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Functional outcome of antibiotic coated interlocking intramedullary nail in open tibia diaphyseal fracture

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Abstract

Introduction: Open fracture of tibia is one of the most common injuries seen in orthopaedic practice. The appropriate treatment of open tibial fractures is one of the priority problems in modern era of traumatology. New tibial titanium nail with a biodegradable gentamicin-loaded coating (UTNPR Otect, Synthes) was CE-certified in August 2005. The main goal of locally delivered antibiotics is to prevent bacterial colonization of the implant surface, thereby reducing the risk of implant-related infections.

Aims and Objectives: To assess functional and clinical outcome after intramedullary locking nail fixation of open fracture shaft of tibia.

Method and Materials: 25 patients were selected of age group 18-65 yrs presenting with open fracture shaft tibia on the basis of OPD and emergency admissions in M.B. Govt Hospital Udaipur. Fractures were classified as per Gustilo Anderson classification. All patients were treated operatively with antibiotic coated intramedullary interlocking nail, and its outcomes were assessed on the basis of Alho and Ekland Criteria and complications were observed with follow up to 6 months clinically and radiological imaging.

Result: In this study of 25 patients of age group 18yrs to 65yrs were treated with antibiotic coated Intramedullary inter locking nail, 80% cases were male and 20% cases were female. Mean time of union 16.5 weeks. No implant related infection occurred only superficial infection found in two patients.

Conclusion: The use of the antibiotic coated nail was good clinical and radiological outcome after 6 months. These preliminary results support the use of antibiotic coated implants as a new potential treatment option for prevention of infection in trauma patients.

Keywords: open fracture, intra medullary nail, antibiotic coated, soft tissue management

Introduction

Open fracture of tibia is one of the most common injuries seen in orthopaedic practice. The appropriate treatment of open tibial fractures is one of the priority problems in modern era of traumatology. Tibia, being a subcutaneous bone, increases the chance of infection and non-union [1]. In choosing the optimal mode of treatment, one has to consider the importance of associated soft tissue injuries along with the configuration of fracture. 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 [2] 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. A new tibial titanium nail with a biodegradable gentamicin-loaded coating (UTNPR Otect, Synthes) was CE-certified in August 2005. In a pilot study of 8 patients with open tibial fractures treated with UTN PRO tect_ intramedullary nails, there were no infections within 1 year and all fractures healed within 6 months [3]. 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 [4].

Material and Method

The data for this study was collected from the patient admitted to Rabindranath Tagore (RNT)

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Medical College & Hospitals Udaipur, on the basis of OPD and emergency admissions during the period of 1st October 2017 to 30th October 2018 and will be treated surgically using antibiotic interlocking nail system who will be diagnosed with open diaphyseal shaft tibia fracture with inclusion criterias.

Study design: This is Prospective study. Prospective Study of patient managed surgically from 1stOctober 2017 to 30thOctober 2018 by antibiotic coated Intramedullary nailing for open tibia shaft fractures, at Maharana Bhoopal Hospital Udaipur. These patients were treated with antibiotic coated tibia nail. Patients were called and informed about the study, written consent was taken, and then they were evaluated.

Sample size: Total 25 patients of open tibia diaphyseal shaft fractures were included in the study were treated surgically by antibiotic coated tibia nail.

Inclusion criteria

1. >18years of age.
2. Open fractures gustillo Anderson type 1, 2, 3A fracture.

Exclusion criteria

1. Associated with head injury.
2. Pathological fracture, fracture non-union and delayed union.
3. Patients not willing and medically unfit for surgery.
4. Patients lost in follow up.
5. Patients with neurovascular injury.
6. Patients with open fracture gustillo and Anderson type 3B and 3C
7. Patients who are pregnant, breast- feeding or planning to become pregnant during the study, a known allergy to aminoglycosides

Surgical technique

The patients were placed in supine limb hanging position on OT table. After administration of anesthesia, the wound was debrided and irrigated copiously by pulsatile lavage. About 3 to 6 litres of normal saline will be used in every case. Dead muscles, devitalized soft tissues would be debrided. The operation was performed on operating table under image intensifier. Under all the aseptic precautions the local area was painted and draped with sterile cloth.



Fig 1: Intraoperative position of nailing

Incision and entry portal: The tibial tuberosity was palpated and 5 cm long incision applied in mi dline from lower pole of patella to tibial tuberosity patellar tendon was cut in line of skin incision.



