



# A Prospective Observational Study of Antibiotic Cement Impregnated Nailing in the Management of Infected Non-Union of Long Bones in A Tertiary Care Hospital in Chengalpattu District

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## KEYWORDS

Infected non-union, antibiotic cement nail, intramedullary nailing, osteomyelitis, fracture stabilization.

## ABSTRACT:

**Background:** Infected non-union of long bones presents significant clinical challenges due to poor vascularization, bacterial biofilms, and chronic infections. Conventional treatments require multiple surgical procedures, increasing morbidity and healthcare costs.

**Objective:** This study evaluates the effectiveness of a single-stage antibiotic cement-impregnated intramedullary nailing procedure in the management of infected non-union of long bones.

**Methods:** A prospective observational study was conducted in a tertiary care hospital in Chengalpet, Tamil Nadu. A total of 37 patients diagnosed with infected non-union were treated with antibiotic cement-impregnated intramedullary nails. Clinical outcomes were assessed through infection resolution, fracture stability, and radiological union.

**Results:** The study observed a high rate of infection control and radiological union. Patients showed significant improvements in infection markers (ESR, CRP) and functional outcomes.

**Conclusion:** Antibiotic cement-impregnated intramedullary nailing is an effective, economical, and single-stage treatment alternative to conventional multi-stage procedures for infected non-union of long bones.

## INTRODUCTION

Managing infected nonunion remains a significant challenge, despite improvements in antibiotics and surgical methods, resulting in high morbidity and increased healthcare costs. Persistent infections often

stem from inadequate blood flow, bacterial adherence to bone and implants, and slow bacterial replication. Effective treatment must focus on both infection control and mechanical stability.<sup>1,2</sup>



Historically, treatment has included surgical debridement and antibiotic therapy, followed by stabilization with internal or external fixation. Local antibiotic therapy has shown effectiveness by delivering high concentrations of antibiotics directly to the infection site, reducing systemic exposure and side effects.<sup>3</sup> This method, particularly with antibiotic-impregnated intramedullary nails, is effective for osteomyelitis and infections from open fractures, ensuring local antibiotic delivery while maintaining alignment and fixation.<sup>4</sup>

The fundamentals of bone infection management involve a comprehensive approach that integrates infection control, stabilization, and soft tissue repair.<sup>5</sup>

Infection management begins with thorough debridement to remove necrotic tissue, followed by irrigation with high-volume of sterile saline (up to 9 liters) to reduce the bacterial load. Deep tissue cultures are essential for accurate pathogen identification, especially in polymicrobial chronic osteomyelitis, enabling targeted antibiotic therapy.

Fracture stabilization is achieved using fixation devices like plates and screws or through antibiotic cement impregnated nailing, which provides both stability and localized antibiotic delivery.<sup>6</sup>

Soft tissue repair, often involving local or free vascularized muscle flaps, restores blood supply and promotes healing.

Surgical considerations include the use of tourniquets to minimize blood loss and atraumatic debridement to preserve viable tissue. The appearance of the "Paprika sign" (pinpoint bleeding) during debridement indicates healthy bone.<sup>7</sup>

High-pressure pulsatile lavage is the preferred irrigation technique, with antiseptics, antibiotics, and soaps sometimes added to enhance bacterial clearance.<sup>8</sup> Wound management involves keeping severe infection cases open for drainage, while closed wounds are considered when effective debridement is achieved.<sup>9</sup> Suction drains prevent fluid accumulation and are removed after 48-72 hours if output is below 30 mL/day.<sup>10</sup> Wick drainage with gauze ensures proper fluid evacuation, preventing infection-related complications. This integrated strategy significantly improves the treatment outcomes for infected nonunion cases.<sup>11</sup>

## Aim

To evaluate the role of antibiotic cement impregnated nailing in the management of infected nonunion of long bones

## Methodology

This study constitutes a prospective analysis carried out at Shri Sathya Sai Medical College and Research Institute from June 2023 to December 2024. It includes a total of 37 cases involving infected nonunion, bone infections, and cases of implant failures associated with nonunion and infection. The study population consisted of seven female and thirty male patients, with ages spanning from 21 to 65 years.

Within this group, 13 patients were identified as having Grade IIIB compound fractures, 7 as Grade II compound fractures, 5 as Grade I compound fractures, and 12 presented with closed fractures at the time of initial assessment.

All 37 patients were diagnosed with infected nonunion upon their initial presentation, with 18 individuals exhibiting bone defects ranging from 1 to 2.5 cm following the first debridement procedure.

The average duration for follow-up was 8 months, although it varied between 4 and 18 months. At the latest follow-up, all patients were free of infection, with the exception of one individual.

