



Original Research Article

The prophylactic use of antibiotic coated intramedullary nail in treatment of open tibia fractures

Pulkit Prakash^{1,*}, Dinesh Kumar¹, Sunil Kumar¹, Ajay Kumar Rajput¹

¹Dept. of Orthopedics, UP University of Medical Sciences, Etawah, Uttar Pradesh, India



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ABSTRACT

Introduction: Open tibia fractures are the most common type of all open injuries and are more prone to infection than other long bones. To control infection various surgical techniques and antibiotic therapy are used. Local delivery of antibiotics at the tissue-implant interface using Gentamicin-coated implants is one of the methods which provide mechanical stability, effectively prevent infection and promote bony union by simple one stage procedure.

Materials and Methods: Thirty 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 six 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 of 30 patients, time taken in wound healing in 15 patients is ≤ 5 weeks. RUST score at 6 months in 16 patients is 8. Infection found in 2 patients and 1 patient undergone non-union. 29 patients can bear weight without pain after 6 months of surgery. 16 patients have fair outcome.

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.

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1. Introduction

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.^{1,2} The annual incidence of open injuries is 11.5 per 100,000 with 40% occurring in the lower limb, commonly in the tibia shaft.³⁻⁶ 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.⁷ Damage to the soft tissue and vasculature surrounding the bone is the main cause for non union.^{8,9} 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%.⁹ 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.^{10,11} 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.^{8,11} There are several studies showing reduction in implant related infection using antibiotic coated implants.^{12,13}

2. Materials and Methods

This prospective study was conducted in the Department of Orthopaedics, U.P. University of Medical Sciences, Saifai.

* Corresponding author.

E-mail address: pulkit124@gmail.com (P. Prakash).

30 patients were treated over a period of 18 months from January 2018 to August 2019 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^2) 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 (Figure 1). After passing the guide wire, serial reaming was done (Figure 2). Appropriate size of antibiotic coated nail measured and inserted into the medullary canal (Figure 3). I.V. antibiotics were given for 5 days post-operatively. Patient followed post-operatively at 1,2,3 and 6 months for outcome assessment.



Fig. 1: Making entry point



Fig. 2: Reaming



Fig. 3: Insertion of nail



Fig. 4: Grade II open fracture

3. Results

All 30 patients (25 males and 5 females) were followed up for minimum of six months duration. The radiological Union was assessed using RUST Score (Table 1) and clinical assessment results were graded as excellent, good, fair and poor (Table 2). The study comprised 76.7% of the patients between 18-40 years of age and 23.3% of the patients between 41-60 years of age. In this study, there was predominance of male population. Males were 83.3% against females 16.7% (Table 3). The most common cause of injury was found to be due to road traffic accident and accounted for 80% of cases. Fibula fracture was associated



Fig. 5: Pre-op x ray



Fig. 7: Range of motion

with 93.3% of patients. Time taken in wound healing in majority of patients was less than 5 weeks (50.0%) (Table 4). Majority of patients (53.33%) had RUST score 8 at six months of duration (Table 5). Two cases got infected in this study and in one case there was non union. Average duration of hospital stay was 16 days. Large numbers of patients had fair outcome- 53.33% (Table 6).

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 4: not healed; Maximum score of 12: completely healed