Fig 2: Incision at entry point of nailing

Entry was made by curved awl, just medial to lateral tibial spine in AP view and just below the articular cartilage in lateral view. The awl is initially inserted at right angle to the bone, and as the entry point is deepened the angle of handle of awl was made downward so that it eventually lies parallel with the tibia. Than a small hand reamer was used to ream only the cancellous bone of the entry portal to accommodate the proximal end of nail.



Fig 3: Bony entry with awl

Insertion of nail: Then appropriate size of nail tightened to the jig and inserted; the orientation of insertion handle kept medially and anteriorly. Tissue protector was used to avoid injury the skin and soft tissue at the knee. The nail was driven with manual pressure and its progress was checked under image intensifiers. As the nail approaches the fracture site, rotation and reduction was checked. Then the nail was driven across the fracture site for a few centimeter and reduction and stability of fracture was checked and then the nail was inserted fully and further the position checked under image intensifier to determine the reduction of fracture and distance from the end of nail to ankle joint.



Fig 4: Insertion of nail

Locking of nail: proximal locking, 8 mm protection sleeve and trocar was inserted through the appropriate hole in the insertion handle until there was inserted through the appropriate hole in the insertion handle until there was cortex contact. The trocar was removed and 4 mm drill sleeve inserted and hole was drilled. The length of the bolt to be inserted was measured. Using a depth gauge then the locking bolt was inserted. Similarly 2nd bolt was inserted. For the distal locking we used free hand aiming method. First the distal hole is seen under image intensifier and the hole made to be seen absolutely round by positioning the X-ray tube at right angle to the leg and incisions were made on the medial side of leg on the centre of hole and then with help of drill bit hole was made, length of the bolt to be inserted was then measured using a depth gauge and bolt inserted using a screw driver.

However in some cases only single locking was done usually distal one.

Then the closure was done. Compression bandage or POP slab was applied. Average operating time for nailing was noted.

Postoperative management and follow-up

Physiotherapy: active toe movements encouraged. The patients were watched for excessive swelling, pain and distal circulation.

Patients were given physio-therapy post operatively by gait training and range-of motion exercise. When no other injuries contraindicated ambulation of patients was done with the help of walker.

For patients who had <50% comminution were allowed Weight bearing as tolerated once the soft tissue of wound were healed.

All the patients were called upon 6th 12th 18th weeks and 6 months and thereafter at every 3 monthly intervals till the union occurs at every visit. Movements at knee and ankle joints were measured.

Results

The study comprised 52% of the patients between 18-34 years of age and 48% of the patients between 35-65 years of age. Males predominated in this series. Males were 80% as against females 20%. The most common cause of injury was found to be due to road traffic accident and accounted for 80% of cases. Majority of fractures were type I -52% 64% of the fractures were found to be in the middle one-third, 12% in the upper one-third and 24% in the lower one-third of the shaft of tibia. 90% of the cases were operated within 24hr of injury. In all patients close nailing was done. Non-comminuted fractures unite early (15.5 weeks) as compare to comminuted (16.2 weeks). In cases dynamization in the form of removal of proximal screw were done. All the cases united successfully after dynamization. 8% of cases got infected in this study. In all the infected cases, infection had to be controlled by appropriate antibiotics, adequate drainage and debridement. None of nail had to be removed to control the infection. None of the cases required bone grafting after the initial surgery. The mean time of hospital stay was ten days (range 5 to 19 days) in the series. Majority of the patients were discharged after 7 days surgery. Discharge was delayed in those cases, which developed some complications. In this series the partial weight bearing was started after an average period of 25.15 days. Full weight bearing was started after an average period of 8.95 weeks. The average union time was found to be 15.8 weeks. There were no cases of significant shortening of the limbs. 1 case had 7° Valgus and 1 case had

10° varus deformity. Two cases went into delayed-union and united after dynamization. The most common complication encountered in this study was in ankle joint stiffness (8%). The final results were excellent to good in 85% of the cases studied.

Radiological outcome



Fig 5: Radiological outcome

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 as below:

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.
4. Conspicuous disfigurement if apposition of the fragments is imperfect because the tibia lies subcutaneously.
5. Slow union as result of severity of the fractures, poor blood supply to one of the fragments and sometimes distraction of the bone fragments.
6. The occasional limitation of joint movement in the knee ankle and foot, usually caused by associated joint, soft tissue or vascular injury.

It is because of these difficulties that have given rise to so much controversy between surgeons as to the best method of managing tibial shaft fractures. Numerous treatment methods exist and excellent results have been reported with conservative as well as surgical methods.

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. Thus when the aim is stable fixation with early restoration of function, unreamed intramedullary nailing offers an attractive treatment option. It also aids in good wound care, early union and low infection rates.

