The outcome of the use of custom made antibiotic cemented nail in management of chronic diaphyseal osteomyelitis

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ABSTRACT

Background

Chronic osteomyelitis of long bone is a difficult condition to treat. Local delivery of antibiotics via custom-made antibiotic cemented nail(ACN) enables delivery of antibiotics at high concentration, which helps in eradication of infection and provides mechanical stability in infected nonunion. The study aims to find out the role of ACN in the control of infection and union of long bones.

Method

30 patients presenting with the feature of chronic osteomyelitis of long bones & infected non-union between 2014 and 2017 at Manipal Teaching Hospital were included. Cases were treated with debridement, sequestrectomy, and the use of ACN. Follow-up of patients was done till control of infection and union. Patients were assessed clinically and on laboratory parameters for control of infection & union.

Result

Among 30 patients, 13 (43%) were infected nonunion, 6 (20%) were of osteomyelitis following open fracture, 5 (17%) were of osteomyelitis following soft tissue procedure and 6 (20%) were of open fracture where ACN was used prophylactically. Infection control was achieved in 28 (93%) cases. The average time of radiological union was 12 months. The average duration of removal of ACN was 7.4 weeks. Complications included the failure of removal of antibiotic cement in one (3%) case & failure of union in one (3%) case.

Conclusion

ACN is an economical method that can be used safely in the management of chronic osteomyelitis of long bones. The technique is simple, cost-effective with excellent results, minimal complications, and can be used in a minimal resources setting.

Keywords: **antibiotic cemented nail; chronic osteomyelitis; infected non-union**

Introduction

Musculoskeletal infection is a challenge to orthopedic surgeons. The rate of infection ranges from 3.6–8.1% (closed fractures) to 17.5–21.2% (open fractures)[1]. Bone with low vascularity is favorable for bacterial growth. Most of the infections are caused by biofilm-forming bacteria[2]. In bone, the concentration of antibiotics is less than 20% of serum levels. Their efficacy is further diminished by biofilms[2].The avascular scar tissue leaves systemic antibiotics ineffective. Infection delays healing[3] requiring surgery and prolonged antibiotic treatment.

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Treatment is by debridement, sequestrectomy, excision of sinuses, and implant removal with the adjunct of local and systemic antibiotics[4]. Appropriate systemic and local antibiotics represent the second main pillar of treatment[5]. Systemic antibiotics cannot reach adequate concentration so antibiotics are used locally to achieve higher concentration (up to 1000 fold) than systemic antibiotics[6].Use of antibiotic-impregnated cement was first reported by Buchholz[7]. High local concentration and low systemic side effects were the major advantages[8]. Antibiotic cement nails (ACNs) offer local delivery of antibiotics while filling the dead space and offering stability to the fracture / nonunion site.

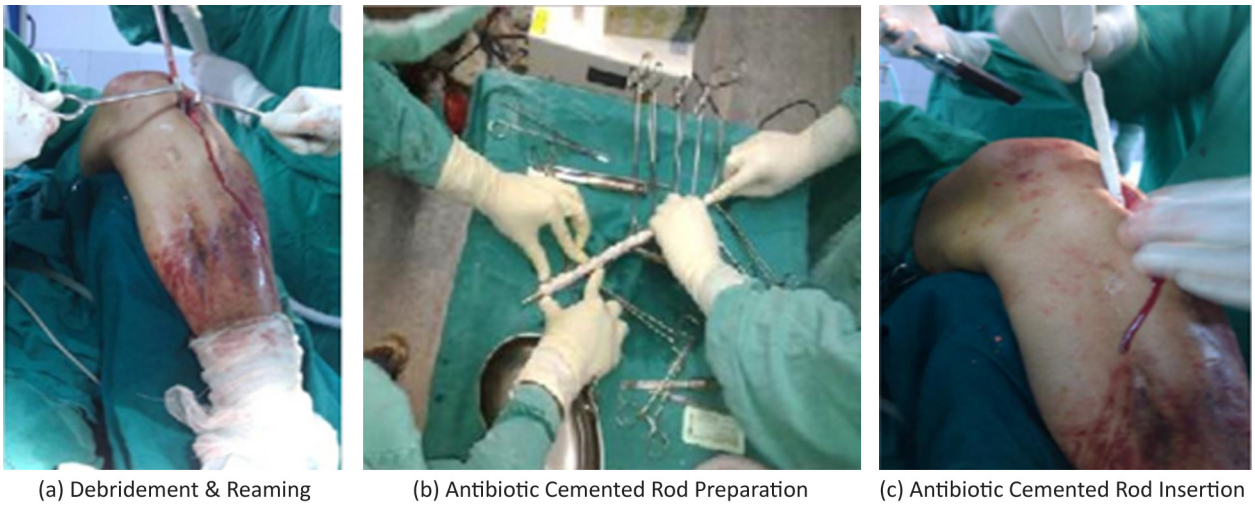
This study was conducted to review the outcome of the use of ACN in the management of chronic diaphyseal osteomyelitis and infected non-union.

