



## **Antibiotic Cement Coated Nailing in Infected Nonunion of Tibia**

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### **Authors' contributions**

*This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.*

### **Article Information**

DOI: 10.9734/JPRI/2021/v33i29B31599

Editor(s):

(1) Dr. Vasudevan Mani, Qassim University, Saudi Arabia.

Reviewers:

(1) Ankita Sen, NRS Medical College, India.

(2) Perkins Muredzi, Harare Institute of Technology, Zimbabwe.

Complete Peer review History: <http://www.sdiarticle4.com/review-history/68467>

**Original Research Article**

**Received 14 March 2021**

**Accepted 23 May 2021**

**Published 26 May 2021**

### **ABSTRACT**

Non-union infected bone is a chronic impairment disorder that causes severe complications for surgeons. In Pakistan a very limited literature was produced in recent years to evaluate the role of antibiotic impregnated cemented nail in infected non-union of tibia. To fill this gap this prospective study was designed to investigate the role of antibiotic Cement Coated Nailing in Infected Nonunion of Tibia in the Orthopedic Department of Liaquat University of medical and health science, Jamshoro, Pakistan, from February 2019 to February 2020. A total of 30 patients with infected "nonunion of the tibia" was enrolled during the research period. Patients within the age range of 22-61 years were part of this research. For surgery, polymer beads were added into the 40 gm cement

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which was prepared by adding 2 gm vancomycin and 2 gm teicoplanin. After that endotracheal tube was cut by a surgical knife to recover antibiotic and cement coated k nail. The nail was then inserted into the tibia. Results demonstrate that in 28 patients 93% utilization of antibiotics cement coated nails helped to eradicate the infection. 24 patients achieved complete bone unification without any need for further procedure. The overall ratio of single-time antibiotic cement coated nail was observed as 70%. The infected nonunion tibia can be effectively treated if the protocol of debridement is correctly followed. Results demonstrate that bone stability can be regained with 22 to 44 weeks. We concluded that antibiotic-impregnated cemented nail is an ideal procedure to control the postoperative infection and achieve reunion.

*Keywords: Non-union infected Tibia; antibiotics soaked cement; k nailing; polymer beads.*

## 1. INTRODUCTION

Non-union infected bone is a chronic impairment disorder that causes severe complications for surgeons. The management of these chronic non-union infections may affect the healthcare department by demanding high cost and long time- effective treatment [1]. Many factors including open fractures, soft tissue loss, an infection that arises after internal fixation, chronic osteomyelitis along with pathological fractures, and removal of damaged tissue from a wound during surgery may contribute to chronic non-union bone infection. The formation of biofilms bacteria in internal implantation causes severe obstacles to deal with the infection [2].

In many orthopedic traumas, the formation of biofilm is a major source of infection. These biofilms are comprised of polysaccharides and protein. When formed, they cause preservation of micro organisms from antimicrobials, opsonization, and phagocytosis which eventually results in chronic infection [3]. Cierny and Mader proposed four principles to deal with the issue of biofilm-forming bacteria. The principles are based on the complete investigation of surgical debridement, stabilization of fracture, soft tissue coverage, and analysis of antibiotics level to eradicate infection. These principles are helpful to cure biofilm infections and must be observed during clinical evaluation [4].

In recent years, infected non-union tibia cases were treated with a two-step procedure. The first step consists of treating debridement by inserting non antibiotic or antibiotic cemented beads into an aseptic nonunion. In the second step, orthopedics recover the stability of bone through internal or external fixations. This trend changes after the introduction of antibiotic permeate cement coated with nails. These antibiotic soaking cement nails gain attention after achieving a high success ratio for the stability of

femur fractures and nonunion infected tibia<sup>5</sup>. These antibiotic nails have fewer side effects on the infection if continuously used for 36 weeks at the local site. These low-cost antibiotic nails converted traditional long-term two-step procedures into the single-stage with a high probability of early mobilization without any pin site infections [1,2].

This study was designed to investigate the role of antibiotic Cement Coated Nailing in Infected Nonunion of Tibia.

