RATE, PREDICTORS AND BACTERIAL ETIOLOGY OF SURGICAL SITE INFECTION AMONG PATIENTS UNDERGOING OPEN UROLOGICAL SURGERY AT MNH, DAR ES SALAAM, TANZANIA

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By

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CERTIFICATION

The Undersigned certifies that, he has read and hereby recommend for acceptance by Muhimbili University of Health and Allied Sciences a dissertation entitled: **"*Rate, predictors and bacterial etiology of surgical site infection among patients undergoing open urological surgery at MNH, Dar es Salaam, Tanzania*"** 'Submitted in partial fulfillment of requirement for degree of Master of Medicine in Urology of Muhimbili University of Health and Allied Sciences'

_____

Prof C. Yongolo

Supervisor

_____

Date

And

_____

Dr. Joel Manyahi MD, MMed (Microbiology)

_____

Date

DECLARATION AND COPYRIGHT

I, **Victor Patrick Sensa** declare that this **dissertation** is my own original work and that it has not been presented and will not be presented to any other University for similar or any other degree award.

Signature _____ Date _____

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DEDICATION

This dissertation is dedicated to my best friend, the love of my life Mgesi, and our children Brinnie, Brittlynn, Brighton and Brayden for their tolerance during my absence.

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ACRONYMS

AIDS – Acquired Immunodeficiency Syndrome

BMC – Bugando Medical Centre

CDC – Center for Disease Control

CNS – Coagulase Negative *Staphylococus aureus.*

CPL - Central Pathological laboratory

ESBL – Extended Spectrum beta-lactamase

HAIs – Healthcare Associated Infections

HIV – Human Immunodeficiency Virus

MDR – Multidrug resistant

MNH – Muhimbili National Hospital

MOHSW – Ministry of Health and Social Welfare

MRSA – Methicilin Resistant *S. Aureaus*

MUHAS – Muhimbili University of Health and Allied Sciences

NINSS – National Nosocomial Infection Surveillance Scheme

OPD – Out patient Department

SPSS – Statistical Package for the Social Science

SSIs – Surgical Site Infections

UK – United Kingdom

USA – United States of America

UTI - Urinary Tract Infection

ABSTRACT

INTRODUCTION

Surgical site infection (SSI) is among the common hospital associated infections in patients undergoing surgery. It is associated with increased length of hospitalization, morbidity as well as increased health care costs. At Muhimbili National Hospital (MNH) little is known on factors predicting the occurrence of SSI.

OBJECTIVES

To determine rate, predictors and bacteria etiology of SSI among patients undergoing open urological surgery at MNH.

MATERIALS AND METHODS

This was a prospective observational study conducted between August 2015 and March 2016, 8 months, at urological surgical ward, MNH. All patients who underwent open urological surgery were consecutively enrolled and followed for a period of 30 days. Prior to surgery, urine sample for culture were collected. On each follow up surgical site was inspected for signs of SSI. Wound swabs were then collected in case of discharge and sent to Central Pathology Laboratory (CPL) microbiology section for culture and sensitivity.

Structured questionnaires were used to record socio-demographic and clinical information from patients and clinical case files. Data were entered and analyzed using Statistical Package for the Social Sciences (SPSS). Bivariate and multivariate analyses were used to find association between dependent and independent variables.

FINDINGS

Out of 182, 40 patients (22%) had surgical site infection. Of 152 patients of whose urine sample for culture were performed 43 (28.3%) had urinary tract infection. On univariate and multivariate analysis, urinary tract infection predicted the occurrence of SSI. Contaminated wound was also a predictor of SSI in both univariate and multivariate analysis. Other factors, shaving more than 30 minutes prior to incision, presence of urinary catheter and clean contaminated surgery were predictors of SSI in univariate analysis but were not independently associated with

SSI on multivariate analysis. Shaving within 30 minutes was an independently protective predictor of occurrence of SSI (**OR** 0.26; 95%**CI** 0.088-0.79**; p-value**<0.05)

E. coli was the commonest bacteria isolated in both UTI and SSI and the most resistant to antibiotics. Other Gram negative bacteria were also involved while *Staph. aureus* dominated the Gram positive isolates. Some isolates occur in both UTI the same patients. Ciprofloxacin was more sensitive to most of the pathogens.

CONCLUSION

Pre-operative UTI and contaminated wound are the two most important predictors of SSI. *E. coli* being commonest pathogens isolated in both UTI and SSI. Most of the involved pathogens were resistant to most of the routine antibiotics.

RECOMMENDATIONS

Education to health professionals on how to care surgical patients is important. Patients should be screened for UTI before any surgical procedure and any SSI should be treated with appropriate antibiotics after culture and sensitivity is done.

1.0 INTRODUCTION

Before the mid-19th century, surgical patients commonly developed postoperative "irritative fever," followed by purulent drainage from their incisions, overwhelming sepsis, and often death. It was not until the late 1860s, after Joseph Lister introduced the principles of antisepsis that postoperative infectious morbidity decreased substantially [1].

Surgical site infection (SSI) is one of the most common healthcare-associated infections (HAIs) and is a major cause of increased length of hospital stay and mortality[2]. Surgical Site Infection can be classified into incisional (superficial and deep) or organ/space occupying infections.

Superficial SSI is frequently diagnosed at the Out Patient Department, OPD, and does not require re-hospitalization, however invasive SSI's are serious requiring re-hospitalization. SSIs result in increased mortality, readmission rate, length of hospital stay and cost for patients and families, and hospitals in terms of bed occupancy

Studies done revealed that anesthetic risk scores, wound class and duration of surgery were significantly associated with SSI. SSIs are the second-most-common type of nosocomial infections, accounting for 20% to 25% of all[3], such studies have been done in many hospitals worldwide[4].

The guidelines of USA Center for Disease Control and Prevention concerning intra-operative microbial contamination and SSI classified surgical procedures into four categories[5]: clean (Class I), clean-contaminated (Class II), contaminated (Class III), and dirty and infected (Class IV). The incidence of infection, morbidity and mortality increases from clean to dirty. The risk of infection is greater in all categories if surgery is performed as an emergency.

Clean operations have uninfected operative wounds without any preoperative infection in the respiratory tract, gastrointestinal tract, or urinary tract. Clean-

contaminated operations are defined as procedures directly to the respiratory tract, gastrointestinal tract or urinary tract, or operations with surgical procedures to those organs which are well controlled. Contaminated operations have open, fresh or accidental wounds. Dirty and infected operations are surgical procedures in highly contaminated sites, such as bacterial infective sites and old traumatic wounds[7].

However, not all urological surgeries can be classified into these categories because of their peculiarities. Using these categories to classify urological surgeries, radical nephrectomy, open adrenalectomy, and intra-scrotal surgeries are categorized as clean operations. Radical prostatectomy, pyeloplasty, and partial cystectomy are categorized as clean-contaminated operations. Ileal bladder should be categorized as a contaminated operation. The removal of a perinephric abscess and repairs for an opened traumatic urinary tract should be categorized as a dirty and infected operation[7].