Methods and materials

This descriptive observational study was carried out in the Orthopaedics department of Manipal Teaching Hospital (MTH), Pokhara during the period of three years starting from June 2014 to July 2017. Ethical approval was taken from Institutional Review Board (IRB), MTH, and written informed consent was taken from each patient. Cases of chronic osteomyelitis presenting in the outpatient department (OPD) of MTH and cases of the infected non-union were enrolled in the study. Patients were evaluated clinically & radiologically. Laboratory investigations such as culture & sensitivity of the discharge from the sinus tract, CBC, ESR & CRP were sent. All cases were classified according to the Cierny–Mader classification. Surgery was planned in patients who were fit for surgery. Cases excluded were uncontrolled diabetes mellitus, tuberculous osteomyelitis, and immunodeficiency.

All surgeries were performed & supervised by a senior surgeon. Intramedullary reaming & lavage were done using a suction tube inserted in the medullary cavity. Sequestrectomy and excision of the sinus was done. In adolescents & adults, Kuntscher nail (K-nail) was used in the femur and V-nail was used for tibia. In children, K wire / Flexible nail was used. Gentamycin & Vancomycin were used with the bone cement. 2g of Vancomycin / Gentamycin was mixed with 20g of bone cement. Manual mixing of cement was performed and the cement was uniformly applied to the nail. Antegrade nailing was performed both for the femur & tibia.

Post-operatively antibiotics were given for a period of 2 weeks parenterally followed by oral antibiotics for a period of 4 weeks. After a period of 6-12 weeks, the ACN was removed. In the case of infected non-union, if infection cleared up after the primary procedure exchange nailing was done with intramedullary interlocking nail (IMILN) after removal of the ACN. In persistent infection after removal of ACN, debridement was done followed by reintroduction of fresh ACN using a combination of two antibiotics (i.e. Gentamycin & Vancomycin) or a new antibiotic was used (eg: Cefopodoxime). After control of infection, fracture stability was achieved by internal fixation with an interlocking nail.



(a) Debridement & Reaming (b) Antibiotic Cemented Rod Preparation (c) Antibiotic Cemented Rod Insertion

Figure 1: a, b, c- debridement and reaming, antibiotic cemented rod preparation, antibiotic cemented rod insertion

Patients were followed up in OPD for the evaluation of control of infection by clinical, radiological & biochemical parameters. Functional results were evaluated with regards to control of infection, bony union, presence of deformity, limb length discrepancy, and complications (intra and post-operative). All the immediate and late outcomes of each procedure were recorded in Microsoft Excel and analyzed with SPSS 23 software.

Results

Among the total of 30 patients, there was male preponderance, 26 (86.7%) male vs 4 (13.3%) female. The age of the patient ranged from 15 years to 61 years. The mean age was 34.06±12.34.

The presenting symptom was pain in the affected thigh or leg in all cases (100%). 12 patients (40%) presented with the discharging sinus and none of the patients had fever at the time of presentation. 1 patient (3%) had limb length discrepancy at the time of presentation. 20 (67%) patients had involvement of tibia and in 10 (33%) cases femur was involved.

