FACTORS ASSOCIATED WITH EARLY FRACTURE RELATED INFECTION AMONG ADULT PATIENTS WITH MALLEOLAR FRACTURES TREATED BY OPEN REDUCTION AND INTERNAL FIXATION AT MUHIMBILI ORTHOPAEDIC INSTITUTE.

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MMed (Orthopedics and Traumatology) Dissertation

Muhimbili University of Health and Allied Sciences

October, 2024

Muhimbili University of Health and Allied Sciences

Department of Orthopaedic and Traumatology

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By

Sebastian George

A Dissertation Submitted in (Partial Fulfilment of the Requirements for the Degree of Master of Medicine (Orthopedics and Traumatology) of

Muhimbili University of Health and Allied Sciences

October, 2024

CERTIFICATION

The undersigned certifies that they have read and hereby recommends for acceptance by the Muhimbili University of Health and Allied Sciences a dissertation entitled **"Factors associated with early fracture related infection among adult patients with malleolar fractures treated by Open Reduction and Internal Fixation at Muhimbili Orthopaedic Institute"** in partial fulfillment of the requirements for the degree of Master of Medicine (Orthopedics and Traumatology) of Muhimbili University of Health and Allied Sciences.

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DECLARATION AND COPYRIGHT

I, **Sebastian George**, declare that this dissertation entitled **"Factors associated with early fracture related infection among adult patients with malleolar fractures treated by Open Reduction and Internal Fixation at Muhimbili Orthopaedic Institute"** is my original work and it has not been presented and will not be presented to any other University for a similar or any other degree award.

Signature……. Date……

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ACKNOWLEDGEMENT

I sincerely appreciate the wonderful guidance and mentoring that my main supervisor, Dr. Violet Lupondo, has given me. Dr. Violet Lupondo has consistently gone above and beyond to ensure my growth as a researcher, from the early stages of proposal development to the final report writing. Her unwavering commitment and genuine interest in my research as shown by her commitment to dedicate her time even during late hours and weekends.

My gratitude goes out to my co-supervisor, Dr. Adam Hussein, for his insightful comments and critical assessments of my work. His painstaking attention to detail and critical analysis have greatly improved my research methods and strengthened the overall consistency of my findings.

I also want to express my gratitude to the leadership of the Muhimbili Orthopaedics Institute, especially to Dr. Lemeri Mchome and Dr. Anthony Assey, for authorizing me to carry out my study and for making the process of gathering data go well. The MUHAS faculty, under the direction of Dr. Joseph Mwanga, and all of the orthopaedic surgeons at MOI deserve recognition as well for their helpful feedback from the proposal's inception. Their advice has been very helpful in determining the course of my research.

We are grateful to all of the patients who agreed to take part in the research because they are the main source of inspiration for all that we do. The completion of this work would not have been possible without their acceptance.

In conclusion, I would additionally like to thank my classmates for being such great guides on our journey. Their friendship and support have increased the value of this encounter.

DEDICATION

First and foremost, I dedicate this dissertation to my late father, George Valentino Sebastiano. I knew him as a loving father; Second my late aunt Lucy Valentino Sebastiano may the Lord provide them eternal comfort. Third, to my mother Gloria Makusa, who has always used prayers to lead, uplift, and support us as we face life's obstacles. Last but not least, my uncle Abdallah Mbagalla, my aunt Ritha Frateni Sebastiano, and my sisters Anna, Maria, Celine, and Sarah George gave me the strength to carry on.

ABSTRACT

Background: Ankle fractures contribute 10% of all fractures and are the most frequent fractures encountered by orthopaedic surgeons. Ankle fractures represent 14% of all fractures requiring hospitalization and 21% of all injuries due to sports. With the advancement of technology and availability of trained orthopaedic surgeons ORIF of malleolar fracture is done of which early fracture-related infection and its associated risk factors are not well documented in our region

Aim: To determine factors associated with early fracture related infection among adult patients with malleolar fractures treated by open reduction and internal fixation (ORIF) at Muhimbili Orthopaedic Institute.

Materials and Methods: This was a prospective observational study involving skeletally matured patients aged 18 years and above whose clinical and radiological examination confirmed the diagnosis of malleolar fractures and they were treated by ORIF. Data collection was done after obtaining informed consent of the participants with the use of a data extraction sheet and questionnaire. Following treatment, patients were followed up for review 2 weeks postoperatively. During the follow-up period patient were assessed in terms of early fracture related infection then correlated with risk factors. Data collection was done by the investigator then cleaned and analyzed by using SPSS version 24

Result: 10% of patients with malleolar fractures developed early fracture related infection following ORIF out of 100 patients. A univariate and multivariate analysis showed that male gender, alcohol intake, diabetes mellitus and open fracture were the independent predictors of early fracture related infection at Muhimbili Orthopaedic Institute.

Conclusion: Factors associated with early fracture related infection among patient with malleolar fractures following ORIF at Muhimbili Orthopedic Insitute are male gender, alcohol intake, diabetes mellitus and open fracture. The result of the current study may in this regard serve as baseline reference for further studies with large sample size**.**

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LIST OF ABBREVIATION

AO	Arbeitsgemeinschaft für Osteosynthesefragen
CRP	C - reactive protein
ESR	Erythrocyte Sedimentation Rate
EFRI	Early fracture related infection
FBP	Full Blood Picture
FRI	Fracture related infection
IRB	Institutional Review Board
MOI	Muhimbili Orthopaedic Institute
MUHAS	Muhimbili University of Health and Allied Sciences
ORIF	Open Reduction and Internal Fixation
UK	United Kingdom
USA	United States of America

DEFINITION OF TERMS

Ankle fracture: refers to a fracture of the malleolar which may involve the lateral malleolus, the medial malleolus, and the posterior malleolus.(1) In this study, ankle and malleolar fractures will be used interchangeably.

Surgical site infection: refers to an infection at the surgical site that develops within 30 days of surgery and can be superficial or deep-seated.(2)

Superficial surgical site infection: refers to an infection that involves only skin and subcutaneous tissue which will require antibiotic treatment and will be diagnosed if will not meet the criteria for diagnosis of deep surgical site infection. (2)

Deep infection is defined as (i) exposed bone at any time point, (ii) infections involving deep soft tissue, muscle, or fascia; (iii) persistent wound discharge or dehiscence; (iv) visible abscess or gangrene that required surgical debridement and implant exchange or removal. (2)

Early fracture related infection: refers to the infection occurring in the first two weeks following ORIF of malleolar fractures. (3)

Late fracture related infection: is the infection occurring after 2 weeks following ORIF of malleolar fractures. (3)

Adult patient: an individual above 18 years of age.

1.0 INTRODUCTION

1.1 **Background information.**

Ankle fractures contribute 10% of all fractures and are the most frequent fractures encountered by orthopaedic surgeons, representing 14% of all fractures requiring hospitalisation and 21% of all injuries due to sports.**(**4,5,6). The incidence of this is reported to range from 71 to 187 per 100,000 person-years.(7)It has therefore been proved that the prevalence rate of ankle fractures is rising especially in female and elderly population(7)

The malleolar fractures may be stable or unstable, closed or open, and can be managed operatively or non-operatively depending on different factors including stability or severity of the injury, general health, and functional status of the patient. ORIF and external fixation methods are both alternatives for surgically treating malleolar fractures. Open fractures need immediate surgical debridement, irrigation, and either a permanent fixation or a temporary external fixation.(1,8)

The external fixation method is frequently used as a temporary fixation but occasionally employed as a definitive management option in conjunction with ORIF in complex malleolar fractures. Malleolar fractures are operated on using the AO principles. Initial care stresses safe injury immobilization along with proper alignment while for effective outcomes, final treatment must include anatomic reduction of the joint as well as care of the soft tissues around.(1,4)

Even though ORIF following malleolar fractures has been shown to have good outcomes, has some postoperative complications, and the total rate of which varies greatly, ranging from 1% to 40%. After ORIF of malleolar fractures, perioperative, early postoperative, and late postoperative complications can all occur. Postoperative wound complications occur most commonly of which infection may have the most disastrous effects.(4,9)

The most frequent ORIF complication, surgical site infection (SSI), has a detrimental effect on bone union and ankle functional recovery. Between 1.44% and 14% of patients who are treated by ORIF for malleolar fractures have been shown to develop Fracture related infection. **(**3,9,10)

One of the most difficult complications following surgical fracture treatment is fracture-related infection (FRI). Reoperations, extended antibiotic treatment, protracted immobilization, loss of function, amputation, increased medical expenses, and an inability to engage in social and professional activities are among the consequences. Infection after surgical fracture treatment was defined in a variety of ways until relatively recently. There was no universal consensus on a precise definition of this condition, therefore terms including osteitis, osteomyelitis, post-traumatic osteomyelitis, implant-related infection, deep infection, and many more were used at random. (11,12)

A group of experts representing the European Bone and Joint Infection Society (EBJIS), the Association for the Study of Internal Fixation (Arbeitsgemeinschaft für Osteosynthesefragen, AO), and recognized orthopaedic trauma hospitals and academic centers proposed a consensus definition in 2017 that included diagnostic criteria. 2018 brought the publication of this definition. Following surgical fixation of a closed or open fracture, the term "fracture-related infections" (FRI) refers to the full range of infections (e.g., acute or chronic, superficial or deep, with or without bone involvement, with or without implants in situ) that may occur. The diagnostic characteristics of FRI provided the basis for the definition of two degrees of certainty. The criteria may be suggestive (infection probably present) or confirmatory (infection definitely present). (13)

In terms of time of development between internal fixation and its diagnosis, infections can be early or late. Early FRI is the infection diagnosed within the first two weeks following internal fixation and late FRI is the infection diagnosed two weeks following internal fixation. Early infection tends to be the result of perioperative or contiguous infection, and is notoriously difficult since it happens before the fracture has united.(3)

Injury characteristics, patient factors, as well as surgery factors are the three main factors in orthopaedic practice that influence vulnerability to early post-operative infection after ORIF of malleolar fractures. (4)

1.2 Problem Statement

Malleolar fractures are common, and ORIF has been shown to positively impact the functional outcome and quality of life of patients. (5)Complications among patients with malleolar fractures managed by ORIF are common, with early fracture related infection accounting for the most at a rate of up to 14.3%. (14). At MOI, the overall prevalence of FRI among patients undergoing Orthopaedic Surgeries was found to be 25%. (15) Where as another cross-sectional study done at MOI involving patients with open tibia fractures managed surgically, it was found that 25.8% of patients had FRI. (16)

Despite this, proportion and analysis of factors associated with early fracture related infection after ORIF of malleolar fractures was not done objectively at MOI.

Evidence from this observation will help to identify the risk factors associated with early fracture related infection and will help to prevent early fracture related infection following open reduction and internal fixation of malleolar fractures.

