

**SURGICAL SITE INFECTION FOLLOWING EMERGENCY
LAPAROTOMY FOR BOWEL SURGERY AT KENYATTA
NATIONAL HOSPITAL**

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**Dissertation Submitted in Part Fulfilment of The Requirements for the
Award of Master of Medicine Degree in General Surgery at The University
of Nairobi.**

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DECLARATION

I hereby certify that this is my original work and has not been presented for a degree in any other university.

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DEDICATION

To my wife, Isabel, children Rochelle and Raphael for their Patience, Love and Support in this Journey.

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LIST OF ABBREVIATIONS

ASA:	American Society of Anaesthesiologists.
CDC:	Centre for Disease Control.
ERC:	Ethical Research Committee.
GIT:	Gastro-Intestinal Tract.
KNH:	Kenyatta National Hospital.
MMED:	Master of Medicine.
NHSN:	National Healthcare Safety Network.
NNIS:	National Nosocomial Infection Surveillance.
SHO:	Senior House Officer.
SOPC:	Surgical Outpatient Clinic.
SSI:	Surgical Site Infection.

ABSTRACT.

A seven (7) month descriptive cross sectional study on surgical site infection (SSI) following emergency laparotomy for bowel pathology was conducted in the general surgical unit at Kenyatta national hospital (KNH). Incidence of SSI, patient related risk factors and microbial profile were described.

Overall SSI incidence was 30.8%. Most of patients were young with mean age of 35.48 ± 1.282 years who were predominantly male (76.7%). The highest incidence of SSI were associated with alcohol consumption and cigarette use, dirty wounds, prolonged antibiotic therapy, perioperative transfusion and American society of anaesthesiologist score of one (1).

Mono microbial infection accounted for most of SSI at 84.8% with the commonest isolate being *Escherichia coli* (48.6%). Most of the poly microbial infections, were mainly two isolates (*Escherichia coli* and *Klebsiella pneumoniae*, *Escherichia coli* and *Proteus mirabilis*, *Streptococcus pyogenes* and *Candida albicans*). From the study there were no anaerobic isolates.

Targeted public health education on harmful effects of alcohol consumption and cigarette smoking should be emphasised. There should be adherence to guidelines on use of blood and preoperative optimisation of patients. Periodic surveillance on SSI by surgical infection prevention committees in the general surgical units will result in reduction of SSI. Hospital based antibiotic stewardship programs should guide in use of antibiotics. Analytical studies looking at relationship between risk factors and SSI would result in identification of independent predictors of SSI in our set up.

1.0 CHAPTER ONE

1.1 INTRODUCTION.

Kenyatta National Hospital (KNH) is a teaching and tertiary referral hospital where patients undergoing complex surgery are referred and attended to. Emergency laparotomy is one of the common surgical procedures accounting for 67% of all abdominal surgeries being performed by general surgeons and supervised surgical residents¹. The overall incidence of SSI in abdominal surgery at the institution is estimated at 22.4%² whereas in Africa, cumulative incidence of SSI in the surgical wards is estimated at 40%³. Despite high volume of emergency bowel surgery at the hospital, incidence of SSI has not been studied.

Factors associated with increased risk of abdominal SSI could be endogenous or exogenous. Endogenous factors include co morbid conditions such as diabetes, nicotine use, steroid use, immunosuppression and prolonged preoperative delay. Exogenous factors include operative characteristics such as lack/inappropriate use of antimicrobial prophylaxis and prolonged intraoperative time, which could also extent into postoperative period where lack/inappropriate use of antimicrobial therapy and blood transfusion have increased risk of infection⁴. Among the risk factors, there are those known to be independent predictors of SSI, these include level of abdominal wound contamination, laparotomy time of more than two hours and patients susceptibility to infection. From these three predictors, National Nosocomial Infection Surveillance (NNIS) risk index is derived which scores the risk of developing abdominal SSI⁵. Finally emergency laparotomy has been associated with increased risk of infection due to suboptimal preoperative physiologic state of the patient⁶.

Gastrointestinal (GIT) SSI commonly is as a result of contamination from coelomic mucosal endogenous flora which tends to be polymicrobial comprising of aerobic, anaerobic, gram positive and negative microorganisms⁷⁻¹⁰.

Therefore improvement in quality of surgical care should focus on prevention of abdominal SSI. Among the strategies used include appropriate choice and use of antimicrobial prophylaxis/therapy and surveillance with feedback to the surgical team¹¹⁻¹⁵. This study looked at incidence of SSI, patient related risk factors and microbial pattern following emergency laparotomy for bowel surgery at KNH, general surgical unit.

1.2 LITREATURE REVIEW.

1.2.1 Epidemiology on SSI.

Surgical site infection (SSI) following abdominal surgery at KNH from local studies is estimated to be 22.4%² while globally, it varies from 2.6-2.9% in developed countries to 2.5-40% in developing countries³. Centre for Disease Control (CDC) estimated risk of developing SSI following laparotomy is about 40 % with higher rate of infection in emergency surgery 25.2%-40% as compared to elective surgery 7.6%^{2,4}.

1.2.2 Pathogenesis of SSI.

Microbial contamination of the abdomen is a necessary precursor of abdominal SSI. Risk of infection can be viewed in the following relationship;

$$\underline{\text{Dose of bacterial contamination} \times \text{virulence}} = \text{Risk of abdominal SSI}^4$$

Resistance of the host patient

Significant dose of bacterial contamination is more than 10^5 microorganisms per tissue. However, in the presence of foreign material, 10^2 microorganisms per tissue can cause infection⁴. Virulence is based on microorganism capacity to produce toxins and provoke endogenous cytokine release resulting in systemic inflammatory response with multiple system organ failure as the ultimate consequence. One of the most common causes of multiple system organ failure in modern surgical care is intra-abdominal infection⁴. Source of pathogens in abdominal SSI commonly is endogenous from the skin or mucosa of hollow viscera however, It could also be exogenous from the environment⁴.

SSI defining criteria involves clinical and laboratory findings developed by CDC-NNIS systems⁴ provided in appendix 1 table 1. Site specific classification of organ/ space SSI include gastrointestinal tract and intra-abdominal space not specified elsewhere in appendix 1 table 1⁴.

1.2.3 Risk Factors associated with SSI.

From the introduction, patient-related risk factors may predispose an individual to develop abdominal SSI but they are not known independent predictors of abdominal infection⁴.

Among the operative characteristics, patient preoperative shower with an antiseptic may reduce skin microbial count but not risk of infection. Recently, surgical team scrubbing of hand and forearm for a minimum two minutes is as effective as traditional ten minutes but optimal scrubbing time is not known. Immediate preoperative shaving of surgical site might

be more beneficial than shaving within twenty four hour as it reduces infection from 7.1% to 3.1%⁴.

Use of antimicrobial prophylaxis is more beneficial than environmental control such as air micro filter, laminar air flow and ultraviolet radiation as it has been shown to reduce infection from 29% to 6%⁴. As an adjunct to surgery, antimicrobial prophylaxis should be within forty eight hours, while therapy for established infection should be within five days⁴. Selection of antimicrobial agent therefore should be based on efficacy against most common pathogens causing abdominal SSI⁴.

Other measures such as conventional sterilization of equipment, use of surgical barrier and excellent surgical techniques have shown to reduce abdominal SSI but are not known independent predictors of SSI⁴.

Risk factors that are known independent predictors of abdominal SSI include⁴⁻⁵

1. Estimation of intrinsic degree of microbial contamination
2. Host susceptibility to infection
3. Duration of laparotomy

From above factors National Nosocomial Infection Surveillance (NNIS) risk index can be determined by assigning score of one to each of the factors. Risk of infection is higher in NNIS risk index cumulative score of more than zero⁵.

Estimation of intrinsic contamination of surgical site is based on surgical wound classification. Among the class wounds, clean wound has a lower infection rate of 3%, clean contaminated 11.5%, contaminated 20% and dirty 40.1%. NNIS risk index score of one (1) is given for contaminated or dirty wounds⁵.

Host susceptibility to abdominal SSI is determined by use of American society of Anaesthesiologist (ASA) physical status. Studies have demonstrated that ASA score of more than two (2) has increased risk of SSI as high as 29.8%. NNIS risk index score of one is given for ASA physical status of more than two (2)⁵.

Prolonged operative time of more than one hundred and twenty (120) minutes has increased risk of SSI of about 31.6%. NNIS risk index score of one is given if laparotomy duration is more than one hundred and twenty minutes (120)⁵. Prompt intervention from time of

diagnosis to laparotomy in one of the studies has been shown to reduce risk of SSI to 11%, but has not demonstrated to be known independent predictor of SSI⁶

1.2.4 Source of abdominal SSI.

Source of pathogens in abdominal SSI could be endogenous or exogenous. Endogenous source could be from the skin or GIT mucosa. Upper GIT mucosa i.e. stomach, duodenum and jejunum contain 10^3 - 10^5 bacteria/ml while lower GIT mucosa i.e. large intestine contains 10^{11} - 10^{13} bacteria/ml. GIT surgical infections tend to be polymicrobial, from previous studies on abdominal SSI , aerobic gram negative bacteria e.g. *Escherichia coli* account for 31.8-45.3%, anaerobic gram negative bacteria e.g. *Bacteroides fragilis* account for 1.6-14.7%, gram positive bacteria e.g. *Enterococcus* account for 32-44.4% and candida species account for 4%⁷⁻¹⁰.

1.2.5 Prevention of SSI.

Improvement in quality of surgical care should focus on prevention of abdominal SSI especially in high risk procedures such as emergency laparotomy¹¹⁻¹⁵. Incidence of SSI following emergency laparotomy is an important component of quality of surgery and hospital care¹¹⁻¹⁵. Surveillance of abdominal SSI following emergency bowel surgery with appropriate feedback of data to surgeons is an important strategy to reduce SSI¹¹⁻¹⁵.

From literature review, emergency laparotomy is a high risk procedure with increased risk of SSI. There was paucity of data in our set up on incidence of SSI following emergency bowel and associated microbial profile. This study determined patient related risk factors, incidence of SSI and microbial profile in patients undergoing bowel surgery.

2.0 CHAPTER TWO

2.1 STUDY JUSTIFICATION.

Emergency laparotomy remained one of the common surgical procedures in our set up, while SSI is one of the most common complications associated with it^{1, 2,4,5,6}.

Previous study at KNH looked at incidence of SSI in abdominal surgery and subsequently recommended studies looking at SSI in elective or emergency surgery¹.

Choice of antibiotic prophylaxis/therapy should be based on its efficacy against the most common pathogens/probable participating bacterial species⁷⁻¹⁰.

Incidence of SSI following emergency laparotomy which is a high risk procedure may be used as a component marker of quality of surgical care at KNH¹¹⁻¹⁵.

2.2 STUDY OBJECTIVE.

2.2.1 Main objective.

The study determined incidence of SSI, following emergency laparotomy for bowel surgery in general surgical unit at KNH.

2.2.2 Specific objective.

1. Incidence of SSI following emergency bowel surgery was described
2. Patient-related risk factors were described.
3. Microbial profile following SSI was also described.

3.0 CHAPTER THREE

3.1 MATERIALS AND METHODS.

3.1.1 Study design.

This was a descriptive cross sectional study that was conducted in seven (7) months.

3.1.2 Study site.

The study site was KNH, the general surgical unit i.e. Accident and emergency department, general surgical wards, emergency operating theatres, intensive care unit (ICU) and surgical outpatient clinic (SOPC)

3.1.3 Study population.

Patients who were 13 years and above scheduled to undergo emergency laparotomy for bowel pathology were recruited in the study.

3.2 Inclusion criteria.

Patients with a diagnosis of acute abdomen due to small and large bowel pathology with an indication for emergency laparotomy were be recruited.

Diagnosis of acute abdomen included patients with blunt injury, penetrating injury, perforated gut and intestinal obstruction.

3.3 Exclusion criteria.

Patients under 12 years of age.

Patients who had abdominal implants.

Patients who declined to participate in the study.

Patients who had undergone re-exploratory laparotomy.

Post-operative cases where the finding was negative exploratory laparotomy.

Patients who had appendicitis.

3.4 Sampling method.

Selection method was non-randomized consecutive sampling until the desired sample size of 120 patients was achieved.

Sample size calculation¹⁶

$$n = \frac{NZ^2P}{(1-P)}$$

$$d^2 (N-1) + Z^2 P (1-P)$$

n =sample size with finite population correction

Z=standard deviation for the 95th percentile confidence interval 1.96

P=prevalence 22.4%²

d= degree of accuracy expressed as a proportion (0.05).

