Infected Non-Unions of Long Bones→ Is Low Cost Antibiotic Nail A Viable Option in Indian Scenario

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ABSTRACT

Introduction: The advent of broad spectrum antibiotics and maintenance of strict asepsis in operation theatres combined with laminar airflow systems has decreased the number of orthopaedic implant associated infections. Most of the non-unions associated with infected implants usually found resistant to conventional methods of management. Aims: To evaluate effectiveness of antibiotic impregnated nails in management of infected non unions of tibia and femur with bone loss less than 4 cm.

Material and methods: This was a prospective study of 20 cases with infected non-unions of femur and tibia which were enrolled for the study. All cases who met the inclusion criteria were managed using antibiotic impregnated nailand were followed up for an average period of 1.2 years with encouraging results. Under suitable anesthesia the infected fracture site was exposed and thorough debridement done. Implant was replaced by Antibiotic impregnated cement K-nail/ V-nail/ Interlocking Nail following adequate reaming. Culture sensitivity was done at weekly intervals, to identify pathogen and the sensitive antimicrobial agent.

Results: At follow-up only one patient had a positiveculture. In all patients except the one with positive culture, there was no discharge at six weeks follow-up. Implant removal was after interval of 6-12 weeks depending on status of infection and callus.

Conclusion: Management of Infected non unions using Antibiotic impregnated K-nail is simple and very effective method which allows infection control, promotes bone union. This simple procedure is encouraging, cost effective and less cumbersome.

Keywords: Infected non-unions, Antibiotic cement nails.

INTRODUCTION

Operative environment underwent revolutionary changes in 21st century with the advent of antisepsis and clean operating room protocol which lead to drastic decrease in infection rates. However with the increasing number of road traffic accidents and increasing use of orthopaedic devices in open fractures primarily, on an average 5% of implants get infected with added consequences¹. Infected non-unions of long bones are a pain in the neck both for the surgeon and patient and its management is a challenging task. In earlier days infected implants associated non-union's were treated by a staged protocol, first stage being implant removal with measures for infection control and the second stage for achieving bony union. Use of stable external fixation devices like ring fixators and LRS (Limb reconstruction system) were used to achieve bony union^{2, 3}. These procedures require increased in patient stay and also great socioeconomic burden. Hence we present a improved method of treatment of these long bone infected non-union, which aim to control infection by providing high doses of local antibiotics and stabilise fracture at single setting with minimal complications⁴. Aim of our study is to evaluate effectiveness of antibiotic nails locally made in the operation theatre in management of infected non-unions of long bones in terms of infection control and bony union.

MATERIAL AND METHODS

This prospective study conducted from January 2012 to July 2014. Inclusion criteria were infected non-unions of tibia and femur with no evidence of union by 6-8 months and with bone loss of less than 4 cm. Patients with radiologically visible or intra-operative finding of gap non-union of more than 4 cm, patients with multiple medical co-morbidities and those with hypersensitivity to antibiotics were excluded from study. Out of twenty five patients who presented to our outdoor with infected non-unions of tibia and femur, fourteen cases met all the criteria and were enrolled for the study. All patients were thoroughly investigated and evaluated by clinical and radiological means. Out of twenty cases there were 18 male and two female patients. Age group of patients ranged from 18 to 65 years with mean age of 42 years. Six cases had sustained closed fractures, three each of grade-2 and 3 Afractures and rest two had sustained Grade-3B fractures. Mean duration from injury to presentation was 7 months (6 - 10 months). Out of twenty cases seven had femoral non- unions and rest had tibia non-unions. Out of seven femur cases three had intramedullary interlocking nail and four had K-Nails. And out of thirteen tibia nonunions eleven had intramedullary nail and two had initial AO fixators (3 months) followed by plaster cast treatment. Staphylococcus aureus was isolated in fifteencases,one each of Proteus species and Pseudomonas aeruginosawas isolated. Rest three cases showed polymicrobial picture.

Procedure: After thorough pre operative evaluation, patients were posted for surgery ia a elective setting. Under regional or general anaesthesia, adequate exposure of the non-union site was done using the older scars. Implant removal was done first. The removed implant along with per operative samples was sent for culture and sensitivity. Non-union site was thoroughly debrided excising all the dead and devitalised bone and soft tissues till freshly bleeding bone

