UNIVERSITY OF NAIROBI

PREVALENCE, RISK FACTORS, AND MICROBIOLOGICAL PROFILE OF EARLY SURGICAL SITE INFECTION FOLLOWING ORTHOPAEDIC IMPLANT SURGERY AT KENYATTA NATIONAL HOSPITAL

BY:

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Department of Surgery.

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LIST OF ABBREVIATIONS AND ACRONYMS

BMI Body Mass index

CDC United States Centers for Disease Control and prevention

CFU Colony-Forming Unit

EMB Eosin methylene blue

HAI Hospital-associated infection

HIC High-income countries

ICU Intensive Care Unit

ISS Injury Severity Score

KNH Kenyatta National Hospital

LMIC Low and middle-income countries

MRSA Methicillin-resistant *Staphylococcus Aureus*

NNIS National nosocomial infections surveillance scale.

ORIF Open Reduction internal fixation

PRBC Packed red blood cells

SAP Surgical antibiotic prophylaxis

SSI Surgical site infection

STUDY DEFINITIONS

Deep Surgical Site Infection: Deep incisional infections are those that invade muscle or fascia (or both)

Organ space Surgical Site Infection: Organ-space SSI include infections involving any part of the anatomy that was opened or manipulated during an operation (other than the incision).

Superficial Surgical Site Infection: Superficial incisional infections that are limited to the subcutaneous fat stratum.

Surgical site infection: Refers to an infection that occurs after surgery in the part of the body where the surgery took place. Surgical site infections can sometimes be superficial involving the skin only. Other surgical site infections are more serious and can involve tissues under the skin, organs, or implanted material.

SUMMARY

Background: The prevalence of surgical site infections (SSI) in orthopaedic surgery has been on the rise especially in low and middle-income countries (LMIC). This has been attributed to the increased number of trauma patients due to the increased incidence of motor vehicle and motor cycle crashes. Kenya has witnessed a similar increase, more so from motor cycle related crashes, leading to an increase in the number of fractures treated operatively. Time to ORIF, duration of surgery, antibiotic prophylaxis are some of the risk factors for SSI, however, data on prevalence and risk factors of SSI within our population to inform preventive strategies remain scarce.

Study objective: To determine the prevalence, risk factors and causative bacterial pathogens using microscopy culture and antibiotic sensitivity patterns of SSI following surgery for long bone fractures at level 6 referral hospital Kenyatta(KNH).

Study design: Prospective observational analytic .

Study setting: The study was carried out in orthopaedic clinic (OC) and wards (OW) at the Kenyatta National Hospital (KNH) between 11th February 2022 and 2nd May 2022

Patients and methods: The collected data were transferred from password-coded data digital collection sheets into analysis software for data cleaning and coding prior to analysis. Data was stored in password-protected computer folders to maintain anonymity of the study subjects. Data analysis was carried out using the Prism 7 (GraphPad Software, San Diego, CA, USA) and SPSS (IBM Statistics Software Version 25, Armonk, New York, USA). Categorial data was reported as frequencies (%). Continuous data were subjected to normality tests (histogram and Q-Q plots with Kolmogorov-Smirnov test) and reported as mean and standard deviation (SD). Comparison of patient and fracture characteristics between patients with and without SSI was carried out using the Independent Student's-t test (continuous variables) and Chi-square statistic (categorical variables). Multivariate logistic regression analysis was performed to identify risk factors for SSI, adjusting for the age,BMI ,sex and comorbidities, and to calculate adjusted odds ratios (ORs) with the corresponding 95% Wald CI. Throughout the analysis, a $p<0.05$ was considered statistically significant at a 95% confidence interval.

Results: A total of 130 patients were recruited into this study. They were generally young (mean age: 33±12.8 years) with a male predominance (83%). The mean body mass index (BMI) was 23.7±2.1 Kg/M2, with 13 (10%) having diabetes mellitus (DM). The most fractured bone was femur (n=66 patients, 50.8%). The mean injury severity score (ISS), pre-operative hospital stay and ASA (American Society of Anaesthesiology) score were 21.6±11.2, 12±9.2 days 1.0±0.1 and respectively. A total of 18 patients (13.8%) developed surgical site infection (SSI). Compared to those without SSI, patients with SSI were predominantly male (p=0.007), had higher BMI (p=0.003) and diabetes mellitus (DM) (p=0.007), had higher incidence of open fractures (p=0.046), higher ISS (p=0.008), and were more likely to require pre-operative blood transfusion ($p<0.001$) and ICU admission ($p<0.001$). In the multivariate adjusted logistic regression model, female sex (OR= 5.52, 95% CI 1.15-26.65, p=0.033), presence of diabetes (OR= 9.72, 95% CI 1.83-51.76, p=0.008), higher BMI (OR= 1.31, 95% CI 1.02-1.69, p=0.033), need for pre-operative blood transfusion (OR= 68.21, 95% CI 5.42-858.32, $p<0.001$) and need for ICU admission (OR= 8.10, 95% CI 5.18-12.65, $p<0.001$) were significant predictors of development of SSI. The commonest organism isolated was staphylococcus aureus (SA) (70%).

Conclusion: The burden of surgical site infections (SSI) following orthopaedic surgery remains high. Diabetes mellitus (DM), higher body mass index (BMI), pre-operative blood transfusion and intensive care unit admission were associated as risk factors for SSI in this study cohort. Commonest isolated organism *was Staphylococcus aureus* (n= 7patients,70%).

Culture isolates display a concerning trend of increased resistance to commonly prescribed antibiotics.

Recommendation: 1.Increased SSI surveillance mearures in Orthopaedic patients with diabetes and obesity comorbidities

2. Routine establishment of sensitivity patterns of SSI isolates to guide antimicrobial selection is recommended.

1. INTRODUCTION

1.1 Background

The burden of healthcare hospital-acquired infections is already high where it affects upto 15% of patients admitted in the regular wards and 50% of patients admitted in the intensive care unit (Nejad et al., 2011). In the developing countries, the prevalence of HAI is underestimated, because HAI diagnosis requires complex surveillance activities, expertise, and resources. In some developed countries, HAI trends are closely monitored using systems in place to facilitate active surveillance. Surgical site infection (SSI) is the most common postoperative incisional complication and comprises approximately 20% of all healthcare-associated infections (Nejad et al., 2011). The prevalence of SSI in patients is at least 5% in patients undergoing a surgical procedure (William et al., 1998; Aktuerk et al., 2006). German Hospital Infection Surveillance system is in place to monitor HAI. In most developing countries such systems are not in place due to healthcare systems deficiencies aggravated by economic problems. In addition, inadequate infection control is worsened by overcrowding and understaffing of health facilities. In some instances, the lack of infection control policies and guidelines adds to the extent of the problem (Monahan et al., 2005).Surgical site infection can result in high morbidity and mortality significantly affecting a patient's quality of life and may result in prolonged duration of hospitalization. This results in higher costs of treatment of SSI and depletion of healthcare resources (Monahan et al., 2005). Mortality within 30 days of surgery is the third-largest contributor to global deaths with more than a third of these deaths attributed to surgical site infection. The incidence rate of SSI is higher in low- and middle-income countries (LMIC) (Monahan et al., 2005). Most of the cost of treatment of SSI is borne by the patient or family members in LMIC unlike in the developed countries where healthcare cost is state sponsored. In addition, patients with orthopaedics SSIs have substantially greater physical limitations and significant reductions in their health-related quality of life (Whitehouse et al., 2002).

Trauma patients tend to have increased hospital stay with some admitted to the ICU. They are thus more predisposed to surgical site infection. In the LMIC countries the time spent while awaiting surgery might be prolonged due to limited theatre space, thus predisposing the patient to colonization by nosocomial bacteria and the risk of developing SSI (Rajput et al., 2018). During SSI surveillance, the risk factors that are monitored can be bundled into preoperative, perioperative, and postoperative. Measures to curb SSI in the preoperative period include having patients bath or shower with a soap just one day before the surgery. Nasal mupirocin in combination with a chlorhexidine body wash before procedures in which *Staphylococcus aureus* is the most common organism likely to cause an infection. (William et al., 1998; Aktuerk et al., 2006).The use of razors for hair removal is associated with increased risk of SSI, therefore removal of hair should not be done routinely. The use of electric clippers is recommended in cases where hair must be removed (Tandon et al., 2015). To minimize the risk of SSI for every procedure being conducted in theatre, all staff need to wear a non sterile wear. The team on duty must remove their jewelry and any artificial nails or polish before operations (Onche et al., 2015).

This aim of this study is to evaluate the rate of SSI, the profile of the bacterial isolates including antibiotic sensitivity patterns, in patients undergoing orthopaedic trauma surgery for fixation of long bone fractures at Kenyatta National Hospital (KNH).

1.2 Problem Statement

There is an increased incidence of orthopaedic trauma patients, this is attributed to the rapid rise of motor vehicle and motorcycle crash cases seen in Kenya. The management of these patients includes ORIF. SSI is a complication of fixation of patients with fractures surgically. Orthopaedic trauma patients with fractures may present with multiple injuries, especially the patients involved in high energy motor vehicle crashes. Some of these patients need ICU admission where many invasive procedures are done, prolonged hospital admission, and usually require multiple blood transfusions. These factors make these patients prone to acquiring nosocomial infection. There has also been an increase in lifestyle diseases such as diabetes mellitus and obesity which are known risk factors for SSI.

The sequelae of infections following ORIF of fractures include septic arthritis, chronic osteomyelitis, and osteoarthritis. These are associated with an increased number of reoperations and decreased functional outcomes for patients. SSI has been shown to lead to an increase in healthcare costs by more than 300% and prolonged duration of hospitalization. In the LMIC set up where SSI surveillance is mostly lacking, with understaffing and delays in access to surgery, the infection rates are bound to be higher than in a developed setting.