N=Population size 210.¹⁷ patients undergoing emergency laparotomy for bowel disease within 7 months

n =118

3.5 Data collection.

The study setting was KNH in the general surgical unit and commenced on approval by the department of surgery and Ethical Research Committee (ERC) - KNH/UON. I, the principal investigator was assisted by two research assistants who were at the level of general surgical residency in clinical rotations. Recruitment of participants who met the inclusion criteria was verbal in the preoperative period where participants were informed of the nature, purpose, potential benefits and harmful effects of the study. Those who agreed to participate in the study, informed consent was obtained and subsequently enrolled in the study. Information obtained included bio data, patient co morbid conditions and surgical diagnosis in the preoperative period. In the post-operative period, intraoperative details, follow up including wound examination, in case of infection, wound class, type of infection and microbial isolate were documented in a structured pretested questionnaire. Phone contact was obtained for those patients who were discharged for follow-up within the 30 day period. Patients discharged within seven days after surgery were given two appointments in the surgical outpatient clinic (SOPC) where wound assessment was done on day fifteen and day thirty. Patients discharged after day seven of surgery were given one appointment on day 30. Phone contacts were used to call and remind patients of booked appointment on day eleven and day twenty six prior to scheduled clinic date on day fifteen and day thirty respectively. Patients who presented after day thirty were treated but not be included in the study. Diagnosis of SSI was made based on CDC criteria in appendix 1 table 1. For established SSI a sample of pus swab/ aspirate was obtained using standard collecting swab stick and/or collecting bottle

which was labelled and attached request form for microscopy and culture. Samples were then be processed and reported at the UON/KNH microbiology department for microbial profile based on their established protocols.

3.6 Patient management.

Patients, who were recruited in the study, were subjected to preoperative and intraoperative care as per KNH protocols. Post operatively, they were assessed every day during clinical ward round and accorded clinical care as per KNH protocol. For those who develop complication, appropriate intervention was carried out.

3.7 Data analysis.

All questionnaires were coded and data entered in computer using SPSS version 20 and analysed.

Descriptive statistics was analysed where discrete variables were summarised with frequencies and percentages. Continuous variables were summarised using mean, median, mode and standard deviation.

Association between SSI type, microbial, anti-microbial profile and patient characteristics were analysed using chi square. Results were presented in tables, graphs and pies charts.

3.8 Study limitations.

Some patients were lost to follow up, however this was mitigated by recruiting more patient hence 120 patients were included in this study.

3.9 Ethical consideration.

The study commenced upon approval by the department of surgery UON /KNH-ERC where by those who agreed to participate, were taken through pre consent counselling before informed consent was obtained. Guardian and next of kin were required to sign consent on behalf of minor and those who were unable to do so respectively.

All data in soft copy was in a password protected database whereas hard copy was kept in a locker and secured. Access was controlled by the principle researcher and limited to the two research assistant on authorization by principle researcher. At completion of study, raw data on hard copy will be destroyed once backed up in a password protected softcopy database for future reference.

Feedback of information; all participants were informed of their individual progress post operatively. Those who would had developed SSI were informed about the infection, outcome of the microbial profile and given appropriate treatment.

4.0 CHAPTER FOUR

4.1 RESULTS.

4.1.1 Overall incidence of SSI.

One hundred and twenty (120) patients were analyzed with overall surgical site infection (SSI) rate at 30.8% (37/120) as shown in table 1 below.

Table 1: Overall incidence of SSI

SSI	Frequency	Percent	Valid Percent (%)	Cumulative Percent (%)
no	83	69.2	69.2	69.2
yes	37	30.8	30.8	100.0
Total	120	100.0	100.0	

4.1.2 SSI classification.

Organ/space SSI had higher incidence as seen in table 2 below.

Table 2: Incidence of SSI types

SSI types	Frequency	Percent (%)	Cumulative Percent (%)
no infection	83	69.2	69.2
Superficial incisional SSI	3	2.5	71.7
Deep incisional SSI	16	13.3	85.0
Organ/space SSI	18	15.0	100.0
Total	120	100.0	

4.2 Association between SSI type and wound classification.

8.3 % (1/12) of clean-contaminated wounds had deep incisional SSI with no superficial incisional or organ/space SSI as seen in table 3 below. 5.6 % (2/36) of contaminated wounds had superficial SSI while 5.6% (2/36) had deep incisional SSI with no organ/space SSI seen in table 3 below. 1.4% (1/72) of dirty wounds had superficial incisional SSI, 18.1% (13/72) had deep incisional SSI while 25% (18/72) had organ/space SSI as seen in table 3 below.

Table 3: Association between SSI type and wound classification

SSI TYPE		Wound Classification			Total
		clean-contaminated	contaminated	Dirty	
no infection	Count	11	32	40	83
	% within SSI Type	13.3%	38.6%	48.2%	100.0%
	% within Wound Classification	91.7%	88.9%	55.6%	69.2%
	% of Total	9.2%	26.7%	33.3%	69.2%
Superficial incisional SSI	Count	0	2	1	3
	% within SSI Type	0.0%	66.7%	33.3%	100.0%
	% within Wound Classification	0.0%	5.6%	1.4%	2.5%
	% of Total	0.0%	1.7%	0.8%	2.5%
Deep incisional SSI	Count	1	2	13	16
	% within SSI Type	6.2%	12.5%	81.2%	100.0%
	% within Wound Classification	8.3%	5.6%	18.1%	13.3%
	% of Total	0.8%	1.7%	10.8%	13.3%
Organ/space SSI	Count	0	0	18	18
	% within SSI Type	0.0%	0.0%	100.0%	100.0%
	% within Wound Classification	0.0%	0.0%	25.0%	15.0%
	% of Total	0.0%	0.0%	15.0%	15.0%
	Count	12	36	72	120
	% within SSI Type	10.0%	30.0%	60.0%	100.0%
	% within Wound Classification	100.0%	100.0%	100.0%	100.0%
	% of Total	10.0%	30.0%	60.0%	100.0%

The association between wound classification and SSI was statistically significant (p-value 0.001).

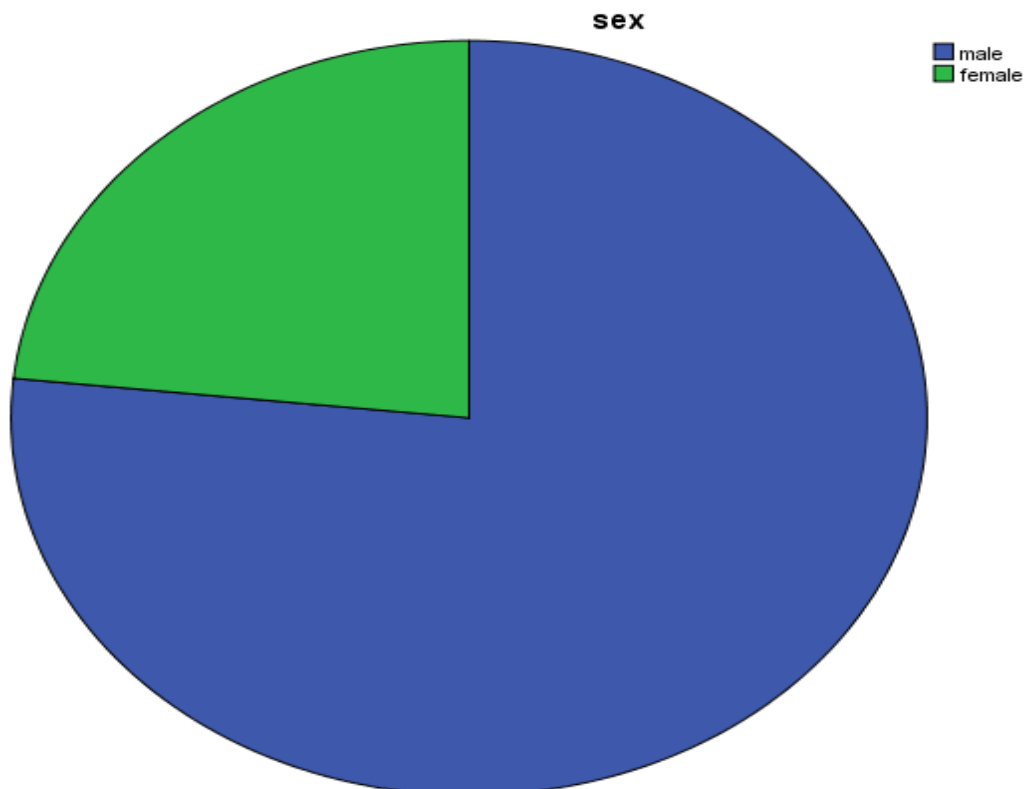
4.2.1 Gender.

Male patients observed accounted for 76.7% (92/120) while female patients accounted for 23.3% (28/120) as seen in table 4 and figure 1 below.

Table 4: Distribution on Gender

Gender	Frequency	Percent (%)	Valid Percent (%)	Cumulative Percent
male	92	76.7	76.7	76.7
female	28	23.3	23.3	100.0
Total	120	100.0	100.0	

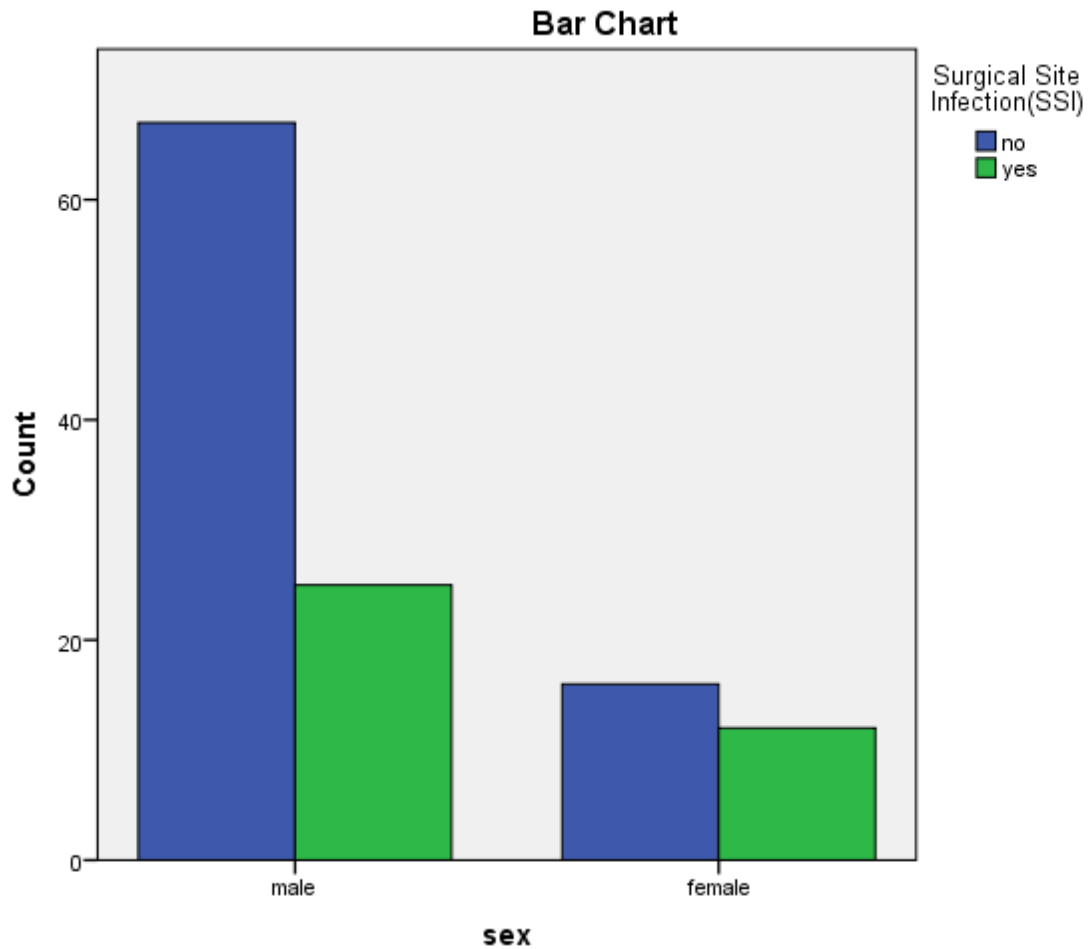
Figure 1: Distribution on Gender



4.3 Association between gender and SSI.

Overall SSI rate was higher in male patients at 20.8% (25/120) as compared to female patients at 10% (12/120) as shown by figure 2 below. The association between gender and SSI was not statistically significant (p- value 0.116).

Figure 2: Distribution, association between Gender and SSI



4.3.1 Age.

From the study the mean age was 35.48 ± 1.282 years with age range of 64 years, median age of 32 years and positive skewness of 1.069 as seen in table 5 below.

