

Original research article

To evaluate the efficacy of antibiotic-coated intramedullary locking nail in the open tibia fractures: prospective observational study

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Abstract

Background: The incidence of a fracture-related infection (FRI) can reach 30% of open tibia fractures (OTF). The use of antibiotic-coated implants is one of the newest strategies to reduce the risk of infection in orthopedic surgery.

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

Materials and Methods: This prospective observational study was carried out in the Department of Orthopaedics, Institute of Medical Sciences, Banaras Hindu University, Varanasi, Uttar Pradesh, India from November 2015 to December 2016. Total 70 patients were treated with gentamicin coated tibia interlocking nail. Patients with Open fractures Gustillo Anderson type 1, 2, 3A fracture were included in this study. Radiological Union was assessed using RUST Score and clinical assessment results were graded as excellent, good, fair and poor.

Result: All 70 patients 44.28% of the patients between 30-40 years of age, 28.57% of the patients between 40-50 years of age and 20% above 50 years and 7.14% of patients below 30 years. Males were 72.86% against females 27.14%. The most common cause of injury was found to be due to road traffic accident and accounted for 55(78.57%) of cases. Fibula fracture was associated with 65(92.86%) of patients. Time taken in wound healing in majority of patients was less than 6 weeks 35 (50%), 6-8 weeks 22(31.43%), 8-10weeks 7(10%) and those were not healed 6(8.57%). Majority of patients 40(57.14%) had RUST score 9 at six months of duration, 15(21.43%) of patients had RUST score 11 and 6(8.57%) patients RUST score was 6 at six months. 6 cases got infected in this study and in 4 cases there was non union. Average duration of hospital stay was 16.5 days. Out of 70 patients, 8(11.43%) patients had excellent outcome, 15(21.43%) had good and 41(58.57%) fair and only 6(8.57%) patients had poor outcome. Average time of wound healing in our study was 4.25 weeks. Out of 70 patients, fracture union was achieved in 68 (97.14%) patients and two patient (2.86%) patient undergone non unions. This study comprised of 70 patients, out of them 41 patients (58.57%) had grade-I, 23 patients (32.86%) had grade-II and 6 patients (8.57%) had grade-III compounding.

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

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 A mention should be made of elderly people, as a substantial difference in the fracture pattern can be observed; moreover, the rate of open fractures in these patients can be as high as 30%, of which 10% are nonunion and 17% are malunion.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 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 anderson 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, thus reducing biofilm formation. 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

Material and methods

This prospective observational study was carried out in the Department of Orthopaedics, Institute of Medical Sciences, Banaras Hindu University, Varanasi, Uttar Pradesh, India from November 2015 to December 2016, after taking the approval of the protocol review committee and institutional ethics committee. Total 70 patients were treated with gentamicin coated tibia interlocking nail. Patients with Open fractures gustillo type 1, 2, 3A fracture were included in this study.

Methodology

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 excluded 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-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 above 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 70 patients (51 males and 19 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 44.28% of the patients between 30-40 years of age, 28.57% of the patients between 40-50 years of age and 20% above 50 years and 7.14% of patients below 30 years. The mean age of such fractures to be 35.65 years in this study, there was predominance of male population. Males were 72.86% against females 27.14% (Table 3). The most common cause of injury was found to be due to road traffic accident and accounted for 55 (78.57%) of cases. Fibula fracture was associated with 65 (92.86%) of patients. Time taken in wound healing in majority of patients was less than 6 weeks 35 (50%), 6-8 weeks 22 (31.43%), 8-10 weeks 7 (10%) and those were not healed 6 (8.57%) (Table 4). Majority of patients 40 (57.14%) had RUST score 9 at six months of duration, 15 (21.43%) of patients had RUST score 11 and 6 (8.57%) patients RUST score was 6 at six months (Table 5). 6 cases got infected in this study and in 4 cases there was non union. Average duration of hospital stay was 16.5 days. Out of 70 patients, 8 (11.14%) patients had excellent outcome, 15 (21.43%) had good and 41 (58.57%) fair and only 6 (8.57%) patients had poor outcome (Table 6). Average time of wound healing in our study was 4.25 weeks. Out of 70 patients, fracture union was achieved in 68 (97.14%) patients and two patients (2.86%) patient undergone non unions. This study comprised of 70 patients, out of them 41 patients (58.57%) had grade-I, 23 patients (32.86%) had grade-II and 6 patients (8.57%) had grade-III compounding. (Table 7)

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

Variable	Excellent	Good	Fair	Poor
Infection at 4 weeks	Control	Control	Control	Not Control
Wound healed at	6 weeks	8 weeks	10 weeks	Not Healed
Radiological union at 6 month (RUST)	13 score	11	9 score	6 score

Score)		score		
Weight bearing without pain at 4 months	Yes	Yes	No	No
Neurovascular complication	Absent	Absent	Absent	Absent /present
Patient compliance	Excellent	Good	Fair	Poor

Table 3: Gender and age distribution of patients

Gender	Number of patients =70	%
Male	51	72.86%
Female	19	27.14%
Age		
Below 30years	5	7.14%
30-40years	31	44.28%
40-50 years	20	28.57%
Above 50	14	20%
RTA	55	78.57%