## INCLUSION CRITERIA

encompass fractures of the tibial and femoral shafts that have led to infected nonunion. This includes cases where surgical intervention has been performed on the femur and tibia, resulting in implant failure and subsequent nonunion due to infection, as well as compound fractures classified as Grade 3A and 3B.

## EXCLUSION CRITERIA

consist of fractures involving the joints, segmental bone defects greater than 3 cm, and patients with psychiatric or neurological conditions that hinder accurate assessment. Additionally, individuals with polytrauma or those who are unstable, as well as pediatric patients with open physal plates and metaphyseal fractures, are excluded from consideration.



The surgical technique focuses on the management of bone fractures, infections, and nonunions, including multiple essential steps:

#### 1. Preoperative Check-up:

Blood tests (CBC, ESR, CRP) are conducted to assess infection and inflammation.

Cultures are taken to identify pathogens, and radiographs are used to estimate bone length and alignment for surgery.

#### 2. Debridement:

Infected bone and soft tissue are carefully removed to promote healing. Samples are taken for culture and sensitivity testing. A fibular osteotomy is performed to improve fracture alignment and aid healing.

#### 3. Preparation of the Nail:

An antibiotic-impregnated intramedullary (IM) nail is prepared in the operating room. The nail is coated with antibiotic cement to reduce infection risk, and its size is chosen based on preoperative measurements.<sup>12,3,14,15</sup>

#### 4. Exchange Nailing:

In cases of nonunion with infection, the IM nail is replaced with a new, antibiotic-coated nail after obtaining culture results.<sup>16</sup>

#### 5. Postoperative Protocol:

The patient begins mobilization with support after 48 hours, with partial weight-bearing initiated after two weeks. Regular clinical and radiological evaluations track bone union, and blood tests monitor infection levels. Antibiotics are adjusted based on culture results, and physiotherapy aids recovery.

This comprehensive approach ensures effective management of fractures, infection control, and optimal healing.

## RESULTS

Among the 37 cases examined, 25 were attributed to compound injuries, while 12 were associated with initially closed fractures. The highest incidence was noted in individuals aged between 20 and 60 years. All incidents were linked to road traffic accidents, and a significant male predominance was observed in the data.

Furthermore, twelve cases required additional surgical procedures.

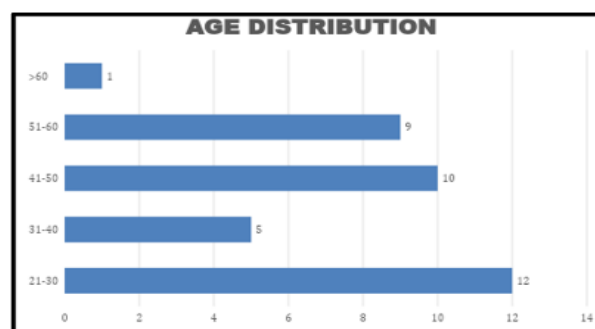
#### Evaluation Criteria:

**Bony Union:** The clinical assessment of the healing process concentrated on the complete absence of pain and tenderness at the fracture site. Radiological evaluation indicated healing through the presence of bridging callus formation on both the periosteal and endosteal surfaces. Bony union was confirmed in thirty-five cases.<sup>17</sup>

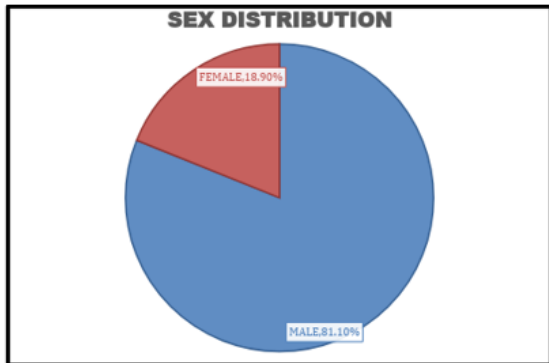
**Infection Control:** The evaluation was based on the presence of wound discharge, observable signs of inflammation, and laboratory tests including CBC, ESR, and CRP. Remission was defined by a marked improvement in symptoms and signs, a consistent decline in ESR and CRP levels, and the absence of any radiological evidence of active infection. Infection control was successfully achieved in thirty-six cases.

