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Original Research Article

Functional outcome of chronic osteomyelitis treated by sequestrectomy & saucerisation with antibiotic bead implantation

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ABSTRACT

Background: Chronic Osteomyelitis has been treated since inception of Orthopaedics, however a ideal treatment eliminating the disease doesn't exist. Numerous treatment modalities & Surgical procedures have been tried with varied results, owing to the chronic nature of the infection, virulence of organism and complex pathogenesis. With time, the antibiotic delivery to target site has expanded to include effective oral agents and local therapy with antibiotics mixed in bone cement or use of biodegradable antibiotic impregnated materials.

Materials and Methods: This study intends to obtain factors which influence the incidence of osteomyelitis in the population & also to know the common means of transmission of bony infection, further identification of the major areas of disease manifestations and means of eradication of the same by our procedure. We conducted a prospective randomized control study on patients diagnosed with chronic osteomyelitis in the age group of 4- 60 years. 30 patients were treated with sequestrectomy and saucerisation & dead space filling with biodegradable antibiotic impregnated calcium sulphate beads for local delivery of antibiotics. The calcium sulfate used in this study was The STIMULAN KIT. This bone void filler kit consists of surgical-grade calcium sulfate powder and a sodium chloride diluent with Vancomycin as the broad spectrum antibiotic.

Result: Functional outcome was evaluated using Enneking Functional Evaluation System which is a 30 point system for both upper and lower limbs. X-rays were used to evaluate the dead space volume (in cc) and bone repair (in %). Each patients were followed up for minimum of six months. The mean score for functional outcome was found to be 29.93. In 18 patients osteomyelitis occurred by hematogenous spread (60%) by superficial skin infection, Mean age of 13 patients (43.3%) were in the age group of 4-10 years. 63.3% of affected individuals were male. Most common site of infection was found to be tibia (33.3%) & most of the culture report from infection site showed no growth(90%). Complications such as prolonged ooze was seen in 15.9% cases. On Statistical analysis of the functional outcome, p value was found to be significant < 0.001.

Conclusion: Antibiotics containing beads (Stimulan Kit) is effective in the treatment of chronic osteomyelitis and in preventing the recurrence of infection. It is imperative to identify various factors responsible for the recurrence of infection. This may help clinicians predict the prognosis of the disease and minimise the risk of adverse outcomes.

1. Introduction

Chronic osteomyelitis is defined as long-standing infection that evolves over months to years, characterized by the persistence of microorganisms, low-grade inflammation,

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and the presence of dead bone (sequestrum) and fistulous tracts.[1,2] Clinical signs persisting for longer than 10 days are associated with the development of necrotic bone and chronic OM.[3,4] Commonly a sequelae to acute hematogenous osteomyelitis or an open fracture or following operative procedure, it is characterized by recurrent pain, pyrexia, redness or with discharging sinuses and has been a devastating complication for ages.[5] The common causative organism is coagulase positive staphylococcus followed by *Pseudomonas*, *E.coli*, *Proteus .spp, Streptococcus, Haemophilus influenza*e, & *Salmonella typhi*.[6,7]

There are several ways to classify OM. The two major classification schemes are those described by Lew and Waldvogel[8] and Cierny et al.[9] The Cierny-Mader OM classification combines both anatomic factors (medullary, superficial, localized, or diffuse OM) and physiological classes (healthy host, systemic and/or local compromise, and treatment worse than the disease.[7,10] This classification applies best to long and large bones and it is not very useful for the digits, small bones, or the skull.[9–11]

Plain radiographs and bone cultures form the mainstays of diagnosis while imaging with radionuclide scans, computerized tomography, and magnetic resonance imaging are used when the diagnosis of osteomyelitis is equivocal or to help gauge the extent of bone and soft tissue infection. In chronic osteomyelitis, surgical debridement of all devitalized bone and soft tissue and removal of foreign bodies, managing dead space, and, when necessary, obtaining bone stability are essential for successful treatment and antibiotic therapy is usually maintained for 4 to 6 weeks.[12,13] Antibiotic delivery has expanded to include effective oral agents and local therapy with antibiotics mixed in polymethylmethacrylate or mixed in biodegradable antibiotic impregnated materials.

