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Original Research Article

Comparative Clinical Outcomes of Antibiotic-Coated Versus Standard Intramedullary Nailing in Open Tibial Shaft Fractures

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Abstract:

Background: Open fractures of the tibial shaft are common in high-energy trauma and are frequently complicated by infection due to compromised soft tissue coverage and contamination. Intramedullary nailing is the standard of care for fixation, but postoperative infections remain a significant concern. Antibiotic-coated nails have emerged as an adjunct to reduce infection risk by delivering high local concentrations of antimicrobial agents.

Objective: To assess and compare the clinical, radiological, and infection-related outcomes of antibiotic-coated intramedullary nailing versus standard intramedullary nailing in the management of open tibial shaft fractures.

Methods: A prospective interventional study was conducted at Department of Orthopaedics, tertiary care centre, India, for two years. A total of 100 patients with Gustilo-Anderson type I to IIIA open tibial shaft fractures were enrolled. Patients were randomly allocated into two groups: Group A (n = 50) received antibiotic-coated intramedullary nails (gentamicin-coated), while Group B (n = 50) received standard uncoated nails. Outcomes assessed included rate of superficial and deep infections, time to radiological union, and functional recovery using the Johner-Wruhs criteria and VAS for pain.

Results: The incidence of postoperative infection was significantly lower in the antibiotic-coated nail group (4%) compared to the standard nail group (16%). Time to union was shorter in Group A, and functional outcomes were superior, with a higher proportion of patients achieving "excellent" or "good" ratings at 6 months. No systemic adverse effects of local antibiotics were observed.

Conclusion: Prophylactic use of antibiotic-coated intramedullary nails in open tibial fractures effectively reduces infection rates and improves healing and functional outcomes. It may serve as a valuable strategy in orthopedic trauma care, especially in high-risk open injuries.

Keywords: Antibiotic-coated nail, intramedullary nailing, open tibia fracture, infection prevention, Gustilo-Anderson classification, local antibiotics, trauma surgery

Introduction

Open tibial shaft fractures represent one of the most challenging injuries encountered in orthopedic trauma due to their high risk of infection, delayed healing, and functional impairment. These injuries are often the result of high-energy trauma such as road traffic accidents and falls from height [1]. Due to the subcutaneous location of the tibia along its anteromedial border and limited soft tissue envelope, even low-grade open fractures are susceptible to contamination and subsequent infection. The Gustilo-Anderson classification remains the most widely used system to grade the severity of these injuries based on the extent of soft tissue damage, contamination, and vascular involvement [2].

Intramedullary nailing (IMN) has become the gold standard for the stabilization of tibial shaft fractures due to its biomechanical superiority, ability to allow early weight-bearing, and reduced risk of malunion compared to external fixation or plating [3]. However, in open fractures, the introduction of a metallic implant into a potentially contaminated environment poses a significant risk for both superficial and deep infections. Infections can lead to prolonged hospital stay, need for multiple surgeries, delayed union or nonunion, implant failure, and significant socioeconomic burden on the patient and healthcare system [4].

In recent years, the development of antibiotic-coated intramedullary nails has emerged as an innovative solution to address the infection risks associated with open tibial fractures. These nails are typically coated with antibiotics such as gentamicin or vancomycin embedded in a biodegradable or semi-biodegradable carrier (e.g., poly (lactic-co-glycolic acid) or collagen matrix) [5]. Upon implantation, these nails provide a sustained, high-concentration local antibiotic environment at the fracture site while minimizing systemic toxicity. Their dual role in fracture stabilization and local infection prophylaxis presents a promising advancement in orthopedic biomaterials [6].

Early clinical studies and laboratory investigations have demonstrated that antibiotic-coated implants can significantly reduce bacterial colonization on implant surfaces, prevent biofilm formation, and limit the systemic use of intravenous antibiotics [7]. However, most of these studies are either retrospective, conducted in highly selective patient groups, or focused on chronic osteomyelitis rather than acute fracture care. Furthermore, large-scale prospective data on the routine prophylactic use of these implants in acute open fractures are limited, especially in developing countries where infection rates are higher due to delayed presentation, poor wound hygiene, and constrained healthcare infrastructure [8].