1.3 Study Question

What is the prevalence and risk factors of early surgical site infection following orthopaedic implant fixation surgery at Kenyatta National Hospital?

1.4 Objectives

1.4.1 Broad Objective

To determine the prevalence of early SSI, risk factors for SSI, the bacterial species causing SSI and their antibiotic sensitivity patterns, following orthopaedic implant fixation surgery at KNH.

1.4.2 Specific Objectives

1. To determine the prevalence of SSI following implant fixation of long bone fractures.

2. To determine the risk factors for SSI development following fixation of long bone fractures.

3. To determine the bacterial species responsible for causing SSI and the antibiotic sensitivity pattern for the bacterial culture isolates.

1.5 Study justification and significance of the study

Surgical site infection (SSI) can be disastrous in orthopaedic practice as it can lead to the dreaded chronic osteomyelitis and increase the cost of care significantly. In a hospital setting such as where this study was carried out, there are challenges such as increased hospital stay for the patients either preoperatively or postoperatively. These are known risk factors for surgical site infection, especially where implant is fixed during surgery. Information gathered from this study has helped to inform factors that were more likely to cause SSI and those that are more likely preventable. The study determined the commonest bacterial isolates and antibiotic sensitivity patterns as seen in patients undergoing Orthopaedics implant surgery at KNH. The hospital can now develop Antibiotic protocol and standard operating procedures for SSI prevention.

2. LITERATURE REVIEW

2.1 Introduction

Surgical site infection is the third most reported nosocomial infection and accounts for 14–16% of all nosocomial infections among hospital inpatients (Aktuerk et al., 2020). Surgical site infections are associated with considerable morbidity, and it has been reported that over one-third of postoperative deaths are related, at least in part, to SSI (William et al., 1998). They have also been shown to lead to an increase in healthcare costs by more than 300% and prolonged hospitalization by an average of 2 weeks (Ansari et al., 2019). In orthopaedic trauma patients, SSI is more devastating as it can result in reduced functional outcomes or disability.

2.2 Pathophysiology of surgical site infection

Surgical site infections develop from interaction of several factors such as the state of immunity of the host, the numbers of bacteria causing contamination and virulence of the bacterial. 1cm of skin contains up to 3 million bacteria. Origins of the bacteria involved include theatre staff, surgical equipment, and theatre environment. Normal flora found on skin,GIT,and genitourinary tract are sources of bacteria causing SSI The folded skin areas like the armpits have a higher temperature and humidity resulting in accelerated bacterial growth. Gram-negative bacilli, *Corynebacterium spp* and *Staph aureus* are examples of bacteria with a tendency to grow in these areas. Some of the areas of the body such as the back have an increased number of sebaceous glands making it a favourite environment where lipophilic microorganisms such as *Propionibacterium* spp and *Malassezia spp* grow (Trampuz et al., 2005).

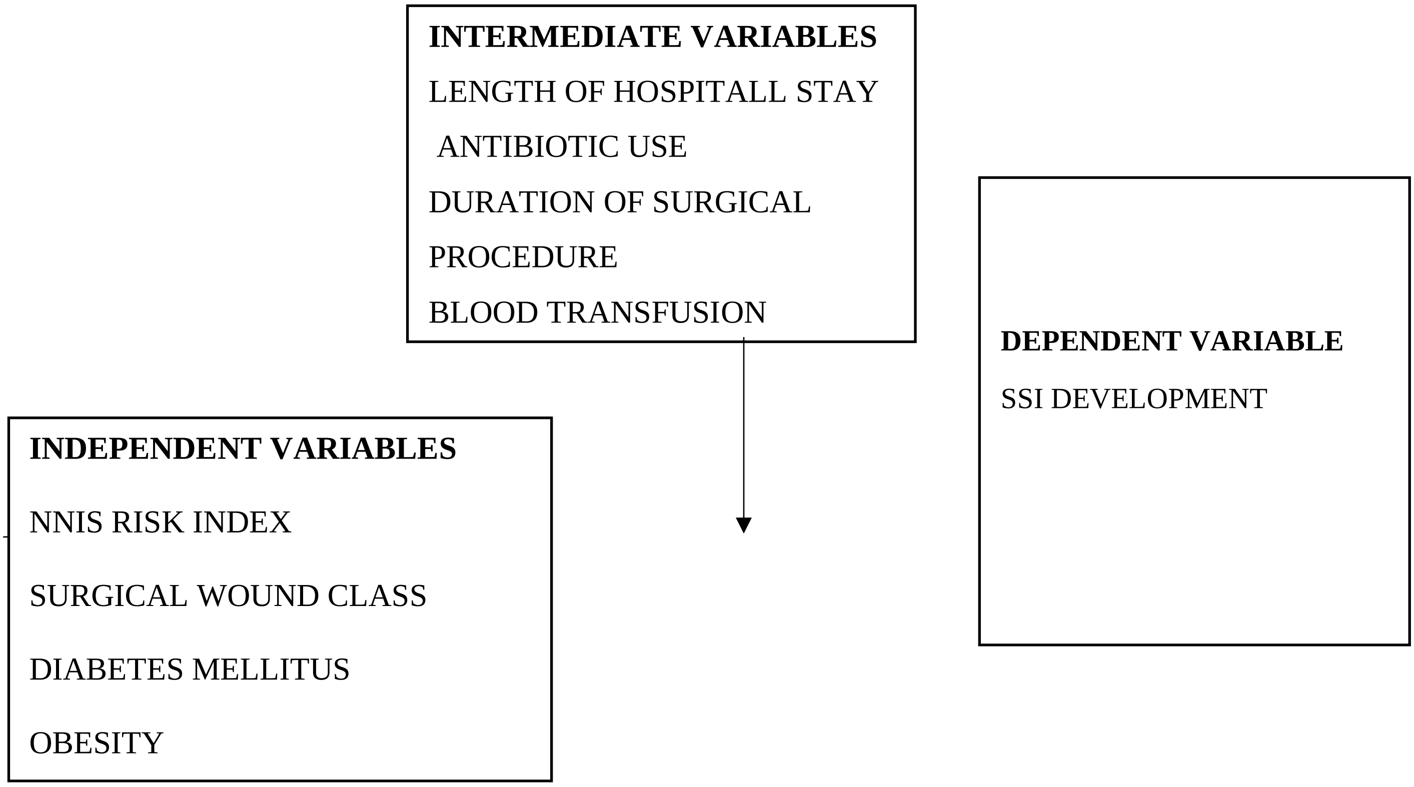
For SSI to develop in the host, the dose of bacterial contamination (inoculum) needed to cause infection must surpass 100,000 CFU/gram of tissue. Implants used in orthopaedic surgery predispose to increased risk of SSI, this is because the bacterial inoculum required to cause an infection is lower in the presence of a foreign material(implants). Every surgical wound has bacterial presence but usually in quantities below the threshold of bacterial inoculum required to cause an infection, therefore no infection develops in these wounds till the required inoculum of 100,000/gram of tissue is surpassed (Thu et al., 2006)

The product of bacterial wound invasion and local wound status are interrelated and will influence bacterial wound flora. Once either of the two factors surpasses a certain threshold, an unchecked exponential proliferation of bacteria will commence, and infection will set in. The breaking point will be determined by the host's ability to resist infection, the dose of the bacterial inoculum, and its virulence. Endogenous pathogens are the biggest participants in surgical site infections. These are the normal flora bacteria that reside on skin,GIT or genitourinary tract. (Thu et al., 2006).

The most isolated pathogen causing SSI is *Staphylococcus aureus*. Approximately 50% of the cases are caused by (MRSA) strain of *Staphylococus aureus*. Nasal passage colonization with MRSA carries an increased for the development of SSI. In one study staph aureus resistant to methicillin was found to be 4.3% of patient's nares passages. In the same cohort by these bacteria, MRSA was responsible for increased incidence of SSIs when compared to the patients who did not have MRSA bacterial colonization (Maksimovic et al., 2006).

2.3 Conceptual framework

Figure 1: Conceptual framework for the study



2.4 The Prevalence of SSI and bacterial isolates causing surgical site infection.

SSI is considered as early if it sets in within 30 days of surgical procedure, whereas intermediate if it occurs between one and three months and late if it develops more than three months after surgery (Trampuz et al., 2006). Elective orthopaedic surgical lists carry out orthopaedic trauma and arthroplasty surgeries involving use of implant and prosthesis fixation. The incidence of SSI following orthopaedic implant surgery ranges from 1% to 22%. (Amaradeep et al., 2019). Infection in implant surgeries can prove to be a challenge to eradicate because bacteria are able to evade antibiotics by forming biofilms on the surface of implants (Trampuz et al., 2006).

The acceptable incidence of SSI in clean surgeries is 1% (Macbeth et al., 2005). Eradication of surgical site infection involving implant surgery is difficult due to biofilm formation by bacteria (Trampuz et al., 2006). Most of the early infections are caused by organisms with high virulence such such as *Staphylococcus aureus* and gram-negative bacilli. Organisms with low virulence such as coagulase-negative staphylococci cause most of the late infections (Trampuz et al., 2005; Trampuz et al., 2006). In a study conducted on patients who underwent orthopaedic surgical procedures by Thuo et al the SSI incidence rate was 12.5% (Thu et al., 2006). The highest incidence was in dirty wounds 44.6% while the incidence in clean wounds was 2%. Independent risk factors in this study include dirty wound class, ASA score of >2, procedures in which external fixation was used, operative duration > 2hrs and emergency surgery from motor vehicle-related trauma. Lack of appropriate prophylaxis was of borderline significance. The NNIS risk index was predictive of SSI for this population.

A study by Maksimovic et al 2006 was looking at orthopaedic surgical patients found the prevalence of SSI was 22.7%, sixty of these patients were diagnosed with SSI during their hospitalization while 3 of the patients developed SSI after discharge. The incidence of SSI was 18.3% in patients with good health and ASA<2and in those with ASA > 2, it was 47.6%. For those with clean wound the incidence of SSI was 13.5%.

