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Dr. Ashok J Sampagar
MBBS, MS Ortho, Senior Resident, Department of Orthopaedics, BIMS, Belagavi RGUHS, Karnataka, India

Dr. Bhavya L
MBBS, Casualty Medical Officer, BIMS, Belagavi, RGUHS, Karnataka, India

Dr. Amit Bilagi
MBBS, MS Ortho, Senior Resident, Department of Orthopaedics, BIMS, Belagavi, RGUHS, Karnataka, India

Corresponding Author:
Dr. Ashok J Sampagar
MBBS, MS Ortho, Senior Resident, Department of Orthopaedics, BIMS, Belagavi RGUHS, Karnataka, India

Prophylactic use of antibiotic-coated intramedullary nails in the treatment of open fractures of the tibia: A clinical observational assessment

Dr. Ashok J Sampagar, Dr. Bhavya L and Dr. Amit Bilagi

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Abstract
Aim: To evaluate the efficacy of antibiotic-coated intramedullary locking nail in the open tibia fractures.
Materials and Methods: It was a one-year clinical observational research at the Department of Orthopaedics, BIMS Medical college, Belagavi, which was conducted in a clinical setting. An interlocking tibia nail was used to treat 70 patients. Those with open fractures of the gustillo type 1, 2, and 3A, 3B were included in this research. There were excellent, good, fair and bad grades for RUST Scores and clinical evaluation scores.
Result: Of the 70 patients, 44.28 percent belonged to 30-40 years age group, 28.57 percent were in the age group 40-50, and 20 percent were above 50. Males (72.86%) outnumbered females. The most prevalent cause of injury was a car collision, accounting for 55 (78.57%) of cases. 92.86 percent of patients had a femur fracture. Wounds healed in less than 6 weeks in 50% of patients, 6-8 weeks in 31.43%, 8-10 weeks in 10%. At six months, 40 patients (57.14%) had RUST score 9, 15 patients (21.43%) had RUSH score 11, and 6 patients (8.57%) had RUSH score 6. Out of 70 patients, 8 (11.14%) had great outcomes, 15 (21.43%) good, 41 (58.57%) fair, and only 6 (8.57%) had bad outcomes.
Conclusion: Implant-related infection is a major stumbling block in the surgical treatment of tibia shaft fracture, according to the present study. Local administration of antibiotics might minimize the risk of infection.

Keywords: fracture, tibia, antibiotic-coated nail

Introduction
When it comes to long-bone fractures in adults, tibia shaft fractures are the most prevalent [1]. Approximately 26 fractures per 100,000 people and 569,000 hospital days are attributed to them each year [1, 2]. Men are three times more likely than women to have a fracture. High-energy trauma in young individuals or low-energy trauma in older persons with osteoporosis is associated with an increased risk of fracture [3]. Approximately 12 percent of tibia fractures in the general population and up to 23 percent in open fractures have a nonunion rate [4]. Two out of every thousand injuries are caused by open tibia fractures [5].
It's worth noting that older patients had a higher risk of open fractures than any other age group, with a 10% nonunion rate and a 17% malunion rate, respectively, in this population [6]. High-energy injuries are often linked with polytrauma, high infection rates, and other consequences that might jeopardise the limb and even the patient's life, making them a difficult therapeutic challenge for orthopaedic surgeons [7]. Plaster immobilisation, debridement, and surgical stabilisation are all options for therapy. For comminuted fractures, the locking of intramedullary nails reduced the incidence of malunion. It was formerly common practise to ream out the endosteal blood supply [8] and promote heat necrosis using interlocking intramedullary nails. Most surgeons oppose the use of intramedullary nailing with reaming for Type III open tibial fractures because of the high incidence of infection after therapy. Osteomylitis and a wound infection may occur after the use of cutting-edge surgical procedures and medications. The risk of profound infection in Gustilo grade III open fractures is roughly 80% [9]. Gustilo's grade raises the risk of infection, according to previous research. The primary purpose of locally given antibiotics is to reduce the risk of implant-related infections by preventing bacterial colonisation of the implant surface.

Additionally, large concentrations of antibiotic may be obtained in the targeted location without the need for high systemic dosages and accompanying adverse effects [10]. While systemic antibiotics may reduce the risk of infections from prosthetic and osteosynthetic devices, their potency is limited [10, 11]. Implant removal, debridement, and long-term antibiotic treatment are required if an implant becomes infected. Antibiotics may be delivered directly to the tissue-implant interface to avoid this kind of implant-related illness. A polylactic acid (PLA) coated intramedullary nail releasing gentamicin is one example of this [10, 12]. Antibiotic-coated implants have been shown to reduce the risk of implant-related infection [13]. Hence the present study was undertaken to assess the outcome of prophylactic use of antibiotic coated intramedullary nail in treatment of open tibia fractures.

Material and Methods

This prospective observational study was carried out in the Department of Orthopaedics, BIMS Belagavi for the period of 1 year, after taking the approval of the protocol review committee and institutional ethics committee. Total 70 patients were treated with gentamicin coated tibia interlocking nail.

Inclusion criteria

Patients with Open fractures gustillo type 1, 2, 3A, B fracture Exclusion criteria. Types III C and D Gustilo patients excluded, pregnant women, patients with cancerous primary illness, patients with weakened vascular systems, and those who were allergic to the antibiotic employed were excluded.