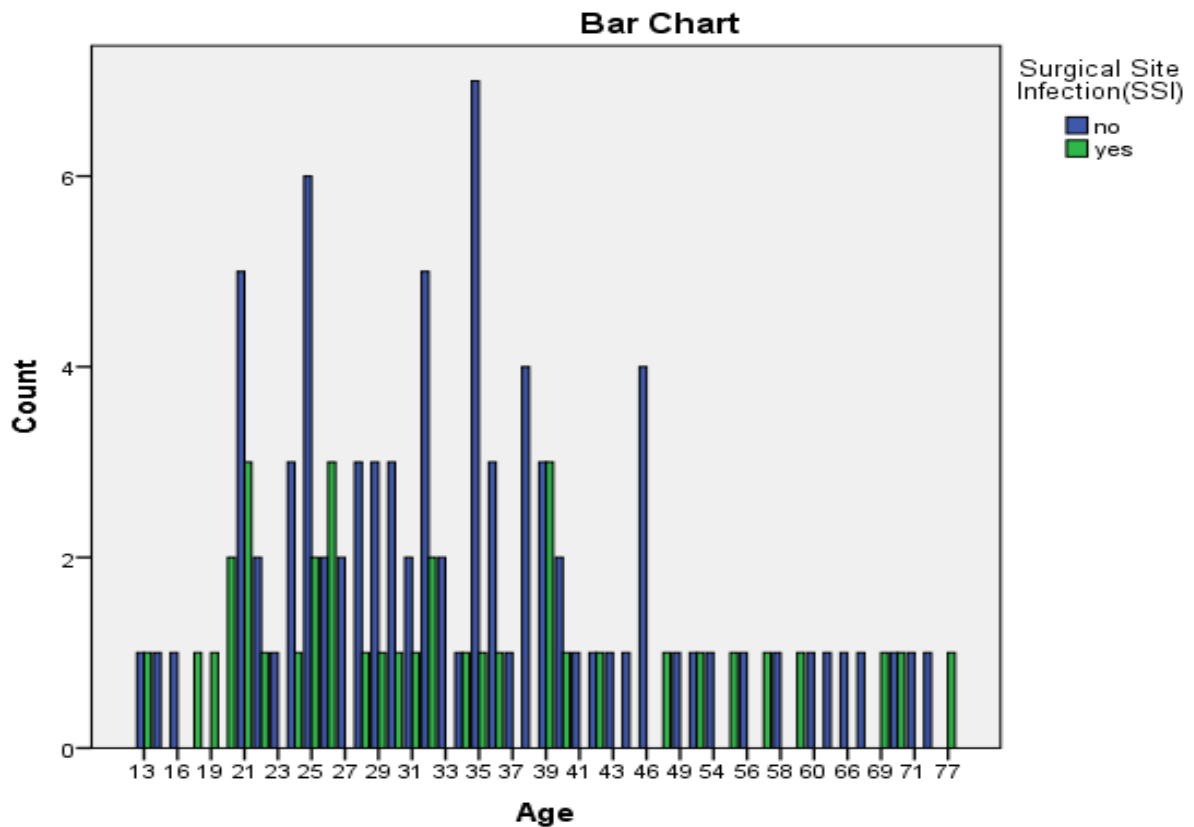
Table 5: Statistics on Age

Mean	35.48
Std. Error of Mean	1.282
Median	32.00
Std. Deviation	14.048
Variance	197.344
Skewness	1.069
Std. Error of Skewness	.221
Range	64
Minimum	13
Maximum	77

4.4 Association between age and SSI.

Peak age of infection was seen at 21, 27 and 39 years as seen in figure 3 below. The association between age and SSI was not significant (p-value 0.715).

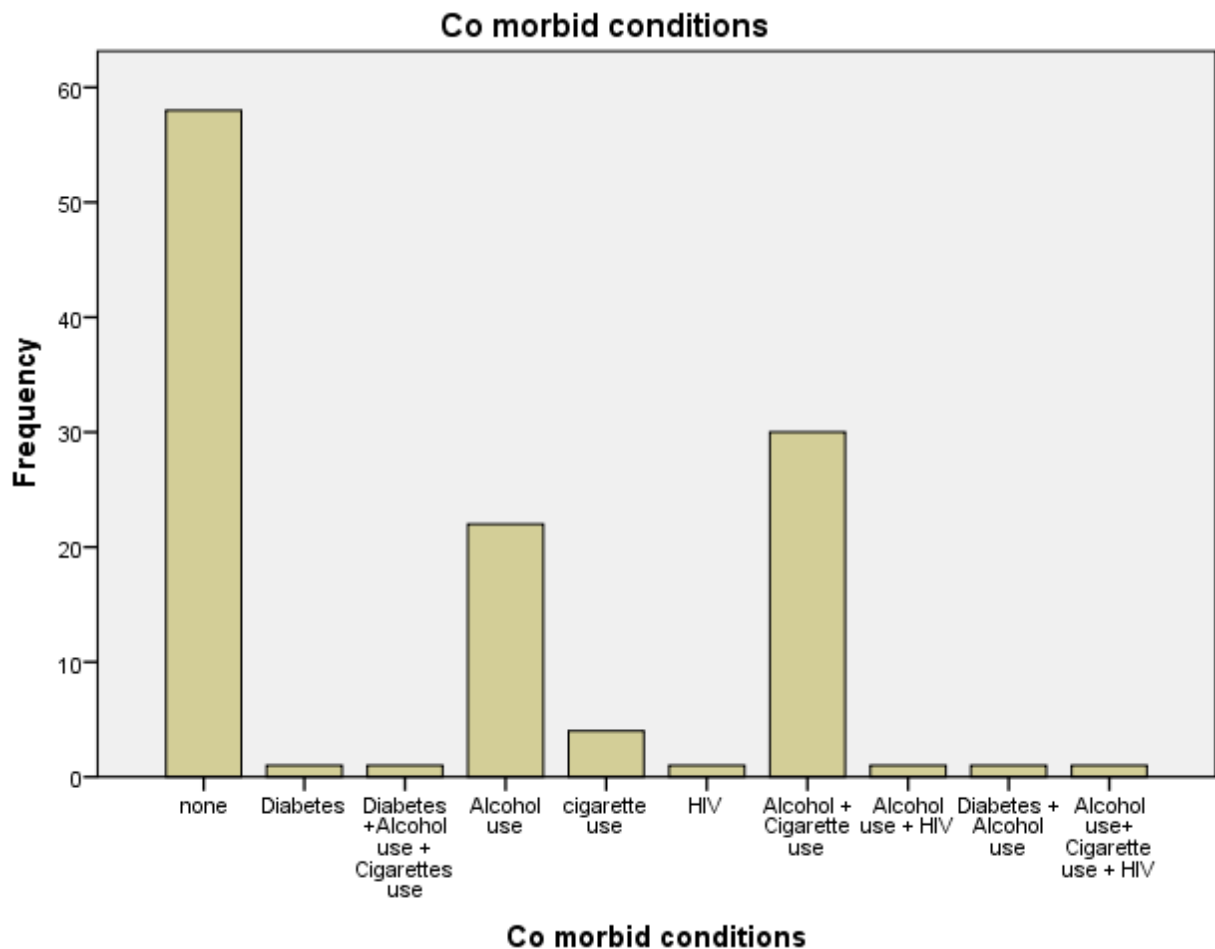
Figure 3: Distribution, association between age and SSI



4.5 Substance use and Co morbid conditions.

51.7% (62/120) of patients had co morbid conditions, consumed alcohol and cigarettes. Combination of alcohol and cigarette use accounting for 25% (30/120) while alcohol use accounted for 18.3% (22/120).co morbid conditions such as diabetes mellitus and HIV accounted for less than 1% (1/120) as seen in figure 4 below.

Figure 4: Distribution of substance abuse and co-morbid conditions



4.6 Association between co morbid factors, substance use and SSI.

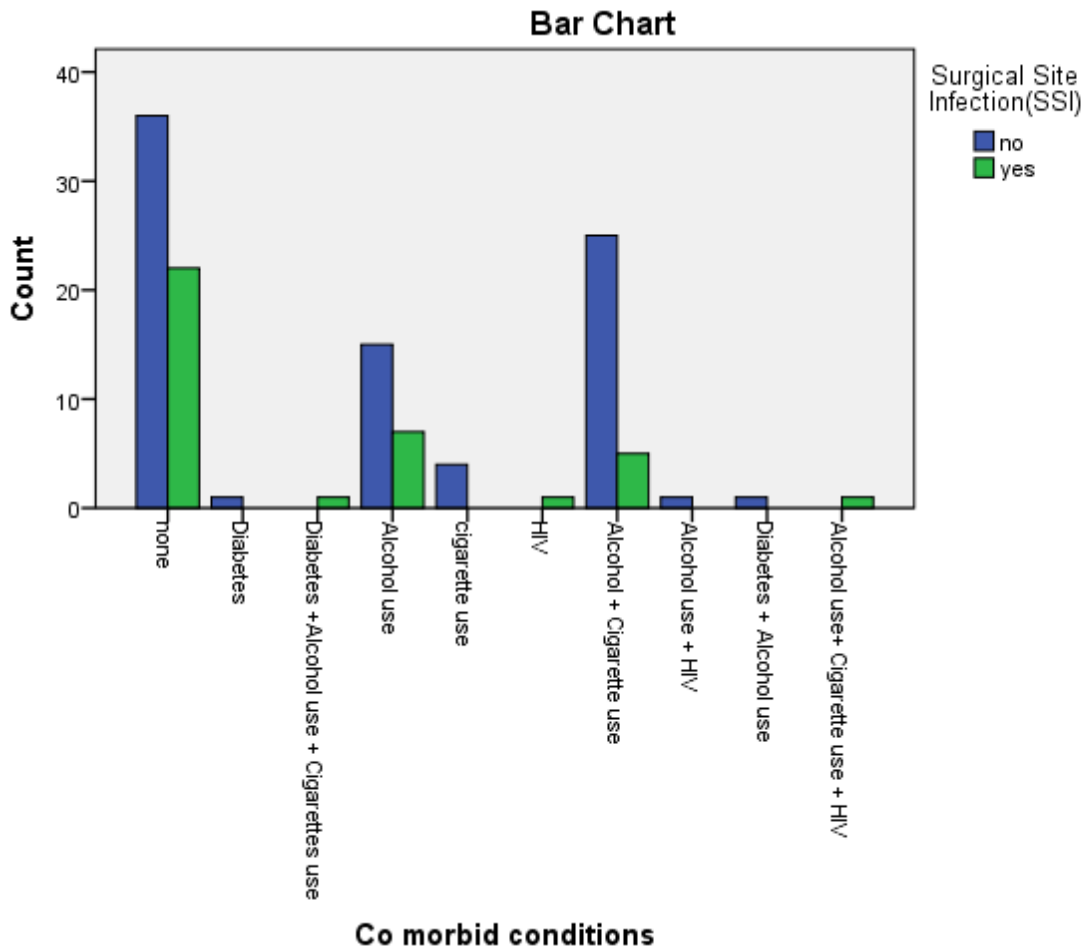
Patients who had diabetes mellitus accounted for less than one 1% (1/120) and did not have SSI. Patients with HIV accounted for less than 1% (1/120) and all had SSI as seen in figure 6 below.

Alcohol use was associated with overall SSI at 5.8% (7/120) whereas alcohol and cigarettes use was associated with SSI at 4.2% (5/120) as seen in figure 5 below.

Patients with diabetes mellitus consumed alcohol and cigarettes accounted for less than 1% (1/120) and all had SSI. Similarly patient with HIV who consumed alcohol and cigarettes accounted for less than 1% (1/120) and all had SSI. On the contrary patients with HIV or diabetes mellitus who consumed alcohol accounted for less than 1% (1/120) and neither has SSI as seen in figure 5 below.

The association between co morbid condition, substance use and SSI was not significant (p-value 0.120).

Figure 5: Association between co-morbid factors, substance use and SSI



4.7 Preoperative duration.

Mean preoperative duration was 30.68 ± 3.067 hours with median duration of 12 hours with range of 216 hours and positive skewness of 2.234 as seen in table 6 below.

