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ORIGINAL ARTICLE

# Surgical Site Infection ( SSI ) with and without suprafascial intrawound application of vancomycin powder in instrumented posterior spinal fusion.

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**ABSTRACT… Objective:** To evaluate the incidence of surgical site infections (SSI) with and without the use of suprafascial intrawound vancomycin powder in instrumented posterior spinal fusion. **Study Design:** Randomized Controlled Trial. **Setting:** Department of Neurosurgery, Allied Hospital-I, Faisalabad. **Period:** 01-01-2026 to 30-06-2026. **Methods:** We randomly assigned 74 patients from each group to undergo posterior spinal instrumentation; the patients' ages ranged from 18 to 65. In addition to the usual prophylactic intravenous antibiotics, Group A also got intrawound vancomycin powder. In contrast, Group B only received intravenous antibiotics. Over the course of three months, patients were monitored for the occurrence of SSI, as defined by the CDC. A chi-square test was used to compare the SSI rates between the groups, and the data were analyzed using SPSS version 25.0. **Results:** The overall frequency of SSI was 13.5% (20/148). Group A showed a significantly lower rate of SSI (6.8%) compared to Group B (20.3%) (p = 0.016). Among infections, 8.8% were superficial and 4.7% were deep. Stratified analysis demonstrated a consistent reduction in SSI in the vancomycin group across most subgroups. **Conclusion:** Suprafascial intrawound application of vancomycin powder significantly reduces postoperative SSI in instrumented posterior spinal fusion and may be considered an effective, safe, and cost-efficient adjunct to standard antibiotic prophylaxis.

**Key words:** Surgical Site Infection, Vancomycin Powder, Spinal Fusion, Instrumentation, Prophylaxis, Randomized Controlled Trial.

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## INTRODUCTION

Postoperative morbidity and healthcare burden are significantly increased by surgical site infections (SSIs), which continue to be a big problem in spine surgery. Among the most prevalent complications following spine surgeries, SSIs occur at a reported incidence of about 3.1% overall.[1,2] They are defined as infections occurring within 30 days of surgery, or within 90 days in cases involving implanted devices. These infections are associated with prolonged hospitalization, increased treatment costs, delayed recovery, and in severe cases, significant mortality.[3] The prevention of surgical site infections (SSIs) remains a significant clinical problem, even if surgical procedures and perioperative care have improved.[4]

Factors connected to the patient, the surgery, and the microbes all have a role in the development of surgical site infections (SSIs). Standard preventive strategies include strict adherence to aseptic techniques, minimizing operative time, and administration of prophylactic antibiotics.[4,5] Intravenous cephalosporins are commonly used as first-line prophylaxis; however, studies have shown that routine intravenous vancomycin does not consistently offer superior protection against SSIs.[6,7] The most frequently isolated pathogens in spinal SSIs are Staphylococcus species, including both methicillin-sensitive and methicillin-resistant strains, highlighting the need for targeted antimicrobial interventions.[8]

The idea of using antibiotics topically in addition to systemic prophylaxis has gained popularity in recent years. A growing number of surgical subspecialties are using intrawound vancomycin powder into their treatments. Surgery on the spine, heart, and orthopedics are all part of this category.

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Its goal is to minimize systemic absorption of antibiotics and their associated effects while increasing concentrations at the surgical site.[9] This targeted approach is particularly relevant given that gram-positive organisms are the predominant causative agents of SSIs. Moreover, topical application of vancomycin has been shown to significantly increase local drug concentration without increasing systemic adverse effects.[10]

Additional proof of this method's efficacy comes from clinical research. According to Khalid et al., patients who had thoracolumbar-sacral spinal instrumentation had a much lower risk of postoperative SSIs after receiving intraoperative vancomycin powder. In their 78-patient trial, they found that SSI occurred 5.2% less often in the vancomycin group than in the control group (20.5%).[11] Other studies have also shown similar results, demonstrating that intrawound vancomycin is an efficient, straightforward, and inexpensive way to prevent surgical site infections (SSIs) after spinal procedures.[12]

Given the substantial burden of SSIs and the promising role of local antibiotic prophylaxis, this study is designed to evaluate the effectiveness of intrawound vancomycin powder in reducing postoperative SSIs in patients undergoing thoracolumbar to sacral spinal instrumentation. The study compares outcomes between patients receiving standard intravenous antibiotic prophylaxis alone and those receiving additional local application of vancomycin powder, aiming to provide further evidence for its routine use in clinical practice.