Methodology

An antibiotic-coated tibia interlocking nail with the ability to release gentamicin over time was employed in this study's experimentation. Gentamicin and a biodegradable polymeric carrier Poly are included in the coating (D, L-Lactide). A 100 mg (1mg/cm^2) dose of gentamicin is contained in a typical sized nail. Pre-operative evaluation and treatment of any life-threatening conditions were assessed and treated. Before any anaesthetic was administered, each patient had a thorough pre-anesthetic examination. The patient was painted and sterile drapes were applied. Excess skin and bone were removed from above the tuberosity of the tibia using an image intensifier before the knee was bent to 90 degrees. Serial reaming was performed once the guide wire was passed. An antibiotic-coated nail is placed into the medullary canal in the correct size. Patients requiring falps and grafts accordingly were performed. After surgery, patients received five days of intravenous antibiotics. The patients were monitored for up to six months after surgery to evaluate the recovery.

Results

All 70 patients (51 men and 19 females) were followed up for minimum of 3 months length. The radiological Union was rated using RUST Score (Table 1) and clinical evaluation findings were classified as outstanding, acceptable, fair and bad (Table 2). The research contained 44.28 percent of the patients between 30-40 years of age, 28.57 percent of the patients between 40-50 years of age and 20 percent beyond 50 years and 7.14 percent of patients below 30 years. The mean age of such fractures to be 35.65 years in this research, there was preponderance of male population. Males were 72.86 percent versus females 27.14 percent (Table 3). The most prevalent cause of injury was determined to be related to road traffic collision and accounted for 55(78.57%) of cases. Fibula fracture was related with 65(92.86%) of patients. Time required in wound healing in majority of patients was shorter 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 57.14% had RUST score 9 at six months of duration, 21.43% of patients had RUSH score 11 and 8.57% patients RUSH score was 6 at six months (Table 5). 6 patients became infected in this research and in 4 cases there was non-union. Average length of hospital stay was 16.5 days. Out of 70 patients, 8 (11.14 percent) patients had outstanding result, 15 (21.43 percent) had good and 41 (58.57 percent) fair and only 6 (8.57 percent) patients had bad outcome (Table.6). Average period of wound healing in our research was 4.25 weeks. Out of 70 patients, fracture union was accomplished in 68 (97.14%) patients and two patient (2.86%) patients underwent non unions. This research composed of 70 patients, out of them 41 patients (58.57%) had grade-I, 23 patients (32.86 percent) had grade-II and 6 patients (8.57 percent) 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

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 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: Demographic profile

Gender	Number of patients =70	%
Male	51	72.86%
Female	19	27.14%
Age		
Below 30 years	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%
6-8 weeks	22	31.43%
8-10 weeks	7	10%
Not healed	6	8.57%

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

Radiological union at 6 month (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%

Table 7: Grade compounding of patients

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

Fig 1: Wounds of the patients

Fig 2: Reaming

Fig 3: Insertion of antibiotic coated nail

Fig 4: Post-operative x-rays of patients

Fig 5: Follow up x-rays of patients showing union of fracture

Discussion

Infected long bone fractures need a technique to manage infection, stabilise the fracture, and accomplish a successful union of the bones. The infection is controlled by surgical debridement and the introduction of antibiotics both locally and systemically. With local treatment, a high concentration of antibiotic may be achieved while having a little effect on the body as a whole [14].

Injuries to the tibia's shaft account for a large percentage of all long bone injuries treated in emergency rooms. For an open tibial shaft injury, there is no one-size-fits-all method of therapy, and this may be harmful. An increased risk of open and infected tibia fractures due to its close proximity to skin. Particularly in spiral and oblique fractures, after swelling subsides, pieces tend to reposition themselves. The alignment or rotational position of the pieces is imprecise since the knee and ankle joints generally move on the same parallel axis. This might create cosmetic and functional handicap.

Surgical treatment of open tibial shaft fractures is aimed at lowering the risk of infection and improving the healing of the fracture. Providing secure internal fixation with an intramedullary nail prevents the common issue of joint stiffness by allowing for early recovery and flexibility of surrounding joints.

Using antibiotic-coated intramedullary locking nails in complex tibia fractures, the researchers set out to see how effective they were. Compared to Javed Aziz *et al*., our research found a mean age of 35.65 years for such fractures (33.28 years) [15].

Males were found to account for 72.86 percent of all fractures, compared to 27.14 percent for females. It's on par with the findings reported by Lin j *et al*. [16].

In the present study half of the patients (58.57 percent) had grade-I compounding; the remainder had grade-II compounding (32.86 percent), and six patients (8.57 percent) had grade-III compounding. There were 13 instances of grade-I fractures and 12 occurrences of other fractures in a research by Bhanu Pratap *et al*. [17].

Only three patients (27.27%) in the research by Khaled Hamed *et al*. [18] had Gustilo type II fractures, whereas eight (72.72%) had type I. Fifty-eight (97.14 percent) of the patients had their fractures healed, whereas the other two patients (2.86%) had non-unions. Bhanu Pratap *et al*. [17] and Thomas Fuchs *et al*. [19] found that none of the patients had non-union as a result of treatment. In our research, the average healing period for a wound was 4.25 weeks. Bhanu Pratap *et al*. [17] found cases of infection in two of the 25 individuals studied. Thomas Fuchs *et al*.[19] found that just one of the 19 participants in their research had an infection. In our investigation, only six of 70 patients were confirmed to be infected, which is consistent with our results. There were 8 patients who showed excellent outcome, 15 showed good outcome and 41 fair outcomes among the 70 patients studied in this research. Only 6 of the patients had poor outcome.

Conclusion

Implant-related infection is a major stumbling block in the surgical treatment of tibia shaft fracture, according to the present study. Antibiotics given at the site of the injury may help prevent an infection from developing.

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