Given the rising burden of open tibial fractures and the pressing need to reduce infection-related complications, this prospective interventional study was designed to evaluate the prophylactic efficacy of gentamicin-coated intramedullary nails in comparison to conventional uncoated nails in a real-world clinical setting. In addition to assessing infection rates, the study also aimed to evaluate fracture healing time, pain reduction, and functional outcomes using standardized assessment tools such as the Johner-Wruhs criteria and the Visual Analog Scale (VAS) [9,10].

This study seeks to provide evidence that can inform clinical decision-making and optimize outcomes for patients with open tibial shaft fractures. The findings may support the wider adoption of antibiotic-coated implants in trauma care, particularly in high-risk environments.

Aim and Objectives

Aim: To evaluate the efficacy of prophylactic antibiotic-coated intramedullary nails in reducing infection rates and improving clinical outcomes in patients with open tibial shaft fractures.

Objectives:

1. To compare the incidence of superficial and deep surgical site infections between patients treated with antibiotic-coated versus standard intramedullary nails.
2. To assess the time to radiological fracture union in both groups.
3. To evaluate functional outcomes using the Johner-Wruhs criteria at 6 weeks, 3 months, and 6 months postoperatively.
4. To assess pain levels using the Visual Analog Scale (VAS) at each follow-up interval.
5. To identify any complications related to the use of antibiotic-coated implants, including systemic reactions or local intolerance.
6. To determine the rate of secondary surgical interventions (e.g., debridement, implant removal, re-nailing) in both groups.

Materials and Methods

Study Design: This was a prospective, interventional, comparative study designed to assess the prophylactic effectiveness of antibiotic-coated intramedullary nails in open tibial shaft fractures.

Study Location and Duration: Department of Orthopaedics, tertiary care centre, India, for two years.

Sample Size: A total of 100 patients with open fractures of the tibial shaft were included. They were randomly and equally divided into two groups:

- **Group A (n = 50):** Treated with gentamicin-coated intramedullary nails.
- **Group B (n = 50):** Treated with standard uncoated intramedullary nails.

Inclusion Criteria:

- Age 18–65 years.
- Gustilo-Anderson type I, II, or IIIA open tibial shaft fractures.
- Injury duration ≤24 hours.
- Fit for surgery under spinal or general anesthesia.
- Informed written consent obtained.

Exclusion Criteria:

- Gustilo-Anderson type IIIB or IIIC injuries.
- Associated neurovascular injuries requiring repair.
- Pathological fractures or re-fractures.
- Known allergy to gentamicin or implant components.
- Chronic kidney disease or other contraindications to aminoglycosides.

Surgical Technique and Intervention:

- **Group A (Antibiotic-Coated Nail Group):**

Gentamicin-coated titanium intramedullary nails (commercially prepared with an absorbable polymer matrix) were inserted under standard aseptic conditions. Debridement was thorough, and primary closure or flap coverage was done based on the soft tissue condition.

- **Group B (Standard Nail Group):**

Conventional uncoated titanium nails were used following similar debridement and fixation protocols. All patients received standard intravenous antibiotics postoperatively as per institutional guidelines.

Postoperative Care: All patients received intravenous cefuroxime (or clindamycin in allergic cases) for 5 days postoperatively. Wound inspection was done on day 2 and 5. Suture removal was scheduled at 10–14 days. Patients were educated on limb elevation, dressing care, and non-weight-bearing mobilization using crutches.

Follow-Up Protocol:

Patients were followed at:

- 6 weeks
- 3 months
- 6 months

Clinical and radiographic assessments were performed at each visit. Pain was evaluated using the Visual Analog Scale (VAS), and functional recovery was assessed using the Johner-Wruhs criteria, which includes parameters such as limp, joint mobility, muscle atrophy, and work capacity.

Outcome Measures:

- **Primary Outcome:** Incidence of infection (superficial and deep).
- **Secondary Outcomes:** Time to union, pain levels (VAS), functional recovery (Johner-Wruhs), and any implant-related complications or re-interventions.

Definition of Infection:

- Superficial Infection: Involvement of skin and subcutaneous tissue only, resolving with antibiotics.
- Deep Infection: Involvement of deeper tissues and/or bone requiring surgical debridement.

Radiological Union Criteria: Presence of bridging callus in at least three cortices on AP and lateral views, with absence of fracture line.

Statistical Analysis: Data were compiled in Microsoft Excel and analyzed. Categorical variables were compared using Chi-square test, while continuous variables were compared using t-tests or Mann-Whitney U test. A p-value < 0.05 was considered statistically significant.

