GHANA COLLEGE OF PHYSICIANS AND SURGEONS

Faculty of Surgery (General Surgery)

THE ROLE OF SUBCUTANEOUS TISSUE IRRIGATION WITH NORMAL SALINE IN DECREASING SURGICAL SITE INFECTION FOLLOWING APPENDICECTOMIES AT THE KORLE-BU TEACHING HOSPITAL

Dr VICTORIA SENA GAWU

Department of Surgery, Korle Bu Teaching Hospital, Accra, Ghana

{MBChB (School of Medical Sciences, KNUST)}

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Submitted to the Faculty of Surgery (General Surgery), in partial fulfilment of the requirements for the conferment of *Fellow of the Ghana College of Surgeons (FGCS)*

Dr Victoria Sena Gawu
Residents Number: GS/12/15/007/M
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DECLARATION

I hereby declare that with the exception of references from related research works which are duly acknowledged, this dissertation was put together by me under supervision and the work presented is entirely my own.

Principal Investigator: Dr. Victoria Sena Gawu

Qualifications: MBChB(KNUST), MGCS

Signature: .....

Date: 27/03/2024

ATTESTATION BY SUPERVISORS

We confirm that we supervised this dissertation titled: THE ROLE OF SUBCUTANEOUS TISSUE IRRIGATION WITH NORMAL SALINE IN DECREASING SURGICAL SITE INFECTION FOLLOWING APPENDICECTOMIES AT THE KORLE-BU TEACHING HOSPITAL, which was undertaken by Dr. Victoria Sena Gawu a senior resident in General Surgery in partial fulfilment of the requirement for the fellowship of the Ghana College of Physicians and Surgeons.

Prof J.N.A CLEGG-LAMPTEY

DEPARTMENT OF SURGERY

UNIVERSITY OF GHANA MEDICAL SCHOOL

UNIVERSITY OF GHANA

DEPARTMENT OF SURGERY

KORLE-BU TEACHING HOSPITAL

SIGNATURE..... DATE..27/03/2024.....

DR. JOACHIM AMOAKO

DEPARTMENT OF SURGERY

UNIVERSITY OF GHANA MEDICAL SCHOOL

UNIVERSITY OF GHANA

DEPARTMENT OF SURGERY

KORLE-BU TEACHING HOSPITAL

SIGNATURE..... DATE..28/03/2024.....

ATTESTATION BY HEAD OF TRAINING DEPARTMENT

I hereby attest that Dr. Victoria Sena Gawu is a senior resident in General Surgery. In compliance of the fellowship requirement for the award of Fellow of the Ghana College of Physicians and Surgeons, she undertook the dissertation titled "THE ROLE OF SUBCUTANEOUS TISSUE IRRIGATION WITH NORMAL SALINE IN DECREASING SURGICAL SITE INFECTION FOLLOWING APPENDICECTOMIES AT THE KORLE-BU TEACHING HOSPITAL"

Signature.....

Date....27/03/2024.....

Prof, James Edward Mensah

MBChB (UG) FWACS (Urology)

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ABSTRACT

BACKGROUND

According to the World Health Organization Surgical Site Infection(SSI) is the most common type of hospital acquired infection in the developing world and it is common after appendicectomy with an incidence of SSI as high as 37.4% in low income countries. Wound irrigation may reduce the level of bacterial contamination in the surgical wound and may reduce SSI but there is lack of evidence for its usage, and the agent to use that is safe, effective and affordable.In Ghana no studies have been conducted on the use of normal saline as irrigation fluid in reducing surgical site infection following appendicectomy.

AIM

To evaluate the role of subcutaneous tissue irrigation at incision site using normal saline, in reducing post appendicectomy surgical site infection at the Korle-Bu Teaching Hospital (KBTH).

METHODOLOGY

This was a randomized prospective study involving patients diagnosed with appendicitis, who underwent appendicectomy at the Korle-Bu Teaching Hospital (KBTH). Recruited patients were randomized into 2 groups. One group had the subcutaneous tissue irrigated with normal saline after closure of the fascia during appendicectomy while the second group, the control group, did not. Patients were followed up with wound inspection on post-operative days 3, 7, 14 and 30 for signs of surgical site infection. All data collected were captured on Microsoft excel work sheet and imported into Statistical Package for the Social Sciences (SPSS version 23) for analysis. A Chi-square test/ Fisher' exact test was used to compare the incidence of SSI between those with irrigation of the subcutaneous tissue and those with non-irrigation of the subcutaneous tissue following appendicectomy. Relative Risk (RR) and their confidence intervals between the two groups were also determined. P-values less than 0.05 was considered statistically significant.

RESULTS

In total one hundred and fourteen (114) patients were recruited for the study, 57 in each arm. The patients were followed up on post-operative days 3,7,14 and 30 for signs of surgical site infection. The overall surgical site infection rate was 8.8%. The surgical site infection rate in the irrigation arm was 3.5 % and non-irrigation arm was 14%.

There was a significant statistical reduction in the rate of SSI when irrigation was done.
Various factors associated with SSI include wound class, duration of hospital stay, male gender and age were identified as risk factors
The commonest organisms isolated were Escherichia coli, Klebsiella pneumonia, Staphylococcus aureus and Pseudomonas aeruginosa.

CONCLUSION:
Irrigation of the subcutaneous tissue using saline solution during appendicectomy is effective in reducing SSI at the KBTH.
Key words: ACUTE APPENDICITIS, IRRIGATION, NORMAL SALINE, SURGICAL SITE INFECTION

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LIST OF ABBREVIATIONS

ASA	American Association of Anaesthesiologist
CDC	Centre for Disease Control and Prevention
CL	Confidence Interval
HAI	Healthcare Associated Infections
IRB	Institutional Review Board
KBTH	Korle-Bu Teaching Hospital
LMIC	Low to Medium Income Countries
SPSS	Statistical Package for the Social Sciences
SSI	Surgical Site Infection
WHO	World Health Organization

1.0 INTRODUCTION

1.1 BACKGROUND

According to Global Surgery, 313 million surgical procedures are done annually worldwide with associated complications.[1] One of the commonest complications of surgery is surgical site infection (SSI) which accounts for about 20% of all post-surgery complications. [2]SSI incidence rates span from about 2.5% in high income countries to 41.9 % in low income countries .[3,4]In India the SSI incidence rate is as high as 30.7%.[5] A prospective cross-sectional study conducted in Kano, Nigeria from 2008 to 2010 found an SSI rate of 20.3 %[6] and a study done in 2012 at the Komfo Anokye Teaching Hospital in Ghana showed an SSI incidence of 40% .[7]

World Health Organization (WHO) and the Global guidelines from the National Institute of health deem SSI as the number one cause of Hospital Acquired Infections (HAI) in developing to developed Countries. [2,8 9]The management of SSI adds to the financial burden of the health care system. It increases admission days, therefore increasing cost of health care.[1,3] Fifty eight (58) million Euros is spent annually to treat SSI in France alone with 3% of all surgical procedures resulting in SSI leading to increased mortality risk and 3-fold increased length of hospital stay.[10]

A study conducted in Durham Regional Hospital found patients who develop SSI are at a double risk of mortality and more often will end up in the Intensive care unit after readmission.[11] SSI plays a significant role in morbidity in the surgical patient and in some cases leads to mortality. Bediako-Bowan et al. at the Korle-Bu Teaching Hospital, Accra on their study on Surveillance of SSI realized those with SSI have a higher mortality risk than those without SSI.[12]Also at a tertiary institution in Accra, Fenny et al. conducted a cost analysis study which showed SSI resulted in longer duration of admission which raises the patients expenditure, with each patient spending over two hundred and fifty dollars ($250) per admission than another patient without SSI.[13] It results in high costs to patients and their families by negatively impacting on the patients' health resulting in loss of income for the patients. SSI has been proposed as a good alternative for assessing the quality of surgical care in low to medium income countries (LMIC) and an important indicator of institutional care quality of patient care.[3] SSI invariably can result in reoperation, decreased quality of life, morbidity and sometimes mortality**.** [14]

Surgical Site Infection is defined as infections of the tissues, organs, or spaces exposed by surgeons during performance of an invasive procedure according to Global Guidelines on SSI [9] It can also

be defined as wound infection with microorganisms especially bacteria, within 30 days following a surgical procedure[15], or one year post operatively if an implanted device is present.[16] They are grouped into incisional and organ/space infections with the incisional surgical site infections further grouped into superficial and deep surgical site infections. The superficial surgical site infection involves the skin and subcutaneous tissue, deep surgical site infections involve the fascia and muscle.

Organ/Space surgical site infection refers to any part of the body manipulated during the procedure, excluding skin incision, fascia or muscle layer.[17]

The development of SSI is related to three factors:

- the degree of microbial contamination of the wound during surgery
- the duration of the procedure (risk increased after 3 hours)
- host factors such diabetes, malnutrition, obesity, immune suppression among other factors

Other factors cited include, but are not limited, to wound class, age, preoperative bathing, hair removal, peri-operative oxygenation, normothermia and hydration. [11]

To prevent surgical site infections, diligent surgery and careful surgical procedures have to be undertaken, with preventive techniques. Protocols also have to be adapted in order to reduce bacterial, viral and fungal contamination.[18,19] According National Institute of health on Global Guidelines in prevention of SSI, these include preoperative bathing, prophylactic antibiotic administration, hair removal, nutritional support, surgical site preparation, surgical preparation, wound irrigation, and advanced dressing which involves use of collagen products, use of platelet rich plasma for dressing and negative pressure wound therapy among others. [9,20]

Wound irrigation is the steady flow of a solution across an open wound surface to achieve wound hydration, remove debris reduce bacterial load and to assist with visual examination.[15] Clinicians are recognizing the benefits of wound irrigation as it preserves newly granulating tissue, removes bacteria and debris and is convenient and comfortable for the patient.[21] Although not a routine practice, it is a rather simple procedure which can dilute body fluids and bacteria.[22] Different agents have been proposed to be effective in wound irrigation: tap water, normal saline, procaine spirit, antibiotic solutions, hydrogen peroxide and povidone iodine.[17,19] However, there is no clear consensus as to the type of agent to use.[21] The World Health Organization (WHO) has

recommended wound irrigation as part of its guidelines in reducing surgical site infections.[9]This study seeks to determine if irrigating the subcutaneous tissue with normal saline will reduce surgical site infections following appendicectomies at the Korle-Bu Teaching Hospital.

1.2 PROBLEM STATEMENT

Acute appendicitis is the most common surgical emergency worldwide.[3,10,23,24]

The estimated overall lifetime incidence is 7-10% with evidence of this increasing**.** [24,25]

Given the worldwide distribution of acute appendicitis, management of this disease entity has been used to assess and compare surgical quality, particularly in low and middle Human Development-Index Countries (LMHDIC).[26, 27]

In Ghana at the Korle-Bu Teaching Hospital and the Komfo Anokye Teaching Hospital, acute appendicitis was found to be the number one cause of emergencies in the surgical department**.**[28,29]

Appendicectomy is the most common abdominal surgical emergency.[18,19] It can be an open procedure or a laparoscopic procedure. Laparoscopic appendicectomy has been gaining grounds worldwide as the procedure of choice in management of acute appendicitis. It was first introduced in 1983, by Kurt Semm a gynecologist in Germany. Laparoscopic appendicectomy results in decreased morbidity and mortality, ensures quick recovery after surgery, results in less postoperative pain, less postoperative ileus, reduced time of stay in the hospital, and better cosmetic outcomes. [30,31] In centres where laparoscopic appendicectomy is the routine procedure done for appendicitis, it has been reported as being less costly than open appendicectomy. Meta-analysis has shown laparoscopic appendicectomy results in decreased rates of SSI. Aziz et al. in their meta-analysis comparing laparoscopic appendicectomy to open appendicectomy with 23 studies found significant reduction in SSI in the laparoscopic group when compared to those who had open appendicectomy.[32]Laparoscopic appendicectomy has an additional advantage of ruling out other differential diagnosis for appendicitis during the surgery especially for women. It is currently the gold standard in management of appendicitis worldwide. [31,32 33]

In low income countries such as Ghana, laparoscopic appendicectomy and for that matter laparoscopic surgeries are not practiced routinely due of lack of equipment, high cost of the surgery, and lack of skilled surgeons in the field of laparoscopy**.**[34]

In Ghana most of the appendicectomies performed are open. One common complication post appendicectomy is wound infection. SSI remains a threat especially for complicated appendicitis and those performed through open surgery. [27] In Korle-Bu Teaching Hospital patients who underwent appendicectomy had three times increased risk of SSI compared to some other procedures such as ventral hernia repairs, cholecystectomies and mastectomies.[23] A meta-analysis that summarizes the global incidence of surgical site infections post appendicectomy suggests an incidence of 7 per 100 appendicectomies but with a higher burden of SSI after appendicectomy in Africa and low-income countries. SSI incidence rate as high as 37.4% was recorded in some regions in Africa after appendicectomy.[20] Another systemic review of literature describing the incidence and management of SSIs after appendicectomy in Low and Middle Human Development- Index Countries (LMHDICs) found an overall pooled rate of 17.9 SSI per 100 open appendicectomies compared to 8.8 SSI per100 laparoscopic appendicectomies.[27] These finding highlights the need for SSI prevention in developing countries like Ghana where most of the appendicectomies are open procedures.

Prophylactic intra-operative wound irrigation before skin closure has been proposed to reduce bacterial wound and surrounding skin contamination to the level that can be managed by host defenses and therefore reduce the risk of SSI post appendicectomy. Prevention is better than treatment. Therefore, a simple and cost-effective means of reducing surgical site infection following appendicectomy may positively influence management.

1.3 JUSTIFICATION OF STUDY

Many factors have been associated with the risk of SSI, and a range of preventive measures have been proposed. Wound irrigation, a simple intervention defined by the flow of a solution across the surface of an open wound to achieve tissue hydration, revoke bacteria and cellular debris. Wound irrigation might reduce the level of bacterial contamination but current data on its role in reducing or preventing SSI following abdominal surgery is conflicting.[6] Rather, non-standardized way with various agents have been used in wound irrigation over the past years and current literature on wound irrigation regimen prior to wound closure is scanty, diverse and conflicting.[2] The guidelines from the United Kingdom National Institute for Health and Care Excellence (NICE) issued in 2008 and updated in 2013 advised against intra operative wound irrigation,

whereas the 2014 guidelines of the Society for Healthcare and Epidemiology of America (SHEA) and WHO and the National Institute of Health on Global guidelines in prevention of SSI have recommended using intraoperation irrigation or lavage. [9,17] Currently wound irrigation is not addressed locally as a means of reducing the rate of SSI in appendicectomy and has not been underlined in current guidelines. Normal saline is relatively inexpensive, it is nontoxic to tissues and does not affect normal skin flora. It is isotonic, does not interfere with the normal healing process, is non allergic and does not alter the normal bacteria of the skin.[21] In Mexico a study done using normal saline for irrigation of subcutaneous tissue after appendicectomy realized a decrease in SSI rate from 40% to 17%.[35]

No studies have clearly shown the benefit of saline irrigation of wounds.[15,19,36,37] Moreover, no study has been done in Korle-Bu Teaching hospital to determine the effect of saline irrigation at appendicectomy in decreasing surgical site infection.

If its use in this study is proven to be effective, it will serve as an affordable and convenient means of contributing to reducing surgical site infections following appendicectomy. Apart from being a stimulus for further research, the study will hopefully serve as a background for developing protocols in wound closure at the Korle-Bu Teaching Hospital.

1.4.1 HYPOTHESIS

There is a decrease in the incidence rate of surgical site infection with irrigation of the subcutaneous tissue with normal saline in appendicectomy at the General Surgical Unit of the Korle-Bu Teaching Hospital.

1.4.2 NULL HYPOTHESIS

There is no difference in the incidence rate of surgical site infection with irrigation of the subcutaneous tissue with normal saline compared to non-irrigation of the subcutaneous tissue in appendicectomy at the General Surgical Unit of the Korle-Bu Teaching Hospital.

1.5 AIM

- To determine the effect of normal saline irrigation after of the incisional site after appendicectomy at the General Surgery unit of the KBTH.

