



Original Research Article

Advantage of antibiotic cement-coated interlocking intramedullary nail (tibia nail/femur nail) over conventionally used antibiotic cement-coated Kuntscher nail in infected nonunion

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ABSTRACT

Background: Open fracture are very prone to chronic infection. The infection of long bones during its process of fracture healing not only delay but may completely abort the fracture healing and leads to nonunion. Infection along with its nonunion is very difficult to treat and a debilitating disorder which bother both the patients and surgeon. However in many studies, this situation is usually managed with multiple steps first to cure the infection before dealing with nonunion. But this is a single step procedure to cure both infection and nonunion simultaneously with intramedullary nail that coated with antibiotic cement. It is difficult to achieves axial and rotational stability along with controlling infection by antibiotic cement-coated Kuntscher nail. This study we have compare the outcome in term of control the infection and treating nonunion and complication associated with these. And also the advantage of antibiotic cement-coated interlocking intramedullary nail (tibia nail / femur nail) for achieving good stability.

Materials and Methods: In our study we included 20 adult patients all have stablised infective nonunion and divided into two group according to types of intramedullary nail used. In group A 12 adult patients with infective nonunion of tibia & femur (9 tibia and 3 femur) were managed using antibiotic cement-coated interlocking intramedullary nail (group A)(tibia nail / femure nail) with proximal and distal locking screws. And in group B 8 adult patients with stablised infective nonunion of tibia & femur (7 tibia and 1 femur) were treated using antibiotic cement-coated K-nail. Combination of Antibiotics used are 4gm vancomycin and 3gm clindamycin in 40gm bone cement package.

Results: Controlled of infection is 90% (18 out of 20 patients) similar in both. Bony union achieved in 83% (10 out of 12 patients) in group A with average time of union is 6 months. Bony union 62.5% (5 out of 8 patients) in group B with average time of union 8 months. The additional procedures in remaining were done as bone grafting, bone marrow infiltration and exchange nailing. Persistence of infection still present in 2 patients. All these patients are followed-up was up to 1 year.

Conclusion: Using of Antibiotic-cement coated interlocking intramedullary nail (tibia nail / femure nail) with locking screws is a simple, economical, and effective single-stage procedure for the management of infected nonunion of the long bones. It has many advantages over conventional antibiotic cement-coated Kuntscher nail, as it eliminates the complications and has good patient compliance. The method can be performed at any hospital with existing easily available instrumentation and is technically less demanding.

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1. Introduction

Infection of long bones during its process of fracture healing becomes very challenging for surgeon. Co-morbid condition such as diabetes, smoking, chronic NSAIDS

further worse the situation and limb threatening problem to patients. Almost orthopedic infections usually caused by proctative layer (biofilm) forming bacteria. These infection very difficult to treat because these are impermeable to immune system and antimicrobial agent and contribute to chronic infection. Throughout debridement of nacroctic

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tissue and removing of fibrous tissue also helps in increase vascularity and increase antibiotic delivery at fracture site. High delivery of antibiotic concentration through antibiotic cement coated intramedullary nail at help in eradication of infection and convert into aseptic condition. Immobilisation of fracture with intramedullary nail promote the fracture healing.

Traditionally, The use of an antibiotic cement-impregnated intramedullary nailing (K-nail) for infected nonunion of tibia and femur fractures has been used for decade.¹⁻⁴ this very effective single-stage procedure for treating infected non-union and have been widely used. This procedure has many limitation in terms of stability and has significant complications like bending of nail, broken nail, migration in joint space. The antibiotic coated interlocking intramedullary nail fills in the dead space, provides a high concentration of antibiotics locally without any significance systemic side effect locally, and gives good mechanical as well as axial and rotational stability.¹⁻⁴ However; this studies have used two groups of patients (one with antibiotic cement coated K nail and another with antibiotic cement coated interlocking intramedullary nail) cases without significant bone defect. The present study was undertaken to analyze the advantage of antibiotic cement coated interlocking intramedullary nail over conventionally use of antibiotic coated k-nail in cases of infected non-union in aspect of controlling infection and achieving fracture union in long bone and associated complications.

2. Materials and Methods

There are 20 patients (of established infected nonunion without significant bone loss) included in our study and all treated with intramedullary antibiotic cement coated nail, divided according to implant used. Group A were treated using antibiotic cement-coated nail (interlocking intramedullary nail) in cases of primarily infected fracture without bone defect. Group B patients are treated with intramedullary antibiotic mixed cement coated K-nail without bone loss.

2.1. Inclusion criteria

Infected nonunion of the tibia and femur with no evidence of union and without bone loss.

2.2. Exclusion criteria

Patients with the intraoperative finding of bone gap nonunion of >1.5 cm.

Patients with multiple medical comorbidities such as cardiac related disease and those with hypersensitivity to antibiotics were excluded from the study.

All patients were thoroughly investigated and evaluated by clinical and radiological means. Preoperative culture and sensitivity of pus discharge and intraoperative soft tissue are

done in all patients.

