

# Management of Chronic Osteomyelitis of Shaft of Long Bones with Antibiotic Impregnated Cement Coated Intramedullary Nailing: A Prospective Analysis

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## Abstract

**Background/Aim:** The aim of this study was to study the outcome of antibiotic impregnated cement coated intramedullary nailing in the management of chronic osteomyelitis of shaft of long bones.

**Materials and Methods:** In this prospective study, 17 patients admitted in our hospital who were diagnosed with chronic osteomyelitis of long bones and culture-positive infected fractures of long bones were considered in the study and they were evaluated for a period of 12 months.

**Results:** Bony union was achieved at around 5 months (20 weeks) on average, and duration for control of infection in case of chronic osteomyelitis was around 4 months, complications such as persistent infection and non-union were around 18 % overall.

**Conclusion:** The main advantage of the antibiotic nail is that both the union and the infection can be addressed at the same surgery. Single-staged antibiotic nailing technique provides good results, lessens the duration of hospital stay, and reduces the morbidity in infected nonunion of long bones with <2 cm defect.

**Keywords:** Antibiotic impregnated cement-coated intramedullary nailing, Chronic osteomyelitis, Infected non-union, Infection.

## Introduction

High-velocity accidents often result in open fractures which pose orthopedic surgeons a difficult challenge in the course of treatment. These fractures have significant soft-tissue loss and the infection rate in these cases is pretty high, raising the danger of osteomyelitis and persistent infection [1].

In 1979, Gustilo [2] used antimicrobials in management of open fractures. The role of antibiotic therapy is always secondary to adequate debridement, irrigation, and definitive wound care in open fractures [2].

In the past 20 years, there has been a significant change in the approach in the treatment infections in orthopaedics. The treatment of osteomyelitis and infected non-union cases has become more methodical and systematic based on the understanding of the natural history of infection. New

treatment options and protocol based therapy have helped surgeons in treating these cases.

Osteomyelitis is a common orthopaedic condition. Either it can be post traumatic or hematogenous. Chronic osteomyelitis often weakens the bone and usually results in pathological fractures. These patients require long-term use of antibiotics systemically causing side effects. Antibiotic cement-coated intramedullary nailing can be very useful in these patients.

Antibiotic to be effective to control infection, the local concentration achieved should be above minimal inhibitory concentration (MIC). The antibiotic-loaded bone cement spacer has the advantage of local release of antibiotics, anatomical structures preservation, and decreased scar-tissue formation.

Bertazzoni Minelli et al. [3] in 2004 in a study stated that most of

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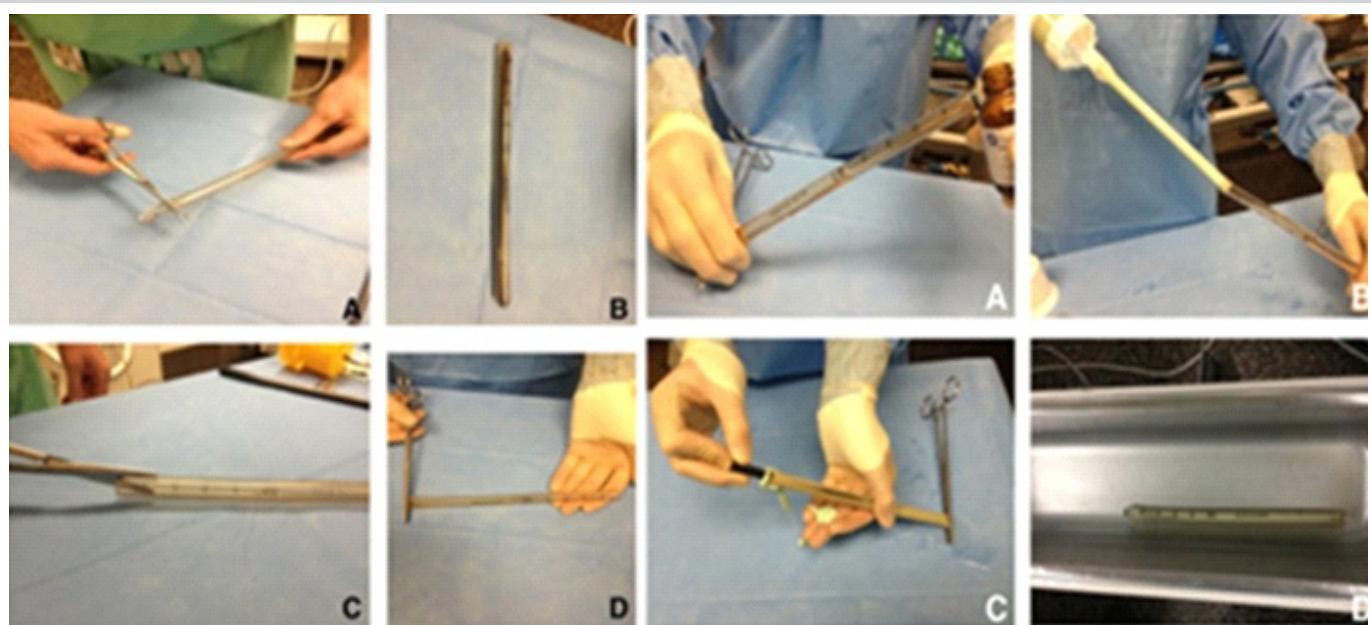
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**Figure 1:** Preparation of tubing and filling with antibiotic cement.