Table 4: Time taken in wound healing

Time taken in wound healing in weeks	Number of patients=70	%
≤6 weeks	35	50%
6-8weeks	22	31.43%
8-10weeks	7	10%
Not healed	6	8.57%

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

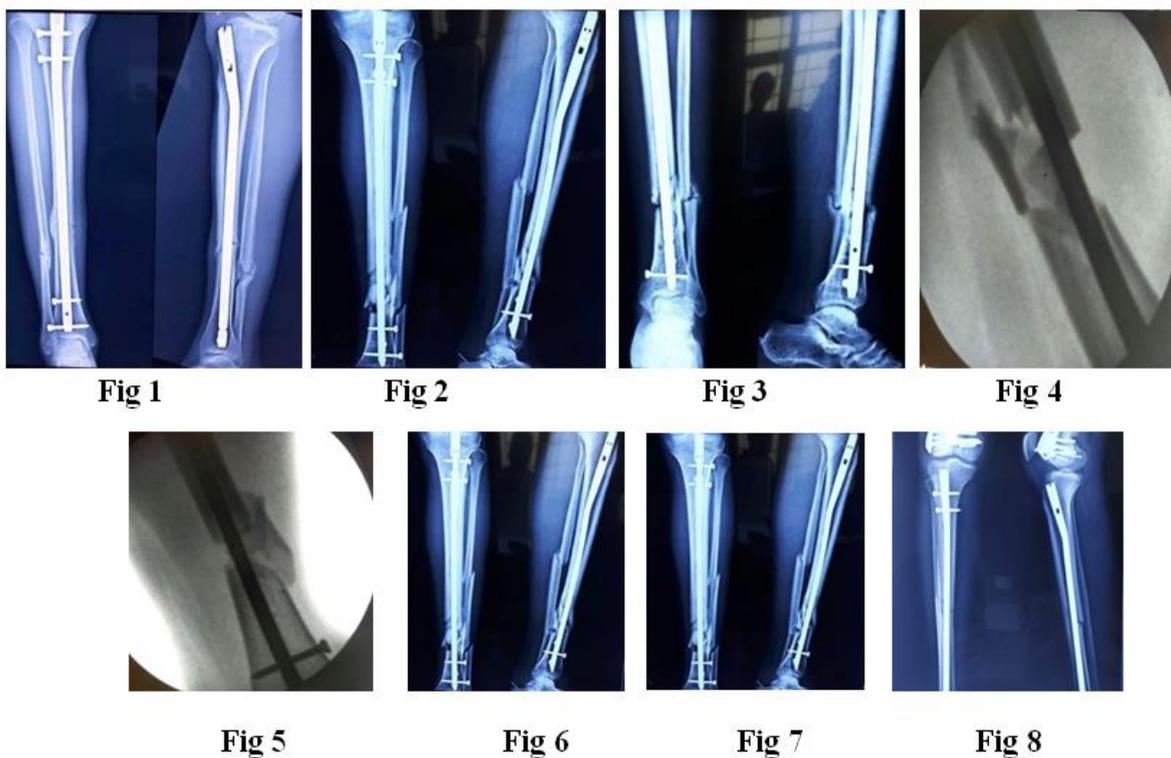
Radiological union at 6month(RUST score)	Number of patients=70	Percentage
6	6	8.57%
9	40	57.14%
11	15	21.43%
13	9	12.86%
Total	70	100%

Table 6: Clinical outcome

Functional outcome	Number of patients=70	%
Excellent	8	11.14%
Good	15	21.43%
Fair	41	58.57%
Poor	6	8.57%
Total	70	100%

Table7: Grade compounding of patients

Grade	Number of patients=70	%
I	41	58.57%
II	23	32.86%
III	6	8.57%



Discussion

Infected long bone fractures require procedure to control infection, provide stability, and achieve union. Surgical debridement and delivery of antibiotic locally and systemically are used to control the infection. Local antibiotic therapy results in high local concentration of antibiotic with minimum systemic level.¹⁴ 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 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. Our study revealed the mean age of such fractures to be 35.65 years. It is comparable to Javed Aziz et al (33.28 years).¹⁵ Our study revealed the sex ratio of fractures to be males were 72.86% against females 27.14%. It is comparable to some other studies on similar fractures by Lin j et al.¹⁶

This study comprised of 70 patients, out of them 41 patients (58.57%) had grade-I, 23 patients (32.86%) had grade-II and 6 patients (8.57%) 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 70 patients,

fracture union was achieved in 68 (97.14%) patients and two patient (2.86%) patient undergone non unions. 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 4.25 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 70 patients, infection was found only in 6 patients. At the end of this study, out of 70 patients, 8(11.14%) patients had excellent outcome, 15(21.43%) had good and 41(58.57%) fair and only 6(8.57%) patients had poor outcome.

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. After looking the result of this study and data from literature suggest that antibiotic coated nail help in preventing infection and union. But we need study with large no of pt to validate it with large no of pt to validate it.

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