Infection Rates in Posterior Instrumented Spinal Fusions: A Retrospective Review of Infection Control Practices and Outcomes

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Abstract

Background and Review of Literature: A surgical site infection after posterior instrumented spinal fusion can negatively affect the patient and increase healthcare costs. Spinal fusions are becoming increasingly common as a surgical intervention to correct a variety of spinal pathologies. Infection in this population poses a significant problem as infection can lead to additional surgeries, debility, or mortality. *Purpose:* A group of neurosurgeons implemented a novel protocol to prevent surgical site infection, including irrigating the wound with Clorpactin and applying vancomycin powder intrawound before closing. This investigation seeks to identify surgical site infections and compare infection control measures. *Methods:* A retrospective chart review was conducted on patients who underwent posterior instrumented spinal fusion between August 2017 and December 2020. Data was collected from the Electronic Medical Records. The data was analyzed using statistical software. *Implications/Conclusion:* The results significantly reduce postoperative infections in the group exposed to the Clorpactin/vancomycin infection control protocol.

Keywords: surgical site infection, instrumented spinal fusion, Clorpactin irrigation, vancomycin powder, intrawound antibiotic

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A surgical site infection (SSI) is a potentially life-threatening complication following a surgical intervention that may result in additional surgeries, longer courses of antibiotics, increased healthcare costs, and increased morbidity or mortality (Di Martino et al., 2019). Surgical site infections after instrumented spinal fusions can cause significant challenges as infections may lead to multiple surgeries, including wound debridement, removal of hardware, destabilization of the spine, and reconstructive surgery (Kalfas et al., 2019). Surgical site infections are defined as infections occurring in the surgical space within 30 days of surgery or 90 days of surgery if implants are utilized (AHRQ, 2019). In posterior instrumented spinal fusions, surgical site infections occur in 2 % to upward of 20% of procedures (Dobran et al., 2019). It is imperative to follow strict infection control practices and develop protocols to decrease surgical site infections in spinal surgeries to improve patient outcomes and decrease healthcare costs. This retrospective chart review seeks to determine if the infection control protocol of utilizing Clorpactin irrigation and intrawound vancomycin powder before closure decreases infection rates in adults who underwent posterior instrumented spinal fusions at an Indiana hospital.

Background

Surgical site infections are a significant reason for hospital readmission, healthcare costs, morbidity, and mortality (AHRQ, 2019). In the United States, surgical site infections are associated with a 3% mortality rate and are estimated to cost $3.3 billion annually (Berrios-Torres et al., 2021). On average, it costs $40,987 to treat a single surgical site infection after a spinal fusion (Rosenthal et al., 2018). The Centers for Disease Control and Prevention (CDC) guidelines include methods to prevent surgical site infections such as antimicrobial prophylaxis, glycemic control, normothermia, and antiseptic prophylaxis (Berrios-Torres et al., 2017). While these guidelines are the core of preventing surgical site infections, they are not specific to a surgical specialty and function as universal best practices. Since spinal fusions have higher infection rates than general surgeries and have several added risk factors, additional measures may be beneficial to prevent the development of a surgical site infection.

Instrumented spinal fusions are procedures to treat spinal conditions such as scoliosis, traumatic injuries, spondylolisthesis, degenerative spine disease, and spinal stenosis (Rosenthal et al., 2018). These procedures can take several hours depending on the complexity and introduce foreign materials to the body. In posterior instrumented spinal fusions, the surgeon introduces instruments such as screws, rods, or cages into the spinal bones to stabilize the spine and fuse the bones (Columbia University, 2021). The fusion helps create a more stable spine, reducing the pressure on nerves or the spinal cord and improving patient pain (Columbia University, 2021).

In the United States, the number of spinal fusions per year has increased 118% from 1999 to 2014 and is the 16th most common surgical procedure (Resiner et al., 2020). These increases are primarily due to an aging population, increased life expectancy, and improved techniques, such as technological advancements, improved diagnostic imaging, and instrumentation techniques (Reisner et al., 2020). According to Martin et al. (2019), costs for elective lumbar fusion surgeries surpassed $10 billion for US hospitals, with the average cost of admission at greater than $50,000.

With the increasing number of surgeries, it is vital to develop practices to reduce infections. To reduce costs, private insurance companies and the Centers for Medicare and

Medicaid have introduced payment models that may not cover the increased length of stays at hospitals, readmissions, or rehab costs because of a surgical site infection (McGirt, 2017). Some intrinsic patient risk factors include advanced age, male sex, diabetes mellites, tobacco/alcohol use, a high American Society of Anesthesiologists (ASA) score, obesity, malnutrition, and an immunocompromised state (Traynelis et al., 2013). Surgical factors include the length of surgery, posterior approach, number of levels of operation, instrumentation, implant material, use of allograft, blood transfusion, and cerebrospinal fluid leak (Traynelis et al., 2013). Many surgical factors place the patient at increased risk for developing a surgical site infection in posterior instrumented spinal fusions.

