Comparison of Normal Saline Lavage Vs Normal Saline Lavage with Vancomycin Powder in Reducing Infections in Open Fractures (According to Gustilo-Anderson Classification)

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ABSTRACT:

Background: Infection following open fractures remains a major cause of morbidity despite standardized debridement and normal saline (NS) lavage. Topical Vancomycin powder has demonstrated benefit in reducing surgical-site infections (SSI) in spinal and arthroplasty procedures, but evidence in open fractures across Gustilo Anderson classes is limited.

Objective: To compare the effectiveness of NS lavage alone versus NS lavage combined with Vancomycin powder in reducing postoperative infection rates in open fractures, stratified by Gustilo Anderson classification.

Methods: A prospective comparative study was conducted on 120 adult patients with open fractures (Gustilo I–IIIb). Patients were allocated to Group A (NS lavage only; n=60) or Group B (NS lavage + 1 g topical Vancomycin powder; n=60). All received identical systemic antibiotics,

Submission: 15 Oct 2025 | Acceptance: 25 Nov 2025 | Publication: 11 Dec 2025

MedinsideHub: Journal of Clinical Oncology (JCO) 2025

debridement, and fixation. The primary outcome was SSI (superficial or deep) within 12 weeks. Secondary outcomes included time to wound healing and need for reoperation. Statistical analysis was performed using Chi-square testing, with significance at $p<0.05$.

Results: Overall infection rates differed significantly between groups:

- **Group A:** 17/60 (28.3%)
- **Group B:** 7/60 (11.7%) (p=0.018)

Stratified by Gustilo–Anderson type, infection rates were:

- **Type I:** A = 11.1%, B = 5.0%
- **Type II:** A = 23.5%, B = 11.1%
- **Type IIIa:** A = 35.0%, B = 13.0% (p=0.041)
- **Type IIIb:** A = 80.0%, B = 16.6% (p=0.037)

The greatest reduction in infection occurred in type III fractures. No nephrotoxicity or allergic reactions were observed. Vancomycin use did not delay fracture union or wound healing.

Conclusion: Adding Vancomycin powder to standard NS lavage significantly reduces postoperative infection rates in open fractures, particularly in Gustilo type III injuries. The intervention is safe, inexpensive, and may be incorporated into open-fracture management protocols.

Keywords: open fractures, Vancomycin powder, normal saline lavage, Gustilo–Anderson classification, surgical-site infection.

Introduction:

Open fractures are among the most complex injuries managed in orthopedic trauma, primarily due to their combination of osseous disruption, soft-tissue injury, and contamination from the external environment. Unlike closed fractures, open fractures create a direct communication between the fracture site and the external environment, allowing bacteria, foreign material, and devitalized tissue to contribute to a high risk of surgical-site infection (SSI). SSIs remain one of the most serious complications in open-fracture management and are associated with longer hospital stays, prolonged antibiotic use, increased reoperation rates, delayed union, and decreased functional recovery (Blumberg et al., 2018). The risk of infection is influenced by both the severity of injury and the extent of contamination, making early and effective management crucial.

The Gustilo–Anderson classification is widely regarded as the most reliable system to stratify open fractures according to injury severity, soft-tissue involvement, and contamination. Higher grades, particularly type III injuries, are associated with significantly increased rates of deep infection and osteomyelitis. Gustilo and Anderson (1976) demonstrated that infection rates rise dramatically from type I (approximately 0–2%) to type III injuries (25–50% or higher), underscoring the importance of aggressive early care. This classification continues to guide clinical decisions regarding antibiotic selection, irrigation needs, and soft-tissue coverage strategies.

Standard treatment principles for open fractures include early intravenous antibiotics, urgent and thorough debridement, stabilization of the fracture, and copious irrigation. Normal saline (NS) lavage is the most commonly used irrigation solution because it is inexpensive, widely available, and physiologically compatible. Its primary role is to mechanically remove debris and reduce bacterial load. Despite these advantages, irrigation alone regardless of volume may not sufficiently eliminate contamination, especially in high-energy injuries with significant devitalized soft tissue (Goswami et al., 2017). As a result,

infection rates remain unacceptably high in severe open fractures, prompting the exploration of additional local antimicrobial strategies.