The duration of infection ranged from 1 month to 27 years. The mean duration of infection was 37.3±65.9 months. Infected non-union cases presented early (within a year) whereas the osteomyelitis following incision & drainage for abscess or due to soft tissue damage presented late (years following the event).

In the study, infected non-union following closed & open fractures accounted for 13 patients (43%); chronic osteomyelitis following fracture & subsequent surgery were 6 patients (20%); chronic osteomyelitis following soft tissue procedure such as drainage of abscess were 5 patients (16%) and cases of prophylactic antibiotic cement nailing done following pin tract infections (after external fixator application for open fracture) before definitive nailing were 6 cases (20%).

Table 1: Use of ACN:Clinical context

Clinical Contexts	No. of cases	Percentage
Infected non unions	13	43%
Osteomyelitis following fracture & surgery	6	20%
Osteomyelitis following soft tissue procedure	5	17%
Prophylaxis in open fracture	6	20%

Among 13 infected non-union cases, 6 cases were closed fractures (46%) for which IMILN was performed and 7 cases were open fractures (54%). Among 6 cases of chronic osteomyelitis following fracture & subsequent surgery, 5 cases (83%) were open fractures and 1 case (17%) was a closed fracture. Among 6 cases for which prophylactic antibiotic cemented nailing was done all were the open fracture for which external fixator was applied initially and later they developed pin tract infection or infection was suspected; so prior to definitive nailing antibiotic cemented nailing was performed.

Prognostication of treatment was done by Cierny & Mader staging. 13 patients (43%) were Cierny & Mader stage IA; 8 patients (27%) were IIA (; 1 patient (3%) was IIB and 8 patients (27%) were IIIA

Table 2 : Cierny and Mader Classification

Cierny & Mader Stage	No of cases	Percentage
IA	13	43%
IIA	8	27%
IIB	1	3%
IIIA	8	27%

16 patients (53%) had *S aureus* growth; 5 patients (17%) had MRSA; 1 patient each (3.3%) had *Klebsiella, S pyogenes & Pseudomonas aeruginosa* growth. 6 patients (20%) had no growth.

Modality of delivery of antibiotic-loaded cement was in 19 patients (63%) V nail; 8 patients (27%) underwent antibiotic cemented K nail fixation and 3 patients (10%) underwent antibiotic cemented K wire usage.

The mean duration of removal of ACN was 7.4±1.4 weeks. The duration of rod removal ranged from 6 weeks to 10 weeks. After removal of ACN, 17 patients (57%) underwent IMILN among which 3 patients (10%) required bone grafting at the time of IMILN. 1 patient (3.3%) underwent plaster cast application after the removal of the antibiotic cemented nail. 12 patients (40%) did not require any subsequent method of fixation.During removal of ACN, 28 patients (93%) had intraoperative culture negative; 2 patients (7%) had a positive intraoperative culture which required a second set of the antibiotic cemented rod. In the study, infection control was achieved in all the cases.

The duration of the union ranged from 9 – 17 months. The mean duration of union was 12

months. 9 cases (53%) united within 9 – 12 months. 1 case (3%) failed to unite within the follow-up period of 18 months.

In the study, during the removal of ACN, the complete removal of the cement was not possible in 1 case. Recurrence of infection was seen in 2 cases in which after removal of ACN the culture results were positive. In these cases, intramedullary reaming was repeated followed by fresh antibiotic cemented rod implantation. 1 case failed to unite within the follow-up period of 18 months.

