

A Prospective Observational Study to Evaluate the Prophylactic use of Antibiotic Coated Intramedullary Nail in Treatment of Open Tibia Fractures

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Received: 05-08-2021 / Revised: 11-09-2021 / Accepted: 22-10-2021

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Conflict of interest: Nil

Abstract

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

Methods: This prospective observational study was carried out in the Department of Orthopedics, Shri Krishna Medical College and Hospital, Muzaffarpur, Bihar, India for 1 year. Total 100 patients were treated with gentamicin coated tibia interlocking nail. Patients with Open fractures gustillo 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: The mean age of such fractures to be 36.15 years in this study, there was predominance of male population. The most common cause of injury was found to be due to road traffic accident and accounted for 79 (79%) of cases. Fibula fracture was associated with 93(93%) of patients. Time taken in wound healing in majority of patients was less than 6 weeks 51 (51%), 6-8 weeks 32(32%) , 8-10 weeks 9(9%) and those were not healed 9(9%). Majority of patents 57(57%) had RUST score 9 at six months of duration, 21(21%) of patients had RUSH score 11 and 9(9%) patients RUSH score was 6 at six months. 7 cases got infected in this study and in 5 case there was non-union. Average duration of hospital stay was 16.8 days. Out of 100 patients, 11(11%) patients had excellent outcome, 21(21%) had good and 59(59%) fair and only 9(9%) patients had poor outcome (Table.6). Average time of wound healing in our study was 4.29 weeks. Out of 100 patients, fracture union was achieved in 97 (97%) patients and two patient 3(3%) patient undergone non unions. This study comprised of 100 patients, out of them 59 patients (59%) had grade-I, 32 patients (32%) had grade-II and 9 patients (9%) 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.

Keywords: prospective observational, open tibia fractures, road traffic accident, Fibula fracture.

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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] 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 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. 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]

Material and methods

This prospective observational study was carried out in the Department of Orthopedics, Shri Krishna Medical College and Hospital, Muzaffarpur, Bihar, India for 1 year. after taking the approval of the protocol review committee and institutional ethics committee.

Methodology

Total 100 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-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 to 6 months for outcome assessment.

Results

All 100 patients (73 males and 27 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% of the patients between 30-40 years of age, 29% of the patients between 40-50 years of age and 20% above 50 years and 7% of patients

below 30 years. The mean age of such fractures to be 36.15 years in this study, there was predominance of male population. Males were 73% against females 27% (Table 3). The most common cause of injury was found to be due to road traffic accident and accounted for 79(79%) of cases. Fibula fracture was associated with 93(93%) of patients. Time taken in wound healing in majority of patients was less than 6 weeks 51 (51%), 6-8 weeks 32(32%), 8-10 weeks 9(9%) and those were not healed 9(9%) (Table 4). Majority of patients 57(57%) had RUST score 9 at six months of duration, 21(21%) of patients had RUSH score 11 and 9(9%) patients RUSH score was 6 at six months (Table 5). 7 cases got infected in this study and in 5 case there was non union. Average duration of hospital stay was 16.8 days. Out of 100 patients, 11(11%) patients had excellent outcome, 21(21%) had good and 59(59%) fair and only 9(9%) patients had poor outcome (Table.6). Average time of wound healing in our study was 4.29 weeks. Out of 100 patients, fracture union was achieved in 97 (97%) patients and two patient 3(3%) patient undergone non unions. This study comprised of 100 patients, out of them 59 patients (59%) had grade-I, 32 patients (32%) had grade-II and 9 patients (9%) 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	10weeks	Not Healed
Radiological union at 6 months (RUST Score)	13 score	11 score	9 score	6 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 =100	%
Male	73	73
Female	27	27
Age		
Below 30 years	7	7
30-40years	44	44
40-50 years	29	29
Above 50	20	20
RTA	79	79

Table 4: Time taken in wound healing

Time taken in wound healing in weeks	Number of patients=100	%
≤6 weeks	51	51
6-8 weeks	31	31
8-10 weeks	9	9
Not healed	9	9

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

Radiological union at 6 months (RUST score)	Number of patients=100	Percentage
6	9	9
9	57	57
11	21	21
13	13	13
Total	100	100

Table 6: Clinical outcome

Functional outcome	Number of patients=100	%
Excellent	11	11
Good	21	21
Fair	59	59
Poor	9	9
Total	100	100

Table 7: Grade compounding of patients

Grade	Number of patients=100	%
I	59	59
II	32	32
III	9	9

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 36.15 years. It is comparable to Javed Aziz et al(33.28years)[15] Our study revealed the sex ratio of fractures to be males were 73% against females 27%. it is comparable to some other studies on similar fractures by Lin j et al[16]

This study comprised of 100 patients, out of them 59 patients (59%) had grade-I, 32 patients (32%) had grade-II and 9 patients (9%) 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 100 patients, fracture union was achieved in 97 (97%) patients and two patient (3%) 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 4.29 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 100 patients, infection was found only in 7 patients. At the end of this study, out of 100 patients, 11(11%) patients had excellent outcome, 21(21%) had good and 59(59%) fair and only 9(9%) 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.

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