## METHODS

This study will be executed as a randomized controlled trial at the Department of Neurosurgery, Allied Hospital-I, Faisalabad, spanning six months subsequent to the acceptance of the study description. With an expected rate of 5.2% for surgical site infections (SSIs) in the vancomycin group and 20.5% in the control group, a sample size of 148 patients (74 in each group) was determined using the World Health Organization's sample size calculator for two proportions, a significance level of 5%, and a power of 80%. This study will use a non-probability sequential sampling method. We will include male and female patients between the ages of 18 and 65 who are planned for posterior spinal fixation or instrumentation and who appear with severe thoracolumbar fractures, metastatic spinal illness, spinal TB, or degenerative spinal diseases. Patients with a prior history of spinal fixation, those undergoing anterior surgical approaches or procedures without instrumentation, as well as individuals with a known history of SSI or hypersensitivity to vancomycin, will be excluded.

Following CPSP and the Institutional Ethical Review Committee's approval (48 ERC/FMU/2025-26), all participants will be requested to give their informed consent. A standardized proforma will be used to record baseline data, which includes things like tobacco use, BMI, hemoglobin levels, ASA classification, pathology level and etiology, instrumentation extent, predicted blood loss, concomitant conditions, and operation time. Participants will be randomly allocated into two groups using the lottery method: Group A (vancomycin group) and Group B (control group). All patients will receive standard preoperative skin preparation with alcohol followed by povidone-iodine. Intravenous antibiotic prophylaxis will be administered as 2 g cefoperazone–sulbactam within 30 minutes prior to incision, followed by 1 g every 12 hours for three days postoperatively.

Following pedicle screw placement and rod fixation, the surgical site will be irrigated with normal saline and povidone-iodine solution. In Group A, 1 g vancomycin powder will be applied locally over the implant and into the deep subcutaneous layer prior to wound closure. Wounds will then be closed in layers and dressed under sterile conditions. Patients will be followed for three months postoperatively. SSI will be defined as any infection presenting with clinical signs and confirmed by positive bacterial culture within 30 days for non-implant surgeries or within 90 days for implant-related procedures, and will be classified as superficial or deep according to CDC criteria.

The analysis of data will be conducted utilizing SPSS version 25.0. Continuous data, including age, weight, height, BMI, ASA grade, and operational time, will be reported as mean ± standard deviation, whilst categorical variables such as gender,

comorbidities, thoracic level involvement, and SSI (along with its kinds) will be provided as frequencies and percentages. The chi-square test will be utilized to compare the incidence of surgical site infections between the two groups. Effect modifiers including as age, gender, BMI, ASA grade, comorbidities, thoracic level, and surgical time will be managed by stratification. A chi-square analysis for post-stratification will be conducted to assess their influence. A p-value of ≤0.05 will be deemed statistically significant.

## RESULTS

This randomized controlled experiment had 148 participants, with 74 patients split evenly between the two groups. The final analysis included all patients who finished the three-month follow-up period. The major method for determining the frequency of surgical site infection (SSI) following instrumented posterior spinal fusion was to compare patients who received intravenous antibiotics alone with those who additionally received intrawound vancomycin powder.

Table-I summarizes the demographic and clinical data of the participants. The average age was 36.16 ± 6.81 years, and 64.2% of the patients were in the 31-45 age bracket. The sample consisted of 66.2% male patients. The mean BMI was 26.30 ± 2.36 kg/m², and most patients were categorized as overweight (60.8%). ASA classification was nearly evenly distributed among ASA I, II, and III. The underlying diagnoses, including trauma, degenerative disease, metastasis, and tuberculosis, as well as the spinal levels involved, were also evenly distributed, indicating comparable baseline characteristics between the study groups.