1.3 Conceptual Framework

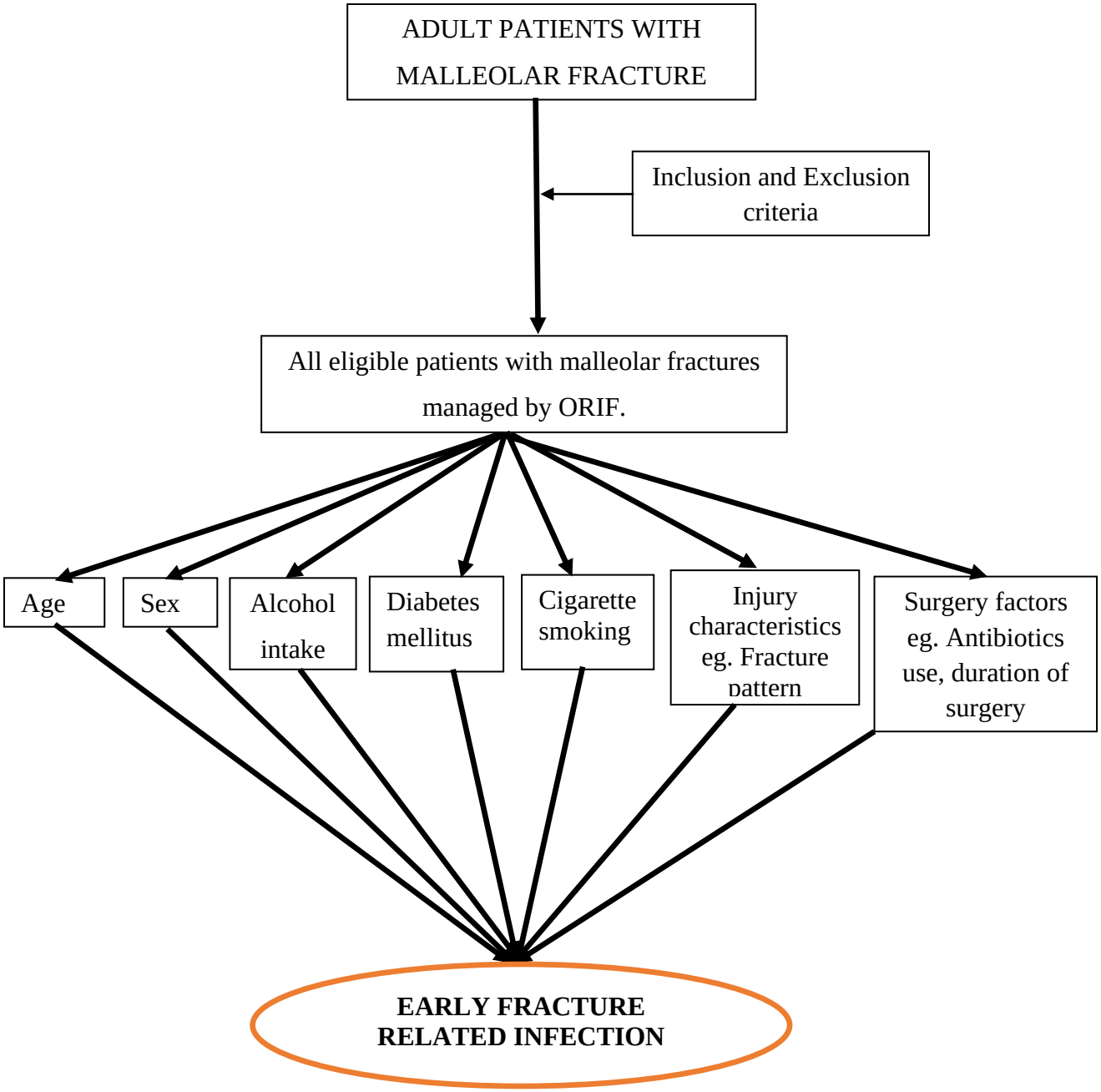


Figure 1:Conceptual framework on determine the proportion and factors associated with early fracture related infection following Open Reduction and Internal Fixation of malleolar fractures at Muhimbili Orthopedic Institute

1.4 Rationale

The study informs service providers about the proportion and factors associated with early fracture related infection following Open Reduction and Internal Fixation (ORIF) of malleolar fractures. The findings of the study provide an insight that may guide orthopedic surgeons in understanding the current situation of early fracture related infection, which could lead to prolonged hospital stays or increased healthcare costs.

Understanding the factors associated with early fracture related infection in patients undergoing ORIF for malleolar fractures at MOI is essential for targeted preventive measures. This knowledge enables informed decision-making and optimizes surgical practices within the Hospital. Therefore, findings of the study can enhance the quality of care provided when implementing evidence-based interventions to patients undergoing ORIF for malleolar fractures.

1.5 Research Questions

(i) What is the proportion of early fracture related infection following open reduction and internal fixation of malleolar fractures at Muhimbili Orthopaedics Institute?

(ii) What are the factors associated with early fracture related infection among patients with malleolar fractures following open reduction and internal fixation at Muhimbili Orthopaedics Institute?

1.6 Broad objective.

To determine the proportion and factors associated with early fracture related infection following Open Reduction and Internal Fixation of malleolar fractures at Muhimbili Orthopedic Institute.

1.6.1 Specific Objectives.

i. To determine the patient factors associated with early fracture related infection following ORIF of malleolar fractures at MOI.

ii. To determine the proportion of patients with malleolar fractures who develop an early fracture related infection following ORIF at MOI.

iii. To determine injury characteristics associated with early fracture related infection following ORIF of malleolar fractures at MOI.

iv. To determine surgery factors associated with early fracture related infection following ORIF of malleolar fractures at MOI.

2.0 LITERATURE REVIEW

2.1 Patient related factors associated with early fracture related infection

Management of malleolar fractures by ORIF is frequently done and has been shown to increase the standard of life and patient results, however, different complications occur among them early fracture related infection as a result of number of factors. (5) Early fracture related infection after ORIF of malleolar fractures can be due to patient factors that are modifiable and non-modifiable like age, sex, diabetes mellitus, alcohol overuse, and smoking. (14)

In Europe, a retrospective study was conducted in Belgium that included 433 patients followed from 2013 to 2017 in which overweight with alcohol abuse were statistically significantly having twice the risk of developing FRI. (5) According to a study conducted in Finland, smoking participants having malleolar fractures managed by ORIF had 4.8 times higher unadjusted risk and 3.7 times higher adjusted risk of developing surgical site infection than non-smokers. Additionally, compared to non-smokers, those who misused alcohol were at 3.8 times increased risk of acquiring surgical site infections (4). A retrospective study that was done in Denmark by Møller et al which included 1043 participants, it was found that 146 (14.0%) of participants developed FRI which was highly linked with obesity and alcohol abuse, however smoking was not statistically significantly associated with FRI. Thus, excessive use of alcohol and obesity are separate risk factors for postoperative infection after ORIF of malleolar fractures. (15)

In a level 3 prognostic study carried out over a decade in Cleveland, Ohio's Metro Health Medical Center with 776 participants, it was discovered that 7.2% of participants experienced postoperative infection, participants with ASA class IV had 9.2 times higher odds of acquiring surgical site infection when compared to participants with ASA class I and Diabetes Mellitus was strongly associated with the occurrence of SSIafter being managed by ORIF of malleolar fractures. (10) Whereas in a level I study that was done by Miller et al that included 478 cases, Diabetes Mellitus was significantly associated with wound complications in particular SSI.(19).

In our region, there is no clear documentation regarding patient related factors associated with early fracture related infection in patients with malleolar fractures managed by ORIF.As a result, the study will offer the fundamental knowledge needed to comprehend those factors.

2.2 Proportion of fracture related infection

In a level III retrospective cohort study that was done by the American College of Surgeons National Surgical Quality Improvement Program between 2006 and 2013 that included 7054 cases of closed malleolar fractures, it was found that 1.6% (106) of cases treated by open reduction and internal fixation developed an early fracture related infection. (12)

Whereas in a cohort study that was done in Norway in northern Europe that included 1004 patients with malleolar fractures, fracture related infection following Open Reduction and Internal fixation was diagnosed in 9% of cases. (21)

In the East African region, unpublished prospective study was done at Kenyata National Hospital, Aga Khan University Teaching Hospital, and Presbyterian Church of East Africa in Kikuyu Kenya between 2019 and 2020. A total of 68 (16.7%) patients with open malleolar fractures treated by ORIF were found to haveearly fracture related infection. This seemed to be high as compared to closed fractures because open fracture increases the risk of infection(22) At MOI, the overall prevalence of FRI among patients undergoing Orthopaedic Surgeries was found to be 25%. (15) Where as another cross-sectional study done at MOI involving patients with open tibia fractures managed surgically, it was found that 25.8% of patients had FRI. (16)

There is a paucity of data in our country regarding the proportion of early fracture related infection among adult patients with malleolar fractures treated with ORIF comparing open and closed fractures.

2.3 Injury Characteristics of malleolar fractures

Knowing fracture characteristics is of paramount as it guides the management and has an influence on the outcome of management.

In a study that was done in Finland it was observed that the majority of patients with malleolar fracture and who developed surgical site infection were patients with severe injury, 61 (47%) of patients with trimalleolar fracture developed surgical site infection. The majority of the patients 104 (79%) who were managed by ORIF of a malleolar fracture and experienced surgical site infection had Weber B fracture. (4)Whereas another retrospective comparative study done between 2003 and 2015 at a level 1 trauma center in University Hospital including 1303 participants with malleolar fractures (Weber B and C), it was found that open injuries were associated with high energy mechanisms and superficial infection occurred more in open fractures as compared to closed fractures. (23) Also, in a case-control study conducted at the University Hospitals of Leicester in the United Kingdom between 2010 and 2013, 717 cases of malleolar fracture managed by ORIF were included in which the odds of acquiring SSI were four times higher for Weber C fractures. (18)

In America, In a level 3 prognostic study carried out over a decade in Cleveland, Ohio's Metro Health Medical Center with 776 participants investigating factors associated with surgical site infection in patients with malleolar fracture managed by operative management, it was found that participants with open malleolar fracture had 4.1 higher the odds of acquiring surgical site infection when compared to those with closed fracture, this might be explained by the fact that open fractures puncture the skin hence creating a point at which bacteria can contaminate the underlying tissues. (10,20)

In Asia, ten studies with a total of 8103 malleolar fracture cases managed by ORIF were taken into consideration in a study carried out at Hubei Medical University's third hospital in China. Of these, 583 individuals (7.19%) had an infection at the surgical site.

High energy mechanisms of injury were observed to increase the likelihood of developing a surgical site infection by 4.24 times, and open fractures increased the likelihood of infection by 5.64 times compared to closed injuries. (P value < 0.05). (19).

In the East African region, there is a paucity of published information regarding the analysis of injury characteristics associated with early fracture related infection among patients with malleolar managed by open reduction and internal fixation. Therefore, this study will give out an insight into these factors.

2.4 Surgery characteristics associated with early fracture related infection

The development of early fracture related infection in patients with malleolar fractures treated by ORIF can be due to surgery factors.