the polymethyl methacrylate (PMMA) spacers maintain the antibiotic release concentration more than MIC for many pathogens within the first few hours to days of implantation [3]. The local delivery of antibiotic will be increased many fold compared to systemic route and systemic antibiotics are not be effective on the biofilm forming organisms. The use of antibiotic cement coated nailing also reduces the side effects of systemic antibiotics when compared to the local delivery of antibiotics. The drug from the cement will be eluted slowly and, thus, provides longer duration of action.

In 2014, Kanakaris et al. [4] in their prospective case series used an intramedullary reaming device, the reamer-irrigator-

aspirator system, in association with antibiotic cement rods for the treatment of lower limb long bone infections [4]. A total of 24 such patients, 16 men and eight women, with a mean age of 44.5 years (17–75), 14 with femoral and ten with tibial infection, were treated. At a mean follow-up of 21 months (8–36), 23 patients (96%) had no evidence of recurrent infection [4].

In 2021, Wang et al. [5], in their study, stated that the treatment principles include eradication/debridement, stabilization, and antibiotic administration [5]. An antibiotic cement-coated nail has shown great prospects due to both local antibiotic elution and stabilization of bone defects [5].

### Materials and Methods

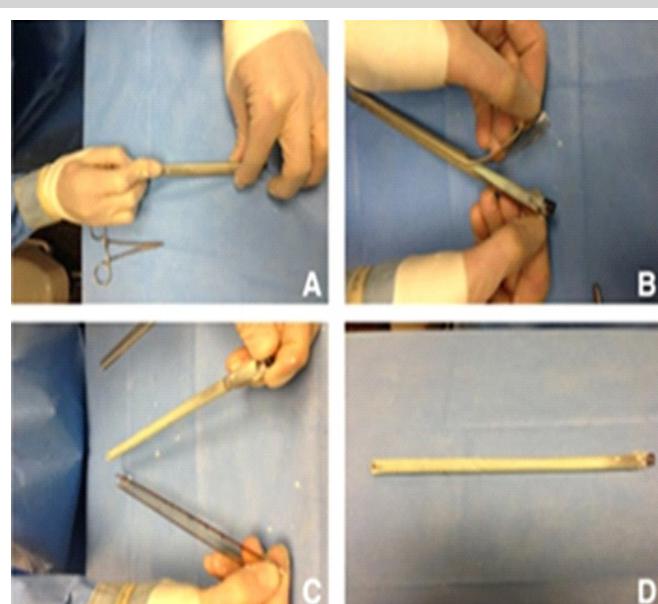
This study was conducted in a hospital affiliated with a medical college from February 2023 to March 2024 in Bengaluru. Seventeen cases admitted in our hospital who were diagnosed with chronic osteomyelitis and with culture-positive infected fractures were considered in the study.

Seventeen patients above the age of 18 who were admitted and who were on follow-up during the period of 12 months with infected fractures with or without implant in situ and patients with chronic osteomyelitis with discharging sinuses were included in the study.

