CHRONIC OSTEOMYELITIS: CLINICAL CHARACTERISTICS, SURGICAL TREATMENT MODALITIES AND EARLY OUTCOMES IN PATIENTS AT MOI TEACHING AND REFERRAL HOSPITAL, ELDORET, KENYA

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THESIS SUBMITTED TO SCHOOL OF MEDICINE IN PARTIAL FULFILLMENT OF THE REQUIREMENT FOR THE AWARD OF MASTER OF MEDICINE DEGREE IN ORTHOPAEDIC SURGERY, OF MOI UNIVERSITY

DECLARATION

DECLARATION BY CANDIDATE

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DEDICATION

I dedicate this thesis to my family and friends for their understanding, support and prayers.

ACKNOWLEDGEMENTS

The author would like to acknowledge Almighty God for His Grace and Blessings. In addition the author appreciates supervisors Dr. B, R. Ayumba and Dr. L.K. Lelei who guided me through research data collection and thesis writing. Also will like to acknowledge Institutional Research and Ethics Committee and Moi Teaching and Referral Hospital for giving me opportunity to carry out research in there institution. Lastly; appreciation goes to my colleagues for their encouragement and motivation.

LIST OF ABBREVIATIONS AND ACRONYMS

AIDS	Acquired immunodeficiency Syndrome
AMPATH	Academic Model Providing Access to Healthcare
AAOS	American Academy of Orthopedic Surgeons
AOM	Acute Osteomyelitis
CBC	Complete Blood Count
COM	Chronic Osteomyelitis
CRP	C - Reactive Protein
CT	Computed Tomography
DASH	Disability of the Arm, Shoulder and Hand
ESR	Erythrocyte Sedimentation Rate
HIV	Human Immunodeficiency Virus
IREC	Institutional Research and Ethics Committee
KMTC	Kenya Medical Training College
MRI	Magnetic Resonance Imaging
MRSA	Methicillin Resistant *Staphylococcus aureus*
MSSA	Methicillin Sensitive *Staphylococcus aureus*
MTRH	Moi Teaching and Referral Hospital
SPSS	Statistical Package for the Social Sciences
IQR	Inter Quartile Range

OPERATIONAL DEFINITION OF KEY TERMS

Amputation: The removal of unsalvageable limb by surgery (arm or leg) or other parts of the body due to chronic osteomyelitis.

Clinical characteristics: clinical features and radiological images as presented by patients.

Incision/Drainage: A surgical cut made to achieve access/window to allow discharge of pus and necrotic material from infected bone with chronic osteomyelitis.

Management: the process of taking history from patients, their clinical examinations and investigations and treatment of chronic osteomyelitis.

Osteomyelitis: is an inflammatory disorder of bone caused by infection with pyogenic organism which may lead to necrosis and destruction of bone; can be **acute** < 4 weeks or **chronic** > 4 weeks.

Outcome: the attainment of one or more of the following in 3 months post treatment of chronic osteomyelitis: full recovery, bone defects, bone deformity or bone loss or draining sinus recurrence (**Early<3 months, late > 12 months).**

Saucerization/curettage: to form a shallow depression by excavation of necrotic tissue to promote granulation and healing of bone and wound with chronic osteomyelitis.

Sequestrectomy: the surgical removal of sequestra in bone with chronic osteomyelitis.

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ABSTRACT

Background: Chronic osteomyelitis is progressive infective inflammatory process resulting in bone destruction and sequestrum formation. It is common in developing countries due to delay in diagnosis and instituting appropriate surgical intervention, hence contributing to a significant health burden. COM is noted to be on the increase at Moi Teaching and Referral Hospital based on the records. Patients managed surgically at MTRH for COM, have been noted with complications such as recurrent draining sinus, limb deformities and limb amputation. This study aimed at identifying clinical features for COM, establishing surgical treatment modalities and early outcomes to aid in developing COM management guidelines at MTRH.

Objective: To describe clinical characteristics, surgical treatment modalities and early outcomes for patients with chronic osteomyelitis at Moi Teaching and Referral Hospital.

Methods: This was a prospective descriptive study that was conducted between 1st January 2017 and 31st December 2017 at MTRH. Census of sixty patients with COM were recruited and managed operatively then followed-up for three months to establish early outcomes. Researcher administered questionnaire was used to collect data on clinical characteristics, surgical modalities and early outcomes. At 12 weeks postoperatively, the Disability of the Arm, Shoulder and Hand (QuickDASH) scoring tool for upper limbs and American Academy of Orthopedic Surgeons' lower limb scoring tool (AAOS) was administered and functional assessment of limbs was established. The data was analyzed using SPSS version 19 and presented in prose, tables, box plots and whisker plots. Wilcoxon rank- sum test, Fisher's exact test and T-test was used to check for associations between Cierny and Mader stages and age, gender and early outcomes.

Results: Male to female ratio was 1.7:1 with 58.3% of the patients being children. Lower limb was mostly affected (85%) with most affected bone being tibia (46.7 %). The commonest clinical presentation was draining sinus (70%) and sequestrum (40%) as the most common radiological image. *Staphylococcocus aureus* (51.8%) organism was the commonest isolate while chronic wounds were the commonest predisposing factor (75%). Most patients were diagnosed at Cierny and Mader stage IIIB (80%). Flucloxacillin (80%) was the most prescribed antibiotic while sequestrectomy (40%) and Incision/Drainage (38.3%) were the commonest surgical treatment options. At 12 weeks of treatment seventy six percent of patients had clinically recovered while those with draining sinus recurrence (18.3%) and limb amputation (5%). Lower limb had AAOS median score of 18.8 (15.9, 18.6) which was considered good functional score in patients (78.6%) while upper limb had QuickDASH median score of 27.1 (20, 27.2) which was considered good functional score. There was statistically significant association between Cierny and Mader stages whereby lower limb functional score was better for stage III than stage IV ($p=0.001$) while in terms of age, Cierny and Mader stage IV where older than stage III ($p=0.039$).

Conclusion: Majority of patients with COM presented with chronic wounds, draining sinus and sequestrum as a radiological image. Sequestrectomy and Incision and drainage were common surgical modalities used which gave good clinical and functional outcomes. Draining sinus recurrence, bone deformity and limb amputations were common complications. Cierny and Mader Stage III had good outcomes compared to stage IV.

Recommendations: Develop management guidelines for COM at MTRH based on clinical characteristics and surgical modalities with good clinical and functional outcomes. Sensitize clinicians on early index of suspicion in diagnosis of COM and appropriate surgery.

CHAPTER ONE

1.0 INTRODUCTION

1.1 Background Information

Chronic osteomyelitis is an inflammatory disorder of bone caused by infection leading to necrosis and destruction of bone. It can affect all ages or involve any bone (Bickler & Sanno-Duanda, 2000). Chronic osteomyelitis is a severe, persistent and sometimes incapacitating infection of bone and bone marrow. It may occur spontaneously or following inadequately treated infected chronic wounds, traumatic wounds and surgical wounds (Biruk & Wubshet, 2007).

In Uganda as in other developing countries, chronic osteomyelitis is a burden on clinical and surgical services, and disproportionately affects the young (Stanley, et al., 2010). One in every 1000 children and one in 5000 adults are at risk of getting osteomyelitis while ten per cent of the orthopaedic clinic patients and 3.5% of surgical patients had a primary diagnosis of chronic osteomyelitis (Ponio and Delos Reyes, 2013). Clinical symptoms of chronic osteomyelitis can be nonspecific and difficult to recognize. They include chronic pain, persistent sinus tract or wound drainage; poor wound healing, malaise, and sometimes fever (Ponio & Delos Reyes, 2013).

The unavailability of sensitive imaging tests across several centres, such as magnetic resonance imaging and bone scintigraphy, have led to difficult in diagnostic accuracy and the ability to characterize the infection in very early stages. Though plain radiography is a useful initial investigation to identify alternative diagnoses and potential complications; diagnosis has remained elusive (Mantero, et al., 2011).

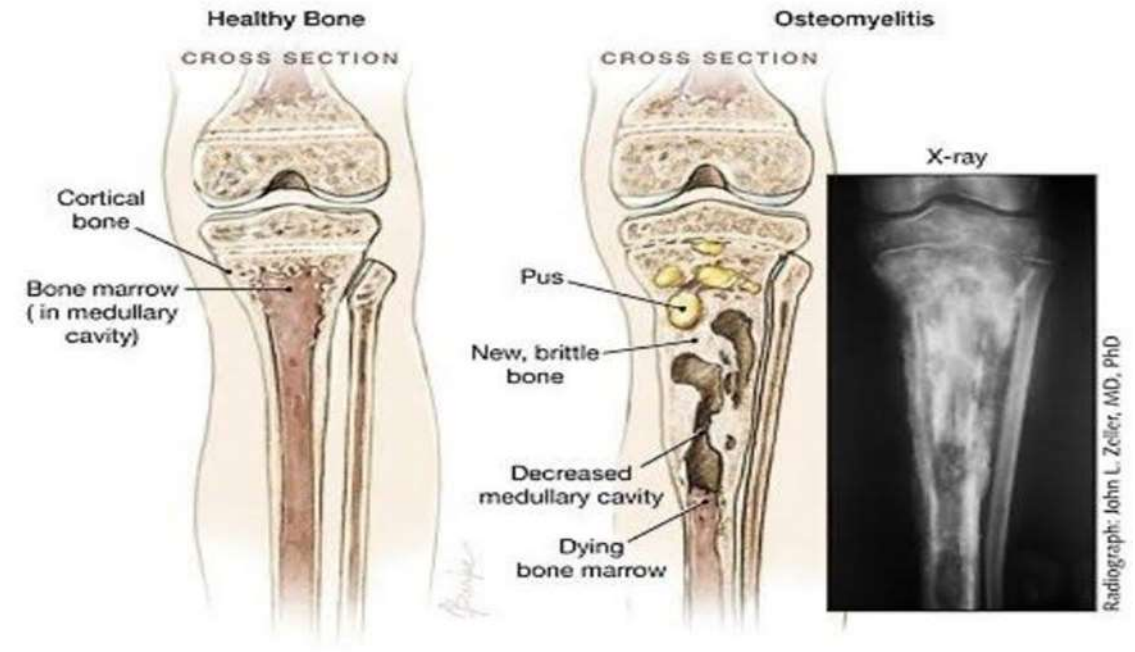


Figure 1: Diagrammatic representation of chronic osteomyelitis (Adapted from Elsevier –Netter Images).

Direct sampling of the wound for culture and antimicrobial sensitivity is essential to target treatment. The increased incidence of Methicillin-resistant *Staphylococcus aureus* to chronic osteomyelitis complicates antibiotic selection. The duration of antibiotic treatment for chronic osteomyelitis is typically 6 weeks. In both situations, however, emperic antibiotic coverage for *S. aureus* is indicated (Ibingira, et al., 2003). Cierny and Mader classified osteomyelitis based on the affected portion of the bone, the physiologic status of the host and the local environment (Cierny, et al., 2003). This classification lends itself to the treatment and prognosis of chronic osteomyelitis (Lew & Waldvogel , 2004).

Surgical debridement is usually necessary in chronic cases. The recurrence rate remains high despite surgical intervention and long-term antibiotic therapy while in

some cases complication was associated with bone defect. In a case study example that was seen in a ten year old who underwent multiple sessions of debridement and sequestrectomy at sub-county hospital in Moyale, Kenya. The same patient was referred to Kenyatta National Hospital with a large bone defect of the tibia which was treated surgically by tibialization of fibula (Fazal & Mwangi, 2013).

The incidence of chronic osteomyelitis is increasing because of the prevalence of predisposing conditions such as chronic wounds from trauma, diabetes mellitus and peripheral vascular disease (Biruk & Wubshet, 2007). In developing countries chronic osteomyelitis remains higher and presents much later than in developed countries (Ayumba ,et al., 2009). Chronic osteomyelitis is a considerable healthcare burden in many developing countries, but this burden is poorly quantified. There are limited data on the burden of chronic osteomyelitis in developing regions (Stanley, et al., 2010). Upon establishment of chronic osteomyelitis, management is challenging, particularly in developing countries where resources are scarce (Ayumba, et al., 2009).

1.2 Problem Statement

Chronic osteomyelitis is missed in early diagnosis due to unclear presentation, hence not properly treated, resulting in severe bone erosion and bone defect seen among patients referred to MTRH. There is increase in number of cases of chronic osteomyelitis referred and treated locally based on records at MTRH. Some of the cases treated surgically at MTRH resulted in large bone defects with some cases developing limb deformities and some ended up with amputations and draining sinus recurrence. Therefore, there is need to characterize chronic osteomyelitis and identify

surgical alternatives that would cause lesser morbidity to the patients with minimal complications and good functional outcome.

Therefore, information obtained from this study will assist in developing management guidelines for COM at MTRH which can also be disseminated to peripheral health centers.