A Level III case-control study with 131 cases and controls conducted at Helsinki University Central Hospital, Helsinki, Finland, between 2006 and 2009, it was discovered that delayed administration of prophylactic antibiotics increased the risk of SSI by 1.9 times and surgery lasting longer than 90 minutes increased the risk of developing SSI by 2.5 times. (20)

A retrospective study conducted in China between 2013 and 2016, which included 2729 malleolar fractures managed by ORIF, the risk of acquiring SSI was found to be 3.1 times higher in patients whose procedures lasted longer than 180 minutes. This is comparable to what the Helsinki study discovered. (21) Whereas in a study done in Hubei Medical University's third hospital in China, 10 studies with a total of 8103 malleolar fracture cases managed by ORIF were considered. Of these, 583 cases (7.19%) experienced SSI. The chance of getting SSI was shown to be 59% lower in people who took prophylactic antibiotics (OR=0.41, P 0.05), but the length of surgery did not appear to be a significant predictor of this risk. (19)

There is scarcity of published data in the East African region on the examination of surgical features linked to early fracture related infection among patients having malleolar fractures managed by ORIF. The study will therefore provide an understanding of the aforementioned problems.

3.0 METHODOLOGY.

3.1 Study designs.

This was Prospective Observational Study design.

It included all patients with malleolar fractures managed by ORIF at MOI as long as they met the inclusion criteria. Baseline patient characteristics, injury characteristics, and surgery characteristics were collected before and during surgery. Then researcher followed every participant 2 weeks post-operatively, observing and recording the occurrence of early fracture related infection. This study design allowed for the calculation of the proportion of patients who developed early fracture related infection among the total number of patients who underwent ORIF at MOI during the study period. The design allowed the researcher to analyze the association between patient-specific factors, injury characteristics, and surgery characteristics with the occurrence of early fracture related infection.

3.2 Study site

This study was carried out at Muhimbili Orthopaedic Institute (MOI), which has a total bed capacity of 362 and nine operating rooms. MOI being a university teaching hospital, it is a tertiary national referral hospital with specialties in Orthopedics, Traumatology, and Neurosurgery. MOI has Orthopaedic Surgeons to the consultants' level offering ankle surgeries in particular malleolar surgeries by ORIF as per AO principles. Patients are received from throughout the nation, and surrounding countries. Patients are operated on an elective or emergency basis and admitted through the emergency department or from the outpatient.

3.3 Study population

The study population targeted patients undergoing ORIF for malleolar fractures at Muhimbili Orthopaedic Institute in Dar es Salaam, Tanzania.

3.4 Eligibility Criteria.

3.4.1 Inclusion Criteria.

Skeletally matured patients with malleolar fractures who underwent ORIF for malleolar fractures were enrolled in the study after signing an informed consent.

3.4.2 Exclusion criteria

- Preexisting deformity of the affected ankle.
- Polytrauma patients with severe head injury, chest, and/or other extremity injuries.
- Participants with fractures of the talus and tibia plafond were excluded from the study.

3.5 Sample size calculation

Taking into account an unpublished study that was conducted in Kenya in 2020 by Muchungu(22), the Proportion of patients with malleolar fractures managed by ORIF and developed early infection was 16.7%

P= 16.7%

Taking into consideration and E-maximum marginal error that can be encountered=5%

From;

$$n_o = Z2\ P\ (100\text{-}P) \over E2$$

Whereby; Z=1.9

P=theproportion of patients with malleolar fractures managed by ORIF

E=Margin of error= 5%

Sample size= 1004patients

However, given the small population of available patients at MOI Fischer's formula is modified by including the finite population correction factor (FPC) as;

$$n = {n_o \over 1 + {(n_o - 1) \over N}}$$

Whereby;

n=sample size of the finite population.

N=Total population from the pilot study which was conducted in which 120 patients with both open and closed malleolar fractures, managed by open reduction and internal fixation, were observed from January to December 2022 with average of 10 patients per month. Considering the 4 months of the data collection process, a cumulative of 40 patients was expected.

Hence;

$n = \frac{1004x40}{1004+(40-1)}$

n= 39

Considering 20% loss of follow up in our region n=47

Hence, the minimum sample size was 47 patients and maximum sample size was 1004patients. During the study period, 100 participants were included which is above the minimum required sample size.

3.6 Sampling technique

In this study, the researcher employed the method of enrolling all available patients during the study period from August 2023 to early April 2024as the population size is manageable and Managed to get 100 participants with malleolar fractures who underwent ORIF. By including all participants as long as they met the inclusion criteria the researcher has had comprehensive data from every eligible patient. With a small population, the data collected from all patients can provide more precise estimates of outcomes and associations, leading to more robust findings and hence enhanced generalizability of the study findings.

3.7 Variables

3.7.1 Dependent variables

Early fracture related infection.

3.7.2 Independent variables

- Age
- Sex
- Fracture type (open or closed), fracture pattern (By Weber classification).
- Mechanism of injury.
- Co-morbidities (Diabetes Mellitus)
- Alcohol abuse
- ASA Class (I-IV)

- Pre-operative stay (time between an injury and surgery)
- Smoking status.
- Type of surgery (emergency or elective).
- Duration of surgery
- Prophylactic antibiotics use (if given or not, time of administration)

3.8 Data collection technique

3.8.1 Data Collection Procedure:

Patients with malleolar fractures attended at MOI emergency department, clinic, and in the wards after being confirmed by radiographs and planned for open reduction and internal fixation were selected for the study. Also, patients with open malleolar fractures who underwent surgical debridement and be treated by ORIF as per AO principles were enrolled in this study.

Data collection commenced after obtaining informed consent from the participants. The investigator employed a data extraction sheet and questionnaire containing independent variables and risk factors including injury characteristics and surgery-related factors. The questionnaire also included dependent variable (early fracture related infection) assessment criteria for diagnosis.

3.8.2 Categorization of Patients:

Patients were categorized in terms of planned status as either emergency or elective. Elective patients are those patients who will be listed for ORIF of malleolar fracture while in the ward and emergency cases are those who were operated on an emergency basis and managed by ORIF as per AO principles.

3.8.3 Patient Information and Risk Factors:

Independent variables like age, sex, diabetes status, smoking status and alcohol status were recorded. Participants were asked if they are known with diabetes mellitus or not if he/she is smoking cigarettes or not as well as if he/she is drinking alcohol or not and will be recorded in the data collection sheet.

3.8.4 Fracture Classification, mechanism of injury:

The mechanism of the injury was recorded in the data collection sheet as motor traffic crash, fall from height, sports injury, trivial and twisting injury. Two radiographs (AP and lateral) done on admission (for new admission with acute open injuries undergoing surgical debridement and managed definitively by ORIF as per AO principles) or pre-operatively for elective patients were used to classify fracture patterns by using the AO/OTA classification as follows:

(i) Type A, infra syndesmotic
(ii) Type B, trans syndesmotic
(iii) Type C, supra syndesmotic

Fracture type whether closed or open was recorded in the data collection sheet, for open fractures Gustilo-Anderson classification system was used as follows;

(i) Type I, wound size less than 1 cm in size, with little muscle damage or contamination.
(ii) Type II, wound size 1 to 10 cm in size, with a moderate soft tissue injury.
(iii) Type III A includes wounds that are >10 cm in size, have high energy, severe soft-tissue injury, have been contaminated, and have enough tissue for flap coverage.
(iv) Type III B severe periosteal stripping; wound requires rotating or free flap soft tissue covering.
(v) Type III C, regardless of the severity of soft tissue injury, is a vascular injury requiring repair.

3.8.5 Time from injury to ORIF and modality of treatment before ORIF:

If the patient had temporary management before being planned for ORIF, time from temporary to definitive management by ORIF was recorded as well and the modality of treatment whether external fixation or P.O.P cast or back slab. Time from injury to definitive operative treatment by ORIF was recorded in weeks as less than 3 weeks or more than 3 weeks.

3.8.6 Antibiotics use and duration of Surgery:

Prophylactic antibiotics. if given or not given was recorded. Antibiotics prophylaxis should be administered within 1 hour of skin incision, at MOI intravenous ceftriaxone is given as prophylactic antibiotic. Also, the duration of the surgery was recorded in which surgery taking more than 3 hours was considered prolonged surgery as calculated from skin incision time.

3.8.7 Assessment and diagnosis of Early Fracture Related Infection:

Patients were followed up postoperatively for review after 2 weeks, during this period they were assessed for any signs of early fracture related infection using confirmatory and suggestive criteria by the International Consensus Meeting in 2017 as follows; (13)

Confirmatory criteria for early fracture related infection were:

(i) Wound breakdown communicating through an implant or bone.
(ii) Purulent/ pus drainage from the wound

Suggestive criteria for early fracture related infection are:

(i) Clinical signs including pain, redness, swelling, warmth and Fever (≥38.38C))
(ii) New onset joint effusion
(iii)Elevated inflammatory markers wereWBC, CRP, and ESR.

