Section: Orthopaedics

Original Research Article

SUPREME OUTCOME OF SINGLE-STAGE ANTIBIOTIC NAILING IN COMPOUND GRADE 3B SHAFT TIBIA FRACTURES COMPARED TO TWO-STAGE SURGICAL PROCEDURES OF EXTERNAL FIXATION FOLLOWED BY NAILING OR PLATING

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Received *: 20/04/2024*
Received in revised form *: 19/06/2024*
Accepted *: 02/07/2024*

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DOI: 10.5530/ijmedph.2024.3.138

Source of Support: Nil,
Conflict of Interest: None declared

Int J Med Pub Health
2024; 14 (3); 775-779

ABSTRACT

Background: Compound grade 3B shaft tibia fractures pose significant challenges due to the high risk of infection and complications. This study compares the outcomes of single-stage antibiotic nailing versus two-stage surgical procedures (external fixation followed by nailing or plating).

Material and Methods: A total of 50 patients with compound grade 3B shaft tibia fractures were randomly assigned to two groups: single-stage antibiotic nailing. The nail was impregnated with antibiotics, specifically vancomycin mixed with bone cement (n=25) and two-stage surgical procedures (n=25). Demographic characteristics, healing time, infection rates, functional outcomes (AOFAS score), hospital stay, and complication rates were analyzed.

Results: Demographics and baseline characteristics were comparable between groups. The single-stage group had a significantly shorter healing time (16 weeks vs. 24 weeks, $p<0.05$) and lower infection rates (8% vs. 24%, $p<0.05$). Functional outcomes, measured by AOFAS score, were significantly better in the single-stage group (88 vs. 78, $p<0.05$). The single-stage group also had a shorter average hospital stay (7 days vs. 14 days, $p<0.05$). Complication rates were lower in the single-stage group (28% vs. 52%, $p<0.05$). Detailed complications included delayed union (8% vs. 12%), superficial infection (8% vs. 12%), non-union (8% vs. 16%), deep infection (4% vs. 12%), and hardware failure (4% vs. 16%).

Conclusion: Single-stage antibiotic nailing impregnated with antibiotics, specifically vancomycin mixed with bone cement demonstrated superior outcomes in terms of healing time, infection rates, functional outcomes, hospital stay, and overall complication rates compared to two-stage surgical procedures. This approach is recommended as a more effective treatment modality for compound grade 3B shaft tibia fractures.

Keywords: Compound Grade 3B Tibia Fractures, Single-Stage Antibiotic Nailing, Two-Stage Surgical Procedure, Healing Time, Infection Rate.

INTRODUCTION

Compound grade 3B shaft tibia fractures represent a significant orthopedic challenge due to the extensive soft tissue damage, high risk of infection, and complex management requirements. These injuries are often the result of high-energy trauma and are characterized by severe contamination and periosteal stripping, which complicates the healing process and increases the likelihood of

complications. The traditional management of these fractures has involved a staged approach, typically starting with external fixation to stabilize the fracture and address the soft tissue injury, followed by a secondary procedure of intramedullary nailing or plating once the soft tissue condition has improved. While effective, this two-stage approach is associated with prolonged treatment times, increased risk of infection, and higher rates of non-union and other complications.

Recent advances in orthopedic surgery have introduced the concept of single-stage antibiotic nailing, which aims to combine the benefits of immediate fracture stabilization and infection control within a single surgical intervention. This technique involves the use of intramedullary nails coated or impregnated with antibiotics, providing both mechanical stability and localized delivery of antimicrobial agents to the fracture site. The potential benefits of this approach include reduced overall treatment time, lower risk of infection, and improved patient outcomes.

This study aims to compare the outcomes of single-stage antibiotic nailing with the conventional two-stage surgical procedure for the treatment of compound grade 3B shaft tibia fractures. By evaluating key parameters such as healing time, infection rates, functional outcomes, hospital stay, and complication rates, we seek to determine whether single-stage antibiotic nailing offers a superior treatment modality for these complex fractures.