Due to the cost to patient's health and healthcare systems, there has been a focus on preventative measures to reduce infection rates. Many studies have evaluated the efficacy of irrigation before surgical closure, but currently, the CDC does not state there is enough evidence to recommend the practice (Berrios-Torres et al., 2017). Additionally, the practice of applying antibiotics to the incision site has been uncertain, and the CDC does not feel that there is significant evidence to recommend it as a practice (Berrios-Torres et al., 2017). Furthermore, the use of antibacterial agents can cause adverse outcomes such as wound dehiscence, decreased bone growth, and drug reactions (Berrios-Torres et al., 2017).

Problem Statement

Despite methods to reduce surgical site infections, current measures still fail to prevent infections from occurring in patients. In patients undergoing posterior instrumented spinal fusions, decreasing the risk of postoperative infection is even more critical as infection can lead to implant removal, destabilization of the spine, extended hospital stays, and costly outcomes (Di Martino et al., 2019). It is essential to evaluate if novel approaches can improve clinical and patient outcomes and decrease healthcare costs. The investigator seeks to determine if there is a significant difference in infection rates between two groups of patients undergoing posterior instrumented spinal fusions with differing infection control practices.

Organizational “Gap” Analysis of Project Site

Currently, there are several infection controls protocols for posterior instrumented spinal fusions at a hospital in central Indiana. While all protocols meet or exceed the standards of infection prevention by the CDC, they differ in approach. All surgeons follow pre-surgical interventions recommended by the CDC, including having the patient do a chlorhexidine scrub the night before surgery and apply mupirocin ointment intranasally (Tomov et al., 2018). Additional standards recommended by the CDC include maintaining body temperature, blood glucose <200 mg/dL, administering prophylactic antibiotics, and utilizing strict surgical antiseptic measures (Berrios-torres et al., 2017). These measures are standard protocols utilized by all surgical groups at the facility.

The first infection control protocol includes irrigating the surgical incision with Clorpactin irrigation and applying vancomycin intrawound before closure. Additional protocols include preoperative optimization of health, placement of drains, and postoperative antibiotics to create a bundled infection prevention protocol. The second group, or the control group, uses various infection control practices, such as intrawound vancomycin, betadine irrigation, or no antimicrobial intervention. Additionally, there are different practices of drains and postoperative antibiotics. Evaluation of the infection control practices and the infection rates will provide a better understanding of best practices.

Review of Literature

A comprehensive literature search was conducted using CINAHL, PubMed, and Cochrane Review. The search terms “infection AND instrumented spinal/spine fusion,” “irrigation AND surgery,” “irrigation AND spinal surgery,” “vancomycin AND spinal fusion,” “Clorpactin OR sodium oxychlorosene” were used. Inclusion criteria included articles that 1) discussed infection in instrumented spinal fusions in patients, 2) articles that discussed the application of intrawound antibiotics or vancomycin in spinal surgical sites 3) articles that discussed the use of Clorpactin for surgical irrigation 4) articles investigating the use of irrigation in spinal surgeries. The results were limited to articles written in English, full text, and written from 2015 to 2021 and only focused on people 18 years or older. All titles were evaluated for relevance to the inclusion criteria. A total of 864 articles were found, and the abstracts were evaluated. After evaluation, a total of 31 articles were included: seven regarding infections in instrumented spinal fusions, fifteen for antibiotic usage intrawound in spinal fusions, and nine articles for irrigation of the surgical site.

Infection Prevention in Instrumented Spinal Fusions

Despite many infection prevention methods, surgical site infections still occur at an alarming rate (Di Martino et al., 2019). Determining methods that decrease infection rates is essential in providing high-quality care and reducing healthcare costs. Patient factors such as the gender of the patient, body mass index (BMI), disease status (such as diabetes, heart disease, autoimmune diseases), smoking status, and nutritional status can impact the likelihood of developing a surgical site infection (Deng et al.,2020; Janssen et al., 2018; Murphy et al., 2016 Rosenthal et al., 2018). These conditions can affect postoperative healing and decrease blood flow to the surgical site, which could alter antibiotic effectiveness (Deng et al., 2020; Murphy et al., 2018). Several risk factors can be addressed before surgery to improve outcomes, such as encouraging the patient to quit smoking, lose weight, or improve nutritional status. While these measures may improve the patient's health, additional measures are needed to prevent infection.