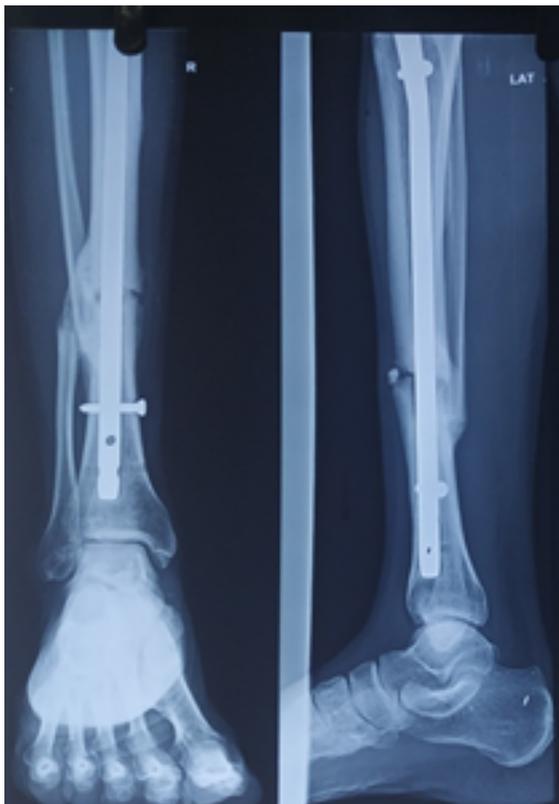


Fig. 6: Fracture union after 8 weeks

4. Discussion

Management of open shaft tibial fractures have been a therapeutic challenge since past. The goal of orthopedic surgeon 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.

This study comprised of 30 patients, out of them 15 patients (50.00%) had grade-I, 13 patients (43.33%) had grade-II and two patients (06.67%) had grade-III compounding. In a study by Bhanu Pratap et al.¹⁴ 13 (52%) cases were of grade-I fractures and 12 (48%) cases were others. In other study by Khaled Hamed et al.¹⁵ also exhibited eight (72.72%) patients had Gustilo type I fracture while three (27.27%) patients had type II fracture.

Out of 30 patients, fracture union was achieved in 29 (96.67%) patients and only one patient (03.33%) patient undergone non union. This was in accordance with the study of Bhanu Pratap et al.¹⁴ and Thomas Fuchs et al.¹⁶ where none of the patient undergone non union.

Average time of wound healing in our study was 4.11 weeks.

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 | 5 weeks | 7 weeks | 10 weeks | Not Healed |
| 3 | Radiological union at 6 month (RUST Score) | 12 score | 10 score | 8 score | 4 score |
| 4 | Weight bearing without pain at 6 months | Yes | Yes | No | No |
| 5 | Neurovascular complication | Absent | Absent | Absent | +/- |
| 6 | Patient compliance | Very good | Good | Fair | Poor |

Table 3: Sex distribution

| Sex | Frequency | % |
|--------|-----------|--------|
| Male | 25 | 83.33% |
| Female | 5 | 16.67% |
| Total | 30 | 100% |

Table 4: Time taken in wound healing

| Time taken in wound healing in weeks | Frequency | % |
|--------------------------------------|-----------|--------|
| ≤5 weeks | 15 | 50.00% |
| 5-7 weeks | 10 | 33.33% |
| 8-10 weeks | 3 | 10.00% |
| Not healed | 2 | 06.67% |
| Total | 30 | 100% |

Table 5: Radiological union at six month (RUST score)

| Radiological union at 6 month(RUST score) | Frequency | Percentage |
|---|-----------|------------|
| 4 | 3 | 10.00% |
| 8 | 16 | 53.33% |
| 10 | 8 | 26.67% |
| 12 | 3 | 10.00% |
| Total | 30 | 100% |

Table 6: Clinical outcome

| Functional outcome | Frequency | % |
|--------------------|-----------|--------|
| Excellent | 3 | 10.00% |
| Good | 8 | 26.67% |
| Fair | 16 | 53.33% |
| Poor | 3 | 10.00% |
| Total | 30 | 100% |

In a study of 25 patients by Bhanu Pratap et al.,¹⁴ infection in two (8.0%) patients were observed. In a similar study Thomas Fuchs et al.,¹⁶ 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 30 patients, infection was found only in two patients.

At the end of this study, out of 30 patients, three (10%) patients had excellent outcome, 24 (80.00%) had good to fair and only three (10.00%) patients had poor outcome.

5. 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.

This prospective study was conducted in a small cohort of patients. Patient demographic and fracture pattern characteristics were random and not specified by the protocol. Furthermore compound grade IIIB and grade IIIC fractures were excluded from study and duration of follow up was also less.

Randomized controlled trials with large sample size and longer duration of follow up are needed to devise a standard treatment protocol for management of open tibia fractures.

6. Source of Funding

None.

7. Conflict of Interest

None.

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Author biography

Pulkit Prakash PG Resident

Dinesh Kumar Associate Professor

Sunil Kumar Professor

Ajay Kumar Rajput Lecturer

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