This study objectives are to explain factors that influences the incidence of osteomyelitis in a given population and to know the common means of transmission and identify the major disease manifestations. Also, it is an attempt to know how to diagnosis the infection by the laboratory methods and evaluate the outcome in the patients treated with sequestrectomy and saucerisation and dead space management done with antibiotic impregnated beads.

2. Materials and Methods

A prospective randomized controlled trial study was carried out for a total of 30 cases of chronic osteomyelitis aged between 4 years to 60 years attending the OPD of Department of Orthopaedics, Gauhati Medical College and Hospital, who meet the inclusion criteria outlined below. This study was conducted for period of 28 months from 1^{st} November 2019 to 31^{st} March 2022. All cases were followed up for a period of 6 months.

2.1. Inclusion criteria

1. All the chronic osteomyelitis cases in age group of 4-60 years of both sexes were selected.
2. Patients with radiological signs of chronic osteomyelitis.
3. Competent neurological and vascular status of the affected limb.
4. Patients who are fit for surgery, give consent for operation & with no medical contraindication.

All the patients in this study were admitted and thorough clinical examination was carried out to look for the present physiological condition of the patient. Demographic data was recorded in predesigned Performa's and the affected limb was examined clinically as well radiographical images were obtained to look for the presence of sequestrum, sinus tracts, involucrum and presence of any associated fracture of the affected limb. Based on the X-ray finding and the physiological condition of the patient the patients were classified according to Cierny-Mader Staging system.

Swabs were taken from the sinus tracts and sent for microbiological studies and patients giving consent for operation, clearing pre anaesthetic evaluation as per the hospital protocol were taken up for surgery. No preoperative antibiotic injection were given. The area of osteomyelitis was approached with standard surgical approaches and infected bones exposed with excision of the sinus tract. The indurated periosteum was then incised and elevated 1.3 to 2.5 cm on each side and a oval cortical window drilled and all sequestrum, purulent material and scarred and necrotic tissue are thoroughly removed till punctate bleeding appears (paprika sign). Appropriate cultures taken and after thoroughly cleaning the dead space is filled up with biodegradable calcium sulphate antibiotic beads (STIMULAN KIT). The wound was closed in multiple layers with a drain placed in situ.

Following tables were used to evaluate the functional outcome: (Table 1)

2.2. Preparation of antibiotic beads and surgical technique

The calcium sulfate used in this study was The STIMULAN KIT. This bone void filler kit consists of surgical-grade calcium sulfate powder and a sodium chloride diluent. In this study Vancomycin hydrochloride was used with the STIMULAN KIT to make the antibiotic bead. The mixing is done manually with 1 g of vancomycin hydrochloride, the calcium sulfate powder and diluent provided in the kit. The paste is blended and assembled on a silicone mould provided with the kit until hardening is achieved. The area of osteomyelitis is approached surgically as explained and thoroughly debrided. The entire cavity is filled with the beads without crushing as this may affect the antibiotic delivery profile and resorption rate.

Table 1: For lower & upper limb

For lower limb						
Score	**Pain**	**Function**	**Emotional**	**External support**	**Functional Independence**	**Gait**
5	None	No Restriction	Motivated	None	Independent	Normal
4	Intermediate	Intermediate	Intermediate	Intermediate	Intermediate	Normal
3	Not disabling	Recreational limitation	Satisfied	Orthosis	Limited	Minimal alteration
2	Intermediate	Intermediate	Intermediate	Intermediate	Intermediate	Intermediate
1	Incapacitating	Partial limitation	Accepts	Cane/crutch	Home	Very altered
0	Extremely incapacitating	Total restriction	No support	Two crutches	Dependent	Difficult
For upper limb						
Score	**Pain**	**Function**	**Emotional acceptance**	**Hand position**	**Manual dexterity**	**Lifting ability**
5	None	No Restriction	Enthused	Unlimited	No limitation	Normal load
4	Intermediate	Intermediate	Intermediate	Intermediate	Intermediate	Intermediate
3	Modest/Not disabling	Recreational restriction	Satisfied	Not above shoulder/no pronation-Supination	Loss of fine movement	Limited
2	Intermediate	Intermediate	Intermediate	Intermediate	Intermediate	Intermediate
1	Moderate/intermittently disabling	Partial occupational restriction	Accepts	Not above waist	Cannot pinch	Helping only
0	Severe/continuously disabling	Total occupational restriction	Dislikes	None	Cannot grasp	Cannot help

