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SHORT TERM CLINICAL OUTCOMES OF ANTIBIOTIC IMPREGNATED CEMENTED INTRAMEDULLARY NAILS IN OPEN FRACTURES OF TIBIA

Orthopedics

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ABSTRACT

Single centre, prospective, observational study of 60-patients with open tibia shaft fractures treated with Antibiotic Impregnated Cemented Intramedullary Interlock (AICII) nail was conducted with respect to their clinical outcomes. 34,20 and 2 patients united at 3-month, 6-month and 9-month respectively (average:4.29±1.98) while 4(6.67%) patients did not show union at 1-year. Average time to union for type 1,2,3a and 3b fractures was3,4.2,5.14 and 6 months respectively. 52(86.67%) did not develop infection. Thus, use of antibiotic impregnated cemented intramedullary interlocking nails in management of open tibial shaft fractures, appears as a safe and effective method in achieving union as well as infection control.

KEYWORDS

Open Fractures, cemented nail, Interlock Nailing, infection, union

INTRODUCTION

Open fractures (Gustilo I-III)(Gustilo & Anderson, 1976) continue to be a common injury with a high risk of complications such as wound infection and delay in union and high chances of non-union (Babhulkar & Raza, 2008).It is estimated that about 45 lakh open fractures occur in India every year. This can ,however, be an underestimation. (Cross, Swiontkowski, & Swiontkowski, 2008) Since the protective skin layer is broken the chances of contamination of the wound are very high and thus, these fractures become particularly worrisome. It is believed that the rate of infection in open fractures ranges from 5% in Gustilo Type I up to 50% in Gustillo Type III.(Craveiro-Lopes, 2016)(Maurer, Merkow, & Gustilo, 1989) Emergency treatment consists of thorough and perhaps ruthless debridement of the wound, that includes removal of all the foreign materials like soil, sand particles, stones and many a times vegetation/leaves along with dead, devascularized and necrosed tissue. This reduces the total bacterial load and helps in reducing the rate of complication.(Babhulkar & Raza, 2008)

The correct and timely management of such injuries is of a great value. While deciding on the plan of management for such injuries various factors need to be taken into account like, patients' general condition and vital parameters, co-morbidities, the mechanism and severity of injury, amount of contamination, fracture type. As the new evidence keeps on emerging, the treatment strategies and guidelines keep on changing and updating. Multiple treatment modalities such as use of external fixators, plates and intramedullary nailing (either reamed or unreamed) are under investigation.

Traditionally, the use of external fixators has been considered as treatment of choice in type II and III open fractures of tibia. However, the external fixation is associated with complications like malunion, delayed union, loss of reduction, refracture, pin tract infection and non-union with the incidence ranging from 21 to 55% (Babhulkar & Raza, 2008).Converting external to internal fixation has a higher (40-70%) risk of infection when the external fixator is used for more than 2 weeks.(McGraw & Lim, 1988) (Craveiro-Lopes, 2016). This leads to increase in time and cost required for treatment of the open fractures.

To avoid this, antibiotic coated implants came into the use. The present study was conducted in a tertiary care institute to evaluate the clinical outcomes of Antibiotic Impregnated Cemented Intramedullary Interlock (AICII) nailing in open fractures of tibia.

MATERIALAND METHODS

After obtaining institutional ethics committee approval, a Single centre, Prospective, observational study of 60 patients suffering from open tibia shaft fractures was conducted over a period of 18 months. 60 consecutive adult patients with diaphyseal open fractures of tibia from type 1 to type 3b Gustilo Anderson classification were recruited.

Data collection: Informed written and valid consent was obtained from each patient recruited in the study. Various clinico-radiological parameters were noted and analysed. The parameters included age, sex, co-morbidities, mode of trauma, grade of fracture, time from injury to presentation at the hospital, time from injury to surgery, duration of surgery, blood loss, wound status at the end of surgery, requirement of additional wound coverage procedure, duration of hospital stay. The patients were then followed up at 1 month, 3-month, 6-month, 9 month and 1-year interval. At each follow up patients were evaluated with respect to their wound status, clinical as well as radiological union of fracture (on anteroposterior and lateral radiographs), presence of infection.