2.0 LITERATURE REVIEW

2.1 Body's response to injury

The body responds to trauma with local and systemic reactions that attempt to contain and heal the tissue damage, and to protect the body while it is injured. The response is remarkably similar whether the trauma is a fracture, burn, sepsis or a planned surgical operation, and the extent of the response is usually proportional to the severity of the trauma. The response, with neuroendocrine and inflammatory cytokine components, increases the metabolic rate, mobilizes carbohydrate, protein and fat stores, conserves salt and water and diverts blood preferentially to vital organs. It also stimulates important protective mechanisms such as the immunological and blood clotting systems[8].

However, the overall result is immunosuppression leading to increased vulnerability to infection. The interplay between the many inflammatory mediators and cellular responses is very complex. Major surgery has other inevitable consequences which predispose to postoperative morbidity. With optimal perioperative management, however, their impact can be minimized[8].

2.2 Initiation of the response

Several noxious stimuli produce the response but they rarely occur alone, and multiple stimuli often produce greater effects than the sum of single responses. The response is modified by the severity of the stimulus, the patient's age, nutritional status, coexisting medical conditions, medication and if the trauma or operation has affected the function of any particular organ[8].

Recent trauma or sepsis will also modify the response to a subsequent surgical operation. Pain, tissue injury, infection, hypovolaemia and starvation play as major stimuli to initiate the response. Hypoxia, hypercarbia or pH changes, hypoglycaemia and hypothermia are important stimuli. Fear, anxiety and emotion also stimulate the sympathetic nervous system. Studies have shown improved recovery times with fewer infections when normothermia is maintained intraoperatively[8].

2.3 Wound Class Definition

Clean - Operations in which no inflammation is encountered and the respiratory, alimentary or genitourinary tracts are not entered. There is no break in aseptic operating theatre technique. ***Clean-contaminated*** -Operations in which the respiratory, alimentary or genitourinary tracts are entered but without significant spillage. ***Contaminated*** - Operations where acute inflammation (without pus) is encountered or where there is visible contamination of the wound. Examples include gross spillage from a hollow viscus during the operation or compound/open injuries operated on within four hours. ***Dirty*** – These are operations done in the presence of pus, where there is a previously perforated hollow viscous or compound/open injury more than four hours old[9].

2.4.1 Major and minor surgical site infections:

A major SSI is defined as a wound that either discharges significant quantities of pus spontaneously or needs a secondary procedure to drain it. The patient may have systemic signs such as tachycardia, pyrexia and a raised white count[9].

2.4.2 Minor wound infections is defined as a wound that may discharge pus or infected serous fluid but should not be associated with excessive discomfort, systemic signs or delay in discharge from hospital. The differentiation between major and minor and the definition of SSI is important in audit or trials of antibiotic prophylaxis and when comparing[9].

2.5 What is the source of the bacteraemia?

Organisms associated with SSIs vary with type of procedure and anatomic location of the operation. Coagulase negative *staphylococcus* (CNS), *enterococcus* species and *E coli* are the most frequently isolated pathogens. An increasing number of SSIs are caused by antimicrobial resistant pathogens and incidence of fungal SSIs has risen in part because of increasing numbers of patients with HIV/AIDS[9].

For most SSIs the source of the pathogen comes from the patient's skin, mucous membranes or bowel and rarely from another infected site in the body i.e.

endogenous sources. Exogenous sources of SSI pathogens are occasionally responsible e.g., organisms from members of surgical team, contaminated surfaces in the operating room, contaminated instruments, surgical gloves or other items used in surgery. Exogenous organisms are primarily aerobic staphylococci or streptococci species.

2.6 What influences the development of infection?

By the end of an operation bacteria and micro-organisms contaminate all surgical wounds but only a small number of patients develop clinical infection. Factors influencing the development of infection include; Number of inoculated bacteria at the wound site, type and virulence i.e. the ability of those bacteria to cause infection, host immune competence and external factors such as duration of surgery. Surgical skill and use of good technique can minimize the number of organisms entering the wound. The effectiveness of the inflammatory response depends on the patient's general health and lifestyle[9].

2.7 Surveillance for surgical site infection:

Accurate surveillance can only be achieved using trained, unbiased and blinded assessors. The US Centers for Disease Control (CDC) definition insists on a 30-day follow-up period for non-prosthetic surgery and 1 year after implanted hip and knee surgery[10].

While advances have been made in infection control practices, including improved operating room ventilation, sterilization methods, barriers, surgical technique, and availability of antimicrobial prophylaxis, SSIs remain a significant cause of morbidity, prolonged hospitalization, and death. SSI is also associated with a mortality rate of 3%, and 75% of SSI-associated deaths are directly attributable to the SSI[10].

A recent prevalence study done in USA found that SSIs were the most common healthcare-associated infection, accounting for 31% of all HAIs among

hospitalized patients[11]. In USA National Healthcare Safety Network data for 2006-2008 (16,147 SSIs following 849,659 operative procedures) showed an overall SSI rate of 1.9 Percent[12].

A study done in North America on surgical wound infection rate for clean contaminated and contaminated wound was found to be less than 10% and approximately 20% respectively when principles of surgery were adhered to[13]

Another study in urological department in Serbia showed that the incidence of SSI was 5.9% in average. The study evaluated the rate of SSI in clean wounds (5.0%), clean contaminated (11.2%) and contaminated wounds (20.7%) [14].

A study done in Japan showed that preoperative UTI was the most important risk factor for development of SSI following urological operations by 55%[15].

A study done in Montevideo Uruguay, showed that SSI occurred in 18% of patients who underwent prostatectomy, with gram negative bacteria being the only isolate that are the characteristics of urinary flora. In these patients 59% had had urethral catheter in-situ[16].

Surgical site infections (SSIs) have become a substantial cause of morbidity in Sub-Saharan Africa. In countries where resources are limited even basic lifesaving operations such as appendectomies, caesarean section and other laparotomies are associated with high infection rates and mortality[9].

A study done in Ibadan, Nigeria on a total of 212 cases, abdominal wound dehiscence showed that contaminated wounds were the most susceptible with an incidence of 19%[17]

SSI is the major cause of nosocomial infections in Tanzania that imposes substantial burdens on healthcare resources[18]. Recent studies reported increase of SSI ranging from 19.4% to 36.7 percent [19, 20, 21] being higher at Muhimbili National Hospital (MNH) compared to other referral hospitals.

At Muhimbili National Hospital in Tanzania, surgical wound infection rate has been increasing over time. Shija in his 1973 dissertation found a prevalence of 6%. This has doubled recently, whereby Wayi in 2000 while working on clean wounds found a prevalence of 12.3 percent[15]. Later, Ussiri et al while working on clean-contaminated and contaminated wounds found a SSI prevalence rate of 15.6 percent[22].

Another recent study done by Akoko et al at MNH found that surgical site infections rates in general surgery was 35.6% indicating that the rates of infections are still on the increase[23]. In this study bacteriological etiology including antibiotic sensitivity were not evaluated.

In most of these studies *Staphylococcus aureus* was reported to be a predominant pathogen followed by *Escherichia coli*, and *Klebsiella* species with varying antimicrobial susceptibility patterns. A study done at Bugando Medical Centre (BMC) reported resistance to ciprofloxacin for *E. coli*, *Klebsiella pneumonia* and *S. aureus* to be 86%, 80% and 54% respectively. Of the *E. coli* and *K. pneumonia* involved in SSI at Bugando Medical Centre 65% and 80% were ESBL producers, respectively[21].