Added preoperative measures may reduce the risk of infection. One method is a preadmission chlorhexidine scrub and intranasal antibiotic ointment to reduce *Staphylococcus aureus* (*S. aureus*) and methicillin-resistant *S. aureus* (MRSA) colonization on the patient (Deng et al., 2020; Tomov et al., 2018). Reduction of *S. aureus* may improve surgical outcomes as approximately 70% of surgical site infections occur from staphylococcus organisms (Deng et al., 2020; Kalfas et al., 2019; Rosenthal, 2018). Infection with *S. aureus* led to a greater probability of hospital readmission and longer lengths of hospital stays (Rosenthal et al., 2019). Pre-incisional antibiotics are considered standard of care and are recommended to reduce surgical site infections (Berrios-Torres et al., 2017). Typically, these antibiotics are first-generation cephalosporins dosed by weight up to one hour before incision (Tomov et al., 2019).

Intraoperative measures such as performing patient skin preparation with alcohol-based skin prep, maintaining normal temperature, and maintaining blood glucose less than 200 are recommended to prevent surgical site infections by the CDC and WHO (Berrios-Torres et al., 2017; WHO, 2016). Intraoperative measures such as irrigating the wound, applying antibiotics, drains, and many other factors have been evaluated, but research is inconclusive on their effectiveness (Tan et al., 2020).

Postoperative measures such as pharmacological measures, dressing care, suture and staple management, or nutrition did not significantly impact surgical site infections (Tan et al., 2020). Postoperative administration of prophylactic antibiotics does not appear to reduce the risk of postoperative infection effectively and is not a recommended practice (Berrios-Torres et al., 2017; Tan et al., 2020).

Intrawound antibiotic prophylaxis

The application of intrawound antibiotics is an increasingly common practice to prevent surgical site infections. One of the most common antibiotics used for intrawound antibiotic prophylaxis is vancomycin (Dodson et al., 2019; Takeuchi et al., 2018). *S. aureus*, a gram-positive bacterium, is a common pathogen in surgical site infections, and vancomycin is particularly effective at inhibiting these bacteria (Dodson et al., 2019). It is theorized that applying an intrawound antibiotic will prevent bacterial invasion and kill bacteria already existing in the wound through high concentrations of antibiotics at the surgical site (Kang et al., 2015). Applying intrawound vancomycin has been associated with decreased surgical site infections (Adogwa et al., 2017; Chotai et al., 2017; Devin et al., 2017; He et al., 2019; Lemans et al., 2019). Several studies have demonstrated the effectiveness of vancomycin powder, reporting a decrease in infection rates from 10.2% to 2.5% (He et al., 2019). In addition to reducing the rate of SSI, it may decrease the severity of the infection and reduce the risk of needing to return to the operating room (Devin et al., 2017). This high concentration at the surgical site seems to limit the growth of staphylococcus and, importantly, MRSA (Adogwa et al., 2017; He et al., 2019). The powder has been shown to reach high local levels but not become absorbed systemically, allowing for inhibition of staph organisms (Adogwa et al., 2017; Murphy et al., 2016). The standard dosage is one to two grams of vancomycin powder applied to the wound, although there is no evidence of which dose is superior (Murphy et al., 2016; Kunakornsawat et al., 2019). Recommendations for application are to apply the vancomycin suprafascially, or in the muscle layer, as vancomycin can impair bone healing, impair dural repair and increase the risk of toxicity if applied below the fascia (Haimoto et al., 2018).

The use of intrawound vancomycin is cost-effective as the average cost of vancomycin powder is $34 for 2 grams (Kang et al., 2015). The application of vancomycin powder is significantly less expensive than the cost of treating a surgical site infection (Kang et al., 2015). Some reported side effects of intrawound vancomycin included nephropathy, ototoxicity, systemic absorption, and culture-negative seroma formation(Ghobrial et al., 2015). These occurred in less than 0.3% of patients (Ghobrial et al., 2015). Additional risks include increasing gram-negative bacterial growth and impaired bone healing (Chotai et al., 2017; Eder et al., 2016; Grabel et al., 2018). Gram-negative bacteria are typically more challenging to treat and more likely to lead to septic shock (Dodson et al., 2019; Grabel et al., 2018). Despite a great deal of research, the effectiveness is still debated (Lemans et al., 2019). Currently, the CDC and WHO do not recommend utilizing antibiotics in incisional wounds to prevent SSIs (Berrios-Torres et al., 2017; WHO, 2016). The FDA has not approved vancomycin for intra-site administration (Kang et al., 2019). Several studies found no significant difference in infection rates (Ludwig do Nascimento, 2019; Kunakornsawat et al., 2019; Takeuchi, 2018).