In a study at Tanta University hospital, SSI was revealed in 10 patients with overall cumulative incidence rate of 8.264 % for which bacteriological culture and sensitivity was done. Increase age >50 years, affliction by diabetes mellitus, prolonged duration of surgery >2hrs and use of drains were associated with increased risk for SSI. The common organisms isolated were *Staphylococcus aureus* (20%), *Pseudomonas spp* (20%). and *Escherichia coli* (20%) (Afifi et al., 2021).

A study conducted-on patients with closed fracture cases undergoing orthopaedic implant surgeries, the incidence of early SSI was 6.89%. *Klebsiella spp* was most common infective organism isolated at 39.53% cases. Surgical site infection was strongly associated with increased age, prolonged duration of hospitalization >7 days, prolonged duration of surgery more than 2 hr,diabetes mellitus and decreased heamoglobin <12gm (Tandon et al., 2015).A similar study by in patients undergoing ORIF with implants and prosthesis. Use of implant u plates and screws was associated with an infection rate of 7.5%. The bacterial isolates numbered 36. The commonest isolated organism was *Staphylococcus aureus* (44%), *Bacteroides fragilis*, *Escherichia coli*, and *Proteus spp* each with 11% respectively (Onche et al., 2015).

Rashid et al studied the rate of pin site/tract infection in patients who had underwent external fixation at KNH, the pin site infection rate was high 87.7%. The predominant organism isolated was Staphylococcus aureus was isolated (30.2%) (Mohammed et al., 2017).Mwaura et al studied the prevalence and factors associated with staphylococcus aureus nasal colonization of orthopaedic patients admitted to KNH wards, the overall prevalence of colonization by Staph Aureus was 24.7% while overall prevalence of colonization by MRSA was 3.03, patients with BMI of >30 were shown to have increased risk of bacterial nasal colonization, the antibiotic sensitivity pattern of isolated MRSA was found to be resistant to ciprofloxacin, clindamycin, Gentamycin and Rifampin while MSSA bacteria were extensively susceptible to ceftriaxone (Mwaura et al., 2021).

Table 1. **Commonly isolated microorganisms associated with** infections **in** fracture fixation devices (adapted from Trampuz et al 2005)

Microorganism	Frequency in %
Staphylococcus Aureus	30
Coagulase negative staphylococci	22
Gram Negative bacilli	10
Anaerobes	5
Enterococci	3
Streptococci	1
Polymicrobial	27
Unknown	2

2.5 Risk factors for SSI.

Factors associated with SSI include increasing age, comorbidities, and coexisting infections, and preoperative factors such as the length of the preoperative hospital stay, ICU admission and perioperative factors such as skin antiseptic preparation, antisepsis, antimicrobial prophylaxis, blood transfusions and length of operative period of surgery contribute to increased risks of SSIs (Afifi et al., 2021). Many limitations are addressed by theatre systems that have improved ventilation, appropriate sterilization of surgical instruments, and placement of barriers to prevent cross infection. stems, optimal surgical techniques.

2.6 Perioperative factors.

2.6.1 Length of Hospital Stay.

Prolonged duration of hospitalization, whether preoperative or postoperative predisposes the patient to risk of bacterial colonization. Polytrauma patients are more predisposed to development of SSI due to prolonged hospital stay. Polytrauma patients with high ISS scores and admitted to ICU following ORIF are at risk of SSI due to their injury severity and frequent exposure to invasive therapeutic procedures. Polytrauma patients admitted to ICU have multisystem derangements that place them into an even more pronounced catabolic and immunocompromised state leading to higher rates of SSI (Suzuki et al., 2010). A study looking at the prevalence of early surgical site infection in implant surgery, the incidence closed fractures was found in (7.09%) with *Klebsiella species* being the most common followed by pseudomonas aeruginosa (27.27%). Half of the patients had prolonged stay in the ward for more than two weeks. The most prevalent bacteria in the group with prolonged stay was, *Pseudomonas aeruginosa* ,this was attributed to bacterial colonization in the preoperative period (Rajput et al., 2018).

2.6.2 Use of prophylactic antibiotics

Routine use of antibiotic prophylaxis for clean non-prosthetic uncomplicated surgery is not recommended. The use of prophylactic antibiotics is indicated for patients undergoing implant surgery (Kolasinski et al., 2018). Cefazolin is usually given as its provides cover against both gram positive and gram-negative bacteria. Cefazolin is widely used for prophylaxis usually a single dose (Harris et al., 2015). Patients allergic to b-lactam antibiotics should receive clindamycin as a first choice. For MRSA, vancomycin is the drug of choice (Fulkerson et al., 2006). Multiple additional post-operative doses of surgical antibiotic prophylaxis are not superior to a single dose in preventing SSI (Classen et al., 2019).

Several studies have demonstrated an effect of the timing of surgical antimicrobial prophylaxis on SSI, but the best time to administer prophylaxis remains to be defined (Classen et al., 2019). Most guidelines recommend appropriate antibiotics administered within 60 minutes prior to incision (Classen et al., 2019). The Royal College of Physicians of Ireland recommend a repeat dose only if there is excessive blood loss ((>1.5 L in adults or 25 mL/kg in children) and prolonged surgical procedures, a prolonged surgical procedure(4hours) (Bratzler et al., 2004) Prophylactic antibiotics should not be used longer than a 24-hour duration (Bratzler et al., 2004). It is important to consider the local epidemiology when making the choice of antibiotic surgical prophylaxis, for example, the susceptibilities of *Staph Aureus* and *Staph epidermidis* to cefazolin in two academic hospitals in the USA were only 74% and 44%, respectively (Fulkerson et al., 2006).

2.6.3 Operative Duration length and wound class

The length of operative duration is an established risk factor for SSI, prolonged duration of operation is associated with an increased risk of SSI when compared to operations completed in normal time. Operative time is affected by other variables such as surgeon experience, surgeon fatigue, operating room staff experience, appropriate equipment availability, soft-tissue characteristics, obesity, and fracture difficulty (Colman et al., 1998). The NNIS risk index is used to stratify rates of SSI and has widely been adopted by other surveillance systems, (ASA) score of 3 or more, a wound class of contaminated or dirty, and an operation lasting for longer than T hours, where T varies with the category of surgical procedure (Culver et al., 1991; Leong et al., 2006). See Appendix A

2.6.4 Perioperative Blood Transfusion

Blood Transfusion in pelvic and acetabular surgery is common due to large incisions, prolonged duration of surgery and complexity of acetabular surgery. Options for blood transfusion include autologous and allogeneic blood. Perioperative allogeneic blood transfusions can cause surgical site infections (Ponnusamy et al., 2014). Blood transfusion through immunomodulation has resulted in increased susceptibility to respiratory tract infection, urinary tract infection, and SSI. The risk of infections can be reduced by irradiation, leukoreduction timing, and blood storage time may minimize these risk (Shander et al., 2009). Most studies in Orthopaedics suggest allogeneic transfusion is associated with increased infections. Allogenic blood transfusion carries a significant dose-dependent increase in both surgical site infection and other infection. (Friedman et al., 2014). The overall infection rate was lower for patients who had no transfusion when compared to autologous transfusion, and those who had allogeneic transfusion (Ponnusamy et al., 2014). Despite all these, the guidelines recommend against denying patients' blood and blood products citing risk of SSI (Berríos-Torres et al., 2017).

2.7 Patient factors

2.7.1 Obesity

Morbid Obesity has been linked with the development of SSI, a body mass index >40 are more likely to develop complications including infection, wound drainage, and dehiscence. This could be the result of patients who are obese requiring larger incisions, more extensive surgical exposure that results in increased intraoperative time, and increased blood loss which in turn increase the risk of SSI development (Karunakar et al., 2005). Morbid obesity (BMI > 40) affects wounds that are in the process of healing in various ways. Healing tissues require high metabolism hence lack enough oxygen delays the process. Oxygen demand is high in immune cells. Oxygen is paramount in the synthesis of reactive oxygen species (Kabon et al., 1998; Kolasinski et al., 2018). In surgical antibiotic prophylaxis concentrations of antibiotics that are Sufficient are unlikely in patients with obesity compared to normal patients.

2.7.2 Diabetes Mellitus

Diabetes mellitus is a known independent risk factor for surgical site infection. This is attributed to the immunocompromised state, vascular microcirculation compromise leading to wound healing potential (McManus et al., 2001). Decreased in white blood cell's function caused by a sustained state of hyperglycaemia lead to the immunocompromised state. The abnormalities seen in PMNs include abnormalities in granulocyte adherence, impaired phagocytosis, delayed chemotaxis, and depressed bactericidal capacity (McManus et al., 2001). The hyperglycaemic state also induces dysfunction of opsonization and immunoglobulins (Hennessey et al., 1991). Wound healing is also affected; hyperglycaemic state is associated with an increase in activity of the enzyme collagenase and diminished collagen content in wounds.(Goodson et al., 1979. Preoperative glucose control with HbA1c levels $< 7\%$ is associated with a decreased risk of postoperative rate of SSI (Kao et al., 2009).

2.7.3 Chronic steroid use

In a retrospective study with 635,265 participants. Preoperative steroid use was reported in 3.2% of patients. Surgical site infection developed in 4.7%. Preoperative steroid use was associated with wound complications in patients (11.1%) compared with (4.5%) of no steroid patients (Ismael et al., 2019). Steroid use causes suppression of various leukocyte inflammatory events. Steroids reduce vascular permeability, inhibit chemotactic response, inhibit leukocyte bacterial adhesion and phagocytosis. The mechanism of immunosuppression by steroids is by binding to receptors within the cytosol resulting in a complex that enters the nucleus causing inhibition of transcription of pro-inflammatory genes (Barnes et al., 1993; Fauci et al., 2020). The ultimate result in the body is impaired wound healing by causing a delay in the arrival of various cell types responsible for the initiation of the healing process and the layout of tissue matrix. Post-operative wound healing is adversely affected as it relies on the body's immune response to injury for wound healing (Barnes et al., 1993; Fauci et al., 2020).