Antibacterial drug resistance is also a problem in rural setting as shown in a study done in 2004 at a remote district hospital in Tanzania, that reported that more than 95% of *S. aureus* isolates were resistant to penicillin and only 1 (0.8%) was resistant to methicillin[24].

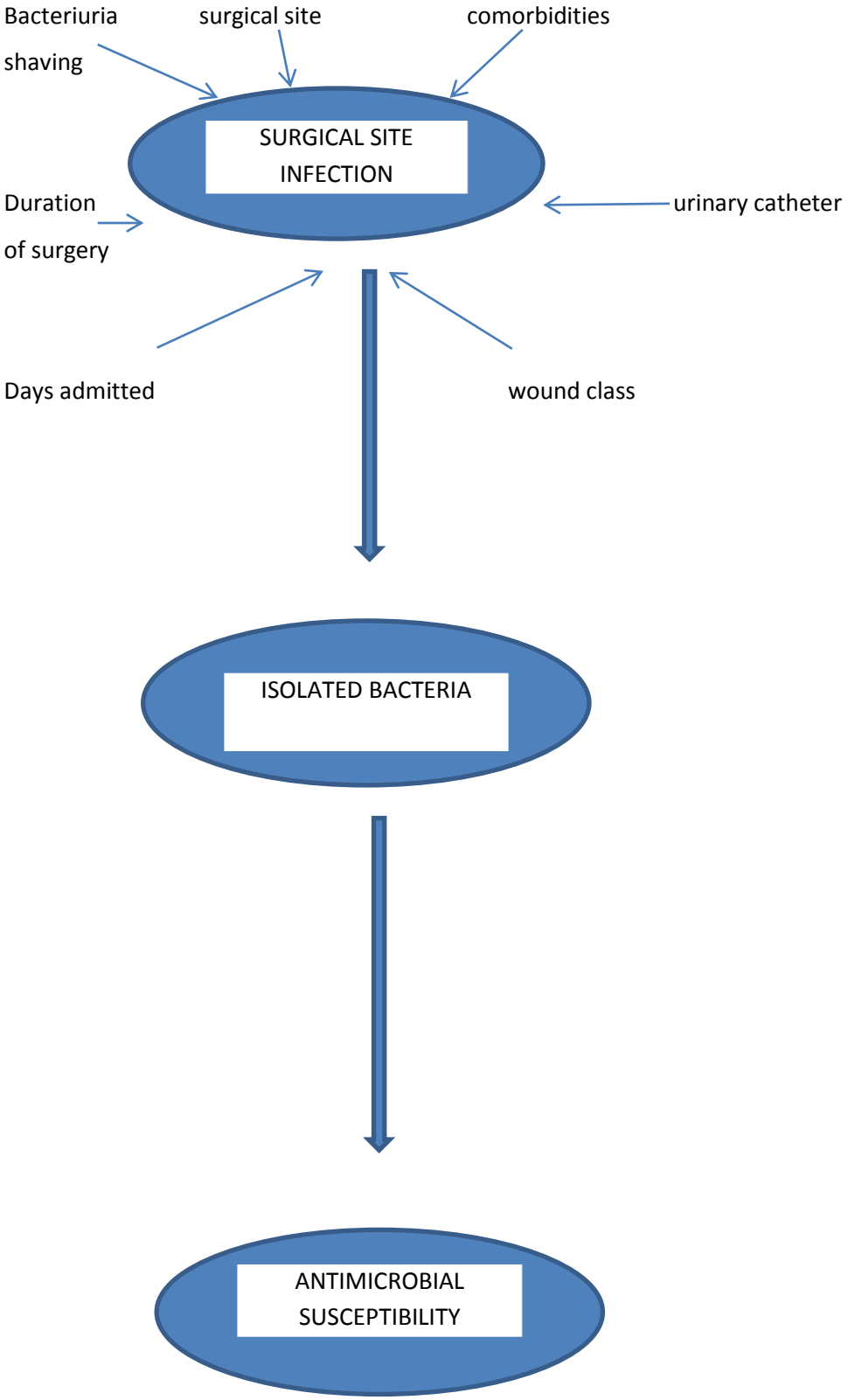
Another recent study from the similar geographical location (BMC) has revealed a significant increase of methicillin resistant *S. aureus* (MRSA) (18.8%) causing SSI[21].

Studies done in Tanzania in the past have shown persistently high levels of antimicrobial resistance in bacteria isolated from urine and bloodstream

infections[25, 26]. But, still there is limited data regarding the magnitude and pattern of antimicrobial resistance among pathogens causing SSI in urological patients.

Recently Manyahi et al found that a high proportion (63%) of the isolates causing SSIs at Muhimbili National Hospital which is a tertiary hospital were MDR, of which (90%) were resistant to more than four classes of antibiotics[27].

3.0 CONCEPTUAL FRAME WORK



4.0 PROBLEM OF STATEMENT

Surgical site infection has been documented in literature from developed and developing countries. They cause substantial morbidity and mortality, causing long hospital stay and estimated additional cost per patient. There was a need to do this determine the magnitude of the problem in our settings and help in planning of preventive measures to curb SSIs.

In Tanzania there are few studies that have been done to determine the prevalence and risk factors for surgical site infection. Most of the studies were done in General surgery and none has been documented in urology. This was intended to help surgical team avoid such risk factors

Studies to determine the microorganisms implicated and their sensitivity to antimicrobial were done in general surgery and not in urology. Though the wound class might be the same in Urological and general surgical procedures, yet, majority of the urological patients requiring surgery are already on indwelling catheter and hence have contaminated wounds and the type of microbial may differ significantly from those in general surgery due to exposure to urine.

From several studies, it has been shown that most of the isolated bacteria were resistant to the commonly prescribed antibiotics for prevention and treatment of SSIs. There was a need to find out the drug of choice that would have been sensitive to most of these pathogens.

5.0 RATIONALE OF THE STUDY

There were no data available on the rate of surgical site infections in urological surgery done at Muhimbili National Hospital and Tanzania in general. Data available only showed the prevalence and risk factors for SSI in general surgery

Microorganisms implicated in SSI in urological procedures had not been studied in our country. With regard to the type of operations we perform mostly clean contaminated, there was a chance for those other types of organism that could cause SSI.

Data on the microorganism sensitivity to antibiotics was not available. Hence this study was aimed at providing statistical information about the rate of surgical site infection, the implicated microorganism and possibly antibiotic sensitivity.

This would assist the physician and surgeons to prescribe the appropriate antibiotic that would be most sensitive to the pathogens responsible. Lastly, the study intended to aid in the change of policy in the prevention of SSI and appropriate management of such infections.

6.0 RESEARCH QUESTION

What is the surgical site infection rate in open urological procedures and bacteriological etiology? What are the predictors and the most sensitive antibiotics in such infection?

7.0 OBJECTIVES

7.1 Broad Objectives

To determine the magnitude, predictors and bacteria etiology of SSI among patients undergoing open urological surgery at MNH.