Irrigation of Surgical Site

Many surgeons irrigate the surgical incision before closure to prevent surgical site infections, but the irrigation and irrigation solution method varies greatly. Irrigating the wound is believed to be beneficial because the irrigation flushes away any bacteria that may have contaminated the wound, and the irrigation aids in removing damaged tissue that could serve as a medium for bacterial growth (Baker et al., 2020; Markel et al., 2021). The irrigation process is critical in procedures that use implants, as implants tend to attract bacteria and have higher biofilm formation (Baker et al., 2020). In spinal fusions, bacteria can adhere to the implants and become covered by biofilm, making it harder for the immune system to recognize bacterial contamination until the bacteria are at a potentially life-threatening level (Ahn et al., 2016). Pulse irrigation is beneficial as the irrigator results in higher pressures than a bulb syringe, allowing for more significant biofilm disruption and bacteria removal (Normal et al., 2017). Additionally, the pulse irrigator has decreased bacterial contamination in muscle layers (Ahn et al., 2016, Normal et al., 2017). Lastly, pulse irrigation promotes granulation tissue growth to enhance wound healing and does not result in additional pain postoperatively (Fel & Gu, 2016).

A variety of solutions have been used and studied. However, there is still uncertainty about the effectiveness of any irrigation solution (Markel et al., 2021). A Cochrane review by Norman et al. (2017) found low-quality evidence to suggest irrigation is beneficial in reducing surgical site infections. However, Norman et al. (2017) found that antibiotic irrigation may have minimal effect, and clinicians should consider the risk of antibiotic resistance. Betadine is an agent commonly used in irrigation solutions. Betadine has broad-spectrum abilities to kill both gram-positive and gram-negative bacteria and does not result in antibiotic resistance (Onishi et al., 2019).

Clorpactin, or sodium oxychlorosene, has been antimicrobial irrigation used to prevent surgical infections since 1955 (Kotechi & Bradford, 2021). Clorpactin has been used in several surgical specialties but is recently used in orthopedic, breast reconstruction, and spinal surgeries (Kotechi & Bradford, 2021; Markel et al., 2020). According to the American Society of Plastic Surgeons, approximately 14% of plastic surgeons report using Clorpactin irrigation in breast reconstruction surgeries primarily due to its ability to penetrate biofilm and its rapid reduction in bacterial load (Dawson et al., 2021). A study by Alentado et al. (2021) found that infection prevention involving Clorpactin reduced postoperative wound infections in spinal procedures, including elective and emergent cases, and was overall safe and effective.

Clorpactin has a relatively neutral pH of 6.5-6.9 and is highly bactericidal by oxidizing cell membranes and destroying biofilm while minimally damaging tissues (Baker et al., 2020; Markel et al., 2020; Kotecki & Bradford, 2021). The pH neutrality makes it less irritating to the tissues while effectively destroying biofilms that is so important in implant surgeries (Kotecki & Bradford, 2021). In a study of osteoblasts, Clorpactin did cause damage to osteoblasts, but the damage was temporary and reversible (Markel et al., 2021). Kotecki & Bradford (2021) found that overall Clorpactin irrigation was comparable to other irrigation methods such as betadine and chlorhexidine. Additionally, Clorpactin is cost-effective as a two-gram vial costs approximately $5 and is prepared by mixing with normal saline (Dawson et al., 2021). Clorpactin may be an excellent irrigation to prevent surgical site infections, but there is limited data on this new approach, particularly in spinal surgeries.

Theoretical Framework or Conceptual Model

The Johns Hopkins Nursing Evidence-Based Model (JHNEBP) will be utilized as a guide to developing and implementing this clinical inquiry (see Appendix A). The JHNEBP comprises three main phases: the practice question, evidence, and translation (Dang & Dearholt, 2017). The JHNEBP is a model designed to bridge the gap between research findings and patient care (Dang & Dearholt, 2017). The first step includes the practice question, which involves defining the problem, developing an evidence-based question, and identifying the stakeholders (Dang & Dearholt, 2017). The practice question was developed by working with surgeons interested in improving postsurgical outcomes in patients undergoing posterior instrumented spinal fusions.

The problem involves a variation in practice within the healthcare setting and affects quality and financial outcomes.

The second phase is referred to as the evidence phase. During this phase, a systematic search for evidence is conducted. This systematic review of literature helps find and evaluate evidence-based knowledge relevant to the clinical question. The systematic search of literature through search engines such as PubMed, CIHAHL, and Cochrane review elicited much research to evaluate. The evidence was graded based on the strength of the individual evidence. The literature was synthesized through a review of the literature. Recommendations for best practice were based on the aggregate results of the evidence search and grading and evaluating the literature.