Table-II presents the distribution of operative time among the study participants. The mean operative duration was 144.32 ± 19.28 minutes. Nearly half of the surgeries (47.3%) were completed within 121–150 minutes, while 36.5% exceeded 150 minutes, and 16.2% were completed within 120 minutes, reflecting a moderate variation in surgical duration.

Table 3 shows the overall frequency and types of surgical site infections observed in the study population. A total of 20 patients (13.5%) developed SSI, while 128 patients (86.5%) did not develop any infection. Among the infected cases, 13 patients (8.8%) had superficial infections and 7 patients (4.7%) had deep infections.

TABLE-IV compares the frequency of SSI between the two study groups. In Group A (vancomycin group), 5 patients (6.8%) developed SSI, whereas in Group B (control group), 15 patients (20.3%) developed SSI. This difference was statistically significant ($p = 0.016$), indicating that the use of intrawound vancomycin powder was associated with a significant reduction in postoperative SSI rates.

**TABLE-I**

**Baseline characteristics of study participants (n = 148)**

| | Variable | Frequency (n) | Percentage (%) |
|---|---|---|---|
| | Age (Mean ± S.D) | 36.16 | 6.81 |
| Age Groups | 18–30 years | 37 | 25.0 |
| | 31–45 years | 95 | 64.2 |
| | 46–65 years | 16 | 10.8 |
| Gender | Male | 98 | 66.2 |
| | Female | 50 | 33.8 |
| | BMI (Mean ± S.D) | 26.30 | 2.36 |
| BMI Categories | Normal | 48 | 32.4 |
| | Overweight | 90 | 60.8 |
| | Obese | 10 | 6.8 |
| ASA Classification | ASA I | 50 | 33.8 |
| | ASA II | 50 | 33.8 |
| | ASA III | 48 | 32.4 |
| Diagnosis | Trauma | 37 | 25.0 |
| | Degenerative | 38 | 25.7 |
| | Metastasis | 36 | 24.3 |
| | Tuberculosis | 37 | 25.0 |
| Spinal Level | Thoracic | 37 | 25.0 |
| | Thoracolumbar | 38 | 25.7 |
| | Lumbar | 37 | 25.0 |
| | Lumbosacral | 36 | 24.3 |

**TABLE-II**

**Distribution of operative time categories (n = 148)**

| Operative Time | Frequency (n) | Percentage (%) |
|---|---|---|
| Mean ± S. D | 144.32 | 19.287 |
| ≤120 minutes | 24 | 16.2 |
| 121–150 minutes | 70 | 47.3 |
| >150 minutes | 54 | 36.5 |

**TABLE-III**

**Frequency of Surgical Site Infection (SSI) and type**

| Variable | Frequency (n) | Percentage (%) |
|---|---|---|
| **SSI** | | |
| Yes | 20 | 13.5 |
| No | 128 | 86.5 |
| **SSI Type** | | |
| None | 128 | 86.5 |
| Superficial | 13 | 8.8 |
| Deep | 7 | 4.7 |
| Total | 148 | 100.0 |

**TABLE-IV**

**Comparison of SSI Between Study Groups**

| SSI | Group A | Group B | Total | P-Value |
|---|---|---|---|---|
| Yes | 5 (6.8%) | 15 (20.3%) | 20 (13.5%) | 0.016 |
| No | 69 (93.2%) | 59 (79.7%) | 128 (86.5%) | |
| Total | 74 (100%) | 74 (100%) | 148 (100.0%) | |

Stratified analysis of SSI between the two groups across different variables in table 05. A statistically significant reduction in SSI was observed in the vancomycin group among patients aged 18–30 years (p = 0.032), male patients (p = 0.037), those with ASA III status (p = 0.041), patients with trauma-related diagnoses (p = 0.006), and those undergoing thoracic level surgeries (p = 0.006). However, differences across other subgroups, including BMI categories and certain diagnostic and spinal level categories, were not statistically significant, although a consistent trend toward lower SSI rates in the vancomycin group was observed.