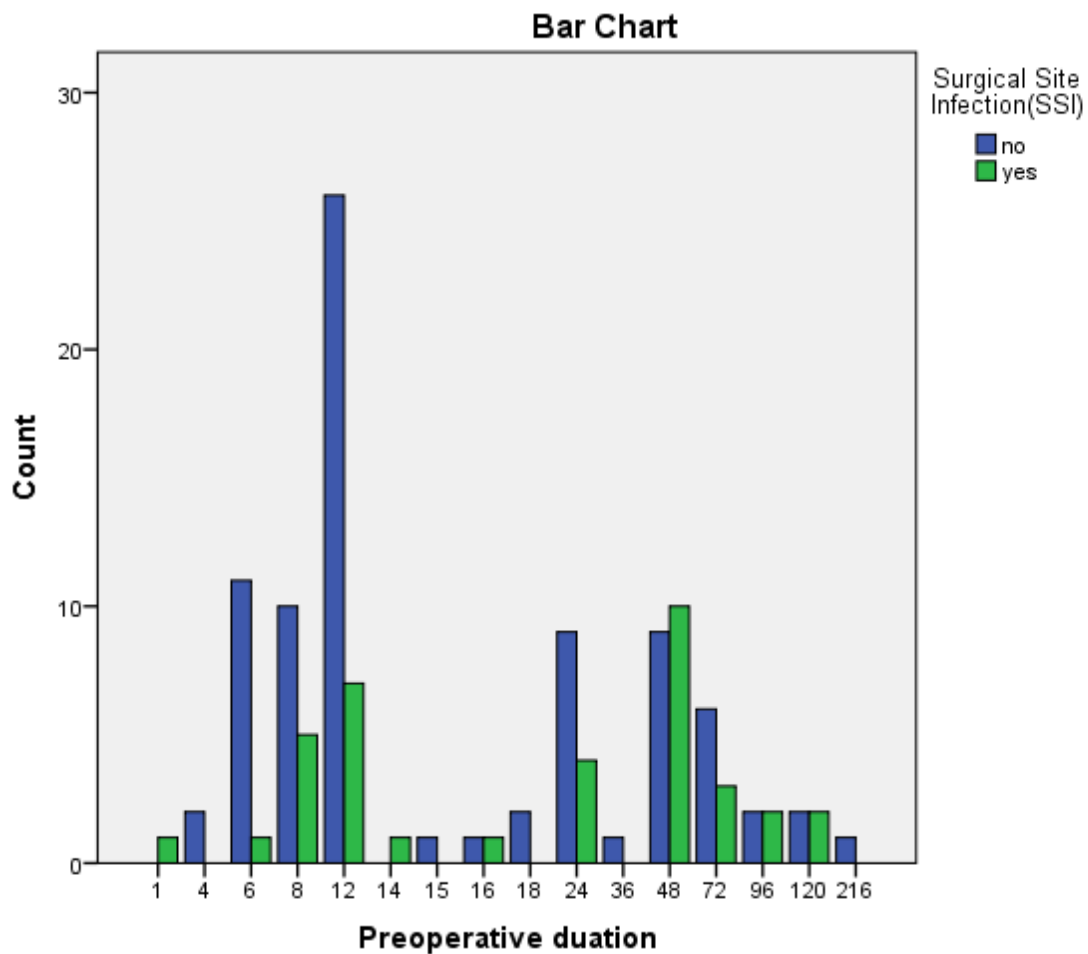
Table 6: Preoperative duration

Mean	30.68
Std. Error of Mean	3.076
Median	12.00
Std. Deviation	33.696
Variance	1135.44
Skewness	2.324
Std. Error of Skewness	.221
Range	215
Minimum	1
Maximum	216

4.8 Association between preoperative duration and SSI.

SSI incidence was higher in patients who had preoperative duration of 48 hour at 8.3 % (10/120), 12 hours at 5.8% (7/120) as seen in figure 6 below. The association between preoperative procedure and SSI was not statistically significant (p-value 0.267).

Figure 6: Association between preoperative duration and SSI



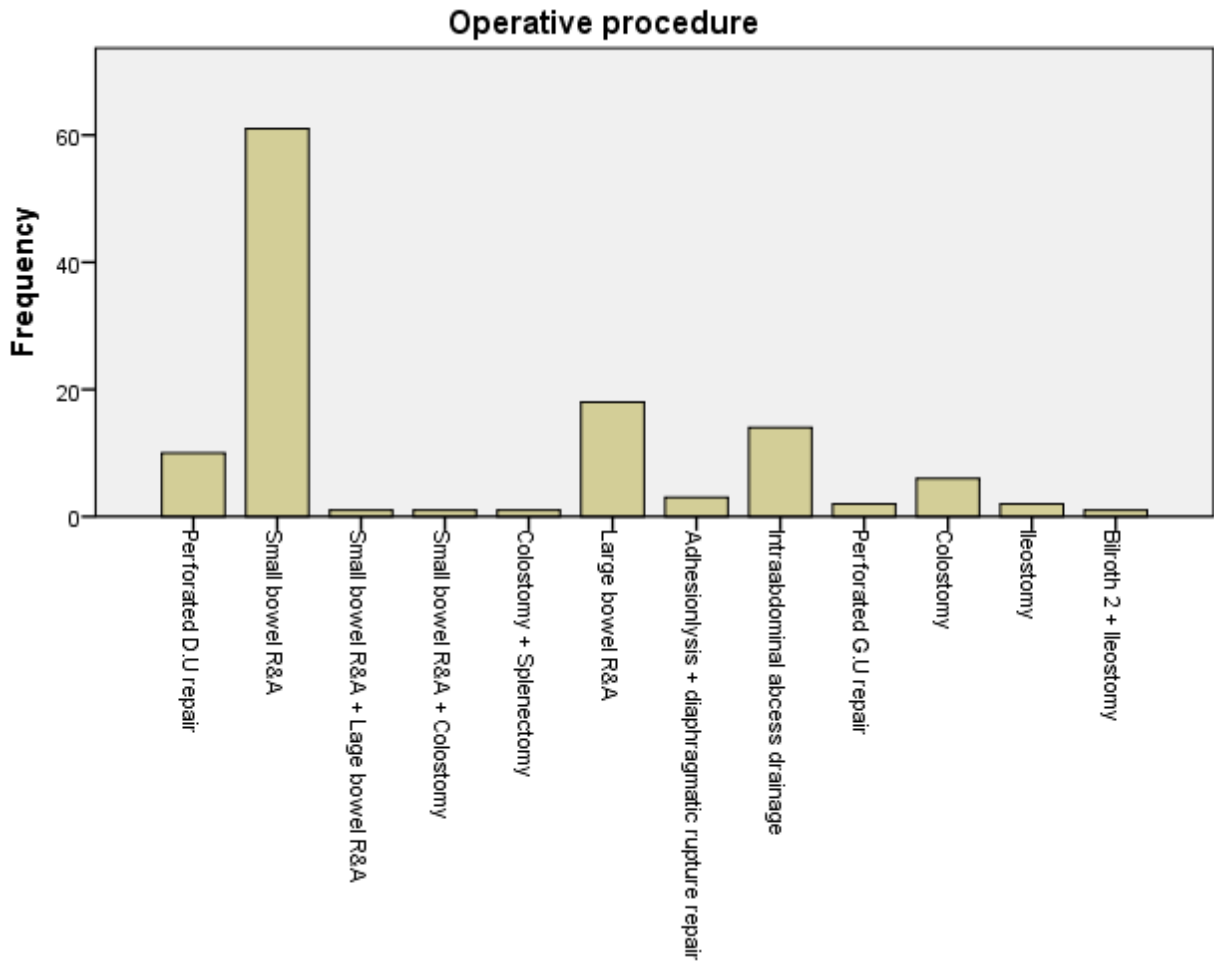
4.9 Operative procedure.

Small bowel pathology with resection and anastomosis accounted for more than half of the procedures at 50.8% (61/120) while intraabdominal abscess drainage accounted for 11.7% (14/120) as seen in table 7 and figure 7 below.

Table 7: Distribution on operative procedure

Operative procedure	Frequency	Percent (%)	Cumulative Percent (%)
Perforated D.U repair	10	8.3	8.3
Small bowel R&A	61	50.8	59.2
Small bowel R&A + Large bowel R&A	1	.8	60.0
Small bowel R&A + Colostomy	1	.8	60.8
Colostomy + Splenectomy	1	.8	61.7
Large bowel R&A	18	15.0	76.7
Adhesionlysis + diaphragmatic rupture repair	3	2.5	79.2
Intraabdominal abscess drainage	14	11.7	90.8
Perforated G.U repair	2	1.7	92.5
Colostomy	6	5.0	97.5
Ileostomy	2	1.7	99.2
Bilroth 2 + Ileostomy	1	.8	100.0
Total	120	100.0	

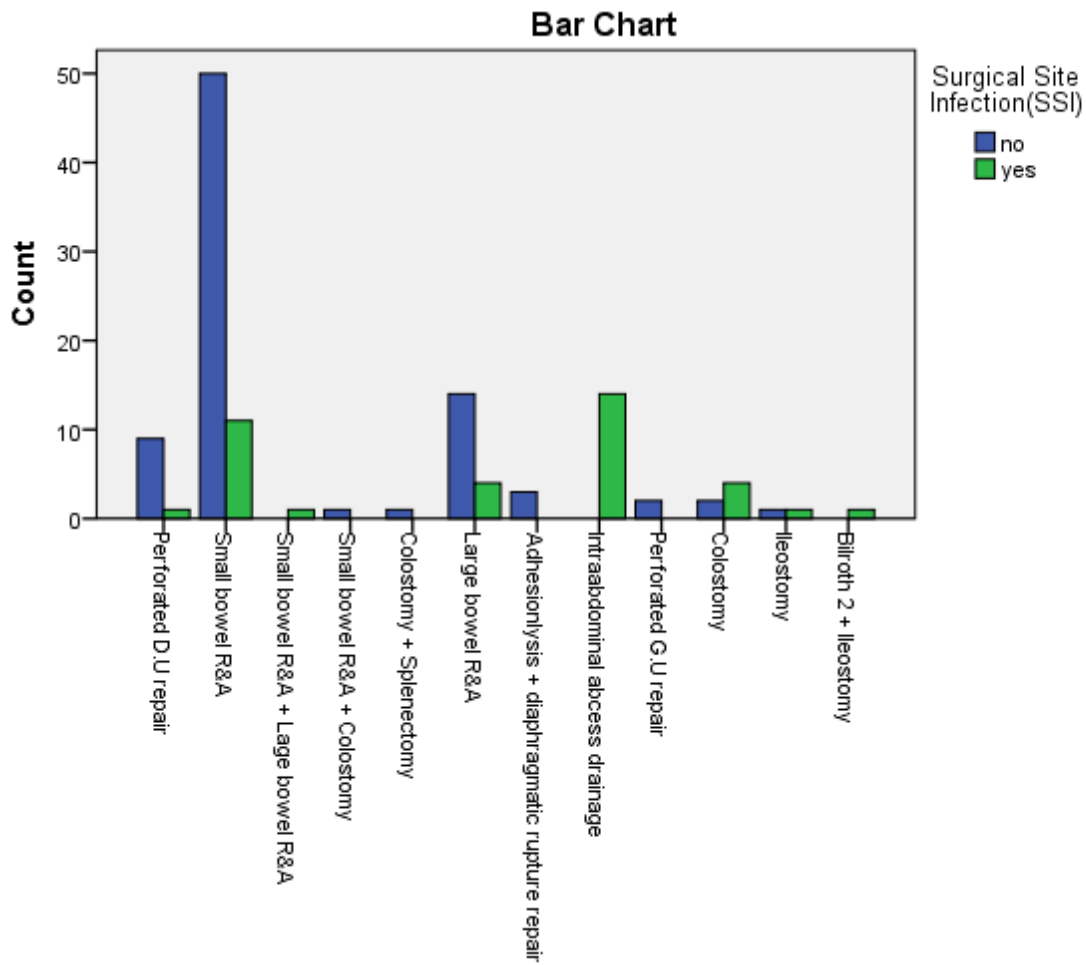
Figure 7: Distribution on Operative procedure



4.10 Association between operative procedure and SSI.

Intraabdominal abscess drainage accounted for most of SSI at 11.7% (14/120) while small bowel resection and anastomosis accounted for 9.2% (11/120) as seen in figure 8 below. There was a significant association between operative procedure and SSI (P-value 0.00)

Figure 8: Association between operative procedure and SSI



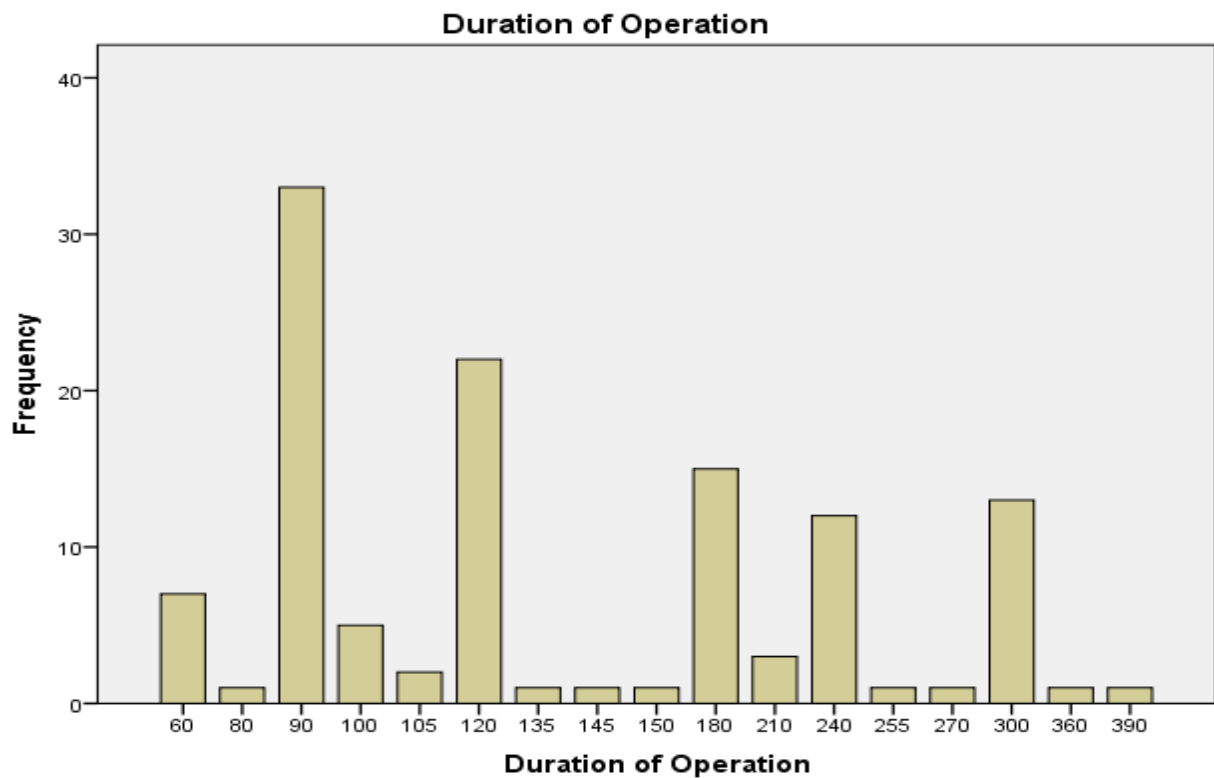
4.11 Duration of operation.

