

## An Observational Study Assessing the Role of Prophylactic Use of Antibiotic Coated Intramedullary Nail in Treatment of Open Tibia Fractures

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### Abstract

**Aim:** The aim of the present study was to assess the prophylactic use of antibiotic coated intramedullary nail in treatment of open tibia fractures.

**Methods:** This prospective study was conducted in the Department of Orthopaedics, ESICMCH, Bihta, Bihar, India. 50 patients were treated over a period of 24 months with gentamicin coated tibia interlocking nail after taking written and informed consent.

**Results:** All 50 patients (42 males and 8 females) were followed up for minimum of six months duration. Males were 84% against females 16%. The radiological Union was assessed using RUST Score and maximum patients had score 8. Time taken in wound healing in majority of patients was less than 5 weeks (52%). Average duration of hospital stay was 16 days. Large numbers of patients had fair outcome- 54%.

**Conclusion:** Antibiotic coated tibia interlocking nail is a good treatment option for open tibial fractures, yields good functional outcome with less complications in these fractures and should be used whenever indicated.

**Keywords:** Open Fracture, Intra Medullary Nail, Antibiotic Coated.

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### Introduction

Tibia shaft fractures are the most common long-bone fractures among adults and children [1]. They have a deep socio-economic impact, accounting for approximately 26 fractures per 100,000 and 569,000 hospital days per year. [1,2] Men have a three times higher risk of fracture than women. Incidence increases in young adults who suffer high-energy trauma or in elderly people who suffer low-energy trauma directed towards poor quality bone tissue due to osteoporosis. [3] Incidence of nonunion in the general population is approximately 12% of all tibia fractures, and in open fractures this can raise up to 23%. [4] Open tibia fractures account for two per 1000 injuries. [5] Open fracture of tibia is one of the most common injuries seen in orthopaedic practice. The appropriate treatment of open tibial fractures is one of the priority problems in modern era of traumatology. Tibia, being a subcutaneous bone, increases the chance of infection and nonunion. In

choosing the optimal mode of treatment, one has to consider the importance of associated soft tissue injuries along with the configuration of fracture. Most of the orthopaedic trauma infections are caused by biofilm-forming bacteria. [6]

Biofilm consists of hydrated matrix of polysaccharide and protein. Once formed, it protects the microorganism from antimicrobials, opsonization, and phagocytosis, thus contributing to the chronicity of infections. [7] In order to cure biofilm-related infection, four principles formulated by Cierny and Mader must be observed: (1) complete surgical debridement with dead space management, (2) fracture/nonunion stabilization, (3) soft tissue coverage, and (4) adequate antibiotic levels. [8]

According to other studies, on increasing grades of Gustilo the chances of infection increases. The effectiveness of systemic antibiotics is limited in reducing risk of infection with use of prosthesis and

osteosynthetic devices. [9,10] Once implant gets infected, then it requires implant removal, debridement and long term antibiotic therapy. This implant related infection is prevented by delivering the antibiotics locally acting on tissue implant interface. One of such method is using a polylactic acid (PLA) coated intramedullary nail releasing gentamicin. [10] There are several studies showing reduction in implant related infection using antibiotic coated implants. [11,12]

The aim of the present study was to assess the prophylactic use of antibiotic coated intramedullary nail in treatment of open tibia fractures.

### Materials and Methods

This prospective study was conducted in the Department of Orthopaedics, ESICMCH, Bihta, Bihar, India. 50 patients were treated over a period of 24 months with gentamicin coated tibia interlocking nail after taking written and informed consent.

Patients included in study were adults (>18years of age) having Gustilo type I, II and type III A compound tibia shaft fractures manageable with intramedullary nailing and excluded were (i) Gustilo type III B, III C, (ii) Females who were pregnant, breast-feeding or planning to become

pregnant during the study, (iii) Patients with consumptive or malignant primary disease, (iv) Vascular compromised patients, (v) Patients suffering from neuropathy and (vi) A known allergy to used antibiotic.

In this study antibiotic coated tibia interlocking nail with property of sustained release of gentamicin was used. The coating contains combination of gentamicin and biodegradable polymeric carrier Poly (D, L-Lactide). An average size nail carries 100 mg (1 mg/cm<sup>2</sup>) gentamicin drug. Protocols given by ethical committee were strictly followed.

