additional investigations to back up this data may be beneficial as this may be a simple and cost effective step in reducing surgical infections.

Local application of vancomycin powder

The use of antibiotics has been very important in decreasing the rates of infection. Administration of systemic intravenous antibiotics perioperatively is standard^[45]. Additionally, topical vancomycin powder has recently been evaluated in the literature. Vancomycin powder has a slow resorption rate which provides a very low rate of systemic effects and excellent local coverage against the common gram positive bacteria associated with surgical site infection, with no evidence of local or systemic toxicity^[46].

The authors' protocol for the use of vancomycin powder is two-fold. When performing a fusion surgery, 1 g of vancomycin powder is mixed in with the bone graft before placement. Additionally, after closure of the deep fascia, another 1 g of vancomycin powder is applied directly onto the surgical wound and subcutaneous tissue prior to skin closure.

Sweet *et al.*^[46] first reported the benefits of using vancomycin powder during spine surgery. They performed a retrospective cohort study on a consecutive series of patients undergoing posterior instrumented thoracic and lumbar spine surgery. This study looked at a total of 1732 patients, 911 of which received 2 g of vancomycin powder, in the protocol listed dose, one gram was mixed with bone graft and 1 g was applied directly to the surgical wound. There was a statistically significant reduction in infection rate in those treated with vancomycin powder and intravenous prophylaxis as compared to intravenous antibiotic prophylaxis alone (0.2% vs 2.6%; $P < 0.0001$).

Fourteen studies were identified that evaluated post-operative infection rates and the use of topical vancomycin powder intraoperatively during spine surgery (Table 2)^[46-59]. Surgical site infection rates in these studies ranged from 0%-6.7%. Of these studies, 11 included a control group in which no vancomycin powder was applied. All groups in all of these studies received standard preoperative intravenous antibiotic prophylaxis. Infection rates without the use of vancomycin powder ranged from 1.2%-13%. The vast majority of these studies showed a significant decrease in overall infection rate when using vancomycin powder in addition to standard preoperative IV prophylaxis.

Kanj *et al.*^[60] evaluated vancomycin prophylaxis at the surgical site in clean orthopaedic surgery. Several of the studies reviewed here were included in their analysis^[46,47,49,54]. Specific to spine surgery, they calculated that a patient is 4 times more likely to develop a deep infection without vancomycin powder prophylaxis than with ($P < 0.001$).

As outlined above, there is an extensive amount of literature available on the use of vancomycin powder for infection prophylaxis in surgical wounds. The majority of the evidence points toward vancomycin powder as a significant factor in reducing SSIs.