Mean operation time was 155.29 ± 7.270 minutes with median duration of 120 minutes, range of 30 minutes with longest operation lasting 390 minutes with positive skewness of 0.903 as seen in table 8 below. Bulk of the operations lasted 90 minutes at 27.5% (33/120), 120 minutes at 18.3% (22/120), 240 minutes at 10% (12/120) and 300 minutes at 10.8% (13/120) as seen in figure 10 below.

Table 8: Duration of Operation

Mean	155.29
Std. Error of Mean	7.270
Median	120.00
Std. Deviation	79.640
Variance	6342.56
Skewness	.908
Std. Error of Skewness	.221
Range	330
Minimum	60
Maximum	390

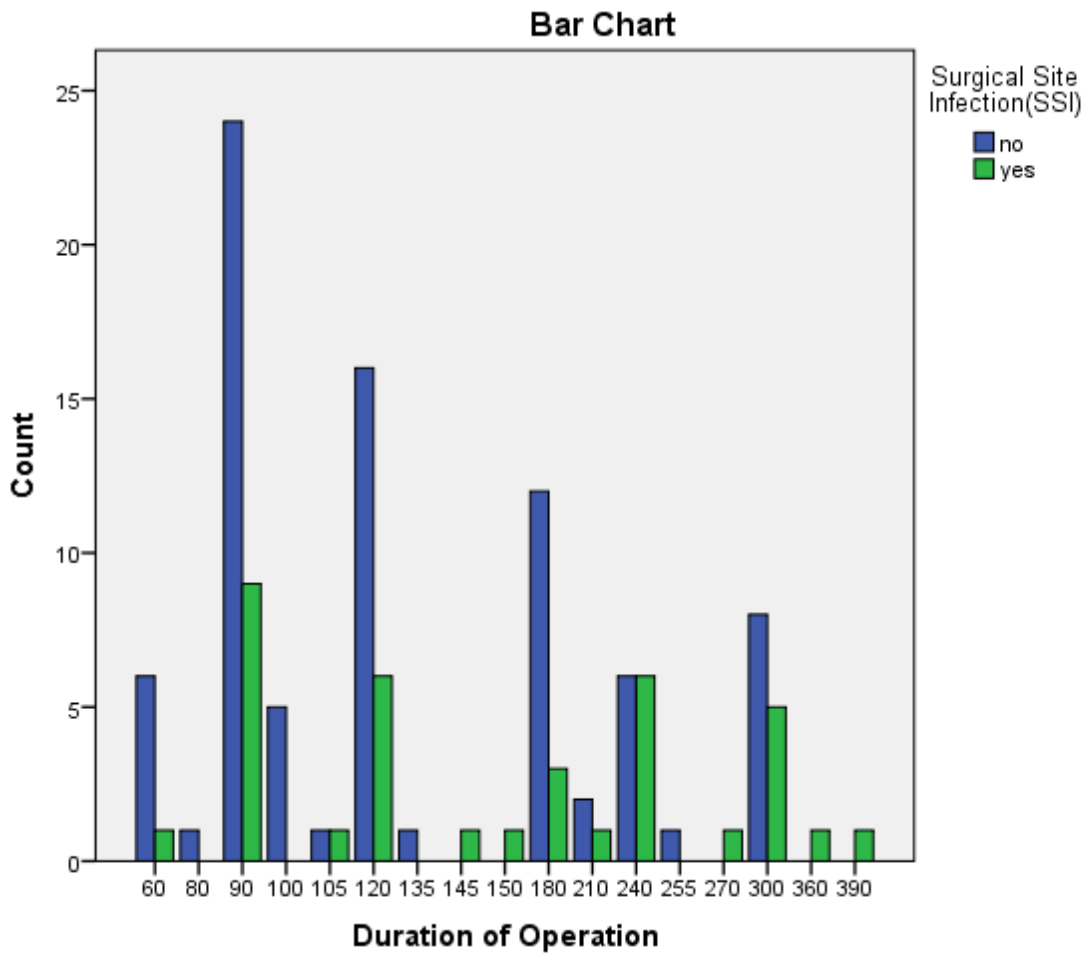
Figure 9: Distribution on operative procedure



4.12 Association between duration of operation and SSI.

Peak SSI was observed in patients who were operated at 90,120,240, 300,360 and 390 minutes at 7.5% (9/120), 5 % (6/120), 5% (6/120), 4.2% (5/120), 0.8 %(1/120) and 0.8 %(1/120) respectively as seen in figure 10 below. From the study association between duration and SSI was not statistically significant (p- value 0.238).

Figure 10: Association between duration of operation and SSI



4.13 Wound classification.

From the study dirty wounds accounted for 60% (72/120), contaminated 30% (36/120) and clean contaminated 10% (12/120) of all patients operated. As seen in table 9 and figure 11 below.

Table 9: Distribution on wound classification

Wound classification	Frequency	Percent (%)	Cumulative Percent (%)
clean-contaminated	12	10.0	10.0
contaminated	36	30.0	40.0
Dirty	72	60.0	100.0
Total	120	100.0	

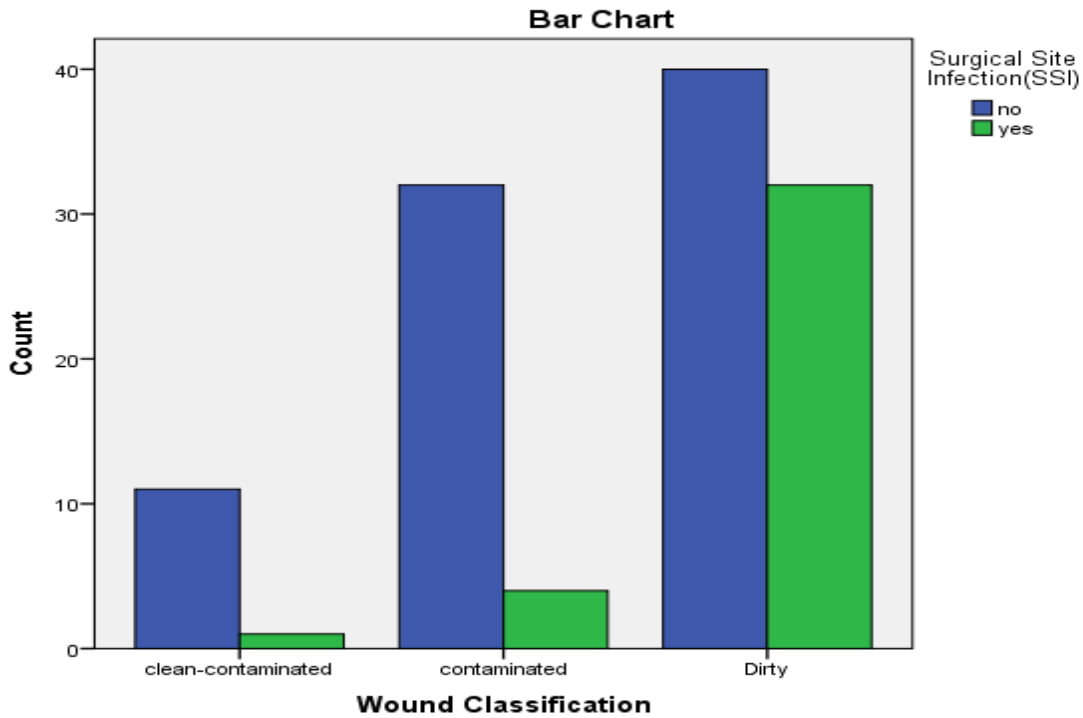
Figure 11: Distribution on wound classification



4.14 Association between wound classification and SSI.

Dirty wounds accounted for 26.7% (32/120) of all SSI, contaminated 3.3% (4/120) while clean contaminated 0.8% (1/120) as seen in figure 12 below. Association between wound class and SSI was statistically significant (p-value 0.00)

Figure 12: Association between wound classification and SSI



4.15 ASA Score.

In the study patients with ASA score 1 accounted for 82.5% (99/120), while ASA 2 accounted for 17.5% (21/120) with positive skewness of 1.732 as shown in table 10 below.

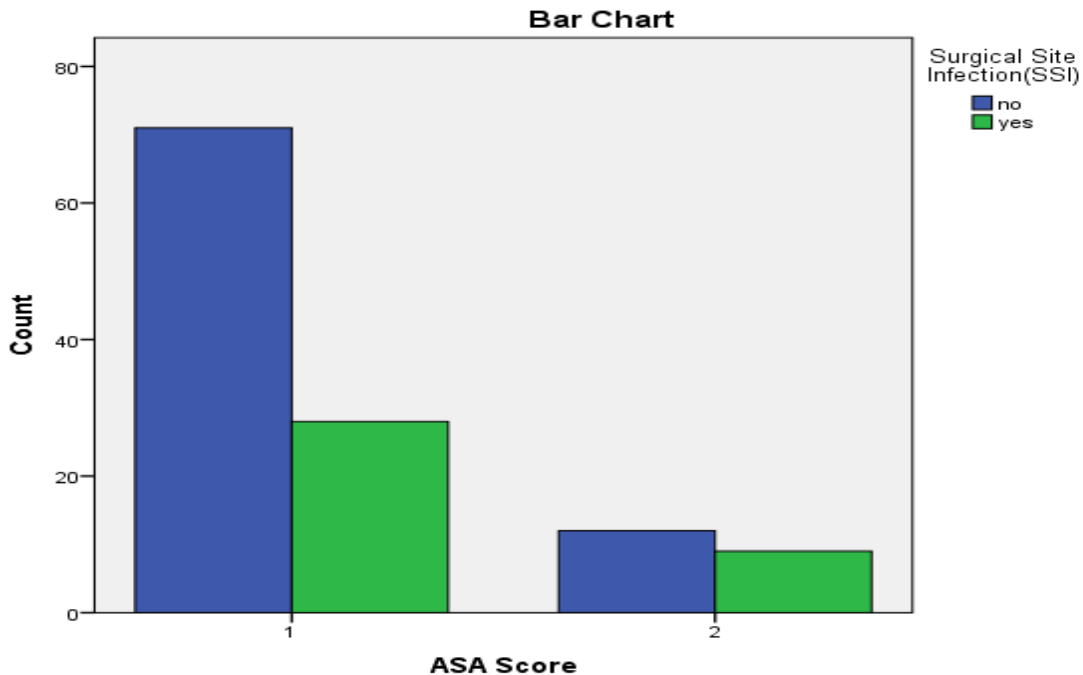
Table 10 : Distribution on ASA score

ASA score	Frequenc y	Percent	Valid Percent	Cumulative Percent
1	99	82.5	82.5	82.5
2	21	17.5	17.5	100.0
Total	120	100.0	100.0	

4.16 Association between ASA score and SSI.

Patient with ASA score 1 had overall SSI rate of 23.3% (28/120) while those with ASA score 2 had SSI rate of 7.5% (9/120) as seen in figure 13 below. Association between ASA score and SSI was not statistically significant (p-value 0.146).

Figure 13: Association between ASA score and SSI



4.17 Perioperative transfusion.

9.2% (11/120) of patients received perioperative transfusion with those receiving 2 units accounting for 5.8% (7/120) as seen in table 11 below.