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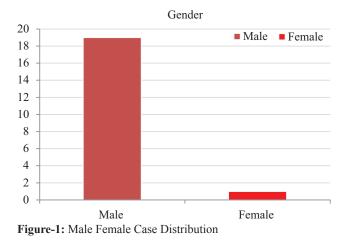
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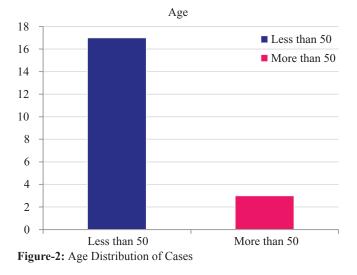
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edges visualised (Papkira sign) (Figure-1). After initial and meticulous debridement, the gap site was measured and ascertained. Those with loss greater than 4 cm underwent stable external fixation in form of ring fixator and LRS. Those with loss less than 4 cm underwent intramedullary reaming followed by antibiotic coated nail

Antibiotic cement nail preparation: Performed manually on a separate trolley taking all the aseptic measures. Before nail preparation done the surgeon and assistant for nail preparation changed the gown and gloves for performing clean portion of the surgery. K-Nail (cases with Femur Non-union) or V-Nail (for Tibia Nonunions) of appropriate diameter 2-3mm thinner than last reamer width was chosen. Nail of 7-8mm diameter were chosen in most cases. The polymethylmethacrylate bone cement of 40 Grams was mixed with appropriate weight of antibiotic powder. Monomer solution added to this powder and mixing done till the material acquired viscous consistency. Manual application of the cement was done in a uniform smooth layer excluding the eye. After adequate setting and hardening, the nail was inserted into the medullary canal. Haemastasis was secured and wound closure done in layers over a romovac drain.

Post-operative protocol: Postoperatively the patients were started on intravenous antibiotics as per the sensitivity profile. Weekly wound cultures and inflammatory markers were done to assess need for long term antimicrobial therapy.



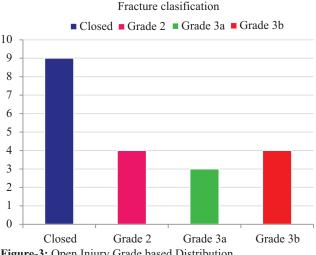


Active and Passive range of motion exercises and non weight bearing mobilisation was encouraged.

Follow-up: Patients were asked to visit OPD once in a month for first three months followed by once in 2-3 months later on. During each follow-up visit patient underwent clinical and radiological evaluation by standard AP, Lateral and Oblique X rays to assess status of non-union. Status of infection was assessed by clinical history and haematological investigations (ESR, CRP, Differential count, Total count). Every patient was clinically and radiologically assessed at end of 6 weeks to find out regarding infection status and signs of union. Cases which showed evidence of union and infection control were continued with nail till fracture union. Paatients with infection control without any signs of union underwent nail removal and exchange intramedullary nailing. Assessment regarding rate of fracture union and infection control and need of any secondary procedures was done during followup.

RESULTS

Outcome of the study analysed in terms of success and failure. Success cases are those where complete clinical and radiological union occurred. Failure cases are those where non-union failed to achieve union with or without control of infection. Average duration of follow-up was 12 months, ranging from 6 months to 24 months. Most common micro-





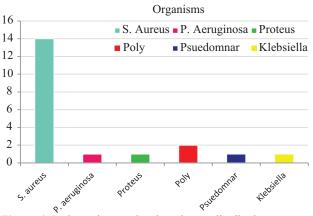
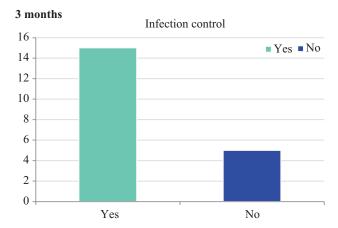