Table 2 Studies evaluating the use of vancomycin powder intraoperatively

Ref.	Study design (level of evidence)	Surgery performed	Groups	Main outcome	Significance
Chobrial <i>et al</i> ^[56] (2014)	Retrospective case series (IV)	Spinal procedures for degenerative disease, trauma, pain and scoliosis	Vancomycin powder (range from 1-6 g) applied to subfascial and epifascial layers but not to bone graft (<i>n</i> = 981)	66 infections identified (6.7%) A number of gram-negative infections were encountered	Vancomycin may increase the incidence of gram-negative or polymicrobial spinal infections
Hill <i>et al</i> ^[55] (2014)	Retrospective cohort (III)	Instrumented or non-instrumented posterior spine surgery in adults	Patients receiving 1-2 g vancomycin powder in surgical bed (<i>n</i> = 150), No vancomycin powder (<i>n</i> = 150)	5 superficial infections in vancomycin powder group (3.3%), 5 superficial and 6 deep infections in control group (7.3%)	Significantly fewer deep infections in patients treated with vancomycin powder (<i>P</i> = 0.0297)
Theologis <i>et al</i> ^[50] (2014)	Retrospective cohort (III)	Complex adult spinal deformity reconstruction	Patients receiving 1-2 g vancomycin powder in subfascial space (<i>n</i> = 151), No vancomycin powder (<i>n</i> = 64)	4 infections in first 90 d in treatment group (2.6%), 7 infections in first 90 d in control (10.9%)	Significantly fewer hospital readmissions within 90 d of surgery when using vancomycin powder (<i>P</i> = 0.01)
Caroom <i>et al</i> ^[49] (2013)	Retrospective comparative study of prospectively collected data (II)	Multilevel posterior decompression and instrumentation for cervical spondylitic myelopathy	1 g vancomycin powder applied subfascially along bone graft and instrumentation (<i>n</i> = 40), No vancomycin powder (<i>n</i> = 72)	Zero infections in vancomycin powder group (0%), 11 infections in control (15%)	Significant decrease in infection rate with use of vancomycin powder (<i>P</i> = 0.007)
Gans <i>et al</i> ^[58] (2013)	Therapeutic retrospective cohort (II)	Pediatric spinal deformity surgery (fusion, growing rods, vertical expandable prosthetic titanium rib)	Patients received 1g vancomycin powder in surgical wound (<i>n</i> = 87)	3 surgical site infections identified (3.4%) The postoperative systemic vancomycin levels remained undetectable. None of the patients experienced nephrotoxicity or red man syndrome	Local application of vancomycin powder is safe without significant changes in creatinine level or systemic vancomycin level
Kim <i>et al</i> ^[57] (2013)	Retrospective cohort (IV)	Instrumented spinal fusion	Patients receiving 1 g vancomycin powder in surgical wound (<i>n</i> = 34), No vancomycin powder (<i>n</i> = 40)	Zero infections in vancomycin powder group (0%)	Significant decrease in infection rate with use of vancomycin powder (<i>P</i> < 0.033)
Martin <i>et al</i> ^[53] (2013)	Retrospective cohort (II)	Adult posterior thoracolumbar or lumbar instrumented fusion for spinal deformity	Patients receiving 2 g vancomycin powder in surgical wound (<i>n</i> = 156), No vancomycin powder (<i>n</i> = 150)	5 infections in control (12.5%), 8 infections in vancomycin powder group (5.1%), 8 infections in control (5.3%)	No significant difference in infection rate with use of vancomycin powder (<i>P</i> = 0.944)
Pahys <i>et al</i> ^[50] (2013)	Therapeutic retrospective cohort (II)	Posterior cervical spine surgery	Group 1: Perioperative antibiotics alone (<i>n</i> = 483), Group 2: addition of alcohol foam prep and drain (<i>n</i> = 323), Group 3: group 2 plus vancomycin powder in wound (<i>n</i> = 195)	9 infections in group 1 (1.86%), 1 infection in group 2 (0.3%), No infections in group 3 (0%)	Significant decrease in infections in both group 2 (<i>P</i> = 0.047) and group 3 (<i>P</i> = 0.048) compared to group 1
Strom <i>et al</i> ^[48] (2013)	Retrospective cohort (IV)	Instrumented and non-instrumented posterior lumbar laminectomy and fusion	Patients receiving 1 g vancomycin powder in surgical wound (<i>n</i> = 156), No vancomycin powder (<i>n</i> = 97)	Zero infections in vancomycin powder group (0%), 11 infections in control (11%)	Significant decrease in infection rate with use of vancomycin powder (<i>P</i> = 0.000018)
Strom <i>et al</i> ^[51] (2013)	Retrospective cohort (IV)	Posterior cervical fusion	Patients receiving 1 g vancomycin powder in surgical wound (<i>n</i> = 79), No vancomycin powder (<i>n</i> = 92)	2 infections in vancomycin powder group (2.5%), 10 infections in control (10.9%)	Significant decrease in infection rate with use of vancomycin powder (<i>P</i> = 0.0384)
Tubaki <i>et al</i> ^[52] (2013)	Prospective randomized controlled trial (II)	Any primary spine surgery excluding biopsy or minimally invasive procedure	Patients receiving 1 g vancomycin powder in surgical wound (<i>n</i> = 433), No vancomycin powder (<i>n</i> = 474)	7 infections in vancomycin powder group (1.61%), 8 infections in control (1.68%)	No significant difference in infection rate with use of vancomycin powder
Molinari <i>et al</i> ^[54] (2012)	Retrospective case series (IV)	Any spine surgery	Patients receiving 1 g vancomycin powder in surgical wound (<i>n</i> = 1512)	Fifteen infections identified (0.99%)	Low rate of deep spinal wound infection for both instrumented and uninstrumented cases