2.7.4 Human immunodeficiency virus

A study in KNH with a total of 154 respondents, forty-six (30%) who were HIV positive, and one hundred. Being HIV seropositive was found not to be associated with an increased risk for early SSI (Kipkemoi et al., 2021). A review on whether HIV positive patients undergoing Orthopaedics surgery had an increased risk of postoperative surgical site infection, results indicated an increased risk, but these results were not robust and conclusive after sensitivity analysis removing poor-quality studies (Kigera et al., 2012)

2.7.5 Conclusion

The acceptable incidence of SSI in clean surgeries is 1% (Macbeth et al., 2005). Factors such as prolonged duration of surgery, prolonged hospital admission including ICU admission and perioperative blood transfusion are associated with SSI development. Prolonged hospital admission predisposes patients to increased risk of bacterial colonization and SSI. In addition, comorbidities such as diabetes mellitus and marked obesity>30 are also established as independent risk factors for SSI development. The most commonly isolated pathogen responsible for SSI is *Staphylococcus aureus (30%)*, with 50% of the cases are caused by (MRSA) strain of *Staphylococcus aureus*. *Pseudomonas aeroginosa* was the most prevalent organism causing SSI in patients who had prolonged hospital stay (Rajput et al.2018).

PATIENTS AND METHODS

3.1 Study Design

Prospective analytical observational

3.2 Study Setting

KNH, wards and clinics. This study was conducted at a level 6 refferal hospital that handles a high number of trauma cases.

3.3 Study population

All orthopaedic trauma patients admitted into the wards who underwent surgical fixation of long bone fractures. Data collection from patients took place at the accident and emergency bay, wards, orthopaedic clinics, ICU and in theatre.

3.4 Selection criteria

3.4.1 Inclusion criteria

1. Skeletally mature patients with long bone fractures who underwent primary internal fixation.
2. Patients with open (class I) fractures who underwent primary internal fixation (Gustillo e tal ,Anderson et al.)
3. Patients with long bone fractures who underwent internal fixation the secondary procedure.

3.4.2 Exclusion criteria

- Patients who had skin conditions at surgical incision site or infections.
- Patients with chronic illness at the time of admission including cancer.

3.5 Ethical Considerations

3.5.1 Ethical Approval

After clearance by the department of Orthopaedic surgery; approval was sort from the KNH-UON ERC (see appendix D). Participating patients or their next of kin were requested to give a written informed consent after clarification on the relevant details of the study including confidentiality and right to appropriate treatment was given by the investigator.

3.5.2 Recruitment and consenting

After obtaining ERC approval, data were gathered from patients via a data collection tool. Patients were recruited into the study by the principal researcher and three assistants.The two assistants were clinicians with experience in orthopaedic practice.The principal researcher and/or his research assistants reviewed the patient's file checking for eligibility of being recruited into the study. Those that meet inclusion criteria were recruited into the study.Participants were informed that they will not be meeting the expenses for the microscopy culture and sensitivity in those patients with a discharging wound. There was no coercion to participate.

3.6 Sampling Process

Consecutive sampling was used to recruit all the patients meeting the inclusion criteria during the study period.

3.7 Sample size Calculation

The sample size was 100 patients as determined by the Fischer's formula where n- the sample size for this study,z- The standard normal deviation at 1.96 corresponding to 95%,p- The incidence of SSI in implant surgery fractures is 8% (0.1), d- The degree of precision at 0.05.

"n=“(1.96〗^2×0.07(1-0.07))/〖0.05〗^2 " =“0.25008816/0.0025 "=100.03≈100 “)

Thus, a sample size of 100 patients.

3.8 Methods

3.8.1 Data collection procedure

Data were collected using a questionnaire that interrogated the study objectives, including wound assessment for the development of infection using the Centre for Disease Control and Prevention criteria. Data were retrieved from patient files, radiographs, admission, history, operation notes, and anaesthesia notes and includes.

- The prevalence of SSI was determined as a proportion (patients with SSI divided by total number of patients) the CDC criteria were used to diagnose patients with SSI. (See appendix B) patients wounds were assessed on day 3, 8 and 30 using the CDC criteria for SSI.
- The NNIS risk index for SSI was determined for each of the patients, this includes the length of duration taken for each surgery.
- Pus or infected fluid obtained from the infection site were cultured on 5% sheep blood and eosin methylene blue (EMB) agar to obtain the bacterial isolates causing infection. Antibiotic sensitivity tests were performed using a standard automated technique VITEK. All culture sensitivity specimens were taken to one standard laboratory.
- Operation data included: Time to surgery including the length of stay for both preoperative and postoperative period, operative time, total blood loss, the total amount of packed red blood cells (PRBCs) transfused, the pattern of administration of prophylactic antibiotics including the timing of administration of Surgical Prophylactic antibiotics.
- For the multiply injured patients the injury severity score (ISS) was calculated for Polytrauma patients using the Abbreviated injury scale and captured in the datasheet. (See Appendix C.)

- Age,sex and factors such as,(BMI),and diabetes mellitus were captured. Pre-operative and patient risk factors that were captured include body mass index (BMI), and diabetes Mellitus. Preoperative random blood sugar (RBS) level was taken for diabetic patients.
- The fractures were categorized as either open or closed fractures, single fracture or multiple. Gustilo and Anderson classification was used to classify open fractures. The method of fixation was recorded as either plating or intramedullary nailing.

3.8.2 Culture Protocol

- Antiseptic solutions were avoided before taking the specimen.
- Sterile culture collection kit was opened, and swab removed.
- Exudate or discharge from the incision site was collected using two swabs
- The swabs were not collected deep into the incision site.
- The swab was placed in a culture transport media (Amies) sleeve making sure the swab tip is not contaminated.
- The culture collection/transport kit was labelled with a study number, age, specimen source, date, and time of culture.
- Specimens were submitted to Microbiology Laboratory within one hour of collection for culture.
- Aerobic cultures were done within one to two hours after delivery to the laboratory.
- Sheep or chocolate blood agar were used for culture, incubated at 35 to 38 degrees celsius for 18 hours followed by further 18 hours of sensitivity testing for various antibiotics was done if growth was obtained.

3.9 Data management and analysis

The collected data was transferred from password-coded data digital collection sheets into analysis software for data cleaning and coding prior to analysis. Data was stored in password-protected computer folders to maintain anonymity of the study subjects. Analysis of the data was carried out using Prism 7 (GraphPad Software, San Diego, CA, USA) and SPSS (IBM Statistics Software Version 25, Armonk, New York, USA). Categorial data has reported as frequencies (%). Continuous data were subjected to normality tests (histogram and Q-Q plots with Kolmogorov-Smirnov test) and reported as mean and standard deviation (SD) since it was normally distributed. Comparison of patient and fracture characteristics between patients with and without SSI was carried out using the Independent Student's t test continuous variables and Chi-square statistic categorical variables. Multivariate logistic regression analysis was performed to identify risk factors for SSI, adjusting for age, sex, body mass index, and comorbidities, and to calculate adjusted odds ratios (OR) with the corresponding 95% CI. Throughout the analysis, a $p<0.05$ was considered statistically significant at a 95% confidence interval.

3. RESULTS

4.1 Patient characteristics, fracture patterns and interventions

A total of 130 patients were recruited to participate in the study. They were generally young (range 19-72years) (mean age: 33±12.8 years) with a male predominance (83%). The mean body mass index (BMI) was 23.7±2.1 Kg/M^2, with 13 (10%) having diabetes mellitus (DM). None of the patients was on corticosteroids at the time of recruitment into the study. The most commonly fractured bone was femur (n=66 patients, 50.8%), with half of these involving the shaft. Majority of the fractures were simple (n=89 patients, 69.5%), closed (n= 122 patients, 93.4%) and clean (n=128 patients, 98.5%). The mean injury severity score (ISS), pre-operative hospital stay and ASA (American Society of Anaesthesiology) score were 21.6±11.2, 12±9.2 days 1.0±0.1 and respectively. Twelve patients (9.2%) required blood transfusion during the pre-operative period. The commonest internal fixation device was plates (n=59, 45.4%), followed by nails (n=53 patients, 40.8%) screws (n=18, 13.8%). The mean duration of surgery was 126.7±38.2 minutes. The mean EBL was 313.8±196.4 mls, with two patients (1.5%) requiring intraoperative blood transfusion. Two patients (1.5%) required admission to the intensive care unit (ICU) after surgery (Table 2-4).

4.2 Comparison of patient characteristics, fracture patterns and interventions between patients with and without surgical site infection (SSI)

A total of 18 patients (13.8%) developed surgical site infection (SSI). Compared to those without SSI, patients with SSI were predominantly male (p=0.007), had higher BMI (p=0.003) and diabetes mellitus (DM) (p=0.007), had higher incidence of open fractures (p=0.046), higher ISS (p=0.008), and were more likely to require pre-operative blood transfusion (p<0.001) and ICU admission (p<0.001) (Figure 2, Table 2).