7.2 Specific Objectives

1. To determine the magnitude of surgical site infection in patients undergoing open urological surgery at MNH

2. To determine the prevalence of bacteriuria in patients undergoing open urological surgery at MNH

3. To determine the factors associated with SSI in open urological procedures at MNH

4. To find out the common bacteriological etiology in SSI in urological surgery at MNH

5. To determine the antibiotics sensitivity to bacteria isolates from urological SSI at MNH.

8.0 METHODOLOGY

8.1 Study design

Observational hospital based study was conducted which involved all patients who underwent open urological surgical procedures at MNH during the period of study from August 2015 to March 2016

8.2 Study area

The study was conducted at MNH, which is the national referral hospital receiving patients from district and regional hospitals within the country but in addition it serves as city hospital by receiving more patients from the three municipalities in the city and nearby district hospitals of Coast Region due its geographical location. The hospital is a teaching hospital for MUHAS students, both undergraduates and postgraduates located within Dar es Salaam city, which has a population of about 4.3 million people. The hospital bed capacity is 1500, and general surgical wards have 120 beds while urology unit has about 62 beds.

8.3 Study population

The study population included all patients who underwent urological surgical procedures at MNH within the period of study, involving male and female patients.

8.4 Inclusion

8.4.1 Inclusion criteria

All patients aged 2 years and above who underwent open urological procedures at MNH. Only patients who consented were included in the study.

8.4.2 Exclusion criteria

Patients who were HIV positive, malnourished, had malignancies and those with chronic illness.

8.5 Sampling

The study involved all urological patients who underwent open urological procedures at MNH.

8.5.1 Sample size

The sample size calculation formula for finite population was applied to calculate the minimum required sample size;

$$n = \frac{Nz^2pq}{d^2 (N-1) + z^2pq}$$

where N = size of population from observational pilot study for patients who underwent open urological surgeries at MNH, about 256 underwent open surgeries for a period of 8 months

n = sample space

d = margin of error (for this study I consider 3%)

q = 1-p

The proportion (p) of patients with surgical site infection in general surgery at MNH is 15.6%[22]

Therefore, from the above formula the required sample size is 176 patients

Adjusting for the non-response rate which is 10%, the minimum sample size will be 195 patients

8.6 Case definition

Superficial incision surgical site infection is an infection occurring within 30 days after operation involving only skin and subcutaneous tissue and one of the following should be present: purulent discharge, pain or tenderness, swelling, redness or heat.

Deep incisional SSI occur within 30 days after operation or up to 1 year if organ transplant was left in-situ, deep into the fascia and muscle with at least one of the following: purulent drainage, or deep incision spontaneously dehiscence or opened by surgeon deliberately, or an abscess

Organ/space SSI occurs within 30 days after operation or up to 1 year if organ transplant was left in-situ and infection should involve the organ or space and at

least one of the following: purulent drainage from a drain that is placed through a stab wound into the organ or space, organisms isolated; an abscess or other evidence of infection involving the organ/space.

8.7 Data collection and specimen processing

Structured standard questionnaires were used to obtain social-demographic and clinical data from patients and the patient's case notes. All patients were recruited on the day of surgery and were identified by hospital number, sex, age, ward and operating room records. For urinary tract infection predicting SSI, just prior to the procedure, urine and/or catheter tip for those who were catheterized (urinary tract system opened), were collected and sent to laboratory for both aerobic and anaerobic culture and sensitivity and their findings were recorded.

Administration of prophylaxis antibiotics (98% received combination of ceftriaxone and metronidazole while 2% of patients received gentamycin and metronidazole) and duration of each operation were also recorded. Surgical wounds were examined 48 hours after surgery, on the 5th, 8-10th day during suture removal and on the 30th day[23] and the findings (presence of purulent discharge, pain or tenderness, swelling, redness or heat) were recorded. Patients' and/or relatives' mobile numbers were recorded and they were used to remind patients to attend the hospital for checkup and their transport fair was compensated. Surgeon examined the wound to determine whether the patient had surgical site infection or not. For those who had had signs of SSI, Pus/or pus swabs were collected and sent to laboratory for culture and sensitivity and the results were recorded. All patients who were involved in the study had to sign an informed consent form. Pus or pus swabs and urine specimens were processed at Central Pathological laboratory at MNH as described by Murray et al[28].

8.8 Laboratory procedure

Gram's stain was performed from the first swab and the second pus swab was inoculated into blood agar (Oxoid, UK) and MacConkey agar (Oxoid, UK); and incubated aerobically at 37°C for 18–24 hours. Urine culture was performed according laboratory standard procedures as described by Murray et al[28],

significant urinary colonization was defined by finding of bacteriuria of $1x10^5$ ^{CFU}/mls and more.

8.9 Data analysis

Data indicating patient's Identification number of the patient, ward, preoperative urine examination, type of operation, existence of comorbidities e.g. Hypertension, patient catheterization, sterility in theatre, preoperative antibiotics, duration of surgery, wound status in the follow-up, type of antibiotics used in the treatment of SSI, pus swab culture results and sensitivity to antibiotics were entered in the computer using SPSS program and frequency distribution were used to determine the proportions. Data were subjected to cross tabulations to assist in drawing correlates and inferences on the variables. Odds ratio were calculated to test the strength of the association between the predictor variables. Analysis was done followed by the interpretation of results.

8.10 Ethical issues

The ethical clearance to conduct the study was obtained from MUHAS IRB. Permission was sought from the hospital ethical clearance committee before the study was carried out. Direct patient identifiers were not collected from patient's case notes, only such information as necessary to carry out the study was collected. Since my study is a prospective follow up, a hospital based one; all patients were required to provide a written informed consent for the study. Parents/guardian gave both informed consent and written consent for patients younger than 18 years of age and participate in the in the study.

9.0 RESULTS

A total of 212 patients underwent open urological surgery during the study period, 9 patients died post operatively and 21 patients were lost to follow up. Hence patients who were available for follow up were 182, and were followed up for a period of 30 days.

Table 1 shows socio-demographic characteristics of the study participants. Majority of the patients (25%) were aged between 54-71years and less than 17 years were the least. Males (79%) contributed most of the participants while nearly 46% had comorbidities (DM and hypertension). Almost 90% were non-smokers.

Table 1 Socio-demographic Characteristics of 182 patients who underwent open urological surgery

Variables	**Frequency (%)**	**Percentage**
Age group (years)		
≤ 17	27	14.9
18 - 35	29	15.9
36 - 53	39	21.4
54 - 71	47	25.8
> 71	40	22.0
TOTAL	**182**	**100**
Sex		
Male	144	79.1
Female	38	20.9
TOTAL	**182**	**100**
Comorbidities		
DM	6	3.3
Hypertension	50	27.5
DM + Hypertension	27	14.8
No comorbidities	99	54.4
TOTAL	**182**	**100**
Cigarette Smoking		
Yes	18	9.9
No	164	90.1
TOTAL	**182**	**100**

Table 2 shows clinical characteristics of patients who underwent open urological surgery at MNH with most patients (37.9%) were admitted one day prior to surgery. Nearly two third did not require shaving at the site of surgery with only 39% requiring urinary catheterization. About 44% of patients screened for bacteriuria pre operatively had had bacteria isolated. Type of wound encountered in most of these patients was clean contaminated by 69%

Table 2; Clinical characteristics of patients who underwent open urological surgery at MNH