1.6 SPECIFIC OBJECTIVES

- To determine the rate of surgical site infection following subcutaneous tissue irrigation with normal saline in appendicectomy wounds
- To determine the rate of surgical site infection following non-irrigation of subcutaneous tissue in appendicectomy wounds
- To compare the rates of surgical site infection in the two groups
- To determine the demographics of patients presenting with appendicitis at the KBTH
- To identify the organisms causing SSI following appendicectomy at the KBTH
- To identify risk factors that increase the chances of developing an SSI at KBTH following appendicectomy

2.0 LITERATURE REVIEW

2.1 INCIDENCE / PREVELENCE OF SS1

According to WHO and the National Institute of Health ,SSI is the second most common hospital acquired infection in Europe and the United States of America and the commonest hospital acquired infection in LMIC. The available evidence on morbidity and mortality in LMIC as well as the impact of healthcare associated infections is low. However WHO postulates that the overall incidence of SSI in LMIC is twice that of high income countries**.** [2,4,9]

SSI occurs in about one third of patients who have had surgeries.[3,16,23] Worldwide incidence ranges from 2.5% to 41%[3] with higher incidence in developing countries like Ghana .[4] About 300,000 to 500,000 cases of SSI occur each year in the United States alone**.** [38]

In Europe it varies from 3% in France, about 9% in Luxembourg and 29% in Spain, accounting for about 20% of hospital acquired infections .[10,13] In India the SSI rate is relatively high: 30.7% of SSI was recorded in a teaching hospital.[5] A 2015 prospective study done in Ethiopia with 105 patients realized an SSI rate of 19.1%. [39] A study in a tertiary institution in Tanzania on Prevalence, Patterns and Predictors of SSI, reported a prevalence rate of 26%.[40] Another prospective cross sectional study conducted in Kano, Nigeria over a 2- year period recognized an SSI rate of 20.3%. [6] Studies in Ghana have shown an SSI rate of 40% in the Komfo Anokye Teaching Hospital. [7]

The variability in SSI rates across continents, countries, and institutions are as a result of differences in characteristic hospital populations, underlying diseases, differences in clinical procedures, parts of the body being operated on, extent of infection control measures and hospital environment.[5]

2.2 THE APPENDIX

2.2.1 ANATOMY AND FUNCTION

The appendix is a worm like structure which arises from the posterior medial aspect of the caecum about two to 3 centimeters below the ileo-caecal junction. The appendix develops from the midgut and initially is seen at eight weeks of gestation. The length and width of the appendix varies from about 5 to 10 cm long and about 0.5 to 1cm wide. [41]The position of the appendix also varies. The most common position where the appendix can be found is behind the caecum that is retrocaecal

position as reported by Clegg-Lamptey et al. who per the autopsy examination of 1358 appendices realized almost 70% of the appendices studied were retroceacal.[42]Other positions the appendix may be found include, the pelvis where it hangs down in the pelvis and is named a pelvic appendix. The pelvic appendix is found in about twenty percent of people. Sometimes it is in front of the ileum and so called a pre-ileal appendix , other times it is found behind the terminal ileum and called a retro-ileal appendix.[43]In some rare occasions the appendix may be found inferior to the liver and so termed sub-hepatic appendix, and because of this position of the appendix, acute appendicitis of a sub hepatic appendix can be confused for a cholecystitis. [43,44]The position of the appendix is of clinical importance as it usually points to the site of maximum tenderness during examinationThe appendix has a very narrow lumen which is continuous with the caecum. In children this lumen is bigger and so able to drain contents easily into the caecum however in the elderly this lumen is smaller, narrower and most times obliterated. Acute appendicitis is therefore not common in the extreme of ages.The blood supply of the appendix is from the appendicular artery which is found in the meso-appendix .The appendicular artery is a branch of the ileocolic artery and it is the sole arterial supply to the appendix. It is an end artery therefore an acute infection of the appendix can result in thrombosis of the artery which leads to gangrene and perforation of the appendix. Aggregates of lymphoid tissues are found in the appendix which are few in children but many from the teenage years to adulthood and almost not existent in the elderly. The role of the appendix is not completely understood and several more studies and its preservation in humans may be necessary to determine its ultimate role.

2.2.2 ACUTE APPENDICITIS

Acute appendicitis is the inflammation of the vermiform appendix. It was first described by Fitz of Harvard in 1886.[45]

The pathophysiology of acute appendicitis is not well understood. There are various theories that have been propounded. These are the Mechanical theory, the infection theory, the dietary fibre theory and the hygiene theory. The mechanical obstruction theory has been the commonest theory propounded.

The obstruction of the lumen of the appendix maybe caused by faecoliths, fibrosis, foreign bodies such as food parasites and calculi or neoplasms in adults and lymphoid hyperplasia in children -as

a result of the obstruction, there is bacterial over growth and increased pressure in the lumen of the appendix. This leads to impaired venous drainage, ischemia of the mucosa and bacterial translocation resulting in gangrene and perforation.[46]

With the dietary fibre theory, it is suggested that people who consume a lot of high fibre in their diet tend to have bulky stools which decreases the faecal transit time and so lessens faecolith formation which can cause luminal obstruction. Therefore people with low cellulose diet tend to be more prone to acute appendicitis and so in those geographic areas, the incidence of acute appendicitis is high. This theory is set to explain why there is low incidence of acute appendicitis observed in some African countries but the incidence has been rising in recent times as a result of urbanization as noted by a studies conducted in Nigeria. [33,47]

Infections by bacteria, viruses and parasites can also cause acute appendicitis.The human appendix serves as a reservoir for many microbes. There has been bacteria cultured from inflamed appendix which was predominately Escherichia coli and Bacteriodes fragalis.[48]

Seasonal outbreaks of viral infections are also thought to cause acute appendicitis. This is said to be a common cause in children. Level of evidence in this case however is low and weak.[44]

Parasitic infestation of the appendix although rare can cause acute appendicitis and has been documented in literature, this is an occurrence especially in developing countries. Some of the parasites causing acute appendicitis include Schistosoma mansoni, Schistosoma haematobium and Ascaris. There have been reports in Nigeria and studies from Southern Africa where parasites were found to be the cause of acute appendicitis.[43,49] Madavo and Hurrez reported of a young Ghanaian man who was operated in the United Kingdom where histology of the appendix reported Schistosoma mansoni as the causative agent.[50]

The hygiene theory was postulated by Baker in the 1980s where he reported that improvement in the sanitary condition in the United Kingdom has led to the increase occurrence of acute appendicitis. He wrote “Children’s immune system gets altered and is no more exposed to bacterial infection, therefore they are exposed more to viral infections which cause lymphoid hyperplasia leading to luminal obstruction and then appendicitis.”[43] Currently this evidence appears weak.

Diagnosis of appendicitis is mainly clinical putting together the signs and symptoms of appendicitis which include: abdominal pain, first localized around the umbilicus and radiates to

the right iliac fossa. In a study by Clegg-Lamptey at the Korle-Bu teaching hospital he realized pain around the umbilicus which later moved to the right iliac fossa was reported in almost fifty percent of the patients. However vomiting was the most common symptom of the patients presenting with acute appendicitis per the study.[51] Other symptoms and signs of acute appendicitis include fever, tenderness especially in the right iliac fossa and rebound tenderness. Leukocytosis is usually present. C-reactive protein is usually elevated.[52,48]Abdominal ultrasound and a CT scan can be used as imaging tools but these are not readily available in resource limited facilities. Scoring systems such as the Alvarado score help in the diagnosis of acute appendicitis. They are fast, non-invasive and cheap.[52] The Alvarado scoring system has a high degree of sensitivity and specicity.The scoring systems have helped reduce the rate of negative appendicectomy. Other scoring systems include Modified Alvarado score, Christian,Izbicki and RIPASA among a few.[53]

Management is mainly through surgery: appendicectomy, but depending on how early the patient presents, sometimes conservative management is employed with use of antibiotics and analgesia. This form of management is not very popular and some centers do not subscribe to it.[48]

The recent global occurrence of COVID-19 pandemic led to some institutions considering conservative management as treatment of uncomplicated acute appendicitis, uncomplicated meaning appendicitis that is simply inflamed but not perforated, ruptured, appendix without an abscess or a mass formation.[54] However surgery still remains the standard of treatment for acute appendicitis.

2.2.3 INCIDENCE OF ACUTE APPENDICITIS

Acute appendicitis is documented as the most common surgical emergency in several studies making it the leading cause of acute abdomen worldwide, with an overall lifetime risk of 7% which makes up a good percentage of emergencies worldwide. [24,25]According to one's geographical location, a lifetime risk of Acute appendicitis in United States of America is reported at 9%, In Europe 3% and in Africa 2%.[52]About 100 per 100000 people per year is reported to be affected in Australia, North America and Europe**.** [20] Addis et al. in the United States also looked at 15 years of data on acute appendicitis and realized a male dominance over females. [55] In 2013, 2375 cases of appendicitis was documented in the public hospitals in Qatar. [25]

In the West African sub region it is the most common cause of acute abdomen. Duduyemi puts the incidence of acute appendicitis as 22.1-49.8 per 100,000 new cases in Abuja, Nigeria.[47]

It occurs between the ages of 10 and 30 with a higher incidence in men than women. Nwashilli et al. in Benin City realized it was more common in patients between the ages of 20 years and 30 years.[24] In Accra Clegg Lamptey and Naaeder in their study of acute appendicitis reported males were twice affected than females and those affected were mainly in the third decade of life.[29] In the Cape Coast Teaching Hospital acute appendicitis was found to be more common in patients from 10 to 30 years and seen more in male patients than female patients.[56] The incidence is decreasing in the western countries but increasing in developing countries due to lifestyle changes.[20]

2.2.4 APPENDICECTOMY

Appendicectomy, the surgical removal of the vermiform appendix is the most common emergency surgery performed worldwide. [16,20,26,27] It is the treatment of choice for acute appendicitis although antibiotic therapy can be used to manage uncomplicated acute appendicitis in carefully selected patients.[20]A population based analysis conducted over a period of 2 decades in Europe realized appendicectomy was fairly safe with a case fatality of 2.1 to 2.4 per 1000 patients. Complicated appendicitis and frail patients as in the elderly were associated with mortality.[57,58] In acute care hospitals in the United States of America, about 300,000 patients have appendicectomies annually.[25] Appendicectomy accounts for 15 to 40% of emergency surgeries conducted in all hospitals in Nigeria.[24]Debrah et al. in a teaching hospital in the Central region of Ghana, found out 1 out of every 5 abdominal surgery was an appendicectomy.[56]

2.3 SURGICAL SITE INFECTION FOLLOWING APPENDICECTOMY

A systemic review done of 35 studies conducted in low to middle income countries realized an overall SSI rate of 17.9% following open appendicectomies and 8.8% following laparoscopic appendicectomies.[27] It is a contaminated procedure, with and SSI rate that could be as high as 40 % as found by Ohene Yeboah et al. in Kumasi, Ghana[28] and as low as 0% as documented in some developed countries.[16] The variability in SSI rates across continents, countries, and institutions are as a result of differences in characteristic hospital populations, underlying diseases, differences in

clinical procedures, parts of the body being operated on, extent of infection control measures and hospital environment.[5]

In a retrospective study conducted in Saudi Arabia, out of 433 appendicectomies done, 31 of the patients developed SSI. The risk factors identified were higher wound class, longer duration of surgery and length of hospital stay.[59]

A systemic review by Danwang et al across 49 countries saw a SSI rate post appendicectomy of 6.2% in developed countries and 11.1 % in developing countries on the average. They realized as the income of the country increased, the rate of SSI post appendicectomy decreased.[20]

In the Netherlands, an SSI rate of 6.6% was found post appendicectomy with higher values in patients with complex appendicitis, such as perforated appendicitis.[60] In the paediatric population in the United states, Kelly et at recognized an SSI rate of 3.3% with marked association to the higher wound classes of 3 and 4.[61]

2.4 BURDEN OF SURGICAL SITE INFECTIONS ON HEALTH SYSTEMS+

Surgical site infections, a component of health care associated infections threatens patients' lives and safety especially in developing countries.[4] It increases morbidity and mortality, and cost of treatment. Patients with SSI are 60% more likely to spend time in the ICU, 5 times more likely to be readmitted to the hospital and twice likely to die compared with those without SSI.[4] It is documented that 77% of all deaths as a result of nosocomial infection is attribute to SSI.

It impacts the patient's health negatively, results in loss of income for the patient as patient is absent from work and costly for the health system.[4] It prolongs hospital stay, increases number of emergency visits, delayed wound healing and prolongs the use of antibiotics.[4,7,19,38,62,9]Prolonged hospital stay results in reduced bed capacity making it difficult to accept new patients. It increases cost to the patient as the patient has to spend extra money on drugs, investigations and further treatment. It results in increase in readmissions and re-operations in many hospitals.[14]

1.5 billion dollars is spent in additional cost yearly in the United states in management of SSI.[38,62]Broex et al. in their cost analysis regarding SSI in Europe and America found out that

patients with SSI spend twice the amount in healthcare cost than patients without SSI and this was markedly attributed to increased length of hospital stay which was also twice as long.[52,63].Kirkland et al. found that averagely patients spend extra 12 days in hospital as a result of SSI and the median cost was US$7486 more than that of an uninfected patient.[11]Another reviewed data of 84 studies puts estimated economic costs of SSI in Europe between 1.47-19.1 billion dollars. Even so, this analysis suggests the SSI attributable economic burden is underestimated. About 58 million Euros is spent yearly in managing SSI in France with an increased risk of mortality an increased length of hospital stay.[64] SSI has direct and indirect cost consequences. A study conducted at the Korle Bu Teaching Hospital recently found on average, a patient with SSI spent over $250 more than patients without SSI. The overall estimated additional cost however was $1985 of which 78% was institutional cost ,15% direct cost to patient and 7% productivity loss.[13]

An opportunity cost to health facilities, hospital resources that could be used for other purposes are channeled in managing the infection and delays other patients' surgeries. All these factors add to the economic burden of the infection.[64]

2.5 MENTAL HEALTH BURDEN OF SSI ON PATIENTS AND PATIENTS RELATIVES

Outside of the patient and health system, there is a burden on patient relatives who take care of them in terms of cost, loss of productivity and mental strain .[14] Patients with SSI especially those with deep SSI are reported to suffer significant pain, isolation and insecurity which has a negative impact on their mental health.[65]In a descriptive study, patients who have had SSI reported insecurities or uncertainties in describing signs and symptoms, about their experience with significant pain, returning to hospital and undergoing readmissions, other complications associated with the SSI, changes in their body appearance, state of being isolated which in diverse ways contribute to reduced quality of life and effect on their mental health tipping them into states of depression. The study also reported equal mental strain on relatives who take care of them indirectly reducing their quality of life.[65]

2.6 ORGANISMS IN SSI

Organisms that cause SSI are from the patients endogenous flora on skin, mucus membranes or from an open viscus or exogenously from operation room environment, instruments, material brought to the operating field and personnel - especially those in the operating team. [66,67,68] The

period of greatest risk however is the time between opening and closing of the operating site;[66] when the mucous membrane or skin is breached during surgery. SSI can be monomicrobial or polymicrobial. A single organism can cause SSI or more than one organism can be present in the wound and cause SSI [16]

Data from the National Nosocomial Infection Surveillance (NNIS) system shows the pathogens causing SSI have not changed significantly over the last decade. The common ones include Staphylococcus aureus, Enterococcus spp and E.coli. Others include Methicillin-resistant S. aureus and Candida albicans.[69,70]According to a report from 28 studies in developing countries S.aureus was the most common organism isolated in SSI. Gram negative rods were also found in many surgical site infection. [4,31,33] In a teaching hospital in India bacteria isolated from patients with SSI include mostly Pseudomonas, Staph pyogenes /Klebsiella, E.coli with 64% demonstrating poly-antimicrobial resistance.[5] Apanga et al in a teaching hospital in Northern Ghana isolated Staphylococcus aureus in 80% of the patient who had SSI, Klebsiella spp was the second common organism isolated. [71] With surgeries that enter hollow viscera like appendicectomy ,gastroduodenal and colorectal surgeries gram negative organisms such as Escherichia coli, Klebsiella, Enterobacter and gram positives such as Enterococcus and anaerobes have been implicated.[66] At a teaching hospital in Northwestern Tanzania, the predominant organism implicated in SSI was Staphylococcus aureus followed by Escherichia coli and Klebsiella.[40]

2.7 WOUND CLASSES

According to the Centres for Disease Control (CDC), surgical wounds can be grouped into 4 classes based on the degree of intraoperative microbial contamination.

These are:

- Class I/Clean: An uninfected operative wound in which no inflammation is encountered and the respiratory, alimentary, genital, or uninfected urinary tract is not entered. These surgeries include excision biopsies such as excision of lipomas, mastectomies, thyroidectomies and elective inguinal hernia repairs. In addition, clean sites are closed primarily and, if necessary, drained with closed drainage. Operative incisions that follow

non-penetrating (blunt) trauma are in this category and elective inguinal hernia repair for example are in this category. SSI rate is usually less than 2%.

- Class II/Clean–Contaminated: An operative wound in which the respiratory, alimentary, genital, or urinary tracts are entered under controlled conditions and without unusual contamination. Specifically, operations involving the biliary tract, appendix, vagina, and oropharynx are included in this category, provided no evidence of infection or major break in technique is encountered. SSI rate is about 3 to 11%.
- Class III/Contaminated: Open, fresh, accidental wounds. In addition, operations with major breaks in sterile technique (e.g., open cardiac massage) or gross spillage from the gastrointestinal tract, and incisions in which acute, non-purulent inflammation is encountered, are included in this category. Infection rate is more than 10% even with preventive antibiotics.
- Class IV/Dirty–Infected: Old traumatic wounds with retained devitalized tissue and those that involve existing clinical infection or perforated viscera. This definition suggests that the organisms causing postoperative infection were present in the operative field before the operation. SSI rate is more than 20%. [72]

It must be noted that although these criteria are detailed to objectively define SSI according to the National Healthcare Safety Network (NHSN)of the CDS it is important to realize that the surgeon's judgment ultimately determines if a patient has SSI or not. For example if there are skin changes around the wound with a discharge that is not pus, the surgeon opinion has to be explicitly expressed if it is an SSI or not.[23]

2.8 RISK FACTOR FOR SSI

Many risk factors can be identified contributing to SSI which comprise, patient and operative characteristics.