2.3. Management is based upon

1. Thorough debridement necrotic soft tissue and removing fibrous tissue locally at fracture site and thorough reaming and irrigation lavage of the medullary canal with saline.
2. Immobilization of fracture using Antibiotic-impregnated cement coating over the intramedullary nail.

2.3.1. Group A

This group included 12 adult patients with established infective nonunion (3 femur and 9 tibias) presenting to SRG Hospital. All patients treated with antibiotic mixed cement coating over interlocking intramedullary nail (femur and tibia nail) using vancomycin and clindamycin. All pt had established infective non-unions with no bone loss, with the mean duration of infection was 3 months.

2.3.2. Group B

This group included 8 adult patients retrospectively studied in SRG hospital Jhalawar with infected non union presented in year 2017-2018. And treated with conventional antibiotic mixed cement coating over K-Nail (1 femur, 7 tibias). These all the patients had compound fracture and developed infective nonunion.

2.4. Operative procedure

After investigation, and radiologically assessment of fracture nonunion patients were posted for surgery. Initially throughout radical debriment of infected necrotic tissue and fibrous tissue removed and sample collected for culture and sensitivity. The intramedullary canal was reamed to size 1 mm more than the prepared antibiotic cement coating nail.

The wound and the entire reamed medullary canal were irrigated with hydrogen peroxide + betadine+ normal saline and lavage of about 1-2 L of normal saline.

The recommended mix ratio of antibiotic to bone cement We used was 4 g of vancomycin and 3 g of clindamycin mixed with every 40 g of bone cement.⁵ Manual mixing and application of the cement was done in a uniform smooth layer excluding the interlocking site to facilitate screw fixation of the nail and the eye to facilitate easy removal later in k-nail. Size of implant was decided according to the length of long bone.

For group A the diameter of interlocking nail is selected as thinner as possible to accommodate 1mm of antibiotic cement coating over it. For femur, we used 9mm diameter and for tibia it was 8mm in diameter. The smooth surface of nail has been roughed with sterile sand papper Before coating with antibiotic mixed cement over the nail to prevent debonding of cement during insertion. The excess

cement over the locking hole is removed before it set. The cement coating done separately on sterile table. It is inserted anterograde manually with the help of zig over the guide wire. Insertion of the nail was guided by guide wire with easy.

Group B for this group of patient 6mm or 7mm of diameter k-nail is selected for the antibiotic mixed cement coating over it. The k-nail was directly inserted anterograde manually with precaution as no guiding wire can be use.



Fig. 1:

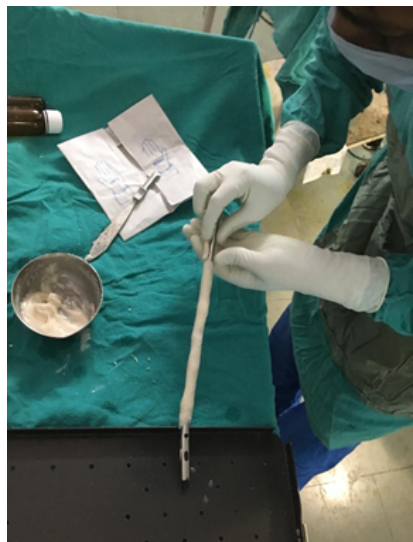


Fig. 2:

K-Nail is clover shaped so cement debonding during insertion is not a common complication in this. However it was avoided by allowing adequate time for the cement

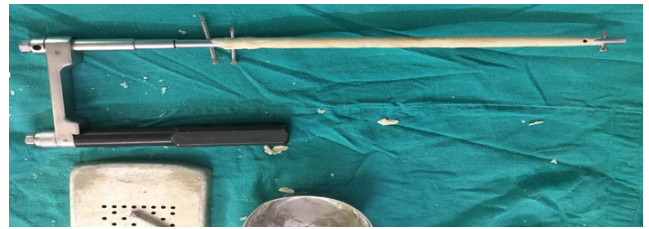


Fig. 3:

to set and gently anterograde insertion without rotatory movement. Wound closure done in layers.

Anteroposterior and lateral radiographs were taken during procedure and thereafter following procedures.

All patients were administered 4–6 weeks of antibiotics.

Control of Infection was monitored by wound discharge, clinical signs of inflammation, and laboratory investigation such as Complete blood count, ESR, and C Reactive protein. Postoperatively regularly dressing and physiotherapy to regain the knee and ankle joint mobility. Bony union assess at 4 weeks of interval by until radiological and clinical sign of union appear.

3. Result

There were total 20 cases of established infected nonunion involved in our study for treatment for antibiotic cement coated intramedullary nail (either K-nail or interlocking Nail). The preoperative and intraoperative specimen of pus and soft tissue showed positive culture for *Staphylococcus aureus* in all 19 cases, one samples were positive for *Klebsiella*. All the patients achieved infection control with normal laboratory parameters and no active discharge in an average of 6 weeks (5-8 week). All patient divided into two group as per type of intramedullary nail used.

3.1. Group A

There are 12 patients included in group A treated with antibiotic cement coated interlocking intramedullary nail.