1.3 Justification of study

The management of chronic osteomyelitis is lengthy, very costly and may have a lasting impact on the independence and quality of life of those affected. Patients with bone defects or deformity are physically, psychologically, emotionally and social-economically affected. Patients with chronic osteomyelitis due to delayed diagnosis ended up with inadequate surgical treatment and worse clinical outcomes which contributed to consumption of more health-care resources. Therefore, there is need for management guidelines in treatment of chronic osteomyelitis. This study obtained information regarding clinical characteristics, surgical treatment modalities and early outcomes which will aid in coming up with management guidelines.

1.4 Research question

What are the clinical characteristics, surgical treatment modalities and early outcomes of chronic osteomyelitis among patients at Moi Teaching and Referral Hospital, Eldoret, Kenya?

1.5 Study Objectives

1.5.1 Broad objective

To describe clinical characteristics, surgical treatment modalities and early outcomes of chronic osteomyelitis among patients at Moi Teaching and Referral Hospital (MTRH), Eldoret, Kenya.

1.5.2 Specific objectives of the study

1. To describe clinical characteristics of patients with chronic osteomyelitis managed at MTRH.
2. To describe surgical treatment modalities of chronic osteomyelitis in patients at MTRH.
3. To describe early outcomes of surgical treatment modalities of chronic osteomyelitis in patients at MTRH.

CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 Introduction

Chronic osteomyelitis can be defined as an inflammatory condition of the bone, which begins as an infection of the medullar cavity, rapidly involving the haversian systems, and extends to involve the periosteum of the affected area. In most cases, bacteria called *Staphylococcus aureus* is presumed to cause osteomyelitis. Osteomyelitis can be categorized as acute or chronic based on histo-pathologic findings and duration of the infection (Lew & Waldvogel, 2004).

Chronic osteomyelitis is associated with inflammatory bone changes caused by pathogenic bacteria and symptoms typically present within two to four weeks after infection. Necrotic bone is present in chronic osteomyelitis and symptoms may not occur until after four weeks of the onset of infection (Mylona, et al., 2009). Certain conditions and behaviours that weaken the immune system increase a person's risk for chronic osteomyelitis, including, diabetes mellitus, sickle cell disease, HIV or AIDS, rheumatoid arthritis, intravenous drug use, alcoholism, long-term use of steroids, haemodialysis and poor blood supply to chronic wounds ((Biruk & Wubshet, 2007).

Acute osteomyelitis (AO) compared to chronic osteomyelitis is differentiated arbitrarily based on time. Acute osteomyelitis process occurs up to one month after the onset of symptoms and the chronic process occurs for longer than one month (Fritz & Mcdonald, 2008). In children, osteomyelitis is usually acute but over time if untreated becomes chronic osteomyelitis (Mader, et al., 2010). Acute osteomyelitis comes on quickly, and is easier to treat, and overall turns out better than chronic osteomyelitis. In children, osteomyelitis usually shows up in arms and leg bones (Jones, et al., 2011). People with diabetes mellitus, HIV, or peripheral vascular

disease are more prone to chronic osteomyelitis, which persists or recurs, despite treatment (Conterno & Turchi, 2013). Among the 90 patients with at least 12 months' follow-up, 11 had chronic osteomyelitis relapse (12.2%) (Mantero, et al., 2011). Chronic or acute osteomyelitis and can affect adult's pelvis or vertebrae of the spine (Hadjipavlou, et al., 2000).

Acute osteomyelitis develops rapidly over a period of 7- 10 days. The symptoms for acute and chronic osteomyelitis are similar and include: Fever, irritability, fatigue, nausea, tenderness, redness, and warmth in the area of the infection, swelling around the affected bone and loss of range of motion (Jones, et al., 2011). Chronic osteomyelitis in the vertebrae makes itself known through severe back pain, especially at night (Mylona, et al., 2009).

2.2 Classification of Osteomyelitis

Cierny and Mader classified osteomyelitis based on the affected portion of the bone, the physiologic status of the host and the local environment. This classification lends itself to the treatment and prognosis of osteomyelitis (Cierny, et al., 2003; Lew and Waldvogel, 2004; Spigiel and Penny, 2005). Anatomical and physiological types by Cierny and Mader are used in determining a stage patient belongs (Lew & Waldvogel , 2004). See table 1 giving a summary of Cieny and Mader classification.

Table 1: Cierny and Mader classification of Anatomical and Physiological types (Cierny, et al., 2003).

Anatomical type

Type	Characteristics
I	Medullary osteomyelitis
II	Superficial osteomyelitis
III	Localised osteomyelitis
IV	Diffuse osteomyelitis

Physiological class

Type	Characteristics
A	Good immune system and delivery
B	Compromised locally (B^L) or systemically (B^S)
C	Requires suppressive or no treatment; Minimal disability; Treatment worse than disease; Not a surgical candidate

Factors affecting physiological class

Systemic factors (	Local factors (
Malnutrition	Chronic lymphedema
Renal or hepatic failure	Venous stasis
Diabetes mellitus	Major vessel compromise
Chronic hypoxia	Arteritis
Immune disease	Extensive scarring
Extremes of age	Radiation fibrosis
Immunosuppression	Small-vessel disease
Immune deficiency	Neuropathy
Tobacco abuse	
Alcohol abuse	
Malignancy	

2.2.1 Anatomic types of Cierny and Mader classification.

Stage I: Medullary osteomyelitis denotes infection confined to the intramedullary surfaces of the bone. Hematogenous osteomyelitis and infected intramedullary rods are examples of this anatomic classification type.

Stage II: Superficial osteomyelitis is a true contiguous focus infection of bone; it occurs when an exposed infected necrotic surface of bone lies at the base of a soft-tissue wound.

Stage III: Localized osteomyelitis is usually characterized by a full thickness, cortical sequestration which can be removed surgically without compromising bony stability. Stage IV: Diffuse osteomyelitis is a through-and-through process that usually requires an intercalary resection of the bone to arrest the disease process. Diffuse osteomyelitis includes those infections with a loss of bony stability either before or after debridement surgery. See figure 2 diagrammatic representation of anatomical types.

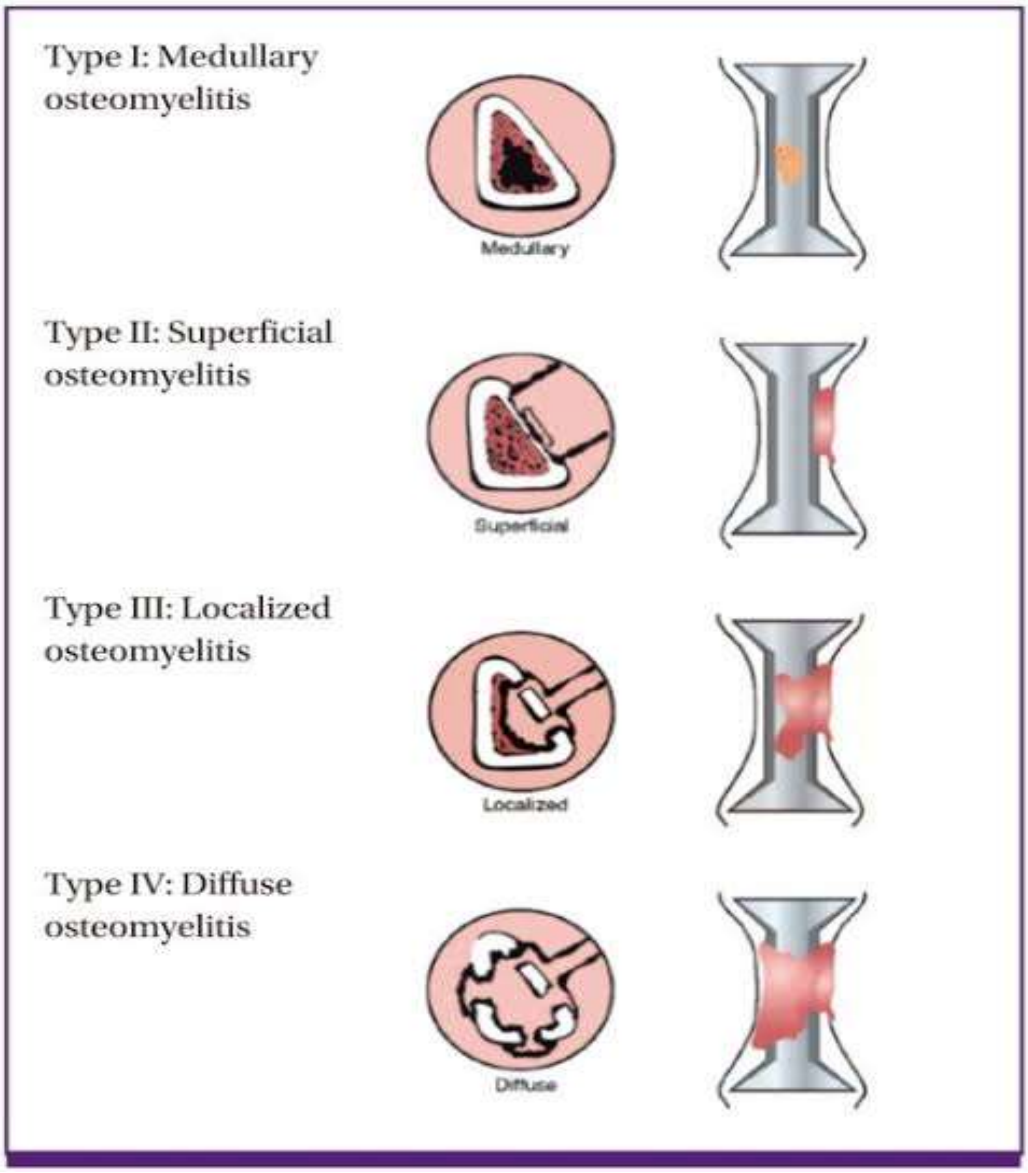


Figure 2: Diagrammatic representation of Anatomical stages of Cierny and Mader classification. (Cierny,et al., 2003).

2.2.2 Physiologic types of Cierny and Mader classification

Class A; denotes a normal host

Class B;denotes a host with systemic compromise, local compromise, or both

Class C; denotes a host for whom the morbidity of treatment is worse than that imposed by the disease.

2.3 Etiology of chronic osteomyelitis

The most common pathogens in chronic osteomyelitis depend on the patient's age. *Staphylococcus aureus* is the most common cause of acute and chronic hematogenous osteomyelitis in adults and children. Group A *Streptococcus, Streptococcus pneumoniae*, and *Kingella kingae* are the next most common pathogens in children. Group B streptococcal infection occurs primarily in newborns (Spigiel & Penny, 2005). In MTRH, the commonest cause in children was *Staphylococcus aureus* (Ayumba, et al., 2009) .

In adults, *Staphylococcus aureus* is the most common pathogen in bone and prosthetic joint infections. Increasingly, methicillin-resistant *S. aureus* (MRSA) is isolated from patients with chronic osteomyelitis (Ponio and Delos Reyes, 2013). MRSA accounted for more than one-third of staphylococcal isolates (Gutierrez, 2005). In more chronic cases that may be caused by contiguous infection, *Staphylococcus epidermidis, Pseudomonas aeruginosa*, *Serratia marcescens*, and *Escherichia coli* may be isolated. Fungal and mycobacterial infections have been reported in patients with chronic osteomyelitis, but these are uncommon and are generally found in patients with impaired immune function (Mantero, et al., 2011).

2.4 Pathogenesis of chronic osteomyelitis

Chronic hematogenous osteomyelitis results from bacteremic seeding into bone with children being the most affected because the metaphyseal regions of the long bones are highly vascular and susceptible to even minor trauma. More than one-half of cases of acute hematogenous osteomyelitis in children occur in patients younger than five years (Mantero, et al., 2011).

Normal bone is highly resistant to infection. Large inoculum of bacteria is typically required to induce osteomyelitis (Mader, et al., 2010). Bacteria possess a variety of virulence factors that contribute to the development and chronicity of osteomyelitis such as proteins called adhesins which facilitate attachment to bone and the ability to form biofilm, a slime layer which shields the bacteria from antimicrobial agents (Mader, et al., 2010).

In addition, the host's immune response to infection can damage bone (Martinez-Anguilar, et al., 2004). Several common cytokines have osteolytic properties, and phagocytes produce toxic oxygen radicals and proteolytic enzymes that can harm host cells. The inflammatory response leads to an increase in intraosseous pressure, which impairs blood flow and leads to ischemic necrosis. It is noted that Infection at the bone locus creates an increase of intramedullary pressure due to inflammatory exudates that strips the periosteum, leading to vascular thrombosis followed by bone necrosis and formation of sequestrum (Martinez-Anguilar, et al., 2004).

Presence of dead bone can act as a non-living surface for biofilm attachment allowing bacteria to adopt a lower metabolic rate and to survive in an environment with lower oxygen tension. Poor blood flow as well as biofilm makes it difficult for antimicrobial agents and host immune cells to access the bacteria (Jones, et al., 2011).

Normally dead bone is surrounded by thick relatively avascular granulation tissue which is hard to allow penetration of antibiotics. Even though this is a typical pathophysiology of haematogenous osteomyelitis, post-traumatic COM also shares some but not all of these characteristics (Biruk & Wubshet, 2007).