Pre-operative management: Immediately after the patient was brought to casualty, patient's airway, breathing and circulation were assessed. Then a complete survey was carried out so as to rule out other significant injuries. Plain radiographs of Anteroposterior and lateral views of – the involved extremity including one joint above and one joint below were taken to assess the extent and geometry of fracture. Mangled Extremity Severity Score (MESS) was calculated and decision whether the limb is salvageable was taken. Relevant clinical photographs were taken. The wound was covered with sterile dressing. Blood Investigations in the form of compete blood count, liver and kidney function tests, Serum electrolytes, Random blood glucose, Prothrombin time and international Normalised ratio (PT-INR) were done.

The patient was taken in the Operating Room under suitable anaesthesia and the wound was debrided thoroughly and irrigated with copious amount of Normal Saline (3 litres,6 litres and 9 litres for grade 1,2 and 3 fractures respectively). A fresh sterile mop was then placed over the wound and surgical incision films was applied over the wound. The drapes, sterile gowns and gloves were changed by the entire team. The Medullary canal was reamed till maximum allowable diameter. Nail length and diameter were determined under fluoroscopic guidance.

An interlocking nail of appropriate length and 8 mm diameter was chosen. Antibiotic cement was prepared by adding vancomycin (1 gram) plus gentamycin (500mg) in 20gram P.M.M.A. high viscosity cement. Diameter of the nail after coating of cement was determined as

1 size smaller than the diameter of largest used reamer. Using sizer plate with holes of different diameters, AICII nail of suitable diameter was prepared. (For a tibia reamed with 12mm reamer, a nail of 8mm diameter with cement coating of size 11mm was used.) Over reaming is done to prevent the debonding of the cement during the insertion of the nail. (Thonse & Conway, 2007) Care was taken not to block the interlocking holes with cement. (Figure 1)

Figure 1: Antibiotic coated cemented nail prepared with taking care not to block interlocking holes with cement.

The nail was allowed to cool down and then mounted on the jig. Nailing was done as per standard interlock nailing procedure. Layered closure of surgical wound was done and the debrided wound of the fracture was either closed with skin tags or kept open or handed over to plastic surgery for flap as per the dimensions of the wound and local skin condition. Care was taken not to keep any bone exposed at the end of the surgery.

Postoperatively intravenous antibiotics were given for 5 days and then changed over to oral antibiotics and continued till 10th day.

RESULTS

The mean age of the patients was 32.7 years with standard deviation of 9.01 years (Range 22 to 51). There was male preponderance 48(80%) in the study while female patients constituted 12(20%) of the study group. In the study, there was Right sided predominance compared to the left side (60% vs. 40%).

It was observed that 10 (16.67%) fractures were Gustilo Type 1, 32(53.33%) fractures were Gustilo type 2, while 14(23.33%) and 4(6.67%) fractures were Gustilo Type 3a and Gustilo Type 3b respectively. The study included only those Gustilo Type 3b cases which were not grossly contaminated. Gross contamination was taken as those cases with Road Traffic Accident (RTA) with crush injuries and bone loss.

It was observed that Road traffic accidents (RTA) was the major cause of the trauma (76.67%) followed by Assault which contributed 13.33% cases. Fall was the third common cause constituting 10% of the cases.

All the 60 patients included in the study were vitally stable. In our study, most of the patients (83.33%) were operated within 24 hours from the time of trauma while 10 patients (16.67%) were treated after 24 hours.

58 (96.67%) patient required 1-2 hours surgical time while 2 patient required 2-3 hours surgical time. Mean surgical time was 1.55 hours with standard deviation of 0.36 hours.

24 patients (40%) had blood loss of 301 to 400 ml,16 patients (26.67%) had blood loss in the range of 101 to 200 ml while 14 patients (23.33%) had blood loss in the range of 201 to 300 ml. 4(6.67%) patients had blood loss in the range of 401 to 500 ml while 2 patients had blood loss of more than 500 ml. The mean blood loss was 311.67 ml with standard deviation of 109 ml. (Table 1).