We evaluated our results and compared them with those obtained by various other studies, our analysis is as follows:

Age distribution

Our study revealed the mean age of such fractures to be 33.4 years. It is comparable to some other studies on similar fractures by other authors.

Table 1: Age distribution of patients

	Minimum age	Maximum age	Mean age
Javed Aziz <i>et al.</i> [5]	17 years	60 years	33.28 years
Khaled Hamed <i>et al.</i> [6]	16 years	89 years	39.5 years
Our study	18 years	58 years	33.4 years

The worst part of the story is that these injuries are encountered in young males below 35 years of age, who are the central pillar of the family. In the present study 52% of patients were between 18-34 years of age.

Sex distribution

Table 2: Sex distribution of patients

Study	Male percentage	Female percentage
Lin j <i>et al.</i> [7]	70%	30%
Khaled <i>et al.</i> [6]	66.45%	33.54%
Court brown <i>et al.</i>	87%	17%
Our study	80%	20%

Table 4: Clinical outcome and comparison of this study

Study	Mean union time	% of cases in which infection occurred	% of cases in which union occurred
Zucman and p mauer <i>et al.</i>	16 weeks	2.1%	97.9%
Helfet <i>et al.</i> [10]	17.71 weeks	5.1%	97%
Lin j <i>et al.</i> [7]	18.2 weeks	4.16%	92%
Our study	16.5 weeks	8%	100%

In our study union achieved in 100%. The results of our study were comparable with other studies.

Table 5: Comparison of union

Study	% of cases in nonunion occurred	% of cases in delayed union occurred	% of cases in union occurred
Duwelius <i>et al.</i> [9]	6%	18%	94%
Khaled <i>et al.</i>	10%	12.5%	90%
Khan and Javed <i>et al.</i>	8%	10%	92%
Our study	0%	8%	100%

Infection-infection rate in our study is 8% which is only superficial infection

Table 6: Infection assessment

Study	Procedure	Sample size	Infection
Yokoyama <i>et al.</i> [11]	EF followed by nail	42	16.7%
Kaftandzhev <i>et al.</i> [12]	EF as definitive treatment	30	24%
Inan <i>et al.</i> [13]	IM nail as definitive	29	10.34%
Our study	Antibiotic IM nail	25	8%

Complications

1. Infection: In our study the infection occurred in 02 cases (8%). There were 2 cases of superficial infection. Infection was resolved by debridement, regular dressing and antibiotics. No infection in close fractures.

In our study majority of the patients were males (80%) as they are more susceptible to trauma because of more outdoor activities. This could be because majority of the females are restricted to the household activities as opposed to the western world

Mode of injury

Table 3: Mode of injury

Study	RTA	Others
Ellis. D. Seddin <i>et al.</i> [8]	60%	40%
C.M. Court Brown <i>et al.</i>	57%	43%
Our study	80%	20%

Road traffic accident was found to be the commonest cause of fracture of the tibia in our study (80%). The incidences of injury due to roadside accidents were shown to be 60% in the series of Ellis. D. Seddin, David TZienter (1985) and 57% in the series by C.M. Court Brown (1991). This incidence was found to be much less than that found in our study.

The reason for this was concluded to be due to

1. Increase in the number of vehicles due to fast living style.
2. Inappropriate safety measures and under trained and understaffed traffic police.
3. Ignorance of traffic rules by general population.
4. Overcrowding which affects the public transport.

Time taken for union

The average time taken by fracture to unite in various studies was around 9-24 weeks. In our study the average time taken by the patient for fracture union was 15.8 weeks.

In our study union achieved in 100%. The results of our study were comparable with other studies.

2. Mal Union: Incidence of malunion was very less. In our study only 2 cases (8%) had mal union. One had 10° varus deformity and one has valgus deformity of 07°.

3. Delayed union: Only 2 cases of delayed union were noted in our study. Dynamization was done in all cases

and fracture united later on.

4. **Anterior knee pain:** In our study 1 case had post operative anterior knee pain. pain was due to excessive nail protrusion from tibial tuberosity,
5. **Ankle stiffness:** In our study ankle stiffness were reported in 02 cases. Stiffness was more in patients with fracture of lower third than of middle third.
6. **Knee stiffness:** Knee stiffness was seen in one case.
7. **Symptomatic hardware:** In our study symptomatic hardware were reported in 2 cases.

Other complications: In one case the distal screw was bent.

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. 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. These good outcomes were observed even in our series of patient with complex tibia trauma.

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