Sweet <i>et al</i> ^[46] (2011)	Retrospective cohort (IV)	Thoracic or lumbar posterior instrumented fusion	Patients receiving 1 g vancomycin powder in bone graft and 1 g applied directly to deep and superficial wound (n = 911).	Two infections in vancomycin powder group (0.2%), Twenty-one infection in control (2.6%)	Significant decrease in infection rate with use of vancomycin powder (P < 0.0001)
O'Neill <i>et al</i> ^[47] (2011)	Retrospective cohort (IV)	Instrumented posterior spine fusion for traumatic injury	No vancomycin powder (n = 821) Patients receiving 1 g vancomycin powder in surgical wound (n = 54), No vancomycin powder (n = 56)	Zero infections in vancomycin powder group (0%), Seven infections in control (13%)	Significant decrease in infection rate with use of vancomycin powder (P = 0.02)

Re-dosing and prolonged postoperative antibiotic course

It is standard for all of our patients undergoing surgery to receive a dose of 1-2 g of cefazolin and 1-2 g vancomycin intravenous within 1 h of incision, depending on patient weight and allergies. This is in accordance with recommendations from the North American Spine Society^[45]. For short, uncomplicated cases, no additional IV antibiotics are required. In various studies, length of surgery has been associated with surgical site infection rate. For that reason, prolonged cases are re-dosed with antibiotics at 4-h intervals during surgery. Additionally, it is the authors' protocol to extend antibiotic coverage with either cefazolin or vancomycin for a full 72 h in high-risk patients. High-risk patients include diabetics, obese patients (body mass index > 30), history of previous postoperative wound infection, complex revision or deformity surgeries lasting more than 6 h.

Little data has been published on extended postoperative antibiotic prophylaxis in spine surgery. Two studies to our knowledge have explored the effects. Ohtori *et al*^[61] in a comparative cohort study evaluated two statistically similar groups undergoing lumbar spine decompression and fusion. Group 1 received 2 d of postoperative IV antibiotics, and group 2 received 9 d IV antibiotics. There was one infection in group 1 (1/70) and no infections in group 2 (0/65), but these results were not significant. The only significant findings were that longer courses of antibiotics resulted in longer hospital stays and longer time to normalize body temperature after surgery.

In a separate retrospective cohort study, Takahashi *et al*^[62] evaluated 4 different prophylaxis measures. One group had 7 d of postoperative antibiotics and no preoperative antibiotic (group 1). The remaining 3 groups all received appropriate preoperative antibiotics as well as postoperative antibiotics for 4 d (group 2), 2 d (group 3), or 1 d postoperatively (group 4). Groups 1, 2, 3 and 4 saw infection rates of 2.6% (14/539), 0.9% (5/536), 0% (0/257) and 0% (0/83) respectively. Although this showed an increase in infection rate with shorter antibiotic duration, there were significant differences among the groups with regard to age, preoperative hospitalization duration, and proportion of patients considered to be compromised hosts.