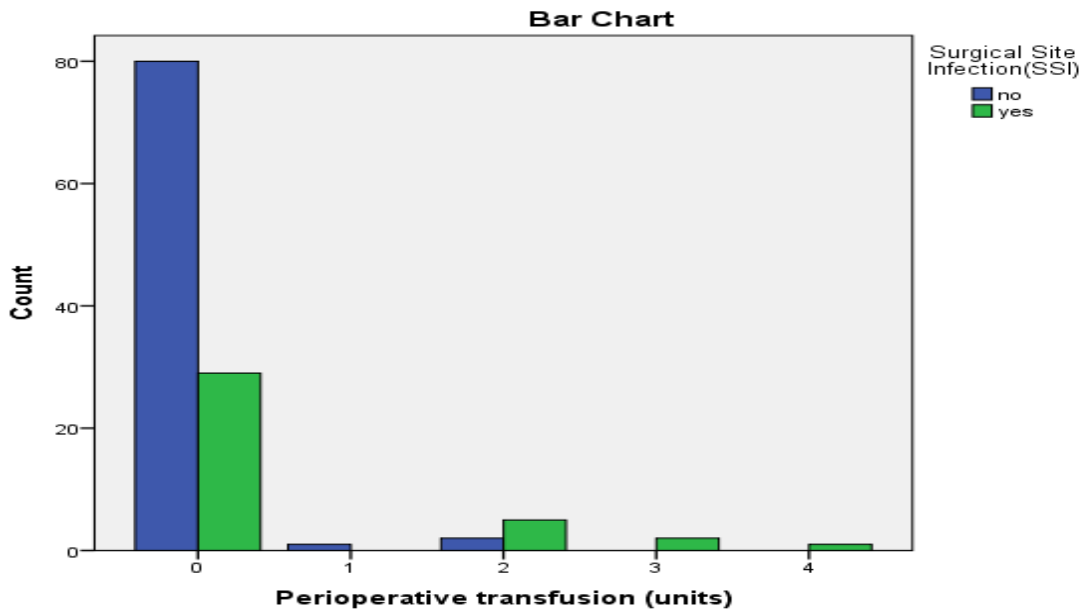
Table 11: Distribution on perioperative transfusion

No. of units	Frequency	Percent (%)	Cumulative Percent (%)
0	109	90.8	90.8
1	1	.8	91.7
2	7	5.8	97.5
3	2	1.7	99.2
4	1	.8	100.0
Total	120	100.0	

4.18 Association between Perioperative transfusion and SSI.

Overall SSI was at 24.2% (29/120) for those who did not receive blood transfusion, 4.2% (5/120) for those who received 2 units, 1.7% (2/120) for those who received 3 units and 0.8% (1/120) those who received 4 units of blood as shown in figure 14 below. Association between SSI and transfusion of blood was statistically significant (p-value 0.009).

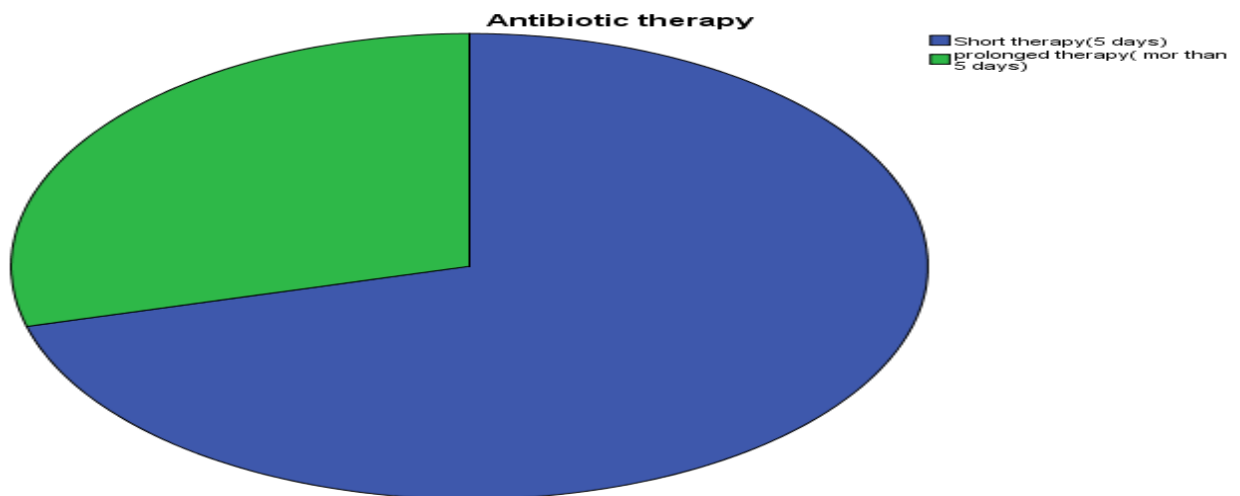
Figure 14: Distribution on perioperative transfusion



4.19 Antibiotic therapy.

70.8% (85/120) of patients received antibiotic short-course therapy whereas 29.2% (15/120) received antibiotics for more than 5 days as seen in figure 15 below.

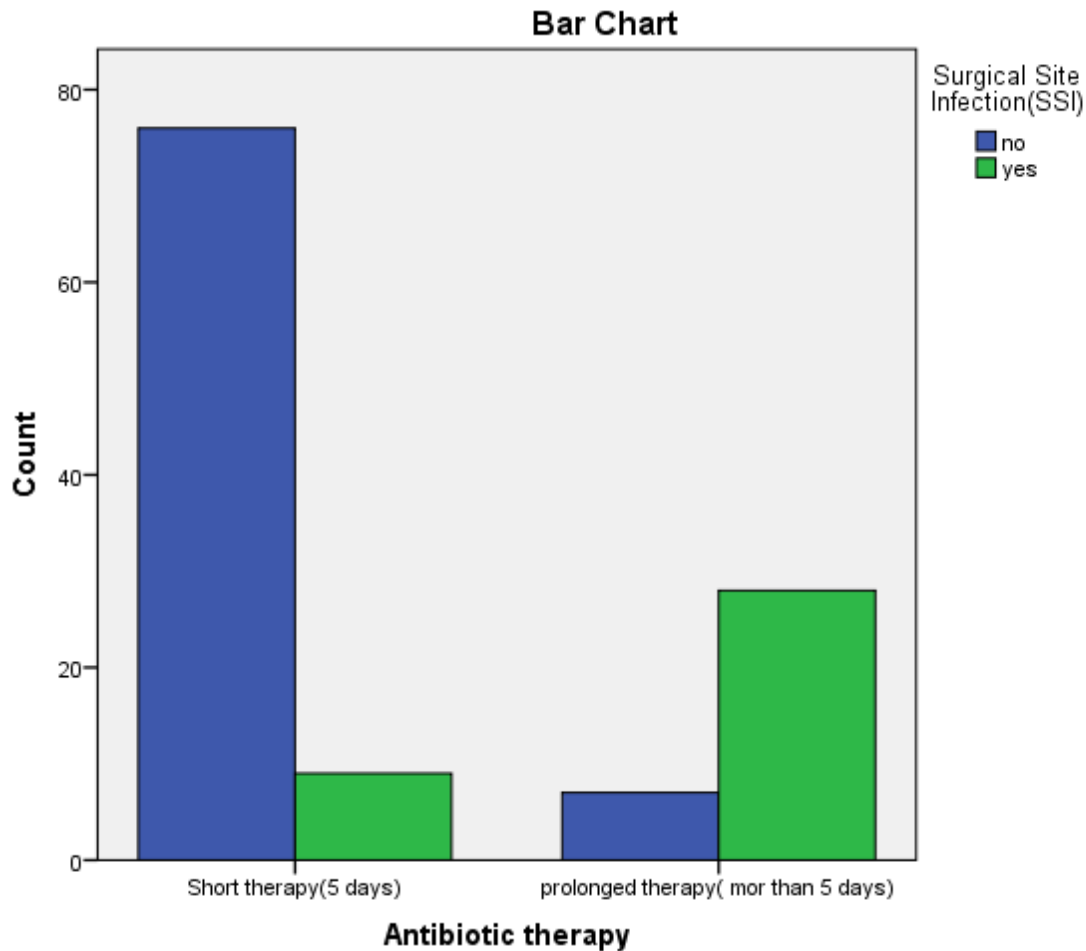
Figure 15: Distribution on antibiotic therapy



4.20 Association between antibiotic therapy and SSI.

Patients who had prolonged antibiotic therapy, 23.3% (28/120) accounted for overall SSI while 7.5% ((9/120) of patients who received short therapy had SSI as seen in figure 16 below. Association between SSI and antibiotic therapy was significant (p-value 0.000).

Figure 16: Association between antibiotic therapy and SSI



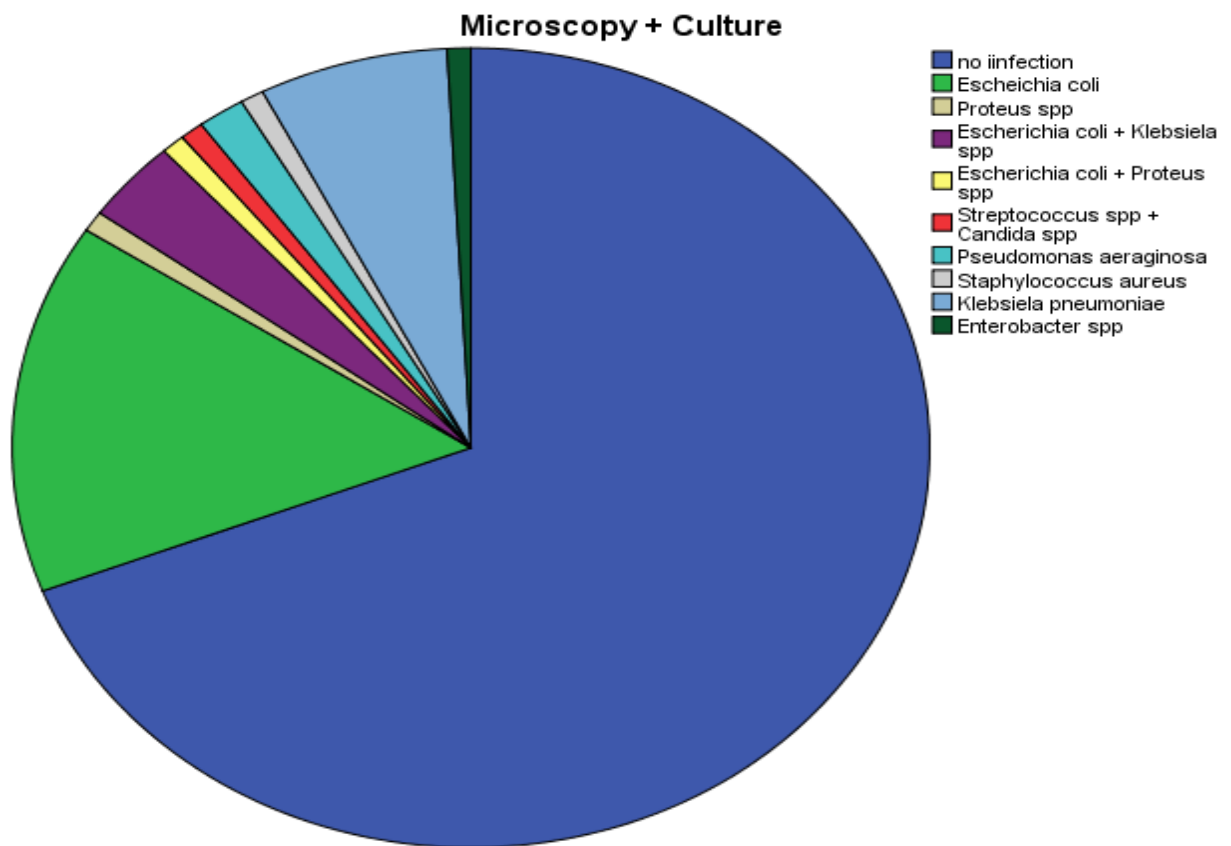
4.21 Microbial profile.

Escherichia coli accounted for 15% (18/120) of all isolates while polymicrobial infections cumulatively accounted for 4.9 % (6/120). Within positive culture isolates, Escherichia coli accounted for 48.6% while polymicrobial infections cumulatively accounted 15.2% for as seen in table 12 and figure 17 below

Table 12 : Distribution of micro-organisms

			Surgical Site Infection(SSI)		Total
			no	yes	
Microscopy + Culture	no infection	Count % of Total	83 69.2%	0 0.0%	83 69.2%
	<i>Escherichia coli</i>	Count % of Total	0 0.0%	18 15.0%	18 15.0%
	<i>Proteus mirabilis</i>	Count % of Total	0 0.0%	1 0.8%	1 0.8%
	<i>Escherichia coli</i> + <i>Klebsiella pneumonia</i>	Count % of Total	0 0.0%	4 3.3%	4 3.3%
	<i>Escherichia coli</i> + <i>Proteus mirabilis</i>	Count % of Total	0 0.0%	1 0.8%	1 0.8%
	<i>Streptococcus pyogenes</i> + <i>Candida albicans</i>	Count % of Total	0 0.0%	1 0.8%	1 0.8%
	<i>Pseudomonas aeruginosa</i>	Count % of Total	0 0.0%	2 1.7%	2 1.7%
	<i>Staphylococcus aureus</i>	Count % of Total	0 0.0%	1 0.8%	1 0.8%
	<i>Klebsiella pneumonia</i>	Count % of Total	0 0.0%	8 6.7%	8 6.7%
	<i>Enterobacter spp.</i>	Count % of Total	0 0.0%	1 0.8%	1 0.8%
Total	Count % of Total	83 69.2%	37 30.8%	120 100.0%	

Figure 17: Distribution of micro-organisms



5.0 CHAPTER FIVE

5.1 DISCUSSION.

SSI incidence is an important outcome in patients undergoing surgical procedures as it is a maker of quality of surgical care.

This study reviewed one hundred and twenty (120) patients.