Blood loss	No. of patients	Percentage of patients
0 – 100 mL	0	0
101 – 200 mL	16	26.67
201 – 300 mL	14	23.33
301 – 400 mL	24	40
401 – 500 mL	4	6.67
>500 mL	2	3.33
Total	**60**	**100**

Legend: Table 1 shows the distribution of patients according to blood loss during surgery

In 24(40%) patient wound cover could be achieved comfortably on table after debridement while in 6(10%) patients the wound had sutures under tension. In 30(50%) patients primary wound cover could not be achieved. Out of them, 20(33.33%) patients required wound cover procedures like flap (12) or skin grafting (8). While the remaining 10 were treated with negative suction dressing. An illustration of sample case is depicted in (Figure 2)

Figure 2 : A sample case with open fracture of tibia. A: Clinical photograph and radiograph at presentation to the hospital. B: Intraoperative image with debridement of the wound and cemented nail preparation and primary closure of the open wound. C: Follow up at 1 month clinical photo with healed wound and a uniting fracture.

Majority (56.67%) of the patients had 5-10 days of hospital stay and 16 patients (26.67%) had 10 to 15 days of hospital stay while 10 patients (16.67%) had 15-20 days of hospital stay. The average length of hospital stay was 10.27 days with standard deviation of 4.76.

In present study 34 patients (56.67%) united in 3 months while 20(33.33%) patients united at 6 months. 2 patients united at 9 months while union was not observed in 4 (6.67%) patients during the course of follow up at 1 year. Average time to union was 4.29 months with standard deviation of 1.98. Time for union as per the grade of fracture is depicted in table 2.

Time to union (in months)	Mean	SD	Range
Grade 1 (n=10)	3	0	NA
Grade 2 (n=32)	4.20	1.47	3 - 6
Grade 3a (n=14)	5.14	2.10	3 - 9
Grade 3b (n=4)	6	0	NA
Total	4.29	1.98	3 - 9

Legend: Table 2 shows distribution of patients according to time to union post-surgery and the grade of fracture.

It was observed that 52 (86.67%) did not develop infection while 8 patients (13.33%) developed infection. The rate of infection as per the fracture grade is shown in Table 3.

Grade	Infection		% infected
	Yes	No	
Grade 1 (n=10)	0	10	0
Grade 2 (n=32)	3	28	10.7
Grade 3a (n=14)	3	11	21.4
Grade 3b (n=4)	2	2	50
Total (n=60)	8	52	13.33

Legend: Table 3 shows the infection rates in patients treated with cemented intramedullary interlocking nails as per the fracture grade.

DISCUSSION:

External fixators have been in use for the treatment of open fractures for many decades now. Once the backbone of the compound fracture management, the popularity of external fixators slowly stated reducing due to high complication rates.(Clifford, Lyons, & Webb, 1987) However, in cases of polytrauma as a strategy of Damage Control Orthopaedics (DCO) it is still the favoured type of fixation.(Hofmann, Dietz, Pairon, & Rommens, 2014) Interlocking nailing in open fractures has been in use since 1970's.(Craveiro-Lopes, 2016) The advantages of using intramedullary nails include better wound

management, easy access to wound closure procedure if required, advantage of primary and definitive surgery in a single sitting. (Agrawal, Chauhan, Maheshwari, & Juyal, 2013; Hofmann et al., 2014) Reamed as well as unreamed nailing has been shown to have similar results as far as long term union and rates of infection is concerned.(Finkemeier, Schmidt, Kyle, Templeman, & Varecka, 2000) However, the overall rate of infection in reamed nailing in open fractures remains to be high.(Court-Brown, 2004) Antibiotic eluting implants have multiple advantages in the treatment of open fractures. They help in control of infection by locally releasing high doses of antibiotics without causing systemic toxicity. They not only provide rotational stability for immediate mobilization of the affected limb post operatively but also avoid multiple complications associated with external fixators like pin tract infections, difficulty in wound dressing and coverage procedures. Thus they are thought to be better choice of implants for treating open fractures.(Craveiro-Lopes, 2016) These implants come with different vehicles for antibiotics, which include polymethyl methacrylate (PMMA), (Wininger & Fass, 1996)(Bowyer & Cumberland, 1994) polylactic acid(PLLA),(Schmidmaier, Lucke, Wildemann, Haas, & Raschke, 2006) and hydrogels. The PMMA cement admixed with antibiotics has been one of the oldest and most widely used methods for this purpose.(Klemm, 1979) Studies have found that use of 1 gram vancomycin with PMMA cement provides local concentration 7-12 times the MIC.(Craveiro-Lopes, 2016) Antibiotic cement nails have been in use for quite a long time, especially in cases with osteomyelitis and infected non-unions. However, there is paucity of literature regarding the use of antibiotic cemented interlocking nails in open fractures. Thus, this study was conducted to analyse the clinical outcomes of AICII nails.