2.5 Clinical characteristics of chronic osteomyelitis

Chronic osteomyelitis is generally secondary to open fractures, bacteremia, or contiguous soft tissue infection. Clinical symptoms of chronic osteomyelitis can be nonspecific and difficult to recognize. Some of the clinical features include chronic pain, persistent sinus tract or wound drainage; poor wound healing, malaise, and sometimes fever (Biruk &Wubshet, 2007)). See diagrammatic representation of chronic osteomyelitis in metaphyseal part of tibia.

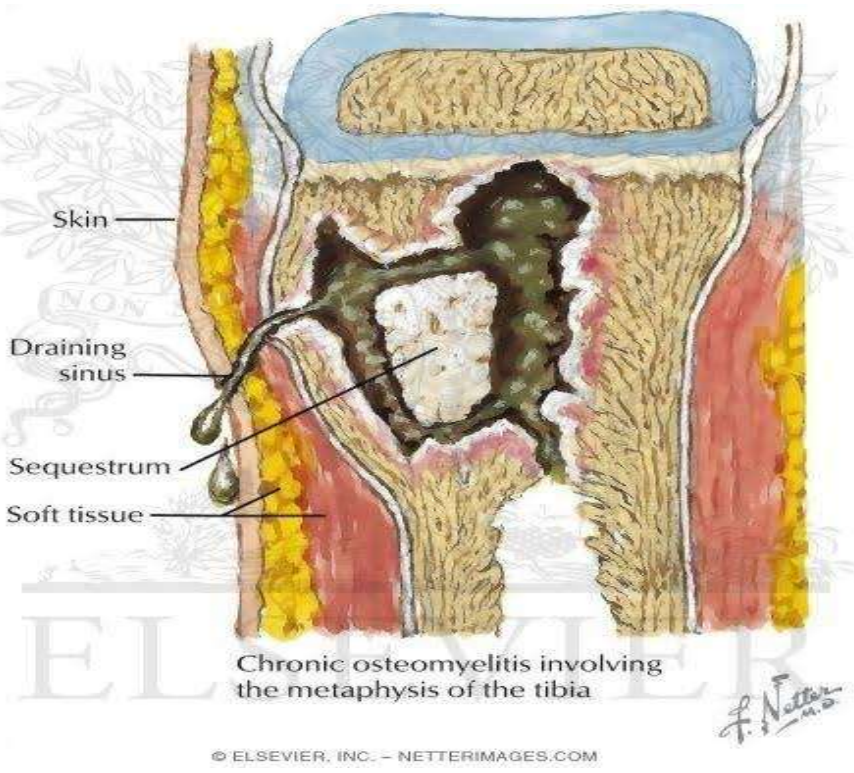


Figure 3: Diagrammatic representation of COM in metaphyseal part of tibia (Adapted from Elsevier-netter.com images).

The incidence of significant infection within three months after an open fracture has been reported to be as high as 27 percent (Mylona, et al., 2009). The incidence appears to be independent of the length of time from the injury to surgery. Only 1- 2 % of prosthetic joints become infected (Meehan et al., 2003).

Chronic osteomyelitis from contiguous soft tissue infection is becoming more common because of the increasing prevalence of diabetic foot infections and peripheral vascular disease (Biruk & Wubshet, 2007). Large percentages of patients with diabetes mellitus develop peripheral neuropathy which may reduce their awareness of wounds and increase the risk of unrecognized infections (Gutierrez, 2005). Peripheral vascular disease which is also common in patients with diabetes mellitus reduces the body's healing response and contributes to chronically open wounds and subsequent soft tissue nfection. These conditions may act synergistically to significantly increase the risk of chronic osteomyelitis in these patients (Jones, et al., 2011).

Hematogenous osteomyelitis is much less common in adults than in children. It typically involves the vertebrae but can occur in the long bones, pelvis or clavicle. Patients with vertebral osteomyelitis often have underlying medical conditions such as diabetes mellitus, cancer, chronic renal disease or a history of intravenous drug use (Hadjipavlou, et al., 2000; Ponio and Delos Reyes, 2013).

2.6 Diagnosis of chronic osteomyelitis

The identification of a bacterial infection may be difficult because blood cultures are positive in only about less than half of the cases (Fritz &Mcdonald, 2008). Because of the difficulty of diagnosis the potential severity of infection in children the high disease recurrence rate in adults and the possible need for surgical intervention

warrants consultation with an infectious disease subspecialist and an orthopedic subspecialist (Ibingira, et al., 2003). The diagnosis of osteomyelitis in adults can be difficult. Therefore, a high index of clinical suspicion is required, along with recognition of clinical symptoms and supportive laboratory and imaging studies (Jones, et al., 2011). The initial evaluation should include questions to determine the patient's history of systemic symptoms which include lethargy, malaise, extremity or back pain, fever and predisposing factors like diabetes mellitus, peripheral vascular disease, history of trauma or intravenous drug use (Jones, et al., 2011).

The physical examination should focus on locating a possible nidus of infection, assessing peripheral vascular and sensory function and exploring any ulcers for the presence of bone infection (Mylona, et al., 2009). If a contiguous infection with ulcer is present, such as in diabetic foot infections, the use of a sterile steel probe to detect bone may be helpful in confirming the presence of chronic osteomyelitis (Fritz and Mcdonald, 2008; Lam, et al., 2016). A study on chronic osteomyelitis predictive value found that the test had a positive predictive value of 89 percent while another study in a population with a lower prevalence of chronic osteomyelitis found a positive predictive value of only 57 percent (Gutierrez, 2005).

2.6.1 Laboratory Studies of chronic osteomyelitis

A complete blood count (CBC) is useful for evaluating leukocytosis and anemia. Leukocytosis is common in acute osteomyelitis before therapy (Spigiel & Penny, 2005). The leukocyte count rarely exceeds 15,000/µL acutely and is usually normal in chronic osteomyelitis. Erythrocyte sedimentation rate and C-reactive protein levels are usually increased (Fritz & Mcdonald, 2008). In study by Ibingira, (2003), ESR

was more than 30mm/hr in 86% of the patients, with leucocytosis in 38% of the patient and 43% of the patients were anaemic.

Blood cultures are positive in only 50% of cases of osteomyelitis and should be obtained before or at least 48 hours after antibiotic treatment (Lam, et al., 2016). Although sinus tract cultures do not predict the presence of gram-negative organisms, they are helpful for confirming presence of *S aureus*. Bone biopsy leads to a definitive diagnosis by isolation of pathogens directly from the bone lesion (Lam, et al., 2016). Once diagnosed, the identification of the causative microorganisms is ideally obtained with specimens from a surgical or needle biopsy to provide the best guidance for antibiotic therapy (Biruk & Wubshet, 2007). Bone biopsy should be performed through uninfected tissue and either before the initiation of antibiotics or more than 48 hours after discontinuance (Mantero, et al., 2011).

Microbial cultures are essential in the diagnosis and treatment of osteomyelitis. The preferred diagnostic criteria for chronic osteomyelitis are a positive culture from bone biopsy and histopathology consistent with necrosis (Montero, et al., 2011). Some studies have assessed treatment outcomes based primarily on bone biopsy results though Positive blood cultures may obviate the need for a bone biopsy especially when they are combined with substantial clinical and radiographic evidence of chronic osteomyelitis (Lam, et al., 2016). Superficial wound cultures do not contribute significantly to the diagnosis of chronic osteomyelitis though the organisms identified by such cultures correspond with bone biopsy culture results in only about one-third of cases (Lam, et al., 2016).

Chronic infections are more likely to have polymicrobial involvement, including anaerobic mycobacterial, and fungal organisms. Specific cultures or microbiologic testing may be required for suspected pathogens. Open bone biopsy with histopathologic examination and culture is the criterion standard for the microbiologic diagnosis of chronic osteomyelitis (Ipkeme, et al., 2007). Biopsy may not be necessary if blood cultures are positive with consistent radiologic findings. Needle biopsy may also be used to obtain bone sample for analysis (Fritz & Mcdonald, 2008). When clinical suspicion is high but blood cultures and needle biopsy have yielded negative results a repeat needle biopsy or an open biopsy should be performed. A bone sample can be collected at the time of debridement for histopathologic diagnosis in patients with compromised vasculature. To obtain accurate cultures, bone biopsy must be performed through uninvolved tissue (Martinez-Anguilar, et al., 2004). Cultures of the sinus tract may be useful if *Staphylococcus aureus* and *Salmonella* species are isolated (Lam, et al., 2016).

2.6.2 Imaging of chronic osteomyelitis

Imaging is useful to characterize the infection and to rule out other potential causes of symptoms. Plain radiography, Technetium-99 bone scintigraphy, and magnetic resonance imaging (MRI) are the most useful modalities (Restrepo et al., 2003). Plain radiography as a modality will show periosteal thickening or elevation, as well as cortical thickening and osseous irregularity with other changes including loss of trabecular architecture, osteolysis, and new bone formation (Ibingira, 2003). See figure 4 showing lytic features of chronic osteomyelitis.

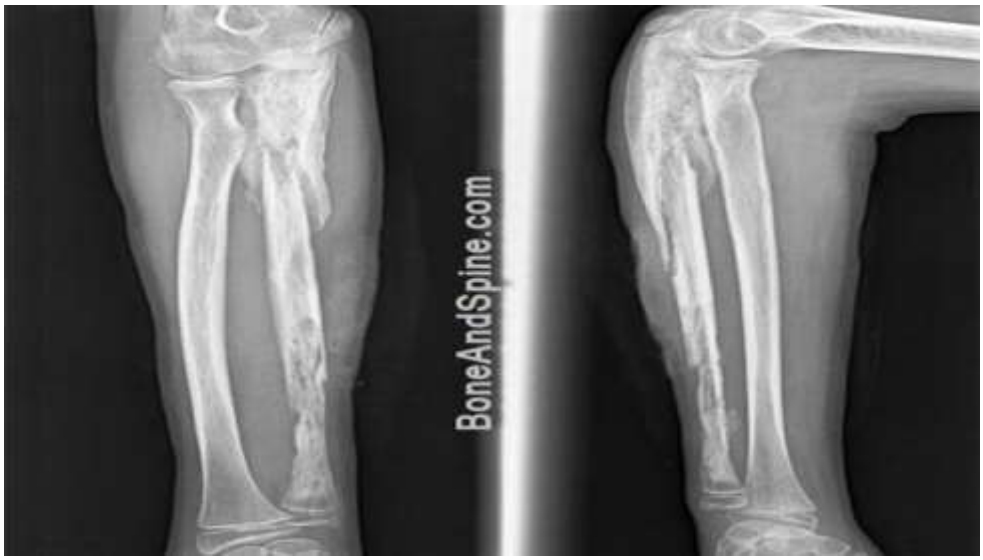


Figure 4: X-ray showing lytic features of COM (Adapted from bone and spine .com).

These changes may not be evident until 5-7 days in children and 10-14 days in adults (Restrepo, et al., 2003). Plain films show lytic changes after at least 50-75% of the bone matrix is destroyed. Therefore, negative radiographic studies do not exclude the diagnosis of acute osteomyelitis (El-Maghraby, et al., 2006). Computed tomography (CT) is useful for guiding needle biopsies in closed infections and for preoperative planning to detect osseous abnormalities, foreign bodies, or necrotic bone and soft tissue. It may also assist in the assessment of bony integrity, cortical disruption, and soft-tissue involvement. Intraosseous fistula and cortical defects that lead to soft tissue sinus tracts are also demonstrated on CT scan images (Restrepo, et al., 2003).

MRI provides better information for early detection of osteomyelitis than do other imaging modalities. MRI can detect osteomyelitis within three to five days of disease onset (Restrepo, et al., 2003). Most studies of the diagnostic accuracy of MRI in detecting osteomyelitis included patients with diabetic foot ulcers. The sensitivity and specificity of MRI in the diagnosis of osteomyelitis may be as high as 90 percent (El-Maghraby, et al., 2006).

MRI shows a localized marrow abnormality in osteomyelitis. T1-weighted images typically show decreased signal intensity, whereas T2-weighted images produce increased signal intensity. Increased intensity on T2-weighted images may indicate sinus tracts, which extend from marrow and bone to skin through soft tissue. A decreased intensity on T1-weighted images with no change on T2-weighted images may indicate surgical or posttraumatic scarring of bone marrow**.** Its use can be limited, however, if surgical hardware is present (Restrepo, et al., 2003). See figure 5 showing MRI lytic images of chronic osteomyelitis.

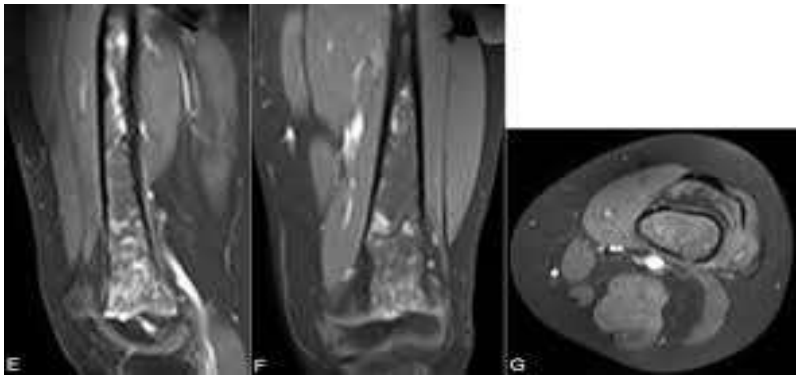


Figure 5: MRI showing lytic changes in COM of distal femur (Adapted from bone and spine.com).