Table 2. Baseline patient characteristics, injury patters and interventions

Variable	**SSI group**	**No SSI**	**Total**	**P-value**
Age (yrs)	36.1±15.0	32.5±12.4	33.0±12.8	0.277[£]
Sex (% male)	11 (61%)	97 (86.6%)	108 (83%)	**0.007**[α]
BMI	25.1±3.0	23.5±1.8	23.7±2.1	**<0.001**[£]
Diabetes mellitus	5 (38.4%)	8 (7.1%)	13 (10%)	**0.007**[α]
Steroid use	0 (0.0%)	0 (0.0%)	0 (0.0%)	N/A
Comminuted fracture	7 (38.9%)	34 (30.4%)	41 (31.5%)	0.470[α]
Open fracture	3 (16.7%)	5 (4.5%)	8 (6.2%)	**0.046**[α]
ISS	28.0±18.9	20.6±9.1	21.6±11.2	**0.008**[£]
Pre-operative stay (days)	7.3±5.6	6.3±6.0	6.5±5.9	0.530[£]
ICU admission	2 (11.1%)	0 (0.0%)	2 (1.5%)	**<0.001**[α]
Wound class (clean)	17 (94.4%)	111 (99.1%)	128 (98.5%)	0.136[α]
Pre-op transfusion	8 (44.4%)	4 (3.6%)	12 (9.2%)	**<0.001**[α]
Intra-op transfusion	1 (5.6%)	1 (0.89)	2 (1.5%)	0.136[α]
Post-op transfusion	1 (5.6%)	1 (0.89)	2 (1.5%)	0.136[α]
Duration of surgery	121.9±39.1	127.4±38.2	126.7±38.2	0.575[£]
Estimated blood loss	355.9±246.1	307.1±188.2	313.8±196.4	0.342[£]

[£]- *Chi-square statistic;* [α]*-Independent Student's-t test. BMI- body mass index ISS- injury severity score, ASA- American Society for Anesthesiology score, ICU- intensive care unit*

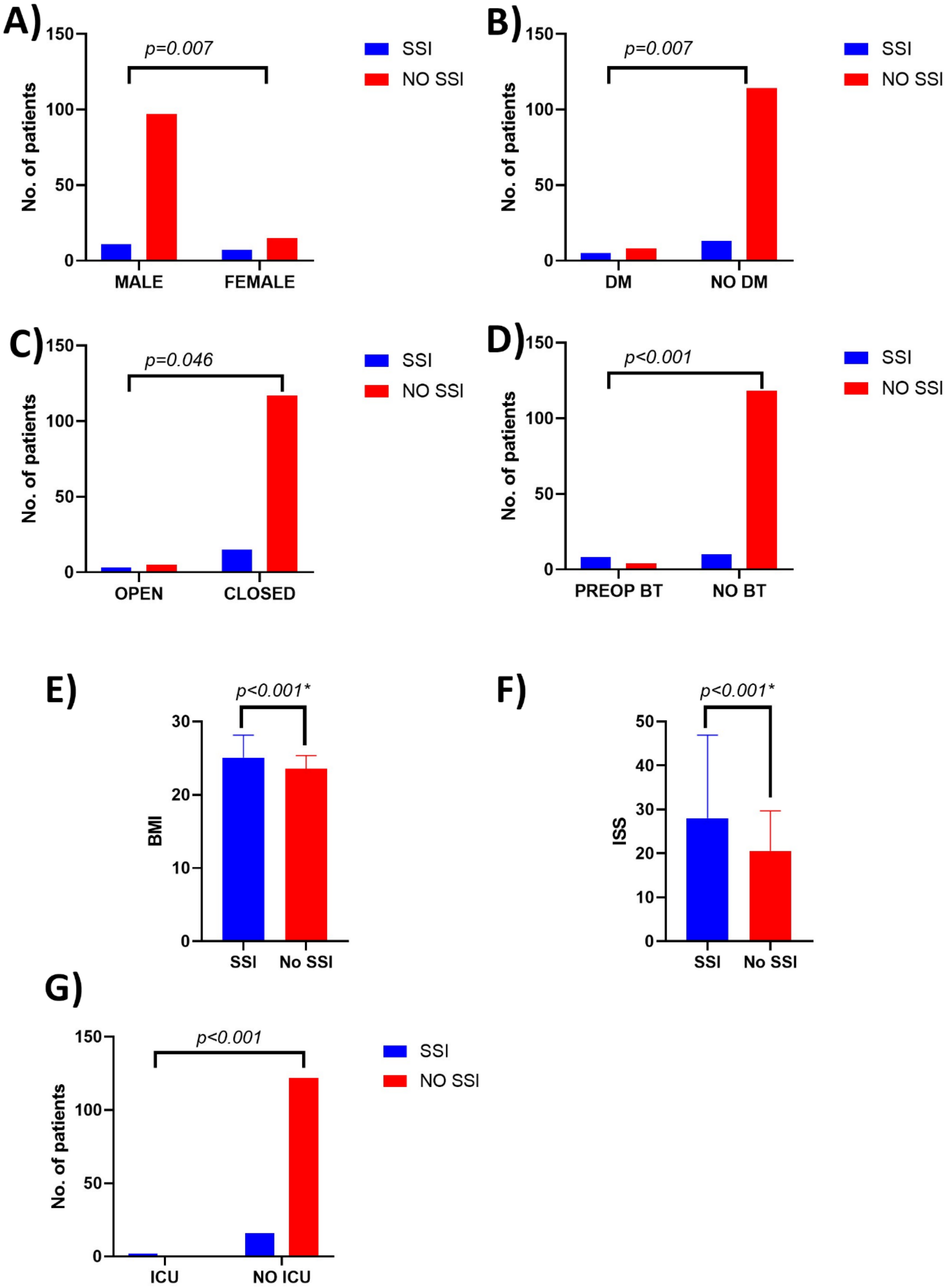
Table 3. Distribution of fractured bones

Location	Bone involved			
Upper limb	Humerus	Proximal		5 (3.8%)
		Shaft		5 (3.8%)
		Distal		5 (3.8%)
	Radius			5 (3.8%)
	Ulna			2 (1.5%)
	Radio-Ulna			12 (9.2%)
Lower limb	Femur	Proximal	Neck	4 (3.1%)
			Intertrochanteric	12 (9.3%)
			Subtrochanteric	8 (6.2%)
		Shaft		34 (26.2%)
		Distal		8 (6.2%)
	Tibia	Proximal		7 (5.4%)
		Shaft		15 (11.6%)
		Distal		8 (6.2%)

Table 4. Type of implant used for internal fixation of fractures

Fixation device		**n (%)**
Plates and Screws	Distal femoral locking plate	1 (0.7%)
	Angle blade plate	1 (0.7%)
	Double plate	23 (17.7%)
	PHILOS plate	5 (3.8%)
	Others	29 (22.3%)
	Dynamic condylar screw	4 (3.1%)
	Dynamic hip screw	11 (8.5%)
	Multiple screws	3 (2.3%)
Nails	Proximal femoral nail antirotation	6 (4.6%)
	Interlocking nail- 2nd Generation	40 (30.8%)
	Reconstruction nail -3rd Generation	7 (5.4%)

Figure 2. Comparison of patient characteristics, fracture patterns and interventions between patients with and without surgical site infection (SSI)



4.3 Risk factors for surgical site infection (SSI)

In the multivariate adjusted logistic regression model, female sex (OR= 5.52, 95% CI 1.15-26.65, p=0.033), presence of diabetes (OR= 9.72, 95% CI 1.83-51.76, p=0.008), higher BMI (OR= 1.31, 95% CI 1.02-1.69, p=0.033), need for pre-operative blood transfusion (OR= 68.21, 95% CI 5.42-858.32, p<0.001) and need for ICU admission (OR= 8.10, 95% CI 5.18-12.65, p<0.001) were significant predictors of development of SSI. Duration and type of procedure were not significantly associated with development of SSI (Table 5).

Table 5. Adjusted odds ratio of factors predictive of development of SSI

4.4 Bacterial species and antibiotic sensitivity pattern of bacterial culture isolates

Variable	Adjusted OR (95% CI)	P-value
Sex	5.52 (1.15-26.65)	***p=0.033***
Diabetes	9.72 (1.83-51.76)	***p=0.008***
BMI	1.31 (1.02-1.69)	***p=0.033***
Pre-op blood transfusion	68.21 (5.42-858.32)	***p<0.001***
ICU admission	8.10 (5.18-12.65)	***p<0.001***
Duration of procedure	1.00 (0.99-1.01)	*p=0.572*
Type of procedure	9.453 (0.48-22.45)	*p=0.793*

Out of the 18 patients who developed SSI, 10 culture was obtained. The other 8 were diagnosed as having SSI on basis of CDC clinical criteria. The commonest organism isolated was staphylococcus aureus (SA) (n=7 patients, 70%). SA was sensitive to oxacillin in 2 patients (28.6%) and clindamycin in only 1 patient (14.2%), but was sensitive to vancomycin in all cases. Other organisms isolated included klebsiella pneumoniae (resistant to ceftazidime), but sensitive to cefepime, ciprofloxacin, amikacin and meropemen), Acinetobacter baumanii (sensitive to ampicillin/sulbactam and meropemen) and Pseudomonas Aeroginosa Pseudomonas aeroginosa isolate was resistant to ceftriaxone, Amoxicillin clavulanate,clindamycin but was sensitive to ceftazidime, amikacin, piperacillin/tazobactm and Meropenem.

4. DISCUSSION

Surgical site infection is a major cause of post-operative morbidity among surgical patients, and is associated with prolonged periods of hospitalization hospital and increased treatment costs (Gillespie et al., 2021; Le et al., 2019). Prevention remains key in mitigating against associated adverse outcomes. Characterization of burden and accurate identification of risk factors for SSI are paramount in informing preventive strategies. The aim of the current study was to determine the prevalence of early SSI, risk factors for SSI, the bacterial species causing SSI and their antibiotic sensitivity patterns, following implant fixation in Orthopaedic patients undergoing surgery at KNH.

In this study, 18 patients (13.8%) developed SSI. This is within range of the 10.2%–20.6% incidence reported in a recent systematic literature review by the world health organization (WHO) on SSI in orthopaedic surgical procedures in low and middle income (LMICs) (WHO, 2018).Similar studies from LMIC the incidence for early SSI rate was 12.3% and 8.2% (Otieno, O.S., 2005, Afifi et al., 2021).This affirms that SSI still remains a significant problem in orthopaedic surgery SSI rate in LMIC are higher than the acceptable 1% SSI rates following clean surgeries(Macbeth et al., 2005).