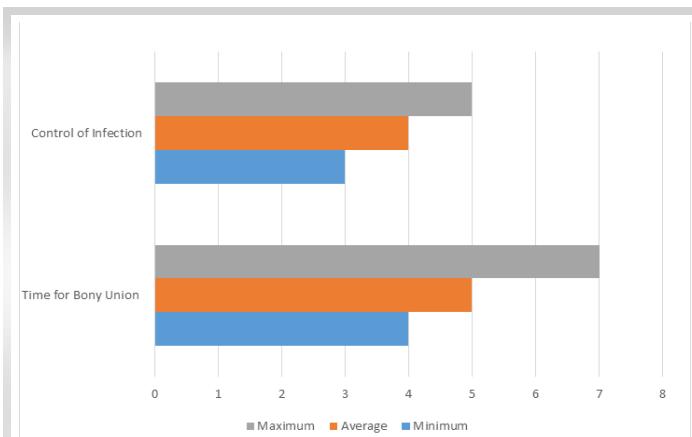
Patients aged <18 years, patients with severe comorbidities, and pregnant woman were excluded from the study.

In patients with implant in situ with nonunion and discharging sinuses, the implant was removed, the non-viable tissue thoroughly debrided till fresh bleed, the sclerotic ends of the fracture were freshened, and sequestrectomy was done.

Intraoperative cultures were taken and sensitivity tested for



**Figure 2:** Cutting of the tube and final preparation of antibiotic impregnated nail.



**Figure 3:** Bar diagram showing durations for bony union and control of infection in months.

deciding the post-operative antibiotic protocol.

Routine procedure for intramedullary nailing was followed and serial progressive reaming was done. Once the nail diameter was determined, cement mantle of 2 mm around the nail to be acquired and therefore nail of 2 mm less required for the regular nailing was used. Sterile tubes with 1/2 or 3/8<sup>th</sup> inch were used with an inner diameter which would be appropriate to our cement mantle and one end sealed. And through 20 cc syringe antibiotic bone cement dough was filled with the other end and nail was inserted inside the tube in the doughy state of cement (Fig. 1).

Once the cement settles, tube was cut open (Fig. 2) and entry holes for screw and guide wires were cleared and nail was inserted into the medullary canal and locked with screws as in case of regular nailing procedure.

Patients were evaluated based on Improvement in symptoms such as reduced signs of inflammation, decreased discharge from sinus, duration of hospital stay, time taken for bony union and time taken for weight bearing, complications, and radiological confirmation of union.

## Results

Seventeen patients fulfilling the inclusion and exclusion criteria were enrolled in the study. The mean age of the study population was 32.7 years. Individuals belonging to age group 18–30 years were 35% and 30–40 years were 30 %. In the study group, 15 (88%) were male and 2 (12 %) were female. Nine (52%) were right side affected and 8 (48%) were left side affected and bone-wise distribution was femur 7 (41%) and tibia 10 (59%).

Patients with chronic osteomyelitis comprised 6 (35%) and were classified further in chronic osteomyelitis based on Cierny-Madner Classification. Two patients were classified into Stage 2 and four patients into Stage 3, respectively. While the remaining 11 (65%) patients were pathologically categorized as infected non-union and were classified based on

Paleys classification with 6 into A2, 3 into B1, and 2 into B2, respectively.

The average duration for attaining bony union was around 5 months (20 weeks) with a minimum duration of 4 months (16 weeks) and maximum duration of 7 months (28 weeks).

The average duration for control of infection in case of chronic osteomyelitis was around 4 months (16 weeks) with a minimum of 3 months (12 weeks) and a maximum of 5 months (20 weeks). (Fig. 3)

Complications were noted in 3 (18%) patients, two cases had persistence of infection and one had non-union with settled infection.

## Discussion

There are two major issues that need to be addressed in infected non-union – one eradication of infection to achieve sterile background and secondly stable union. While the conventional method is cumbersome and a staged procedure involving control of infection first, followed by the union takes a prolonged duration of treatment which is often challenges the patience of both surgeons and patients, while more active and aggressive method involves addressing both infection and union in a single stage. Microorganisms generally forms a layer of biofilms around the implants which are generally resistant to systemic and oral antibiotics, so antibiotic-coated nailing can achieve both eradication of infection and bony union.

