



ANTIBIOTIC IMPREGNATED CEMENT COATED NAILING IN MANAGEMENT OF INFECTED NON-UNION OF LONG BONE DIAPHYSEAL FRACTURES

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ABSTRACT **Introduction:** Infected nonunion of long bones is a chronic and debilitating disorder. The problems in treating them are infection, instability, and deformity. Traditionally, it is managed by two-stage procedure for controlling the infection first and then treating the nonunion. Effectiveness of antibiotic impregnated cement coated intramedullary nail as a single stage treatment modality for treating infection and achieving stability at the same time has been described in the literature currently..

Materials and Methods: Fifteen patients (above 18 years of age) with infected non-union of femur and tibia were selected and surgically treated with antibiotic cement coated iln. Antibiotic cement nail was prepared using endotracheal tube method. Antibiotics used are vancomycin 4 mg . Functional results were evaluated with regard to control of infection, bony union, and complications.

Results: Infection was controlled in 85% of the patients. With Average period of follow-up of 12 months bony union was achieved in 10 of 15 (66%) patients with antibiotic cement nailing as the only procedure with average time of union of 32 weeks. Remaining 5 patients required additional procedures like bone grafting or exchange nailing and these were done in two patients, with union of fracture. Recurrence of infection occurred in two cases. Complications encountered were difficult nail removal in two cases, broken nail in one case, and bent nail in one case.

Conclusion: Antibiotic cement impregnated nailing is a simple, economical and effective single stage procedure with better patient compliance for the management of infected nonunion of long bones. Instruments are easily available and performed at any orthopaedic center.

KEYWORDS : Antibiotic cement coated nail, bone cement, vancomycin, infected nonunion.

INTRODUCTION

Infected nonunion of tibia and femur are common in clinical practice¹. Various factors contribute to infected non-unions, including open fractures, loss of soft tissue or bone, infection after internal fixation, chronic osteomyelitis with pathologic fractures, and surgical debridement of infected bone². Heretofore, there has still been a challenge for orthopedic surgeons about the treatment of infected nonunion of tibia and femur.

Most of the orthopaedic trauma infections are caused by biofilm-forming bacteria³. Once formed, it protects the microorganism from antimicrobials, opsonization, and phagocytosis, thus contributing to the chronicity of infections⁴.

According to Gustilo,⁵ problems associated with infected nonunion are avascularity at the fracture site due to scarring and cicatrization as a result of multiple surgeries, drug resistance to pathogenic organisms, restriction of neighbouring joint motion, and gap nonunion. Infection creates an unfavourable environment for fracture healing, especially when it is associated with mechanical instability⁶. Excellent knowledge of the pathophysiology of lesions and the biomechanical concept of fixation techniques is essential for better functional outcome⁷.

Conventionally, treatment of an infected nonunion follows a two-stage procedure. The first stage comprises of debridement with or without antibiotic cement bead insertion and systemic antibiotics to convert an infected nonunion to an aseptic nonunion. The second stage is performed to achieve stability by either external or internal fixation with or without bone grafting^{8,9-12}.

Single staged procedures such as debridement and application of external fixator or use of antibiotic cement impregnated intramedullary nails (ACIINs) have been described.¹³ However, a high prevalence of pinsite infections, muscle contractures, and joint stiffness has been observed in association with external fixation. The use of an antibiotic cement impregnated IM nailing for infected nonunion of tibia and femur fractures has been well documented in the literature¹³⁻²⁰. The cement nail provides stability across the fracture site, unlike cement beads, and osseous stability is important in the management of an infected nonunion^{19,20}. Secondly, antibiotic cement allows higher concentration of antibiotic at the local site than is

achievable with systemic antibiotics and is associated with fewer side effects.

Local antibiotic therapy is a useful technique that results in high local concentrations of antibiotics and is associated with fewer side effects. Broad spectrum antibiotics such as clindamycin and vancomycin are used in our study. Two antibiotics with bone cement widen the spectrum of activity and also enhance the elution properties of the two antibiotics^{7,21}.