Several risk factors for SSI were identified. Presence of diabetes mellitus (DM) and higher body mass index (BMI) were associated with higher risk of SSI, in keeping with previous reports in the literature (Martin et al., 2016; Zhang et al., 2015). This has been attributed to altered immunity, poor wound healing and impaired tissue perfusion in DM (Dryden et al., 2015; Rubin, 2006). Pre-operative blood transfusion requirement and need for post-operative ICU admission in patients who eventually developed SSI reflects higher injury severity, which has been reported to increase risk of SSI (Jamulitrat et al., 2002). Although majority of patients with SSI were males, female sex conferred a higher risk of SSI in the current study. This is contrary to evidence in literature in which male sex is generally considered a risk factor for SSI (Aghdassi et al., 2019; Offner et al., 1999). Subgroup analysis revealed higher BMI (24.58±2.97 vs 23.57±1.84, p=0.004) and higher prevalence of DM (22.7% vs 7.4% p=0.045) among females, providing plausible explanation of observed higher risk of SSI among females. Similarly, although intraoperative duration and type of surgical procedure has been reported to modify risk of SSI (Cheng et al., 2017), this trend was not observed in the current study. The average duration of hospital stay in the current was 6.5±5.9 days, although prolonged this was also comparable to a study (Rajput et al.) that had more than half the admitted patients develop SSI with an average duration of hospital stay for more than 2 weeks. The average duration of surgical operation in the current study was126.7± 38.2 minutes this was higher than the T time of 2hrs recommended by NNIS as the average operative time for long bone fixation. (see Appendix A). Despite the average prolonged durations of operation this was not reported to modify the risk of SSI.

Of note, microbiological profile and sensitivity analysis was only available for 10 patients (7.7%). In those with culture isolate results, staphylococcus aureus (SA) was the commonest organism isolated, which is in keeping with microbiological profiles of orthopaedic SSI reported in literature (Motififard et al., 2021; Tuon et al., 2019). Majority of isolates were resistant to commonly prescribed antibiotics such as oxacillin (n=5 patients, 71.4%) and clindamycin (n=6 patients, 85.7%), a concerning trend due to increased risk of treatment failure and further progression of infection cascade. All SA isolates were however sensitive to vancomycin. *Pseudomonas aeroginosa* isolate was resistant to ceftriaxone, Amoxicillin clavulanate, clindamycin but was sensitive to Ceftazidime, Amikacin, Piperacillin/Tazobactm and Meropenem. Also of concern was the sensitivity pattern of *Acinetobacter baumanii,* which was resistant to 3rd generation cephalosporins, quionolones, aminoglycosides, and only sensitive to ampicillin sulbactam and meropenem. The microbiological profile of isolate observed in the current study provides further justification for need of routine establishment of sensitivity patterns of SSI isolates to guide treatment.

5. LIMITATIONS AND DELIMITATIONS

1. Loss to follow up of some patients during study period this was made up for by increasing the sample size.

7. CONCLUSION

The burden of surgical site infections (SSI) following orthopaedic surgery remains high. Diabetes mellitus (DM), higher body mass index (BMI), pre-operative blood transfusion and need for post-operative intensive care unit admission were identified as risk factors for SSI in this study population. Microbiological (culture and sensitivity) analysis appears to be underutilized. Culture isolates display a concerning trend of increased resistance to commonly prescribed antibiotics.

8. RECOMMENDATION

2. Increased SSI surveillance measures in Orthopaedic patients especially those with diabetes mellitus and obesity comorbidities undergoing implant fixation surgery.

2. Routine establishment of sensitivity patterns of SSI isolates to guide antimicrobial selection and develop institutional guidelines for antibiotic protocols for SSI prevention.

3. Further studies to look at the duration of surgery and length of hospital stay as risk factors for SSI.

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7. APPENDICES

Appendix A

The table shows the operative duration by NNIS denoted as T OR p75 in minutes (75th percentile time)

(Adopted from G.Leong. 2006)

Category of Surgical procedure	P75 (minutes)	T(h)
ORIF of long bone	130	2
Knee Arthroplasty	121.8	2
Hip Arthroplasty	130.8	2
Limb Amputation	85	1

Appendix B CDC criteria for Diagnosis of SSI

CRITERIA	Superficial incisional SSI Must meet the following criteria:
	Date of event occurs within 30 days after any NHSN operative procedure (where day 1 = the procedure date) AND involves only skin and subcutaneous tissue of the incision AND patient has at least one of the following: A. purulent drainage from the superficial incision. B. organism(s) identified from an aseptically-obtained specimen from the superficial incision or subcutaneous tissue by a culture or nonculture based microbiologic testing method which is performed for purposes of clinical diagnosis or treatment (for example, not Active Surveillance Culture/Testing (ASC/AST)). C. superficial incision that is deliberately opened by a surgeon, physician* or physician designee and culture or non-culture based testing of the superficial incision or subcutaneous tissue is not performed AND patient has at least one of the following signs or symptoms: localized pain or tenderness; localized swelling; erythema; or heat. D. diagnosis of a superficial incisional SSI by a physician* or physician designee.

Appendix C: Abbreviated Injury Scale (AIS) and ISS (Injury severity score).

AIS SCORE	INJURY
1	Minor
2	Moderate
3	Serious
4	Severe
5	Critical
6	Unsurvivable

ISS= sum of squares for the highest AIS grades in the three most severely injured ISS body regions.

ISS = $A^2 + B^2 + C^2$ where A, B, C are the AIS scores of the three most severely injured ISS body regions scores range from 1 to 75,a single score of 6 on any AIS region results in automatic score of 75

Appendix D: Consent form

Research topic

Prevalence, risk factors, and microbiological profile of early surgical site infection following orthopaedic implant surgery at kenyatta national hospital

English version

This form will ask for consent from patients who have long bone fractures and will undergo internal fixation surgery using Orthopaedic implants. The study cohorts will be followed up from the time of admission and for up to 30 days following implant fixation surgery. The outcomes of interest are prevalence, risk factors, and microbial profile of early surgical site infection.

Principle investigator Dr.Mohamed Ahmed Sheikh

Department Orthopaedics Unit Department of Surgery.

Supervisors Dr.Kirsteen Awori and Ezekiel Oburu.

This informed consent form has three parts:

Information sheet (to share information about the research with you)

Certificate of consent (for signatures if you agree to take part)

Statement by the researcher

Part 1 Information sheet

My name is Dr.Mohamed Ahmed Sheikh,I am a postgraduate Orthopaedics surgery student in the department of Orthopaedic Surgery at University of Nairobi school of Medicine i am carrying out a study titled "PREVALENCE, RISK FACTORS, AND MICROBIOLOGICAL PROFILE OF EARLY SURGICAL SITE INFECTION FOLLOWING ORTHOPAEDIC IMPLANT SURGERY AT KENYATTA NATIONAL HOSPITAL."

I am conducting a study on prevalence, risk factors, and microbiologic profile of early surgical site infection following Orthopaedic internal fixation surgery, a prospective cohort study at KNH.

Surgical site infections can have serious complications in Orthopaedics surgery. I am setting out to determine the prevalence, risk factors of SSI such as prolonged length of stay, prolonged operative time which are common in our setup. I would also determine the bacterial species that are causing these infections and antibiotic sensitivity patterns. I am inviting you to willingly take part in this study.

Benefits of the study

The study will enable us to know the incidence of SSI following internal fixation using implants, the risk factors associated with SSI in the study cohort and determine the causative organisms and antibiotic sensitivity patterns. This might decrease the incidence of SSI, by determining the commonest risk factors that are preventable and such as a reduction in length of stay in hospitals. The overall effect is the reduction of the cost of treatment and improvement in the lifestyle of patients.

Costs and potential harms

The patients who will consent to the study will not have any risks for participating in the study. The Study involves using a pretested questionnaire to collect data on duration of hospital stay, length of operative duration, reviewing patients' surgical sites for signs of surgical site infection, and collection of pus swabs if there is any discharge. There will be no extra cost incurred by the patient for participating in the study. There will be no financial grants to the participants.

Your obligations

If you agree to participate in this study the following will happen:

During surgery, operative data such as the length of operative duration, Surgical Antibiotic, prophylaxis will be recorded. while in the postoperative period the wounds will be monitored for signs of development of surgical site infection and any discharge from the surgical site will be taken for microscopy culture and sensitivity. The surgical sites will be inspected on postoperative day 3, day8, and day 30. Patients will be followed up for a duration of 30 days postoperatively. If you are found to have an infection at any point in the study, you will receive the standard treatment and care.

Your treatment for the injury you have will continue as planned and will not be affected by your participation in the study.

Confidentiality

All the information gathered will be taken in confidence and no one will see it except my assistant, my supervisors and I, all who are duty-bound to ensure confidentiality.

The patient's name or identity will not appear in any research document. The information about the patient will be identified by a unique research number and only the researchers can relate the number to you/your patient as a person. Other than for (William et al., 1998) above, your information will only be used for this study and will not be shared with anyone else unless authorized by the Kenyatta National Hospital/University of Nairobi - Ethics and Research Committee (KNH/UoN-ERC).

Study Credibility and Legitimacy

My two supervisors approved this study. It was appraised and approved by the Chairman of the Department of Orthopaedic Surgery, School of Medicine at the University of Nairobi. It was then submitted to KNH/UoN-ERC, which reviewed and approved it to be done for a duration of four months. KNH/UoN-ERC is the regulatory body in the hospital whose work is to make sure research process is safe for the participants and that you are protected from harm.

Whom to Contact

You can ask questions or seek clarifications about the study any time you wish to. If need be, you may also talk to anyone you are comfortable with about the research before deciding.