Nuclear imaging can be helpful in diagnosing osteomyelitis. Three-phase Technetium-99 bone scintigraphy and leukocyte scintigraphy are usually positive within a few days of the onset of symptoms (El-Maghraby, et al., 2006). The sensitivity of bone scintigraphy is comparable to MRI, but the specificity is poor. Leukocyte scintigraphy also has poor specificity, but when combined with three-phase bone scintigraphy, sensitivity and specificity are improved. Bone and leukocyte scintigraphy can provide valuable information if MRI is contraindicated or unavailable (El-Maghraby, et al., 2006).Other imaging modalities seem promising for the diagnosis of osteomyelitis but they are not routinely used. Positron emission

tomography has the highest sensitivity and specificity more than 90 percent but it is expensive and not as widely available as other modalities (Restrepo, et al., 2003). See figure 6 showing bone scan images of chronic osteomyelitis.

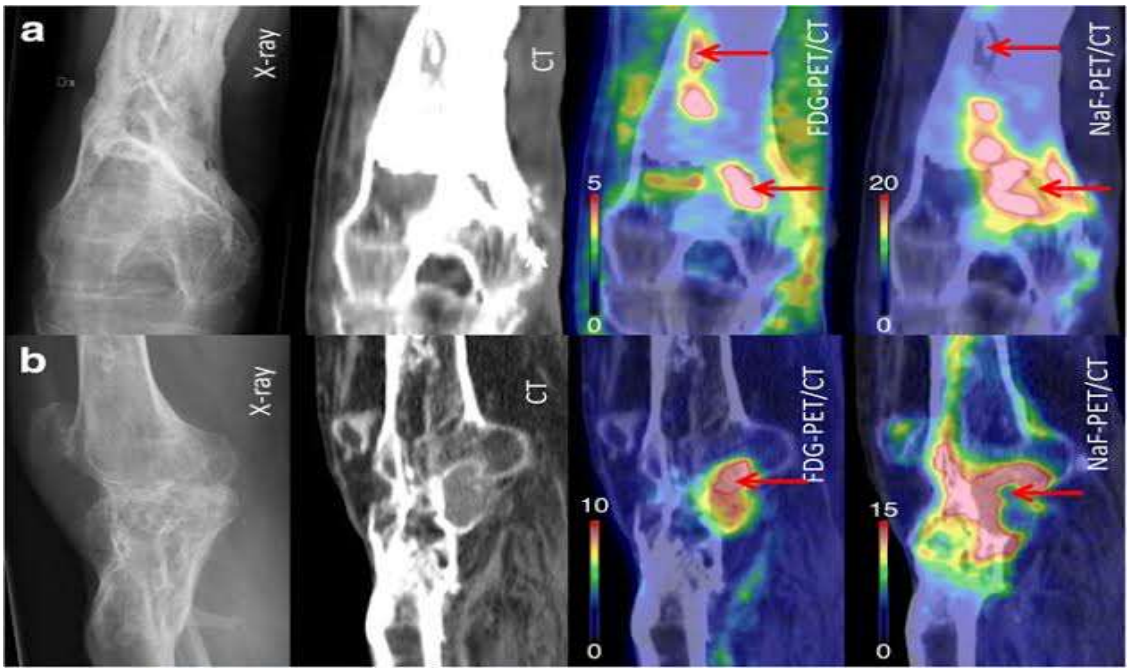


Figure 6: PET showing areas with COM in a distal femur (Adapted from bone and spine .com).

The role of musculoskeletal, al ultrasonography in the diagnosis of osteomyelitis is evolving. Some studies suggest that in some patients, such as those with sickle cell disease, detection of sub periosteal fluid collections can be useful or even diagnostic; however, reliable estimates of sensitivity and specificity are lacking (Lam, et al., 2016).

2.7 Antibiotic coverage and surgical treatment modalities of COM

Although randomized controlled trials are lacking, therapy with four days of parenteral antibiotics followed by oral antibiotics for a total of four weeks seems to prevent recurrence in children who have no serious underlying pathology (Tice, et al.,

2003). In immuno-compromised children, the transition to oral antibiotics should be delayed, and treatment should continue for at least six weeks based on clinical response (Spiegel and Penny, 2005).

Surgical treatment in immuno-competent children is rare (Tice, et al., 2003). Typical regimens involve at least 4 to 6 weeks of parenteral administration, although conversion to oral antibiotics is possible in appropriate cases with agents such as clindamycin or fluoroquinolones. Antibiotic regimens for the empiric treatment of chronic osteomyelitis, particularly in children, should include an agent directed against *S. aureus* (Mantero, et al., 2011). Cloxacillin antibiotics are first-line options unless MRSA is suspected. If methicillin resistance among community isolates of *Staphylococcus aureus* is greater than 10 percent, MRSA should be considered in initial antibiotic coverage (Martinez-Aguilar, et al., 2004).

In patients with diabetic foot infections or penicillin allergies, fluoroquinolones are an alternate option for staphylococcal infections whereby these agents have been noted to be as effective as beta-lactams (Meehan, et al., 2003; Tice, et al., 2003). Other treatment alternatives that have gained increased acceptance include outpatient parenteral therapy and combination regimens with agents such as rifampin. More recently, newer antibiotics such as linezolid have shown promise for the treatment of resistant microorganisms in chronic osteomyelitis (Martinez-Aguilar, et al., 2004).

Although antibiotic therapy will always constitute a major component of chronic osteomyelitis treatment, the challenges for successful treatment revolve around the interface of impaired vascularity that develops in the regions of infected bone. Sequestrum which is devitalized areas of infected bone which form in chronic osteomyelitis cannot be reached adequately by leukocytes or perfused in sufficient

concentrations by systemic antibiotics (Mylona, et al., 2009). Even in the surrounding areas of living bone, the tissue is still compromised by the relative hypoperfusion resulting from the inflammatory process that impairs blood flow within the vascular channels (Bickler & Sanno-Duanda, 2000).

The treatment of chronic osteomyelitis depends on appropriate antibiotic therapy and often requires surgical removal of infected and necrotic tissue. Choice of antibiotic therapy should be determined by culture and susceptibility results. In the absence of such information, broad-spectrum, empiric antibiotics should be administered. False-negative blood or biopsy cultures are common in patients who have begun antibiotic therapy. If clinically possible, delaying antibiotics is recommended until microbial culture and sensitivity results are available (Tice, et al., 2003). Indications for surgery include antibiotic failure, infected surgical hardware, and chronic osteomyelitis with necrotic bone and soft tissue (Parsons & Strauss, 2004).

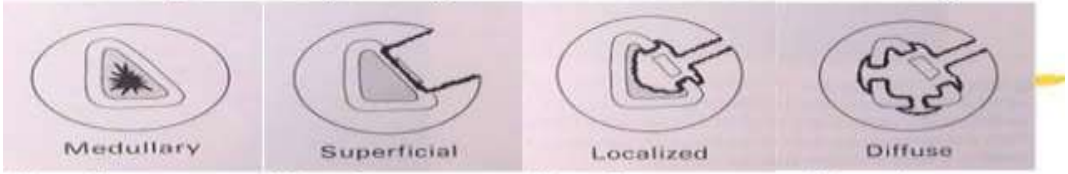
Management of COM requires thorough debridement of infected bone and soft tissues coupled with rigid stabilization with external fixators, elimination of dead space, often requiring soft-tissue flap coverage, and staged bone reconstruction. When such a surgical approach is accompanied by appropriate antibiotics based on the sensitivity of the microbes isolated from the infected site, the infected focus is eliminated and bone length and integrity are restored (Ipkeme, et al., 2013).

The debridement of necrotic tissue and the restoration of viable vascularity to the infected site have been the goals of the surgical component to chronic osteomyelitis treatment. Traditional surgical philosophy emphasizes the thorough excision of necrotic and infected tissue to the point of healthy bleeding (paprika sign) (Bickler and Sanno-Daunda, 2000). Unfortunately, the results of adequate tissue debridement

can often leave a considerable defect (Parsons & Strauss, 2004). Besides the use of debridement and sequestrectomy as a sole management option, the procedure may be combined with other procedures like muscle flap interposition, bone grafting, primary or secondary skin grafting, antibiotic impregnated beads or the Lautenbach technique (Hashmi, et al., 2004).

In recent years, several advancements have improved the management of the resultant dead space. Multiple techniques of tissue transfer, including myocutaneous flaps and vascularized bone grafts, have increased the success rate in restoring the defect with viable tissue and vascularity. Patients with chronic osteomyelitis can be treated by curettage of the lesions and packing of the bone cavities with plaster of Paris pellets containing antibiotics (Fucidin & Amoxycillin). Antibiotic beads have increased the surgeon's ability to provide local antimicrobial control after debridement (Ipkeme, et al., 2007). Other methods have included the Ilizarov technique, which produces distraction osteogenesis that results in highly vascular new bone (Parsons & Strauss, 2004). According to Cierny and Mader classification each stage has its own management procedure (Mader ,et al., 2010). See figure 7 showing Cierny and Mader diagrammatic representation.

Management (Cierny and Mader classification)



Stage 1	**Stage 2**	**Stage 3**	**Stage 4**
Necrosis limited to medullary contents, cancellous bone is involved **Etiology:** Hematogenous **Treatment** Excision of bone, with antibiotic-loaded cement beads.	Necrosis related to exposed surface, cortical bone **Treatment** Early: Antibiotics Late: Superficial debridement, Bone grafting maybe required.	Limited area of dead bone with medullary infection **Etiology:** Trauma, involving stage 2 &3,iatrogenic **Treatment** Antibiotics, Debridement, Dead space management, Temporary stabilization,bone graft	Entire circumference **Treatment:** Antibiotics. Stabilization, Extemal fixation Debridement, Possible ablation.

Figure 7: Cierny and Mader classification and management (Mader, et al., 2010).

2.8 Early outcomes of surgical treatment.

The cornerstone for treatment for COM is adequate surgical debridement with removal of all infected bone. This procedure necessarily creates a potential dead space which must be dealt with appropriately to reduce the chances of re-infection. Local antibiotic delivery systems do not only provide the opportunity to deal with the dead space, they offer the chance for sterilization of the local environment and therefore promote healing (Ipkeme, et al., 2013).

Antibiotic impregnated polymethylmethacrylate (PMMA) and the low pressure antibiotic irrigation and clearance system (Lautenbach technique) are two commonly used local antibiotic delivery systems (Hashmi, et al., 2004). The use of non-biodegradable PMMA bone cement raises two issues that need for a second surgery to remove the beads and the risk of retained beads which can then serve as a nidus for re-infection. The Lautenbach procedure presents the challenges of wound leakage and re-colonization by hospital-acquired hydrophilic organisms (Hashmi, et al., 2004).

Despite the use of surgical debridement and long-term antibiotic therapy, the recurrence rate of chronic osteomyelitis in adults is about 30 percent at 12 months. Recurrence rates in cases involving *Pseudomonas aeruginosa* are even higher, nearing 50 percent (Tice, et al., 2003). The optimal duration of antibiotic treatment and route of delivery are variant and restricted to individual basis (Parsons & Strauss, 2004). For chronic osteomyelitis, parenteral antibiotic therapy for two to seven days is generally recommended, with a transition to oral antibiotics for a total treatment period of six to eight weeks. Long-term parenteral therapy is likely as effective as transitioning to oral medications, but has similar recurrence rates with increased

adverse effects (Tice et al., 2003). Surgery is necessary to preserve viable tissue and prevent recurrent systemic infection (Parsons and Strauss, 2004).

In Marais, et al., (2016) study success rate was 84 % of patients managed curatively at 2-year follow-up. The bone Infection Unit in the UK had cure rate of 90 % at 5-year follow-up. In the study by Marais, et al., (2016) showed overall success rate was 96.2 % (95 % CI 80.4–99.9 %) after a minimum of 12 months of follow-up. Remission was achieved in all patients treated curatively (one-sided 95 % CI 73.5–100.0 %). Palliative treatment was successful in 92.8 % of cases (95 % CI 66.1–99.9 %), with suppression in 46 % and remission in the remaining 54 % of these patients (Marais, et al., 2016).

The overall mean final AAOS Lower Limb Outcomes score in Marais study was 86.6 (51–100). This equated to a statistically significant (p value < 0.001) mean improvement of 28.3 (95 % CI 21.0–35.7, SD 17.0) (Marais, et al., 2016). In the upper limb, the mean final overall Quick DASH score was 75(72.5–86.4), with a mean improvement of 54.3(45.5–84.1). There was comparable improvement in the functional outcome scores in the palliative and curative treatment groups (Marais, et al., 2016).