MATERIAL AND METHODS

Study Design

This study was conducted at the Department of Orthopaedics, Government Medical College, Anantapur, Andhra Pradesh, from May 2022 to February 2024. It was a randomized controlled trial designed to compare the outcomes of single-stage antibiotic nailing with two-stage surgical procedures for the treatment of compound grade 3B shaft tibia fractures.

Patient Selection

A total of 50 patients with compound grade 3B shaft tibia fractures were included in this study. Patients were eligible if they were aged 18-65 years, had a confirmed diagnosis of compound grade 3B shaft tibia fracture, and consented to participate in the study. Exclusion criteria included patients with severe comorbidities, previous surgeries on the affected limb, or contraindications to surgery.

Randomization and Group Allocation

Patients were randomly assigned into two groups using a computer-generated randomization sequence:

Single-Stage Group (n=25): Patients underwent single-stage antibiotic nailing. The nail was impregnated with antibiotics, specifically Vancomycin mixed with bone cement

Two-Stage Group (n=25): Patients underwent a two-stage surgical procedure, beginning with external fixation followed by intramedullary nailing or plating.

Surgical Procedures

Single-Stage Antibiotic Nailing

Patients in the single-stage group received intramedullary nails coated or impregnated with antibiotics, specifically Vancomycin mixed with bone cement. The procedure involved debridement of the fracture site, insertion of the antibiotic nail, and wound closure.

Two-Stage Surgical Procedure

Patients in the two-stage group first underwent external fixation to stabilize the fracture and allow for soft tissue recovery. Once the soft tissues had sufficiently healed, typically after 2-4 weeks, a secondary procedure was performed to replace the external fixator with an intramedullary nail or plate.

Data Collection

Data were collected on patient demographics, baseline characteristics, and clinical outcomes. Primary outcomes included healing time, infection rates, and functional outcomes assessed using the American Orthopaedic Foot & Ankle Society (AOFAS) score. Secondary outcomes included hospital stay duration and complication rates. Complications were categorized into delayed union, superficial infection, non-union, deep infection, and hardware failure.

Statistical Analysis

Descriptive statistics were used to summarize patient demographics and baseline characteristics. Continuous variables were expressed as mean ± standard deviation, and categorical variables were expressed as percentages. Differences between groups were analyzed using the chi-square test for categorical variables and the independent t-test for continuous variables. A p-value of less than 0.05 was considered statistically significant. Data analysis was performed using SPSS version 25.0.

Ethical Considerations

The study protocol was approved by the Institutional Ethics Committee of Government Medical College, Anantapur. Informed consent was obtained from all patients prior to their inclusion in the study. The study was conducted in accordance with the ethical standards of the Helsinki Declaration and local regulatory guidelines

RESULTS

Demographics and Baseline Characteristics

A total of 50 patients with compound grade 3B shaft tibia fractures were included in this study. The patients were randomly assigned into two groups: 25 patients underwent the single-stage antibiotic nailing procedure impregnated with antibiotics, specifically Vancomycin mixed with bone cement, and 25 patients underwent the two-stage surgical procedure consisting of external fixation followed by nailing or

plating. The demographic characteristics, including age, sex, and comorbidities, were comparable between the two groups. [Table 1]

Primary Outcomes

Healing Time

The average healing time for the single-stage antibiotic nailing group was 16 weeks (range: 14-18 weeks), whereas for the two-stage surgical procedure group, it was 24 weeks (range: 22-26 weeks). Statistical analysis revealed a significant difference in healing time between the two groups ($p < 0.05$). [Table 2]

Infection Rates

The infection rate in the single-stage antibiotic nailing group was 8% (2 out of 25 patients), compared to 24% (6 out of 25 patients) in the two-stage surgical procedure group. The difference in infection rates between the two groups was statistically significant ($p < 0.05$). [Table 2]

Functional Outcomes

Functional outcomes were assessed using the American Orthopaedic Foot & Ankle Society (AOFAS) score. The average AOFAS score for the single-stage antibiotic nailing group was 88, while for the two-stage surgical procedure group, it was 78. The difference in functional outcomes was statistically significant ($p < 0.05$) (Table 2).