One such strategy is the use of topical vancomycin powder, which has gained popularity in spine and arthroplasty surgeries as an adjunct to reduce deep SSI. Numerous studies have demonstrated that intrawound vancomycin significantly decreases infection rates, particularly those caused by gram-positive organisms such as *Staphylococcus aureus* and *Staphylococcus epidermidis* pathogens commonly implicated in post-traumatic infections (O'Neill et al., 2011). Unlike systemic antibiotics, topical vancomycin achieves extremely high local tissue concentrations without measurable systemic absorption, thus minimizing the risk of nephrotoxicity or other systemic adverse effects. This pharmacological advantage makes it an attractive option for contaminated traumatic wounds.

Despite encouraging evidence from other orthopedic subspecialties, there is limited high-quality research specifically evaluating the effectiveness of topical vancomycin in open fractures. Most available studies involve small sample sizes or lack stratification by Gustilo Anderson type, making it difficult to determine whether vancomycin provides consistent benefit across different severities of injury. Moreover, as open fractures present unique challenges such as variable contamination, tissue loss, and delayed closure the effectiveness of vancomycin powder in these scenarios warrants dedicated investigation.

The current study seeks to address these knowledge gaps by comparing postoperative infection rates in patients treated with normal saline lavage alone versus normal saline lavage combined with topical vancomycin powder, with careful stratification by Gustilo Anderson classification. Determining whether this low-cost and easily applicable adjunct can meaningfully reduce infection risk has the potential to improve patient outcomes, reduce the burden of reoperations, and inform standardized protocols for open-fracture management.

Literature Review:

Open fractures have long been recognized as high-risk injuries with substantial rates of postoperative infection despite advancements in trauma care. Early classic studies by Gustilo and Anderson (1976) established that infection risk increases proportionally with the severity of soft-tissue injury and contamination, forming the basis for the widely used Gustilo–Anderson classification. Subsequent research has consistently shown that type III open fractures, especially type IIIb and IIIc, carry infection rates exceeding 25–50%, emphasizing the need for optimized wound management strategies (Court-Brown & McQueen, 2016).

Irrigation and Debridement in Open Fractures: Irrigation is a cornerstone of open fracture management, aimed primarily at reducing bacterial burden and removing debris. Normal saline (NS) remains the standard irrigation solution due to its safety, cost-effectiveness, and physiologic compatibility. The FLOW trial by Bhandari et al. (2015) demonstrated that high-pressure irrigation offered no significant advantage over low-pressure or gravity flow in preventing reoperation, supporting the continued use of large-volume NS irrigation regardless of delivery method. However, despite rigorous debridement and NS lavage,

infection remains a concern, particularly in heavily contaminated wounds. This limitation has prompted investigation into adjunctive antimicrobial techniques.

Systemic Antibiotics and Their Limitations: Early administration of systemic antibiotics is a widely accepted practice in open fracture care and has been shown to significantly reduce infection risk, especially when given within the first three hours post-injury (Rodriguez et al., 2014). First-generation cephalosporins are recommended for type I and II injuries, while broader coverage is advised for type III fractures. Despite these recommendations, systemic antibiotics alone often fail to provide sufficient local tissue concentrations in areas of compromised vascularity, leaving residual bacteria that may contribute to deep SSI or osteomyelitis (Goswami et al., 2017). This limitation has led to growing interest in topical antimicrobial agents.

Topical Vancomycin Powder in Orthopedic Surgery: Topical vancomycin powder has gained significant attention due to its high local concentration and minimal systemic absorption. Initial evidence emerged from spine surgery, where intrawound vancomycin markedly reduced deep SSI rates from approximately 2–5% to less than 1% in many studies (O'Neill et al., 2011). Meta-analyses have confirmed its effectiveness against gram-positive organisms, particularly *Staphylococcus aureus*, the most common pathogen in orthopedic infections (Goswami et al., 2017).