Patient characteristics

These include Diabetes Mellitus, nicotine use, alcohol abuse, chronic steroid use, malnutrition, age, coexistent infection at a remote body site and prolonged preoperative hospital stay.[3,21]

Operative factors

These include Preoperative factors, Intra operative factors and post-operative factors. Preoperative factors include preoperative antiseptic showering, preoperative hair removal, patient skin preparation in the operating room, preoperative hand/forearm antisepsis of the surgeon, management of infected personnel, antimicrobial prophylaxis. Intraoperative factors include – operating room environment (ventilation), environmental surfaces - (tables, floors, walls, ceilings, lights,) inadequate sterilization of surgical instruments, surgical attire and drapes (scrubs, suits, caps shoe covers, masks, gloves, gowns), asepsis and surgical technique. Postoperative factors include-incision care (whether the incision is closed primarily, or second look before closure, after 24 hours or left to heal by secondary intention) and discharge planning.[9,21]

The risk of an SSI developing will depend on the dose and virulence of the pathogen and the patient's level of resistance. This risk of surgical site can be made using the following relations

$$\frac{Dose\ of\ Bacterial\ Contamination \times Virulence}{Resistance\ of\ the\ host\ Patient} = Risk\ of\ Surgical\ Site\ Infection^{35}$$

A 10^5 microorganisms per gram of tissue contamination increases the risk of SSI. But this dose may be much lower if there is for instance presence of foreign material example; sutures in the wound.[73]

In the 1970s and 1980s 2 significant epidemiologic studies were conducted by the CDC to ascertain other factors contributing to SSI apart from wound classes. They concluded that having an abdominal surgery puts one more at risk of SSI,[23,74] with colorectal surgeries being the foremost

of all abdominal surgeries with the highest risk of SSI .[14]The duration of surgery longer than 2 hours was identified as a risk factor and also a patient being diagnosed and managed for 3 or more conditions serve as a risk factor**.**[14]

Other risk factors contributing to SSI are American Society of Anesthesiology (ASA) score of II or more **.**[23,74]

In addition open surgeries have been found to be associated with increased risk of SSI compared to laparoscopic surgeries. In a retrospective observational study by Ursuku et al. in Japan, it was found out that open surgery was the single independent factor for developing incisional SSI**.**[75]

Others risk factors include male gender, preoperative BMI greater than or equal to 20.8 kg/m2 and operative time more than 220 minutes.

According to the American College of Surgeons National Surgical Quality Improvement Program database for general surgical operations performed over a period of 2 years from 2005 to 2007, infectious complication rates increased linearly with operation time at a rate of 2.5% every half hour. Infection complications risks also increased every 30 minutes of operation time with respect to cases lasting 1 hour, with the risk about twice at 2.1-2.5 hours. They concluded that infectious complications are associated with increased operation time.[76]

Concerning appendicectomy specifically, a retrospective multicenter study of 637 patients who underwent appendicectomy in institutions in the Netherlands over a period of one year between 2015 to 2016 realized the main risk factor for developing SSI were those with complex appendicitis**.**[60]

2.9 CDC CRITERIA FOR SURGICAL SITE INFECTION

The CDC's National Nosocomial Infections Surveillance (NNIS) System has developed standardized surveillance criteria for defining SSIs.[77] These are categorized as follows

a) Superficial Incisional SSI

Infection occurs within 30 days after the operation and infection involves only skin or subcutaneous tissue of the incision and at least one of the following:

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 and superficial incision is deliberately opened by surgeon, unless incision is culture-negative.
4. Diagnosis of superficial incisional SSI by the surgeon or attending physician.

Do not report the following conditions as SSI:

1. Stitch abscess (minimal inflammation and discharge confined to the points of suture penetration).
2. Infection of an episiotomy or newborn circumcision site.
3. Infected burn wound.
4. Incisional SSI that extends into the fascial and muscle layers (see deep incisional SSI).
Note: Specific criteria are used for identifying infected episiotomy and circumcision sites and burn wounds.

b) Deep Incisional SSI
Infection occurs within 30 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 deep soft tissues (e.g., fascial and muscle layers) of the incision and at least one of the following:
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 (>38ºC), 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 reoperation, or by histopathologic or radiologic examination.
4. Diagnosis of a deep incisional SSI by a surgeon or attending physician.

c) Organ/Space SSI
Infection occurs within 30 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 histopathologic or radiologic examination.
4. Diagnosis of an organ/space SSI by a surgeon or attending physician.[77]

2.10 WOUND IRRIGATION

The prevention of SSI is complex and requires the integration of a range of preventive measures before, during and after surgery. However, the implementation of these measures is not standardized worldwide.[78] These include but not limited to Preoperative bathing, optimal time for preoperative surgical antibiotic prophylaxis, mechanical bowel preparation (which involves giving a purgative to the patient to empty the bowel before bowel surgery) , hair removal, surgical site preparation, surgical hand preparation(scrubbing of hands), enhanced nutritional support, perioperative oxygenation, maintaining normal temperature, draping and gowning, wound protector devices, **incisional wound irrigation**, use of surgical gloves, changing of surgical instruments, antimicrobial coated sutures, surgical antibiotics prolongation and advanced dressings[20] -which involves use of collagen products, use of platelet rich plasma for dressing and negative pressure wound therapy among others**.**

WHO Global Guidelines for the prevention of surgical site infection provides recommendations concerning reduction of SSI risk. The aim of these guidelines is to provide a comprehensive range of evidence-based recommendations for interventions to be applied during the pre, intra and post-operative periods for the prevention of SSI while also considering aspects related to resource availability and values and preferences. [1] Each recommendation is categorized on the basis of existing scientific data, theoretical rationale and applicability.

The science behind wound irrigation is to flush the surgical site with a solution that will physically remove cellular debris and decrease bacterial load.[15]

Wound irrigation has been recommended by WHO as part of its guidelines in reducing surgical site infections. [1] The guidelines from the United Kingdom National Institute for Health and Care Excellence (NICE) issued in 2008 and updated in 2013 advised against intra operative wound irrigation, whereas the 2014 guidelines of the Society for Healthcare and Epidemiology of America (SHEA) have recommended using intraoperation irrigation or lavage.[17]

Antibiotic irrigation using various antibiotics such as cefazolin, kanamycin, neomycin, gentamycin, metronidazole and so forth have been used for wound irrigation. [79,80]

Use of Kanamycin in one study has been shown to significantly lead to reduction in SSI post herniorrhaphy and peripheral vascular surgeries.[80]

Parcell et al. found the use of antibiotics in wound irrigation in appendicectomy is superior to both saline and Dakin solution[79]

Normal saline is found to be cheap -safe, does not affect normal skin flora -nontoxic to tissues and is readily available in any operating room.[15,19] A study done in Mexico on use of saline irrigation of subcutaneous tissue after appendectomy saw a decrease in the incidence of SSI , to about 17% whereas without use of saline was about 40%.[35]

Saline wound irrigation is said to diminish the infection rate markedly by reducing bacterial inoculum present at the time of skin closure.[81,23]

Hayashi et al. in Japan, saw a reduction in shunt infection from 13.1% to 1.1% after using saline in irrigation after shunt procedures.[81]

A systemic review and meta-analysis of studies conducted in Mexico, Jordan and Turkey of about 1200 patients saw no significant reduction in SSI after abdominal wound irrigation with normal saline over no irrigation prior to wound closure. [15] In comparing wounds that were cleansed with 1% povidone iodine and normal saline, it was realized that 1% povidone was more effective in reducing infection than normal saline[19] , however Dire et al. found no difference in infection rate using the 2 solutions[36]. Also analyses of 41 RCT reporting on data from over 9000 patients confirms intra operative wound irrigation before skin closure serves a good and economical means to reduce SSI, and antibiotic solutions were superior to use of povidone iodine or normal saline in reducing SSI[82] Hassan A Hassan et al. at the Al-Kadhimiya Teaching Hospital found irrigation of the subcutaneous tissue with normal saline is an effective method in decreasing the rate of bacterial contamination when compared to povidone iodine soaking.[19]

Wound syringe irrigation with normal saline is a safe, cheap, and readily available procedure in any operating room which does not impair the healing process, permits a better cosmetic result, and shortens hospital stays and expenses. No study has been conducted in Ghana to investigate the role of saline irrigation as a method of preventing wound infection. This method if proven useful can be utilized in appendectomies in Ghana and be included in our protocols in the prevention of SSI

3.0 MATERIALS AND METHODS

3.1 STUDY DESIGN

This research was a prospective randomized trial involving patients diagnosed with appendicitis for appendicectomy at the KBTH surgery department. Recruited participants were randomized blindly into two groups. One arm of the study population had irrigation of subcutaneous tissue with normal saline during appendicectomy and the other arm no irrigation of subcutaneous tissue with normal saline. They were followed up for 30 days post- surgery to assess the risk of surgical site infection.

3.2 STUDY SETTING

The study site was the Department of Surgery, General Surgery unit, KBTH, Accra. KBTH is the largest tertiary center in Ghana receiving referrals from all over the country. It is the third largest hospital in Africa. It also serves as a Teaching Hospital and training centre for the University of Ghana Medical School, The Ghana College of Physicians and Surgeons, The West Africa College of Surgeons and The West Africa College of Physicians. It was established in October 1923 and currently has a bed capacity of over 2000 and serves mainly the southern part of Ghana. KBTH has 21 clinical and diagnostic departments. The surgery department consists of 10 units; Urology, Plastics and Reconstruction Surgery, General Surgery, Ophthalmology, Ear Nose and Throat, Dental Surgery, Trauma and Orthopedics Surgery, Neurosurgery, Paediatric Surgery and Cardiothoracic Surgery. There are 4 general surgery wards, each with a capacity of about 35 beds. From records in 2021, a total of 2411 general surgery cases were done; out of this, 217 were appendicectomies making 9% of surgeries performed at the General Surgery Unit. There are twelve (12) General Surgeons in the unit with at least 2 senior residents and 3 junior residents on each floor.

3.2.1 TEAM MEMBERS

2 senior residents, four residents-junior residents, four house officers and 4 nurses were recruited for the study. Team members were taken through the subject matter of the study, the aim and objectives of the study and the details of the methodology. The doctors were taken through the

informed consent form and how to go about seeking consent from the patients in a polite and friendly manner. Team members were also educated on the CDC guidelines for SSI and how to identify them.

3.2.2 ROLE OF TEAM MEMBERS

The principal investigator was responsible for the overall running of the study. The principal investigator was responsible for overseeing the work of the team members, making sure patients are recruited as and when they come by the residents. The principal investigator also recruited patients and performed some of the surgeries. Compilation of data and entering the data into excel spread sheet to be presented to the statistician was also the responsibility of the principal investigator.

The senior residents and residents also recruited patients as and when and reported back to the principal investigator. They also took part in performing the surgeries and the follow ups.

The house officers recruited patients and helped with the follow ups. However they did not operate on any of the patients.

The nurses' main responsibility was carrying out the dressings and recording the state of the wounds according to the CDC guidelines and recording them appropriately and alerting the principal investigator.

Overall all team members were tasked with the role to ensure the study was run peacefully and smoothly.

3.2.3 TRAINING OF TEAM MEMBERS

The training of team members was done over a period of 2 days through discussion groups formed by the principal investigator and the other team members. Training on the importance of the study, the objectives set for the study and the methodology were taught. Team members were taught about the inclusion and exclusion criteria so as to find eligible participants. The protocol of the follow ups were also taught and coordination between team members was emphasized.

3.2.4 PRE-STUDY PREPARATIONS AND TESTING

Before active recruitment was started, a pre-recruitment of 5 patients was done by team members following the protocol by which they were trained. This was to ensure team members understood their roles and understood the way the study was to be conducted

3.3 STUDY POPULATION

Patients who had been physically examined and clinically diagnosed with appendicitis, between November 2022 to 30th November 2023 in the General Surgery department of the KBTH from whom informed consent has been sort.

3.4 INCLUSION CRITERIA

- Patients 13 years and older who have been diagnosed with appendicitis and scheduled to undergo appendicectomy through a right lower abdominal incision.

3.5 EXCLUSION CRITERIA

- Patients who underewent laparotomy for appendicectomy
- Patients who underwent laparoscopic surgeries for appendicectomy
- Complicated appendicitis-appendiceal mass, appendiceal abscess, generalized peritonitis from perforated appendix.

3.6 SAMPLE SIZE DETERMINATION

A study done at the Komfo Anokye Teaching Hospital showed 40% prevalence of SSI following appendicectomy. According to a Mexican study when normal saline was used in irrigation of the subcutaneous tissue at appendicectomy the incidence of SSI reduced to about 50%.[35]Assuming this study expected irrigation of the subcutaneous tissue to reduce SSI by 60%, from 40% to 16%, using the power of 80% and significance level of 5%, the sample size was calculated as follow as:

$$n = \frac{2\bar{p}(1-\bar{p})(Z_{\alpha/2} + Z_{\beta})^2}{(P_1 - P_2)^2}$$

Where,

n= is the sample size

P_1 =proportion of SSI following abdominal surgeries = 0.40

P_2 = expected proportion of SSI following irrigation of the subcutaneous tissue =0.16

$\bar{p}$ = mean proportion of SSI

$Z_{\alpha/2}$ = value on the standard normal distribution at 95% confidence level= 1.96

Z_{β} = value on the standard normal distribution at 80% power = 0.84

$$n = \frac{2(0.28)(1-0.28)(1.96+0.84)^2}{(0.40-0.16)^2}$$

n=54.9≈55

The minimum sample size required for the study is 55 per group. Accounting for 10% attrition, the sample size will be 61 per group, giving a total size sample of 122.

3.7 STUDY PROCEDURE

The study recruited consecutive cohort of patients diagnosed with appendicitis for appendicectomy through a right lower quadrant incision at the Surgical Unit of the KBTH.

The protocol of the study, significance, benefits were explained to the prospective recruits, and informed consent obtained before recruitment.

This was done at the surgical emergency and on the various surgical wards the patients were admitted to. Data on socio demographics such as age, sex, level of education, religion, marital status, BMI, smoking status, alcohol use, presence of any chronic illness and so forth were obtained.

The data was collected by the principal investigator, supported by fellow surgical residents and surgical house officers.

The participants were blindly randomized into two groups, those that had their subcutaneous tissue irrigated with normal saline before skin closure at appendicectomy and those who did not have irrigation of the subcutaneous tissue before skin closure. The randomization sequences was computer generated. The permutated block randomization technique was used. This form of randomization is easy in terms of generation of codes, cost effective, not labour intensive, and user friendly. It is a preferred method of randomizing in clinical trials because it ensures equal numbers of participants in each arm of the study and eliminates conscious bias. The patients were assigned into two groups with randomization ratio of 1:1. This was done with a software program on randomizer.org.A block size of 2, the number per set together with the total number of patients to be recruited was fed into the software on randomizer.org which generated a random table.This table has been attached to the work and can be found in the appendix.

The allocations concealment technique used in the study was the Sequential Numbered Opaque Sealed Envelope. (SNOSE).Again this technique was adopted because it is cost effective, simple and did not make use any sophisticated technology. The 2 sets of 61 different papers were labelled through printing of the respective sequential numbers generated by the permuted block on. These numbers according to the permutated block randomization are either irrigation of subcutaneous tissue or non-irrigation of subcutaneous tissue. The report table from the randomization sheet was also generated. The in-printed numbered papers and the report sheet were placed in brown opaque envelops and sealed. They were tested ensure it was not transparent and one cannot see through under lighting. The envelopes were put in a Tupperware container and placed in a locker under lock and key in theatre. The locker was opened when a patients recruited into the study was brought to theatre for surgery.

After induction of anaesthesia the Tupperware container was brought and an envelope was then picked.Picking was done by the circulating nurse, the anaesthetist, the principal investigator or another doctor who was not involved in the surgery at that time. The envelop is opened and the number picked was correlated with the randomization sheet to inform the intervention which will be applied;whether irrigation of subcutaneous tissue or non-irrigation of subcutaneous tissue,

This information was kept by the one that picked the envelope and the intervention to be carried out was not disclosed to the surgeon until closure of the external oblique aponeurosis when the surgeon will either irrigate or not. Antibiotics in the form of intravenous metronidazole and

intravenous ciprofloxacin were given at the time of induction to cover Gram negative and anaerobic organisms.