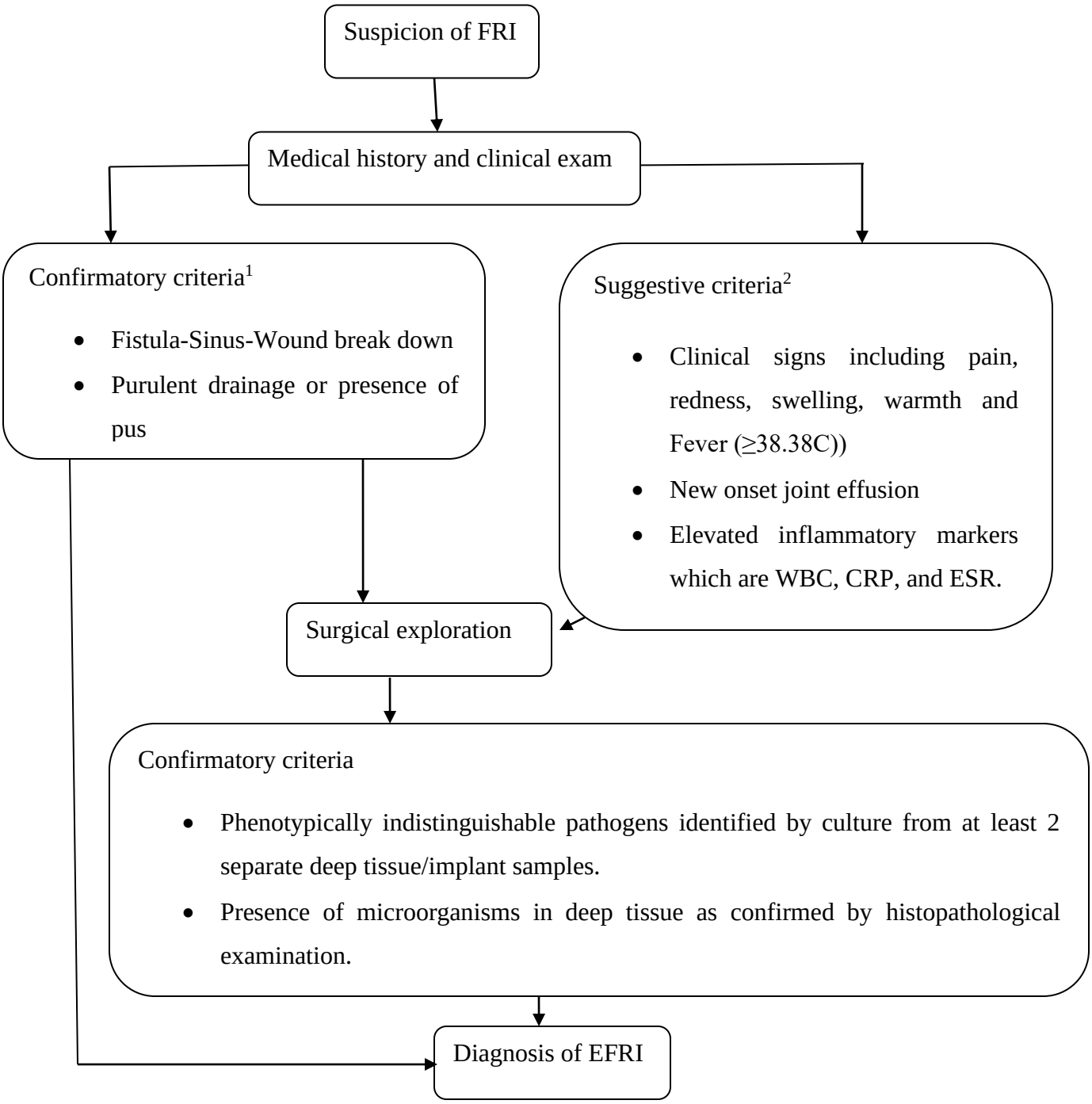


Figure 2: Diagnostic algorithm for a suspected early FRI, using the updated definition criteria of the FRI as adopted from the International Consensus Meeting.

1. Any of these criteria will diagnose the presence of an infection independently. For instance, the presence of purulent drainage from the wound does not need microbiological culture for confirmation of infection.
2. Suggestive criteria should prompt the surgeon to consider further investigations which may lead to identifying possible confirmatory criteria.

During the study period, 10 patients had pus drainage from the wound and were diagnosed with Early Fracture Related Infection at 2 weeks follow up period.

3.8.8 Management of early fracture related Infection:

When early fracture related infection was diagnosed patients were managed according to the protocol by proper antibiotics according to the Standard Guideline Treatment.

3.9 Investigation tools

Questionnaires were used to record data collected from various sources including the patients themselves, patients' files, and document from the operating room, nurses, and anesthetists.

3.10 Management and Analysis of Data.

The acquired data were coded, cleaned, and analyzed using SPSS software version 24. To ensure correctness, consistency, and logic, the lead investigator cleaned the data. Continuous variables with normal distribution were represented using means and standard deviations, while skewed data were summarized with medians and interquartile ranges. Categorical variables were presented as proportions or percentages, and tables were utilized to present the data.

Following testing for assumptions, categorical variables were compared using Fisher's exact or Chi-square tests, while continuous variables were compared using either the Student's t-test or the Mann-Whitney-U test. Logistic regression was employed to perform a multivariate analysis of risk factors associated with early fracture related infection in specific objectives i, iii, and iv. For associations, a p-value of less than 0.05 was regarded as significant.

3.13 Ethical issues

In the research, ethical issues such as confidentiality of information were addressed in the data collection tools, which may either benefit, risk, or harm the study. These issues were considered by the researcher, and ethical clearance was obtained and approved by the Institutional Ethical Review Board of the Muhimbili University of Health and Allied Sciences (MUHAS) to conduct the study.

Before commencement of data collection, the researcher requested permission from the Director of Muhimbili Orthopedic Institute to recruit the study participants. Confidentiality was maintained throughout and after the study. To maintain the anonymity of the respondents, questionnaires were designated with no names or any individual identifiers. Moreover, all participants were informed of the study objectives to enable them to make an informed and voluntary decision to participate or not.

For mentally incompetent adult individuals meeting inclusion criteria, the next of kin was used to obtain informed consent. Participants were provided with the right to withdraw from the study without any penalty, and upon voluntary consent of participation, they were provided with a signed written form.

All conventional post-operative care options were provided for the study participants.

3.14 Dissemination plan,

After the study is completed and the Institutional Review Board (IRB) has approved the research findings, copies of the study must be made available to and stored at the Department of Orthopedics and Traumatology at MOI, the MUHAS Library, and the College of Medicine. The abstract will be presented at the annual MUHAS conference, and a manuscript will be prepared for publication.

4.0 RESULT

4.1 Socio-demographic characteristics of patient with malleolar fractures who underwent ORIF (N=100)

This study included a total of 100 adult patients with malleolar fractures managed by open reduction and internal fixation. The mean age of study participants at the time of surgery was 44.2 years with standard deviation (SD) of ±13.2years, median age of 43 (IQR: 21) and ranged from 22 to 67 years. More than half of the participants (70.7%) were between the age of 18 and 38 years,

Majority of patients with malleolar fractures managed by ORIF at MOI were females 71.0% as shown in the table below:

Table 1: Socio-demographic characteristics of patient with malleolar fractures undergoing ORIF (N=100)

Variables	Frequency (n)	Percentage (%)
Age group (years)		
22-45	58	58.0
46-69	42	42.0
Gender		
Male	29	29.0
Female	71	71.0
Smoking status		
No	97	97.0
Yes	3	3.0
Alcohol intake		
No	83	83.0
Yes	17	17.0
Diabet Mellitus		
No	90	90.0
Yes	10	10.0
ASA score		
Class I	68	68.0
Class II	32	32.0

Table 2: Demographic characteristics associatedwith early fracture related infection in patient with malleolar fractures after ORIF at MOI(N=100).

Variable		Patients with malleolar fractures after ORIF		Chi-square	p-Value
		Not Infected (%)	Infected (%)		
Age group					
	22-45	53(91.4)	5(8.6)	0.292	0.589
	46-69	37(88.1)	5(11.9)		
Gender					
	Male	22(75.9)	7(24.1)	9.071	**0.003**
	Female	68(35.8)	3(4.2)		
Smoking					
	No	90(92.8)	7(7.2)	7.835	0.288
	Yes	0(0.0)	3(100)		
Alcohol intake					
	No	80(96.4)	3(3.6)	6.120	0.145
	Yes	10(58.8)	7(41.2)		
Diabete Mellitus					
	No	83(92.2)	7(7.8)	4.938	**0.026**
	Yes	7(70.0)	3(30.0)		
ASA score					
	Class I	61(89.7)	7(10.3)	0.02	0.886
	Class II	29(90.6)	3(9.4)		

Of the personal characteristics investigated, Male gender and diabetes mellitus were significantly associated with development of early fracture related infection (P value 0.003 and 0.026 respectively). Participants who had history of smoking and drinking alcohol has shown the trend toward increased risk of developing early fracture related infection but did not reach statistical significance. Age and ASA score ware not shown to be associated with risk of developing early fracture related infection.

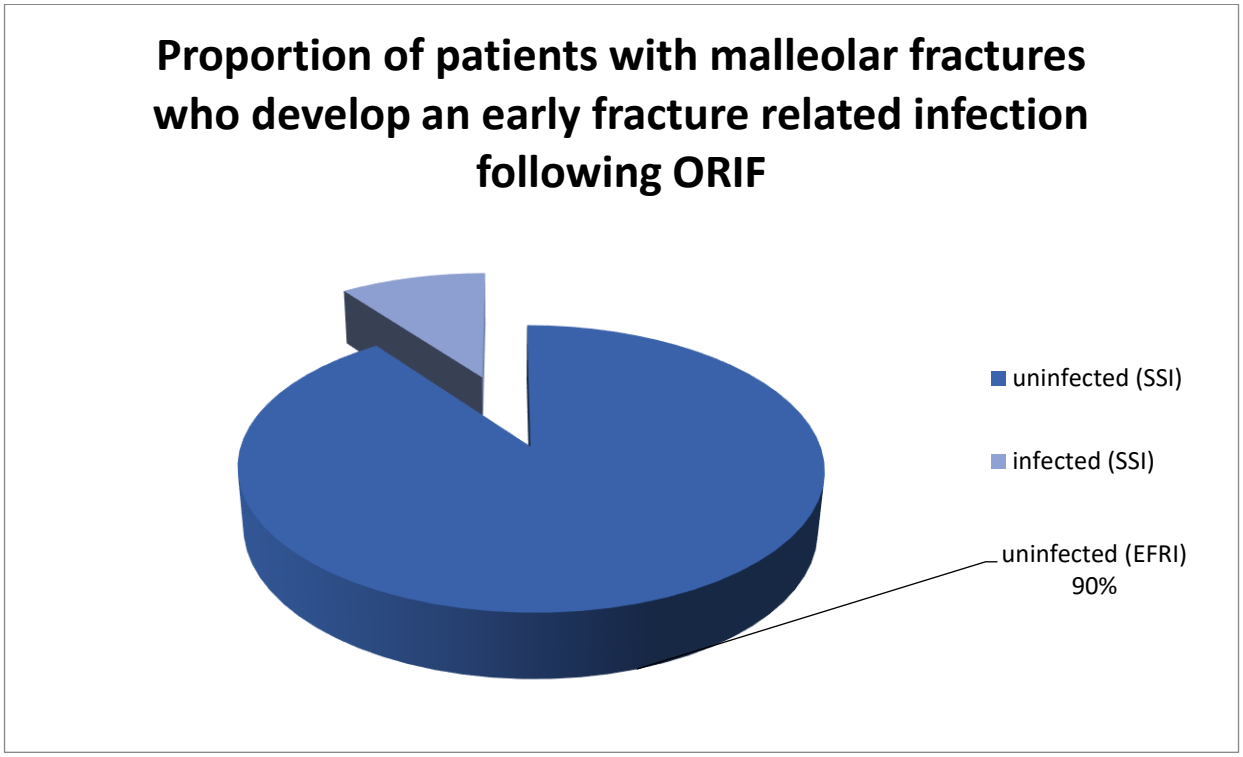


Figure 3: Proportion of patients with malleolar fractures who develop an early fracture related infection following ORIF at MOI

During the study period, 10 participants (10%) developed early fracture related infection.

Table 3: Fracture characteristics associated with early fracture related infection in patient with malleolar fractures after ORIF at MOI (N=100).