If you have any query about the research you want addressed by another person other than the researchers, please feel free to contact the following who will address your concerns:

Secretary, Kenyatta National Hospital/University of Nairobi Ethics and Research Committee, College of Health Sciences

P.O. Box 19676-00202 Nairobi

Telephone: +254202726300-9 Ext 44355

Email: uonknh_erc@uonbi.ac.ke

DR. KIRSTEEN AWORI

Senior Lecturer, Department of Human

Anatomy; and Consultant Orthopaedics and Spine Surgeon, Kenyatta National Hospital, Nairobi Kenya.

Email: kawori@uonbi.ac.ke

Po box 30197 00100 Nairobi Kenya.

3. DR. EZEKIEL OBURU

Lecturer Department of Orthopedics College of health sciences University of Nairobi and Consultant Orthopedics Surgeon Kenyatta National Hospital,

TEL 0708728060

Email oburue@gmail.com

PO BOX 30197 00100 Nairobi Kenya.

4. Principal researcher

Dr.Mohamed Ahmed Sheikh

Resident Orthopaedics Surgery

Email moahabos@gmail.com

Tel 0726916792

Part II: Consent Certificate (confidential once signed) Study Number _______.
I... freely give consent to take part in the study conducted by Dr. Mohamed Ahmed Sheikh, the nature of which has been explained to me by him/his research assistant. I have been informed and have understood that my participation is voluntary and understand that I am free to withdraw from it any time I wish and this will not in any way alter the care given to me/my patient. The results of the study may or may not benefit me/my patient directly but may benefit similar future patients. Furthermore, it will help medical professionals to better understand "PREVALENCE, RISK FACTORS, AND MICROBIOLOGICAL PROFILE OF EARLY SURGICAL SITE INFECTION FOLLOWING ORTHOPAEDIC IMPLANT SURGERY AT KENYATTA NATIONAL HOSPITAL"

SIGNED CONSENT………………………………………… a

(Patient/Kin)

Date..

Thumb print of participant if Unable to sign due to illiteracy

DD/MM/YY

Statement by a witness if participant is illiterate

I have witnessed the accurate reading of the consent form to the participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Name of witness…………………………………………………………………

Signature of witness…………………………………………………………….

Date…..

Part III: Statement by the researcher

I have clearly read out the information sheet to the participant, and to the best of my ability made sure that the participant understood the following:

All information gathered will be treated with confidentiality.

Refusal to participate or withdrawal from the study will not compromise the quality of care and treatment given to the patient.

The results of this study might be published in a reputable journal to enhance the knowledge of the "PREVALENCE, RISK FACTORS, AND MICROBIOLOGICAL PROFILE OF EARLY SURGICAL SITE INFECTION FOLLOWING ORTHOPAEDIC IMPLANT SURGERY AT KENYATTA NATIONAL HOSPITAL "

In addition, I confirm that the participant was given opportunity to seek clarification about his concerns in the study, and all the queries clarified to the best of my ability.

I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this Informed Consent Form has been provided to the participant and duly signed by the participant.

Name of researcher taking consent……………………………………………………

Signature of researcher taking the consent……………………………………………

Date……………………………………………………………………………………

Appendix E

FOMU LA IDHINI

MADA YA UTAFITI: KUENEA, MAMBO YA HATARI, NA WASIFU WA MICROBIOLOJIA WA MAAMBUKIZI YA ENEO LA UPASUAJI MAPEMA KUFUATIA UPASUAJI WA KIPANDE CHA MIFUPA KATIKA HOSPITALI YA TAIFA YA KENYATTA.

TAFSIRI YA KIWAHILI

Fomu hii itaomba idhini kutoka kwa wagonjwa ambao wamevunjika mifupa kwa muda mrefu na watafanyiwa upasuaji wa kurekebisha ndani kwa kutumia vipandikizi vya Mifupa. Vikundi vya utafiti vitafuatiliwa kuanzia wakati wa kuandikishwa na kwa hadi siku 30 baada ya upasuaji wa kurekebisha vipandikizi. Matokeo ya manufaa ni kuenea, sababu za hatari, na wasifu wa microbial wa maambukizi ya mapema ya tovuti ya upasuaji.

Mtafiti mkuu Dkt.Mohamed Ahmed Sheikh

Wahadhiri wasimamizi Dkt. Kirsteen Awori na Dkt.Ezekeil Oburu

Wote wa kitengo cha upasuaji wa mifupa katika Chuo Kikuu cha Nairobi na hospitali kuu ya Kenyatta.

Makubaliano haya yana sehemu tatu:

Maelezo kuhusu utafiti huu.

Cheti cha Kibali (kitakacho tiwa sahihi na wahusika wanaokubali kujumuishwa utafitini)

Ithibati ya mtafiti

Sehemu ya kwanza: Maelezo

Utangulizi

Jina langu ni Dr.Mohamed Ahmed Sheikh, mimi ni mwanafunzi wa uzamili wa Upasuaji wa Mifupa katika idara ya Upasuaji wa Mifupa katika Chuo Kikuu cha Nairobi shule ya Tiba ninafanya utafiti unaoitwa " KUENEA, MAMBO YA HATARI, NA WASIFU WA MICROBIOLOJIA WA MAAMBUKIZI YA ENEO LA UPASUAJI MAPEMA KUFUATIA UPASUAJI WA KIPANDE CHA MIFUPA KATIKA HOSPITALI YA TAIFA YA KENYATTA.”

Ninafanya utafiti kuhusu kuenea, mambo ya hatari, na wasifu wa microbiologic wa maambukizo ya mapema ya tovuti ya upasuaji kufuatia upasuaji wa kurekebisha ndani wa Mifupa, utafiti unaotarajiwa wa kundi katika KNH.

Maambukizi ya tovuti ya upasuaji yanaweza kuwa na matatizo makubwa katika upasuaji wa Orthopediki. Ninakusudia kubainisha kuenea, sababu za hatari za SSI kama vile muda mrefu wa kukaa, muda mrefu wa operesheni ambao ni kawaida katika usanidi wetu. Ningeamua pia spishi za bakteria zinazosababisha maambukizo haya na mifumo ya unyeti wa viua vijasumu.

Faida ya Utafiti huu

Utafiti utatuwezesha kujua matukio ya SSI kufuatia urekebishaji wa ndani kwa kutumia vipandikizi, vipengele vya hatari vinavyohusishwa na SSI katika kundi la utafiti na kubainisha viini vya sababu na mifumo ya unyeti wa viua vijasumu. Hii inaweza kupunguza matukio ya SSI, kwa kubainisha sababu za hatari zinazoweza kuzuilika na kama vile kupunguza muda wa kukaa hospitalini. Athari ya jumla ni kupunguzwa kwa gharama ya matibabu na uboreshaji wa mtindo wa maisha wa wagonjwa.

Gharama na Madhara za Utafiti

Wagonjwa ambao watakubali utafiti hawatakuwa na hatari zozote za kushiriki katika utafiti. Utafiti unahusisha kutumia dodoso lililojaribiwa ili kukusanya data kuhusu muda wa kukaa hospitalini, urefu wa muda wa upasuaji, kukagua maeneo ya wagonjwa ya upasuaji kwa dalili za maambukizo ya tovuti ya upasuaji, na ukusanyaji wa usufi wa usaha ikiwa kuna usaha wowote. Hakutakuwa na gharama ya ziada itakayotumiwa na mgonjwa kwa kushiriki katika utafiti. Hakutakuwa na ruzuku za kifedha kwa washiriki.

Jukumu Lako Katika Utafiti

Ukikubali kushiriki katika utafiti huu yafuatayo yatafanyika:

Wakati wa upasuaji, data ya upasuaji kama vile urefu wa muda wa operesheni, Antibiotic ya Upasuaji, prophylaxis itarekodiwa. wakati katika kipindi cha baada ya kazi majeraha yatafuatiliwa kwa ishara za maendeleo ya maambukizi ya tovuti ya upasuaji na kutokwa yoyote kutoka kwenye tovuti ya upasuaji itachukuliwa kwa utamaduni wa microscopy na unyeti. Maeneo ya upasuaji yatakaguliwa siku ya 3, siku ya 8, na siku ya 30 baada ya upasuaji. Wagonjwa watafuatiliwa kwa muda wa siku 30 baada ya upasuaji. Iwapo utapatikana kuwa na maambukizi wakati wowote katika utafiti, utapokea matibabu na utunzaji wa kawaida.

Matibabu yako ya jeraha ulilonalo yataendelea kama ilivyopangwa na hayataathiriwa na ushiriki wako katika utafiti.

Faragha ya Habari za Mhusika

Taarifa zote zitakazokusanywa zitachukuliwa kwa siri na hakuna atakayeziona isipokuwa msaidizi wangu, wasimamizi wangu na mimi, wote ambao tuna wajibu wa kuhakikisha usiri.

Jina au utambulisho wa mgonjwa hautaonekana katika hati yoyote ya utafiti. Taarifa kuhusu mgonjwa itatambuliwa kwa nambari ya kipekee ya utafiti na ni watafiti pekee wanaoweza kuhusisha nambari hiyo na wewe/mgonjwa wako kama mtu. Kando na (William et al., 1998) hapo juu, maelezo yako yatatumika kwa utafiti huu pekee na hayatashirikiwa na mtu mwingine yeyote isipokuwa kama yameidhinishwa na Hospitali ya Kitaifa ya Kenyatta/Chuo Kikuu cha Nairobi - Kamati ya Maadili na Utafiti (KNH/UoN-ERC).

Uhalali wa Utafiti huu

Wasimamizi wangu wawili waliidhinisha utafiti huu. Ilitathminiwa na kuidhinishwa na Mwenyekiti wa Idara ya Upasuaji wa Mifupa, Shule ya Tiba katika Chuo Kikuu cha Nairobi. Kisha iliwasilishwa kwa KNH/UoN-ERC, ambayo ilikagua na kuidhinisha ifanywe kwa muda wa miezi minne. KNH/UoN-ERC ndilo shirika la udhibiti katika hospitali ambalo kazi yake ni kuhakikisha kuwa mchakato wa utafiti uko salama kwa washiriki na kwamba unalindwa dhidi ya madhara.