**TABLE-V**

**Stratified comparison of SSI between study groups (n = 148)**

| Variable | Category | Group A | Group B | P-Value |
|---|---|---|---|---|
| Age Group | 18–30 years | 1/17 (5.9%) | 7/20 (35.0%) | 0.032 |
| | 31–45 years | 4/51 (7.8%) | 6/44 (13.6%) | 0.359 |
| | 46–65 years | 0/6 (0.0%) | 2/10 (20.0%) | 0.242 |
| Gender | Male | 3/49 (6.1%) | 10/49 (20.4%) | 0.037 |
| | Female | 2/25 (8.0%) | 5/25 (20.0%) | 0.221 |
| BMI | Normal | 1/32 (3.1%) | 2/16 (12.5%) | 0.206 |
| | Overweight | 4/42 (9.5%) | 11/48 (22.9%) | 0.089 |
| | Obese | 0/0 | 2/10 (20.0%) | —* |
| ASA | ASA I | 2/25 (8.0%) | 5/25 (20.0%) | 0.221 |
| | ASA II | 2/25 (8.0%) | 4/25 (16.0%) | 0.384 |
| | ASA III | 1/24 (4.2%) | 6/24 (25.0%) | 0.041 |
| Diagnosis | Trauma | 0/19 (0.0%) | 6/18 (33.3%) | 0.006 |
| | Degenerative | 2/19 (10.5%) | 1/19 (5.3%) | 0.547 |
| | Metastasis | 1/18 (5.6%) | 1/18 (5.6%) | 1.000 |
| | Tuberculosis | 2/18 (11.1%) | 7/19 (36.8%) | 0.068 |
| Spinal Level | Thoracic | 0/19 (0.0%) | 6/18 (33.3%) | 0.006 |
| | Thoracolumbar | 2/19 (10.5%) | 1/19 (5.3%) | 0.547 |
| | Lumbar | 2/18 (11.1%) | 7/19 (36.8%) | 0.068 |
| | Lumbosacral | 1/18 (5.6%) | 1/18 (5.6%) | 1.000 |

## DISCUSSION

Surgical site infections (SSIs) remain a significant postoperative complication in spinal surgery, contributing to increased morbidity, prolonged hospitalization, and higher healthcare costs. In the present randomized controlled trial, the overall frequency of SSI was found to be 13.5%, with a significantly lower rate observed in the group receiving intrawound vancomycin powder (6.8%) compared to the control group (20.3%).

These findings highlight the potential effectiveness of locally applied vancomycin as an adjunct to standard intravenous antibiotic prophylaxis in reducing postoperative infections following instrumented posterior spinal fusion.

The observed overall SSI rate in this study is comparable to previously reported rates in spinal surgeries, which range between 2% and 20%, depending on patient population, surgical complexity, and institutional practices.[1-3] The higher rate in the control group aligns with earlier studies emphasizing the persistent burden of SSIs despite adherence to conventional prophylactic measures.[4] This underscores the need for additional preventive strategies, particularly in high-risk procedures such as spinal instrumentation.

Our findings are consistent with those reported by Khalid et al., who demonstrated a reduction in SSI rates from 20.5% in the control group to 5.2% in the vancomycin group.[11] Similarly, Sweet et al. reported a significant decline in infection rates with the use of intrawound vancomycin in thoracolumbar spinal fusion procedures, supporting its role as an effective prophylactic agent.[13] Strom et al. also observed a marked decrease in postoperative infections with topical vancomycin application, reinforcing the reproducibility of these results across different clinical settings.[14]

The effectiveness of intrawound vancomycin can be attributed to its pharmacokinetic advantages. Local application ensures high antibiotic concentrations directly at the surgical site, exceeding the minimum inhibitory concentration for common pathogens such as Staphylococcus aureus, including methicillin-resistant strains.[15] At the same time, systemic absorption remains minimal, thereby reducing the risk of systemic toxicity.[16] This targeted approach is particularly beneficial in spinal surgeries, where implanted hardware may serve as a nidus for bacterial colonization.