Postoperatively the operated limb was stabilised as required and i.v antibiotics were started. Injection Ceftriaxone @ 75mg/kg body weight/ day in two divided dose 12 hourly and Injection Amikacin 15mg/kg body weight/day after negative skin test were used for 5 days post-operatively. After discharge, oral antibiotics were given for 6 weeks based on the culture and sensitivity profile. Patients were followed-up after 2 weeks, 4 weeks, 6 weeks, 3 months and 6 months of surgery. During follow up patients were examined clinically and radiograpically to look for the condition of the residual cavity, sinus tract and any signs of new bone formation. Amorphous mineralization was not counted as bone repair. The Enneking Functional Evaluation/ Musculoskeletal Tumour Society System[8,12,14] which is a 30 point system was used for functional score for both upper and lower limbs. The defect size was measured using 2-plane film radiographs from edge to edge, and maximum dimensions were determined and the defect volume, in cubic centimetres, calculated. The patients were evaluated for complications related to the osteomyelitis or the local antibiotic therapy.

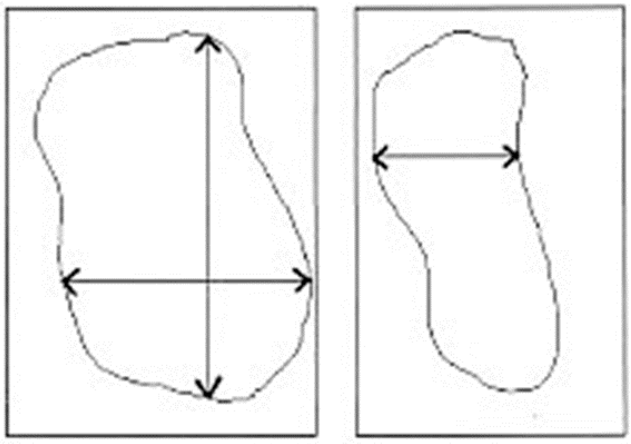

Figure 1: Method to measure defect size.
Note, the maximum dimensions are chosen on the anteroposterior and lateral radiographs (arrows). The defect volume, in cubic centimetres, is determined

Outcome parameters. The Primary outcome was eradication of infection at a minimum of 6 months after surgery. Failure of treatment was defined as recurrent infection with recurrent sinus formation; positive culture; further surgery performed for infection; or any patient requiring antibiotic treatment for persisting infection.

3. Results

3.1. Age distribution

Minimum age was 4 years and maximum age was 50 with a mean age of 14.966, range 4 - 50 and SD: 11.77 (Table 2).

Table 2: Age group distribution

Age group	Patients	Percentage
<10	13	43.3
10-20	10	33.3
21- 30	5	16.7
> 30	2	6.7
Total	30	100.0

3.2. Sex distribution

In this study there were 19 male and 11 female patients (Table 3).

Table 3: Sex distribution

Sex	Patients	Percentage
Male	19	63.3
Female	11	36.7
Total	30	100.0

3.3. Site of infection

In this study chronic osteomyelitis was located in distal end of radius in 2 patients, in femur in 4 patients, in fibula in 3 patients, in humerus in 9 patients, in shaft radius in 2 patients, and in tibia in 10 patients. (Table 4)

Table 4: Site involved

Site	Patients	Percentage
DER	2	6.7
Femur	4	13.3
Fibula	3	10.0
Humerus	9	30.0
Radius (Shaft)	2	6.7
Tibia	10	33.3
Total	30	100.0

3.4. Etiology

In this study we have found that in 18 patients osteomyelitis occurred by hematogenous spread by superficial skin infection (Furuncle/boil), in 1 patient the cause of osteomyelitis was pin tract infection, and in 11 patients there was a history of trauma at the effected site. (Table 5)

4. Discussion

Kulowski, in 1931 showed that with radical excision, immobilisation and open wound dressings without

