

**Assessment of the Prophylactic Use of Antibiotic Coated Intramedullary Nail in Treatment of Open Tibia Fractures in Adults**Manishi Anant<sup>1</sup>, Neeraj Kumar<sup>2</sup><sup>1</sup>Assistant Professor, Department of Orthopaedics, ICARE Institute of Medical Science and Research & Dr BC Roy Hospital, Haldia, West Bengal, India<sup>2</sup>Assistant Professor, Department of Orthopaedics, ICARE Institute of Medical Science and Research & Dr BC Roy Hospital, Haldia, West Bengal, India

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Conflict of interest: Nil

**Abstract:****Aim:** To assess the outcome of prophylactic use of antibiotic coated intramedullary nail in treatment of open tibia fractures.**Materials and Methods:** 50 patients were selected with open fracture of shaft tibia, treated operatively with antibiotic coated intramedullary interlocking nail and were followed up for a minimum of four months duration. Radiological Union was assessed using RUST Score and clinical assessment results were graded as excellent, good, fair and poor.**Result:** In this study all 50 patients (35 males and 15 females) were followed up for a minimum of four months duration. The mean age of the study population was 35.5 years. Males were 70% against females 30%. The most common cause of injury was found to be due to road traffic accidents and accounted for 78% of cases. Fibula fracture was associated with 92% of patients. Time taken in wound healing in majority of patients was less than 4 weeks 27 (54%), 4-6 weeks 32%, 6-8 weeks 8% and those were not healed 6%. Majority of patients (56%) had RUST score 10 at four months of duration, Large numbers of patients had fair outcome- 56%. Average time of wound healing in our study was 4.1 weeks.**Conclusion:** The use of the antibiotic coated nail has good clinical and radiological outcome at six months and preliminary results support the use of antibiotic coated implants as a new potential treatment option for prevention of infection in open tibia fractures.**Keywords:** RUST Score, Intramedullary Nail, Clinical Assessment, Antibiotic Coating.This is an Open Access article that uses a funding model which does not charge readers or their institutions for access and distributed under the terms of the Creative Commons Attribution License (<http://creativecommons.org/licenses/by/4.0>) and the Budapest Open Access Initiative (<http://www.budapestopenaccessinitiative.org/read>), which permit unrestricted use, distribution, and reproduction in any medium, provided original work is properly credited.**Introduction**

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 the modern era of traumatology. Tibia, being a subcutaneous bone, increases the chance of infection and non-union. [1] Open injuries of tibia account for almost 50% of all open injuries and are more prone to infection than other long bones. [2,3] The annual incidence of open injuries is 11.5 per 100,000 with 40% occurring in the lower limb, commonly in the tibia shaft. [4-7] In choosing the optimal mode of treatment, one has to consider the importance of associated soft tissue injuries along with the configuration of fracture. Various modalities of treatment are practiced ranging from plaster immobilization to debridement and surgical stabilization. The locking of intramedullary nails decreased the prevalence of malunion in

comminuted fractures. Until recently, majority of the interlocking intramedullary nails involved reaming which destroys the endosteal blood supply [8] and causes thermal necrosis of tibia. The rate of infection after treatment of open tibial fractures with intramedullary nailing with reaming have been relatively high causing most surgeons to discourage its use for Type III open tibial fractures.

A new tibial titanium nail with a biodegradable gentamicin-loaded coating (UTN PRO tect, Synthes) was CE-certified in August 2005. In a pilot study of 8 patients with open tibial fractures treated with UTN PRO tect intramedullary nails, there were no infections within 1 year and all fractures healed within 6 months. [9] The main goal of locally delivered antibiotics is to prevent bacterial colonization of the implant surface, thereby reducing the risk of implant-related infections. Another benefit of local delivery

systems is that high concentrations of the antibiotic are achieved in the desired area without high systemic doses and associated side effects. [10]

The effectiveness of systemic antibiotics is limited in reducing risk of infection with use of prosthesis and osteosynthetic devices. [11,12] 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. [13,12] There are several studies showing reduction in implant related infection using antibiotic

coated implants. [14,15]

**Material and Methods**

This observational study was carried out in the Department of Orthopaedics, ICARE Institute of Medical Science and Research & Dr BC Roy Hospital, Haldia, West Bengal, India After taking informed consent detailed history was taken from the patient or the relatives if the patient was not in good condition. Total 50 patients were treated with gentamicin coated tibia interlocking nails.

**Inclusion Criteria**

- >18years of age.
- Open fractures Gustilo type 1, 2, 3A fracture

**Exclusion Criteria**

- Gustilo type III B, III C,
- Females who were pregnant, breast-feeding or planning to become pregnant during the study,

- Patients with consumptive or malignant primary disease,
- Vascular compromised patients,
- Patients suffering from neuropathy
- A known allergy to antibiotics.