CHAPTER THREE

3.0 RESEARCH METHODOLOGY

3.1 Study Setting

Moi Teaching and Referral Hospital (MTRH) is located in western region of Kenya in Eldoret town, Uasin Gishu County. It has a catchment population of over 24 million including western part of Kenya and across borders to Eastern part of Uganda and South Sudan. It is 310 km North West of Nairobi within longitudes 34° 50' and 35° 34' and latitudes 0° 03' and 0° 55'. The hospital is located along the Nandi Road, East of Eldoret town with over 1000 beds capacity. It offers both outpatient and inpatient care in general and private (Memorial wing and Amenity wing). It has nursing school training centre and Academic Model Providing Acess to Healthcare (AMPATH) Centre which are specialized in HIV/AIDS research and management of chronic conditions and Chandaria Cancer centre which caters for cancer conditions and other chronic conditions. In addition MTRH has specialized hospitals; Shoe for Africa Children's Hospital, Mother Riley and Baby Hospital and Mental Health Centre. It offers training for Moi University College of Health Sciences, Eldoret KMTC and Baraton University, College of Health Science.

3.2 Research Design

The study was prospective descriptive study, conducted from 1st January 2017 to 31st December 2017.

3.3 Study Population

Patients with COM managed surgically at MTRH orthopeadic wards and clinic.

3.4 Eligibility Criteria

3.4.1 Inclusion criterion: All age group patients managed operatively for chronic osteomyelitis at MTRH between 1st January 2017 and 31st December 2017.

3.4.2 Exclusion criteria: Patients managed operatively for chronic osteomyelitis in other facilities and were on follow up at MTRH. Patients with recurrence post operatively prior to this study for chronic osteomyelitis.

3.5 Recruitment and Study Sample Size determination

Forty four patients was average number of patients treated surgically for chronic osteomyelitis at MTRH per year for the last 4 years. Due to low numbers treated at MTRH per year, census study was chosen as sampling method.

Census of 63 patients with chronic osteomyelitis who were admitted to orthopedics ward between 1st January 2017 and 31st December 2017 were recruited after consenting. Among these patients three were lost to follow up. Therefore, 3 patients were excluded from study and 60 patients were followed up for 12 weeks post operatively for chronic osteomyelitis (Appendix 14).

3.6 Study Execution

Questionnaire was used to collect data on clinical characteristics and surgical modalities of patients with chronic osteomyelitis. Laboratory results which included full heamogram, ESR, Hb,WBC and culture and sensitivity test were obtained from patients file and laboratory records and tabulated in researcher administered questionnaire. The information on types of surgical modalities of chronic osteomyelitis done on recruited subjects was obtained from the theatre records and patient file and tabulated in researcher administered questionnaire.

The type of antibiotic used by patient was obtained from patient treatment sheet and records. Follow up was done at end of 6 weeks to check on progress and completion

of antibiotics. The second follow up was done at the end of 12 weeks to evaluate functional outcomes post-operatively and patient clinical satisfaction. QuickDASH scoring tool for upper limb functional assessment and AAOS lower limb scoring tool for lower limb functional assessment were administered.

3.7 Data collection tool and technique

Questionnaire was used to collect data on clinical characteristics and surgical modalities. QuickDASH tool was used for evaluation of upper limb functionality (Appendix11) while AAOS tool was used for evaluation of lower limb functionality (Appendix 12).

3.8 Data management and analysis

Data was collected and processed by cleaning, coding, entry and analysis. Data was analyzed using SPSS version 19. Descriptive statistics was analyzed using categorical variables; frequency tables and percentages. To test association between outcome and age, gender variables Fisher exact test and Wilcoxon rank test and T -test was used while measures of central tendencies and p-value were calculated.

3.9 Ethical consideration

Approval was sought from School of Medicine and MTRH and IREC No.1679.

Consent was sought for the patients above 18 years while parents assented for minors.

The patients consented prior to enrolment, after being duly informed and having understood all the benefits of the study.

The patients had the freedom of withdrawing at any time during the study without any conditions or consequences.

The confidentiality of the data obtained was maintained throughout the study period.

Information obtained from this study was disseminated to MTRH for purpose of developing management guidelines.

Information obtained from this study are in the process of being published in peer review journals.

3.10 Limitation

Antibiotic choice was based on patients' affordability and adherence.

The follow-up period in this study was short therefore might not have given the ultimate results in long term since COM may recur or deteriorate over time due to relapse after end of 3months.

Loss to follow up of 3 patients during period of study.

Limitation was mitigated by phone call, message reminder on follow up clinics and medication adherence.

CHAPTER FOUR

4.0 RESULTS

4.1. Introduction

The results presented here are based on 60 patients with chronic osteomyelitis who underwent surgical treatment at MTRH. The recruitment period of study was between January 1st to 31st December 2017 and patients were followed up for a period of 3 months post-surgery to evaluate clinical and functional outcomes after treatment.

4.2 Social Demographic Characteristics of chronic osteomyelitis

Table 2: Sex, age and occupation in patients with chronic osteomyelitis

Variable	Categories	Frequency	Percentage
Sex	Female	22	36.7
	Male	38	63.3
Age	Children	38	63.3
	Adults	22	36.7
Occupation	Unemployed	50	83.3
	Business	6	10.0
	Employed	4	6.7

Table 2, shows that most of the patients were males 38 (63.3%) with majority being children 38 (63.3%) while in terms of occupation most patients were unemployed 50 (83.3%) with those in business 6 (10%) and employed 4 (6.7%).

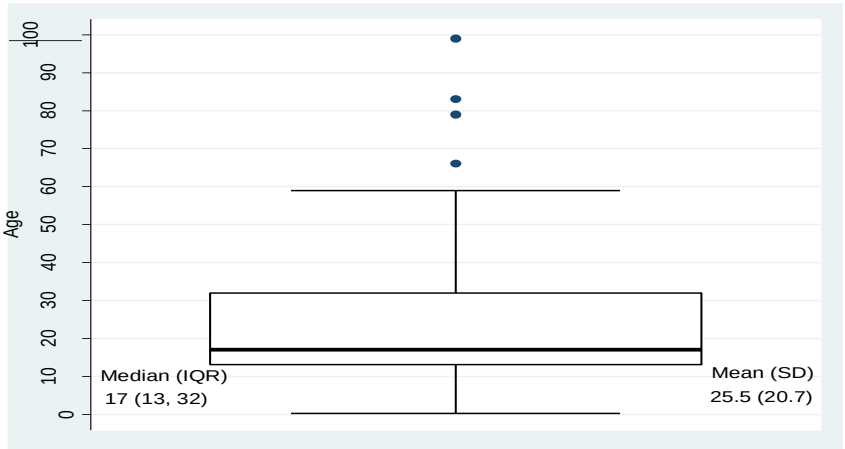


Figure 8: Age distribution in patients with chronic osteomyelitis

Figure 8, shows that median age of the patients was 17 (IQR 13, 32) years which ranged from 3 to 99 years. The age distribution was skewed with 4 patients aged above 60 years being regarded as outliers.

4.3 Clinical Characteristics of chronic osteomyelitis

About two thirds 37 (61.7%) of the patients were referred to MTRH, from peripheral health facilities 35 (94.6%) only 2 were from private practitioner. Illness duration ranged from 1 month to 8 years.

Table 3: Limb and bones involved in chronic osteomyelitis

Limbs	Bone type	Frequency	Percentage
Bone involved (upper limb)	Humerus	3	5.0
	Radius	3	5.0
	Ulna	2	3.3
	Digits	1	1.7
(lower limb)	Tibia	28	46.7
	Femur	17	28.3
	Fibula	2	3.3
	Digits	2	3.3
	Talus	1	1.7
	Calcaneus	1	1.7

Table 3, Shows that 9 (15%) of the patients had upper limb affected, the rest had a lower limbs affected. Tibia was the most affected bone 28 (46.7%) while the least affected bones were digits, talus and Calcaneus. Table 4: show prevalent symptoms and signs with draining sinus 42 (70%), swelling 22 (36.7%) and pain 20 (33.3%).

Table 4: Signs and symptoms for patients with chronic osteomyelitis

Variable	Category	Frequency	Percentages
Symptoms and signs	Draining sinus	42	70.0
	Swelling	22	36.7
	Pain	20	33.3
	Chronic wound	16	26.7
	Deformity	6	10.0
	Fever	3	5.0
	Erythema	1	1.7

Table 5: Predisposing factors in patients with chronic osteomyelitis

Conditions	Frequency	Percentage
Sickle cell disease	1	1.7
Peripheral vascular disease	1	1.7
Diabetes mellitus	3	5.0
Trauma	24	40.0
Chronic wound	45	75.0

Table 5, Shows that three quarter 45 (75%) of the patients had chronic wound as the predisposing factor and trauma 24 (40%)

Table 6: Radiological findings in patients with chronic osteomyelitis

Radiological features	**Frequency**	**Percentage**
Sequestrum	24	40.0
Bone erosion/lytic	18	30.0
Periosteal reaction	14	23.3
Deformity	9	15.1
Cloacae	8	13.3
Osteopenia	7	11.7
Fracture	6	10.0
Soft tissues swelling	4	6.7

Table 6, shows that the commonest radiological image among most of the patients was sequestrum contributing about 40% with most presentations having more than one radiological feature.

Table 7: Types of microorganism cultured from debridement tissue.

Micro-organisms	Number of patients	Percentage
Staphylococcus aureus	15	51.8
Staphylococcus epidermidis	3	10.3
Enterobacter species	1	3.4
MRSA	1	3.4
Pseudomonas aeruginosa	2	6.9
Polymicrobial organism	1	3.4
No growth	6	20.8
Totals	**29**	**100**

Table 7, shows that Twenty nine (48.3%) samples were collected and cultured. *Staphylococcus aureus* 15 (51.8%) was the commonest organism cultured followed by *Staphylococcus epidermidis* 3 (10.3%) while MRSA was only 1 (3.4%). Number of cases cultured without bacterial growth 6 (20.8%) on sample collected.

Table 8: Laboratory findings in patients with chronic osteomyelitis

Variable	Category	Frequency	Percentage
Hb	Low (0 – 11.9)	29	48.3
	Normal (12.0 – 17.5)	31	51.7
WBCs	Normal (0 – 11.0)	45	75
	High (>11.1)	15	25

Table 8, shows that Only 15 (25%) of the patients had high White Blood Cell (WBC) and 29 (48.3%) were found to have low haemogbin (Hb).

Table 9: Cierny and Mader stages in patients with chronic osteomyelitis.

Cienyand Mader	**Stages**	**Frequency**	**Percentages**
	IIIA	2	3.3
	IIIB	48	80.0
	IV	10	16.7
Totals		**60**	**100**

Table 9, shows Cierny and Mader classification, with majority 48 (80.0%) of patients being classified as Stage IIIB with only 2 (3.3%) in stage IIIA and the remaining were stage IV 10 (16.7%).

4.4 Treatment Modalities of chronic osteomyelitis

Table 10: Antibiotic options and surgical modalities of chronic osteomyelitis

Variable	Class of antibiotics	Frequency	Percentage
Antibiotics			
	Clindamycin	12	20.0
	Flucloxacillin	48	80.0
Definitive treatment	Sequestrectomy	24	40.0
	Incision/drainage	23	38.3
	Curretage/saucerization	8	13.3
	Amputation	3	5.0
	Bone transport	1	1.7
	Tibialization	1	1.7

Table 10, shows that Flucloxacillin was the most common antibiotic prescribed by many clinicians 48 (80%). As a definitive treatment option sequestrectomy 25 (40%) was the most frequent surgical modality followed by incision and drainage 22 (38.3%) while the least surgical modality used was tibialization 1 (1.7%) and bone transport 1 (1.7%).

Table 11: Cierny and Mader stages in patients with chronic osteomyelitis

	Treatment modality						
Cierny Mader classification	Amputation	Bone transport	Saucerization curretage	Incision drainage	Sequestrecto my	Tibialization	**totals**
IIIA	0	0	0	2	0	0	**2**
IIIB	0	1	6	19	21	1	**48**
IV	3	0	2	1	4	0	**10**
Totals	**3**	**1**	**8**	**22**	**25**	**1**	**60**

Table 11, shows that the most common surgical modality was sequestrectomy and incision /drainage.

Cierny and Mader Stage IIIA had incision and drainage as the only surgical modality. Stage IIIB had incision and drainage and sequestrectomy as surgical modalities while stage IV had amputation and sequestrectomy as the commonest surgical modalities.

4.5 Early Outcome of Treatment

More than half of the patients took less than 10 days in the hospital. The mean hospitalization period was 11.9 (SD 8.2) days with a median of 10 (IQR 6, 17) days. The minimum period a patient stayed in the ward was 2 days while 35 days was the longest period.