The standard treatment for chronic osteomyelitis is usually systemic antibiotics and surgical debridement. However, infective foci can still adhere to implants and form biofilm or a slime layer and will be resistant to antibiotics and are persistent of infection. In addition, infection may also results in decreased blood supply to the affected bones and therefore reducing the delivery of systemic antibiotics to the infected site. Hence, antibiotic cement impregnated nail acts as a carrier and platform for the release of drug locally which achieves a many fold high MIC at the site of infection and controls it.

*Staphylococcus aureus* was the most common organism from the culture taken from the infected site. All previous studies on treatment of infected nonunion such as Thonse and Conway [6], Bhatia et al. [7], Dhanasekhar et al. [8], Paley and Herzenberg [9] and Shyam AK et al. [10] have obtained similar results.

Vancomycin is the drug of choice in methicillin-resistant *S. aureus* and it was used in all the patients and also has ideal properties to be impregnated with PMMA. For vancomycin to be effective, the concentration of drug must be greater than the MIC >50% of the dosing interval. Intramedullary vancomycin can achieve a supratherapeutic concentration of >100 mg/mL, yet an undetectable concentration in systemic circulation. Higher concentration of antibiotic can be achieved locally up to

36 weeks using antibiotic-loaded cement.

Paley and Herzenberg [9] in 2002 first used antibiotic coated intramedullary nail to treat osteomyelitis in his series of nine cases [9]. Although union was not achieved, the infection was controlled in all cases with no recurrence. The highest incidence of nonunion was in the patients of age 25–40 years followed by age around 55 years and was probably due to increased incidence of road traffic accidents in the active age group and poor quality of bones and health in achieving infection and combating infection in the elderly population [9].

Bony union was achieved in 10 of 11 cases of infected non-union in our study. This was comparable with many other studies. Thonse and Conway [6] achieved 84% bony union in their study of 52 patients, which is the largest study on antibiotic cement-coated interlocking intramedullary nail for infected non-union [6]. However, Bhatia et al. [7] achieved only 60% of bone union probably due to their use of K nail instead of interlocking nail. Saravanan et al. [11] achieved union in 23 out of 25 patients out of which 20 patients had union with antibiotic cement-coated K nail [11].

Probably, the most famous study conducted on antibiotic cement-coated intramedullary spacers was done by Paley and Herzenberg [9] in 2002, which is the first study to report the use of fabricated intramedullary spacers and they achieved control of infection in all nine patients [9]. Some important conclusions were discussed in their study. The antibiotic coated rods act as intramedullary spacers filling the dead space and eluting antibiotic maintaining higher concentration locally even up to 36 weeks and providing stability at the same time. A combination of vancomycin and tobramycin was used in their study [9]. Bhatia et al. [7] achieved 95% infection control using

**Declaration of patient consent:** The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient has given his consent for his images and other clinical information to be reported in the Journal. The patient understands that his name and initials will not be published, and due efforts will be made to conceal his identity, but anonymity cannot be guaranteed.

**Conflict of Interest:** NIL; **Source of Support:** NIL

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vancomycin and teicoplanin [7].

The average duration of bony union in our study was about 20 weeks and that for control of infection was around 16 weeks. This is in accordance with other studies. All the studies report an average time union of around 5 to 8 months.

## Conclusion

The idea of antibiotic cement coated intramedullary interlocking nail has reached significant results and upgrades since introduction in the year 2002 in treating infected nonunion and chronic osteomyelitis with intramedullary infections. The main advantage of the antibiotic nail is that both the union and the infection can be addressed at the same surgery. Single-staged antibiotic nailing technique provides good results, lessens the duration of hospital stay, and reduces the morbidity in infected non-union of long bones with <2 cm defect.

## Limitations of our study

Small sample size, single-center study – conducted at one tertiary care center, reducing external validity, no control group, short follow-up period, functional, and quality-of-life outcomes were not quantitatively assessed using validated scoring systems, limiting comprehensive evaluation of patient recovery.

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