At this time, current evidence-based guidelines from the North American Spine Society only state that prolonged regimens may be considered when significant comorbidities or complex situations exist^[45]. Comorbidities and complex situations considered applicable include obesity, diabetes, neurologic deficits, incontinence, preoperative serum glucose of > 125 mg/dL or a postoperative serum glucose level of > 200 mg/dL, trauma and prolonged multilevel instrumented surgery. A randomized prospective analysis of postoperative prophylactic antibiotic duration and surgical site infection rate may provide better evidence. The current recommendations additionally provide for repeated dosing of antibiotics intraoperatively at 3-4 h intervals for prolonged cases to maintain therapeutic antibiotic levels throughout the procedure. The superiority of one drug has not been demonstrated in the literature.

Wound irrigation with diluted povidone-iodine solution

The current infection prevention protocol involves irrigation of the surgical wound with diluted povidone-iodine solution (150 mL of saline + 5 mL of betadine aqueous solution which contains 10% povidone-iodine).

Irrigation of a surgical wound is a commonplace practice prior to closure. There is limited amount of orthopedic literature directly evaluating irrigation solutions and techniques in a clean, primary surgery. Bhandari *et al*^[63] evaluated the efficacy of various irrigating solutions in removing adherent bacteria from bone in a mice model. They found that the fewest number of residual colony-forming units were found after exposure to povidone-iodine, chlorhexidine-gluconate, and soap solutions. Normal saline was the least effective. When low-pressure pulsatile lavage was added, no growth was observed after wash with soap solution, and there was near complete removal of adherent bacteria with the povidone-iodine and chlorhexidine-gluconate solutions. As it pertains to orthopaedic clinical practice, four studies were identified in whose

Table 3 Clinical orthopedic studies evaluating surgical wound irrigation before closure

Ref.	Study design (level of evidence)	Surgery performed	Groups	Main outcome	Significance
Yazdi <i>et al</i> ^[64] (2014)	Prospective randomized controlled trial (I)	Arthroscopic ACL reconstruction	Irrigation with 0.9% normal saline and 80 mg/L gentamicin (n = 180), Irrigation with 0.9% normal saline (n = 180)	One infection in gentamicin group (0.57%), Four infections in normal saline alone group (2.2%)	Decreased rate of infection when using gentamicin in irrigating solution (P = 0.4)
Brown <i>et al</i> ^[65] (2012)	Retrospective cohort (IV)	Primary total hip or total knee arthroplasty	Soak wound with 500 mL 0.35% povidone-iodine followed by 1 L NS pulse lavage prior to closure (n = 688), Pulse lavage with 1 L NS only prior to closure (n = 1862)	One infection in betadine group (0.15%), Eighteen infections in saline alone group (0.97%)	Significant decrease in 90-d infection rate when soaking surgical wound with betadine solution prior to closure (P = 0.04)
Chang <i>et al</i> ^[66] (2006)	Prospective randomized controlled trial (I)	Instrumented lumbosacral posterolateral fusion for degenerative spinal disorder with segmental instability	Wounds irrigated with 0.35% povidone-iodine (n = 120), Wounds irrigated with normal saline (n = 124)	No infections in povidone-iodine group, 4.8% infection rate in saline group	Overall infection rate was statistically significant when comparing betadine solution group with no betadine group (P = 0.029)
Cheng <i>et al</i> ^[67] (2005)	Prospective randomized controlled trial (I)	Spinal decompression with or without fusion	Wounds irrigated with 0.35% povidone-iodine (n = 208), Wounds irrigated with normal saline (n = 206)	No infections in povidone-iodine group, 3.5% infection rate in saline group	Overall infection rate was statistically significant when comparing betadine solution group with no betadine group (P = 0.007)

ACL: Anterior cruciate ligament.

main goal was measuring outcomes of irrigating surgical wounds with antimicrobial solutions and comparing to normal saline irrigation (Table 3)^[64-67].

Most notably, as it relates to spine, Chang *et al*^[66] and Cheng *et al*^[67] performed prospective randomized controlled studies comparing intraoperative wound irrigation using normal saline to 0.35% povidone-iodine solutions. Both studies found a statistically significant decrease in post-operative infections with the use of povidone-iodine solution.