Variable	Patients with malleolar fractures after ORIF		Chi-square	p-Value
	Not Infected (%)	Infected (%)		
Side				
Left side	42(91.3)	4(8.7)	0.161	0.688
Right side	48(88.9)	6(11.1)		
Mechanism of injury				
Motor trafic crush	51(91.1)	5(8.9)	2.53	0.639
Fall from height	8(100)	0(0.0)		
Sport injury	1(100)	0(0.0)		
Trivial injury	3(100)	0(0.0)		
Twisting injury	27(84.4)	5(15.6)		
Type of fracture				
Open fracture (GA-type II)	5(100)	0(0.0)	9.361	**0.009**
Open fracture (GA-type IIIA)	4(57.1)	3(42.9)		
Closed fracture	81(92.0)	7(8.0)		
OTA Classification				
44-A1	1(100)	0(0.0)	2.767	0.601
44-A2	1(100)	0(0.0)		
44-B1	5(100)	0(0.0)		
44-B2	58(86.6)	9(13.4)		
44-C1	25(96.2)	1(3.8)		

Of the fracture characteristics investigated, open fracture was significantly associated with development of early fracture related infection while mechanism of injury and fracture type by OTA classification has shown the trend to be the risk of developing EFRI but did not reach the statistical significance.

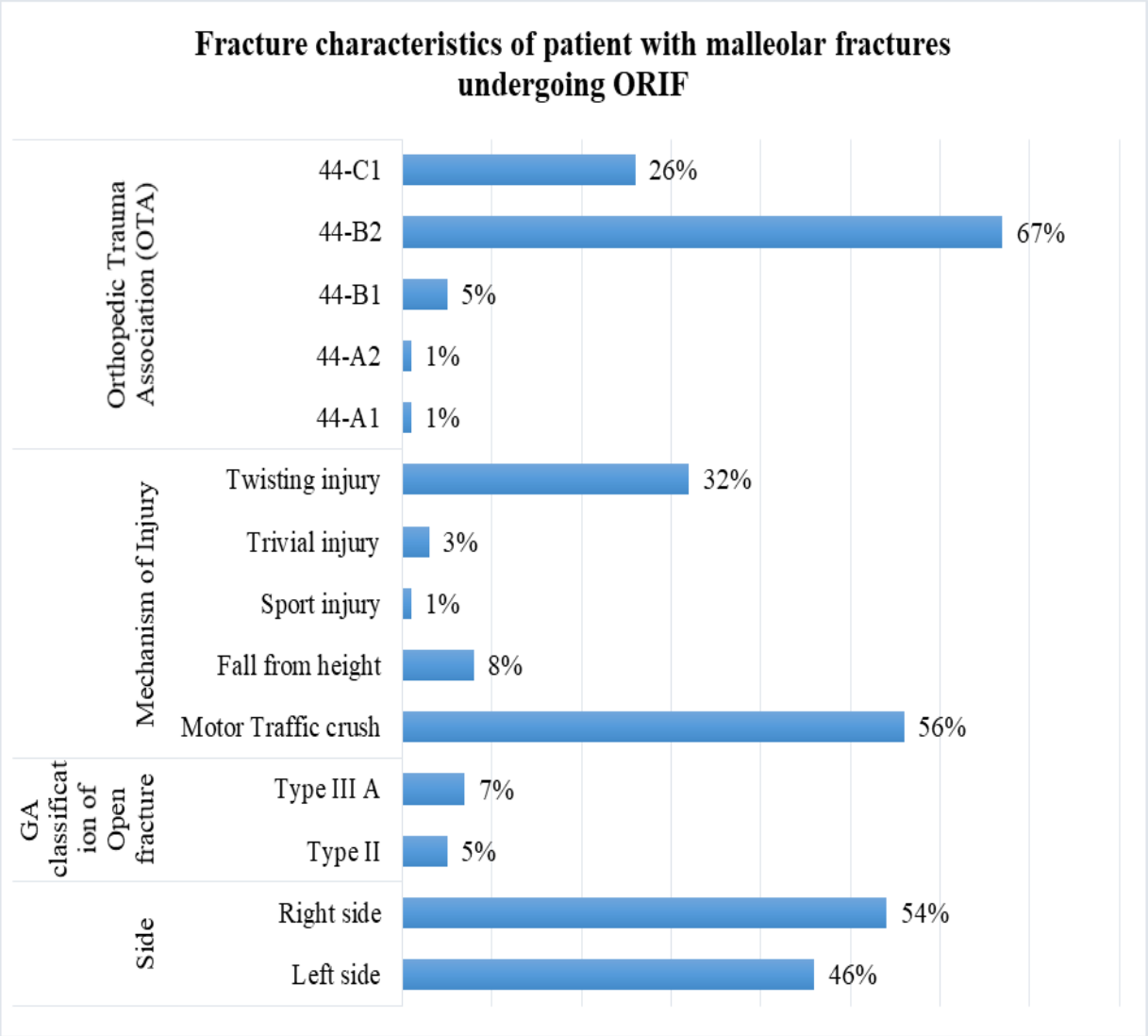


Figure 4: Fracture characteristics of patient with malleolar fractures undergoing ORIF

Table 4: Surgery characteristics associated with early fracture related infection in patient with malleolar fractures after ORIF at MOI (N=100).

Varible	Patients with malleolar fractures after ORIF		Chi-square	p-Value
	Not Infected (%)	**Infected (%)**		
External fixatation applied temporally				
No	75(91.5)	7(8.5)	1.084	0.298
Yes	15(83.3)	3(16.7)		
Treatment before surgery				
P.O.P with window	3(100)	0(0.0)	1.66	0.645
Full cast	1(100)	0(0.0)		
External fixation	14(82.4)	3(17.6)		
Back slab	72(91.1)	7(8.9)		
Duration from injury to surgery				
Less than 21 day	17(100)	0(0.0)	3.948	**0.047**
More than 21 day	73(88.0)	10(12.0)		
Duration of surgery				
Below 3 hours	74(88.1)	10(0.0)	3.693	0.06
Over 3 hours	16(100)	0(0.0)		

All of patients (100%) were administered pre-op antibiotic and underwent elective surgery (planned AS).

Participants who underwent ORIF more than 21 days after injury had 3.9 significant risk of developing EFRI as compared to those who were operated within 21 days from date of injury (P=0.047) whereas other investigated factors showed the trend to be the risk for developing EFRI but did not reach the statistical significance.

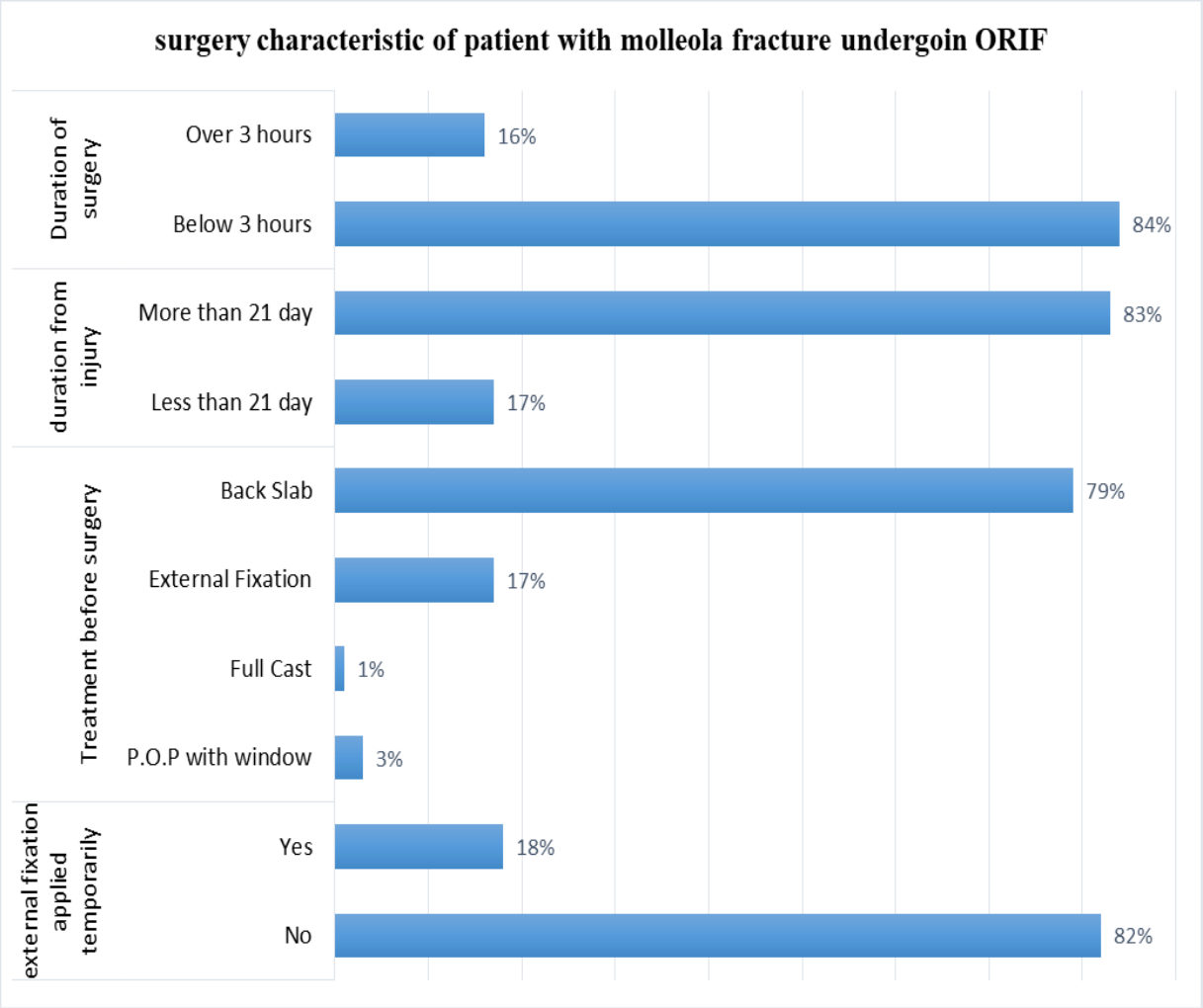


Figure 5: Surgery characteristics of patient with malleolar fractures undergoing ORIF

Table 5: Univariable and multivariable analysis of the factors associated with early fracture related infection following ORIF of malleolar fractures

Variable	Category	Univariable analysis			Multivariable analysis		
		cOR	95% CI	p-Value	aOR	95% CI	p-Value
Age group	22-45	1.43	0.39 – 5.30	0.590			
	46-69	Ref					
Gender	Male	7.21	1.72 – 30.30	0.007	7.18	1.61 – 31.88	**0.010**
	Female	Ref					
Alcohol intake	Yes	18.67	4.14 – 83.98	0.000	17.99	3.85 – 84.13	**0.000**
	No	Ref					
DiabeteMilletus	Yes	5.08	1.07-24.11	0.041	7.27	1.15-46.08	**0.035**
	No	Ref					
ASA class	Class II	1.11	0.26-4.60	0.020	1.16	0.26-5.17	**0.040**
	Class I	Ref					
Side	Left	1.31	0.35 – 4.96	0.689			
	Right	Ref					
Type of fracture	Open	3.85	0.85-17.59	0.081	6.84	1.20 – 39.02	**0.030**
	Closed	Ref					
Staged done	Yes	2.14	0.49-9.23	0.307			
	No	Ref					

Key: cOR: crude Odds Ratio, aOR: adjusted Odds Ratio, Ref: Reference Category
Note: Odds ratio derived from Multivariate logistic regression, dependent variable diagnosis: infected |not infected

After adjusting for other factors in univariate and multivariable analysis, Male gender, alcohol intake, diabetes mellitus and open fractures were the independent predictors of developing early FRI on the current study.