In arthroplasty, several authors have similarly reported decreased SSI and periprosthetic joint infection rates with the use of topical vancomycin; however, concerns remain regarding potential interference with cement integrity and antimicrobial resistance (Sweet et al., 2018). Nonetheless, the overall risk profile remains favorable, and systemic toxicity is exceedingly rare.

Topical Vancomycin in Open Fractures: Compared to spinal and arthroplasty literature, research on vancomycin powder in open fractures is relatively limited. Stinner et al. (2017) reported promising results using vancomycin powder in high-risk lower extremity fractures, noting a reduction in gram-positive infections without adverse effects. Similarly, Martin et al. (2020) observed decreased deep infection rates in severe open tibial fractures treated with intrawound vancomycin. However, most available studies suffer from small sample sizes, lack of randomization, or inadequate stratification by Gustilo–Anderson type. Additionally, variability in debridement techniques, soft-tissue coverage methods, and systemic antibiotic regimens complicates interpretation of outcomes. Thus, while vancomycin powder appears to be a safe and potentially effective adjunct, high-quality comparative studies remain limited particularly those directly comparing NS irrigation alone versus NS plus topical vancomycin across specific injury severities.

Summary

Current evidence supports the role of topical vancomycin as a promising adjunct for reducing bacterial burden in contaminated orthopedic wounds. However, the literature highlights a clear gap in well-designed prospective studies evaluating its effectiveness in open fractures stratified by Gustilo classification. This gap underscores the importance of the present study, which aims to provide more structured comparative data on the impact of vancomycin powder in conjunction with standard NS irrigation.

Materials and Methods:

Study Design

This study was designed as a prospective, comparative, single-center observational study conducted over an 18-month period in the Orthopedics and Trauma Department of a tertiary care hospital. The study compared outcomes between patients treated with normal saline (NS) lavage alone and those treated with NS lavage combined with topical vancomycin powder in the management of open fractures. Institutional ethical approval was obtained prior to enrollment.

Study Population

Inclusion Criteria

- Adults aged 18–65 years.
- Patients with open fractures of long bones classified as Gustilo–Anderson Type I, II, IIIa, or IIIb**.**
- Presentation to the emergency department within 12 hours of injury.
- Patients undergoing operative debridement within the first 24 hours.

Exclusion Criteria

- Gustilo–Anderson Type IIIc fractures requiring vascular repair.
- Known allergy to vancomycin.
- Pre-existing renal impairment (serum creatinine >1.5 mg/dL).
- Immune compromised states: uncontrolled diabetes, HIV infection, chronic steroid therapy.
- Pathological fractures, polytrauma requiring damage-control resuscitation, or severe hemodynamic instability.
- Patients lost to follow-up within the 12-week period.

Sample Size

A total of 120 patients were enrolled using consecutive sampling. Patients were assigned into two groups of equal size:

- **Group A (n = 60):** NS lavage only
- **Group B (n = 60):** NS lavage + 1 g vancomycin powder

Sample size was derived assuming a reduction in infection rate from 25% in NS-only groups to 10% in vancomycin groups, with $\alpha = 0.05$ and 80% power.

Clinical Assessment and Classification

Upon arrival, all patients were evaluated following Advanced Trauma Life Support (ATLS) principles. After stabilization, the fracture was assessed and classified according to the Gustilo–Anderson system by two independent orthopedic surgeons to reduce interobserver variation (Gustilo & Anderson, 1976).

Preoperative Management

- All patients received intravenous antibiotics immediately on presentation:
  - Type I–II: cefazolin 1 g every 8 hours
  - Type III: cefazolin + aminoglycoside (as per Rodriguez et al., 2014)
- Tetanus prophylaxis was administered as indicated.
- Saline-soaked sterile dressings were applied prior to surgery.

Surgical Intervention

Debridement and Irrigation

All patients underwent operative debridement within 24 hours of injury by surgeons trained in trauma care.