Days admitted pre op		
1 day	69	37.9
2 days	47	25.8
3 days	16	8.8
>3 days	50	27.5
TOTAL	**182**	**100**
Shaving		
Within 30 minutes	38	20.9
More than 30 minutes	23	12.6
No need	121	66.5
TOTAL	**182**	**100**
Urinary catheter		
inserted	71	39.0
Not inserted	111	61.0
TOTAL	**182**	**100**
Preoperative bacteriuria		
Yes	44	28.9
No	108	71.1
TOTAL	**152**	**100**
Wound class		
clean	39	21.5
Clean contaminated	126	69.2
Contaminated	17	9.3
TOTAL	**182**	**100**
Duration of surgery (Minutes)		
≤ 90	55	30.2
>90	127	69.8
TOTAL	**182**	**100**

Prevalence of UTI in patients who underwent urological surgery (table 3)

Patients in age groups 36-53 and 54-71 had prevalence of UTI of 33.3 (**OR** 6.25, 95%**CI (**1.28-30.55)**, p-value** <0.05) and 31.9 (**OR** 5.86, 95%**CI (**1.23-28.04); **p-value** <0.05) respectively. On multivariate analysis only the age group of 36-53 years had an association with infection of the urinary tract(**OR**6.59;95%**CI** 1.2-36.21;**p-value**<0.05).

Presence of urethral catheter was strongly associated with urinary tract infection with OR 2.9 and when the causal-association of presence of catheter analyzed by multivariate logistic regression and UTI was statistically significant with OR 2.32, CI(1.07-5.03), p-value<0.05. Other factors such as sex, comorbidities and days admitted were not associated with urinary tract infection.

Table 3; Prevalence of urinary tract infection among patients who underwent open urological surgery

Variable	f	Prevalence	cOR(95%CI)	p-value	aOR (95%CI)	p-value
Age in years						
≤17	2	7.4	1		1	
18-35	3	10.3	1.44(0.22-9.37)	0.70	1.35(0.196-9.244)	0.76
36-53	13	33.3	6.25(1.28-30.55)	0.02	6.59(1.20-36.21)	0.03
54-71	15	31.9	5.86(1.23-28.04)	0.03	4.59(0.80-26.27)	0.87
>71	11	27.5	4.74(0.96-23.46)	0.56	2.88(0.51-16.39)	0.23
Sex						
Male	37	25.7	1.53(0.62-3.77)	0.354	1.67(0.57-4.86)	0.35
Female	7	18.4	1		1	
Comorbidities						
Diabetic	2	33.3	2.10(0.36-12.35)	0.410	2.26(0.27-18.72)	0.45
Hypertension	17	34.0	2.17(1.01-4.68)	0.049	1.26(0.49-3.29)	0.63
HT + DM	6	22.2	1.20(0.427-3.39)	0.727	1.02(0.29-3.62)	0.97
None	19	19.2	1		1	
Days admitted						
One day	19	27.5	1		1	
2 days	7	17.5	0.46(0.18-1.20)	0.114	0.395(0.14-1.15)	0.088
3 days	2	12.5	0.38(0.08-1.81)	0.223	0.252(0.045-1.41)	0.116
>3 days	16	32.0	1.24(0.56-2.74)	0.598	1.193(0.47-3.04)	0.712
Urinary cath.						
Inserted	26	36.6	2.90(1.49-6.00)	0.002	2.32(1.07-5.03)	0.033
Not inserted	18	16.2	1		1	

Predictors of SSI (Table 4)

Of 182 patients who underwent open urological surgery, 22% (40/182) developed SSI. Predictors for SSI were as follows:

Age

Age had no influence in causing SSI though most infections were encountered in patients with advanced age but the differences were not statistically significant.

Comorbidities

Out of 6 patients who had DM, 2 (33.3%) of them developed SSI. Also around 26% of patients who had HT developed SSI with almost the same rate (26.9%) of patient with both Diabetes and hypertension developing SSI. The differences observed were not statistically significant.

Cigarette smoking

In this study 18 (12.7%) patients were cigarette smokers with only 16.7% having SSI compared to 22.6% in patients who were nonsmokers though the difference observed was not statistically significant (p-value = 0.568).

Days admitted prior to surgery

There was no association between SSI and number of the days the patients spend before surgery.

Shaving

Among patients who underwent open surgery 61(33.5%) required shaving of the incision site before surgery. Some shaved more than 30 minutes before surgery while others were shaved on the operating table. Thirty eight patients were shaved within 30 minutes and had had SSI of 31.6% (p-value = 0.035). Those who were shaved 30 minutes or more, prior to surgery had 39.1% prediction of causing SSI (p-value = 0.012). Compared to patients who did not need to shave, shaving either within or more than 30 minutes had had statistically significant risk of causing SSI.

Urinary catheter

Urinary catheters were inserted in 73 patients and out of these, 33.8% developed SSI compared to 14.4% of patients who had no catheter in situ. There was a statistically significant association between presence of urinary catheter and SSI (p-value = 0.003).

Pre-operative bacteriuria

Among 152 patients who had had their urine cultured prior to surgery, 44 urine samples grew bacteria. Out of these 59.1% had SSI compared to 10.1 for those with no bacteriuria. On bivariate analysis, urinary tract infected predicted the occurrence of surgical site infection (cOR12.79; 95%CI5.66 – 28.94; p<0.05).

Wound class

Surgical site infection rate for clean contaminated and contaminated wounds were 23% (p-value = 0.027) and 53% (0.001) respectively. Contaminated wound was a strong predictor for SSI though the number of patients involved was small (only 17 patients).

Duration of Surgery

Majority (142 surgeries) of patients had had lengthy surgery more than 90 minutes. Out of these, 33.8% had SSI compared to those with less than 90 minutes duration but the difference was not statistically significant (p-value = 0.052).

Table 4: Predictors of SSI in patients who underwent open urological surgery at MNH from August 2015 to March 2016

Variable	Surgical Site Infection				
	Yes n (%)	No n (%)	cOR	95%CI	P value
Age In Years					
≤17	3(11.1)	24(88.9)	1		
18 – 35	9(31.0)	20(69.0)	2.087	0.466 – 9.346	0.336
36 – 53	8(20.5)	31(79.5)	2.065	0.494 – 8.626	0.320
54 – 71	13(27.7)	34(72.3)	3.056	0.785 – 11.915	0.107
>71	10(25.0)	30(75.0)	2.667	0.659 – 10.786	0.169
Cigarette smoking					
Yes	3(16.7)	15(83.3)	0.686	0.188 – 2.500	0.568
No	37(22.6)	127(77.4)	1		
Comorbidities					
DM	2(33.3)	4(66.7)	2.25	0.38 – 13.24	0.37
Hypertension	13(25.5)	38(74.5)	1.54	0.68 – 3.46	0.25
DM + Hypertension	7(26.9)	19(73.1)	1.66	0.61 – 4.53	0.33
No comorbidities	18(18.2)	81(81.8)	1		
Days admit pre-op					
1 day	14 (20.3)	55(79.7)	1		
2 days	7(14.9)	40(85.1)	0.687	0.254 – 1.859	0.460
3 days	1(6.3)	15(93.7)	0.262	0.032 – 2.155	0.213
>3 days	18(36.0)	32(64.0)	2.210	0.970 – 5.034	0.059
Shaving					
Within 30 minutes	12(31.6)	26(68.4)	2.478	1.068 – 5.747	0.035
>30 minutes	9(39.1)	14(60.9)	3.451	1.308 – 9.105	0.012
No need	19(15.7)	102(84.3)	1		
Urinary catheter					
Inserted	24(33.8)	47(66.2)	3.032	1.472 – 6.246	0.003
Not inserted	16(14.4)	95(85.6)	1		
Pre-operative UTI					

