



GENTAMYCIN COATED INTRAMEDULLARY NAIL FOR OPEN DIAPHYSEAL FRACTURES OF TIBIA: A PROSPECTIVE STUDY

Orthopaedics

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ABSTRACT

The treatment of open fractures is still problematic despite many advances in the management of these fractures.

Objective- To investigate the use of the gentamicin coated intramedullary tibial nail in the surgical treatment of open diaphyseal tibial fractures
Place & duration of study- The study was conducted at a tertiary level post-graduate institute, INDIA. The cases were operated from March 2016 to August 2018 and were followed up for one year.

Design and Methodology- In this prospective case series the implant is a titanium alloy (Ti-6Al- 7Nb) nail coated with fully resorbable amorphous poly (D,L- lactide) containing gentamycin sulphate. The present study enrolled 30 patients with fracture of the tibia and the average age of 33.9 (23–54) years and mean time from injury to surgical treatment was 9.2 hours.

Results- All fractures united within 11 months. None of the patients has deep or chronic osteomyelitis, where 6 patients (20%) had superficial infections which responded to the antibiotic completely. At 12 months post-operatively, 73% (22 patients) have excellent knee function as per Surgeons Assessment of Final Outcome of fractures, 20% (6 patients) have a good function, 7% (2 patients) have a fair function.

Conclusions- Gentamicin-coated intramedullary nail in the surgical treatment of open fractures of the tibial shaft resulted in good functional outcomes within 12 months after surgery.

KEYWORDS

antibiotic nail, open fractures, infection, union, knee function

INTRODUCTION-

The treatment of open fractures is problematic in spite of many advances in the treatment. Overall infection rates are about 1–4% depending upon the severity of the fracture, soft tissue condition and general condition of the patient [1]. The incidence rate of infection was 3.2% (13 patients) in a study conducted by Gaebler et al among 467 patients after interlocking tibial nailing [2]. Petrisor B et al stated that infection rate in open tibial fractures after nailing is 6 to 33% [3]. Gustilo et al also reported an increased risk of infections with increased soft tissue injury [4]. In August 2005 a new gentamycin coated tibial nail was CE-certified (UTN PROtect). In a pilot study of 8 patients with open tibial fractures treated with gentamycin coated intramedullary nails, there were no infections within 1 year and all fractures healed within 6 months [5].

The present study aimed to evaluate the clinical and radiological outcomes of Gentamycin coated intramedullary interlocking nail in the management of open diaphyseal fractures of the tibia in 30 patients.

MATERIALS AND METHODS-

The OSSIPRO, Matrix implant is a titanium alloy (Ti-6Al- 7Nb) nail coated with fully resorbable amorphous poly (D,L- lactide) containing gentamycin sulphate. Depending upon the size of the implant the range of antibiotic varied from 20 g to 50 g [6].

STUDY DESIGN

This was a prospective study on Gentamycin coated intramedullary nail for open diaphyseal fractures of the tibia from March 2016 to August 2018. Informed consent was obtained from all individual participants included in the study. Surgeries were performed by different trained orthopaedic surgeons according to AO protocol and manufacturer's instructions. Follow-up visits were performed at 5 weeks, 3 months, 6 months and 1 year post-operatively. The study was conducted at tertiary level post-graduate institute, INDIA.

Inclusion and exclusion criteria

Patients were included in the study if they met the following criteria: Any type of open diaphyseal fracture tibia amenable for nailing, who

are medically fit and skeletally mature. Patients with gentamycin allergies, morbid obesity, pregnant, breast feeding and not giving written consent were excluded from the studies.

Data collection

The time duration between the injury and surgical procedure was noted. A thorough history was taken regarding chronic illness and severe infections in the past. The final results were recorded in four groups into excellent, good, fair and poor based on 1. The final functional outcome, 2. The duration required to return to occupation and 3. Persistence of pain based on Surgeons Assessment of Final Outcome of fractures [7].

Classification

Open fractures were classified based on Gustilo Anderson classification [8]. This classification system takes into consideration the extent of soft tissue injury, the extent of contamination and fracture severity and therefore has a prognostic element [9].

Radiographic assessments

Patients were subjected for X-rays before surgery, post-operatively at 5 weeks, 3 months, 6 months and 12 months after surgery. Consolidated fracture healing was defined as the bridging of at least three of four cortices in the anterior-posterior (AP) and lateral view of the standard radiograph of the tibia [10].