After induction of general anaesthesia, to maintain uniformity in the surgical procedure, standard protocol as practiced in the general surgery theatres of the KBTH of cleaning with savlon mixed with spirit was used and patient draped. The skin incision was made; Lanz incison **(Figure 3.7.1)** which was deepened through subcutaneous tissue to external aponeurosis which was split along its fibres. The internal oblique and transversalis fascia were bluntly separated and parietal peritoneum opened into the peritoneal cavity. Any fluid encountered, peri-appendiceal fluid or pus was suctioned or mopped. The ceacum was identified and delivered into the wound, the tinea of the caecum was followed to its termination and the appendix delivered. The appendix was held with Babcock's forceps, a window in the mesentery near the base of the appendix was created, an artery forceps was applied and the mesentery divided and ligated **(Figure 3.7.2**). The appendix was ligated at its base and excised at about 5mm distal to the ligature which was vicryl 0. The abdominal cavity was cleaned with swab on stick. The parietal peritoneum was closed with vicryl 2.0 .The internal oblique and transversus abdominis muscles were closed with vicryl 0. The external oblique aponeurosis was also closed with vicryl 0.

For patients who belong to the intervention group, the subcutaneous tissues were irrigated with 300 ml of normal saline delivered in a 50 cc syringe **(Figures 3.7.3 and 3.7.4)** in jet fashion with the force of one hand at a distance of about 2 cm from the wound edge a perpendicular fashion, while suctioning the fluid collected. **(Figures 3.7.5 and 3.7.6)** The skin was closed with nylon 2.0 in an interrupted stitch fashion. The wound was dressed with sterile dressing. For patients in the control group, the wound was closed in the manner described without normal saline irrigation of the subcutaneous tissue. Post-surgery all patients were given pain medication which was IV paracetamol and IM pethidine for the first 24 hours and switched to orals as tolerated. Intravenous antibioticas were continued as form of treatment again to cover enteric Gram negative and anaerobic organisms.The antibiotics given were; per the protocol at the department, Metronidazole and Ciprofloxacin in intravenous forms. These were switched to orals as tolerated by post-operative day two.

The operations were performed by the principal investigator, other resident surgeons and consultant surgeons.

In the era of COVID-19, safety protocols were laid down by the KBTH for all patients and staff to follow. These were adhered to in the study. These included;

Compulsory wearing facemasks, on the wards and in theatre.

Avoiding overcrowding on the wards, in the lifts and in the theatres.

Regular washing of hands with soap and water by staff and using of alcohol hand sanitizer especially by the patients.

Avoiding touching of face, nose, mouth and washing of hands right after.

Figure 3.7.1 Incision made at the start of the operation

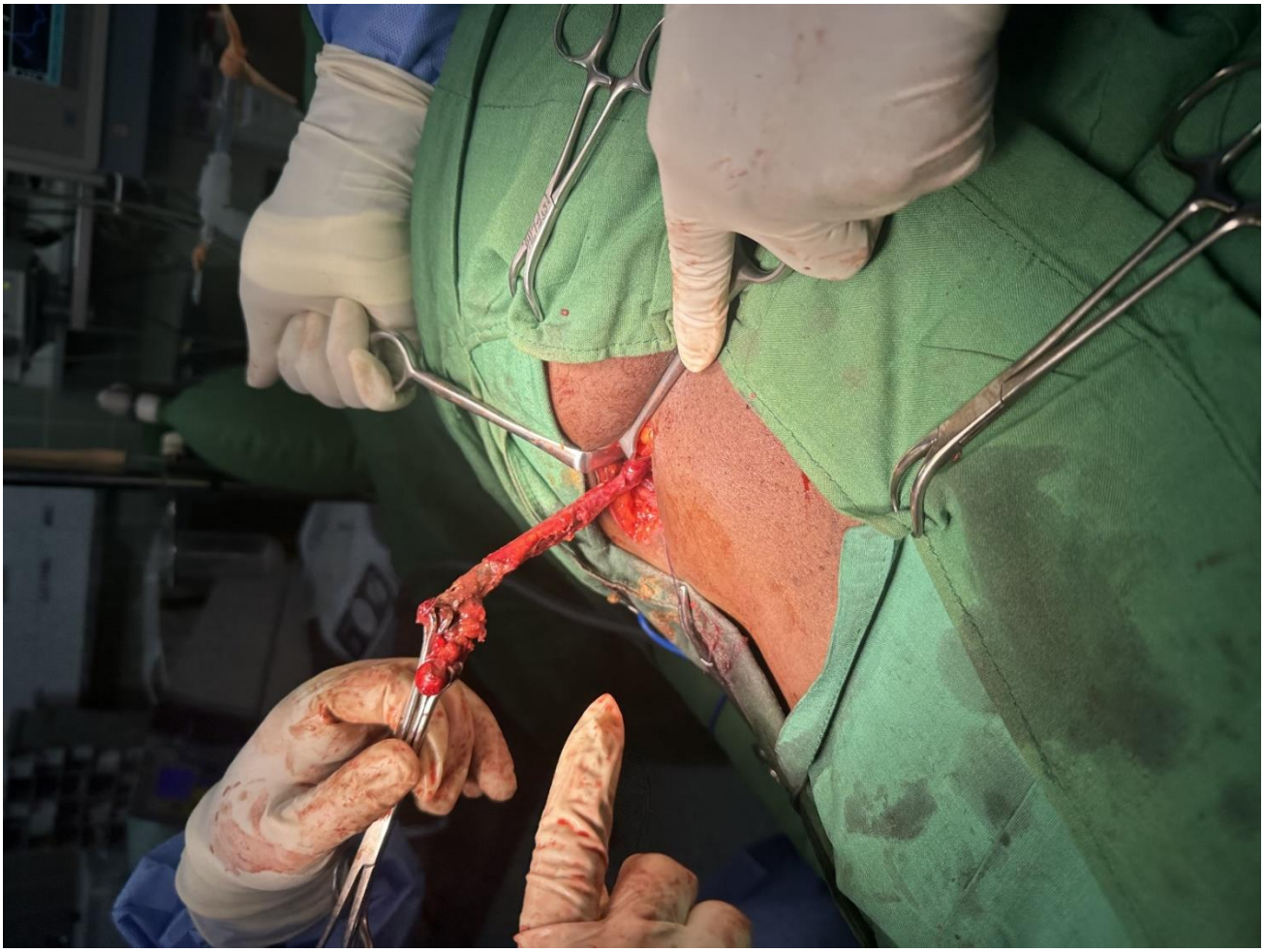


Figure 3.7.2 Perforated appendix

Figure 3.7.3 50 ml syringe to be used for irrigation

Figure 3.7.4 50 ml syringe and kidney dish containing normal saline to be used for irrigation

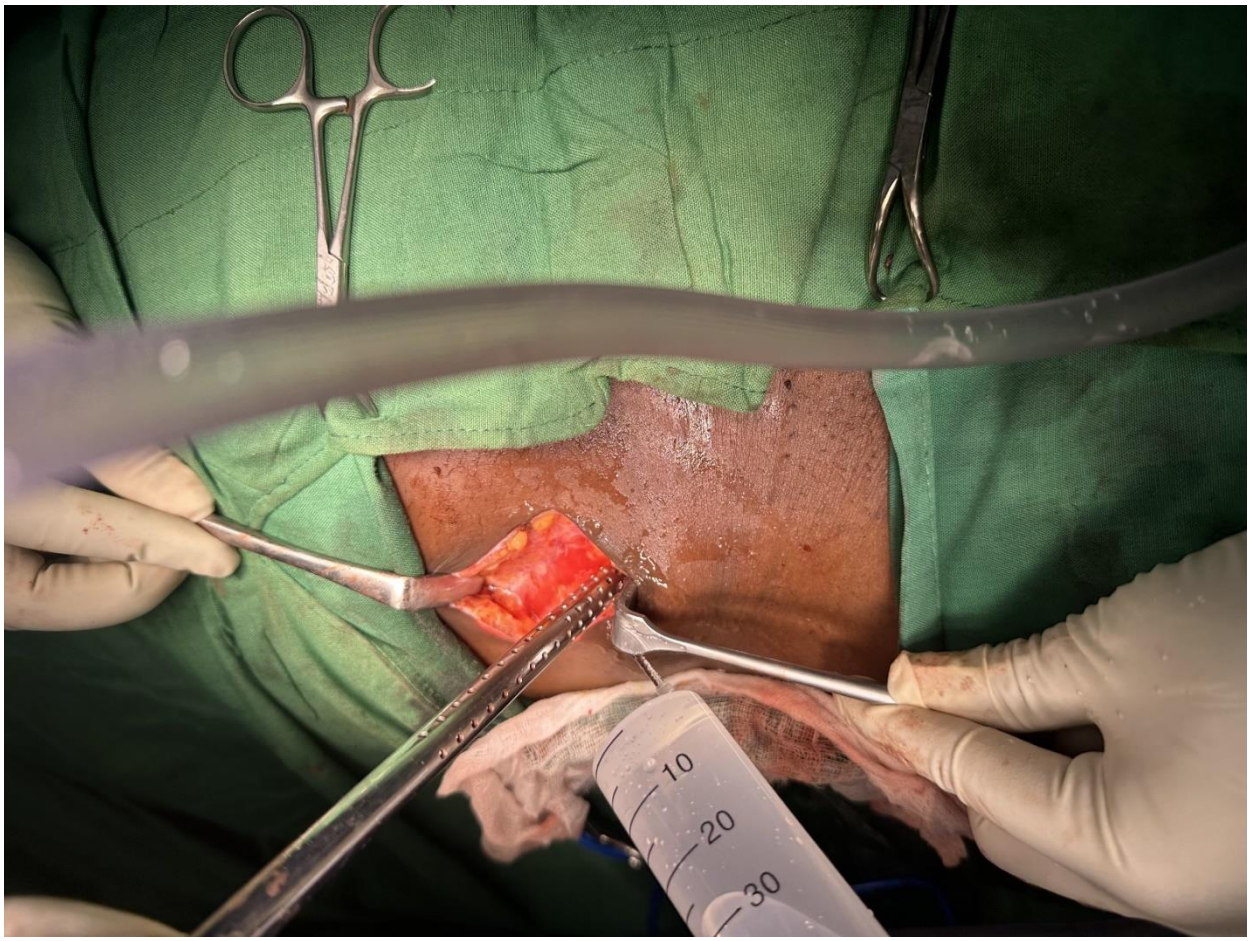


Figure 3.7.5 Normal saline being used for wound irrigation

Figure 3.7.6 normal saline irrigation

3.8 OUTCOME MEASURE

3.8.1Primary outcome

Surgical site infection following open appendicectomy with or without irrigation of the subcutaneous tissue with normal saline

3.8.2 Secondary outcome

Ascertain the organisms causing surgical site infection following appendicectomy and identify the risk factors in developing surgical site infections,

3.9 WOUND ASSESSMENT

Wounds were inspected post operation day 3 in the hospital by the nurse in charge on the particular floor, who had been trained on how to diagnose SSI based on the CDC criteria and the principal investigator and the other doctors in the study team. The nurses were blinded to the group to which the patient was assigned. For the patients who did not have their dressing at the KBTH they were followed up with a standardized telephone interview to ascertain signs and symptoms based on the CDC criteria for diagnosis of SSI on the designated days for wound assessment. If there was any sign or symptom of SSI the patient was invited back to KBTH immediately. The wound was further assessed on day post-operative day 7, 14 and 30 on outpatient basis at by the Principal investigator or on the ward by the nurse in charge for any signs of SSI and whether the wound has healed without SSI. **(Figures 3.9.1 and 3.9.2)**.These days are in line with the hospital's protocol of follow up dates after appendicectomy.For those patients with purulent discharge of the wounds, a wound swab was taken and sent for culture and sensitivity.The cost for the culture and sensitivity was borne by the Principal investigator and the results made available to the surgeons managing the patient for appropriate management to be given.

Figure 3.9.1 Patient with SSI

Figure 3.9.2 Appendicectomy wound healed without SSI

3.10 MITIGATING THE EFFECTS OF CONFOUNDERS

The primary outcome of surgical site infection has some various confounding factors that must be mitigated.

We used these approaches to mitigate the confounding factors;

Exclusion of patients with generalized peritonitis secondary to appendicitis, patients with appendiceal abscesses or masses and patients requiring laparotomy for appendicitis for a particular reason.

Correct randomization of the patients into the two arms of the study to take care of the known and unknown confounders by ensuring the statistical differences between the two groups are minimized.

The protocol of the recruitment process and procedure of the surgery were standardized and adhered to. The only difference was whether a patient's subcutaneous tissue will be irrigated or not.

3.11 BENEFITS AND CONFIDENTIALITY

There was no benefit financially to the participants. Neither did the study cause any harm or pain to the participants in anyway. The recruitment process took about ten to fifteen minutes.

Participation in the study was voluntary and patients could refuse to take part in the study which was explained to them. Patients at any point were also at liberty to leave the study.

Data collected was safeguarded to ensure the privacy of the participants were protected throughout the study and after the study.

3.12 DATA HANDLING AND ANALYSIS

Data security in this study was enforced. Quality assurance was also effected. The Declaration of Helsinki for human subjects in medical research guided the conduct of the study in its entity. The Principal investigator was primarily and solely responsible for the data gathered and that the data gathering process was adequate, accurate, relevant and not excessive, in that important and straight forward questions were asked in order not to waste time. The Principal investigator was responsible also for the proper storage of the data and each patient was given a unique study number.

The Data collected was entered into Microsoft Excel. Backup of the data was stored on icloud with access limited to the Principal investigator only. The data was not within the reach of any other person or persons. The data collected will be in storage for 5 years before final disposal. The Principal investigator would be the only authorized person who would have access to the stored data.

Statistical Package for Social Sciences (SPSS) version 23 was used for the data analysis. Firstly, a thorough examination of demographic characteristics was undertaken. Descriptive statistics was used to analyze the socio-demographic characteristics using charts. This included assessing the age distribution, gender representation, marital status, occupational backgrounds, educational levels, nationality, and religious affiliations of the patients.

Additionally, an in-depth descriptive analysis of health status and history factors was conducted and presented using frequency tables. This involved evaluating parameters such as Body Mass Index (BMI), immunosuppression status, presence of uncontrolled diabetes, history of chemotherapy, presence of chronic conditions, and lifestyle factors such as alcohol consumption and smoking habits.

Comparison of the two surgical approaches, subcutaneous tissue irrigation versus non-irrigation was done, duration of surgery and surgeon grade affecting SSI were analyzed.

A Chi-square test was performed to test associations between categorical variables. A logistic regression analysis was used to ascertain associations between the potential risk factors for SSI. Statistical significance was established at $p < 0.05$.

3.13 DATA AND SAFETY MONITORING BOARD (DSMB) CHARTER

A data and safety monitoring board was set up for the study upon recommendation by Institutional review board of the KBTH.

The data and safety monitoring board set some guidelines and charter to follow.

The responsibility of the data and safety monitoring board were as follows;

1. Review the final protocol and recommend its approval by the Korle-Bu Teaching Hospital - Institutional Review Board

2. Give input which would help the investigator protect the safety of the study participants.

3. Provide input in planning and for data safety and monitoring.

4. Consider factors external to the study when relevant information becomes available, such as scientific or the therapeutic developments that may have an impact on the safety of the participants or the ethics of the study.

5. Periodically assess the data quality and timelines, patient recruitment and other factors relevant to the study
6. Give input to the investigator for a possible full scale study at the completion of this study.
7. Monitor the progress of the study.

MEMBERSHIP

1. Dr. Prince Larvie (Chairman)

2. Dr. Sena Fenu

3. Dr. Joelle Amissah

4. Dr. Dickson Bandoh

The chairman was responsible for overseeing the meetings and developing the agenda in consultation with the investigator.

3.13.1 DSMB MEETING

The DSMB met before patient enrolment, 1 month after 50% of patient enrolment and at 3 months after 100% of patient enrolment. The meetings were convened in person and by conference call. The meetings were closed to the public because confidential patient information was addressed.

The DSMB at any point could make recommendation for either continuation or termination of the study. Termination could be suggested at any time, the reasons for early termination could be if any serious adverse events affected more than one-third of the study participants enrolled or data quality problems ensued so severe that correction would not be feasible.

3.13.2 CONFIDENTIALITY AND OBJECTIVITY

All materials, discussions and proceedings of the DSMB were completely confidential. Members and other participants in DSMB meetings were expected to maintain confidentiality. In order to maintain their objectivity, DSMB members could not discuss the study with the investigators except during DSMB meetings.