11 cases in this group achieved infection control by 6 weeks and 1 after 2nd week required debridement with one antibiotic cement block insertion to control infection and wound healed with no discharge after 11th week. Cultures obtained at the time of rod removal were negative in all patients. Fracture union with radiological callus was seen in 10 cases out of 12 and with the average time to union being 8 months(range, 6-11 months) for this group.

Remaining 2 cases required exchange nailing, bone grafting, bone marrow infiltration.

3.2. Group B

In this group there 7 patients achieved infection control by 6.5 weeks. 1 patient required additional procedure. Clinical

and radiological bony union achieved in 5 patients with the average time to union being 8 months (range, 7–11 months) for this group.

Remaining 3 cases required bone grafting, bone marrow infiltration.

The complication in this group reported are 1 patient report bending and broken k-nail, one patient reported bending of k-nail, one reported migration into adjacent joint difficult nail removal seen in three patients, which may be attributed to improper nail preparation and late presentation to hospital and finally k-nail removed with corticotomy.



Fig. 4:

4. Discussion

Infection over long bone fractures not only retard the fracture healing but also increase morbidity and functional disability of patients. Which leads to delay the union or sometime completely abort the fracture healing process. In such cases it require the procedure to provide stability along with controlling infection to achieve union.⁶ Traditionally multistep approach is widely used to deal the infected nonunion, first step to cure the infection along with or without external fixator. After controlling the infection nonunion is treat with internal fixation with without bone grafting. Which causes a significant morbidity and increases the hospital stay and economical loss. Using an antibiotic mixed cement coated interlocking intramedullary nail instead of conventionally used antibiotic coated K-nail for infected nonunion not only control the infection but also provide the rotational & axial stability to enhance the bony union and it has less complication compare to antibiotic-cement coated k-nail such as difficulty in removal, bending,



Fig. 5:



Fig. 6:



Fig. 7:



Fig. 8:

migration into adjacent joint, prone to broken. Easy removal after fitting with conical bolt provide great advantage for antibiotic mixed cement coated interlocking intramedullary nail (tibia/femur nail) compare to k-nail as it can bend insitu rotate, migrate into medullary canal and which make it difficult to locate the eye for removal.

Surgical debridement of necrotic tissue and higher concentration of antibiotic either locally very effective to eradicate the infection.⁶

This method of local delivery of antibiotics also used in many condition related to chronic bone infection and open fracture.⁷ PMMA cement is the most commonly used and also a cost-effective antibiotics delivery material. After being mixed into the PMMA cement and coated over implant, these antibiotics are steadily released from the cement's surface and from cracks and voids in the cement⁸ results in high local concentration of antibiotic with minimum systemic toxicity.⁶

The selected antibiotics are should have a broad spectrum of activity, heat stable with good elution properties from the cement and should have low allergenicity. Many previous study in the past used a combination of vancomycin with gentamicin or tobramycin. In our study, we used a combination of vancomycin and clindamycin as most of the culture and sensitivity reports from the patients at our center were reporting *S. aureus*.



Fig. 9:



Fig. 10:



Fig. 11:



Fig. 12:

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. There is a high local concentration of antibiotic even in the presence of extensive scarring and compromised vascularity. Patients with elevated renal parameters can be treated with effective concentration of antibiotic without side effects.⁹

Other conventionally used external fixator or Ilizarov is cumbersome and very poor patient compliance. Patient compliance is found poor with this method as in external fixator or Ilizarov the apparatus is bulky and prone for pin-tract infection. For this, regular follow-up is cumbersome for a patient with external fixator. In patients with ACIIN Postoperative morbidity is less due to early passive mobilization of the limb, and it essentially helps in early rehabilitation.¹⁰

5. Conclusions

ACIINs is a good procedure to achieve early infection control, provide stability, and bone union with single-stage procedure in infected long bone fractures without bone gap.

In group A, infection was controlled in all cases. Bony union achieved in 10 out of 12 cases (83%). Rest 2 cases required further additional procedures such as bone marrow infiltration, plasma-rich protein infiltration, or bone grafting, exchange nailing. Recurrence of infection occurred in two cases. Average time to union being 8 months (range, 6–11 months) for this group.

In group B all patients achieved infection control. Clinical bony union achieved in 5 patients with the average time to union being 8.5 months (range, 7–11 months) for this group.

5.1. Remaining 3 cases required bone grafting, bone marrow infiltration

The complication in this group reported are 1 patient report bending and broken k-nail, one patient reported bending of k-nail, one reported migration into adjacent joint. Difficult nail removal seen in three patients.

Thus, both antibiotic coated interlocking intramedullary nailing and antibiotic coated K-nail are effective method to control infection and achieve bony union as single step procedure. However there many disadvantages with antibiotic coated k-nail.

1. Difficulty in removal:- uneven or thicker coating leads to difficulty in removal, and after bending or mig prevent of the nail bending, to be broken nail and to achieve better rotational and axial stability and for very easy removal/ exchange antibiotic coated interlocking intramedullary nailing is a better choice with better patient compliance and satisfaction. This

method achieves infection control, promotes bone union, and mechanical stability.

6. Source of Funding

None.

7. Conflict of Interest

None.

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