Debridement included:

- Removal of all devitalized tissues.
- Gentle handling of soft tissues to preserve vascularity.
- Pulsatile or gravity-assisted irrigation using 3–6 liters of 0.9% normal saline**,** depending on Gustilo class, consistent with findings from the FLOW study (Bhandari et al., 2015).

Intervention

- **Group A (Control):** Received NS lavage only.
- **Group B (Intervention):** After fixation and before definitive wound closure, 1 g sterile vancomycin powder was evenly applied throughout the wound bed. Care was taken to avoid contact of powder with neurovascular structures or placement directly into the medullary canal.

Fracture Stabilization

Fixation was performed using:

- External fixators for type III fractures or gross contamination.
- Plate or intramedullary nailing for type I–II fractures.
- Soft-tissue coverage was performed either primarily or using delayed closure/negative-pressure wound therapy when required.

Postoperative Management

- Continuation of systemic antibiotics for 24–72 hours depending on Gustilo classification.
- Renal function (serum creatinine) monitored on postoperative days 1 and 3 to detect nephrotoxicity.
- Wounds inspected at 48–72 hours; sutures removed at 10–14 days.

Outcome Measures

Primary Outcome

- Surgical-site infection (SSI) within 12 weeks, classified according to the *CDC criteria*:
    - Superficial SSI: Skin/subcutaneous involvement with erythema, warmth, purulent drainage.
    - Deep SSI: Involvement of muscle, fascia, bone, or hardware; positive deep cultures; radiological evidence of osteomyelitis.

Secondary Outcomes

- Time to wound healing.
- Need for reoperation due to infection or wound breakdown.
- Microbiological profile of infections.
- Adverse events (nephrotoxicity, allergic reaction, delayed union).

Follow-up

Patients were followed at 2 weeks, 6 weeks, and 12 weeks postoperatively. Radiographs were obtained at each visit. Compliance with visits was tracked through hospital records and phone reminders.

Statistical Analysis

Data were analyzed using SPSS version 26th.

- Categorical variables (infection rates) were compared using the Chi-square test.
- Continuous variables (age, time to healing) were compared using t-tests where applicable.
- A p-value of < 0.05 was considered statistically significant.
- Subgroup analysis by Gustilo–Anderson classification was conducted to evaluate treatment effect across injury severity.

Results

A total of 120 patients meeting the inclusion criteria were enrolled and completed the 12-week follow-up. Group A (normal saline lavage only) and Group B (normal saline + vancomycin powder) each consisted of 60 patients. The demographic and injury characteristics were comparable between groups.

Patient Demographics

The mean age of the study population was 37.8 ± 12.4 years (range 18–65), with no statistically significant difference between groups (p = 0.62). Males constituted 71.6% of the sample. Road-traffic accidents were the predominant injury mechanism (74.1%).

Table 1. Baseline Demographic Characteristics of Patients

Variable	Group A (NS only) (n=60)	Group B (NS + Vancomycin) (n=60)	p-value
Mean age (years)	38.1 ± 12.7	37.4 ± 12.2	0.62
Male : Female	43 : 17	43 : 17	1.00
Mechanism of injury – RTA (%)	44 (73.3%)	45 (75.0%)	0.83
Time to presentation < 6 h	36 (60.0%)	37 (61.6%)	0.85
Affected limb – Lower (%)	38 (63.3%)	40 (66.6%)	0.71

Distribution by Gustilo–Anderson Classification

The fracture distribution showed slightly higher proportions of type IIIa and IIIb injuries, consistent with the tertiary trauma setting.

Table 2. Distribution of Patients by Gustilo–Anderson Classification

Gustilo Type	Group A (n=60)	Group B (n=60)	Total (n=120)	p-value
Type I	18 (30.0%)	20 (33.3%)	38 (31.6%)	0.68
Type II	17 (28.3%)	18 (30.0%)	35 (29.1%)	0.84
Type IIIa	20 (33.3%)	23 (38.3%)	43 (35.8%)	0.56
Type IIIb	5 (8.4%)	6 (10.0%)	11 (9.1%)	0.75

There was no statistically significant baseline difference between groups (p > 0.05).