Yes	26(59.1)	18(40.9)	12.794	5.655 – 28.94	<0.001
No	14(10.1)	124(89.9)	1		
Wound class					
Clean	2(5.1)	37(94.9)	1		
Clean contaminated	29(23.0)	97(77.0)	5.327	1.209 – 23.46	0.027
Contaminated	9(53.0)	8(47.0)	20.250	3.651 – 112.3	0.001
Duration of surgery					
0 to 90 minutes	7(17.5)	33(82.5)	1		
>90 minutes	48(33.8)	94(66.2)	2.407	0.992 – 5.842	0.052

Multivariate logistic regression (Table 5)

On multivariate analysis some features were significantly found to predict SSI such as pre op UTI, and contaminated surgery. Only shaving within 30 minutes was significantly protective against SSI. Urinary catheter and shaving more than 30 minutes were not significant predictors for SSI. They are just confounders or there are other factors that confounded these two factors. Pre-operative bacteriuria and contaminated surgery were strong predictors for development of SSI (table 5 below).

Table 5: Multivariate logistic regression analysis of predictors for SSI among patients who underwent open urological surgery at MNH from August 2015 to March 2016

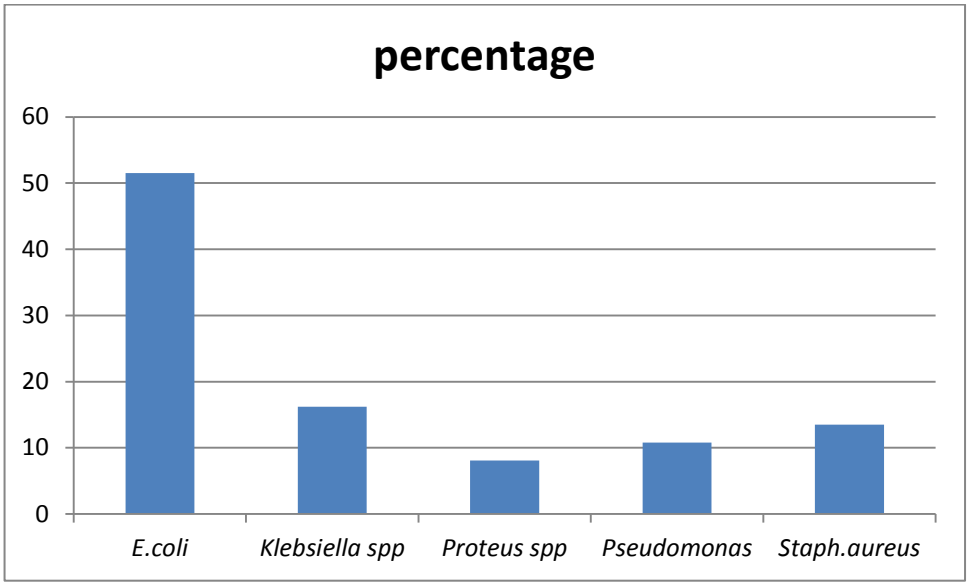
Variables	aOR	95% CI	P-value
Shaving			
Within 30 minutes	0.263	0.088 – 0.785	0.017
>30 minutes	0.420	0.122 – 1.448	0.170
Urinary catheter	1.670	0.664 – 4.198	0.275
Pre-op bacteriuria	9.730	3.929 – 24.095	<0.001
Contaminated surgery	24.997	2.578 – 242.420	0.005

Bacterial isolates

SSI isolates

Of 40 wound swabs collected patient with clinical SSI, 37 were culture positive. Overall Gram negative were common than Gram positive. Of all Gram negative bacteria isolates, *Escherichia coli* 19 (51.4%) was the commonest followed by *Klebsiella pneumoniae* 6(16.2%), *Pseudomonas aeruginosa* 4(10.8% and *Proteus mirabilis* 3(8.1%) and). Among Gram positive *staph aureus* predominated.

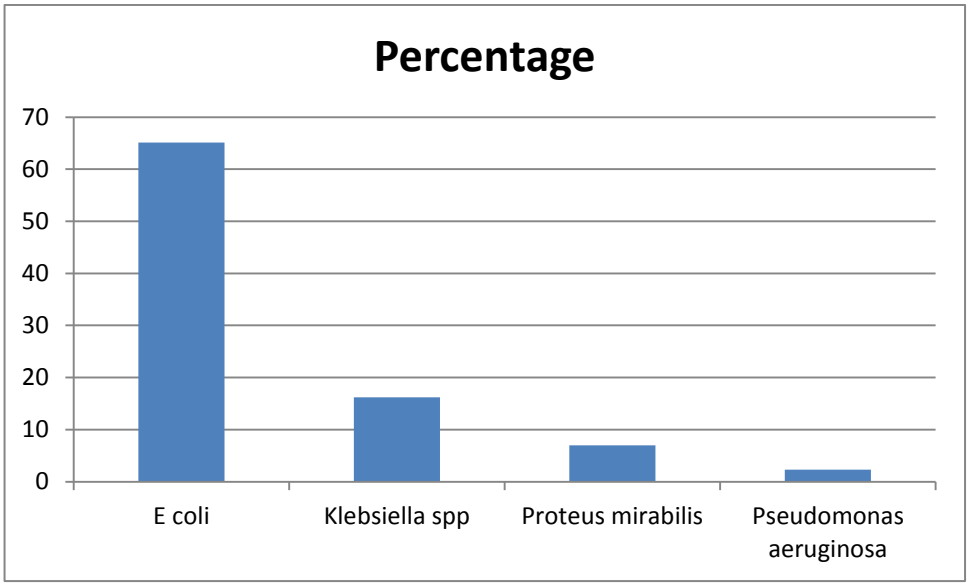
Fig 1: Bacteria isolated from pus culture of the infected wound in patients who underwent open urological surgery at MNH from August 2015 to March 2016.



Urine culture

A total of 152 urine samples were cultured, sample being taken the morning of surgery. Out of which 43 (28.3%) samples grew only Gram negative bacteria and none of the Gram positive bacteria was grown. Bacteria isolated were *E coli* 28(65.1%) as the most cause of UTI, *Klebsiella spp* 11(25.6%), *Proteus mirabilis* 3(7.0%) and *Pseudomonas aeruginosa* 1(2.3%). One of the urine cultures grew mixed growth and was considered contaminated, hence was not included in the analysis.

Fig 2: Bacteria isolated from urine culture of patients who underwent open urological surgery at MNH from August 2015 to March 2016



Antimicrobial resistance

Most of the *E. coli* isolated was highly resistant to most of antibiotics used from 66% ciprofloxacin, through 82% Co-trimoxazole, 84% Amoxyclav and ceftriaxone to 86% Gentamycin. Ceftriaxone was highly resisted by most of the microorganism isolated, *S. aureus* being the least resistant by 42% to *P. aeruginosa* by 92%. Ciprofloxacin is the drug to which most of the pathogens are least resistant from 16% in *P. aeruginosa* to 66% in *E. coli*.