Yazdi *et al*^[64] evaluated the effect of gentamicin in irrigating solutions during arthroscopic anterior cruciate ligament (ACL) reconstructions in a prospective randomized controlled study. Although infection rates were lower for the group receiving gentamicin as opposed to normal saline alone, statistical significance was not achieved.

Brown *et al*^[65] retrospectively reviewed total knee and hip arthroplasties before and after initiating a protocol to soak the surgical wound with 0.35% povidone-iodine solution prior to closure. They found a significant decrease in 90-d postoperative infection rate when using the betadine solution.

Based on these studies, it appears that there is a significant advantage for infection prophylaxis when irrigating a surgical wound with a povidone-iodine solution.

Duraprep prior to skin closure

The final intraoperative step occurs just prior to skin closure. There is often significant handling of the skin at closure, which could potentially contaminate the surgical site. As a safeguard, prior to skin closure, DuraPrep is

used over any exposed skin as a prophylactic measure.

In a level I prospective randomized study evaluating the efficacy of both ChlorPrep (2% CHG and 70% isopropyl alcohol) and DuraPrep (0.7% iodine and 74% isopropyl alcohol) in lumbar spine surgery, Savage *et al*^[68] found that both skin preparations significantly reduced bacterial flora growths after application. Cultures were taken from the skin before application, after application, and after skin closure for 100 consecutive patients randomly assigned to one of the two preparations. They found that for the ChlorPrep and DuraPrep groups, positive cultures were found, respectively, in 84% and 80% pre-preparation, 0% and 6% post-preparation, and 34% and 32% after closure. As outlined, there was a significant increase in the number of positive cultures following skin closure. It is unclear whether this is from recolonization or possibly disruption of the natural skin flora beneath the epidermis during surgery. The bio-burden on the skin at the end of a case is not the same as in the beginning. It has not been shown that this increase results in an increased rate of postoperative infection. Further studies are needed to evaluate the effectiveness of intraoperative reapplication of a skin prep solution before skin closure.

DISCUSSION

Several factors have been identified as risk for surgical site infection. Although multiple reviews have addressed these risk factors and prophylactic measures individually, it is difficult to control for and evaluate all factors affecting an individual patient. In response to an increasing number of SSIs at the authors' institution,

a new surgical protocol was initiated in an effort to reduce infection rates after an intensive epidemiological investigation failed to reveal a common source. In view of the absence of a clear cause of the increased infection rate, the authors decided to implement the ten-step protocol targeting areas highlighted by the literature search. The purpose of the current study was analyzed the literature for each of the 10 steps and evaluated our own experience. As to which factor or factors affected the decreased infection rate is an area of future research.

The use of vancomycin powder has been studied extensively in the literature. We have employed the routine use of 1 g mixed in with bone graft when used and an additional 1 g spread directly over the surgical site after closure of the deep fascia. Only two of the 11 studies comparing use of vancomycin powder in spine surgery to a control failed to show a significant difference. The vast majority of the literature has found significantly lower rates of infection with routine use of vancomycin powder. Its use in spine surgery is well supported by several studies and routine use is more than acceptable.

Also strongly supported is routine irrigation of surgical wounds. Irrigation of the surgical wound has been evaluated in several surgical settings. Chang *et al*^[66] and Cheng *et al*^[67] both evaluated the use of 0.35% povidone-iodine solution irrigation in spine patients. Both studies were prospective randomized controlled studies and provided strong evidence that irrigation with 0.35% povidone-iodine significantly reduces surgical site infection in spine surgery. Also supported is the use of CHG cloths in a preoperative setting. Their use for preoperative cleansing has showed a significant reduction in skin bacterial colonization. Additionally, in a systematic review, CHG cloths have been shown to reduce the incidence of surgical site infection.