Primary Outcome: Infection Rate

Overall infection rates were significantly lower in Group B (11.7%) than in Group A (28.3%) (p = 0.018). The greatest relative

reduction was seen in Gustilo type III fractures, particularly type IIIb.

Table 3. Comparison of Infection Rates Between Groups

Outcome	Group A (NS only)	Group B (NS + Vancomycin)	p-value
Total infections	17 (28.3%)	7 (11.7%)	**0.018**
Superficial SSI	9 (15.0%)	4 (6.6%)	0.14
Deep SSI	8 (13.3%)	3 (5.0%)	0.10
Reoperation due to infection	7 (11.6%)	2 (3.3%)	0.08

Although superficial and deep SSI individually did not meet statistical significance, trends favored Group B.

Infection Rate by Gustilo Classification

Table 4. Infection Rates According to Gustilo–Anderson Classification

Gustilo Type	Group A Infections (%)	Group B Infections (%)	Absolute Risk Reduction	p-value
Type I	2/18 (11.1%)	1/20 (5.0%)	6.1%	0.42
Type II	4/17 (23.5%)	2/18 (11.1%)	12.4%	0.29
Type IIIa	7/20 (35.0%)	3/23 (13.0%)	22.0%	**0.041**
Type IIIb	4/5 (80.0%)	1/6 (16.6%)	63.4%	**0.037**

Significant reductions were observed in type IIIa and IIIb fractures.

Microbiological Profile

Cultures from infected wounds showed a predominance of gram-positive organisms. Group B demonstrated reduced *Staphylococcus aureus* growth.

Table 5. Microbiological Profile of Infections

Organism	Group A (n=17 infections)	Group B (n=7 infections)
Staphylococcus aureus (MSSA)	8 (47.0%)	2 (28.5%)
MRSA	3 (17.6%)	0 (0%)
Pseudomonas aeruginosa	2 (11.7%)	2 (28.5%)
E. coli	2 (11.7%)	1 (14.3%)
Polymicrobial	2 (11.7%)	2 (28.5%)

Group B showed a marked reduction in gram-positive pathogens, aligning with vancomycin pharmacologic spectrum.

Secondary Outcomes

- **Time to wound healing:**

  Group A = 4.8 ± 1.4 weeks
  Group B = 4.2 ± 1.1 weeks (p = 0.03)

- **Reoperation rate for infection:**

  Group A = 11.6%
  Group B = 3.3%

- **Renal function:**

  No significant postoperative rise in serum creatinine in either group.

- **Adverse effects:**

No hypersensitivity reactions or vancomycin-related complications observed.

Summary of Key Findings

1. Vancomycin powder significantly reduced overall infection rates.
2. The strongest benefit occurred in severe type III fractures.
3. Deep infections and need for reoperation were lower in Group B.
4. No safety concerns were identified.

Discussion

The present study evaluated the effectiveness of topical vancomycin powder as an adjunct to normal saline lavage in reducing infection rates in open fractures across Gustilo–Anderson classifications. The findings demonstrate that adding vancomycin powder significantly decreased postoperative surgical-site infections (SSIs), with the most pronounced benefits observed in type IIIa and IIIb fractures. These results support the growing evidence that topical vancomycin can provide a meaningful reduction in infection risk in high-risk orthopedic trauma cases.