Table 4; Pattern of antimicrobial resistance of bacteria isolated in pus from patients who underwent open urological surgery at MNH from August 2015 to March 2016

	E. coli	***K. pneumoniae***	***P. mirabilis***	***P. aeruginosa***	***S. aureus***
ceftriaxone	84.2	78.0	62.0	92.0	42.0
Gentamycin	86.0	62.3	57.3	12.0	36.0
Ciprofloxacin	66.0	49.2	48.0	16.0	27.0
Amoxvclav	84.0	90.0	82.4	14.3	68.4
Co-trimoxazole	82.3	88.1	66.9	48.3	29

There are some bacteria species that were found in urine and ultimately were isolated from pus swab taken from SSI. Fourteen different bacteria isolated in the urine were the same bacteria isolated from the infected wound. Ten patients had had urine and pus swab isolation of E *coli*, 2 patients *Klebsiella spp* isolated in both urine and SSI and 2 patients whom *Proteus mirabilis* were isolated both in the urine and on the wound.

Study limitations

It was difficult to follow up patients coming from up country because they found it difficult to come down to Dar es Salaam at the 30th day follow up and this might affect the results of the study.

10.0 DISCUSSION

Surgical site infection remain to be at the top of the most cause of health care associated infections, leading to increased hospital stay to the patients, use of antibiotics and mortality as postulated by Klevens et al in their study in some of the US hospitals[2]. This study was to determine the rates of surgical site infection and their predictors in open urological surgeries, the bacteriological etiology and their sensitivity to antibiotics in our practice here.

10.1 Social and Demographic features;

In open urological surgeries, male predominate, with female contributing only 20.9% of total surgeries. This is explained by the anatomical differences between male and female patients when it comes to genital-urinary system. Most surgeries are done in the urethra (of which the male urethra is longer and more complex than female urethra), prostate gland and scrotum. Few surgeries are shared in both male and female such that are done in the kidneys, ureters and urinary bladder.

10.2 Magnitude of SSI;

Marković-Denić L et al did a study in Serbia and found that rate of SSI for clean wounds was 5%, clean contaminated (11.2%) and contaminated wound was 20.7%[14]. In this study the rate was found to be 5.1% for clean wound, 22.8% for clean contaminated and 52.9% for contaminated wounds. The discrepancy in the rate in clean contaminated and contaminated could be explained by extent of antibiotic resistance, different environmental exposure (First world against third world), dressing techniques in our wards.

Studies done in North America showed rate of SSI to be around 20% overall[13] while studies in Tanzania showed the SSI rate ranging from 19.4% to 36.7 percent[19, 20, 21] and being higher at MNH compared to other referral Hospitals. In this study, the overall SSI rate was around 22% which is within ranges of other studies done in North America and Tanzania.

10.3 Other associated factors;

Shaving the patient's surgical site within 30 minutes before surgery is associated with a significant reduction of risk of causing SSI and this is explained by the fact

that the bacteria do not get enough time to form colonies so that when making an incision, there is no significant number of bacteria clusters to contaminate the wound.

In this study, patients with urinary catheter prior to surgery had had a significant risk factor for development of SSI. Also patients with urinary tract infection prior to surgery was the most important risk factor for SSI following urological surgery by 59.1% (P value = 0.000). The finding was almost the same to what Hamasuma R et al found in their study in Japan that pre-operative UTI had had a risk of causing SSI by 55 percent[15].

A significant number of patients had UTI before surgery and this was predicted by the presence of urinary catheter and the age between 36 and 53 years of age.

The number of days the patient is hospitalized was also linked by the rate of SSI. This is reflected in this study as patients who stayed in the hospital for prolonged time were those who got SSI postoperatively.

10.4 Bacteriology;

The most common bacteria isolated were gram negative *Escherichia coli,* followed by other urinary pathogens such as *Klebsiela species and Proteus mirabilis.* These same organisms were commonly isolated in pus cultured from SSI with *E. coli* causing nearly half of the infections. The gram negative urinary pathogens caused more than 70% of all SSI. This is reflected in a study done in Monteydeo Uruguay, that patient who got SSI after prostatectomy had had a gram negative bacteria isolate as the only implicated microorganism[16]. In other studies done in Tanzania in general surgery, showed that the most isolated bacteria were *Staphylococcus aureus* followed by *E coli* and *Klebsiella spcies*[21], implying that *S. aureus* is common skin commensal making it a rampantly available bacteria to contaminate the wound.

In this study, the bacteria isolated from the cultured pus, were highly resistant most of antibiotics tested. E coli were more than 80% resistant to most of antibiotics except on ciprofloxacin which was 66% resistant. This is also seen in a study done by Manyahi et al which showed that Gram negative isolates from

infected surgical wounds were multidrug resistant[27]. Ciprofloxacin was much more active against many pathogens as compared to other agents. In this study, resistance to ciprofloxacin was 66%, 49% and 27% for E. coli, Klebsiela pneumonia and S. aureus respectively. This was slightly lower but showing the same trend compared to a study done at Bugando Medical Centre which reported resistance to ciprofloxacin of 86%, 80% and 54% of the E. coli, Klebsiela pneumonia and S. aureus respectively[21]. This study only tested the commonly used antibiotics to treat patients in urological surgery and the pattern of resistance is similar to other studies done elsewhere

Some bacteria isolated in urine were the same bacteria isolated in the pus pointing out that UTI prior to surgery most likely will end up infecting the wound. The fact that the bacteria isolated were similar in both UTI and SSI, does not confirm that these were exactly the same strains and this will need genetic mapping to conclude.

11.0 CONCLUSION

Patients who get SSI stay in the hospital for quite a number of days, increasing cost of stay with more morbidity

Rate of SSI in open urological surgeries are the same to those observed in general surgery procedures elsewhere. Wound class affects the rate of SSI rate, being very low in clean wounds and very high in contaminated wounds.

A good number of patients had had urinary tract infection prior to open urological surgery, and urinary tract infection is the single most predictor of SSI. The other factors are contaminated wound, while shaving within 30 minutes before surgery was protective against SSI.

Commonest bacteria isolates in the urinary tract which are gram negative bacteria are the ones implicated in the SSI.

Isolated bacteria are increasingly becoming more resistant to antibiotics. This leads to more morbidity as a result of SSI

12.0 RECOMMENDATIONS

Continuing medical education should be given to all staffs that will be involved in peri-operative and postoperative care of the patient on the prevention of surgical site infections.

All patients with urinary catheter are potentially infected; hence urine culture and sensitivity should be done prior to surgery. All patients with urinary tract infections should be given antibiotics to clear the infection before surgery.

Patients with wound sepsis, pus/pus swabs culture and sensitivity should be done and the patient should be prescribed the appropriate sensitive antibiotic. Traditional prescription of certain antibiotics to all patients should be stopped and the patients SSI should be individualized.