The DSMB charter was read and approved by:

Dr. Prince Larvie-Chairman

Dr. Sena Fenu- Executive secretatary

Dr. Joelle Amissah- Member

Dr. Dickson Bandoh- Member

3.14 ETHICAL CLEARANCE

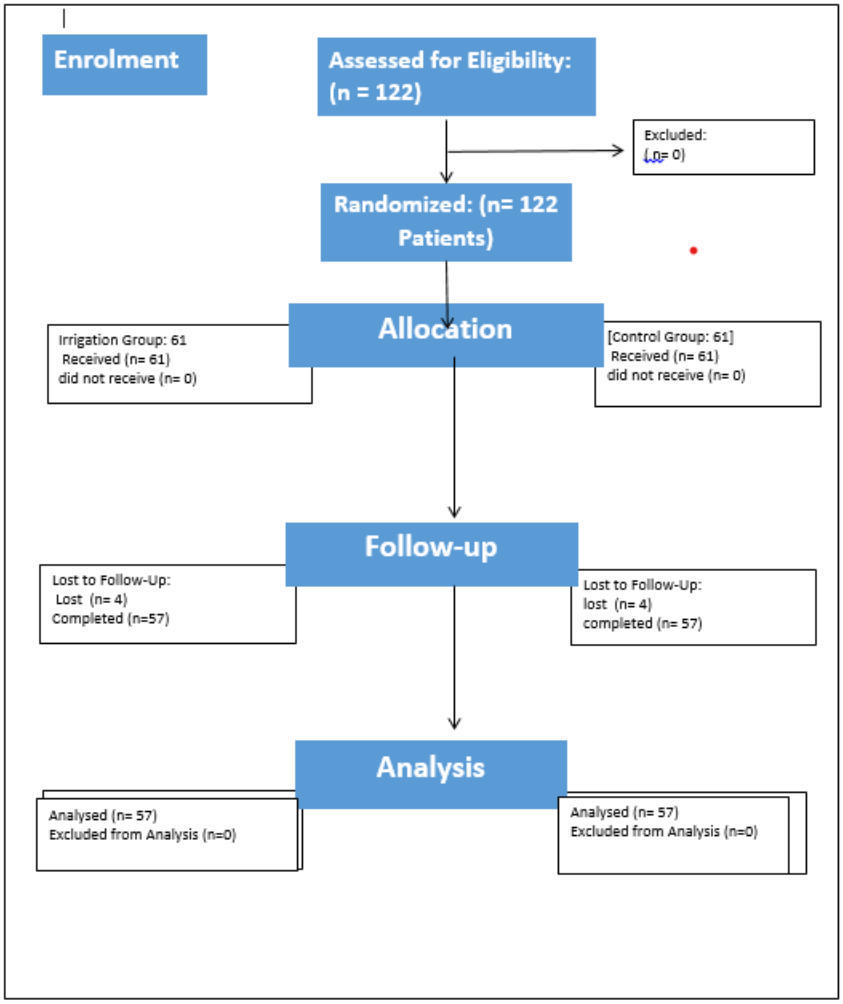
Ethical clearance was obatianed from the Institutional Review Board of the Korle-Bu Teaching Hospital, KBTH-MD/G3/22. Informed consent was sought from patients after the study protocols were explained to them. With the patients under the age of 18 years, their parents or guardians signed the informed consent. Patients were free to leave the study and opt out anytime they so wished. Patients were given concise and adequate information about the study and what it entails. Their reviews for assessment of the wounds were also scheduled in line with the normal timed reviews they would have had for change of dressings and outpatient visitation if they had not been recruited into the study. A wish to decline participation or not to be involved in the study would not affect the medical care given to them. All information obtained was confidential and not revealed to any 3rd party. The study was conducted in accordance with the principles of the Declaration of Helsinki on Human Subjects.[83]

4.0 RESULTS

Patients who had been physically examined and clinically diagnosed with appendicitis, between November 2022 to 30th November 2023 in the General Surgery department of the KBTH from whom informed consent has been sort.

The sample size calculated for this study was 55 per group, but with a 10% attrition rate making the overall sample size, 61 per group therefore 122 patients in total. Within the period of data collection, a total of 122 patients were recruited, however 114 was the final number at the end of the study as 8 participants were lost to follow up because they did not report for review or dressing at the KBTH and others could not be reached via phone calls.

The final number of 114, 57 patients had non-irrigation of subcutaneous tissue, and an equal number of patients had irrigation of subcutaneous tissue.



4.1 Age of patients

The mean (SD) age for this study population was 32 (11.8) years. The largest proportion fell within the 20-30 years category, constituting 33.3% of the total sample size, followed closely by individuals aged 31-40 years at 28.1%. Those below 20 years of age represented 16.7%, while individuals aged 41 years and above accounted for 21.9% of the participants. **(Figure 4.1).**

The mean (SD) age for the non-irrigation group and the irrigation group were 35.0(11.9) and 28.6(10.8) respectively. However, the chi-square test suggested that this difference was not statistically significant ($\chi^2 = 7.684$, $p = 0.053$) **(Table 4.1).**

Figure 4.1 Age group of patients

4.2 Sex of patients

Sex distribution within the research sample revealed a notable gender imbalance, with males comprising the majority at 77.2%, while females represented 22.8% of the participants **(Figure 4.2)** The male population distribution in the non-irrigation and irrigation groups were 36.8% and 40.4%, respectively. However, there was no statistically significant difference between the two groups in terms of gender distribution ($\chi^2 = 0.797$, $p = 0.372$) **(Table 4.1).**

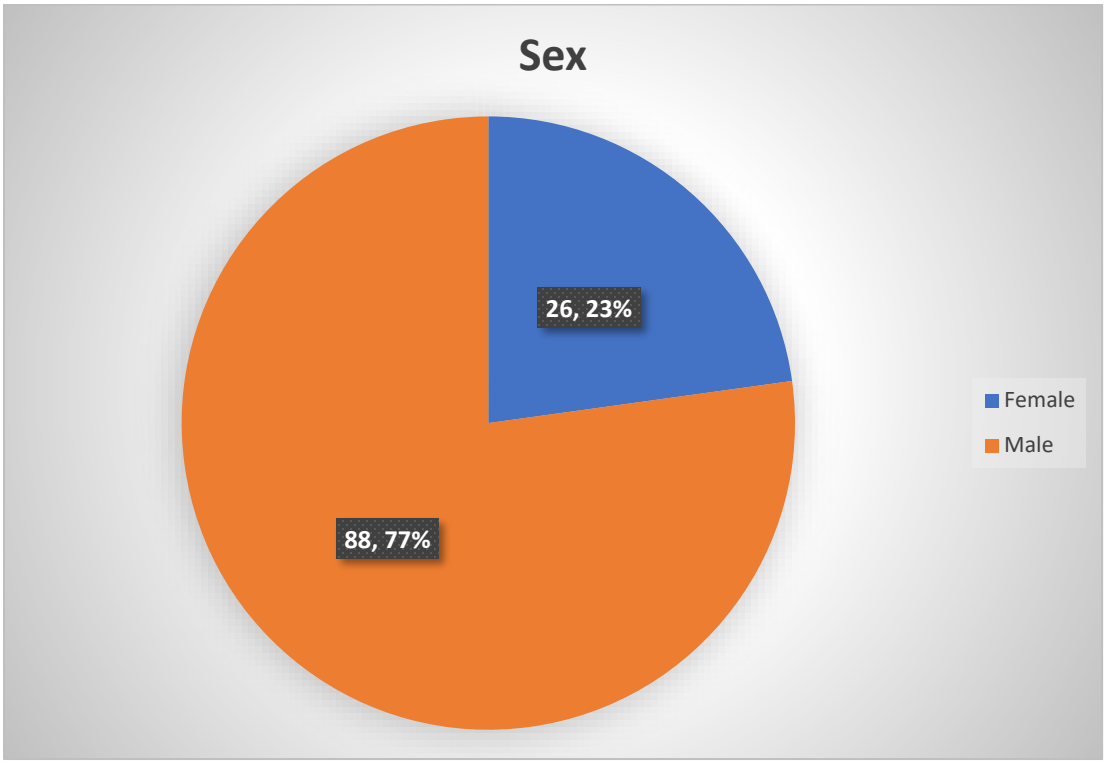


Figure 4.2 Sex of participants

4.3 Marital status of participants

The marital status distribution within the research sample highlighted a significant majority of single individuals, accounting for 65.2% of the participants. In contrast, married individuals constitute a smaller proportion at 34.8% **(Figure 4.3).** The Marital status also showed no significant variation between the two groups, with similar proportions of married individuals in both the non-irrigation and irrigation groups **(Table 4.1).**

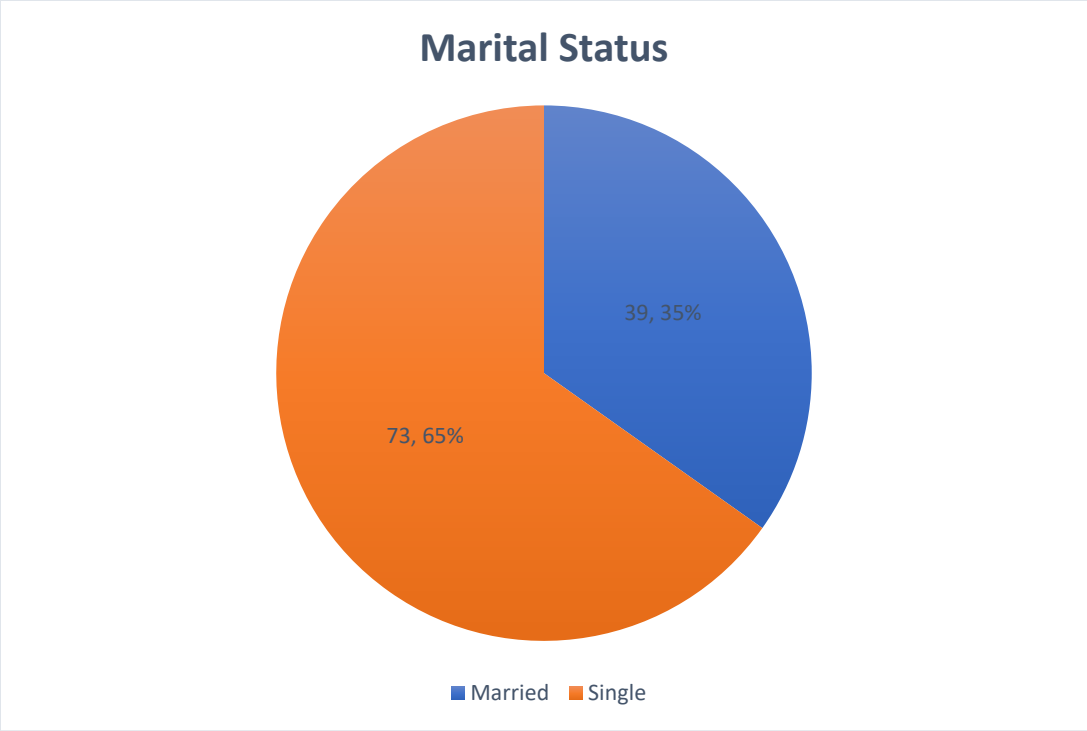


Figure 4.3 Marital status of participants

4.4 Occupational status of participants

The occupation distribution among the study participants demonstrated significant majority being employed, constituting 67.0% of the sample. Students represented the second largest occupational group, comprising 26.8% of the participants. In contrast, the proportion of unemployed individuals was comparatively smaller, accounting for 6.3% of the sample **(Figure 4.4).** Occupation distribution showed a trend towards higher representation of employed individuals in both groups, with slightly higher numbers in the non-irrigation group. However, the chi-square test suggests that this difference is not statistically significant ($\chi^2 = 4.095$, $p = 0.129$**) (Table 4.1).**

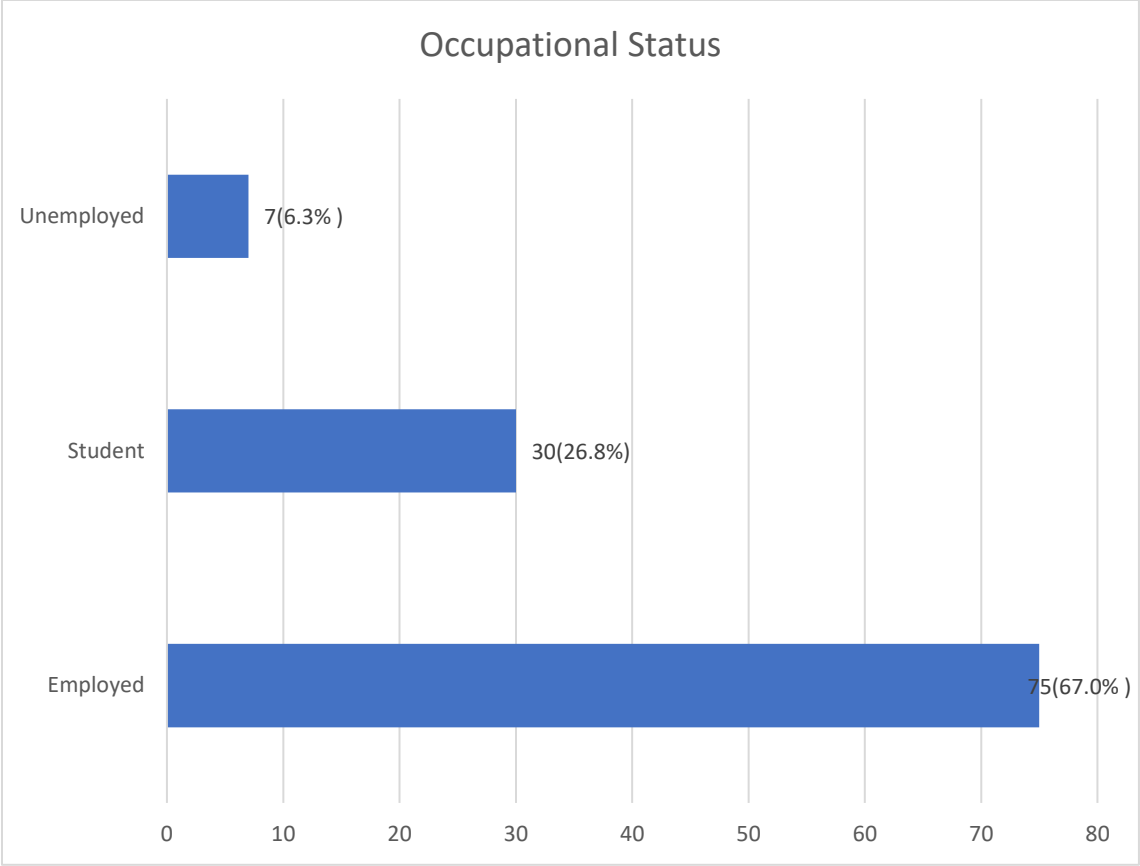


Figure 4.4 Occupational status of participants

4.5 Educational level of participants

Senior High School (SHS) graduates comprised the largest group, representing 43.0% of the participants, followed closely by individuals with tertiary education, constituting 36.4% of the sample. Those with education up to Junior High School (JHS) represented 15.0% of the participants, while individuals with no formal education or primary education were relatively smaller groups, each accounting for 2.8% of the sample **(Figure 4.5**).Educational level distribution also exhibits no significant difference between the two groups, with similar proportions across different educational categories **(Table 4.1).**

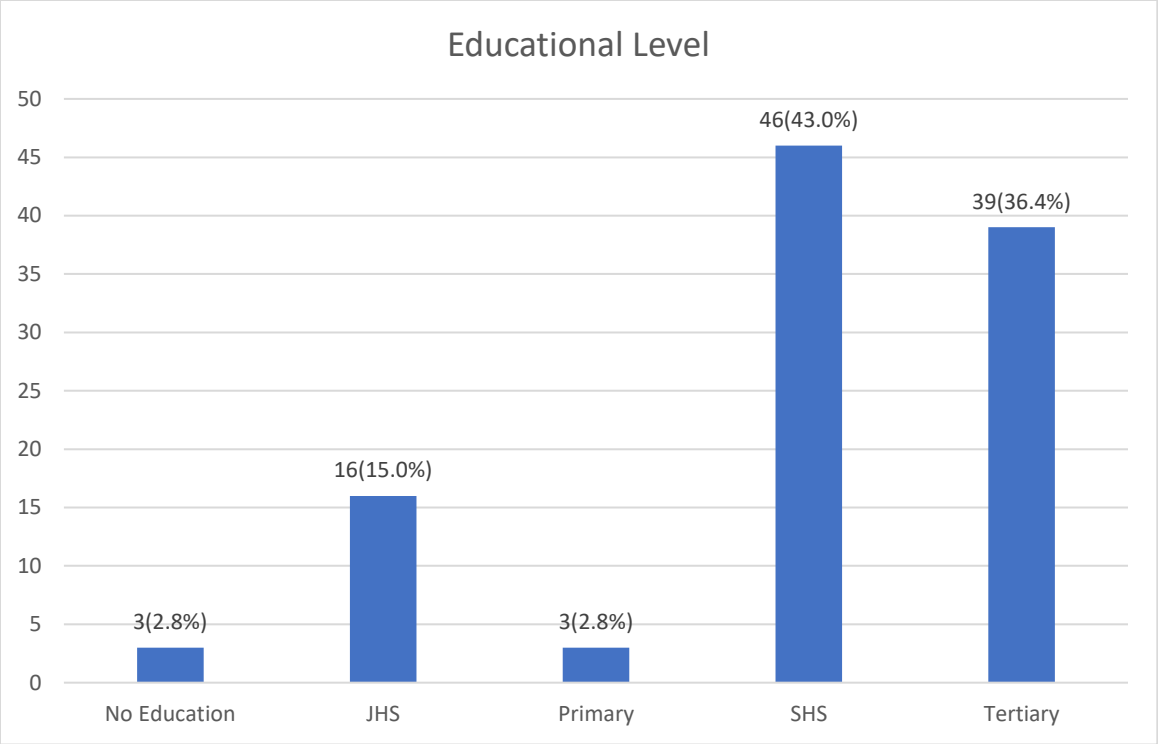


Figure 4.5 Educational Level of participants

4.6-Nationality of participants

The nationality breakdown within the research sample demonstrated a predominant representation of Ghanaian participants, comprising 98.2% of the total sample size. In contrast, foreign nationals constituted a much smaller proportion, accounting for only 1.8% of the participants. **(Figure 4.6)** However, there was no statistically significant difference between the two groups in terms of nationality **(Table 4.1).**