5.1.1 SSI incidence.

The overall incidence of SSI was 30.8%, this is not different from earlier studies that showed incidence of SSI following emergency laparotomy at 27.5- 40%^{2,5}. In this study, Organ/space SSI type accounted for the most of the infections at 48.64 %, deep incisional SSI 43.24% and superficial incisional SSI 8.11%. This result was different from an earlier local study which showed organ/space SSI at 37.5%, deep incisional SSI 37.5% and superficial incisional SSI 25%. However, the previous local study did not discriminate emergency and elective surgery².

5.1.2 Gender distribution and SSI.

Male patients accounted for 76.7% while female patients were at 23.3% which was similar to a previous local study which had male patients at 75.9% and female patients at 24.1%². In this study SSI rate was higher in male patients at 20.8 % as compared to female 10 %.

5.1.3 Wound classification and SSI.

In this study, dirty wounds accounted for 86.5% of all SSI, contaminated wounds 10.8 % and clean contaminated wounds 2.7%. This differed from an earlier local study which showed SSI for dirty wounds at 39.2%, contaminated wounds at 23.3% and clean-contaminated wounds at 37.5%, however, the earlier study did not dichotomize elective and emergency procedures².

From this study, the association between wound class and SSI was statistically significant (p-value 0.00) which was consistent with earlier studies whereby contaminated and dirty wounds were known predictors of SSI^{2, 5, and 6}.

5.1.4 Wound classification and SSI types.

Findings on wound classification revealed clean contaminated wounds had 8.1% superficial incisional SSI, this differed from an earlier local study which revealed clean contaminated wounds to have superficial incisional SSI rate at 19%.

Contaminated wounds had 5.6% superficial incisional SSI and 5.6% deep incisional SSI, which differed with an earlier local study where infection rate was higher at 23.1% for superficial incisional SSI and 23.1% for deep incisional SSI ².

The association between SSI and wound type was significant (p-value 0.001) and was consistent with earlier studies. This finding is linked to intrinsic degree of microbial contamination as a known independent predictor of SSI^{5,6}.

5.1.5 Age and SSI.

Mean age was 35.48±1.282 which is a lower age group and more productive with peak age of infection being at 21, 27 and 39 years even though the distribution is positively skewed and hence association between age and SSI was not significant (p-value 0.715). This is consistent with a previous study where age was a risk factor but not known independent predictor of SSI⁵.

5.1.6 Co morbid factors, substance use and SSI.

Fifty one point seven percent (51.7%) patients had co morbid conditions i.e. diabetes mellitus, HIV and substance abuse with alcohol alone, alcohol and cigarettes accounting for more than half of all observed conditions in this study. From this study diabetes mellitus, HIV, overall were less than one percent .The association between SSI, substance abuse and co-morbid conditions from this study was not significant. Earlier studies had shown co-morbid condition and substance abuse served as risk factor but were not known independent predictor of SSI.^{5, 6, and 7}.

5.1.7 Preoperative duration and SSI

The average preoperative duration was 30.68±3.067 hours with peak SSI was observed at 48th and 12th hour. Even though the distribution was skewed, the association between preoperative duration and SSI was not significant (p-value 0.267).This relates to other studies where length of preoperative stay was a risk factor but not known predictor of SSI^{5, 6}.

5.1.8 Operative procedure and SSI.

More than half of the patients operated had small bowel resection and anastomosis while intra-abdominal abscess drainage accounted for 11.7% with most of this procedure resulting in SSI. There was a significant association between operative procedure and SSI (p-value 0.00).This is consistent with earlier studies where degree of wound contamination is directly related to the operative procedure and known predictor of SSI^{5, 6}.

5.1.9 Duration of operation.

The mean operative time was 155.29 ± 7.270 minutes with range of 330 minutes, 45.8% of procedures, took less than 120 minutes. This varied from previous local where 92% of all procedures lasted more than 180 minutes². Peak in SSI was at 90 minute with all procedures lasting more than 360 minutes having SSI. The distribution was positively skewed with association between duration of operation and SSI not being significant. This was inconsistent with previous studies where duration of operation > 120 minutes was a known predictor of SSI^{5,6}.

5.1.10 ASA Score and SSI.

Eighty two point five percent (82.5) % of patients reviewed had ASA Score of 1 while 17.5% had ASA score of 2 with positive skewness of 1.732. ASA score of 1 patients accounted for 23.3% of overall SSI while patients with ASA score of 2 accounted for 7.5%. Association between ASA score and SSI from the study was not statistically significant (p-value 0.146). From earlier studies, ASA score of more than 2 is a known predictor of developing SSI^{5,6}. In this study however, majority of the patients were young with ASA score less than 2. Due to skewness in distribution of the patients, data was insufficient to draw conclusion.

5.1.11 Perioperative transfusion and SSI.

Nine point two percent (9.2%) of reviewed patients had blood transfusion with overall SSI at 6.6%. The association between transfusion and SSI was significant (p-value 0.009). In earlier studies, blood transfusion was a risk factor but not known independent predictor of SSI^{5,6}.

5.1.12 Antibiotic therapy and SSI.

On antibiotic therapy 70.8% of patients were treated within five (5) days whereas 29.2% received antibiotics for more than 5 days. Patients who had prolonged antibiotic therapy, accounted for 23.3% of overall SSI, while patients on short antibiotic therapy had overall SSI rate of 7.5% which was statistically significant (p-value 0.000). Increased infection rate in the patients who received prolonged antibiotic therapy could possibly be due to inappropriate selection of antibiotics. ^{5,6}.

5.1.13 Microbial profile.

Mono microbial infections accounted for 84.8% of all SSI, while polymicrobial infections accounted for 15.2%. Escherichia coli was the most common isolated bacteria at 48.6% which was consistent with an earlier study where Escherichia coli was the commonest isolate in SSI secondary to bowel procedures². There were no anaerobic isolates from his study which was consistent with an earlier local study².

5.2 CONCLUSION.

Overall SSI rate was 30.8%, with organ/space SSI accounting for the most of infections. In the emergency setting dirty wounds accounted for most of the cases undergoing emergency laparotomy.

Young male patients were at a higher risk of undergoing emergency laparotomy for small bowel pathology with increased risk of SSI. There was increased rate of SSI among patients who consumed alcohol and smoked cigarettes.

Prolonged preoperative duration did not necessarily result in increased in rate of SSI, however, operative procedure, ASA score, prolonged antibiotic therapy and perioperative transfusion were all associated with increased risk of SSI.

Escherichia coli was the most common isolate with mono microbial infection accounting for most of the SSI, unlike in other studies where polymicrobial infection accounted for most of abdominal SSI. From this study there were no anaerobic isolates.

5.3 RECOMMENDATION.

Young male individuals are likely to develop acute abdomen, therefore there should be public education program on potential harmful effects of alcohol use and cigarette smoking.

SSI surveillance at general surgical unit with appropriate feedback to the clinical team and hospital management would result in initiatives aimed at reducing SSI. Infection control committees within surgical units as well as hospital based antibiotic stewardship based programs should be in place to guide judicious use of antibiotics in treatment and prevention of surgical infections.

Reduction in preoperative and operative duration, judicious use of blood and blood products and use of appropriate antibiotic therapy could reduce the incidence of SSI in emergency bowel surgery.

Analytical studies looking at the identified risk factors vs. SSI, would be able to define independent predictors of SSI in our local setting.

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APPENDICES

APPENDIX I: TABLES.

Table 1; CDC criteria for SSI

Criteria for defining a surgical site infection
<i>Superficial incisional SSI</i>
Infection occurs within thirty days after the operation <i>and</i> infection involves only skin or subcutaneous tissue of the incision <i>and</i> at least <i>one</i> of the following: <ol style="list-style-type: none">1. Purulent drainage, with or without laboratory confirmation, from the superficial incision.2. Organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial incision.3. At least one of the following signs or symptoms of infection: pain or tenderness, localized swelling, redness, or heat <i>and</i> superficial incision Is deliberately opened by surgeon, <i>unless</i> incision is culture-negative. <ol style="list-style-type: none">4. Diagnosis of superficial incisional SSI by the surgeon or attending physician. Do <i>not</i> report the following conditions as SSI: <ol style="list-style-type: none">1. Stitch abscess (minimal inflammation and discharge confined to the points of suture penetration).2. Infection of an episiotomy or new-born circumcision site.3. Infected burn wound.4. Incisional SSI that extends into the fascia and muscle layers (see deep incisional SSI). <i>Note:</i> Specific criteria are used for identifying infected episiotomy and circumcision sites and burn wounds.
<i>Deep incisional SSI</i>
Infection occurs within thirty days after the operation if no implant is left in place or within one year if implant is in place and the infection appears to be related to the operation <i>and</i> infection involves deep soft tissues (e.g., fascia and muscle layers) of the incision <i>and</i> at least <i>one</i> of the following: <ol style="list-style-type: none">1. Purulent drainage from the deep incision but not from the organ/space component of the

surgical site.

2. A deep incision spontaneously dehisces or is deliberately opened by a surgeon when the patient has at least one of the following signs or

Symptoms: fever ($>38^{\circ}\text{C}$), localized pain, or tenderness, unless site is culture-negative.

3. An abscess or other evidence of infection involving the deep incision is found on direct examination, during re-operation, or by histopathology

Or radiologic examination.

4. Diagnosis of a deep incisional SSI by a surgeon or attending physician.

Notes:

1. Report infection that involves both superficial and deep incision sites as deep incisional SSI.

2. Report an organ/space SSI that drains through the incision as a deep incisional SSI.

Organ/space SSI

Infection occurs within thirty days after the operation if no implant is left in place or within 1 year if implant is in place and the infection appears to be related to the operation

and

infection involves any part of the anatomy (e.g., organs or spaces), other than the incision, which was opened or manipulated during an operation

and at least *one* of the following:

1. Purulent drainage from a drain that is placed through a stab wound into the organ/space.

2. Organisms isolated from an aseptically obtained culture of fluid or tissue in the organ/space.

3. An abscess or other evidence of infection involving the organ/space that is found on direct examination, during reoperation, or by

Histopathology or radiologic examination.

4. Diagnosis of an organ/space SSI by a surgeon or attending physician

Drawn with courtesy from; infection control and hospital epidemiology vol.20; no.4 pg. 252.

APPENDIX II: STATEMENT OF CONSENT.
SURGICAL SITE INFECTION IN PATIENTS UNDERGOING EMERGENCY
EXPLORATIVE LAPAROTOMY AT KENYATTA NATIONAL HOSPITAL

Part 1; INFORMATION SHEET.

Introduction.

I am Dr. Miima Elikanah Sammy postgraduate student in the University of Nairobi, School of Medicine Department of Surgery at KNH carrying out the study titled above.

Purpose of the study.

I am carrying out a study to look at infections that occur on the abdomen after surgery into the abdominal cavity following diseases of the intestines. My study wants to find out some of the patient conditions such as diabetes, cigarette smoking, use of drugs called steroids and HIV condition, if they have higher risk of causing infection. I will also look at what percent of patients who undergo surgery develop infection. Finally those who get infection I will look at the kind of bacteria that is responsible for the infection. Results of this study will be used to find ways of reducing infection in surgery and therefore improve quality of surgical care. This information I am sharing with you as I invite you to voluntarily participate in this study. You are free to ask questions and clarification where you do not understand.

Type of research intervention.

My study will involve a patient being recruited before surgery, follow up during and after surgery. Before, during and after surgery you will be treated as per KNH-patient care protocols. After surgery on day two, your surgical wound will be examined for possible infection. If there is an infection, specimen of pus will be obtained from the wound and taken to laboratory for investigation.

Follow up.

During this period of your care in the ward you will be seen by a clinician every day, assessed on your recovery and given appropriate treatment for any complication. Once you are discharged, if it is within seven days we will review you in the SOPC on day fifteen and day thirty whereas if discharged after seven days, we will review you in the clinic on day thirty. For the visit there will be facilitation in terms of bus fare. You will be contacted on the

phone number you have provided of your visit on day eleven and day twenty six. Those who present after day thirty will not be included in the study however they will be accorded clinical care.

Confidentiality and dignity.

The information you will share with me or research assistant as well as your health records will remain confidential. It will be under lock and key for the hardcopy whereas the softcopy will be filed in a password protected database, accessible to me and research assistants on my authority. Your name will not be used in the study instead; we will give you an identifier number. You will be treated with respect and dignity during your care at the hospital.

Sharing the results

Information during this study about your medical care and progress will be given to you. The results of this study will be released to relevant health care workers and policy makers at Ministry of Health.

Risks

There might be pain and discomfort during examination of surgical wound and obtaining of laboratory specimen which is minimal and should cease within minutes after procedure. If pain persists, pain killers will be available.

Cost and compensation

There will be no extra cost incurred for participating in this study. Compensation will be limited to return bus fare to attend clinic.

This proposal has been reviewed and approved by UON/KNH ethics committee. This is a committee tasked with making sure that during your participation in this study you are protected from harm.