One of the measures employed in this current report is double gloving with frequent changing of outer gloves. The majority of the available literature on gloving techniques focuses on double gloving and perforation rates. It has been shown in several studies that double gloving reduces rate of perforation to the inner gloves. With respect to infection, Rehman *et al*^[44] had perhaps the most relevant study. In a retrospective study on spine fusions in which one group the surgeon removed outer gloves prior to instrumentation, there was a significant decrease in infection rates with removing outer gloves. It was also shown by Ward *et al*^[43] that changing outer gloves during a case significantly reduces contamination of gloves as seen by bacterial cultures taken from the gloves. This practice was largely adopted from reports in arthroplasty cases. Changing of the outer gloves prior to implanting total hips was shown to decrease infection rates. The routine changing of outer gloves at distinct points in a case to reduce infection is strongly supported.

HbA1c has been studied as a possible marker for increased infection risk. Although early studies identified

elevated HbA1c as a significant risk factor for infection, there has been some variation in the literature. The majority of finding point to an increased infection rate with high HbA1c, but some has found no correlation. It is possible that perioperative and intraoperative glucose levels or even absolute diabetic status are more significant. It remains to be seen if an individual's risk changes with improving their HbA1c preoperatively. The literature is lacking a level I prospective randomized study discussing the relationship between preoperative HbA1c and the risk of elective spine surgery postoperative wound infection. Ethically such a study cannot be done, as one simply cannot take a patient with poor diabetic control to an elective spine surgery. Therefore, it remains to be seen whether the postoperative spine wound infection risk changes if a diabetic is able to bring down HbA1c prior to an elective procedure. However, with the current available data, adoption of a protocol that tightly controls preoperative HbA1c to 7.0 makes sense as, in general, it improves the patient health status and may reduce the risk of postoperative wound infection.

Keeping an operating room door taped shut is an idea that has not yet been evaluated in the literature. Although Young and O'Reagan^[36] showed a trend of increased infection rate in cardiac surgery with increasing numbers of door openings, the effect of limiting traffic remains to be seen. The available studies appear to support the practice limiting the number of openings of the main operating room door in order to reduce the postoperative spine wound infection especially in a long spine cases.

Similarly, there is insufficient evidence as of yet in the literature to define the risk of surgical site infection based on number of personnel in the operating room. As seen by Olsen *et al*^[38] there was a trend towards increased number of infections based on increasing personnel in the operating room. As they pointed out though, this was likely a proxy of case length and complexity. But with the thought in mind that more people means more possibilities of contamination, it is still possible that limiting the number of personnel in the operating room can be protective against surgical site infection. This practice seems to be supported but is lacking higher level evidence.

Flash sterilization, although useful if equipment needs reprocessed quickly, may present some risk to the patient. Spine surgery deals with very durable bone and soft tissue that can potentially persist on the equipment with insufficient cleaning. Tosh *et al*^[40] showed that residual tissue was commonly seen in arthroscopic equipment under endoscopic evaluation after flash sterilization. The Fifth Decennial International Conference on Healthcare-Associated Infections identified flash sterilization as a likely source of increased infection rate at one institution. Although available literature on flash sterilization and the primary outcome of surgical site infection is limited, it can be identified as a possible avoidable cause of infection. To

our knowledge, there is no literature available evaluating the use of flash sterilization in spine surgery. Additional investigations as to the benefit of reducing utilization of flash sterilization may be of benefit to support or refute the utility of restricting its use.

The use of preoperative antibiotic prophylaxis has become an important part of infection prevention. Current recommendations additionally advise on repeated dosing every 3-4 h during prolonged cases. Extending antibiotics beyond 24 h postoperatively has been evaluated, but no level 1 evidence exists. The current literature has not shown any benefit with extended antibiotics. A prospective randomized study may better help identify if there is utility in extending antibiotics in specific patients.