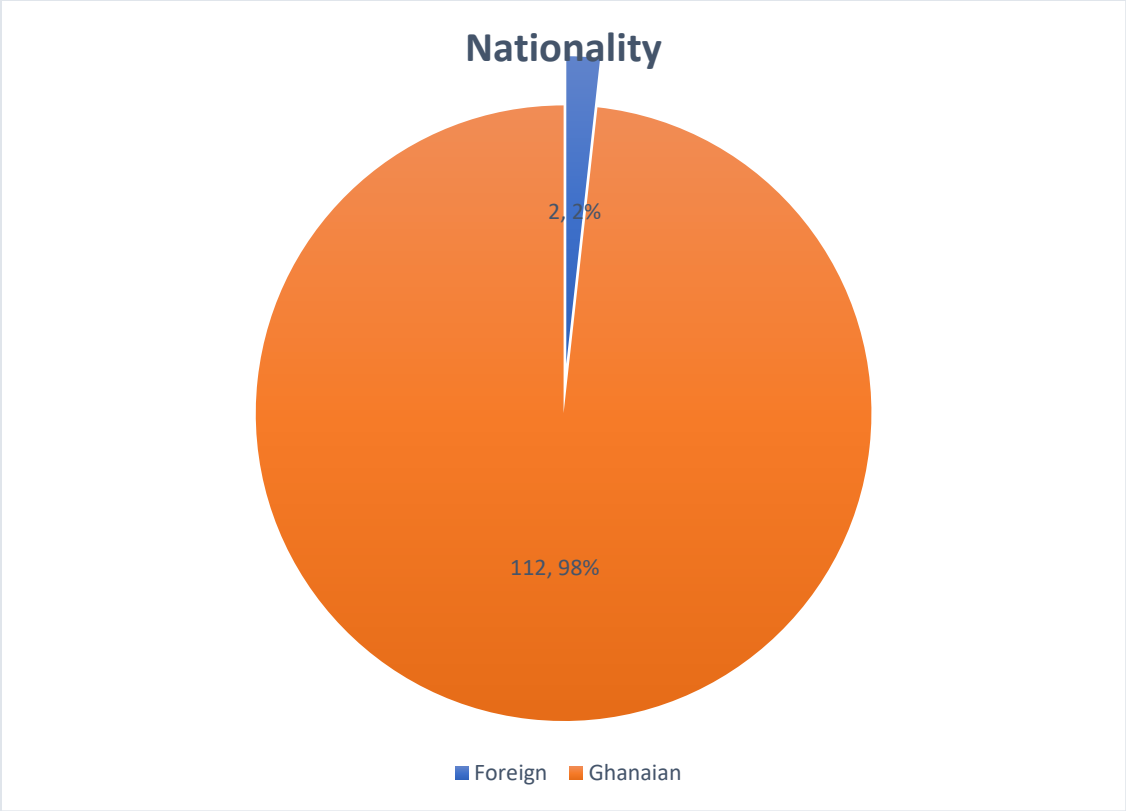


Figure 4.6 Nationality of participants

4.7 Religion of participants

Most of the participants were Christians, constituting 87.7%. Islam represented the second most prevalent religion among the participants, accounting for 9.6%. A smaller proportion of individuals identified as having no religious affiliation, comprised 2.6% of the participants **(Figure 4.7**).This distribution indicates a predominantly Christian population within the study sample. However, like the other demographic variables, there was no statistically significant difference between the two groups in terms of religion distribution ($\chi^2 = 2.766$, $p = 0.251$). **(Table 4.1)**

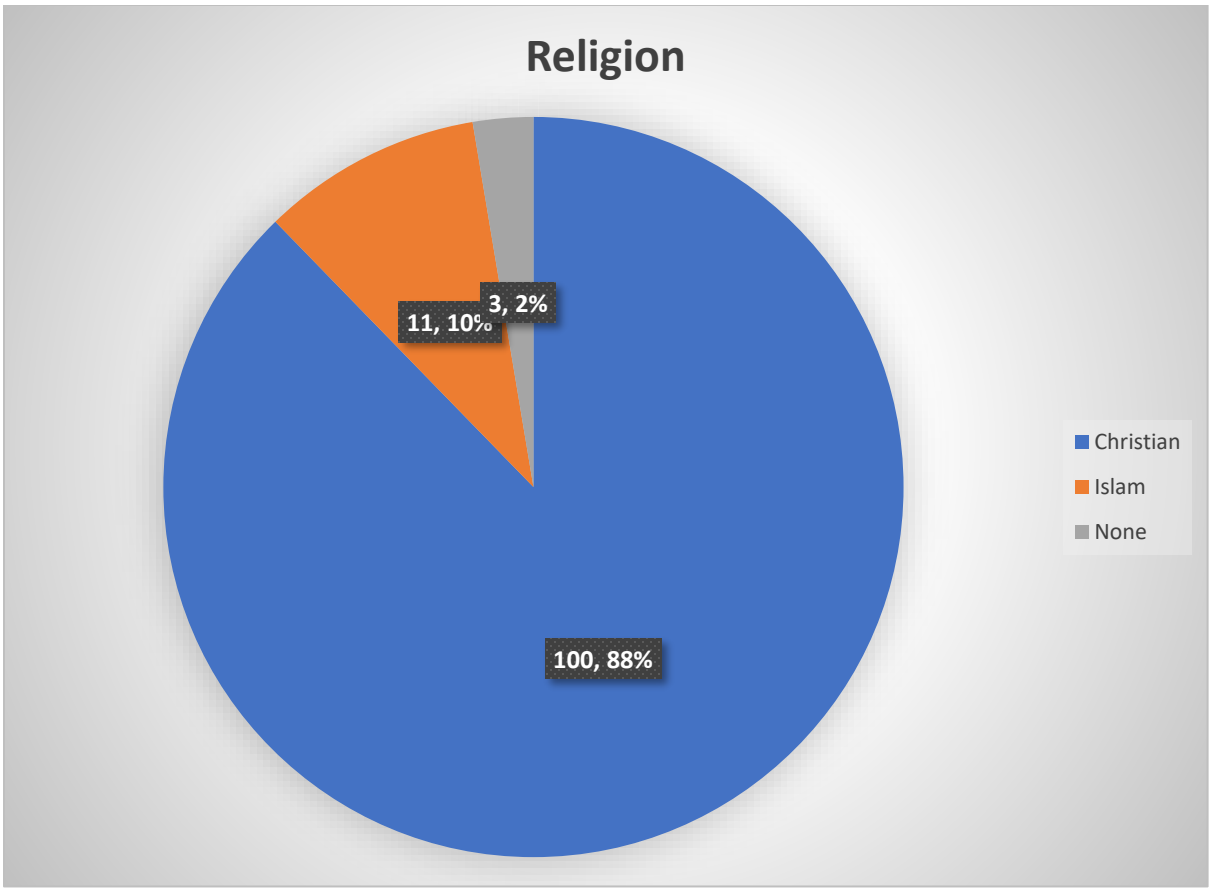


Figure 4.7 Religion of Participants

4.8 Comparison of demographics between irrigation and non-irrigation groups.

Over all in terms of demographic characteristics between the two arms there was no statistical difference **(Table 4.1).**

Table 4.1 Comparison of demographic Characteristics between irrigation and non-irrigation Groups in Appendicectomy Patients.

	Non-irrigation of subcutaneous tissue	Irrigation of subcutaneous tissue	Person Chi-Square	P-Value
Age group	**Freq(%)**	**Freq(%)**	7.684	.053
< 20 years	5(4.4)	14(12.3)		
20-30 years	17(14.9)	21(18.4)		
31-40 years	20(17.5)	12(10.5)		
41+ years	15(13.2)	10(8.8)		
Mean (SD)	35.0(11.9)	28.6 (10.8)		
Sex			.797	.372
Female	15(13.2)	11(9.6)		
Male	42(36.8)	46(40.4)		
Marital Status			1.928	.165
Married	23(20.5)	16(14.3)		
Single	33(29.5)	40(35.7)		
Nationality				1.000
Foreign	1(0.9)	1(0.9)		
Ghanaian	56(49.1)	56(49.1)		
Occupation			4.095	.129
Employed	41(36.6)	34(30.4)		
Student	10(8.9)	20(17.9)		
Unemployed	4(3.6)	3(2.7)		
Educational level			4.167	.384

No Education	2(1.9)	1(0.9)		
JHS	9(8.4)	7(6.5)		
Primary	0(0.0)	3(2.8)		
SHS	20(18.7)	26(24.3)		
Tertiary	20(18.7)	19(17.8)		
Religion			2.766	.251
Christian	52(45.6)	48(42.1)		
Islam	3(2.6)	8(7.0)		
None	2(1.8)	1(0.9)		

4.9 Body Mass Index of participants

The Body Mass Index (BMI) classification showed a significant proportion of individuals fell within the normal weight range, constituting 47.7% of the sample. However, a considerable number were overweight (25.6%) and obesity represented 12.8%. **(Table 4.2)**

The mean (SD) BMI for this study population was 23.97 (4.89) Kg/m^2. Additionally, the presence of underweight individuals was noted, comprising 14.0% of the participants. The mean (SD) values were 25.4 (5.27) and 22.8 (4.29) for non-irrigation group and the irrigation group respectively. However, the chi-square test suggested this difference was not statistically significant ($\chi^2 = 6.744$, $p = 0.081$) **(Table 4.4).**

Table 4.2: BODY MASS INDEX

BMI Class	Freq [n=114]	%
Normal Weight	41	47.7
Obesity	11	12.8
Overweight	22	25.6
Underweight	12	14.0
Mean (SD)	23.97 (4.9)	

4.10 Immunosuppression status, smoking and alcohol Intake

In terms of immunosuppression status, the majority of individuals (97.4%) did not exhibit any immunosuppressive conditions, while a small percentage (2.6%) were immunocompromised. **(Table 4.3).**

Furthermore, the analysis highlighted a low prevalence of uncontrolled diabetes, with only 0.9% of participants reporting this condition **(Table 4.3**). None of the patients had ever been given any form of chemotherapy or were undergoing chemotherapy at the time of the study. Kidney disease, liver disease, chronic steroid use, and HIV were each reported by less than 2% of the participants. For the above factors related to immunosuppression, there was no statistically significant differences between the two groups, as indicated by a p-value of 1.000 for each variable **(Table 4.4**).

Majority of participants (71.1%) reported no alcohol consumption, while 28.9% acknowledged alcohol consumption. **(Table 4.3).** There was a slightly higher proportion of patients who reported alcohol use in the non-irrigation group (16.7%) compared to the irrigation group (12.3%), but this difference was not statistically significant ($\chi^2 = 1.066$, $p = 0.302$) **(Table 4.4).**

Significant portion of individuals (90.4%) identified as non-smokers, and 9.6% were smokers. **(Table 4.3).** Smoking status showed no significant difference between the two groups, with comparable percentages of smokers and non-smokers in both the non-irrigation and irrigation groups respectively. ($p = 0.751$) **(Table 4.4)**

Table 4.3: Immunosuppression status, uncontrolled diabetes, smoking and alcohol Intake

	Freq [n=114]	%
Immunosuppression Status		
No	111	97.4
Yes	3	2.6
Uncontrolled Diabetes		
No	113	99.1
Yes	1	0.9
History Of Chemotherapy		
No	114	100.0
Chemotherapy Session		
No	114	100.0
Presence Of Chronic Conditions		
Kidney Disease	1	0.9
Liver Disease	2	1.8
Chronic Steroid Use	1	0.9
HIV	1	0.9
Alcohol		
No	81	71.1
Yes	33	28.9
Smoking		
Non Smoker	103	90.4
Smoker	11	9.6

4.11 Comparison of Immunosuppression status, alcohol and smoking status between irrigation and non-irrigation groups

There was no statistical difference using the Chi-square between the irrigation and non-irrigation groups in terms of BMI, Immunosuppression status, alcohol intake and smoking. **(Table 4.4)**

Table 4.4 Comparison of BMI Immunosuppression status, Alcohol and Smoking status between irrigation and non-irrigation groups

	Non-irrigation of subcutaneous tissue	Irrigation of subcutaneous tissue	Person Chi-Square	P-Value
BMI Class	**Freq(%)**	**Freq(%)**	6.744	.081
normal weight	16(18.6)	25(29.1)		
obesity	8(9.3)	3(3.5)		
overweight	12(14.0)	10(11.6)		
underweight	3(3.5)	9(10.5)		
Mean (SD)	25.4(5.27)	22.8(4.29)		
Immunosuppression				.243*
No	54(47.4)	57(50.0)		
Yes	3(2.6)	0(0.0)		
Uncontrolled Diabetes				
No	57(50.0)	56(49.1)		1.000*
Yes	0(0.0)	1(0.9)		
Chemotherapy				-
No	57(50.0)	57(50.0)		
Chemotherapy Session				
No	57(50.0)	57(50.0)		
Kidney Disease				1.000*
No	56(49.1)	57(50.0)		
Yes	1(0.9)	0(0.0)		
Liver Disease				1.000*
No	56(49.1)	56(49.1)		
Yes	1(0.9)	1(0.9)		
Chronic Steroid Use				1.000*
No	56(49.1)	57(50.0)		
Yes	1(0.9)	0(0.0)		

Alcohol			1.066	.302
No	38(33.3)	43(37.7)		
Yes	19(16.7)	14(12.3)		
Smoking			.101	.751
Non smoker	51(44.7)	52(45.6)		
Smoker	6(5.3)	5(4.4)		

4.11 Surgery type

All the appendicectomies done except one was under emergency conditions, accounting for 99.1% of cases and one was an elective (interval) appendicectomy. All appendectomies performed were performed open. **(Table 4.5)**

Table 4.5 Surgery type

Surgery detail	**Freq [n=114]**	**%**
Type Of Surgery		
Elective	1	0.9
Emergency	113	99.1
Type Of Appendectomy		
Open	114	100.0

4.12 ASA Score

In terms of the American Society of Anaesthesiologists (ASA) score, most participants had a relatively low risk profile, with 89.5% categorized as ASA score I indicating healthy individuals. However, a smaller proportion of participants (10.5%) were classified as ASA score II, suggesting mild systemic disease **(Table 4.6)** .The irrigation group had a slightly higher proportion of patients classified as ASA Score I (47.4%) compared to the non-irrigation group (42.1%). Conversely, the

non-irrigation group had a higher percentage of patients classified as ASA Score II (7.9%) compared to the irrigation group (2.6%). However, the chi-square test suggested this difference was not statistically significant ($\chi^2 = 3.353$, $p = 0.067$). (**Table 4.9)**

Table 4.6 ASA Score

ASA Score	Freq{n=114}	%
I	102	89.5
II	12	10.5

4.13 Duration of surgery

The duration of surgeries varied, with the majority (55.3%) lasting less than one hour, followed by 43.9% falling within the 1-2 hour range. Only a minimal portion of surgeries (0.9%) extended beyond two hours **(Table 4.7**). There were no statistical significant differences between the two groups across the specified time intervals -1-2 hours, 2-3 hours, and less than 1 hour, as the chi-square test yields a p-value of 0.424. **(Table 4.9)**

Table 4.7 Duration of surgery

Duration of surgery	Freq{n=114}	%
1-2 Hours	50	43.9
2-3 Hours	1	0.9
< 1 Hour	63	55.3

4.14 Grade of surgeon

The grade of surgeons involved in the procedures varied, with a notable presence of senior residents (54.5%) and residents (40.2%), while consultants accounted for a small proportion (5.4%) **(Table 4.8).** This distribution suggested a combination of more experienced and experienced doctors conducting the procedures. The grade of the surgeon showed no significant difference between the two groups, with similar percentages of procedures performed by

consultants, residents, and senior residents in both the non-irrigation and irrigation groups (p = 0.914). **(Table 4.9)**

Table 4.8 Grade of surgeon

Grade of surgeon	Freq{n=114}	%
Consultant	6	5.4
Resident	45	40.2
Senior Resident	61	54.5

4.15 Antibiotic Administration

Antibiotics of Metronidazole and Ciprofloxacin were administered to all participants. All patients in both groups received antibiotics, indicating no difference in antibiotic administration between the non-irrigation and irrigation groups.