Figure-4: Pathogenic organism based case distribution

6 Months



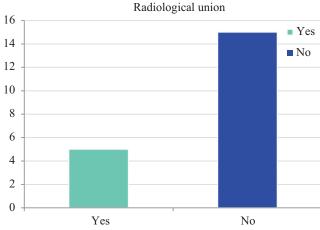


Figure-5: Infection Control and Radiological union at 3 months

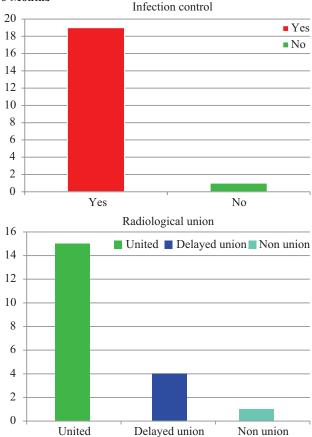


Figure-6: Infection Control and Radiological union at 6 months

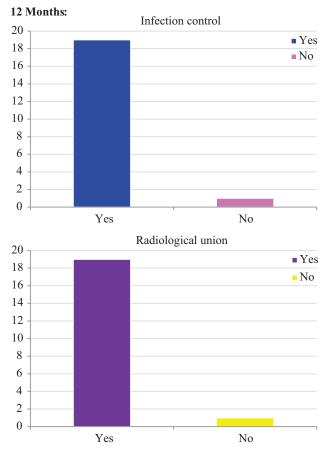


Figure-7: Infection Control and Radiological union at 12 months

organism isolated in our study was Staphylococcus aureus. Out of the 20 patients who underwent antibiotic coated cement nail, 15 patients had excellent infection control at 6 weeks follow-up. Among these 15 patients, 5 had signs of radiological fracture callus, and were continued with the nail in situ till complete bony union. Rest of the 10 patients who had no evidence of radiologicl callus at 12 weeks post surgery were treated with antibiotic nai removal and definitive fixation using exchange nail with iliac crest bone grafts. Out of these 10cases 8 patients achieved bony union by six months post revision nailing. One case required additional surgical procedure like dynamisation and one case ended up in non union.

Overall, 15 cases achieved infection control and bony union at the last follow-up.

Failure – One case (7%) of femur non-union where infection was not controlled by 6 weeks failed to achieve infection control at 12 weeks follow-up. Patient underwent cement nail removal and was managed by papineau method of open dressing and bone grafting. Patient achieved union at 6 months post papineau procedure. Four cases went for delayed union and revision nailing or bone grafting had to be done.

Complications: Most common complication in our series was stiffness of knee joint (5 cases), cement debonding occurred in 3 cases where cement nail retained till fracture union. Cement debonding was managed copius saline irrigation and over reaming the medulla and creation of

channel distally for complete removal.5

DISCUSSION

Management of infected non-union is a challenging task for orthopaedic surgeon. The increasing trend of high velocity road traffic accidents and consequent open fractures and increased use of foreign bodies for fracture fixation are some of the causes for incidence of infected non-unions. Pathophysiology of infected non-unions of long bones after intramedullary nailing includes spread of infection along the intramedullary canal⁶. Presence of a foreign metal implant in vivo and also biofilm formation makes control of infection very difficult by routine intravenous antibiotics. Also due to long standing infection and repeated surgeries, there is excessive fibrosis and granulation tissue which further decrease antibiotic penetration into the non union site. ⁷ The traditional treatment protocols for infected non-union which included debridements, stable external fixation and long term systemic antimkicrobial therapy are associated with high rate of complications including stiffness, contractures, pin tract infections and great socioeconomic burden.

Antibiotic cement nails technique first described by Paley and Herzenberg⁸ later by Thonse and Conway. Antibiotic cement nails prepared using PMMA bone cement and heat stable broad spectrum antibiotics. Most commonly heat stable antibiotics like vancomycin, Tobramycin and Gentamycin are used.9 Use of intramedullary, non interlocked implants like Enders nail and K nail have been described in multiple studies.¹⁰ Antibiotic Cement coated nails being in a intramedullary location have close proximity to the non union site and provide high local concentration of greater than 200 times the minimal inhibitory level. Also they avoid any systemic effects and easy operative technique. Thonse and Conway in their study where infected non-unions were managed by antibiotic nails they achieved infection control in 85 % of cases and union was seen in 84% cases. Around 27% patients required additional procedures for infection control and union. Most common complication in their series was cement debonding. Our study differs from their study where in antibiotic cement interlocking nails were used. Infection control of our study (92%) is comparable to their study (85%).

Shyam AK, Sancheti PK et al in their study where infected non-union with different gap width were managed by antibiotic nail achieved infection control in in all cases where bone loss was > 6cm, they also achieved union with antibiotic nail in 3 cases where bone loss was < 3.2cm rest requiring revision nailing and bone grafting. Rate of infection control and union rate of our study are comparable to the results of this study.

Only one case in our series which remained ununited even after revision procedure had Pseudomonas Infection. Most common complication encountered was joint stiffness. This may be explained by the fact that cases with k nail and V nail could not be mobilised early due to unstable fixation. Next most common complication encountered was cement debonding. The important limitations of this study was small sample size and narrow inclusion criteria. Larger sample size and long term followup is required to draw conclusions regarding predictors of outcome.

CONCLUSION

Antibiotic impregnated intramedullary nailing is a simple, very effective method of management of infected non-unions with bone loss < 4cm where it offers best results in terms of infection control (92%). The method by itself achieved bony union in only 33% cases, rest of patients require revision nailing along with bone grafting to achieve union. 25% cases required additional procedures, to achieve union after revision nailing. So, we recommend use of antibiotic cement nails for control of intramedullary infection and this should be followed by revision nailing, there by complications (cement debonding, stiffness) reduced and high success rate achieved with the procedure.

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