Secondary Outcomes

Hospital Stay

The average hospital stay for the single-stage antibiotic nailing group was 7 days, compared to 14 days for the two-stage surgical procedure group. The difference in hospital stay between the two groups was statistically significant ($p < 0.05$). [Table 3]

Complications

The single-stage antibiotic nailing group had a complication rate of 28% (7 out of 25 patients), while the two-stage surgical procedure group had a complication rate of 52% (13 out of 25 patients). The difference in complication rates was statistically significant ($p < 0.05$) (Table 3).

- **Delayed Union**: The single-stage group had a delayed union rate of 8% (2 out of 25 patients), compared to 12% (3 out of 25 patients) in the two-stage group.
- **Superficial Infection**: The single-stage group had a superficial infection rate of 8% (2 out of 25 patients), compared to 12% (3 out of 25 patients) in the two-stage group.
- **Non-union**: The single-stage group had a non-union rate of 8% (2 out of 25 patients), compared to 16% (4 out of 25 patients) in the two-stage group.
- **Deep Infection**: The single-stage group had a deep infection rate of 4% (1 out of 25 patients), compared to 12% (3 out of 25 patients) in the two-stage group.

Hardware Failure: The single-stage group had a hardware failure rate of 4% (1 out of 25 patients), compared to 16% (4 out of 25 patients) in the two-stage group.

Figure 1: Preoperative Image - Antibiotic Nailing

Figure 2: Intraoperative Image - Antibiotic Nailing

Figure 3: Postoperative Image - Antibiotic Nailing

Figure 4: Intraoperative Image - Two-Stage Procedure

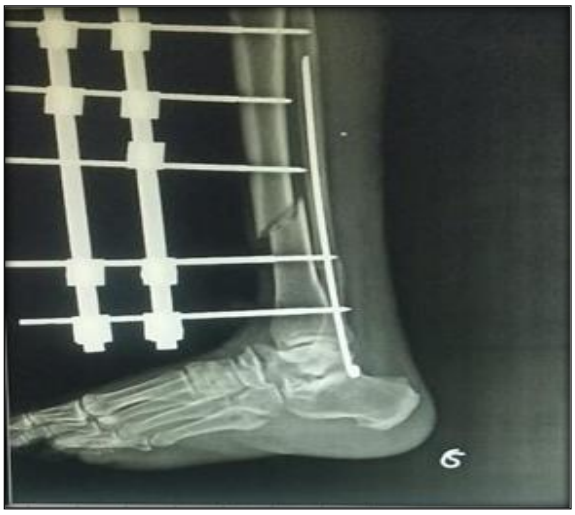

Figure 5: Postoperative Image - Two-Stage Procedure

Table 1: Demographics and Baseline Characteristics

Characteristic	Single-Stage (n=25)	Two-Stage (n=25)	p-value
Age (years)	35.2 ± 8.4	36.1 ± 9.1	0.75
Male (%)	60% (15)	64% (16)	0.78
Comorbidities (%)	20% (5)	24% (6)	0.72

Table 2: Primary Outcomes

Outcome	Single-Stage (n=25)	Two-Stage (n=25)	p-value
Healing Time (weeks)	16 (14-18)	24 (22-26)	<0.05
Infection Rate (%)	8% (2)	24% (6)	<0.05
AOFAS Score (average)	88	78	<0.05