ACIINs provides a high concentration of antibiotics locally, fills dead space, gives good mechanical stability at fracture site, and thereby promotes bone healing.^{14,16} Thus, ACIINs provides all the advantages of cement beads¹⁷. This study was undertaken to evaluate the usefulness of ACIIN in case of infected nonunion of long bones.

Antibiotic at the local sites for up to 36 weeks thus having a therapeutic effect on refractory infection^{18,19}. Hence, unlike traditional methods of management of infected nonunion antibiotic cement coated nailing acts as a single stage procedure by providing stability and treating infection at the same time along with other advantages like early mobilization, avoidance of pin site infections, ease of performance and being cost effective.

Antibiotics used for this purpose should have special properties such as broad spectrum of activity, heat stability, and low allergenicity. Gentamicin has been the most widely used agent followed by vancomycin^{7,21}. In our study, we used the combination of vancomycin with teicoplanin as both have the desired properties. The purpose of our study was to evaluate the outcome of antibiotic cement coated nailing in the management of infected nonunion of tibia in terms of infection control and bony union.

MATERIALS AND METHODS

This study conducted from sept 2019 to sept 2021. Inclusion criteria were infected nonunion of the tibia and femur with no evidence of union and without bone loss. Patients with the radiologically visible or intraoperative finding of gap nonunion of >1 cm.

patients with multiple medical comorbidities and those with hypersensitivity to antibiotics were excluded from the study. All patients were thoroughly investigated and evaluated by clinical and radiological means.

Fifteen cases of infected nonunion were included in our study for treatment of infected nonunion and to evaluate the results. There were 12 tibia and 3 femur cases above the age of 18 years, were treated using antibiotic cement coated nail in cases of primarily infected fracture (in which no primary intervention had been done) and secondarily infected fractures (in which the prior intervention was done and got infected) with no bone defect. Preoperative investigations like complete blood count, erythrocyte sedimentation rate, C-reactive protein, culture and sensitivity of pus discharge are done in all patients.

Management is based upon:

- Radical thorough debridement locally at fracture site and thorough reaming and lavage of the medullary canal
- Antibiotic-impregnated cement coating over the nail
- Mechanical stability by Intra-medullary interlocking nail.

Operative procedure

After thorough preoperative evaluation, informed consent were taken for surgery. The first step in cases previously operated involves removal of the implant. This was followed by thorough debridement of the infected bone and soft tissues with copious lavage. Specimens of the bone, soft tissues and any purulent material were sent for culture and sensitivity. After that, intramedullary canal was adequately reamed and prepared to fit a larger diameter nail, it was thoroughly washed with saline.

The surgical team then changed their gowns and gloves. The limb was prepared again and re-draped. An appropriate size antibiotic impregnated nail was prepared on a separate sterile table. The required length of the nail was determined with the same standard method used to determine the length of interlocking nail. Nail of 8 or 9 mm diameter was chosen and coated with bone cement up to 1 mm less than the diameter of the last reamer used. 40 gm of cement was thoroughly mixed with 4 gm vancomycin. An endotracheal tube of the internal diameter same as the desired diameter of the cement coated nail was then filled with the doughy mixture of antibiotics and cement. Nail of diameter 2 mm less was then pushed through this endotracheal tube and allowed to set for 10-15 minutes. The endotracheal tube was then cut open using a surgical knife to retrieve the nail uniformly coated with antibiotic cement. Eyes of the nail were kept uncovered to facilitate easy removal later. The nail was then inserted antegrade in the tibia. Nail-cement debonding during insertion was avoided by allowing adequate time for the cement to set and bond with the nail.

Postoperative protocol

Post-operatively, the wound was inspected at 48-72 hours intervals and the patient was administered intravenous antibiotics as per culture and sensitivity reports for 2-4 weeks. The patient would then be discharged on oral antibiotics for a time period depending on individual patient characteristic, condition of the wound and the organism involved.