## 2. METHODOLOGY

This prospective study was conducted in Orthopedic Department of Liaquat University of medical and health science, Jamshoro, Pakistan from the February 2019 to February 2020. A total of 30 patients with infected nonunion of the tibia were enrolled during the research period. Patients within the age range of 22-61 years were part of this research. Concerning the inclusion criteria, the researchers only selected patients with a bone gap less than 2 cm at the time of tibia diaphyseal fracture. Those patients were treated with antibiotic cement-coated nailing. In the matter of study exclusion criteria, all the patients having a history of allergies from vancomycin or teicoplanin were excluded. Before surgical intervention, patients underwent thorough clinical and laboratory examination. The evidence of bacterial cultures was observed under the electron microscope.

Of the 30 patients, 17 patients had open fractures whereas thirteen had undergone multiple procedures. In 16 patients researchers observed staphylococcus aureus during laboratory evaluation of the patient's specimen before surgery. Out of these 16 patients, 14 revealed resistances to gentamicin. The remaining eight had clinical evidence of infection.

After clinical and laboratory evidence gathering, patients were prepared for surgical intervention. Written consents were requested from patients after informing them about the objectives and side-effects of antibiotics used for the research. In previously operated patients, their implant, debridement of soft tissue and infected bone, was removed with the help of copious lavage. The specimens of soft tissue were sent to the laboratory to evaluate the culture and sensitivity. On the other hand, intramedullary was washed with saline and prepared with reamers for fitting larger diameter nail in the cut. The limb was prepared again and re-draped. The length of the nail was determined by using the standard method of determining interlocking nails. This appropriate nail was prepared with antibiotics and set on the sterile table. On the other hand, 6 to 7 mm Kutscher nail was coated with bone cement. This nail was coated up to 1 mm and the researchers ensured that this nail was less in diameter compared to the previously used reamer. Polymer beads were added into the 40 gm cement which was prepared by adding 2gm vancomycin and 2 gm teicoplanin. As the desired diameter of the coated nail, the researchers prepared an endotracheal tube with a mixture of antibiotics and cement. By means, endotracheal tube 2mm K nail was pushed inside and enabled to set for 15 minutes. After that, a surgical knife to recover antibiotic cut the endotracheal tube and cement coated k nail. The nail was then inserted into the tibia. During insertion, the researchers ensured minitiarisation of the cement debonding by giving adequate time to cement for settling with a nail.

After the surgery, the wound was investigated for 48 to 72 hours. Within that period, the researchers administered selected antibiotics based on culture and sensitivity results. These antibiotics were injected for 2- 4 weeks. After monitoring the condition of the wound, patients were discharged and shifted to oral antibiotics. After the healing of the wound, the researchers applied a patellar tendon-bearing cast and allowed patients to undertake their normal heavy loads. This cast was changed after six months and applied until the radiological clinical assessment confirmed the bone union. Ankle

and knee mobility was regaining by physiotherapy. This physiotherapy was conducted until the researchers got a satisfactory movement range. Patients were followed up for every week in the intial discharge month. After that, the researchers requested them to visit the health institution once in a month. After one month they were then followed up after 2-3 months. A total of 13 months was the average follow-up duration.

The evaluation of patients depended on bone union and infection control. For examination they were categorized into four dimensions;

- Infection control with the bony union,
- infection controlled with fracture healing with the partial union,
- infection controlled without healing fracture, and
- continuous infection without fracture healing.

Their condition status helped the researchers to decide further insertions<sup>1</sup>.

### 3. RESULTS

From the average follow-up of 13 weeks, the researchers observed that in 28 patients 93% utilization of antibodies cement coated nails helped to eradicate the infection. 24 patients achieved complete bone unification without any need for further procedure. The condition of 6 patients needed an additional procedure to gain bone union. But unfortunately, one patient refused to undergo further procedure. Out of these 6, the researchers exchanged nailing in 3 patients with new antibiotic we exchange nailing with new antibiotic cement nail and success to achieve bone union. So, the overall ratio of single-time antibiotic cement coated nail was observed as 70%. The mean time of bone union was 33 weeks. Some patients gained union within 24 weeks whilst some required time duration of 44 weeks. Those patients who underwent through nailing once reported 32 weeks as the average meantime.