5.0 DISCUSSION

5.1 Discussion of key findings

This study investigated the factors associated with early fracture-related infection (EFRI) following open reduction and internal fixation (ORIF) for malleolar fractures at Muhimbili Orthopaedic Institute (MOI) in Tanzania. The study found that 10% of the 100 patients who underwent ORIF developed EFRI. Several factors, including patient factors, fracture severity (open vs. closed), and surgical techniques, affect the EFRI rates after ORIF for malleolar fractures. This infection rate falls within the range reported in previous studies on EFRI following ORIF for malleolar fractures. In a study that was done in level 1 trauma centre in MetroHealth Medical centre in Ohio USA the proportion of patients with malleolar fractures managed by ORIF and developed infection was 7.2%(10) Whereas in a study that was done in Northern Europe in Norway it 9%.(21) While in unpublished multicenter study that was done in Kenya the infection rate was as high as 16.7%, this seemed to be high because it involved open malleolar fractures alone which increases the risk of acquiring EFRI.(22)The 10% infection rate that was noted emphasizes how critical it is to put in place efficient preventive measures in order to reduce the risk of EFRI in this patient population.

5.1.1 Patient related factors associated with early fracture related infection in patient with malleolar fractures following ORIF at MOI.

Several significant findings are presented from the analysis of demographic variables associated with early fracture-related infection (FRI) after open reduction internal fixation (ORIF) for malleolar fractures at Muhimbili Orthopaedic Institute (MOI).

Contrary to predictions, in patients with malleolar fractures, in the present study age does not seem to significantly affect the likelihood of early FRI post-ORIF. Despite the fact that infections tend to occur slightly more frequently in older individuals, the difference was not statistically significant ($p = 0.589$). Age group did not show a significant correlation with early FRI post-ORIF in the univariable and the multivariable analysis after controlling for other factors ($p = 0.590$). This result of the current study is contrary to earlier studies' findings by Pilskog et al and Sun et al which revealed that being older is a risk factor for fracture related infection.(13,9). This may be due to the fact that with increasing age in the general population

patients with co-morbidities will be more and hence the risk of developing fracture related infection. (21) Majority of patients in our study fell between the ages of 22 and 45 years which make them to have decreased frequency of co-morbidities and hence reduced risk of developing fracture related infection.

In the current study gender emerges as a key determinant of early FRI, with male patients showing a higher risk than female patients ($p = 0.003$). This result is consistent with previous research showing that male gender is linked to a higher risk of FRI. Male gender was found to be a significant predictor of early FRI post-ORIF in both the univariable and multivariable analyses ($p = 0.007$ and 0.010, respectively) even after controlling for other factors, male patients had significantly higher probabilities of acquiring FRI than female ones this may be due to the fact that male tend to have behaviors which predisposes to develop infection.

Whereas in the current study, alcohol was not significantly associated with development of EFR following ORIF of malleolar fractures at MOI ($p = 0.145$), but after controlling other factors alcohol use was consistently found to be a significant risk factor for early FRI post-ORIF in both univariable and multivariable analyses ($p < 0.001$). Patients with a history of alcohol use showed significantly increased odds of developing EFRI.This finding is similar to the study done by Shao et al which show that participants who were drinking alcohol had higher risk of developing fracture related infection.(26) This can be due to the fact that alcohol abuse reduces the immune capacity hence susceptibility to infection.(26)

Remarkably, the current study found no significant correlation between smoking and early FRI post-ORIF ($p = 0.288$). Although smoking is generally recognized to increase the risk of surgical site infections, its effect on the development of FRI in patients who have had ORIF after malleolar fractures has not been shown in this study. The findings of this study are inconsistence with previous study by Olsen LL et al and Nasell et al which reveals smoking increases the risk of developing FRI following ORIF of malleolar fractures (16,24)as smoking results in a negative but reversible effect on tissue oxygen levels as a result of toxins like carbon monoxide which binds haemoglobin and shifts the oxygen dissociation curve to the left

hence susceptibility to infection.(16,24) This may be due to the reason that smoking quantification was not done in our study.

Following ORIF for malleolar fractures, diabetes mellitus is found to be a significant risk factor for early FRI ($p = 0.026$) in the current study even after controlling other factors, diabetes mellitus was found to be a significant predictor of early FRI post-ORIF in both the univariable and multivariable models ($p = 0.041$ and 0.035, respectively). Compared to non-diabetics, individuals with diabetes had greater odds of developing FRI. This result is in line with previous studies by Rascoe et al, Sun Y et al, and Shao J et alwhich show diabetes to be a significant risk factor for EFRI.(10,9,20)This can be explained due to the fact that diabetes mellitus causes micro and macro angiopathy as well as neuropathy which results into susceptibility of infection.(30)

The occurrence of early FRI post-ORIF does not seem to be influenced by the ASA score, which represents the patient's preoperative physical status ($p = 0.886$). Similar infection rates are seen in patients in ASA Classes I and II, indicating that general health state may not be a significant factor in determining FRI risk in the current study. A significant association between ASA class and early FRI post-ORIF was found by univariable analysis ($p = 0.020$) however after the multivariable analysis's adjustment for other variables revealed that ASA class was not a significant predictor of infection risk ($p = 0.040$). The findings are not in keeping with previous studies which showed that higher ASA class is associated with the risk of development of FRI.(10) This might be due to the fact that patients who underwent ORIF for malleolar fractures fell in ASA I or II and no study participant with ASA III or IV was operated. This means that patients being in ASA I or II protected them from being at risk of developing EFRI.

5.1.2 Fracture characteristics associated with early fracture related infection in patient with malleolar fractures following ORIF at MOI

Compared to closed fractures, open fractures (both GA-type II and IIIA) had a significantly higher risk of developing EFRI ($p = 0.009$). There was no significant association between open fracture and early FRI post-ORIF in univariate analysis ($p = 0.081$) however after the multivariable analysis's adjustment for other variables revealed that open fracture was a significant predictor of infection risk ($p = 0.030$).The result of this study is in line with previous studies done by Simske NM et al, Shao J et al and Bergström et alwhich show that open fracture is a significant risk factor for the development of FRI.(18,20,24) This can be explained by the fact that open fractures puncture the skin hence creating a point at which bacteria can contaminate the underlying tissues.(25)

Other characteristics which are Mechanism of injury and fracture type by AO/OTA Classification (44-ABC) were not shown to be risk factors for developing EFRI in the current study. High energy mechanisms of injury like motor traffic crush is associated with more severe injuries and open fractures which seem to be risk factors for developing EFRI. The findings in the current study are contrary to pre-existing study findings which show high energy mechanisms are associated with development of EFRI as high energy injuries are associated with soft tissue injury and dislocation which seem to increase the risk of fracture related infection.(26) Whereas the current study found there was no statistical significance between development of EFRI and fracture type by AO/OTA class and mechanism of injury, this finding is in line with pre-existing study findings. (26) This can be due to the fact that majority of the patients were operated after 21 days when soft tissue has healed hence reducing the risk of infection.

5.1.3 Surgery characteristics associated with early fracture related infection in patient with malleolar fractures following ORIF at MOI

This study investigated surgery factors associated with early fracture related infection among 100 adult patients with malleolar fractures managed by ORIF at MOI. Of the factors investigated, patients who underwent ORIF more than 21 days post injury had 3 times risk of developing EFRI compared to those who were fixed within 21 days. This finding was statistically significant (P=0.047**).** But after univariable and multivariable analysis, pre-operative length of stay was not a significant independent predictor of EFRI following malleolar ORIF. Also, duration of surgery was not significantly associated with development of EFRI in the current study; this may be due to the fact that more than 80% of patients at MOI had ORIF within 3 hours. Other factors investigated in the current study did not show statistical significance for the development of EFRI. This is in line with previous studies which show that surgery performed for more 3 hrs has no increased risk of developing FRI. (26)

6.0 STUDY LIMITATIONS AND MITIGATIONS CONCLUSION AND RECOMMENDATION

6.1 Conclusion

This study found that the proportion of early fracture related infection among adult patients with malleolar fractures following ORIF at MOI is 10% with factors associated with its development being male gender, alcohol intake, diabetes mellitus and open fracture.

The results of this study provides an insight in clinical practice especially while preparing patients for malleolar ORIF as they highlight the importance of glycemic control in diabetic patients, urgent measures in open fractures and the needy of counseling patients to reduce alcohol intake.

Generally, the findings of the current study provide valuable highlight of the proportion and factors associated with early fracture related infection among adult patient following ORIF of malleolar fractures at MOI.

6.2 Study limitations and mitigations

This study was limited by small number of subjects with malleolar fractures undergoing open reduction and internal fixation of malleolar fractures. Due to that, the researcher employed the method of enrolling all available patients by including all participants as long as they meet the inclusion criteria the researcher managed to reach 100 participants as researcher was able to collect data from every eligible patient, ensuring a complete dataset without the need for sampling or extrapolation that lead to Increased Precision. Also, there is minimized Selection Bias as by including all available patients, the potential for selection bias is reduced, ensuring that the findings are representative of the population.

Alcohol intake was taken as either participant is taking alcohol or not but was not quantified, this might have influenced the results. Also, smoking status of the patient was taken as either currently smoking or not but not quantified this might have influenced the results as our study found that there is no association between smoking and development of early fracture related infection.

Also, in the current study for diabetes status participant was asked either He/She is known diabetic or not but laboratory values like glycated haemoglobin was not taken into account, this might have influenced the results but all diabetic patients were reviewed by physicians and cleared for surgery as sugar was controlled.

6.3 Recommendation

Following the observed findings in this study, we recommend the following:

1. Surgeons should consider patient with malleolar fractures for ORIF one the blood sugars has been controlled and patient should be counseled to stop drinking alcohol to reduce the risk of developing fracture related infection.
2. Separate studies for closed and open fractures for malleolar ORIF has to be done to validate the findings of the current study.
3. The result of the current study may in this regard serve as baseline reference for further prospective studies with large sample size and multicenter to investigate further the factors associated with fracture related infection among adult patients following malleolar ORIF including both early and late infection as well as taking into account deep tissue culture to provide strong evidence for clinical decision making and preventive measures.

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APPENDICES.

Appendix I: Questionnaire (English Version).

Questionnaire of factors associated with early fracture related infection in patients with malleolar fractures following Open reduction and internal fixation atMOI.

Code no: ……..