The last phase is translation, which includes translating the evidence into practice (Dang & Dearholt, 2017). An action plan is created during this phase, and implementation occurs (Dang & Dearholt, 2017). After the plan has been implemented, the results are evaluated to determine the action's effectiveness (Dang & Dearholt, 2017). For this project, results will be evaluated to determine if there is a significant difference in postoperative infection rates between the two interventions. The last step of translation includes reporting the stakeholders' outcomes and disseminating the findings (Dang & Dearholt, 2017). This will be done through a dissemination meeting with the stakeholders and creating an educational poster to disseminate at Marian University.

Goals, Objectives, and Expected Outcomes

This project aims to collect retrospective data to evaluate the effectiveness of an infection control protocol to improve patient outcomes at an Indiana hospital. The results of this study can ultimately improve the quality of care and reduce costs to the hospital. The objective is to determine if one protocol is significantly more effective at reducing surgical site infections in patients who underwent posterior instrumented spinal fusions. The expected outcome is that the group exposed to the protocol, including irrigation with Clorpactin and application of intrawound vancomycin powder, will have decreased rates of surgical site infections.

Project Design/Methods

This project was a retrospective chart review on patients who underwent a posterior instrumented spinal fusion from August 2017 through December 2020 at a single-site hospital. Data was collected for all surgeries that involved a posterior approach and instrumentation in cervical, thoracic, and lumbar fusions. Exclusion criteria included patients under 18, infection as an indication for surgery, and anterior approach. The sample includes approximately 1,100 patients divided into two groups based on exposure to infection control protocols. The retrospective design was selected to determine if the infection control protocol significantly decreased surgical site infections in posterior instrumented fusions.

Project Site and Population

The investigator implemented the project at a hospital facility located in central Indiana specializing in caring for spine disorders. The hospital is in a large suburb of Indianapolis, IN, and attracts patients from across the state. It is a physician-owned hospital with three operating rooms and twenty inpatient beds (Schrag, 2017). Two major surgical groups and several contracted surgeons provide inpatient and outpatient surgical services, pain management, imaging, and physical therapy. The surgeons are comprised of neurosurgeons and orthopedic surgeons.

The population will include adult patients who underwent posterior instrumented spinal fusion at this center between 2017-2020. Inclusion criteria comprise of patients who underwent surgery at this hospital between the specified dates, those greater than or equal to 18 years old at the time of surgery, posterior approach, and single or multilevel fusion involving instrumentation. Only patients with private insurance are approved for surgery at this hospital location.

Measurement Instruments

To measure the outcomes, data were collected from electronic medical records. Data collected included demographic data such as age (in years) and gender. Health information such as the patient's BMI, smoking status, prior spinal surgery, and if the patient had diabetes, and if they had diabetes at time of surgery the most recent hemoglobin A1C. These health factors were chosen as they have been associated with an increased risk of surgical site infection (Traynelis et al., 2013). Additional surgical factors such as if the procedure was one level or multiple levels, length of surgery, and infection control protocol exposure were collected. These are surgical factors that can impact the risk of postoperative surgical site infections (Traynelis et al., 2013). Lastly, infection data was collected, such as if the patient was diagnosed with an infection within 90 days of the procedure, if the infection was deep or superficial, and the organism present.

Data Collection Procedures

Before data collection, data points were selected with the physicians and investigator. A template was designed in REDCap, a web-based program developed for secure data collection so that data collection is uniform. All data was collected from documents and records created before the investigation, mainly from the electronic medical records. Data was collected on all patients who underwent posterior instrumented spinal fusions between August 1, 2017, and December 31, 2020. All data was collected by the primary investigator. Data collection took place over a period of three months.

Procedure codes were used to identify patients who underwent posterior instrumented spinal fusion surgeries. Infections were identified through ICD-10 diagnosis of wound infection. The patient's age was calculated by age at the time of surgery. Medical and surgical history was collected from preoperative consult, anesthesia preoperative consult, and the surgeon's history and physical. Intraoperative information was gathered from the postoperative surgeon report, anesthesia intraoperative report, and intraoperative nursing report. Medication data was collected from both the postoperative surgical report and verified with the medication administration records. Laboratory values were taken from lab reports. Infection data was collected from microbiology results, ICD-10 codes, and office consult notes.