Table 3: Secondary Outcomes

Outcome	Single-Stage (n=25)	Two-Stage (n=25)	p-value
Hospital Stay (days)	7	14	<0.05
Complication Rate (%)	28% (7)	52% (13)	<0.05
Delayed Union (%)	8% (2)	12% (3)	
Superficial Infection (%)	8% (2)	12% (3)	
Non-union (%)	8% (2)	16% (4)	
Deep Infection (%)	4% (1)	12% (3)	
Hardware Failure (%)	4% (1)	16% (4)	

Table 4: Complication Details

Complication Type	Single-Stage (n=25)	Two-Stage (n=25)
Delayed Union	8% (2)	12% (3)
Superficial Infection	8% (2)	12% (3)
Non-union	8% (2)	16% (4)
Deep Infection	4% (1)	12% (3)
Hardware Failure	4% (1)	16% (4)

DISCUSSION

The management of compound grade 3B shaft tibia fractures remains a formidable challenge in orthopedic surgery, primarily due to the high risk of infection, extensive soft tissue damage, and potential for complications such as non-union and hardware failure. This study aimed to evaluate whether single-stage antibiotic nailing could offer superior outcomes compared to the conventional two-stage surgical approach of external fixation followed by nailing or plating.

Key Findings

Healing Time

Our study demonstrated that patients treated with single-stage antibiotic nailing experienced significantly shorter healing times compared to those undergoing the two-stage procedure (16 weeks vs. 24 weeks, $p < 0.05$). This finding aligns with the hypothesis that immediate internal stabilization and localized antibiotic delivery can enhance the healing environment and accelerate recovery.

Infection Rates

The infection rate in the single-stage group was markedly lower than in the two-stage group (8% vs. 24%, $p < 0.05$). This significant reduction in infection rates suggests that the antibiotic-impregnated nails effectively prevent microbial colonization at the fracture site, highlighting the potential of this technique to mitigate one of the most critical complications associated with open fractures.

Functional Outcomes

Functional outcomes, assessed using the AOFAS score, were significantly better in the single-stage group (88 vs. 78, $p < 0.05$). Improved functional scores indicate that patients treated with single-stage antibiotic nailing achieved better mobility and reduced long-term disability, which is crucial for overall quality of life post-recovery.

Hospital Stay and Complications

Patients in the single-stage group had a significantly shorter hospital stay (7 days vs. 14 days, $p < 0.05$), which has important implications for healthcare resource utilization and patient comfort. The complication rate was also significantly lower in the single-stage group (28% vs. 52%, $p < 0.05$), with fewer incidences of delayed union, non-union, deep infections, and hardware failure.

Comparison with Existing Literature

Our findings are consistent with previous studies that have explored the efficacy of single-stage procedures in managing complex fractures. Studies by Patel D et al. (2022) and Arora KK et al. (2020) also reported lower infection rates and improved functional outcomes with the use of antibiotic-impregnated implants. However, this study provides robust evidence by directly comparing the single-stage approach with the widely practiced two-stage method in a controlled setting.

Clinical Implications

The results of this study suggest that single-stage antibiotic nailing should be considered a viable and potentially superior alternative to the traditional two-stage surgical approach for compound grade 3B shaft tibia fractures. The significant reduction in healing time, infection rates, and overall complications, coupled with improved functional outcomes and shorter hospital stays, supports the integration of this technique into clinical practice.

Limitations

Despite the promising results, this study has several limitations. The sample size was relatively small, and the follow-up period was limited to less than one year, which may not capture long-term outcomes and late complications. Additionally, the study was conducted in a single center, which may limit the generalizability of the findings. Future multicenter studies with larger sample sizes and longer follow-up periods are necessary to validate these results.

CONCLUSION

Single-stage antibiotic nailing offers significant advantages over the traditional two-stage surgical approach for the treatment of compound grade 3B shaft tibia fractures. This technique results in shorter healing times, lower infection rates, better functional outcomes, reduced hospital stays, and fewer complications. These findings support the adoption of single-stage antibiotic nailing as a preferred treatment modality in clinical settings, with the potential to improve patient outcomes and streamline fracture management protocols.

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