Instruction (Tick and fill in the blank where appropriate)

Age… (Years)

Gender: Male ☐ Female ☐

Smoking status: Yes ☐ . No ☐

Alcohol intake: Yes ☐ No ☐

Diabetes Mellitus: Yes ☐ No ☐

ASA Score (i) Class I ☐

(ii) Class II ☐

(iii) Class III ☐

(iv) Class IV ☐

Fracture characteristics

1. Right side ☐ Left side ☐
2. Open ……. ☐
3. If open and done on an emergency basis, the time of administration of antibiotics from the time of injury ☐ Time of initial debridement ☐
4. Gustilo-Anderson classification for open fracture;
   a) Type I, wound size less than 1 cm in size, with little muscle damage or contamination. ☐
   b) Type II, wound size 1 to 10 cm in size, with a moderate soft tissue injury. ☐
   c) Type III A includes wounds that are often >10 cm, have high energy, severe soft-tissue injury, have been contaminated, and have enough tissue for flap coverage. ☐

d) Type III B severe periosteal stripping; wound requires rotating or free flap soft tissue covering. ☐

e) Type III C, regardless of the severity of soft tissue injury, is a vascular injury requiring repair. ☐

5. Closed ……. ☐

6. If closed, and done on an elective basis, intra-operative antibiotics given

Yes ☐ No ☐

7. Mechanism of injury

Motor traffic crush ☐

Fall from height ☐

Trivial injury ☐

Sports Injury ☐

Twisting injury ☐ ☐

8. Fracture type by AO/OTA classification system

……

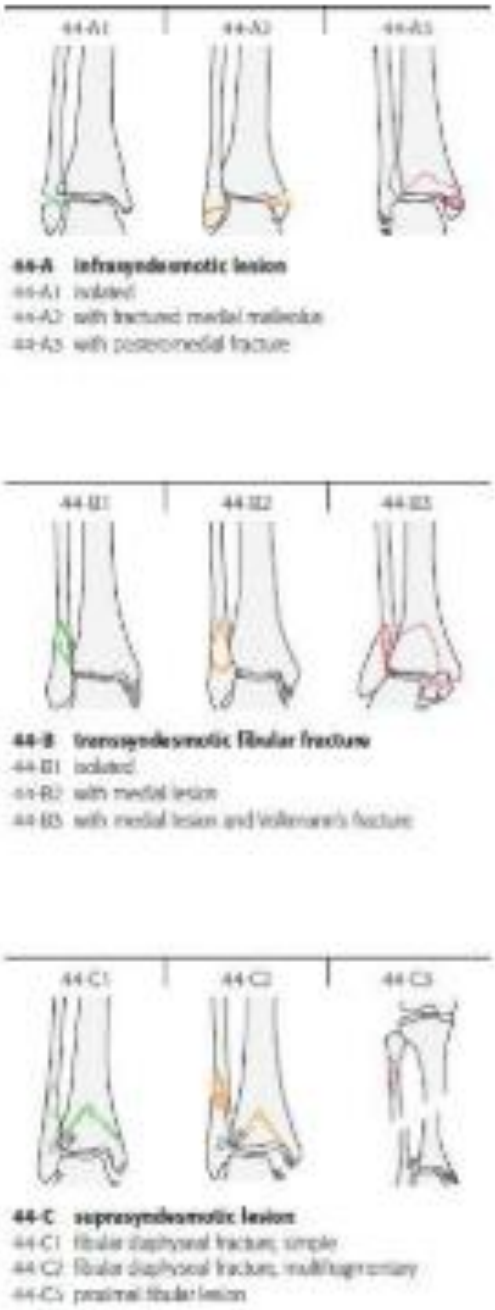


Figure 6: AO/OTA classification of malleolar fractures.

Surgery characteristics

(i) Modality of temporary treatment ……..

(ii) Preoperative stay before surgery in days

(a) ≤ 21 ☐

(b) Greater than 21 ☐

(iii) Planned surgery as

(a) Elective ☐

(b) Emergency ☐

(iv) Duration of surgery

Below 3 hours ☐

Over 3 hours ☐

(v) Intra-operative bleeding amount in MLS ☐

Assessment

1. Early fracture related infection confirmatory criteria

iii) Wound breakage ☐

iv) Pusdrainage from the wound ☐

v) Culture

Positive ☐ Negative ☐

vi) If culture positive, organism (s) identified ……...

Sensitivity pattern ……..

2. Early fracture related Infection using suggestive criteria

(i) Pain yes ☐ no ☐

(ii) Swelling yes ☐ no ☐

(iii)Warmth yes ☐ no ☐

(iv)Redness yes ☐ no ☐

(v) Temperature (Celsius)

38.3and below ☐ above 38.3 ☐

(vi) ElevatedC - reactive protein

Yes ☐ no ☐

Value ……

(vi) FBP: Elevated total WBC…….

Yes ☐ no ☐

Value …….

Appendix II: Questionnaire (Swahili version).

Nambari ya dodoso: ……..

Maelekezo (Weka alama ya vema au jaza nafasi wazi)

Umri: ……(Miaka)

Gender: Mwanaume ☐ Mwanamke ☐

Unavuta sigara: Ndio ☐… Hapana ☐

Una kunywa pombe: Ndio ☐ Hapana ☐

Una Kisukari: Ndio ☐ Hapana ☐

MAKSI ZA ASA (i) Daraja I ☐

(ii) Daraja II ☐

(iii) Daraja III ☐

(iv) Daraja IV ☐

Maelezo ya mvunjiko

9. Upande wa kulia ☐ pande wa kushoto ☐
10. **Mvunjiko wazi.** Ndio ☐ Hapana ☐
11. Kama ni mvunjiko wazi na uli fanywa kwa dharura, muda wa kupewa dawa ya antibayotiki kutoka kuumia ☐ Muda wa upasuaji wa kusafisha ☐
    Aina za mvinjiko wazi kwa kutumia Gustilo na Anderson

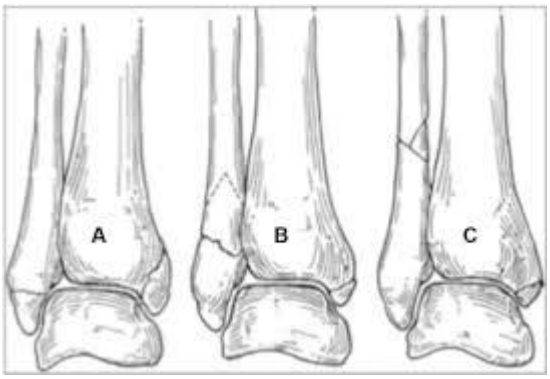
    f) Aina ya I, ukubwa wa kidonda chini ta sentimita 1, misuli ime umia kidogo na kidonda kina uchafu kidogo ☐
    g) Aina ya II, ukubwa wa kidonda ni sentimita 1 hadi 10, tisu zime umia kiwango cha kawaida. ☐
    h) Aina ya III A, inajumuisha kidonda cha ukubwa zaidi ya sentimita 10, kani kubwa, tisu zime umia sana, kima chafuka, lakini kuna tisu za kutosha kufunga kidonda ☐
    i) Aina ya III B, III inajumuisha kuumia tabaka la nje la mfupa, na kuhitaji tisu za ziada kuweza kufunga kidonda ☐
    j) Aina ya III C, bila kujali kiwango cha kuumia kwa tisu, kuumia kwa mishap ya ateri kunako hitaji upasuaji. ☐
12. Sio wazi …… ☐
13. kama sio mvinjiko wazi, je amepewa antibiotiki kabla ya upasujai
    Ndio ☐ Hapana ☐ Muda kabla ya upasuaji ……..

Aina ya antibiotiki

(a) Caftriaxine
(b) Metronidazole
(c) Gentamycin
(d) Zingine ……

14. Namna ya kuumia
Ajali za barabarani ☐
Kudondoka kutoka umbali mrefu ☐
kuumia bila nguvu kubwa ☐
Majeraha ya michezo ☐
Mvinjiko kwa kuzunguka ☐

15. Aina ya mvunjiko kwa kutima mfumo wa Danis-Weber
……



Sababu za kiupasuaji

(vi) Muda wa kusubiria upasuaji
(c) Chini ya siku 21 ☐
(d) Zaidi ya siku 21 ☐

(vii) Ulifanyiwa upasuaji kama
(c) Kwa kupangwa ☐
(d) Dharura ☐

(viii) Muda wa upasuaji
Chini ya masaa matatu ☐
Zaidi ya masaa matatu ☐

(ix) Kiwango cha kuvuja damu kwa mililita ☐

Uchunguzi wa kidonda

3. Maambukizi ya kidonda yapo kwa kutumia viashiria vya hakika

iii) Kidonda kime achia ☐

iv) usaha kwenye kidonda ☐

v) Vimelea vime ota

Ndio ☐ Hapan ☐

vi) Kama vimelea vime ota, aina ya vimelea ……...

dawa zinazo ua ……..

4. Maambukizi ya awali kwa kutumia viashiria vya uwezekano

(vii) Maumivu Nd☐ hapana☐

(viii) Uvimbe N☐ Hapan☐

(ix) Warmth Ndio ☐ Hapana ☐

(x) Redness yes ☐ ☐

(xi) Halijoto

38.3 au chini ☐ aidi ya 38.3 ☐

(vi) Elevated C - reactive protein

Ndio ☐ hapana ☐

Kiwango ……

(xii) Picha ya damu: kiwango cha seli nyeupe za damu kimepanda…….

Ndio ☐ Hapan ☐

Kiwango …….

Appendix III: Consent form (English Version)

Part A:

Introduction: I am Dr. Sebastian George, a MUHAS student pursuing a Master of Medicine in Orthopedics and Traumatology. I am doing a study on factors associated with early post-operative infection among patients with malleolar fractures treated by open reduction and internal fixation at Muhimbili Orthopaedic Institute. Before consenting to participate in the study, please read this form carefully and make sure you understand it.

Purpose of the study: The purpose of this study is to obtain data regarding factors associated with early post operative infection among adult patients with malleolar fractures treated by ORIF at MOI which will be used in protocol change and preventive measures in the hospital and our nation at large for the betterment of treatment of a patient with ankle fractures.

Despite that, it is a partial fulfillment of my Master's degree in Orthopaedics and Traumatology.

Study procedures: Your socio-demographics, a brief medical history from the past, and your social history are the major pieces of information that are needed from you and will be documented on data-collecting sheets. Wound progress will be checked during follow-up visits at two weeks. Only if you exhibit symptoms of infection during follow-up visits will additional laboratory tests, such as complete blood counts, C-reactive proteins, erythrocyte sedimentation rates, and pus swabs for culture and sensitivity, be performed**.**

Risks and benefits: Since you won't receive any interventions other than the treatment being offered, there are no risks directly associated with the study. However, there may be advantages, such as the possibility of early detection and diagnosis of surgical site infection and other complications, which can then be managed in accordance with the treatment protocol.

Confidentiality: The data will be entered in a collection sheet that will not display your name but will use codes for research purposes and is strictly confidential.

Participant information: Your voluntary involvement in this study will not have any impact on your management at any point if you decide not to participate or withdraw from the study.