**Table 1. Information related to infection status of selected participants**

<b>Infection status</b>	<b>No of cases</b>	<b>Percentage %</b>
Controlled	28	93.3%
Non controlled	2	6.99%

**Table 2. Information related to bone union status of selected patients**

Bone union status	No. of cases	Percentage %
Without extra procedure	24	80%
With extra procedure	6	20%

**Table 3. Information related to procedure applied to 6 patients**

Procedure details	No. of cases	Percentage %
Exchange interlocking nail with bone grafting	3	50%
Refused for extra procedure	2	33.3%
Bone grafting	1	16.66%

#### 4. DISCUSSION

Infectious non-union fractures need proper treatment to regain bone union [5]. A wide range of literature was produced on the benefits of antibiotic-loaded cemented nails [6,7,8,9,10,11]. In the past, there was no single universal treatment accepted to manage the infected non-union fractures. Traditionally two-step procedure was applied to manage these fractures. This two-step procedure firstly dealt with infection and then treated the permanent failure of bone healing (non-union) [6]. Administration of antibiotics locally or systemically is essential to managing the infection. The study reported that infection for a long duration and repeated debridement generate excessive fibrosis around the non-union site. This fibrosis creates obstacles in antibiotic permeability [12]. Polymer beads soaking with antibiotics and bone cement was considered as the best treatment for managing osteomyelitis and open fractures [13,14]. Although these beads cannot provide stability beyond the fracture site. These beads are hard to place in the intramedullary canal because after the ingrowth of fibrosis their removal becomes challenging. The selection of antibiotics depends upon its activities. Low allergenicity antibiotics with good elusion properties from the cement are preferred by many surgeons. In the past majority of the researchers used a combination of vancomycin with gentamicin or tobramycin [15,16]. In the current study, the culture and sensitivity results of the patients enabled researchers to make the decision to utilize a combination of vancomycin and teicoplanin. These antibiotics were considered as suitable because of evidence of gentamicin resistant staphylococcus aureus. Previous literature reported that a frequent number of gentamicin resistant species may cause deep infections including medullary infections [17,18]. The current study is unique that very limited researches have been

undertaken which use teicoplanin antibiotic to establish the stability and biocompatibility with bone cement. The stability of fracture can be achieved after internal and external fixations. However, external fixations reported a high frequency of pin-site infections, muscle contractures, and joint stiffness. In case of internal fixations, implants are prone to infections and they can easily formulate biofilms which causes hurdles in managing infection by systemic antibiotics [18,19]. Many studies reported that these antibiotic coated cemented nail helps to provide the stability at non-union site without causing any systemic toxicity [20,21]. They help to transform a two-step procedure into a single step for the early mobilization of the patient without any major complications like pin site infections, joint stiffness, muscle contractures. In a previous study of Conway [22], they observed 85% success of antibiotics cemented coated nail whereas the success ratio in Qiang et al was comparatively higher. In the small sample size of Qiang et al. [23], they observed 94.4% controlled infection. This current study validates these results because researchers observed infection eradication in 93.3% of cases. Two patients of the current study reported broken nails and patients with bent nails due to apparent indulgence in early in weight-bearing activities. The difficulty in nail removal was observed in one of the patients. This could have been due to improper preparation of nails or delay in removal from the patient side.

#### 5. CONCLUSION

The infected nonunion tibia can be effectively treated if the protocol of debridement is correctly followed. Results demonstrate that bone stability can be regained with 22 to 44 weeks. We concluded that antibiotic-impregnated cemented nail is an ideal procedure to control the postoperative infection and achieve reunion.

## CONSENT

As per international standard or university standard, patients' written consent has been collected and preserved by the author(s).

## ETHICAL APPROVAL

As per international standard or university standard written ethical approval has been collected and preserved by the author(s).

## COMPETING INTERESTS

Authors have declared that no competing interests exist.

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*Peer-review history:*  
*The peer review history for this paper can be accessed here:*  
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