**Table 1: Maurizio Catagni's Classification<sup>18</sup>**

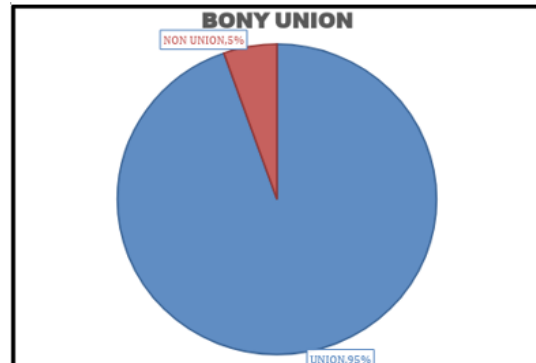
C1: Infected non-union accompanied by atrophy	12
C2: Infected non-union characterized by hypertrophy, - Deformity	10
C3: Infected non-union presenting hypertrophy, + Deformity	4
C4: Infected non-union featuring a gap measuring < 5 cm	11
C5: Infected non-union exhibiting a gap ranging from 5 - 10 cm	-
C6: Infected non-union involving a gap > 10 cm	-



**Graph 1: Age Distribution**



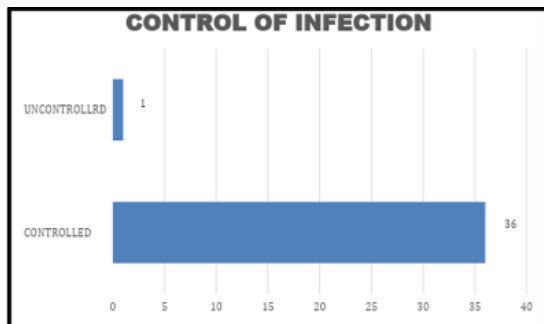
Graph 2: Sex Distribution



Graph 4: Bony Union

Table 2: Control of the Infection

Treated Bone	Cases	Control Infection of
TIBIA	28	27
FEMUR	9	9



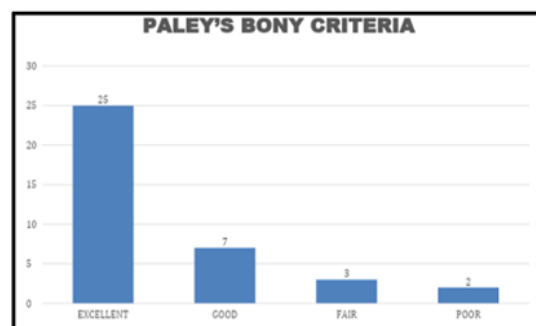
Graph 3: Control of Infection

Table 3: Union of the bone

Treated Bone	Cases	Bony Union
TIBIA	28	27
FEMUR	9	8

Table 4: PALEY'S BONY CRITERIA

Bony Criteria	Bony Union	Infection	Deformity	(LLD) Limb length discrepancy
Excellent	Achieved	Absent	<7°	<2.5 cm
Good	Achieved	Any 2 criteria		
Fair	Achieved	Any 1 criteria		
Poor	Non-Union	Regardless of whether the aforementioned criteria are met.		



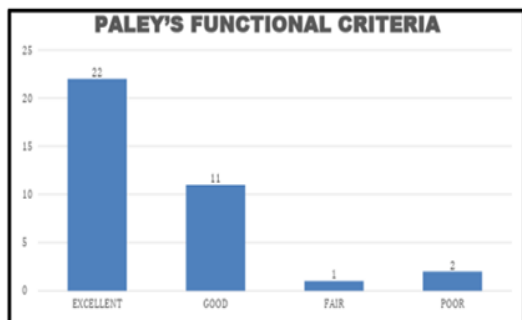
Graph 5: Paley's Bony Criteria

Table 5: PALEY'S FUNCTIONAL CRITERIA

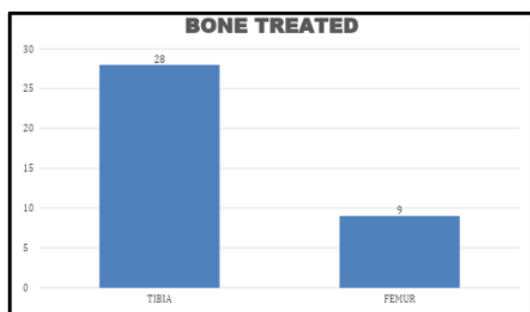
Criteria	Activity	Limp	Equinus Rigidity of Ankle	Soft Tissue Rigidity	Pain
Excellent	+	Negat	Negati	Nega	Nega



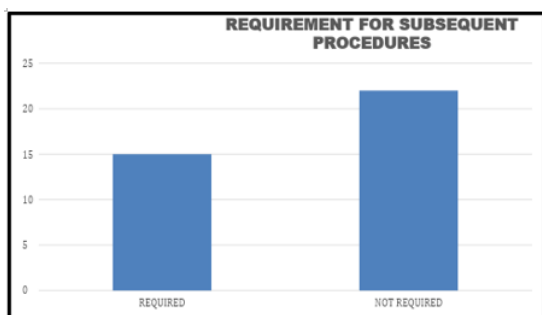
ent		ive	ve	tive	tive
Good	+	1-2 of the following criteria			
Fair	+	3-4 of the following criteria			
Poor	-	Whether any other criteria are present or not			