As soon as the wound healed, a patellar tendon-bearing cast or brace was applied and gradual weight bearing was permitted. The cast was changed every six weeks and continued till union was confirmed based on clinical and radiological assessments. Active physiotherapy for regaining ankle and knee mobility was instituted till the range of movement was satisfactory. Patients were followed up every week for first one month after discharge, then once a month for three months and then once every 2-3 months till the final follow-up. The average period of follow-up was 13 months.

Patients were evaluated in terms of infection control and bony union. They were divided into following categories (1) infection controlled, sound bony union (2) infection controlled, signs of fracture healing with partial union (3) infection controlled, no signs of fracture healing (4) infection persisting, no signs of fracture healing. Depending on the above, it was decided which patients needed further intervention like bone grafting or exchange nailing, etc.

RESULTS:

out of 15 cases of nonunion, 12 cases were tibia and 3 were femur.

	No of cases	percentage
Tibia	12	80
Femur	3	20

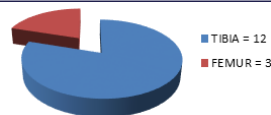


Fig:1 Number of cases involved in the study

After an average follow up of 12 months, complete bone union was achieved in 10 out of 15 cases which doesn't required any additional procedure. 2 patients shows no signs of fracture healing and required additional bone grafting and exchange nailing after 40wks of follow up.

Infection was recurred in 2 cases one in tibia and one in femur which was managed by iv antibiotic administration and 1 case underwent into nonunion.

DISCUSSION

The main concern for infected nonunion long bone fractures is control the infection and to provide stability to achieve union.

In conventional two stage procedure, control of infection first and subsequently treat the nonunion.

Surgical debridement and delivery of antibiotic locally and systemically are used to control the infection. Local antibiotic therapy results in high local concentration of antibiotic with minimum systemic level.

Various delivery systems were developed to achieve desired level of concentration of antibiotics systemically and locally, and is essential to control infection. PMMA cement, however, is the most commonly used and cost effective delivery material.

After being mixed into the PMMA cement, antibiotics are steadily released from the cement's surface and from cracks and voids in the cement.

Antibiotic-impregnated polymethylmethacrylate cement beads for local delivery of antibiotics without any systemic toxicity has been well documented. Gentamycin and vancomycin are common choices for local delivery of antibiotics because of their broad spectrum of activity, heat stability, and low allergenicity, have good elution property.

Wider surface area of elution allows for high antibiotic concentration along entire length of the bone. This is essential as necrotic and avascular segments are impermeable to systemic parenteral antibiotic therapy.

To achieve stability across fracture site external or internal fixation can be adopted. However, external fixation is associated with high prevalence of pin-site infections, muscle contractures, and joint stiffness. Ilizarov fixator, though excellent modality to treat infected nonunion, is a cumbersome and has a low acceptability among patients. Internal fixators acts as a foreign body and forms biofilm, which makes very difficult to eradicate by systemic antibiotics.

Without causing any systemic toxicity and also providing stability at nonunion site, antibiotic impregnated intramedullary nailing delivers a high concentrations of antibiotics locally, converting two stage procedure of treating nonunion into a single stage procedure.

In our study, one patient reported with broken nail and one patient with bent nail which was due to non-compliance and early unprotected weight bearing. Another complication observed in our study was difficult nail removal, seen in two patients, which may be attributed to improper nail preparation and late presentation to hospital for removal. Recurrence of infections occurred in two patients in our study.



Fig 2: Antibiotic coated cement tibial nail.



A case of antibiotic coated intramedullary nailing for tibia in a case of infected nonunion.

- a) preoperative xray
- b) immediate postoperative xray
- c) follow up x-ray after 6 months.

CONCLUSION:

Antibiotic cement coated nailing is an economical and effective single stage procedure to achieve infection control and provide stability, bone union in infected long bone fractures without bone gap. In our study, infection was controlled in 85% of cases. Bony union achieved in 10 out of 15 cases (66%). 2 cases required further additional procedures such as bone marrow infiltration, plasma rich protein infiltration, or bone grafting. Recurrence of infection occurred in two cases. Hence it is concluded that antibiotic cement coated intramedullary nailing is a cost effective and single stage procedure without much complications in infected nonunion tibial and femur shaft fracture cases.

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