Ethical Considerations/Protection of Human Subjects

The Marian Internal Review Board (IRB) and St. Vincent IRB approval were attained before the start of the investigation. The St. Vincent IRB was the IRB of record. The investigator used computers that were encrypted, password-protected, and on a secure network. The investigator logged out of all computers before leaving the workstation and only worked in a private environment. The data was stored in an encrypted cloud-based program, REDCap, that is password protected. Only research staff had access to this database. The research staff included the investigator and two registered nurses who were employees at the hospital and function in a research role.

The investigator completed training through the Collaborative Institutional Training Initiative training (CITI program) to learn about ethical research. The investigator also underwent training for Health Insurance Portability and Accountability Act (HIPAA) compliance training at the hospital to promote data safety.

An informed consent waiver was requested as the participants were at minimal risk for harm. The risks included loss of confidentiality. Risks were minimized wherever possible. The waiver was requested because the investigation posed minimal risk to the participants; the waiver would not adversely affect the rights of participants as all HIPPA rules and regulations were followed, data was protected, and the investigation could not practically be carried out without the waiver.

Data Analysis and Results

Data Analysis

Data was de-identified before being exported to an excel spreadsheet for analysis. The total number of patients undergoing posterior instrumented spinal fusion was 1,015. There were 11 postoperative infections identified. The overall rate of infection was 1.1%. The sample was divided into two groups to determine the infection rates and demographic information for each group. An independent statistician was consulted to assist with data analysis. For nominal data, an independent t-test was performed. For categorical variables, a chi-square test of association was performed. These tests were performed using the statistical software program: Statistical Package for the Social Sciences (SPSS, Version 26, IBM Corp.). The groups were numerically coded as "1" being the group exposed to the Clorpactin/vancomycin protocol and "2" being the group not exposed to that protocol. The primary investigator did all coding and analysis of the data. The significance was evaluated at $p \leq .05$.

A chi-square test was utilized to determine if the groups had similar sample characteristics to determine if the groups were similar. These characteristics included gender, previous spine surgery(yes/no), the number of levels (single or multilevel), smoking status (yes/no), and if the patient was a diabetic(yes/no). An independent sample t-test was run for age, BMI, length of surgery, and hemoglobin A1C. Additionally, demographic data was analyzed using frequency and percentages for nonparametric variables. For parametric variables, mean, standard, and deviation were recorded.

Results

The chart review included patients who underwent posterior spinal fusion from August 1, 2017, to December 31, 2020. The sample included a total of 1,015 patients. The average age of the patient was 53.23 years old at the time of the surgery. There were 496 female (48.87%) patients and 519 male (51.13%). The average BMI was 31.52, with the low being a BMI of 17 and a high of 76. Of those patients, 160 (15.76%) were current smokers, and 171 (16.85%) had diabetes (see *Appendix B* for demographic tables).

The group exposed to the infection control protocol including Clorpactin irrigation and vancomycin, or "Group A," included 305 charts, while the group not exposed to the infection control protocol, "Group B," included 710 charts. Overall, there were no postoperative infections in Group A and 11 postoperative infections in Group B. A chi-square test was utilized to determine if there was a significant difference between the two groups. The results showed a significant difference $X^2(1, n=1015)= 4.777, p= .029$.

When simply comparing the various intraoperative protocols, there is not a significant difference between using Clorpactin/vancomycin, vancomycin powder, betadine, or no intervention. A one-way ANOVA was utilized to compare the four types of intraoperative protocols and infections. The one-way ANOVA shows $F (3,1011)= 1.083, p= .355$. This indicates that there is not a significant difference in postoperative infection rates between the four intraoperative measures.

Out of the 1,015 participants, 11 developed postoperative surgical site infections. The infections included nine deep infections and two superficial infections. Of the eleven infections, seven were infected with *Staphylococcus aureus* (2 MRSA), two with *Streptococcus*, one with *E. coli,* and one with *Serratia Marcescens*. Additionally, the study found nine postoperative seromas (n=9).

Group Comparison

To determine if the two sample groups were similar, an analysis of the group variables was compared. A chi-square test was performed on gender, previous spine surgery, number of levels, smoking status if the patient had diabetes, and the ASA class. The chi-square test for gender resulted in X^2 (1, 1015)= .072, p= .789. For previous spinal surgery, the X^2 (1,1015)= 1.487, p= .223. Number of levels was X^2 (1,1015)= 8.894, p=.003. Smoking status X^2(1,1015)= 15.684, p=.000. To compare diabetic patients, X^2(1, 1015)= .229, p=.632. Lastly, in comparing the ASA class, the X^2 (3,976)= 1.228, p=.746. Group B had a higher proportion of one-level operations than Group A. Also, there was a significantly higher number of people who smoke in group B.