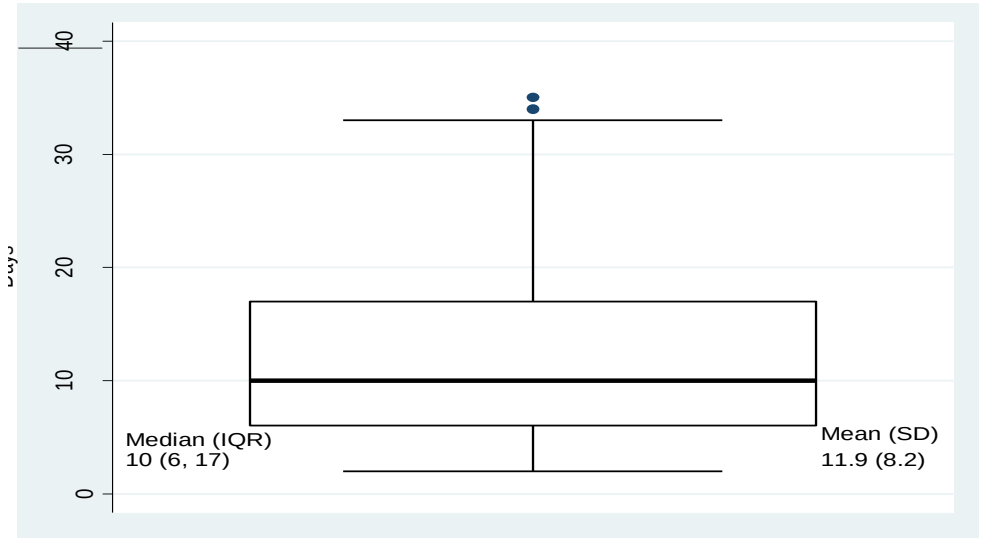


Figure 9: Hospitalization duration among patients surgically treated for COM

Table 12: Clinical outcomes in patients surgically treated for COM

Variable	Category	Frequency	Percentage
On follow-up 12 weeks	Full recovery	45	75.0
	Persistent bone sinus	11	18.3
	Bone loss	4	6.7
Function	Normal	47	78.3
	Partial	10	16.7
	Loss of function	3	5.0
Patient satisfaction	Satisfied	44	73.3
	Partially satisfied	12	20.0
	Not satisfied	4	6.7

Table 12, shows that at 12 weeks after treatment 45 (75%) patient had recovered fully while 3 (5%) patients lost their limbs. In this study 4 (6.7%) patients were not satisfied.

Table 13: Lower and upper limb outcome scores in patients

Variable limb	Observations	Mean(SD)	Median(IQR)	Minimum	Maximum
Lower limb (AAOS)	51	18.8(7.1)	16.5(15.9,18.5)	15.9	52.3
Upper limb (QuickDASH)	9	27.1(12.6)	21(20, 27.2)	20	54.5

Table 13, shows that the lower limb score ranged from 15.9 to 52.3 with a median of 16.5 (IQR 15.9 18.5) with 78.6% of the patients scoring 15.9 which was considered normal function while mean score of 18.8 (SD 7.1) which showed good functional outcome.

The upper limb score ranged from 20 to 54.5 with a mean score of 27.1 (SD 12.6) while median of 21 (IQR 20, 27.2), with overall 66.7% patients having functional score 21 which is considered normal functional score while 2 patients had higher upper limb scores (41.8, and 64.5) respectively which was considered partial to impaired loss.

Table 14: Cierny and Mader stages in lower limb function in patients with COM

Cierny Mader Classification	**Lower limb function**		
	Normal	**Moderate**	**severe**
Stage IIIA	2 (100%)	0	0
Stage IIIB	37(95%)	2(5%)	0
Stage IV	4(40%)	4(40%)	2(20%)

Table 14, Shows that lower limb had Cierny and Mader stage (IIIA) 100% having good functional outcomes, while stage IIIB (95%) had good functional outcomes but stage IV (60%) with partial to impaired functional outcomes.

Table 15: Cierny and Mader stages in upper limb function in patients with COM

Cierny Mader Classification	Upper limb function		
	Normal	Moderate	Severe
Stage IIIA	0	0	0
Stage IIIB	7(77.8%)	1(11.1%	1(11.1%)
Stage IV	0	0	0

Table 15, shows that upper limb had all patients in Cierny and Mader stage IIIB with 77.8% being good functional outcome.

Table 16: Cierny and Mader stages in relation to age in patients with COM

Cierny Mader Classification	N	Age		
		Median(IQR)	Minimum	Maximum
Stage IIIA	2	14.5(12, 17)	12	17
Stage IIIB	48	16(12, 32)	3	99
Stage IV	10	26(22, 44)	14	66

Table 16, shows that those who had Cierny and Mader stage IV had median of 26 years (IQR 22, 44) compared to stage III with median 16 years (IQR12, 32).

Table 17: Association between Cierny and Mader stages and age, gender and outcomes

		Cierny and Mader Classification		
Variable	**Category**	**Stage III**	**Stage IV**	**p-value**
Sex	Female	19	3	0.732[f]
	Male	31	7	
Age	Median(IQR)	16(12, 32)	26(22, 44)	0.039[w]
Illness duration	Median(IQR)	2(1, 7)	2(1.25, 3)	0.824[w]
Patient satisfaction	Satisfied	42(95.5)	2(4.5)	0.001[f]
	Partially satisfied	8(66.7)	4(33.3)	
	Not satisfied	1(25)	3(75)	
Upper limb	Quick DASH	27.1(12.6)	-	-
Lower limb	AAOS	16.5(2.2)	28.4(11.9)	<0.001t
[w] *Wilcoxon rank-sum test;* [f] *Fisher's Exact test and T-test*				

Table 17, shows that there was stastitically significant association between Cierny and Mader classification and patient satisfaction where among those satisfied, 95.5% were stage III compared to stage IV 4.5% (p=0.001). On average those with stage IV Cierny and Mader were significantly older (p=0.039) 26 years (IQR 22, 44) compared to those who were in stage III 16 years (IQR 12, 32). Lower limb had better outcome (mean score 18.8) compared to upper limb (mean score 27.1). Patients in Cierny and Mader IV had significantly worse outcome mean (28.4) compared to Cierny and Mader stage III mean (16.5).

CHAPTER FIVE

5.0 DISCUSSIONS

5.1 Clinical Characteristics of chronic osteomyelitis

In this study two thirds (63.3%) of the patients with chronic osteomyelitis were predominantly male concurring with study by Ibingira, (2007) which had more males (76%) and study by Ponio and Delos Reyes, (2013) which had 54% males. The reason why more males were affected than females could be attributed to more exposure in males than females due to outdoor nature of work whereby majority are involved in manual work or casual labour and boys tend to be involved in outdoor activities than girls.

More than half (58.3%) of patients were children with a median age of 17 (IQR 13, 32) and age ranging from 3 to 99 years which is in agreement with study by Biruk and Wubshet, (2007) which had a median age of 18 years and age ranging from 1 month to 84 years with mean age of 18.5. However, study by Ipkeme, et al., (2013) disagrees with this study with a mean age of 30 months being patients surgically treated for COM. The possible reason why majority were children could be attributed to exposure of children to injuries more than adults especially while playing or during daily duties. In addition, minor trauma to metaphyseal area affects blood supply hence delay healing process. Also poor wound care among children post injury can progress to involve bone; therefore, contributing to higher percentage of COM in children. The wide variation in terms of age shows that COM can affect any age group though more common in children than adults.

The duration of illness ranged from 1 month to 8 years in this study which contrasts that by Biruk and Wubshet, (2007) whereby patient's duration of illness ranged from 3 months to 2 years. This variation could be explained by the fact that study by Biruk was based on pediatric population with narrow age bracket. Most of the patients were referred to MTRH, majorly from public health facilities (94.6%) which is in agreement with study by Ponio and Delos Reyes, (2013) whereby most patients (95%) treated were already treated elsewhere prior to referral. Therefore, higher rate of referral shows possibility of delayed diagnosis and treatment which contributed to prolonged duration of illness and worsening of outcomes. Majority of patients (94.6%) were referred from peripheral facilities having been treated elsewhere without much improvement then were referred for further management.

In this study fifteen percent of the patients had upper limb affected with COM while majority with eighty five percent had lower limbs affected which is in agreement with study by Ipkeme, et al., (2013) which showed that sixty seven percent of patients had lower limbs more affected than upper limbs. Lower limbs could have been more affected than upper limbs due to proximity to the ground hence more exposure to objects close to ground which are hit while walking or playing football especially among boys. In this study most affected bone was tibia (46.7%) followed by femur (28.3%) while upper limb most affected bone was humerus (5%). This was in agreement with other studies by Ponio and Delos Reyes, (2013) and Ipkeme ,et al., (2013) with most affected bone being tibia (35 % and 45.5 % respectively).

Tibia could have been affected more than other bones due to anatomical subcutaneous nature of antero-medial aspect part of tibia bone. This could be attributed to easy part to injure due to proximity to ground and most anterior part with direct contact with

objects slightly below knee level. Presence of wounds post injury of limbs can progress to involve bone if not treated well; henceforth, can complicate to become acute osteomyelitis which further progresses to become chronic osteomyelitis if not treated well.

The prevalent symptoms and signs were draining sinus (70%) which concurs with study by Ibingira ,et al., (2003) and Ipkeme ,et al., (2013) which had draining sinus (93% and 84% respectively). Presence of sinus tract in COM had predictive value of 89% according to study by Gutrierrez, (2005). Therefore presence of a draining sinus is a diagnostic feature clinically for COM in absence of other diagnostic tools. *Staphylococcus aureus* (51.8%) was the commonest organism cultured followed by *Staphylococcus epidermidis* (10.3%) which concurs with study by Ponio and Delos Reyes, (2013) which had Methicillin Sensitive *Staphylococcus aureus* (40%) while a quarter of cases cultured were without bacterial growth (20.8%) which contrast study by Fritz and Macdonald, (2008) which showed that less than 50% of cultures were negative. This could be explained by the fact that most patients treated surgically were on antibiotic treatment prior to surgery.

The common predisposing factor reported in patients was chronic wounds (75%) which was associated with trauma causing soft tissue injury which progressed to become COM due to poor wound care. However, in contrast to this study by Ponio and Delos Reyes, (2013) showed 88% had no predisposing factor. The differences can be explained by the fact that the study was based on pediatric group which could have been associated with haematogenous infection common in children than adults.

The radiological findings of the patients showed that sequestrum (40%) is the common radiological image among patients with COM which concurs with study by Ibingira ,et al., (2009) with sequestrum (53.5%). Sequestrum develops from untreated chronic wounds which can lead to bone lysis and development of sinus tract involving 50-70% of the cases as seen in study by Restropo, et al., (2003). According to Cierny and Mader classification, majority (80%) of patients were classified as stage IIIB with only (3.3%) classified as stage IIIA which concurs with study by Ponio and Delos Reyes, (2013) with stage III (63%) and stage IV (19%) respectively. According to study by Biruk and Wubshet, (2007) it was noted that most of the patients were Cierny and Mader stage III (80%) which concurs with this study. Outcomes of Cierny and Mader stage IV showed partial impairment contributing to over 60% of cases with amputation contributing (5%). Patients with Cierny and Mader stage IV had reduced normal function to impaired function especially among the amputees; henceforth, reducing their ability to function normally in performing daily duties.

In this study patients were found with leukocytosis (25%) and aneamia (48.3%) which was in agreement with study by Biruk and Wubshet, (2007) which showed leukocytosis (38%) and aneamia (43%) also concurring with study by Ponio and Delos Reyes, (2013 which showed leukocytosis of 29% and 50% respectively. Anaemia is associated with poor healing of wounds due to poor perfusion of tissues around the injury area. Leukocytosis in chronic osteomyelitis may be normal or slightly elevated but commonly elevated in acute state of infection as seen by Mantero, et al., (2011).

5.2 Treatment Modalities for chronic osteomyelitis

Flucloxacillin (80%) antibiotic was the most prescribed by clinicians which was in agreement with the study by Ponio and Delos Reyes, (2013) with oxacillin (93%) as common medication. Oxacillin is one of the medications considered for first line in developed countries with MSSA chronic osteomyelitis as reported in study by Conterno and Turchi, (2013). Patients in this study had one surgical intervention (100%) which was in contrast to Ipkeme, et al., (2013) which had more than one surgical intervention.

The definitive surgical treatment option that was common was sequestrectomy (40%) followed by incision/drainage with (38.3%). According to Cierny and Mader stages the stage IIIA had incision and drainage as the only surgical modality while Cierny and Mader stage IIIB had incision and drainage with sequestrectomy as surgical modalities while Cierny and Mader stage IV had amputation and sequestrectomy as there surgical modalities. Three patients who had amputation had severe bone infection involving more than 50 % in addition to skin infection with skin loss of more than 50% with exposed bone in one case. Reconstructive surgeries for salvage was not tenable among these patients due to need for complex Taylor frame which was not affordable at the time. Therefore, these patients ended up being amputated as an alternative surgical procedure. Patients in Cierny and Mader stage IIIA benefited from incision and drainage alone because bone infection was localized affecting mainly medullary canal and small part of cortex which needed incision and drainage alone. Cierny and Mader stage IIIB and stage IV had large or diffuse part of bone cortex affected hence, sequestrectomy was needed to remove extensive bone and

necrotic tissue. Amputation was done for those in stage IV with severely affected bone requiring removal of large bone segment.