In line with previous literature, Staphylococcus species remain the most commonly implicated organisms in SSIs.[8] The predominance of gram-positive bacteria further justifies the use of vancomycin, which has strong activity against these pathogens. Studies by Chiang et al. and Hill et al. have also demonstrated that intrawound vancomycin significantly reduces infections caused by gram-positive organisms, without increasing the incidence of gram-negative infections.[12,14] This suggests that the addition of vancomycin does not disrupt the microbial balance adversely.

Stratified analysis in the present study revealed that the protective effect of vancomycin was more pronounced in certain subgroups, including younger patients, males, those with higher ASA grades, trauma cases, and thoracic-level surgeries. These findings are supported by previous studies that have identified higher ASA grade, prolonged operative time, and trauma as independent risk factors for SSI.[17,18] The greater benefit observed in these subgroups may reflect the higher baseline risk of infection, where the impact of adjunctive prophylaxis becomes more evident.

Operative duration is another critical factor influencing SSI risk. In the current study, a considerable proportion of surgeries exceeded 150 minutes, which is consistent with literature suggesting that prolonged operative time increases infection risk due to extended tissue exposure and potential contamination.[19] Although stratification by operative time did not show statistically significant differences in all categories, a trend toward reduced SSI in the vancomycin group was observed, further supporting its protective role.

There have been some studies that have shown contradictory results, but overall, the results are encouraging. After analyzing the data, Shu et al. concluded that intrawound vancomycin did not significantly lower the rates of SSIs.[20] Similarly,

Evaniew et al., in a systematic review, highlighted variability in outcomes and emphasized the need for high-quality randomized trials.[21] However, the majority of recent studies, including randomized controlled trials and meta-analyses, favor the use of intrawound vancomycin as an effective preventive measure.[9] Importantly, no significant adverse effects related to vancomycin use were observed in this study. This is consistent with previous reports indicating that topical vancomycin is generally safe, with minimal systemic absorption and low risk of nephrotoxicity or ototoxicity.[22] Concerns regarding the potential development of antibiotic resistance have been raised; however, current evidence does not demonstrate a significant increase in resistant organisms with local vancomycin use.[9]

It is important to note that this study has several limitations. The results may not be applicable to a broader population because the study only used data from one location and had a limited sample size. Further information on pathogen-specific efficacy may have been obtained via a more comprehensive analysis of the microbiological profiles of the infecting organisms. It is recommended that future multicenter research verify these results and establish uniform criteria with larger samples and longer follow-up times. In patients undergoing instrumented posterior spinal fusion, the risk of surgical site infections can be significantly reduced by injecting vancomycin powder into the incision. In conjunction with routine intravenous antibiotic prophylaxis, it offers a safe, simple, and cost-effective way to prevent surgical site infections (SSIs). This supports the growing body of evidence that suggests it should be routinely used in spinal surgeries, particularly for patients at high risk.

## CONCLUSION

The intrawound use of vancomycin powder markedly decreases the occurrence of surgical site infections in instrumented posterior spinal fusion. Patients administered vancomycin had significantly reduced infection rates in contrast to those getting conventional prophylaxis alone. This approach is secure, economical, and improves localized antibiotic administration without systemic toxicity. Its regular application may enhance surgical results and reduce postoperative problems.

## CONFLICT OF INTEREST

The authors declare no conflict of interest.

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| AUTHORSHIP AND CONTRIBUTION DECLARATION | |
|---|---|
| 1 | **Shamsu Rahman:** Study design, data collection, manuscript writing. |
| 2 | **Muhammad Abdur Rehman:** Data analysis. |
| 3 | **Inamullah Asghar:** Editing. |
| 4 | **Taimoor Anwar:** Interpretation of results. |
| 5 | **Anum Wahab:** Data collection, referencing. |
| 6 | **Nazar Hussain:** Methodology, quality insurer. |