Jukwa la Malalamishi na Habari Zaidi

Waweza kutuuliza maswali yoyote wakati wowote au umuulize yeyote utakaye kuhusu mchakato wa utafiti huu kabla au hata baada ya kukubali kuhusishwa.

Iwapo una swali lolote kuhusu utafiti huu ambao waona heri lishughulikiwe na mtu mwingine isipokuwa watafiti, waweza kuwasiliana na wafuatao ambao wako tayari kuushughulikia ipasavyo:

1. Katibu, Kenyatta National Hospital/University of Nairobi Ethics and Research Committee, College of Health Sciences

Anuani ya posta 19676-00202 Nairobi

Nambari ya simu: +254202726300-9 Ext 44355

Barua pepe: uonknh_erc@uonbi.ac.ke

Wahadhiri Wasimamizi Kutoka Chuo Kikuu cha Nairobi:

Dkt.Kirsteen Awori

Mhadhiri Mkuu, Idara ya Binadamu Anatomia; na Daktari Mshauri wa Mifupa na Upasuaji wa Mgongo, Hospitali ya Kitaifa ya Kenyatta, Nairobi Kenya.

Barua pepe: kawori@uonbi.ac.ke

Po box 30197 00100 Nairobi Kenya.

Dkt Ezekiel Oburu

Mhadhiri Idara ya Mifupa Chuo cha Sayansi ya Afya Chuo Kikuu cha Nairobi na Daktari Mshauri wa Upasuaji wa Mifupa katika Hospitali ya Kitaifa ya Kenyatta, Rununu 0708728060

Barua pepe oburue@gmail.com

PO BOX 30197 00100 Nairobi Kenya.

Mtafiti mkuu

Dk.Mohamed Ahmed Sheikh

Upasuaji wa Mifupa ya Mkazi

Barua pepe moahabos@gmail.com

Simu 0726916792

Sehemu ya Pili: Cheti cha Kibali (siri baada ya kutiwa sahihi) Nambari *Maalum*_______Mimi……………………………………………….............................ninakubali kwa hiari kuhusishwa kwa utafiti unaoendelezwa na Dkt. Mohamed Ahmed Sheikh kuambatana na maelezo yeye mwenyewe/ msaidizi wake amenipa. Ninaelewa kwamba nimehusishwa kwa hiari na kwamba niko huru kujiondoa wakati wowote nitakao hata bila sababu, na hii haitaathiri kwa namna yoyote matibabu ipasayo. Aidha naelewa kwamba matokeo ya utafiti huu huenda usi nifaidi binafsi lakini huenda ukawa wa manufaa siku zijazo kwa waathiriwa wa moto kama nilivyo. Kuna uwezekano utafiti huu utaongeza maarifa kwa taaluma ya utabibu kuhusu “PREVALENCE, RISK FACTORS, AND MICROBIOLOGICAL PROFILE OF EARLY SURGICAL SITE INFECTION FOLLOWING ORTHOPAEDIC IMPLANT SURGERY AT KENYATTA NATIONAL HOSPITAL.”

SAHIHI (KIBALI HALISI) ……………………………………

(Mgonjwa/jamaa)

Tarehe...

Siku/mwezi/mwaka

Chapa cha kidole gumba cha kushoto kwa wasio na elimu

ya kusoma na kuandika

Taarifa ya shahidi ya makubaliano na mhusika asiyejua kusoma

Nimeshuhudia mgonjwa akisomewa kwa njia inayoeleweka kwa rahisi, naye akapewa fursa nzuri ya kuulaza maswali. Nina dhibitisha mhusika alipeana kibali kwa hiari yake mwenyewe.

Jina la shahidi..................................…………………………………………………

Sahihi la shahidi..................................…………………………………………….

Tarehe...…………………………………………

Siku/mwezi/mwaka

Sehemu ya tatu: Taarifa ya Mtafiti

Nimesomea mhusika na kadiri ya uwezo wangu kumuelewesha yafuatayo:

Habari zozote zitokazo kwake zitawekwa siri.

Kukataa kupeana kibali cha kuhusishwa kwa utafiti huu haitaathiri matibabu anayostahili.

Matokeo ya utafiti huu kwa jumla utachapishwa katika jarida la kisayansi au utabibu ama upasuaji kuweza kuchangia maarifa ya “prevalence, risk factors, and microbiological profile of early surgical site infection following orthopaedic implant surgery at kenyatta national hospital.”

Nimehakikisha kwamba mhusika amepewa fursa kamili ya kuuliza maswali kuhusu kuhusika kwake kwa utafiti huu na kwamba kwa kadiri ya uwezo wangu nimemuelewesha ipasavyo.

Ninahakiki kwamba mhusika hajalazimishwa kupeana kibali kuhusika kwenye utafiti huu bali amekubali kwa hiari.

Nakala ya kibali hiki kimewasilishwa kwa mhusika naye akatia sahihi ipasayvo.

Jina la mtafiti aliyepewa kibali cha mhusika
………………………………………………………

Sahihi ya mtafiti mhusika
....………………………………………………

Tarehe………………………………………………………………………………

Appendix F: Data collection sheet

Patient Data

1. Study number ………………

2. Age in years ……………….

3. Sex M ….F……..

4. Are there any Comorbidities present? Tick appropriately

NO………………………

If yes (fill appropriately)

Diabetes…………………………………if yes FBS preoperatively……………

BMI…………………………………….

Chronic medication steroid use……………..

5. Tick Appropriately Fracture pattern

simple………. Or Comminuted……………..

Closed fracture pattern………..

Open fracture Gustilo I fractures only……………………………..

6. By using the Abbreviated Injury Scale (AIS) and ISS (Injury severity score).

AIS SCORE	INJURY
1	Minor
2	Moderate
3	Serious
4	Severe
5	Critical
6	Unsurvivable

HEAD……………………………………………………………………………

CHEST…………………………………………………………………………..

ABDOMEN……………………………………………………………………….

PELVIS……………………………………………………………………………………….

The ISS (Injury Severity Score) SCORE……………………………………………………

7. Date of admission………………………………………………………………………

Date of operation……………………………………………………………………….

Length of pre-operative hospital stay (Wards)…………………………………………

Length of post-operative hospital stay (wards)…………………………………………

ii) ICU admission YES …………NO………..DURATION ……………

iii) Total duration of hospital stay…………………………………………………….

8. Operation Data

Prophylactic antibiotics administered

Yes………or NO……

IF YES

Which Antibiotic……………………………………………

Dosage………………………………………………

Time of administration within I hour prior to incision…………………..

Other ……….Specify ……………………………

Was a repeat dose of the antibiotic given………………………………

ASA Score………………………………………………….

Wound Class ……………………………………………….

Intraoperative duration from cutting time to closing time………………………

NNIS risk index score…………………………………………………………..

Estimated blood loss amount……………………………………………..

ii) Blood transfusion…………………………………………………………

Preoperative transfusion ………. Yes…… amount………………..NO…..

Intraoperative transfusion……………YES……amount (pints)………NO……

Postoperative transfusion…………..yes………amount (pints) ……NO…….

Type of blood transfused…….Allogeneic PRBC …….. Or Allogeneic whole blood…………

iii) Surgical procedures (ORIF)

Plating……………………..

Nailing………………………

DHS…………………………

TBW…………………………

Other Surgical Operations

Abdominal laparotomy……………………………..

Other surgical procedures……………………………

9. Wound assessment using CDC Criteria on postoperative days 3, day 8 and day 30.

Upon review in the post op days 3 and assessment for SSI

Date of SSI diagnosis…………

Presence of purulent drainage from the superficial incision…YES………….NO…………

IF YES, organism(s) identified from an aseptically-obtained specimen from the superficial incision or subcutaneous tissue by a culture and antibiotic sensitivity pattern

………………………………………………………………………………………………
…….

Diagnosis by Surgeon, physician or physician designee…/ Clinical diagnosis

Superficial incision that is deliberately opened by a surgeon, physician or physician designee and culture AND patient has at least one of the following signs or symptoms:

Localized pain or tenderness…yes……….NO…….

Localized swelling; ………………Yes…………….NO…..

Erythema; or heat. ………………YES …………NO…..

Upon review in the post op days 8 and assessment for SSI

Date of SSI diagnosis…………

Presence of purulent drainage from the superficial incision…YES………….NO…………

IF YES, organism(s) identified from an aseptically-obtained specimen from the superficial incision or subcutaneous tissue by a culture and antibiotic sensitivity pattern

…………………………………………………………………………….

Diagnosis by Surgeon, physician or physician designee…/ Clinical diagnosis

Superficial incision that is deliberately opened by a surgeon, physician or physician designee and culture AND patient has at least one of the following signs or symptoms:

Localized pain or tenderness…yes……….NO…….

Localized swelling; ………………Yes…………….NO…..

Erythema; or heat. ………………YES …………NO…..

Upon review in the post op days 30 and assessment for SSI

Date of SSI diagnosis…………

Presence of purulent drainage from the superficial incision…YES………….NO…………

IF YES, organism(s) identified from an aseptically-obtained specimen from the superficial incision or subcutaneous tissue by a culture and antibiotic sensitivity pattern………………………………….

………………………………………………………………………………………………….

Diagnosis by Surgeon, physician or physician designee…/ Clinical diagnosis

Superficial incision that is deliberately opened by a surgeon, physician or physician designee and culture AND patient has at least one of the following signs or symptoms:

Localized pain or tenderness…yes……….NO…….

Localized swelling; ………………Yes…………….NO…..

Erythema; or heat. ………………YES …………NO…..

PLAGARISM REPORT

...EVALENCE, RISK FACTORS, AND MICROBIOLOGICAL PROFILE ...F EARLY SURGICAL SITE INFECTION FOLLOWING ...RTHOPAEDIC IMPLANT SURGERY AT KENYATTA NATIONAL ...OSPITAL

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