Any life threatening conditions assessed and treated pre-operatively. After performing pre-anesthetic check-up, all patients were operated under spinal/epidural anesthesia. Patient was painted and sterile draping done. Knee flexed to 90° and entry point was made from the bare area over the tibial tuberosity under image intensifier. After passing the guide wire, serial reaming was done. Appropriate size of antibiotic coated nail measured and inserted into the medullary canal.

I.V. antibiotics were given for 5 days post-operatively. Patient followed post-operatively at 1,2,3 and 6 months for outcome assessment.

### Results

**Table 1: Sex distribution**

Sex	N	%
Male	42	84
Female	8	16
Total	50	100

All 50 patients (42 males and 8 females) were followed up for minimum of six months duration. Males were 84% against females 16%.

**Table 2: Radiological union at six month (RUST score)**

Radiological union at 6 month (RUST score)	Frequency	Percentage
4	6	12
8	28	56
10	10	20
28	6	12
Total	50	100

The radiological Union was assessed using RUST Score and maximum patients had score 8.

**Table 3: Time taken in wound healing**

Time taken in wound healing	N	%
≤5 weeks	26	52
5-7 weeks	16	32
8-10 weeks	5	10
Not healed	3	6
Total	50	100

Time taken in wound healing in majority of patients was less than 5 weeks (52%).

**Table 4: Clinical outcome**

Functional outcome	Frequency	%
Excellent	5	10
Good	13	26
Fair	27	54
Poor	5	10
Total	50	100

Average duration of hospital stay was 16 days. Large numbers of patients had fair outcome- 54%.

### Discussion

Fractures of the tibia are the most common long bone fractures. Open injuries of tibia account for almost 50% of all open injuries and are more prone to infection than other long bones. [13,14] The annual incidence of open injuries is 11.5 per 100,000 with 40% occurring in the lower limb, commonly in the tibia shaft. [15-18] These usually result from high-energy injuries and are frequently associated with polytrauma, high rates of infection and other complications which may threaten the limb and occasionally life and are generally a therapeutic challenge to the orthopedic surgeon. [19] Damage to the soft tissue and vasculature surrounding the bone is the main cause for non union. [20,21] After using advance surgical techniques and antibiotics, there are chances of wound infection and osteomyelitis. In Gustilo grade III open fractures, rate of deep infection is about 80%. [21]

In a study by Bhanu Pratap et al [22] 13 (52%) cases were of grade-I fractures and 12 (48%) cases were others. In other study by Khaled Hamed et al [23] also exhibited eight (72.72%) patients had Gustilo type I fracture while three (27.27%) patients had type II fracture. All 50 patients (42 males and 8 females) were followed up for minimum of six months duration. Males were 84% against females 16%. The radiological Union was assessed using RUST Score and maximum patients had score 8. Time taken in wound healing in majority of patients was less than 5 weeks (52%). Average duration of hospital stay was 16 days. Large numbers of patients had fair outcome- 54%. Long term infection and repeated debridement create excessive fibrosis around the nonunion site and hinder antibiotic permeability. [24] Hence, delivery of antibiotics to the local site is far more beneficial than systemic administration of antibiotics. The use of antibiotic-impregnated polymethylmethacrylate cement beads for local delivery of antibiotics without any systemic toxicity has been well documented for the management of osteomyelitis and open fractures. [25,26] However, these antibiotic cement beads do not provide any stability across fracture site and cannot be placed in the intramedullary canal as it entails difficult removal due to fibrous ingrowths.

The antibiotics that are used for this purpose should have a broad spectrum of activity, should be heat stable, have good elution properties from the cement and should have low allergenicity. Most of the researchers in past used a combination of vancomycin with gentamicin or tobramycin. [27-29]

In other study by Khaled Hamed et al [30] also exhibited eight (72.72%) patients had Gustilo type I fracture while three (27.27%) patients had type II fracture. Out of 40 patients, fracture union was achieved in 38 patients and only two patients undergone non-union. This was in accordance with the study of Bhanu Pratap et al [31] And Fuchs T et al [32] where none of the patient undergone non-union. In a study of 25 patients by Bhanu Pratap et al [31] infection in two (8.0%) patients were observed. In a similar study Thomas Fuchs et al [32] out of 19 patients noticed infection in only one (5.26%) patient.

### Conclusion

Antibiotic coated tibia interlocking nail is a good treatment option for open tibial fractures, yields good functional outcome with less complications in these fractures and should be used whenever indicated.

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