In this study the minimum period a patient stayed in the ward was 2 days while 35 days was the longest period. Most of the patients took average of than 10 days in the hospital with mean hospitalization period of 11.9 (SD8.2) days in contrast with Biruk and Wubshet, (2007) study which showed that hospital stay had an average of 45 days. These variations could be due to different treatment regimens and proper planning duration prior to surgery and post-surgery whereby some cases had staged surgeries henceforth, increasing hospital stay. Also in this study patients were referrals from peripheral centres for surgical intervention which could have decreased hospital stay due to quick surgical intervention on admission with single surgical modality rather than staged surgeries.

5.3 Clinical and Functional Outcomes of chronic osteomyelitis

At 12 weeks after treatment for COM patients had clinically recovered (75%) which contrasts with Nigerian study where patients had recovered clinically (77%) in 6 weeks but in agreement to Marais ,et al., (2016) study that had (98%) clinically cured at 6 weeks. While remission according to Conterno and Turchi, (2013) cochrane study showed 78.8% of the study population had cured. In this study three patients had lost part of their limbs while those with relapse were at 18.3% which was in agreement with Ibingira ,et al., (2003) which had 20% recurrence rate and Montero ,et al., (2009) which had 12.2% recurrence of draining sinus. Six percent of the patients were classified as not satisfied which concurs with study by Montero, et al., (2009) with 12.2% considered not satisfied. In this study majority of those not satisfied were in

Cierny and Mader stage IV with poor outcomes noted by majority of the recurrence (18.3%), amputation (5%) and bone transport (1.7%).

Lower limb staging according to Cierny and Mader stage IIIA had 100% of patients having good functional outcome scores while stage IIIB had 95% of patients with good functional outcome scores which contrasting stage IV with only (40%) having good functional outcome scores while (60%) had partial to impaired functional outcome scores. Upper limb had all patients in Cierny and Mader stage IIIB with patients (77.8%) having good functional outcome. Those who had chronic osteomyelitis on their lower limbs were doing slightly better than those with chronic osteomyelitis on their upper limbs. Those patients who had Cierny and Mader stage IV had median age of 26 years (IQR 22, 44) which was older than stage III with median age of 16 years (IQR 13 32). Older patients had poorer outcomes than younger patients which may be explained by the fact that younger patients are affected more at the metaphyseal region of the long bones compared to adults; therefore, good blood supply can be reduced with minor injury than that of adults leading to poor perfusion henceforth, poor wound healing.

The lower limb functional score ranged from 15.9 to 52.3 with a mean of 18.8 (SD 7.1) percent. Seventy eight percent of the patients scored 15.9 which was considered a good functional score. This study contrasts that by Marais ,et al., (2016) done for 12 months which gave functional outcome score of 86.6 with range of (51-100) and mean of 28.3 which was considered good functional score. Functional score was good for both studies though variation in scores could be attributed to difference in duration of assessment whereby in this study assessment was done at 3 months while in Marais study it was done at end of 12 months.

The upper limb mean score ranged from 20 to 54.5 with a mean score of 27.1 (SD 12.6) which was considered good functional score. Only 2 patients were considered outliers on upper limb scores 41.8, and 54.5 which was considered partial to impaired functional score. It contrasts that study by Marais ,et al., (2016) whereby in their study for 12 months involving upper limb scores using QuickDASH score was 75 (72.5-86.4) with mean of 54.3 which was considered good functional score. The differences in functional scores could be attributed to difference in duration of assessment which was done at the end of 12 months with comparative mean differences at two different levels. However, outcomes for the two groups were considered good functional scores though ranges had wide variation.

In this study there was no stastistically significant difference between Cierny and Mader association and age and gender. There was a significant association between Cierny and Mader classification and patient satisfaction with those satisfied (95.5%) were stage III compared to stage IV (4.5%) (p=0.001). On average those with stage IV Cierny and Mader were significantly older ((P=0.039) with median age of 26 years (IQR 22, 44) compared to those who were in stage III with median age of 16 years (IQR 12, 32). Lower limb (mean score 18.8) had better outcome compared to upper limb (mean score 27.1). Patients in Cierny and Mader IV had significantly worse outcome mean (28.4) compared to Cierny and Mader III mean (16.5). This could be attributed to delayed treatment in Cierny and Mader stage IV patients compared to stage III henceforth, presented with diffusely infected bone requiring sequestrectomy and extensive debridement.

CHAPTER SIX

6.0 CONCLUSION AND RECOMMENDATION

6.1Conclusion

COM presented with chronic wound, draining sinus, culture of *S.aureus* and sequestrum as the commonest clinical findings.

Sequestrectomy and Incision /drainage were the commonest surgical modalities with normal functional outcomes.

Recurrent draining sinus and limb amputations were some of the complications.

Cierny and Mader stage III had better functional outcomes compared to Cierny and Mader stage IV.

6.2 Recommendations

Sensitize clinicians to have high index of suspicion for COM in case of presence of chronic wound, sinus tract, and sequestrum on imaging.

Adoption of Sequestrectomy and Incision /drainage as some of the surgical modalities in treatment of chronic osteomyeitis.

Long term study can be considered in the near future to assess for long term outcomes.

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APPENDICES

Appendix 1: IREC Approval

INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

MOI TEACHING AND REFERRAL HOSPITAL
P.O. BOX 3
ELDORET
Tel: 33471/2/3

MOI UNIVERSITY
SCHOOL OF MEDICINE
P.O. BOX 4606
ELDORET

Reference: IREC/2016/76
Approval Number: 0001679

21st July, 2016

Dr. Charles Kimeli Cherop,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.

Dear Dr. Kimeli,

RE: FORMAL APPROVAL

The Institutional Research and Ethics Committee has reviewed your research proposal titled:-

"Clinical Characteristics, Surgical Treatment and Early Outcomes in Patients with Chronic Osteomyelitis at Moi Teaching and Referral Hospital".

Your proposal has been granted a Formal Approval Number: ***FAN: IREC 1679*** on 21st July, 2016. You are therefore permitted to begin your investigations.

Note that this approval is for 1 year; it will thus expire on 20th July, 2017. If it is necessary to continue with this research beyond the expiry date, a request for continuation should be made in writing to IREC Secretariat two months prior to the expiry date.

You are required to submit progress report(s) regularly as dictated by your proposal. Furthermore, you must notify the Committee of any proposal change (s) or amendment (s), serious or unexpected outcomes related to the conduct of the study, or study termination for any reason. The Committee expects to receive a final report at the end of the study.

Sincerely,

PROF. E. WERE
CHAIRMAN
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

cc CEO - MTRH Dean - SOP Dean - SOM
Principal - CHS Dean - SON Dean - SOD

Appendix 2: MTRH Approval

MOI TEACHING AND REFERRAL HOSPITAL

Telephone: 2033471/2/3/4
Fax: 61749
Email: director@mtrh.or.ke
P. O. Box 3
ELDORET

Ref: ELD/MTRH/R.6/VOL.II/2008

28th July, 2016

Dr. Charles Kimeli Cherop,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.

RE: APPROVAL TO CONDUCT RESEARCH AT MTRH

Upon obtaining approval from the Institutional Research and Ethics Committee (IREC) to conduct your research proposal titled;-

"Clinical Characteristics, Surgical Treatment and Early Outcomes in Patients with Chronic Osteomyelitis at Moi Teaching and Referral Hospital".

You are hereby permitted to commence your investigation at Moi Teaching and Referral Hospital.

DR. WILSON ARUASA
CHIEF EXECUTIVE OFFICER
MOI TEACHING AND REFERRAL HOSPITAL

CC - Deputy Director (CS)
- Chief Nurse
- HOD, HRISM

Appendix 3: Data Collection Tool.

CHRONIC OSTEOMYELITIS: CLINICAL CHARACTERISTICS, SURGICAL TREATMENT MODALITIES AND EARLY OUTCOMES IN PATIENTS AT MOI TEACHING AND REFERRAL HOSPITAL, ELDORET, KENYA.

1. Patient Code no …….....Residence……urban/rural…….

Tel no……..…….

2. Age……Gender……

Address …….Ward……...

IP/NO……..Occupation……

Duration of illness……..

3. Date of admission……OPD date……..

4. Referral Yes ---- No----

If yes from :Health facility…….

: Private practitioner…….....

: Others ……

5. Presenting symptoms and signs

Bone involved

……..epiphyseal……metaphyseal…….diaphysis….others

(a) Pain Yes---- No----

(b) Swelling Yes---- No----

(c) Direct sinus Yes---- No----

(d) Deformity Yes---- No----

(e) Fever/warmth Yes---- No----

(f) Erythema Yes…. No….

(g) Chronic Wound Yes…. No….

(h) Others ……

6. Predisposing factors:

(a) Malnutrition Yes---- No----

(b) Bone disease Yes---- No----

If yes state the type……Acute……chronic……..

(c) Sickle Cell Disease Yes--- No----

(d) Diabetes mellitus Yes ---- No----

(e) Peripheral vascular disease. Yes---- No----

(f) Trauma Yes---- No----

(g) Immunosuppression Yes---- No----

(h)Wound /abscess Yes…… No……

7. Co morbidity

(a) UTI ---- (b) respiratory tract ----

(c) Skin infection ---- (d) neurological ----

Others……..

8. X-ray/Ct Scan/MRI on admission

(a) Erosion of bone /lytic Yes---- No----

(b) Deformity Yes---- No----

(c) Fracture - Yes---- No----

(d) Periosteal reaction Yes….. No…..

(e) Limb Length discrepancy Yes…. No….

(f) Cortical thickening Yes…. No….

(g) Hyperdensity Yes… No….

(h) Osteopenia Yes… No….

(i) Soft tissue swelling Yes… No….

(j) Increased joint space Yes… No….

(k) Cloacae Yes… No….

(l) Involucrum Yes No…

(d) Normal Yes---- No----

(e) Others……

9. Laboratory tests

(a) Hb……

(b) ESR…….

(c) WBCs…….< 40000 ……. 4000-11000 ……>11000……

(h)Bone biopsy/Blood culture positive……..Mono…poly..

Negative……

Sensitivity……

10. Treatment

Antibiotics ……. duration of use……..

Surgery

(a) Saucerization/cauterization Yes… No…..

(b) Drilling /window creation Yes---- No-----

(c) Sequestrectomy Yes…… No……

(d) Incision /drainage Yes….. No…….

(e) Bone transport Yes…… No…….

(f) Amputation Yes No……..

(g) Others……

(h) Biopsy Yes---- No-----

11. Date of discharge----------

12. Duration in hospital……..

13. Outcome on follow up between after 12 weeks.

(a) Full recovery Yes---- No….

(b) Persistent bone sinus Yes---- No----

(c) Bone defect Yes---- No-----

(d) Deformity Yes---- No----

(e) Fractured bone Yes….. No----

(f) Non union Yes…. No……

(g) Malunion Yes…. No…….

(h) Others…….

14. Function	Normal	Yes….	No…
	Partial	Yes….	No…
	Loss of function	Yes….	No…..

15. Patient satisfaction

Satisfied	Yes…..
Partially satisfied	Yes…..
Not satisfied	Yes….

16. Classification based on Cierny and Mader classification:(Appendix 5)

Anatomical type……physiological type…….

Appendix 4: Cierny and Mader classification of Chronic Osteomyelitis

Table II: Cierny and Mader classification system[9]

Anatomic type	
Type	**Characteristics**
I	Medullary osteomyelitis
II	Superficial osteomyelitis
III	Localised osteomyelitis
IV	Diffuse osteomyelitis

Physiological class	
Class	**Characteristics**
A	Good immune system and delivery
B	Compromised locally (B^{L}) or systemically (B^{S})
C	Requires suppressive or no treatment; Minimal disability; Treatment worse than disease; Not a surgical candidate

Factors affecting physiological class	
Systemic factors (^{S})	**Local factors (^{L})**
Malnutrition Renal, liver failure Alcohol abuse Immune deficiency Chronic hypoxia Malignancy Diabetes mellitus Extremes of age Steroid therapy Tobacco abuse	Chronic lymphedema Venous stasis Major vessel compromise Arteritis Extensive scarring Radiation fibrosis

Appendix 5: Time Schedule

ACTIVITY	**START**	**COMPLETE**	**RESPONSIBLE PERSON**
Concept Development of proposal	SEPT 2015	DEC 2015	Researcher
Proposal Writing	JAN 2016	APRIL 2016	Researcher
IREC Approval	APRIL 2016	JULY 2016	IREC
Data collection	JAN 2017	DEC 2017	Researcher/Research assistant/
Data Analysis	JAN 2018	APRIL 2018	Researcher/Statistician consultation
Thesis Writing	MAY 2018	SEPT 2018	Researcher
Thesis presentation/Mock/Final	OCT 2018	MARCH 2020	Researcher/Supervisors/Examiners
Submission of bound thesis	MARCH 2020		Researcher

Appendix 6: Estimated Cost of study

ITEM	**QUANTITY**	**UNIT PRICE(ksh)**	**TOTAL(Ksh)**
Laptop computer	1	65,000	65,000
Printer and photocopier	1	10000	10000
Stationary	-	-	5000
Statistical consultation/IREC	-	-	30000
Internet services and communication	-	-	20000
Publications	-	-	50000
Miscellaneous	-	-	30000
GRAND TOTAL	-	-	**210,000**

Appendix 7: Introduction Letter

I am CHARLES KIMELI CHEROP a medical doctor currently pursuing master's degree in orthopedic surgery at Moi University, College of Health Science- Eldoret. My study topic: **CHRONIC OSTEOMYELITIS: CLINICAL CHARACTERISTICS, SURGICAL TREATMENT MODALITIES AND EARLY OUTCOMES IN PATIENTS MANAGED AT MOI TEACHING AND REFERRAL HOSPITAL, ELDORET, KENYA**

Therefore, you are requested to participate in this research study. The information provided is about the nature of study and the process in undertaking the study. All information about the study shall be provided and explained to you once you have understood the scope of the study and willing to participate. Once you have agreed to be part of the study, you will be required to sign in agreement or on behalf of the child/minor. Voluntarily you can decide to participate or withdraw from the study any time. During the study we are not anticipating any discomfort. The study is crucial in providing clinicians with knowledge essential in patient management for chronic osteomyelitis and minimizing complications.