Table 4.9 Comparison of ASA Score, Type of Surgery, Duration, Grade of Surgeon and antibiotic use between irrigation and non-irrigation groups.

	Non-irrigation of subcutaneous tissue	Irrigation of subcutaneous tissue	Person Chi-Square	P-Value
Asa Score	Freq(%)	Freq(%)	3.353	.067
I	48(42.1)	54(47.4)		
II	9(7.9)	3(2.6)		
Type of Appendicectomy				1.000*
Elective	0(0.0)	1(0.9)		
Emergency	57(50.0)	56(49.1)		
Type of Appendicectomy				
Open	57(50.0)	57(50.0)		
Duration of Surgery			1.717	.424
1-2 hours	27(23.7)	23(20.2)		
2-3 hours	1(0.9)	0(0.0)		
< 1 hour	29(25.4)	34(29.8)		
Grade of surgeon			.181	.914
Consultant	3(2.7)	3(2.7)		
Resident	21(18.8)	24(21.4)		
Senior Resident	31(27.7)	30(26.8)		
Antibiotics Given				-
Yes	57(50.0)	57(50.0)		

4.16 Wound Class

Majority of wounds were contaminated (60%), followed by dirty wounds (37%) and clean contaminated wounds (3%).(**Figure 4.8)** There was no statistical significant distinction observed between the non-irrigation and irrigation groups, as the chi-square test yielded a p-value of 0.437**.(Table 4.10)**

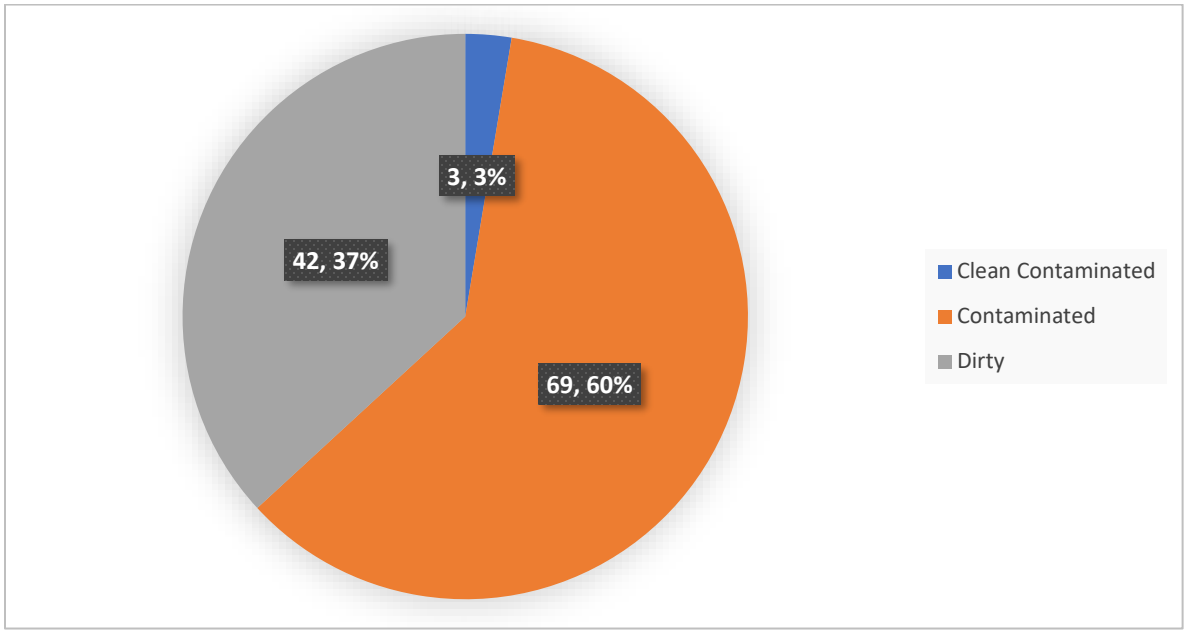


Figure 4.8 Wound Class

4.17 Duration of Admission

Significant portion of participants (71.9%) were discharged within 2-3 days, with 25.4% requiring a longer stay of 4-7 days. A small proportion (2.6%) were on admission for periods exceeding 7 days**.(Figure 4.9)** Duration of admission did not show a significant difference between the two groups, with similar proportions of patients staying in the hospital for 2-3 days, 4-7 days, and more than 7 days (p = 0.499**).(Table 4.10)**

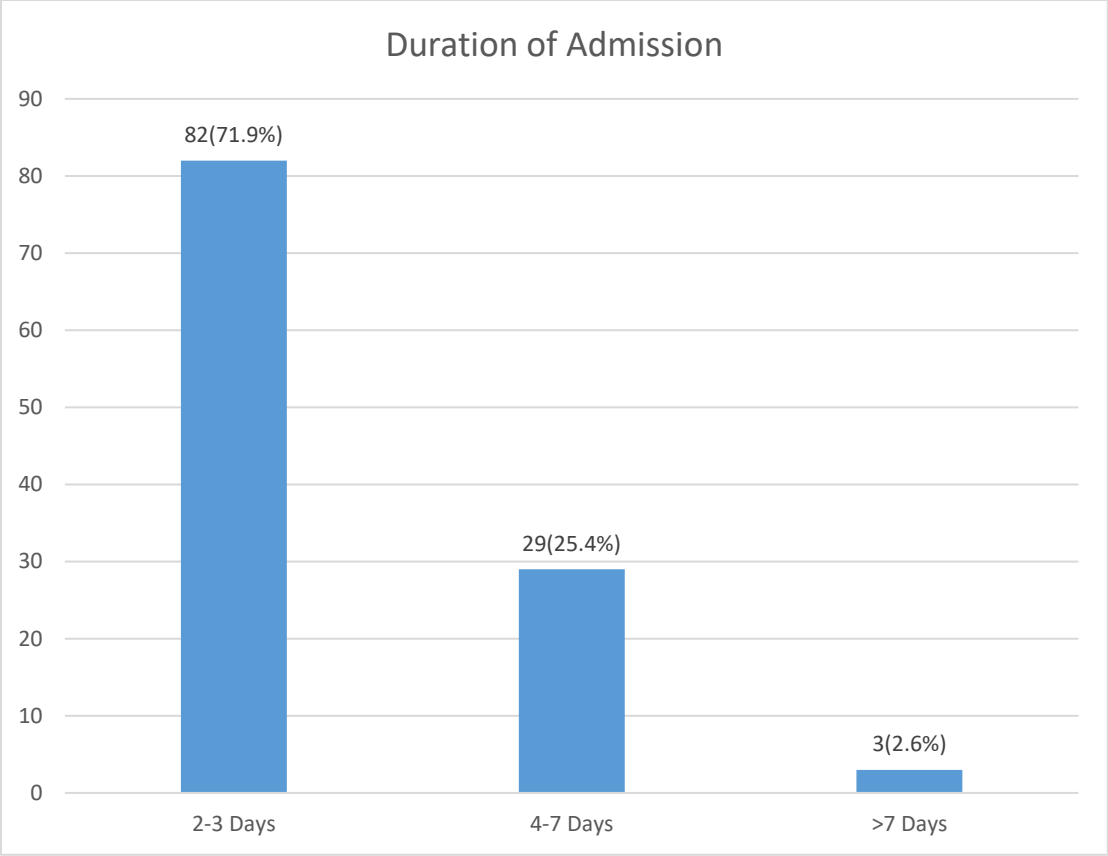


Figure 4.9 Duration of admission

Table 4.10 Comparison of duration of admission and wound class between non-irrigation and irrigation Groups

	Non-irrigation of subcutaneous tissue	Irrigation of subcutaneous tissue	Person Chi-Square	P-Value
Duration of Admission	**Freq(%)**	**Freq(%)**	1.391	.499
2-3 days	43(37.7)	39(34.2)		
4-7 days	12(10.5)	17(14.9)		
>7 days	2(1.8)	1(0.9)		
Wound Class			.603	.437
Contaminated	38(33.3)	34(29.8)		
Dirty	19(16.7)	23(20.2)		

4.18 Surgical site infections rate following appendicectomy

The analysis of SSI revealed that 8.8% of participants experienced SSI following appendicectomy. **(Figure 4.10)**

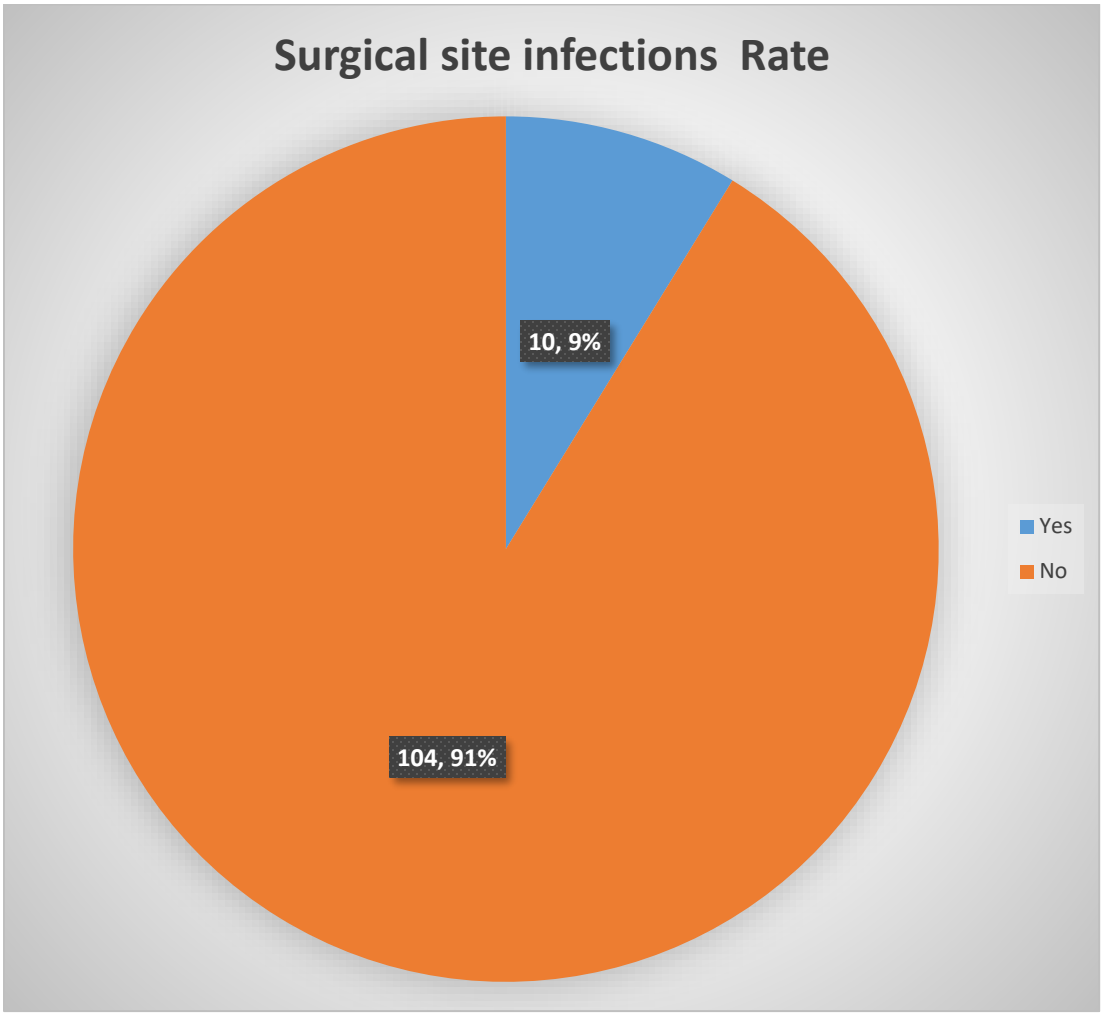


Figure 4.10 Surgical Site Infections Rate

4.19 Surgical Site Infection following subcutaneous tissue irrigation with normal saline

Following Subcutaneous Irrigation, SSI rate recorded was 3.5% whilst majority of the patients did not develop SSI (96.5%). **(Figure 4.11)**

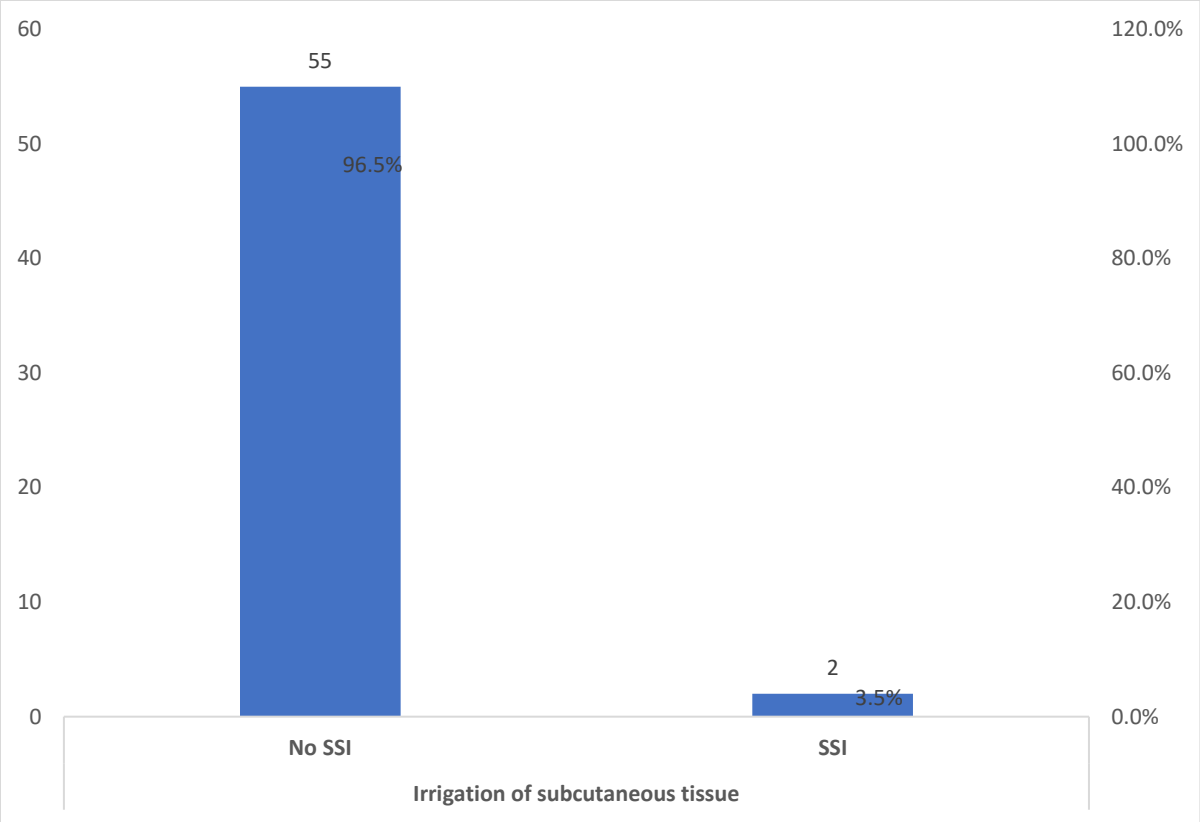


Figure 4.11 SSI following irrigation

4.20 The rate of Surgical Site Infection following non-irrigation

The rate of surgical site infection following non-irrigation of subcutaneous tissue in appendectomy was 14% whilst 86% of the patients did not developed SSI. **(Figure 4.12)**