Contacts and Questions: If you have any questions at any moment, please do not hesitate to contact the principal investigator Dr. Sebastian George, Muhimbili University of Health and Allied Sciences,P.O.Box 65001, Dar es Salaam) Mob 0754750948. For your rights as a participant in this research; informing problems, fear, or complaints, please contact Dr. Nahya Masoud, Director Research, Publications and Innovation. P.O.BOX 65001 Dar es Salaam. Tel 0221503026.

Part B

Participant consent: I willingly agree to participate because I have read, understood, and agree to all the investigator has just completely stated to me as evidenced by writings hereunder.

Signature……

Or participant's thumbprint (indicate right or left).

Witness signature……..……

Date……

Appendix IV: Consent Form (Swahili version)

FOMU YA IDHINI YA KUSHIRIKI KATIKA UTAFITI

Namba ya Utambuzi……

UTANGULIZI.

Habari! Mimi ni Daktari Sebastian George mwanafunzi wa Shahada ya Uzamili katika fani ya mifupa na ajali katika chuo Kikuu cha Afya na Sayansi Shirikishi Muhimbili. Ninafanya utafiti kwa wagonjwa wenye Mivunjiko ya visigino katika Mguu na kutibiwa kwa upasuaji na kuwekewa chuma cha ndani katika taasisi ya Tiba ya Mifupa Muhimbili (MOI).

Dhumuni la utafiti huu: Kupata taarifa kuhusu wagonjwa wenye mvunjiko katika visigino vya miguu miguu na wakatibiwa kwa kupasuliwa na kuwekewa chuma cha ndani na Kuainisha sababu za kupata maambukizi ya awali kwa wagonjwa hawa.

Pamoja na hayo, utafiti huu ni moja ya mahitaji ili kuhitimu shahada ya uzamili ya Udaktari Bingwa wa Binadamu ya Chuo Kikuu cha Afya na sayansi shirikishi Muhimbili.

Nini kitafanyika katika kushiriki utafiti huu;

Endapo utakubali kushiriki katika utafiti huu, utaulizwa maswali yaliyo kwenye dondoo maalumu kuhusu taarifa zako za za kijamii, historia ya matibau na taarifa za jumla, pamoja na kufanyiwa uchunguzi wa afya kwa kadiri Daktari anaye kuhudumia atakavyo ona, utapangwa kwenye orodha ya upasuaji wa kuwekewa chuma cha ndani na baadaye utaonwa wiki ya pili baada ya upasuaji ili kuona maendeleo ya kidonda na ikiwa umepata maambukizi ya awali utafanyiwa vipimo an uchunguzi pamoja na kupewa matibabu stahiki kwa kadiri ya miongozo ya matibabu.

Usiri katika utafiti.

Taarifa zote zitakazo kusanywa kwa kwa kutumia dondoo zitaingizwa kwenye kompyuta bila majina kamili ili kutotambulijka.Taarifa hizi ni siri na matumizi yake ni utafiti pamoja na matibabu yako tu.

Madhar ya ushiriki.

Hatutegemei upate madhara yoyote kwa kushiriki katika utafiti huu.

Hiari ya ushiriki katika utafiti.

Ushiriki katika utafiti huu ni wa hiari. Ikiwa uta amua kuto shiriki katika utafiti huu, una hakikishiwa kuendelea kupata matibabu kama kawaida kwa kadiri ya miongozo ya matibabu. Pia una ruhusiwa kuacha kuendeleana utafiti muda wowote hata kama umesha ridhia kwa kusaini idhini ya utafiti huu.

Faida za kushiriki katika utafiti.

Ikiwa uta hiari kushiriki katika utafiti huu na ukapata maambukizi ya awali katika kidonda, uta nufaika kwa kupata vipimo vya damu pamoja na kujua aina ya bakteria ambao wamesababisha maambukizi hayo, utapata matibabu kwa kadiri ya miongozo na uta shauriwa ipasavyo.

Gharama katika utafiti

Hakuna gharama yoyote unazo takiwa kulipia ili kushiriki utafiti huu.

Mawasiliano

Ikiwa una maswali ya ziada juu ya utafiti huu usisite kuwasiliana na Mtafiti Daktari. Sebastian George, MUHAS, S.L.P 65001 Dsm. Simu 0754750948. Ikiwa una maswali juu ya haki ya kushiriki wako katika utafiti huu wasiliana na Mwenyekiti wa Kamati za Tafiti na Machapisho, S.L. P. 65001Dsm. Nambari ya simu 2150302-6.

SAHIHI

Je una ridhia kushiriki?

Ndio nina kubali…….. Hapana sija kubali……

Mimi…….nimesoma fomu hii ya idhini ya utafiti na nime elewa hivyo nakubali kushiriki katika utafiti.

Sahihi ya Mshiriki……

Sahihi ya Mtafiti……..

Tarehe…….

Appendix V: Ethical Clearance

UNITED REPUBLIC OF TANZANIA

MINISTRY OF EDUCATION, SCIENCE AND TECHNOLOGY

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES

OFFICE OF THE DIRECTOR – RESEARCH, PUBLICATIONS AND INNOVATION

Ref. No.DA.282/298/01.C/1879 Date: 28/08/2023

MUHAS-REC-08-2023-1879
SEBASTIAN GEORGE
SCHOOL OF MEDICINE
MUHAS

RE: APPROVAL FOR ETHICAL CLEARANCE FOR A STUDY TITLED: FACTORS ASSOCIATED WITH EARLY POST-OPERATIVE INFECTION AMONG ADULT PATIENTS WITH MALLEOLAR FRACTURES TREATED BY OPEN REDUCTION AND INTERNAL FIXATION AT MUHIMBILI ORTHOPAEDIC INSTITUTE

Reference is made to the above heading.
I am pleased to inform you that the Chairman has on behalf of the University Senate, approved ethical clearance of the above-mentioned study, on recommendations of the Senate Research and Publications Committee meeting accordance with MUHAS research policy and Tanzania regulations governing human and animal subjects research.

APPROVAL DATE: 28/08/2023
EXPIRATION DATE OF APPROVAL: 28/08/2024

STUDY DESCRIPTION:
Purpose:
The purpose of this prospective cohort study is to determine the factors associated with early postoperative infection following Open Reduction and Internal Fixation of malleolar fractures at Muhimbili Orthopedic Institute.

The approved protocol and procedures for this study is attached and stamped with this letter, and can be found in the link provided:
https://irb.muhas.ac.tz/storage/Certificates/Certificate%20-%2014844.pdf and in the MUHAS archives.

The PI is required to:

1. Submit bi-annual progress reports and final report upon completion of the study.
2. Report to the IRB any unanticipated problem involving risks to subjects or others including adverse events where applicable.
3. Apply for renewal of approval of ethical clearance one (1) month prior its expiration if the study is not completed at the end of this ethical approval. You may not continue with any research activity beyond the expiration date without the approval of the IRB. Failure to receive approval for continuation before the expiration date will result in automatic termination of the approval for this study on the expiration date.
4. Obtain IRB amendment (s) approval for any changes to any aspect of this study before they can be implemented.
5. Data security is ultimately the responsibility of the investigator.
6. Apply for and obtain data transfer agreement (DTA) from NIMR if data will be transferred to a foreign country.
7. Apply for and obtain material transfer agreement (MTA) from NIMR, if research materials (samples) will be shipped to a foreign country.
8. Any researcher, who contravenes or fail to comply with these conditions, shall be guilty of an offence and shall be liable on conviction to a fine as per NIMR Act No. 23 of 1979, PART III section 10 (2)
9. The PI is required to ensure that the findings of the study are disseminated to relevant stake holders.
10. PI is required to be versed with necessary laws and regulatory policies that govern research in Tanzania. Some guidance is available on our website https://ethr.muhas.ac.tz/.

Dr. Nahya Salim Masoud,

Chairperson, MUHAS Research and Ethics Committee



Appendix VI: Introduction Letter

UNITED REPUBLIC OF TANZANIA
MINISTRY OF EDUCATION, SCIENCE AND TECHNOLOGY
MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES
OFFICE OF THE DIRECTOR – POSTGRADUATE STUDIES

In reply quote:
Ref. No. HD/MUH/T.159/2021

04th September, 2023

The Executive Director,
Muhimbili Orthopaedics Institute,
P.O. Box 65474,
DAR ES SALAAM

Re: INTRODUCTION LETTER

We would like to inform you that the bearer of this letter is **Sebastian George** with **Reg. No. HD/MUH/T.159/2021** is a student at Muhimbili University of Health and Allied Sciences (MUHAS) "pursuing **MMed. Orthopaedics/Traumatology**.

As part of his studies, he will be doing an elective research titled: "**Factors Associated with Early Post-Operative Infection Among Adult Patients with Malleolar Fractures Treated by Open Reduction and Internal Fixation at Muhimbili Orthopaedic Institute.**" he is being supervised by Dr. Adam Hussein from MUHAS and Violet Lupondo from MOI.

The research has been approved by the Chairman of University Senate.

Kindly provide him the necessary assistance to facilitate the conduct of his research.

We thank you for your cooperation.

Victoria Mwaanwa
For: DIRECTOR, POSTGRADUATE STUDIES

c.c **Sebastian George**

9 United Nations Road; Upanga West; P.O. Box 65001, Dar Es Salaam; Tel. G/Line: +255-22-2150302/6; Ext. 1015; Direct Line: +255-22-2151378; Telefax +255-22-2150465; E-mail: dpgs@muhas.ac.tz; Web: https://www.muhas.ac.tz

Appendix VII: Permission Letter

UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH

MUHIMBILI ORTHOPAEDIC INSTITUTE (MOI)

MOI
MUHIMBILI ORTHOPAEDIC INSTITUTE

Ref.PA. 290/338/01/74 **14th Sept, 2023**

Muhimbili University of Health and Allied Sciences

Dar -es Salaam

Tanzania.

RE: APPROVAL FOR CONDUCTING RESEARCH STUDY

Reference is made to your letter with reference number HD/MUH/T.159/2021 dated on the 20th August, 2023 for conducting research study about. **"Factors Associated with Early Post- Operative Infection Among Adult Patients with Malleolar Fractures Treated by Open Reduction and Internal Fixation at Muhimbili Orthopaedic Institute".**

On behalf of the Management I would like to officially inform you that, your permission has been granted for your student **Sebastian George** to conduct study at Muhimbili Orthopaedic Institute (MOI).

It's my hope that your stay at MOI will be fruitful. For any clarification contact CRTM +255713764522.

Dr. Joel J Bwemelo, CRTM
For: MOI Executive Director
Cc: Director of Post Graduate studies
Cc: Supervisor

Muhimbili Orthopaedic Institute (MOI), Upanga West Plot No. 1048/2, Kalenga Street, P. O. Box 65474 - Dar es Salaam; Telephone Number +255 -022-2151298/2152937/2152938 Fax: +255 -022-2151744
Website: www.moi.ac.tz, info@moi.ac.tz,