You will be given a chance to ask questions or clarify any issue. If you agree to be in the study, you will be given a copy of this consent form for your records. The process of your participation will involve, history taking, examination, sample collection, review of your investigations done; Laboratory and radiographs and questionnaire filling with help of researcher and also follow-up at clinics and telephone conversations.

You have been chosen to participate in the study because you were diagnosed with chronic osteomyeltis. The duration of your participation in the study will be a period of 3 months. As participant in the study the mode of treatment shall be the same as prescribed by the doctor in the hospital and it will not prolong your hospital stay. After being discharged from the hospital we are requesting to make follow-up through telephone calls and organizing for reviews during your subsequent visits at the clinic.

Information provided shall be kept confidential. More information about the study can be obtained in Institutional Review Ethics Committee (IREC). Telephone number 053 33471. IREC is a committee that reviews studies for safety and to protect the rights of study subjects.

Yours faithfully,

Charles Kimeli Cherop

Contact 0723927 558

Appendix 8: Consent form for Adults.

Declaration

I**……..... (**Adults (>18) hereby give consent to participate in the proposed study: **CHRONIC OSTEOMYELITIS: CLINICAL CHARACTERISTIC, SURGICAL TREATMENT MODALITIES AND EARLY OUTCOMES IN PATIENTS MANAGED AT MTRH, ELDORET, KENYA.** I have read the information sheet and I understood the aim of the study and what will be required of me if I participate in the study. The risks and benefits have been explained to me. Any questions I have concerning the study have been adequately answered. I understand that I have the freedom of withdrawing from the study at any time I choose to do so, without having to give a reason. Also I understand that I may be required to respond to questionnaires when required upon.

I consent voluntarily to participate in the study,

Subjects Name……

Signature……

Name of the study……

Date……..

Appendix 9: Assent Form: Minors < 18

TITLE: CHRONIC OSTEOMYELITIS: CLINICAL CHARACTERISTICS SURGICAL TREATMENT MODAITIES AND EARLY OUTCOMES IN PATIENTS AT MTRH, ELDORET, KENYA.

ASSENT FORM FOR MINOR. FILLED BY PARENT/ LEGAL GUARDIAN

I……of……phone number……

As the parent/ legal guardian hereby voluntarily agree my son/ daughter to participate in the study mentioned above. Terms and conditions explained as above will be adhered to.

Name of participant …….

Date……

Name of parent/Legal Guardian …….

Signature……..

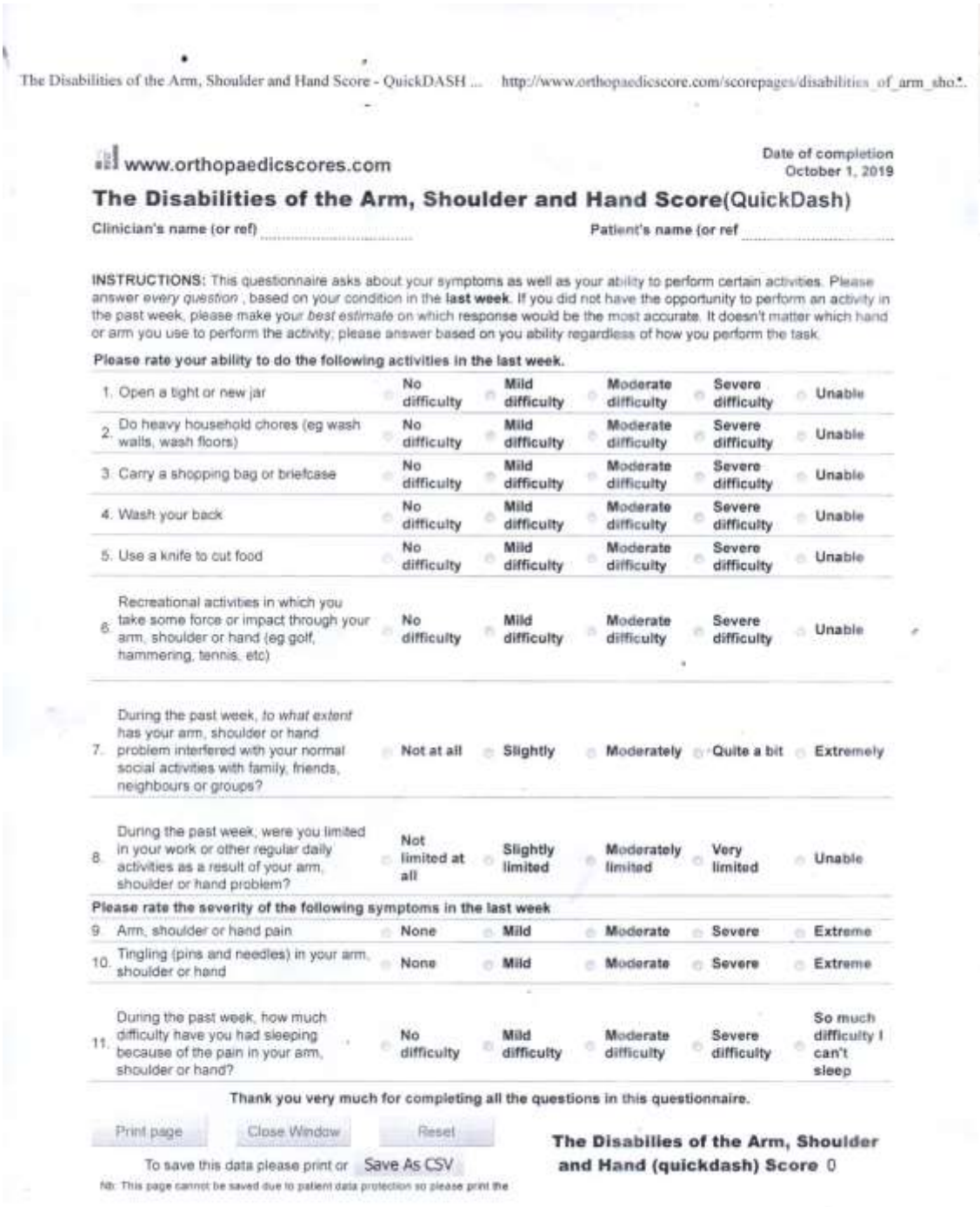
Date ……

Appendix 10: Total records of cases treated for Osteomyelitis per year at MTRH between 2012 and 2015

Table 2: Showing number of cases surgically treated for Acute and Chronic Osteomyelitis at Moi Teaching and Referral Hospital between 2012 and 2015.

Year	**2015**	**2014**	**2013**	**2012**
Chronic Osteomyelitis	53	45	37	42
Acute Osteomyelitis	10	4	5	7
Totals	63	49	42	48

Appendix 11: QuickDASH for Upper limb Assessment of Function



The Disabilities of the Arm, Shoulder and Hand Score - QuickDASH ... http://www.orthopaedicscore.com/scorepages/disabilities_of_arm_sho...

www.orthopaedicscores.com

Date of completion
October 1, 2019

The Disabilities of the Arm, Shoulder and Hand Score(QuickDash)

Clinician's name (or ref) ..... Patient's name (or ref .....

INSTRUCTIONS: This questionnaire asks about your symptoms as well as your ability to perform certain activities. Please answer *every question* , based on your condition in the **last week**. If you did not have the opportunity to perform an activity in the past week, please make your *best estimate* on which response would be the most accurate. It doesn't matter which hand or arm you use to perform the activity; please answer based on you ability regardless of how you perform the task.

Please rate your ability to do the following activities in the last week.

1.	Open a tight or new jar	No difficulty	Mild difficulty	Moderate difficulty	Severe difficulty	Unable
2.	Do heavy household chores (eg wash walls, wash floors)	No difficulty	Mild difficulty	Moderate difficulty	Severe difficulty	Unable
3.	Carry a shopping bag or briefcase	No difficulty	Mild difficulty	Moderate difficulty	Severe difficulty	Unable
4.	Wash your back	No difficulty	Mild difficulty	Moderate difficulty	Severe difficulty	Unable
5.	Use a knife to cut food	No difficulty	Mild difficulty	Moderate difficulty	Severe difficulty	Unable
6.	Recreational activities in which you take some force or impact through your arm, shoulder or hand (eg golf, hammering, tennis, etc)	No difficulty	Mild difficulty	Moderate difficulty	Severe difficulty	Unable
7.	During the past week, *to what extent* has your arm, shoulder or hand problem interfered with your normal social activities with family, friends, neighbours or groups?	Not at all	Slightly	Moderately	Quite a bit	Extremely
8.	During the past week, were you limited in your work or other regular daily activities as a result of your arm, shoulder or hand problem?	Not limited at all	Slightly limited	Moderately limited	Very limited	Unable

Please rate the severity of the following symptoms in the last week

9.	Arm, shoulder or hand pain	None	Mild	Moderate	Severe	Extreme
10.	Tingling (pins and needles) in your arm, shoulder or hand	None	Mild	Moderate	Severe	Extreme
11.	During the past week, how much difficulty have you had sleeping because of the pain in your arm, shoulder or hand?	No difficulty	Mild difficulty	Moderate difficulty	Severe difficulty	So much difficulty I can't sleep

Thank you very much for completing all the questions in this questionnaire.

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The Disabilies of the Arm, Shoulder and Hand (quickdash) Score 0

Appendix 12: AAOS Functional tool for assessment of Lower Limb Functions

Lower Limb

Outcomes Questionnaire

Developed by:

American Academy of Orthopaedic Surgeons®
American Association of Hip and Knee Surgeons
American Orthopaedic Society for Sports Medicine
Hip Society
Knee Society
Orthopaedic Rehabilitation Association
Orthopaedic Trauma Association
Arthroscopy Association of North America
American Orthopaedic Foot and Ankle Society
Musculoskeletal Tumor Society

Based on the Version 2.0 Lower Limb Outcomes Intrument

Revised, renumbered, reformatted August 2005

Lower Limb Questionnaire

Instructions

Please answer the following questions for the lower limb being treated or followed up. If it is BOTH lower limbs, please answer the questions for your **worse** side. All questions are about how you have felt, on average, during the **past week.** If you are being treated for an injury that happened less than one week ago, please answer for the period since your injury.

1. During the **past week**, how **stiff** was your lower limb? (Circle one response.)

1 Not at all 2 Mildly 3 Moderately 4 Very 5 Extremely

2. During the **past week**, how **swollen** was your lower limb? (Circle one response.)

1 Not at all 2 Mildly 3 Moderately 4 Very 5 Extremely

During the **past week**, please tell us about how painful your lower limb was during the following activities. (Circle ONE response on each line that best describes your average ability.)

	Not painful	Mildly painful	Moderately painful	Very painful	Extremely painful	Could not do because of lower limb pain	Could not do for other reasons
3. Walking on **flat** surfaces?	1	2	3	4	5	6	7
4. Going up or down stairs?	1	2	3	4	5	6	7
5. Lying in bed at night?	1	2	3	4	5	6	7

6. Which of the following statements **best** describes your ability to get around most of the time during the **past week**? (Circle one response.)

1 I did not need support or assistance at all.
2 I mostly walked without support or assistance.
3 I mostly used one cane or crutch to help me get around
4 I mostly used two canes, two crutches or a walker to help me get around.
5 I used a wheelchair.
6 I mostly used other supports or someone else had to help me get around.
7 I was unable to get around at all.

7. How difficult was it for you to put on or take off socks/stockings during the **past week**? (Circle one response.)

1 Not at all difficult 2 A little bit difficult 3 Moderately difficult 4 Very difficult 5 Extremely difficult 6 Cannot do it at all

Appendix 13; Showing Limb functional scoring tools: QuickDASH (upper limb) and AAOS (lower limb)

Variable (Function)	QuickDASH (upper limb score)	AAOS (lower limb score)
Normal	<30	<30
Moderate	30-60	30-60
Loss of function	>60	>60

Appendix 14: Patient flowchart showing patient recruitment and follow up.