Table 3: Complications

Complications	No. of cases	Percentage
Failed cement extraction	1	3%
Failed union	1	3%
Recurrence of infection	2	6%

closed and open fractures respectively. The infected foci within the bone are surrounded by a sclerotic, avascular bone covered by a thickened periosteum and scarred muscle. The avascular envelope of scar tissue renders systemic antibiotics ineffective[11]. The problems associated with infected non-unions are the development of sequestrum, sinus tracts, malunion, limb length inequality[12]. Compound fractures have a higher incidence of infected non-union than closed fractures[13].In this study, there were 13 cases of infected non-union among which 6 occurred in closed fractures and 7 in compound fractures. The treatment options include removal of the nail, debridement, and lavage, use of external fixator or cast, and bone grafting at the nonunion site[14].Skeletal stability is very important to achieve a good result which is provided by the use of plaster cast, external fixator & intramedullary nail[15].The traditional tool for bone stabilization is the external

(a) Antibiotic cemented K nail insertion in femur fracture

(b) Removal of Antibiotic cemented K nail

(c) Exchange nailing with IMILN

Figure 2: a, b, c,: Antibiotic cemented K nail insertion in femur fracture. Removal of antibiotic cemented K nail. Exchange nailing with IMILN

Discussion

Chronic osteomyelitis is a difficult condition to treat. Untreated, it may cause significant bone loss and soft tissue damage. Management includes debridement, drainage, obliteration of dead space, and antibiotics. The primary goal of treatment is to eradicate the infection[9,10].

The incidence of infection after intramedullary nailing of tibial fracture was 1.5% and 14%[10] in fixator and the most common complication is pin tract infection[16].

Antibiotic-impregnated cement was used for the first time by Buchholz and Engelbrecht[7]. Klemm was the first to use antibiotic cement beads in cases of osteomyelitis[8].Nevertheless antibiotic-impregnated cement beads fail to provide mechanical stability in infected non-union and are difficult to remove after 2 weeks due to ingrowth of granulation tissue.

Paley and Herzenberg used self-made ACN to treat infection after intramedullary nailing of long bones with good results[17].ACN provides stability, is easy to insert & remove, and provides all the advantages of the cement beads. Moreover, it is more effective in controlling bacterial spread along with the infected implant and involves the entire length of the bone. Intimate contact with the endosteal surface reduces the distance needed for the diffusion of antimicrobials[18].

The use of ACN was done in three clinical contexts. First in the case of infected nonunion of fracture of long bones where both infection control & mechanical stability was paramount to a good outcome. The Second was in established chronic osteomyelitis following open fracture & surgical procedure. Third was as a prophylaxis to prevent intramedullary infection following external fixator application for compound fracture.

ACN provides temporary stabilization of compound fractures and provides prophylaxis & treatment of medullary osteomyelitis. ACN may be used as an intermediate step prior to definitive IM nailing after external fixation[19].Conversion to intramedullary nailing from external fixation may be delayed to provide time for the management of soft tissue damage or other associated injuries. The risk of infection after conversion to IM fixation after 2–3 weeks of external fixation has been reported as high as 50%[20].Staged conversion to IM nailing after external fixation has been performed after an interim period of antibiotics and splinting. ACN with the staged protocol has the potential to improve this treatment method[21].In this study, in 6 cases of compound fractures, ACN was used after the removal of the external fixator followed by IM nailing. In all cases, infection control and union were achieved. Similar results are seen in a study conducted by AK Bhadra et al[22] where 30 patients underwent antibiotic cement nails after established medullary osteomyelitis and as prophylaxis of medullary osteomyelitis.

ACN has been described in the literature by Ohtsuka et al[23] and Madanagopal et al[24]. They both showed success using an ACN in the treatment of a tibial infection after intramedullary nailing. Paley and Herzenberg[17] showed their preliminary experience in the management of nine patients.Recurrent infection was not seen during the time of follow-up.

Recently, Thonse and Conway[25] presented a clinical experience of ACN. They concluded that local treatment added to intramedullary stability seems to be a good alternative in the treatment of infected long bones.

The drawback of ACN is after the period of 6 weeks, it has to be exchanged. This involves another surgical procedure and under anesthesia. Besides this, there are no major local and systemic complications associated with the technique.

Conclusion

The use of antibiotic cemented nail (ACN) is an economical method that can be safely used as an adjunct to debridement, intravenous antibiotics, and stabilization in the management of chronic diaphyseal osteomyelitis of long bones. The technique is simple, cost-effective with excellent results, minimal complications, and can be used in a minimal resources setting. ACN provided good infection control and stability in fracture healing.

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