An independent t-test was done to look for differences in the group's age, BMI, length of surgery, and hemoglobin A1C results. Age was significantly different with X^2(1013, n=1015)= 5.982, p=.003. The mean age for Group A was 54.657 (SD= 9.205), while Group B had a mean age of 52.614 (SD=10.289). BMI also showed a significant difference in the values with X^2(1013, n=1015)= 7.407, p=.006. The mean difference was 1.31 years between the two groups. Group A had a mean BMI of 30.63 (SD= 6.035), and Group B had a mean BMI of 31.917 (SD = 7.254). The length of surgery (p=.925) and HgB A1C (p=.229) were not statistically significant. These statistics show that the groups are not significantly different in most aspects and help explain that the differences found in infection rates are due to the infection control protocols as opposed to group differences.

Discussion

Overall, the statistical analysis shows that the group exposed to the infection control protocol including Clorpactin and vancomycin powder resulted in significantly fewer postoperative infections than the control group. The infection control protocol includes many factors such as preoperative optimization of health, drain use, and removal protocols, and postoperative antibiotics. The group exposed to the infection control protocol resulted in zero infections in posterior instrumented spinal fusions between 2017 and 2020. The control group had an overall infection rate was 1.1%, which is considerably lower than the risk of SSI post instrumented spinal fusion in the literature (Rosenthal et al., 2019). While these infection rates are lower than the literature, the goal is to prevent postoperative infections in all patients.

When comparing the control group to the protocol group, there were many similarities. If the two groups are similar, then the difference in the protocol is likely to be truly from the protocol and not due to group variation. A statistical difference occurred in BMI, age, smoking rates, and the number of levels. Group A had a statistically significantly higher age than group B and had a higher percentage of multilevel fusions. Group B had a statistically significant higher BMI and smoking status among the patients. This difference may show the difference in preoperative optimization of health before surgery in the two groups. While they were different, Group A had a higher average age which could increase the risk of post-surgical site infection (DiMartino et al., 2019). Additionally, both groups had an average BMI greater than 30, which would place both groups at increased risk for postoperative infection (DiMartino et al., 2019).

Clorpactin has not been well studied, despite its use in surgery since 1955 (Kotechi & Bradford, 2021). Clorpactin irrigation seems to have benefits such as decreasing bacterial load and an ability to break down biofilm (Kotechi & Bradford, 2021). The results from this investigation show that Clorpactin along with vancomycin powder may be beneficial in reducing postoperative infections posterior spinal fusions. While this is a critical aspect of the infection control protocol, not all results can be attributed to the intraoperative measures. The one-way ANOVA did not show a significant difference in infection rates in those exposed to Clorpactin/vancomycin and the other intraoperative infection prevention measures. This simply means that compared to vancomycin powder only, betadine irrigation, or no intervention, the results were not significant enough to indicate that Clorpactin/vancomycin alone resulted in fewer infections. The relatively low number of postoperative infections resulted in a more difficult achievement of statistical power. Additional studies on intraoperative measures would be beneficial to determine the effectiveness of each intervention.

This review was limited in that only one hospital was utilized, and the hospital only accepts private insurance, so those on Medicare/Medicaid were excluded. This may result in a homogenous group of sample participants. Additionally, the investigation did not analyze the difference in techniques of application of vancomycin powder, and the use significantly varied. Some surgeons applied as little as a half gram, and others applied up to three grams. One or two grams of vancomycin was the most common range. Lastly, the investigation was limited by time constraints as only one investigator collected and analyzed the data.

This investigation would benefit from additional statistical analysis to control for the group variables and additional analysis into the factors associated with infections. A multivariable analysis would be beneficial to see if any other variables were a risk factor.

Additional research needs to be conducted on the use of Clorpactin as irrigation in surgeries, mainly instrumented spinal surgeries. Randomized controlled studies, prospective studies, or studies with a larger population would be beneficial to determine the overall effectiveness of these protocols and particularly the use of intraoperative interventions such as Clorpactin or vancomycin.

The overall infection control protocol, however, is successful, as it resulted in significantly fewer infections than the control group. The key findings of this investigation are that a comprehensive infection control protocol including the use of Clorpactin and vancomycin showed a decrease in postoperative infections. This adds to the literature that Clorpactin and vancomycin powder show promise as a method to help prevent surgical site infections.

Conclusion

In conclusion, surgical site infections are detrimental to the patient and costly to the healthcare system. It is in the best interest of patients and healthcare to reduce, minimize, or eradicate surgical site infections. Methodical management to reduce infections, including preoperative patient optimization, intraoperative measures, and postoperative measures should be utilized. Through this retrospective review, with methodical interventions along with the protocol of Clorpactin irrigation and vancomycin powder, surgical site infections can be reduced.