Who to contact

1. Principal researcher

Dr. Miima Elikanah Sammy

Department of Surgery, School of Medicine, University of Nairobi

P.O. Box 19676-00202 KNH, Nairobi, Kenya

Mobile no. 0734674706

University of Nairobi

Supervisors;

Prof. Joseph S. Oliech,

Professor of General Surgery/Urology,

Department of Surgery, School of Medicine, University of Nairobi

P.O. Box 19676-00202 KNH, Nairobi, Kenya

Prof Peter L .W. Ndaguatha

Professor of General Surgery/Urology,

Department of Surgery, School of Medicine, University of Nairobi

P.O. Box 19676-00202 KNH, Nairobi, Kenya

Dr. Elly Nyaim Opot

Lecturer of general surgery

Department of Surgery, School of Medicine, University of Nairobi

P.O. Box 19676-00202 KNH, Nairobi, Kenya

For any ethical concern

3. Secretary,

KNH/UON-ERC,

P.O. Box 20723-00202 KNH, Nairobi, Kenya

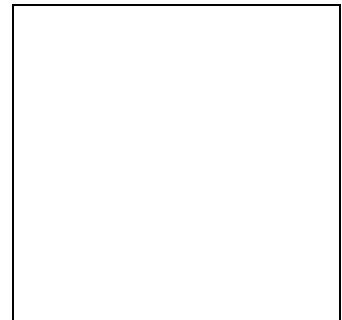
Tel +254-020-2726300-9 Ext 44355

Email: KNHplan@Ken.Healthnet.org

Part 2; **CONSENT CERTIFICATE BY PATIENT.**

I _____ voluntarily give consent of myself or for my proxy (Name) _____ to participate in the study being conducted by Dr Sammy Elikanah Miima whose nature has been explained to me by himself/his research assistant after being explained to and understanding the study. I understand that participation in this study is voluntary and I am free to withdraw from it at any point of the study without altering of medical care given to me.

Signature_____



Witness_____

Statement by the witness if participant is unable to read/write.

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_____ (Dd/mm/yy)

Part 3; STATEMENT BY RESEARCHER

I have accurately read out the information sheet to the participant, and to the best of my ability made sure that the participant understands that the following will be done:

- Refusal to participate or withdrawal from the study will not in any way compromise the medical care given.
- All information provided by the patient will be treated as confidential.
- The results of this study might be shared with relevant healthcare as well as policy makers and also published in relevant medical journals.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and 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.

Name of researcher/person taking consent _____

Signature of researcher/person taking consent _____

Date _____ (dd/mm/yy)

APPENDIX III: FOMU YA RIDHAA KWA MGONJWA/MDHAMINI MAAMBUKIZI KATIKA WAGONJWA WANA OHUDUMIWA KWA UPASUAJI WA TUMBO WA DHARURA KATIKA HOSPITALI YA TAIFA YA KENYATTA

Sehemu ya kwanza; **Maelezo**

Utambulisho

Kwa jina naitwa daktari Miima Elikanah Sammy ni mwanafunzi wa shahada ya uzamili katika Chuo kikuu cha Nairobi kitengo cha Tiba ya Upasuaji katika hospitali ya Taifa ya Kenyatta.

Dhumuni/lengo kuu

Lengo kuu la utafiti huu ni kujua maambukizi yanayotokea kwenye tumbo baada ya upasuaji kwa magonjwa ,yanayodhuru matumbo.Utafiti huu utachunguza kama ugonjwa wa kisukari,uvutaji wa sigara,matumizi ya madawa yanayoitwa steroids na ugonjwa wa ukimwi, yatachangia kuongezeka kwa hali ya maambukizi.Nitachunguza asilimia ya wagonjwa wa upasuaji wanaopata maambukizi.Wagonjwa wanaopata maambukizi nitafanya utafiti kwenye maabara kutambua aina ya bakteria inayohusishwa na maambukizi.Matokeo ya utafiti huu itachangia kutafuta njia ya kupunguza maambukizi katika upasuaji na kuboresha huduma ya upasuaji.Habari ninayowasiliana nawe ni kukualika kujiunga na utafiti huu kwa hiari yako na una haki ya kuuliza maswali kuhusu utafiti huu.

Taratibu ya utafiti huu

Kama mshiriki katika utafiti huu, utajiunga kabla ya upasuaji na kuhudumiwa wakati na baada ya upasuaji. Matibabu utakayopokea ni kulingana na taratibu za hospitali kuu ya Kenyatta.Siku ya pili baada ya upasuaji tutachunguza kidonda ya upasuaji kama kunauwezekano wa maambukizi.Kukiwa na maambukizi sampuli ya usaa itachukuliwa na kupelekwa kwenye maabara kwa uchunguzi.

Kufuata matibabu.

Ukiwa kwenye wodi utahudumiwa na muuguzi/daktari kila siku na kupewa huduma inayohitajika.Baada ya matibabu utapata ruhusa ya kwenda nyumbani na kuhudumiwa kwenye kliniki.Ukipata ruhusa kabla ya siku saba utahitaji kuzuru kliniki siku ya kumi na tano na siku ya thelathini ilihali ukipata ruhusa baada ya siku saba utahitajika kliniki siku ya

thelathini. Utapewa nauli ya kusafiri hospitali na kurudi nyumbani . Nambari yako ya simu tutahitaji ilituwasiliane nawe siku ya kumi na moja na siku ya ishirini na sita.Wale ambao hawatafika kliniki hizo siku hawatausishwa kwenye utafiti lakini watapokea matibabu.

Usiri na hadhi.

Habari ambayo wewe kama mgonjwa utawasiliana na mimi itahifadhiwa kwa siri.jina lako halitatumikiwa kwenye utafiti bali utapewa nambari ya siri.Wakati wa matibabu kwenye hospitali taratibu za hospitali kuu ya Kenyatta zitazingatiwa.

Ugavi wa matokeo.

Wakati wa matibabu utajulishwa kuhusu taratibu wa matibabu na maendeleo yako ya kiafya.Matokeo ya utafiti huu itahusisha wahudumu wa afya na wadau kwenye idara ya afya.

Tahadhari.

Kuna uwezekano wa uchungu wakati kidonda inapochunguzwa na wakati sampuli ya usaa inachukuliwa . Uchungu ukizidi utapewa dawa kutuliza.

Gharama na fidia.

Hakuna gharama zaidi ukishiriki kwenye utafiti huu.fidia utapata kama nauli kukuwezesha kufika kliniki kwa siku zilizotengwa.

Kibali.

Pendekezo la utafiti huu imekaguliwa na kupewa kibali na kamati ya maadili ya chuo kikuu cha Nairobi na hospitali kuu ya Kenyatta.

Mawasiliano

1. Mtafiti mkuu

Dr Miima Elikanah Sammy

Kitengo cha upasuaji, shule ya utabibu, chuo kikuu cha Nairobi

Anwani 19676-00202 KNH, Nairobi, Kenya

Nambari ya simu 0734674706

2. Chuo kikuu cha Nairobi; wasmamizi

Profesa Joseph S. Oliech

Profesa wa upasuaji

Kitengo cha upasuaji, shule ya utabibu, chuo kikuu cha Nairobi

Profesa Peter L.W. Ndaguatha

Profesa wa upasuaji

Kitengo cha upasuaji, shule ya utabibu, chuo kikuu cha Nairobi

Dr. Elly Nyaim Opot

Mkufunzi wa upasuaji

Kitengo cha upasuaji, shule ya utabibu, chuo kikuu cha Nairobi

Shauku kuhusu maadili ya utafiti wasiliana na;

3. Katibu

KNH-UON; ERC

Anwani 20723-00202, KNH, Nairobi, Kenya

Nambari ya simu; +254-020-2726300-9 ext. 44355

Barua pepe; KNHplan@ken.healthnet.

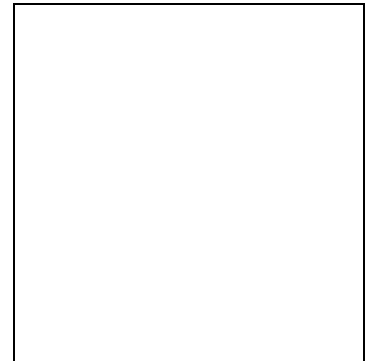
Sehemu ya pili ; Idhini ya mgonjwa

Mimi (Jina) _____ kwa hiari yangu ama kwa niaba ya mgonjwa wangu (Jina la Mgonjwa) _____ nimekubali kushiriki katika utafiti huu unaofanywa na Daktari Miima Elikanah Sammy baada ya kupata maelezo kuhusu utafiti huu na kuelewa bila masharti yoyote. Naelewa kwamba nina uwezo wa kujiondoa kwenye utafiti huu wakati wowote bila tishio la kutopata matibabu dhabiti.

Sahihi/ama alama ya kidole cha gumba kwenye sanduku →

Sahihi _____

Tarehe _____ (Siku/Mwezi/Mwaka)



Jina la shahidi.....

Sahihi.....

Tarehe..... (Siku/Mwezi/Mwaka)

Sehemu ya tatu; Dhibitisho la mtafiti

Hii kudhihirisha kwamba mimi na wasaidizi wa uchunguzi tumumjulisha mshiriki ama msimamizi wake kuhusu utafiti huu na tumejibu maswali aliyouliza kwa kina . Tumemjulisha yafuatayo;

Atashiriki kwa hiari.

Hatanyiomwa matibabu kwa kutoshiriki uchunguzi huu

Hatagharamika zaidi kifedha kutokana na uchunguzi huu

Hakuna madhara yatakayomjiri kwa kushiriki uchunguzi huu.

- Anaweza kujiondoa kutoka kwa utafiti huu wakati wowote bila kuhatarisha matibabu anayoyapata katika hospital kuu ya Kenyatta.
- Habari zozote kumhusu hayatapeanwa ila kwa ruhusa kutoka kwake (mshiriki) na au kutoka kwa mdhamini mkuu wa utafiti wa hospital kuu ya Kenyatta na chuo kikuu cha matibabu.

Jina la mtafiti ama msimamizi wake.....

Sahihi.....

Tarehe.....(Siku/Mwezi/

Mwaka)

APPENDIX IV: QUESTIONNAIRE

SSI IN EMERGENCY LAPAROTOMY QUESTIONNAIRE

Patient characteristics

Patient identification code _____

Age (years) _____ Gender male female

Date of admission _____ (dd/mm/yy)

Co-morbid conditions

Diabetes yes no

Steroid use yes no

Alcohol use yes no

Cigarettes yes no

HIV Yes no

Operation

Date of operation _____ (dd/mm/yy)

Preoperative duration _____ (hours)

State what was done; _____

Wound classification Clean contaminated

Contaminated Dirty

ASA score 1 2 3 4 5

Duration of operation _____(minutes)

Peri-operative transfusion yes no if yes unit(s)

Antibiotics prophylaxis/therapy

Prophylaxis (24 hours)

Short therapy (5 days)

Prolonged therapy (≥ 5 days)

Surgical site infection

Surgical site infection yes no

Date of detection _____(dd/mm/yy)

SSI type superficial deep organ/space

Microscopy and culture report.

APPENDIX V: KNH/ UoN -ERC LETTER OF APPROVAL



UNIVERSITY OF NAIROBI
COLLEGE OF HEALTH SCIENCES
P O BOX 19676 Code 00202
Telegrams: varsity
(254-020) 2726300 Ext 44355

KNH/UON-ERC
Email: uonknh_erc@uonbi.ac.ke
Website: www.uonbi.ac.ke

KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/375

Link: www.uonbi.ac.ke/activities/KNHUoN

13th November 2014

Dr. Miima E. Sammy
Dept. of Surgery
School of Medicine
University of Nairobi



Dear Dr. Miima

Research proposal – Surgical site infection following emergency laparotomy for bowel surgery at Kenyatta National Hospital (P543/09/2014)

This is to inform you that the KNH/UoN-Ethics & Research Committee (KNH/UoN-ERC) has reviewed and **approved** your above proposal. The approval periods are 13th November 2014 to 12th November 2015.

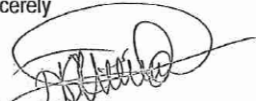
This approval is subject to compliance with the following requirements:

- Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
- All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH/UoN ERC before implementation.
- Death and life threatening problems and severe adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH/UoN ERC within 72 hours of notification.
- Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH/UoN ERC within 72 hours.
- Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal.*)
- Clearance for export of biological specimens must be obtained from KNH/UoN-Ethics & Research Committee for each batch of shipment.
- Submission of an *executive summary* report within 90 days upon completion of the study
This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/or plagiarism.

For more details consult the KNH/UoN ERC website www.uonbi.ac.ke/activities/KNHUoN.

Protect to discover

Yours sincerely



PROF. M. L. CHINDIA
SECRETARY, KNH/UON-ERC

- c.c. The Principal, College of Health Sciences, UoN
The Deputy Director CS, KNH
The Assistant Director, Health Information, KNH
The Chairperson, KNH/UON-ERC
The Dean, School of Medicine, UoN
The Chairman, Dept. of Surgery, UoN
Supervisors: Prof. Joseph S. Oliech, Prof. Peter L.W. Ndaguatha, Dr. Opolot Elly Nyaim

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