Table 5: Etiology

Etiology	Patients	Percentage
Boil	18	60.0
Pin Tract	1	3.3
Trauma	11	36.7
Total	30	100.0

Table 6: Skin condition during followup

	SC	With Beads	
		Patients	Percentage
2 weeks	Discharge	4	13.3
	Healed	26	86.7
4 weeks	Discharge	0	0
	Healed	30	100
6 weeks	Discharge	0	0
	Healed	30	100
3 months	Discharge	0	0
	Healed	30	100
6 months	Discharge	0	0
	Healed	30	100

Table 7: Infection status

Follow up	IS	With Beads	
		Patients	Percentage
2 weeks	Quiescent	30	100
	Active	0	0
4 weeks	Quiescent	30	100
	Active	0	0
6 weeks	Quiescent	30	100
	Active	0	0
3 months	Quiescent	30	100
	Active	0	0
6 months	Quiescent	30	100
	Active	0	0

Table 8: Function, dead space and bone repair

Followup		N	Mean	SD
2 weeks	Function	30	20	4.05322
	DS	30	26	12.13613
4 weeks	Function	30	24.0667	2.73774
	DS	30	19.4587	8.48208
	BR	30	0.242	0.03707
6 weeks	Function	30	26.2667	2.05171
	DS	30	12.8433	5.36919
	BR	30	0.4913	0.07763
3 months	Function	30	27.8667	1.84649
	DS	30	6.0633	2.60401
	BR	30	0.7553	0.05643
6 months	Function	30	29.9333	0.2582
	DS	30	0.4053	0.26333
	BR	30	0.986	25.56556

Figure 2: Preparation of the antibiotic beads

Figure 3: Sequestrectomy, saucerisation and filling cavity with antibiotic beads

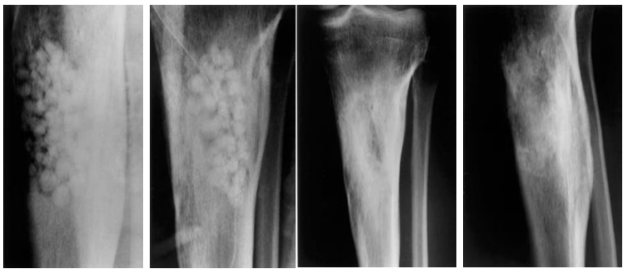

Figure 4: Post operative, and follow up x-rays at 3 and 6 months

antibiotics, was successful in 74% of 130 patients with chronic osteomyelitis, at one year after surgery. Since then, principles of treatment have evolved. Despite these advances, there remains a significant risk of recurrence. In recent years, staged surgery, involving repeated excisions, placement of PMMA-gentamicin loaded beads or rods, or irrigation systems and delayed skin closure, has been used to improve outcomes.[12] However, PMMA carriers have to be removed, as they prevent bone ingrowth and can lead to antibiotic resistance.[14] Multistage surgery often requires prolonged hospital stay with high costs.[13] Also outcomes have been variable, with infection recurrence rates commonly reported to be above 10%[12] and sometimes as high as 45%.[15] It is reported that immunocompromised patients with polymicrobial cultures tend to have worse outcomes with this treatment.[12] On the other hand, bioabsorbable antibiotic-impregnated materials offer the possibility of single-stage surgery, with reduced hospital stay and a more patient friendly approach to treatment.

The present study showed that out of 30 patients examined 63.3% were males. The results were in agreement with that concluded by Trueta & Mogar (1954) Gullen and Glass (1955) and Dich et al (1975) who also found the sex distribution to be high in male.

In this study we found that out of 30 patients, 13 patients (43.3%) were in the age group of 4-10 years followed by patients in 10-20 years of age group with 33.3% incidence. The results presented here were in agreement with Esmail et al (1984), Sorenson et al (1988), who found that hematogenous osteomyelitis, acute or chronic, is more common in children because their bones which are actively growing and have rich blood supply. Mccarrol and Key found the ages ranged from 10 months to 14 years, the average being 7.7 years.