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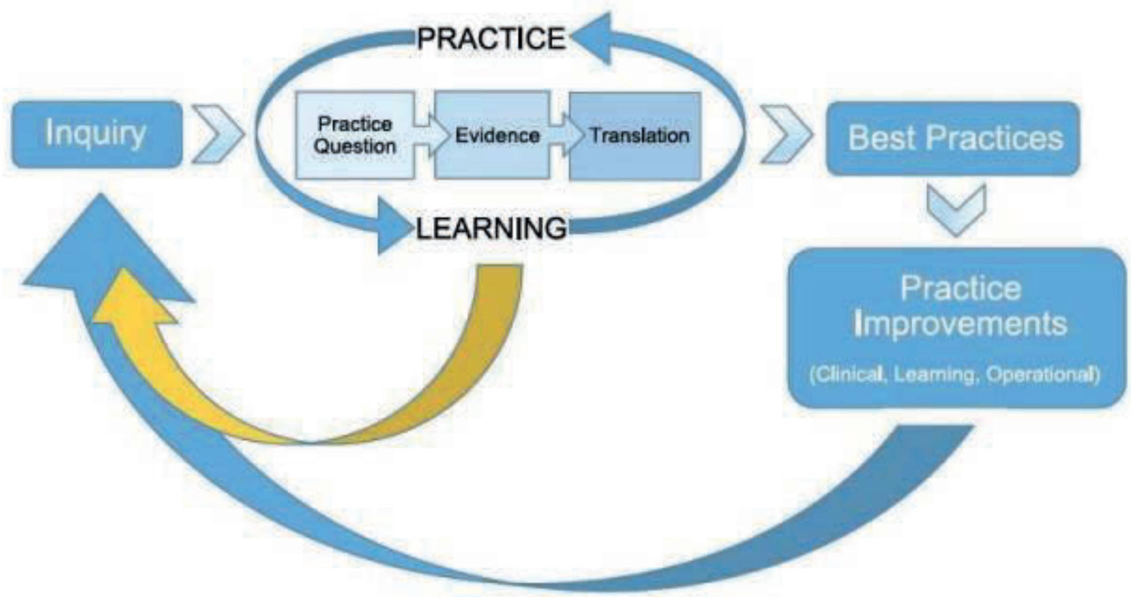
Appendix A



(Dang & Dearholt, 2017)

Appendix B

Demographic and Clinical Characteristics of the Sample
n=1015

Variable	*N*	*%*	
Gender			
Female	496	48.9	
Male	519	51.1	
Previous Spine Surgery			
Yes	463	45.6	
No	552	54.4	
Number of Levels			
One	650	64	
Multiple	364	35.9	
Smoker			
Yes	160	15.8	
No	855	84.2	
Diabetic			
Yes	171	16.8	
No	844	83.2	
Postoperative Infection			
Yes	11	1.1	
No	1004	98.9	
	Mean	**Standard Deviation**	**Range**
Age	53.23	10.0159	18-76
BMI	31.5225	6.93346	17.5-73.36
Length of Surgery	212.55	86.924	51-783
HgB A1C	6.95	1.256	5-12

Demographic and Clinical Characteristics of Group A
n=305

Variable	**n**	**%**	
Gender			
Female	151	49.5%	
Male	154	50.5%	
Previous Spine Surgery			
Yes	148	51.5	
No	157	48.5	
Number of Levels			
One	174	57.0	
Multiple	130	42.6	
Smoker			
Yes	27	8.9	
No	278	91.1	
Diabetic			
Yes	54	17.7	
No	251	82.3	
Postoperative Infection			
Yes	0	0	
No	305	100	
	Mean	**Standard Deviation**	**Range**
Age	54.66	9.2055	18-73
BMI	30.60	6.0352	18.8-53.5
Length of Surgery	212.15	66.45	88-517
HgB A1C	7.12	1.451	5-12

Demographic and Clinical Characteristics of Group B
n= 710

Variable	**n**	**%**	
Gender			
Female	345	48.6	
Male	365	51.4	
Previous Spine Surgery			
Yes	315	44.4	
No	395	55.6	
Number of Levels			
One	476	67.0	
Multiple	234	33.0	
Smoker			
Yes	133	18.7	
No	577	81.3	
Diabetic			
Yes	117	16.5	
No	593	83.5	
Postoperative Infection			
Yes	11	1.5	
No	699	98.5	
	Mean	**Standard Deviation**	**Range**
Age	52.61	10.2898	18-76
BMI	31.92	7.25374	17.5-73
Length of Surgery	212.72	94.408	51-783
HgB A1C	6.87	1.141	5-11