The final measure explored here is use of DuraPrep on exposed skin prior to wound closure. As was shown by Savage *et al.*^[68] the use of DuraPrep significantly reduces the chances of obtaining a positive culture from the skin at the start of a case. However, cultures at the end of a case show a drastic increase in positive growth. Although it has not been evaluated in the literature, we have employed routine repeat cleansing of the skin prior to closure. It is thought that this theoretically reduces the bacterial load while closing. Since this is a time with significant handling of the skin, it is plausible that this may decrease contamination of the surgical wound and thus surgical site infection.

In conclusion, several details surrounding surgery have been evaluated in the literature as both patient risk factors and prophylactic measures for decreasing rates of SSIs. With the multivariable setting that is inherent in spine surgery, it is difficult to evaluate changes in all variables simultaneously. The authors attempted to control for 10 factors and found support in the literature for the majority of the 10 steps taken. This protocol resulted in a significant reduction in SSIs in the senior author's practice. Postoperative surgical site infection will remain a matter of concern for patients, surgeons and healthcare providers. Future prospective randomized studies that include some or all of the 10 steps discussed in this report are necessary to confirm whether the 10 steps adopted by the authors were in fact science or fiction in the battle for infection control.

ARTICLE HIGHLIGHTS

Research background

Surgical site infections (SSIs) are the most common hospital acquired infections. The rates of infection following spine surgery have been reported to range from less than 1% to 10.9%. Surgical site infection in spinal surgery is associated with significantly increased morbidity and costs.

Research motivation

In response to an increasing number of SSIs at the authors' institution, a new ten step surgical protocol was initiated in an effort to reduce infection rates after an intensive epidemiological investigation failed to reveal a common source.

Research objectives

To define a ten-step protocol that reduced the incidence of surgical site infection

in the spine surgery practice of the senior author and evaluate the support for each step based on current literature.

Research methods

Ten-step protocol was implemented. (1) Preoperative glycemic management based on hemoglobin A1c (HbA1c); (2) skin site preoperative preparation with 2% chlorhexidine gluconate disposable cloths; (3) Limit operating room traffic; (4) cut the number of personnel in the room to the minimum required; (5) absolutely no flash sterilization of equipment; (6) double-gloving with frequent changing of outer gloves; (7) local application of vancomycin powder; (8) re-dosing antibiotic every 4 h for prolonged procedures and extending postoperative coverage to 72 h for high-risk patients; (9) irrigation of subcutaneous tissue with diluted povidone-iodine solution after deep fascial closure; and (10) use of DuraPrep skin preparation at the end of a case before skin closure. Through an extensive literature review, the current data available for each of the ten steps was evaluated.

Research results

Use of vancomycin powder in surgical wounds, routine irrigation of surgical site, and frequent changing of surgical gloves are strongly supported by the literature. Preoperative skin preparation with chlorhexidine wipes is similarly supported. The majority of current literature supports control of HbA1c preoperatively to reduce risk of infection. Limiting the use of flash sterilization is supported, but has not been evaluated in spine-specific surgery. Limiting OR traffic and number of personnel in the OR are supported although without level 1 evidence. Prolonged use of antibiotics postoperatively is not supported by the literature. Intraoperative use of DuraPrep prior to skin closure is not yet explored.

Research conclusions

Several details surrounding surgery have been evaluated in the literature as both patient risk factors and prophylactic measures for decreasing rates of SSIs. The authors attempted to control for 10 factors and found support in the literature for the majority of the 10 steps taken. This protocol resulted in a significant reduction in SSIs in the senior author's practice.

Research perspectives

In the current era of pay per performance, there is a major drive in all hospitals to reduce postoperative infection to the minimum. A variety of measures have been initiated and evaluated in the literature to reduce the occurrence of SSIs. Postoperative surgical site infection will remain a matter of concern for patients, surgeons and healthcare providers. Future prospective randomized studies that include some or all of the 10 steps discussed in this report are necessary to confirm whether the 10 steps adopted by the authors were in fact science or fiction in the battle for infection control.

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