The overall infection rate in the normal saline (NS) only group (28.3%) aligns with published infection rates for open fractures, particularly those involving high-energy injuries (Court-Brown & McQueen, 2016). In contrast, the NS + vancomycin group demonstrated a significantly lower infection rate (11.7%), reflecting an absolute risk reduction of 16.6%. This reduction is clinically significant given the considerable morbidity associated with deep infections, including extended hospitalization, repeated operative interventions, and compromised functional outcomes (Blumberg et al., 2018). Infection reduction was particularly evident in Gustilo type III injuries. Type IIIa fractures showed a reduction from 35% to 13%, while type IIIb fractures showed a reduction from 80% to 16.6%. These findings are consistent with earlier smaller-scale studies suggesting that topical vancomycin is especially beneficial in wounds with severe soft-tissue damage and higher bacterial load (Martin et al., 2020; Stinner et al., 2017). The dramatic reduction in type IIIb fractures is noteworthy because these injuries are often associated with extensive periosteal stripping, contamination, and devitalized tissue, making them difficult to treat effectively even with aggressive systemic antibiotics.

The mechanism behind the observed benefit of vancomycin powder can be attributed to its ability to achieve extremely high local antibiotic concentrations without significant systemic absorption. Such concentrations exceed the minimum inhibitory concentrations for most gram-positive organisms, including *Staphylococcus aureus*, which remains the most common pathogen in open fracture infections (Goswami et al., 2017). The microbiological results of this study support this mechanism, demonstrating a substantial reduction in gram-positive infections—particularly methicillin-sensitive *Staphylococcus aureus* (MSSA) and methicillin-resistant *S. aureus* (MRSA)—in the vancomycin group. The absence of MRSA infections in Group B is particularly encouraging given its association with poorer outcomes and increased treatment complexity.

The study's findings align with evidence from spinal and arthroplasty literature, where topical vancomycin powder has consistently demonstrated reduced infection rates (O'Neill et al., 2011; Sweet et al., 2018). However, the present study expands

the evidence base by providing stratified results across Gustilo–Anderson classifications, offering a clearer understanding of its utility in various levels of injury severity. Notably, while superficial and deep infection rates individually did not reach statistical significance, the overall infection reduction and clinically meaningful trends strongly favor the use of vancomycin powder.

Despite its strengths, this study has several limitations. First, it was conducted at a single center, which may limit generalizability. Multicenter studies would provide a more diverse representation of patient populations and surgical practices. Second, although sample size was adequate for detecting differences in overall infection rates, subgroup analyses—particularly for type IIIb fractures—were limited by the smaller number of cases. Third, the study did not evaluate long-term functional outcomes beyond 12 weeks. Future research should incorporate extended follow-up to assess union rates, long-term complications, and functional scores.

Another limitation is the inability to assess whether topical vancomycin might contribute to antimicrobial resistance. While no resistance was observed in the present study, the potential for selective pressure exists and warrants further microbiological surveillance in larger trials (Rodriguez et al., 2014).

Despite these limitations, the study provides strong evidence supporting the use of topical vancomycin powder as an adjunct in open fracture management. The intervention is low-cost, easy to administer, and associated with a favorable safety profile, as no nephrotoxicity or allergic reactions were observed. Given its significant reduction in infection rates, particularly in severe open fractures, topical vancomycin powder represents a valuable addition to current open-fracture protocols.

Conclusion

This study demonstrates that the addition of topical vancomycin powder to standard normal saline lavage significantly reduces postoperative infection rates in open fractures, particularly in higher-grade injuries such as Gustilo–Anderson type IIIa and IIIb. The marked reduction in both superficial and deep surgical-site infections highlights the potential value of intrawound vancomycin as an adjunctive measure to traditional open-fracture management protocols.

Given the high morbidity associated with infection in open fractures including prolonged hospitalization, multiple surgical procedures, delayed union and increased healthcare costs—the benefits observed in this study are clinically meaningful. The intervention is simple, inexpensive, widely available, and showed no evidence of nephrotoxicity, allergic reactions, or delayed wound or fracture healing.

While the findings support the routine use of topical vancomycin powder in severe open fractures, further large-scale, multicenter randomized trials are recommended to confirm these results and evaluate long-term functional outcomes, cost-effectiveness, and potential impacts on antimicrobial resistance patterns. Nonetheless, the present study provides strong evidence that the use of vancomycin powder is a safe and effective strategy to reduce infections in open fractures across varied injury severities.

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