The site of infection in the present study which revealed that tibia, humerus, femur, fibula, radius are the common site of infection and the percentage of incidences were 33.3%, 30%, 13.3%, 10% and 6.7% respectively The present findings were in agreement with those found by Mousa (1996) & Donia (2004), which showed that tibia and femur were under the high risk of osteomyelitis. There is some disagreement as to whether the femur or tibia is more

frequently involved.[4] Nathan Smith, Phemister in detailed report found the tibia to be the frequent site of the disease followed by femur and then humerus. In contrary to other studies where femur is more common site than humerus, in our study we have found that humerus is more commonly involved than femur.

We found that, hematogenous spread was the most common cause via superficial skin infection with 60% incidence followed by trauma seen in 36.7% cases. Haematogenous spread was most commonly in paediatric age group.[15] In adults trauma was the most common cause. These findings were in agreement with those found by Esmail et al (1984) and Sorenson et al (1988), who found that hematogenous osteomyelitis, is more common in children because their bones which are actively growing and have rich blood supply. Haboosh (1983), Yilmaze et al (2001), Donia (2004) reported almost similar results. Trauma apparently is a common predisposing cause. Schmidt found a history of trauma in two-thirds of the cases analysed in the surgical clinic at Bonn.

We found that most of the culture report showed no growth, only 2 patients showed growth of gram positive cocci and 1 patient showed growth of *E.coli*. This was not similar to other studies of Ferguson et al, Laura Prieto Perez et al, where staphylococcus aureus was the most common organism followed by other gram positive cocci like coagulase negative staphylococci and also aerobic gram negative bacilli and anaerobes. The probable cause of finding no growth in our study might be that, almost all of the patients visited their local practitioners, quacks before coming to our institution, who treated them with oral and injectable antibiotics. There were no documentation of the previous antibiotic therapy due to which we could not set a proper antibiotic free period before planning our operative intervention.

Using (Stimulan Kit) We found that, patients showed proper healing of dead space with no signs of recurrence within the period of 6 months follow-up and also showed a good functional outcome assessed by Enneking Functional Evaluation system with score ranging from 29/30 – 30/30 at the end of 6 months. These findings were in agreement with studies of Gauland et al in a study in 354 patients, Ferguson et al. in a study in 193 patients, McNally et al. in a study in 100 patients, with no signs of recurrence in mean follow-up period of 12 months. On statistical analysis, in regards of functional outcome p value was found to be < 0.001, which is statistically significant.

We also saw that out of 30 patients who were treated with antibiotic beads two patients presented with prolonged wound ooze (longer than 2 weeks post operatively) which was similar to the findings in studies of Ferguson et al where prolonged ooze was seen in 15.9% cases. In our study one was self limiting and the other patient also presented with wound dehiscence which had to be managed with secondary closure. There was no recurrence in further follow-up.

Two important questions remain unanswered. Can this technique be used without systemic antibiotics? If further studies prove successful without systemic antibiotics, there could potentially be significant cost savings. Turner et al. (1998) showed in an animal model that calcium sulfate delivers adequate killing levels in tissue for up to six weeks with safe serum levels. If the same holds true in humans, then perhaps systemic antibiotics can be avoided. Hospitalization time would be shortened and overall care easier. The second important question is late relapse. Chronic osteomyelitis is notorious for late relapse, even with aggressive systemic therapy and surgical treatment. At least in this small series with short-term follow-up, the control of the infection was excellent. Since the bone repair was substantial, follow-up surgery with autogenous iliac bone grafting and all its inherent problems hopefully will be avoided. This is one added advantage with the use of this biodegradable and osteoconductive implant.

5. Conclusion

In all 30 patients the local antibiotic calcium sulfate implants fully biodegraded and the bone showed progressive repair without evidence of either residual or new osteolysis, unusual periosteal changes during the course of therapy. Thus, we conclude that local antibiotic delivery with calcium sulfate is proved to be effective for infection control and bone repair. The advantage being that this implant does not need to be removed and may be an adjunct to systemic antibiotics for chronic osteomyelitis.

Limitation of this study acknowledge that with more number of cases and with longer duration of Follow-up, the results and observations might throw some light on the late complications if any of the impregnated antibiotic beads and also if any chronic side effects of the procedure can be observed with long term studies.

6. Source of Funding

None.

7. Conflict of Interest

None.

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