

Original research article

Clinical and functional outcome of gentamicin coated intramedullary locking nail in the management of open tibia fractures**Dr. Mohammad Sabir Ali¹, Dr. Shree Prakash Singh², Dr. Vinod Kumar Singh³****¹Senior Resident, Department of Orthopaedics, Anugrah Narayan Magadh Medical College and Hospital, Gaya, Bihar, India****²Professor and HOD, Department of Orthopaedics, Anugrah Narayan Magadh Medical College and Hospital, Gaya, Bihar, India.****³Professor, Department of Orthopaedics, Anugrah Narayan Magadh Medical College and Hospital, Gaya, Bihar, India.****Corresponding Author: Dr. Mohammad Sabir Ali****Abstract**

Aim: The aim of this study was to evaluate the outcome of antibiotic-coated intramedullary locking nail in the open tibia fractures.

Materials and Methods: This clinic-observational study was carried out in the Department of Orthopaedics, Anugrah Narayan Magadh Medical College and Hospital, Gaya, Bihar, India for 18 months. Total 80 patients were treated with gentamicin coated tibia interlocking nail. Radiological Union was assessed using RUST Score.

Result: out of 80 patients 46.25% between 26-40 years of age, 28.75% of the patients between 41-55 years of age and 16.5% above 55 years and 8.75% of patients below 25 years. Males were 75% against females 25%. Time taken in wound healing in majority of patients was less than 6 weeks 42 (52.5%), 6-8 weeks 26(32.5%), 8-10 weeks 7(8.75%) and those were not healed 5(6.25%) . Majority of patients (56.25%) had RUST score 9 at six months of duration, 22.5% of patients had RUST score 11 and 8.75% patients RUST score was 6 at six months.

Conclusion: Implant related infection pose an important challenge in the surgical treatment of tibia shaft fracture. Local administration of antibiotics might minimize the risk of infection.

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 orthopaedic surgeon.⁷ 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 supply⁸ 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. 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 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.^{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.^{10,12} There are several studies showing reduction in implant related infection using antibiotic coated implants.^{13,14}

Material and methods

This clinic-observational study was carried out in the Department of Orthopaedics, Anugrah Narayan Magadh Medical College and Hospital, Gaya, Bihar, India for 18 months. after taking the approval of the protocol review committee and institutional ethics committee.

Methodology

Total 80 patients were treated with gentamicin coated tibia interlocking nail. Patients with Open fractures gustillo type 1, 2, 3A fracture were included in this study.

Patients with Gustilo type III B, III C, Females who were pregnant, Patients with consumptive or malignant primary disease, Vascular compromised patients, allergy to used antibiotic were exclude from the study. 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/cm²) gentamicin drug. Protocols given by ethical committee were strictly followed. Any life threatening conditions assessed and treated preoperatively. After performing pre-anaesthetic 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 to 6 months for outcome assessment.

Results

All 80 patients (60 males and 20 females) were followed up for minimum of 3 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 46.25% of the patients between 26-40 years of age, 28.75% of the patients between 41-55 years of age and 16.5% above 55 years and 8.75% of patients below 25 years. The mean age of such fractures to be 34 years in this study, there was predominance of male population. Males were 75% against females 25% (Table 3). The most common cause of injury was found to be due to road traffic accident and accounted for 65(81.25%) of cases. Fibula fracture was associated with 73(91.25%) of patients. Time taken in wound healing in majority of patients was less than 6 weeks 42 (52.5%), 6-8 weeks 26(32.5%), 8-10 weeks 7(8.75%) and those were not healed 5(6.25%) (Table 5). Majority of patents (56.25%) had RUST score 9 at six months of duration, 22.5% of patients had RUSH score 11 and 8.75% patients RUSH score was 6 at six months (Table 5). 7 cases got infected in this study and in 4 case there was non-union. Average duration of hospital stay was 15 days. Large numbers of patients had fair outcome- 56.25%. Average time of wound healing in our study was 4.20 weeks. Out of 80 patients, fracture union was achieved in 78 (97.5%) patients and two patient (2.5%) patient undergone non unions.

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 6; not healed; Maximum score of 15: 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	6 weeks	8weeks	10 weeks	Not Healed
3	Radiological union at 6 month (RUST Score)	13 score	11 score	9 score	6 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 and age distribution of patients

Gender	Number of patients =80	%
Male	60	75%
Female	20	25%
Age		
18-25 years	7	8.75%
26-40years	37	46.25%
41-55years	23	28.75%
Above 55	13	16.25%
RTA	65	81.25%

Table 4: Time taken in wound healing

Time taken in wound healing in weeks	Number of patients=80	%
≤6 weeks	42	52.5%
6-8 weeks	26	32.5%
8-10 weeks	7	8.75%
Not healed	5	6.25%

Table 5: Radiological union (RUST score)

Radiological union at 6 month(RUST score)	Number of patients=80	Percentage
6	7	8.75%
9	45	56.25%
11	18	22.5%
13	10	12.5%
Total	80	100%

Table 7: Clinical outcome

Functional outcome	Number of patients=80	%
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Excellent	10	12.5%
Good	18	22.5%
Fair	45	56.25%
Poor	7	8.75%
Total	80	100%

Discussion

Fractures of the shaft of the tibia are among the most common long bone injuries presenting for treatment. Every open fracture of the tibial shaft must be assessed individually and it can be dangerous to establish fixed routines of treatment. A number of difficulties which may arise in the treatment of fractures of the shaft of the tibia are 1. A high incidence of open and infected fractures because tibia lies superficially just beneath the skin. 2. A tendency to re-displacements of the fragments when the swelling subsides, particularly in oblique and spiral fractures. 3. Cosmetic and sometimes functional disability if the alignment or rotational position of the fragments is imperfect because the knee and ankle joints normally move in the same parallel axis.

The goal of orthopaedic 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. Our study revealed the mean age of such fractures to be 34 years. it is comparable to Javed Aziz et al(33.28years).¹⁵ Our study revealed the sex ratio of fractures to be 75% male and 25 % female .it is comparable to some other studies on similar fractures by Lin j et al. ¹⁶

This study comprised of 80 patients, out of them 45 patients (56.25%) had grade-I, 28 patients (35%) had grade-II and 7 patients (8.75%) had grade-III compounding. In a study by Bhanu Pratap et al.¹⁷ 13 (52%) cases were of grade-I fractures and 12 (48%) cases were others. In other study by Khaled Hamed et al.¹⁸ also exhibited eight (72.72%) patients had Gustilo type I fracture while three (27.27%) patients had type II fracture. Out of 80 patients, fracture union was achieved in 78 (97.5%) patients and two patient (2.5%) patient undergone non union. This was in accordance with the study of Bhanu Pratap et al. ¹⁷ and Thomas Fuchs et al.¹⁹ where none of the patient undergone non union. Average time of wound healing in our study was 4.20 weeks. In a study of 25 patients by Bhanu Pratap et al.¹⁷ infection in two (8.0%) patients were observed. In a similar study Thomas Fuchs et al.¹⁹ 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 80 patients, infection was found only in 7 patients. At the end of this study, out of 80 patients, 10(12.5%) patients had excellent outcome, 18(22.5%) had good and 45(56.25%) fair and only 7(8.75%) patients had poor outcome.

Conclusion

In this prospective study we showed that use of antibiotic coated nail to treat open tibial fracture was associated with an absence of deep wound infections, good fracture healing.

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