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APPENDIX I

Questionnaire

1. Serial No ----------
2. Hospital reg. no----------
3. Ward ----------
4. Recruitment date ----/----/----
5. Age ----------
6. Sex ----------
7. District ----------
8. Co morbidities ----------

    i. DM,
    ii. HTN
    iii. HIV
    iv. Others specify----------

9. History of

    i. Cigarate smoking

10. Days post admission

    i. One
    ii. Two
    iii. Three
    iv. Others specify……

11. Diagnosis ----------
12. Procedure----------
13. Shaving surgical site (tick)

    i. on the table $\leq$ 30 mins
    ii. in the ward > 30mins

14. Urine and/or catheter for culture and sensitivity

i. yes
ii. No

15. Bacteria isolated ……
16. Drugs sensitive to the bacteria……..
17. Date of surgery ---/---/-----/
18. Duration of surgery

i. <30 minutes
ii. 30 – 90 minutes
iii. >90 minutes

19. Type of surgery

i. Clean
ii. Clean contaminated
iii. Contaminated
iv. Dirty

20. SPC insitu (circle)

i. No
ii. < 7 days
iii. 7 – 14 days
iv. > 14 days

21. Intensive Care Unit admission post-surgery

i. Yes
ii. no

22. Wound status post op

i. 48 hours post op --------(septic) ---------(not septic)
ii. 5^{th} day post op ---------- (septic) --------- (not septic)

iii. 8^{th} – 10^{th} day post op --------(septic) ----------(not septic)

iv. 30^{th} day post or ---------- (Septic) ----------

23. On discharge antibiotics----------

24. Microorganisms cultured from the pus swabs ----------

25. What was the drug of which this organism was sensitive to?

APPENDIX II

Informed consent form

ID no_____

Consent to participate in the study assessing the rates of surgical site infection and the predictors in open urological surgeries, the bacteriological etiology and their sensitivity to antibiotics at Muhimbili National Hospital

Greetings! My name is Dr Victor Patrick Sensa, a postgraduate student at Muhimbili University of Health and Allied Sciences.

The purpose of the study

To assess the rates of surgical site infection and the predictors in open urological surgeries, the bacteriological aetiology and their sensitivity to antibiotics at Muhimbili National Hospital.

What participation involves

If you agree to participate in the study, you will be followed up for 30 days after the operation. You will be reviewed 3 times: 48 hours after the operation, then 5-8 days during stitch removal and lastly after 30 days. Hence after discharge from the hospital you will be required to come again 2 times. If your wound will be infected then pus swab will be taken for bacteriological culture and sensitivity.

Confidentiality

All information collected on the questionnaires will be entered into a computer with identification number. The questionnaires will be handled with great secrecy in order to maintain confidentiality throughout the study.

Risks

Risks associated may be mild discomfort during wound examination and mild pain when taking pus swabs. Otherwise no other expected risks.

Right to withdraw and alternatives

Taking part in this study is completely voluntary. If you choose not to participate in the study, you will continue to receive all services that you would normally from the hospital

Benefits

If you agree to participate in this study, there is no direct benefit apart from knowing the type of organism infecting your wound and the appropriate management rather the results will be used for future plan of prevention of such infections and how to treat them appropriately.

In case of any injury

Apart from examining your wound and taking pus swab from your wound, we don't expect any harm from your participation.

Who to contact

If you have any question about the study, you should contact Dr. Victor P. Sensa on +255 787 771 177, P. O. Box 34302 Dar es Salaam

I you have questions/concerns about your rights as participant, you may contact
Prof Mainen J Moshi. B Pharm (UDSM), PHD (Glasgow),
The Director of research and publications,
Muhimbili University of Health and Allied Sciences (MUHAS),
P.O Box 65001,
Dar es salaam

Phone= + 255-22-2152489

Signature

I ..... have read the content of this form. My questions have been answered. I agree to participate in this study.

Signature of participant .....

Signature of witnes .....

Date of signed consent ..../...../201..

Participant agrees ___ participant does NOT agree ____

APPENDIX III

Kiswahili version of informed consent

ID no .....

Hati ya ukubali wa kushiriki kwenye utafiti utakaoangalia ukubwa wa maambukizo kwenye vidonda vya upasuaji na viashiria vyake katika upasuaji wa nyia ya mkojo, aina ya vimelea vinavyohusika na aina ya dawa inayoweza kuwaua katika Hospitali ya Taifa Muhimbili.

Salaam! Naitwa Daktari Victor Patrick Sensa, mwanafunzi wa uzamili katika chuo kikuu cha Tiba za Afya cha Muhimbili.

Lengo la utafiti

Kuangalia ukubwa wa maambukizo kwenye vidonda vya upasuaji na viashiria vyake katika upasuaji wa nyia ya mkojo, aina ya vimelea vinavyohusika na aina ya dawa inayoweza kuwaua katika Hospitali ya Taifa Muhimbili.

Ushiriki wako ni wa namna gani?

Ukikubali kushiriki, utafuatiliwa kwa muda wa siku 30 baada ya upasuaji kufanyika. Kidonda kitachunguzwa mara 3: masaa 48 baada ya upasuaji, siku 5 mpaka 8 wakati wa kutoa nyuzi na mwisho siku ya 30 toka upasuaji. Baada ya kuruhusiwa kutoka hospitali itakubidi uje tena mara 2 kwa ajili kuchunguza maendeleo ya kidonda. Kama kidonda kitakuwa na maambukizi, uchafu au usaha utachukuliwa kwenda kupimwa maabara aina ya vijidudu na dawa inayoweza kutibu.

Usiri

Taarifa zote zitakazokusanywa kwenye dodoso, pamoja na vipimo vitatambulika kwa namba na sio jina ili kuongeza usiri. Usiri huu utalindwa hata baada ya kukamilika kwa utafiti huu.

Madhara

Mbali na maumivu kidogo unayoweza wakati wa kuangalia kidonda, hatutegemei kwamba utapata madhara mengine yoyote.

Haki ya kujitoa

Ushiriki wako kwenye utafiti huu sio wa kulazimishwa. Ukiamua usishiriki, utaendelea kupata huduma za hospitali kama kawaida.

Faida

Hakuna faida ya moja kwa moja kwenye ushiriki wako katika utafiti zaidi ya kulijua tatizo lako kwa undani zaidi. Faida itakuwa zaidi kama baadae utafanyiwa upasuaji au mtu mwingine yeyote, tutakuwa tumeweka mikakati mipya ya kuzuia maambukizi kama hayo yasitokee.

Mawasiliano

Ukiwa na maswali yoyote kuhusu utafiti huu, wasiliana name Dr. Victor P. Sensa simu namba +255 787 771 177, S.L.P 34302 Dar es Salaam

Ukiwa na maswali kuhusu haki zako kama mshiriki, wasiliana na

Prof Mainen J Moshi. B Pharm (UDSM), PHD (Glasgow),
Mkurugenzi wa utafiti na machapisho,
Chuo Kikuu cha Afya na Tiba Muhimbili (MUHAS),
S. L. P 65001,
Dar es salaam

Simu + 255-22-2152489

Sahihi

Mimi_____ nimekubali kushiriki utafiti huu baada ya maswali yangu yote kujibiwa.

Sahihi ya mshiriki _____

Sahihi ya shahidi _____ tarehe __/__/201_

Mshiriki amekubali _____ Amekataa ____