The procedure of making antibiotic nail is simple and consumes minimal extra time and overall surgical time is almost similar to a standard intramedullary nailing. In this study, the mean surgical time was 1.55 hours with standard deviation of 0.36 hours. This was comparable to a study of tibial nailing in open fractures by Ji J et al.(Ji, Zhao, He, & Zhou, 2009) who reported average duration of surgery to be 94 minutes (range 60-132 minutes) and mean blood loss of 122 mL (100-350 mL). Mukherjee S. et. al (Mukherjee et al., 2017) studied nailing vs plating in tibial fractures and reported average blood loss of 165.00±5.31 ml. Our study had mean blood loss of 311.67 ml with standard deviation of 109 ml. The higher blood loss in our study may be due to the fact that thorough debridement and reaming of the bone was carried out and no tourniquets were used.

Agrawal A. et. al. (Agrawal et al., 2013) studied the outcomes of nailing in compound tibial fracturs and found that the average time to union was 16.0 weeks in Gustillo type I cases, 18.3 weeks in the type II cases, 23.6 weeks in the type III A cases, 28.4 weeks in the type III B cases and 32 weeks in the type III C cases while the mean time to union was 20.7 weeks. Srinivas et al(Srinivas & Nazeer, 2017) found that the average time to union was 26 weeks for type I fractures, 29 weeks for type II, 34 weeks for type IIIA, 38 weeks for the type IIIB fractures. In our study, all type 1 fractures united within 3 months, average time to union for type 2 fractures was 4.2 months and type 3a and 3b united in 5.14 months and 6 months respectively.

None of the above-mentioned studies have, however, used antibiotic cement coated nails. The study which had the most similar methodology to our study was by Lopes et al(Craveiro-Lopes, 2016) who conducted a prospective, controlled cohort trial of thirty patients with open fractures of the tibia and divided the patients into two groups- one who underwent standard nailing and the other who underwent antibiotic cemented nailing. They found that the healing time was significantly more for non- cemented group, at an average of 7.5 months (3-18 months) compared to 4.5 months (2-8.5 months) for the cemented nail group (P = 0.02). They also found that the complication rate including infection was 64% (9/14) in the standard nailing group and 25% (4/16) for the cemented nailing group. In our study a total of 8 patients (13.33%) were infected. No infection was seen in patients with fracture type 1. The infection rate in type 2 was 10.7% while that in type 3a and 3b were 21.4% and 50% respectively. The authors strongly believe that the relatively lower infection rates are as a result of through and ruthless debridement, large amount of saline irrigation, careful handling of the fracture fragments and rotational stability with the use of interlocking nails and most importantly the local delivery of high dose antibiotic which provides effective infection control without causing systemic toxicity.

Complications and its management: Infection was the most common complication. 8 patients who were infected were treated with nail removal and exchange nailing. 4 of them went on to unite after cemented exchange nailing. Debonding of cement during nail removal was seen in 4 cases (50%). The leftover cement in the canal was removed using long handle scoops, j hooks and reamers. 4 patients did not show signs of union till 1 year follow up. These 4 cases along with were treated with debridement and Illizarov ring fixator.

Limitations: Smaller sample size and absence of control group were the limitations of our study

CONCLUSION

The use of antibiotic impregnated cemented intramedullary interlocking nails in management of open tibial shaft fractures, is a safe and effective method in achieving union as well as infection control. In future randomised, controlled, double blind trial will be needed for establishing more evidence regarding the efficacy of antibiotic coated intramedullary interlock nailing in open fractures.

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