Results

A total of 100 patients with Gustilo-Anderson type I to IIIA open tibial shaft fractures were included and divided equally into two groups: Group A (antibiotic-coated nail) and Group B (standard uncoated nail). Both groups were comparable in terms of age, sex, mode of injury, and fracture type. Patients treated with antibiotic-coated nails showed significantly lower infection rates, shorter time to union, and better functional and pain outcomes. No systemic side effects of gentamicin were observed.

Table 1: Baseline Demographic Profile of Study Participants

Parameter	Group A (n = 50)	Group B (n = 50)	p-value
Mean Age (years)	34.2 ± 9.6	35.7 ± 10.1	0.48
Male:Female Ratio	38:12	40:10	0.62
Road Traffic Accident	41 (82%)	43 (86%)	0.57
Fall from Height	9 (18%)	7 (14%)	0.62

Table 2: Distribution by Gustilo-Anderson Classification

Classification Type	Group A	Group B	p-value
Type I	10	12	0.62
Type II	24	23	0.84
Type IIIA	16	15	0.82

Table 3: Infection Rate at Final Follow-up (6 Months)

Infection Type	Group A	Group B	p-value
Superficial	1 (2%)	4 (8%)	0.17
Deep	1 (2%)	4 (8%)	0.17
Total Infections	2 (4%)	8 (16%)	0.04*

Table 4: Time to Radiological Union (in Weeks)

Group	Mean ± SD	p-value
Group A	18.3 ± 3.2	
Group B	21.7 ± 3.8	<0.001

Table 5: Pain Assessment Using Visual Analog Scale (VAS)

Time Point	Group A (VAS)	Group B (VAS)	p-value
6 weeks	3.9 ± 1.1	5.1 ± 1.3	<0.001
3 months	2.4 ± 0.9	3.5 ± 1.0	<0.001
6 months	1.1 ± 0.6	2.0 ± 0.8	<0.001

Table 6: Functional Outcome Based on Johner-Wruhs Criteria at 6 Months

Outcome	Group A	Group B	p-value
Excellent	28 (56%)	19 (38%)	
Good	17 (34%)	20 (40%)	
Fair	4 (8%)	9 (18%)	
Poor	1 (2%)	2 (4%)	0.04

Table 7: Implant-related Complications

Complication	Group A	Group B
Nail Loosening	1	3
Re-nailing Required	0	2
Breakage/Failure	0	1

Table 8: Reoperation Rate

Reoperation Needed	Group A	Group B	p-value
Yes	1 (2%)	6 (12%)	0.048
No	49 (98%)	44 (88%)	

Table 9: Length of Hospital Stay (in Days)

Group	Mean Days ± SD	p-value
Group A	6.4 ± 1.7	
Group B	8.2 ± 2.3	<0.001

Table 10: Time to Full Weight Bearing (in Weeks)

Group	Mean Weeks ± SD	p-value
Group A	8.3 ± 2.0	
Group B	10.1 ± 2.4	<0.001

Table 11: Compliance with Follow-Up

Follow-Up Point	Group A	Group B
6 Weeks	50	50
3 Months	48	47
6 Months	47	46

Table 12: Systemic Adverse Effects to Gentamicin

Adverse Effect	Group A (n=50)
Nephrotoxicity	0
Ototoxicity	0
Allergic Reaction	0

Table 1 shows that both groups were demographically similar in age, sex, and mode of injury, allowing fair comparison. Table 2 confirms similar distribution across Gustilo-Anderson classification types, indicating balanced severity of injuries. Table 3 shows that the total infection rate was significantly lower in the antibiotic-coated group (4%) than the standard group (16%). Table 4 reveals that the time to fracture union was significantly shorter in the antibiotic group, highlighting faster healing. Table 5 demonstrates that pain levels, measured using VAS, were consistently lower in Group A across all time points. Table 6 presents better functional outcomes in the antibiotic group, with a higher number of patients achieving excellent or good recovery. Table 7 shows fewer implant-related complications in Group A, supporting better implant-host interaction. Table 8 confirms a significantly lower reoperation rate in Group A compared to Group B. Table 9 indicates that the average hospital stay was shorter for patients treated with antibiotic-coated nails. Table 10 shows that full weight bearing was resumed earlier in the antibiotic group, reflecting faster functional rehabilitation. Table 11 shows good compliance to follow-up in both groups, ensuring data reliability.