Graph 6: Paley's Functional Criteria



Graph 7: Bone treated



Graph 8: Subsequent procedures require

Table 6: Period of Follow up

Maximum	For 18 months
Minimum	For 4 months
Average	8 months

Table 7: Rate of Union

Treated bone	Min. duration	Max. duration	Average
TIBIA	For 20 weeks	For 32 weeks	26 weeks
FEMUR	For 18 weeks	For 28 weeks	24 weeks

- Two patients with nonunion decided they didn't want to have more surgeries to help their bones heal.
- Three patients had to get their nails replaced.
- Eight patients needed surgeries on their soft tissues to help control infections and get their bones to heal properly.
- Impingement of Patellar tendon was observed in a case involving the tibia during weight-bearing activities.
- An implant removal procedure was performed subsequent to the achievement of union.

**Table 8: Complications**

Persisting Nonunion	2
Uncontrolled Infection	1
Nail bending	1
Nail breakage	1
Impingement of Proximal nail	2
Migration of Distal nail	1
Debonding of Nail cement	2

**DISCUSSION**

Orthopaedic treatment for infected nonunion and segmental bone issues is really challenging. It requires comprehensive plans that not only address the infection but also ensure the bone structure remains intact to promote effective healing.<sup>42</sup> About 70% of patients end up with osteomyelitis, which is a common outcome in these cases and often involves multiple types of bacteria. Staphylococcus aureus is the most frequently identified



pathogen, a finding that our research and existing studies consistently support.<sup>43</sup>

To tackle these infections, Gentamicin and Vancomycin are commonly used for localized antibiotic treatment. These antibiotics are preferred because they can target a wide range of bacteria, remain effective under different conditions (heat resistant), and have a low risk of causing allergic reactions, making them suitable for many patients. Importantly, both clinical and experimental research has shown that these antibiotics can be effectively released over time when mixed with bone cement. This controlled release allows for ongoing antimicrobial action without hindering the bone healing process.<sup>20,22,,29</sup>

In our research, we successfully managed to control infections in 36 out of 37 cases, which aligns closely with the results reported by Ashok et al. in the Indian Journal of Orthopedics in October 2009.<sup>44</sup> While Ashok et al. used exchange nailing for all their cases, we only applied this method in three instances. Despite this difference in approach, we achieved successful bone healing in 35 out of 37 patients, showcasing the effectiveness of our treatment plan.

Conversely, various studies have yielded different results; for example, Zhang Qiang et al. reported successful bony union in 11 out of 19 cases, whereas Thonse et al. achieved union in 17 out of 20 cases.<sup>16,18</sup> These differences underscore the variability in treatment outcomes across various research efforts, highlighting the challenges associated with managing infected nonunion and segmental bone defects.

In summary, our research adds to the expanding evidence base that supports the efficacy of localized antibiotic delivery in treating infected nonunion and segmental bone defects. This emphasizes the necessity for customized treatment approaches that focus on both controlling infection and promoting bone healing.

Paley et al. have shown that infection control was successful in approximately 85% of cases, with bony union occurring in about 90% of patients treated with the Ilizarov technique. Our findings suggest even more promising outcomes within this specific patient group. The average time required for bony union was found to be 26 weeks for the tibia and 24 weeks for the femur, which closely corresponds with the findings of Han SK

et al., who reported an average of 26.4 weeks for the tibia and 31.5 weeks for the femur.

The use of external fixators is frequently associated with challenges such as low patient compliance, complications at pin sites, and increased difficulties in obese patients, which heightens the risk of pin site infections.

## CONCLUSION

The application of "Antibiotic cement impregnated nailing" provides a dual advantage by effectively managing infections while simultaneously enhancing stability, thereby promoting bone union that would typically necessitate two separate surgical procedures.

This method offers a notable benefit over external fixators by reducing the risk of complications and improving patient adherence to treatment. It is a safe, patient-focused strategy that can be easily implemented within hospital environments. The technique utilizes commonly available tools and materials, presenting a practical and cost-effective solution to a complex clinical challenge. In summary, this innovative approach serves as a flexible option for addressing orthopedic infections and facilitating healing.

"Antibiotic cement impregnated nailing is a straightforward, cost-effective, and highly efficient alternative compared to traditional methods for managing infected nonunion of the femur and tibia."

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