In this study antibiotic coated tibial interlocking nails with the property of sustained release of gentamicin was used. The coating contains a 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 the ethical committee were strictly followed. Any life threatening conditions assessed and treated preoperatively. 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<sup>0</sup> 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. Patients followed post-operatively at 1,2,3 and 4 months for outcome assessment.

**Statistical Analysis**

The recorded data was compiled and entered in a spreadsheet computer program (Microsoft Excel 2010) and then exported to the data editor page of SPSS version 19 (SPSS Inc.,

Chicago, Illinois, USA). Descriptive statistics included computation of percentages.

**Results**

**Table 1: Radiological union scale in Tibial (RUST) fractures**

Score per cortex	Callus	Fracture line
1	Absent	Visible
2	Present	Visible
3	Present	Invisible

Minimum score of 5; not healed; Maximum score of 14: completely healed

**Table 2: Criteria for assessment of the result**

S. No.	Variable	Excellent	Good	Fair	Poor
1	Infection at 4 weeks	Control	Control	Control	Not Control
2	Wound healed at	4 weeks	6 weeks	8 weeks	Not Healed
3	Radiological union at 6 month (RUST Score)	14 score	12 score	10 score	5 score
4	Weight bearing without pain at 4 months	Yes	Yes	No	No
5	Neurovascular complication	Absent	Absent	Absent	+/-
6	Patient compliance	Very good	Good	Fair	Poor

**Table 3: Gender distribution**

Sex	Frequency	%
Male	35	70%
Female	15	30%
Total	50	100%

**Table 4: Age distribution**

Age	N=50	%
18- 20 years	6	12
20-40years	22	44
40-60 years	14	28
Above 60	8	16

**Table 5: Time taken in wound healing**

Time taken in wound healing in weeks	Frequency	%
≤4 weeks	27	54%
4-6 weeks	16	32%
6-8 weeks	4	8%
Not healed	3	6%
Total	50	100

**Table 6: Radiological union at four month (RUST score)**

Radiological union at 4 month (RUST score)	Frequency	Percentage
5	4	8%
10	28	56%
12	12	24%
14	6	12.0%
Total	50	100%

**Table 7: Clinical outcome**

Functional outcome	Frequency	%
Excellent	6	12%
Good	12	24%
Fair	28	56%
Poor	4	8%
Total	50	100%

**Table 8: Grade compounding of patients**

Grade	N=50	%
I	27	54
II	19	38
III	4	8

## Discussion

Management of open shaft tibial fractures have been a therapeutic challenge since the past. The goal of orthopedic surgeons is to decrease the infection rate and improve fracture healing after surgical treatment of open tibial shaft fractures reducing the complications. By providing stable internal fixation with intramedullary nail, motion of adjacent joints and early rehabilitation can be started; thus preventing the frequent problem of joint stiffness. The purpose of this study was to evaluate the efficacy of antibiotic-coated intramedullary locking nail in the compound tibia fractures and comparing the results with those in literature. Our study revealed the mean age of such fractures to be 35.5 years. It is comparable to some other studies on similar fractures by other authors.

Javed Aziz et al (33.28years). [16] Our study revealed the sex ratio of fractures to be 70% male and 30% female. It is comparable to some other studies on similar fractures by other authors Lin j et al. [17]

This study comprised of 50 patients, out of them 27 patients (54%) had grade-I, 19 patients (38%) had grade-II and 4 patients (8%) had grade-III compounding. In a study by Bhanu Pratap et al. [18] 13 (52%) cases were of grade-I fractures and 12 (48%) cases were others. In other study by Khaled Hamed et al. [19] also exhibited eight (72.72%) patients had Gustilo type I fracture while three (27.27%) patients had type II fracture. Out of 50 patients, fracture union was achieved in 49 (98%) patients and only one patient (2%) had non union. This was in accordance with the study of

Bhanu Pratap et al.<sup>18</sup> and Thomas Fuchs et al. [20] where none of the patients had non union. Average time of wound healing in our study was 4.1 weeks.

In a study of 25 patients by Bhanu Pratap et al.<sup>18</sup> infection in two (8.0%) patients were observed. In a similar study Thomas Fuchs et al.<sup>20</sup> out of 19 patients noticed infection in only one (5.26%) patient. These findings are consistent with the findings of our study where in a group of 50 patients, infection was found only in 3 patients. At the end of this study, out of 50 patients, 6 (12%) patients had excellent outcome, 12 (24%) had good and 28 (56%) fair and only 4 (8%) patients had poor outcome.

### Conclusion

Antibiotic coated tibial 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. This prospective study was conducted in a small cohort of patients.

Patient demographic and fracture pattern characteristics were random and not specified.

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