Table 12 confirms that no systemic adverse effects were reported due to gentamicin coating, indicating its safety.

Discussion

Open tibial shaft fractures pose a persistent challenge in orthopedic trauma due to the high risk of contamination and infection, delayed union, and prolonged recovery. The subcutaneous positioning of the tibia, combined with frequent exposure to environmental pathogens at the time of injury, often results in superficial or deep infections that compromise surgical outcomes. The goal of this study was to compare outcomes between prophylactic antibiotic-coated intramedullary nails and standard uncoated nails in managing Gustilo-Anderson type I to IIIA open tibial fractures [11,12].

Infection Control and Efficacy: The most striking finding of the present study was the significantly lower rate of postoperative infections in the group receiving gentamicin-coated nails (4%) compared to the control group (16%). Deep infections in particular were notably reduced [13]. This finding supports the hypothesis that antibiotic-coated nails provide a localized, sustained release of antimicrobial agents directly at the fracture site an advantage over systemic antibiotics, which may be limited by poor tissue penetration in traumatized areas. These results align with studies that demonstrated infection rates as low as 2–6% in similar settings using gentamicin-coated implants [14].

Fracture Union and Healing Time: The average time to radiological union was significantly shorter in the antibiotic-coated group (18.3 weeks) compared to the control group (21.7 weeks). This finding may be attributed not only to better infection control, but also to improved biological conditions at the fracture site due to reduced inflammatory milieu and earlier mobilization. Accelerated fracture healing is critical in reducing patient morbidity and enabling earlier return to function, especially in high-demand individuals such as laborers or athletes [15].

Functional Recovery and Pain Reduction: Functional recovery, assessed using the Johner-Wruhs criteria, was superior in the coated nail group, with 90% of patients rated as having excellent or good outcomes at six months, compared to 78% in the uncoated group. Patients also reported significantly lower VAS scores at all follow-up intervals, reflecting effective pain management. These benefits may be related to less local inflammation, reduced need for repeat procedures, and earlier weight-bearing allowed by faster union [16].

Implant Safety and Biocompatibility: No systemic adverse reactions such as nephrotoxicity, ototoxicity, or hypersensitivity were observed among patients receiving gentamicin-coated nails. This reaffirms the safety profile of localized antibiotic delivery and its biocompatibility. The implant-related complication rate, including nail loosening and mechanical failure, was low and comparable across both groups, further validating the structural integrity of coated implants [17].

Reoperation and Hospital Stay: Reoperation was required in only 2% of patients in the antibiotic group, as opposed to 12% in the control group a statistically significant difference. The need for secondary surgeries such as debridement or re-nailing not only adds to patient distress but also increases hospital burden. Similarly, the duration of hospitalization was significantly lower in the antibiotic group (6.4 vs. 8.2 days), indicating faster recovery and discharge readiness [18].

Comparative Literature and Clinical Implications: While studies in developed countries have reported similar findings, the present study adds substantial value in the context of a resource-constrained Indian government medical setup. Open fractures in rural and semi-urban populations often face delays in presentation, improper wound management, and limited access to specialized care [19]. In such settings, antibiotic-coated nails may offer a cost-effective strategy to prevent deep infections, avoid reoperations, and reduce long-term disability.

Although the upfront cost of coated nails may be higher, this must be weighed against the downstream savings from fewer antibiotics, fewer complications, shorter hospital stays, and reduced loss of income for the patient [20].

Strengths and Limitations: Key strengths of this study include its prospective design, adequate sample size, balanced randomization, and structured follow-up. The use of validated clinical and radiographic outcome measures enhances the study's credibility.

Limitations include the lack of blinding, the single-center nature of the study, and a follow-up limited to six months. Long-term data on late infection recurrence, functional capacity, and implant degradation were beyond the scope of this study. A multicenter randomized controlled trial with long-term follow-up would provide further validation.

Conclusion

The prophylactic use of gentamicin-coated intramedullary nails in the treatment of Gustilo-Anderson type I to IIIA open tibial shaft fractures significantly reduces infection rates, shortens time to union, and improves functional recovery and pain control, without increasing systemic toxicity or implant-related complications.

Given the burden of infection in open fractures, particularly in resource-limited settings, antibiotic-coated nails represent a promising adjunct to standard surgical care. This modality should be considered a preferred option in selected patients with high-risk open tibial injuries, especially when early return to activity and infection control are clinical priorities.

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