RESULTS-

The present study enrolled 30 patients with fracture of the tibia and the average age of 33.9 (23–54) years and mean time from injury to surgical treatment was 9.2 hours. It was observed that comminuted fractures of the distal end tibial were more common in young and middle-age groups, with a higher incidence in 3rd and 4th decade of life. At 6 months postoperative follow up, none of the patients has deep or chronic osteomyelitis, where 6 patients (20%) had superficial infections which responded to the antibiotic completely. 24 patients didn't have any complications of infection. At 5 weeks after surgery, most of the patients showed partially healed fractures. At 6 months postoperatively 11 patients had healed fractures (6 patients with ¾ and

5 patients with 4/4 bridged cortices. At 9 months postoperatively 14 patients showed healed fractures (8 patients with $\frac{3}{4}$ and 6 patients with 4/4 bridged cortices), 5 patients had partially healed fractures. All fractures united within 11 months after surgery. At 12 months postoperatively, 73% (22 patients) have excellent knee function as Surgeons Assessment of Final Outcome of fractures, 20% (6 patients) have good function and 7% (2 patients) have a fair function.

DISCUSSION-

Tibia being a subcutaneous long bone is highly vulnerable for open fractures [11]. High-velocity trauma results in open fractures with significant contamination which may lead to infection and non-union [1]. Management of infected non-unions of the tibia is challenging for a surgeon requiring complex management protocols. The primary aim is to provide mechanical stability using various treatment modalities and control of infection. Studies in the literature emphasize the importance of extensive surgical debridement to eliminate the infection. However, surgical debridement and systemic antibiotic treatment without local antibiotic augmentation are associated with a higher rate of recurrence and subsequent operations [12, 13].

The antibiotic-impregnated nail was first described by Dror Paley which provides mechanical stability to the bone, releases a high local concentration of antibiotic without systemic side effects and fills the dead space which prevents the growth of bacteria and biofilm formation after radical debridement [14]. In our present study, we used Gentamycin coated intramedullary nails in all patients for open diaphyseal fractures of the tibia which resulted in good clinical and radiological outcomes at 1 year postoperatively. We believe that gentamycin coated intramedullary nails helps in controlling infection promotes fracture union and early mobilization of the patient.

The average age of subjects in our study was 33.9 which was comparable to Srinivas et al [16], Brown C et al [17], Keating et al [18] and Singer et al [19] but was less compared to Fuchs et al [15].

Table 1: Comparing incidences of open fractures in all the studies

Study	Gustilo type			
	I	II	IIIA	IIIB
Present	8(27%)	12(40%)	7(23%)	3(10%)
Fuchs T et al	3(25%)	2(16%)	4 (33%)	3(25%)
Srinivas P et al	15(34%)	19(44%)	9(20%)	1(2%)
Brown C et al	-	14(36%)	14(36%)	11(28%)
Keating et al	14(15%)	34(37%)	35(38%)	8(9%)
Singer et al	6(15%)	11(27%)	16(39%)	8(19%)

Fracture union steadily progressed with time in all patients post-operatively. None of the patients had non-union or delayed union nor any patient required dynamisation. The average union time in our study is 30 weeks which was comparable to a similar study by Fuchs et al [15]. The average union time was 29.02 weeks in the study by Srinivas et al [16] and 36.7 weeks by Court-Brown et al [17].

Table 2: Shows duration of union compared to other studies.

Study	Union					
	%	No.	Type I	Type II	Type IIIA	Type IIIB
Present	100	30	27.2 wks	30.1	32.3	35
Fuchs T et al	100	21	28	31	32.2	41
Srinivas P et al	95	42	26	29	34	38
Brown C et al	95	37		23.5	27.2	50.1
Keating et al	91	85	28-reamed	28	34	30
			21-unreamed	27	31	35
Singer et al	89	37	19	28	31	24

No patient developed nonunion in the present study, which was comparable to study by Fuchs et al. The incidence of Nonunion was a bit more and comparable in other studies using normal nail in open fractures by Srinivas et al [16], Brown C et al [17], Keating et al [18] and singer et al [19].

The infection rate in our study was comparable to a similar study by Fuchs et al [15] using an antibiotic nail. The infection rate is higher in other studies using a normal interlocking nail in open fractures. Gentamycin coated intramedullary nail provides the benefit of high local concentrations of the antibiotic in the desired area without systemic toxicity. It also prevents bacterial colonization on the implant surface, thereby reducing the risk of implant-related infections.

Table 3: showing a comparison of infection with other studies

Study	Deep Infection					
	No.	%	Type I	Type II	Type IIIA	Type IIIB
Present	0	0	-	-	-	-
Fuchs T et al	0	0	-	-	-	-
Srinivas P et al	3	7%	0	2	1	0
Brown C et al	4	11%	-	1	0	3
Keating et al	2	4%	0	1	0	1
Singer et al	5	12%	1	1	1	2

CONCLUSION-

Primary antibiotic interlocking intramedullary nailing for open fractures of the tibial shaft is an excellent mode of treatment. It reduces the incidence of complications like infection and nonunion. The preliminary results from these studies are hopeful for better management of open fractures. Hence, we recommend the following protocol for open fractures diaphyseal tibia (Gustilo type I, type II and type IIIA) thorough debridement with or without wound closure along with primary antibiotic interlocking nailing and at a later date, split skin graft or flap or delayed primary closure

Conflict of interest-

Nothing to declare and there is no conflict of interest with no source of funding.

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