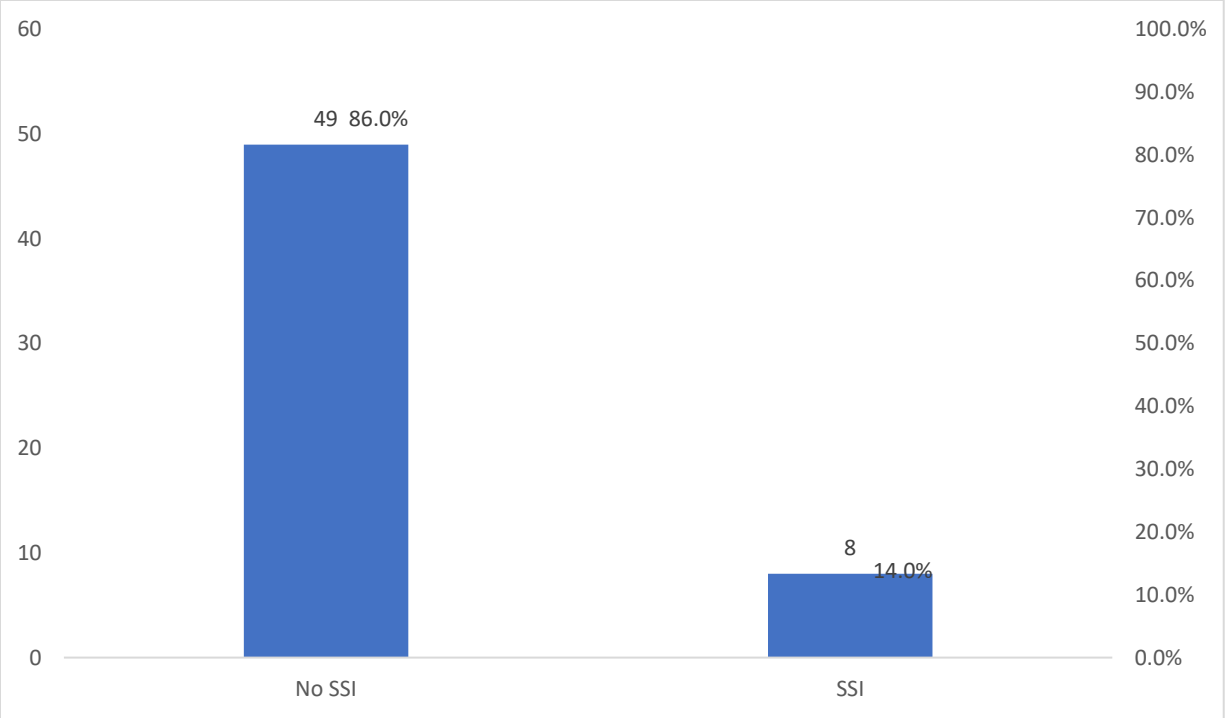


Figure 4.12 SSI following non-irrigation

4.21 Comparing the rates of Surgical Site Infection in the two groups

A comparison of the SSI rates in those who had irrigation of subcutaneous tissue wounds, against those with non-irrigation of subcutaneous tissue in appendectomy wounds revealed a statistical significance difference between the two groups (p=0.047).(**Figure 4.13**)

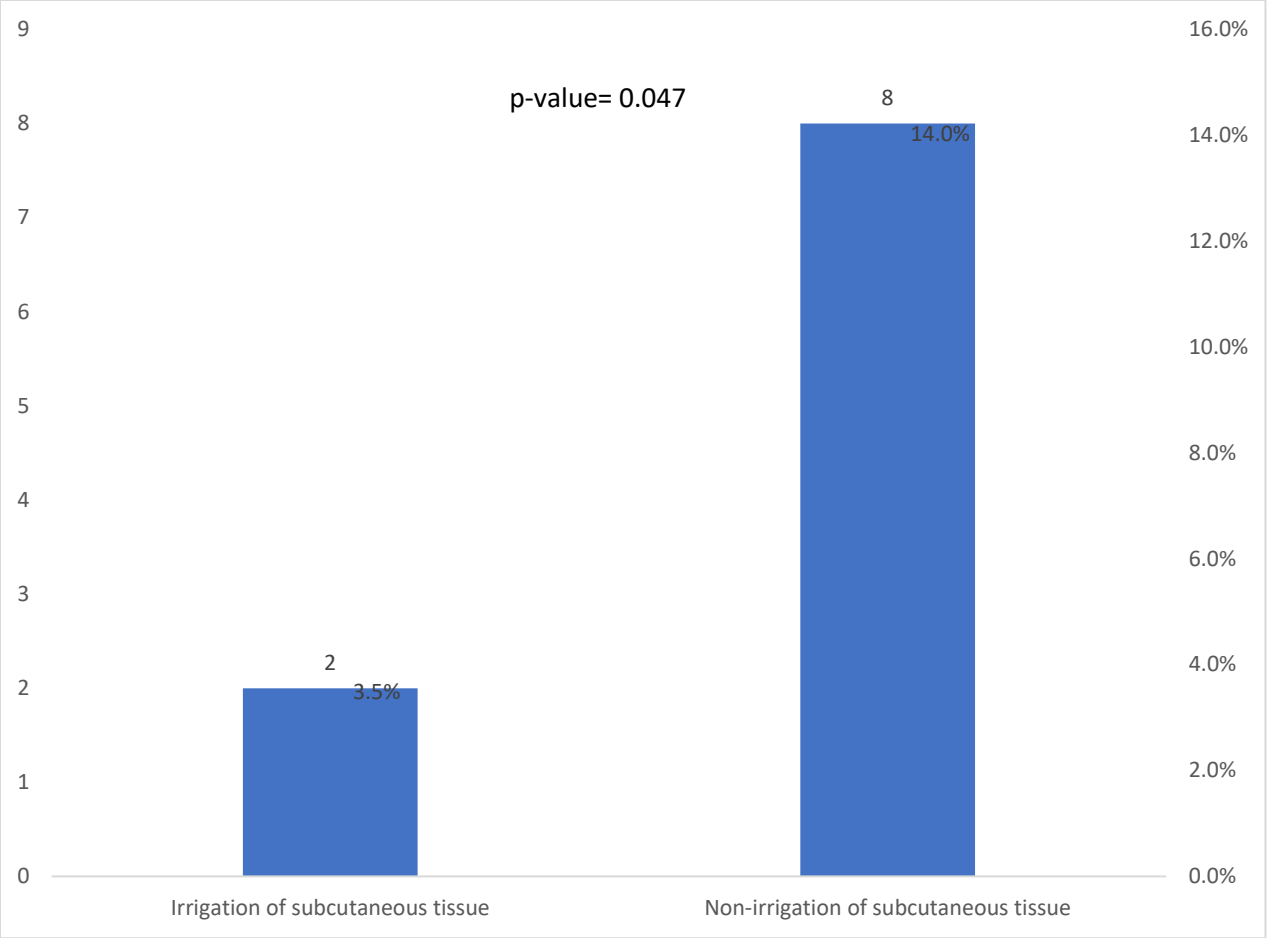


Figure 4.13 Comparison of SSI in the 2 groups

4.22 The Microbial profile

For those that developed SSI, wound swabs were taken for culture and sensitivity. 7 out of 10 swabs were taken for culture and sensitivity. Out of the 7, one sample did not culture any organism,

E-Coli emerged as the most frequently identified pathogen, contributing 33.3% of SSI detected. Staphylococcus aureus, another common pathogen implicated in SSI, is identified in 8.3% of the samples taken.

Other organisms isolated included Klebsiella pneumoniae, Pseudomonas aeruginosa and enterococcus faecalis**. (Figure 4.14)**

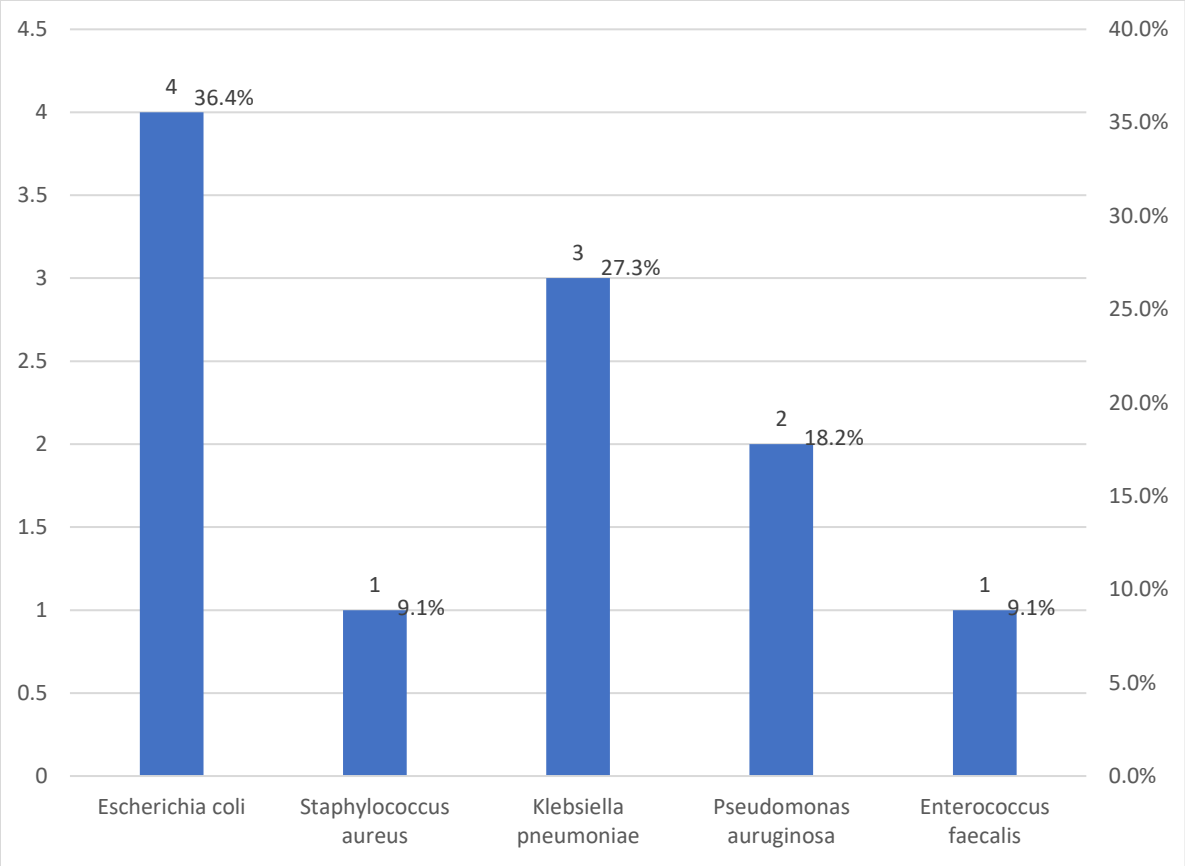


Figure 1: 4.14 Microbial profile

4.23 Antibiotic sensitivity

A greater proportion of the organisms cultured were sensitive to Amikacin.

Other antibiotics that recorded sensitivity were Ceftazidime, Cefuroxime,Meropenem and Ampicillin. **(Figure 4.15)**

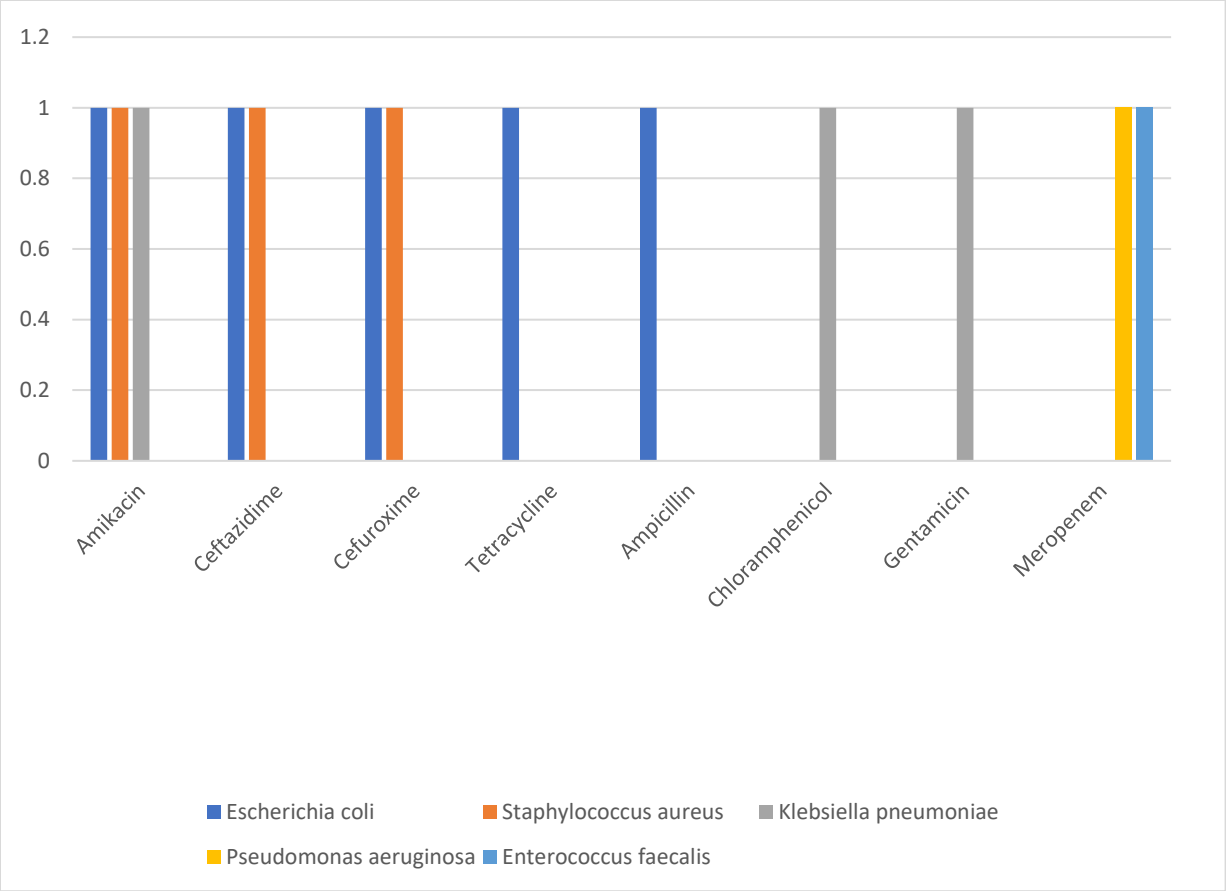


Figure 2: 4.15 Antibiotic sensitivity

4.24 Demographics factors and SSI at KBTH following appendicectomy

Occupation demonstrated a statistically significant association with SSI incidence (Chi-Square = 6.541, p = .038).

Employed individuals exhibited higher rates of SSI compared to students or the unemployed.

Age appeared to play a role in SSI incidence, with individuals aged 20-30 years exhibiting the highest rate of SSI at 2.6%, while those under 20 years showed no instances. Rates remained relatively consistent among older age groups, ranging from 2.6% to 3.5%. Regarding sex males comprised the majority of the sample at 69.3%, they reported a higher proportion of SSI (7.9%) compared to females, with 0.9% SSI rate. In terms of nationality, majority of the participants were Ghanaian, with a negligible proportion of foreign nationals. Both groups exhibited similar rates of

SSI. Also, educational level and religion showed no substantial influence on SSI occurrence across the study population.

4.25 BMI, Immunosuppression state and SSI at KBTH Following appendicectomy

The data revealed varying rates of SSI among different weight categories. Normal weight individuals constitute the majority, with SSI rate of 4.7%.Obese and overweight participants show slightly lower SSI rates at 2.3% and 3.5% respectively, and no SSI were reported among underweight individuals. Regarding immunosuppression status, the majority of participants were not immunosuppressed, with a relatively low SSI rate of 7.9%. However, among those with immunosuppression, the SSI rate was slightly higher at 0.9%. The analysis of uncontrolled diabetes, history of chemotherapy, and chemotherapy sessions indicated majority of participants did not have these conditions or underwent chemotherapy. Instances of chronic conditions such as kidney disease, liver disease, and chronic steroid use were minimal, with no reported SSI except for a single case of liver disease.

Furthermore, examining lifestyle factors, individuals who did not consume alcohol showed a relatively low SSI rate of 5.3%, compared to those who did, at 5.3%. Similarly, non-smokers exhibited a slightly lower SSI rate of 1.8%, compared to smokers at 7%. **(Table 4.11)**

Table 4.11 BMI, Immunosuppression, alcohol and smoking status and SSI at KBTH following appendicectomy

	SSI			
	Not Present	**Present**	**Person Chi-Square**	**P-Value**
BMI Class			4.017	.404
Normal Weight	37(43.0)	4(4.7)		
Obesity	9(10.5)	2(2.3)		
Overweight	19(22.1)	3(3.5)		
Underweight	12(14.0)	0(0.0)		
Immunosuppression Status				.243*

No	102(89.5)	9(7.9)	
Yes	2(1.8)	1(0.9)	
Uncontrolled Diabetes			1.000*
No	103(90.4)	10(8.8)	
Yes	1(0.9)	0(0.0)	
History Of Chemotherapy			
No	104(91.2)	10(8.8)	-
Chemotherapy Session			
No	104(91.2)	10(8.8)	-
Presence Of Chronic Conditions			
Kidney Disease	1(0.9)	0(0.0)	1.000*
Liver Disease	1(0.9)	1(0.9)	.168*
Chronic Steroid Use	1(0.9)	0(0.0)	1.000*
HIV	0(0.0)	1(11.1)	-
Alcohol Status			.472*
No	75(65.8)	6(5.3)	
Yes	29(25.4)	4(3.5)	
Smoking Status			.248*
Non Smoker	95(83.3)	8(7.0)	
Smoker	9(7.9)	2(1.8)	

*= Fisher's exact

4.26 ASA score, urgency of Surgery, duration of Surgery, surgeon's grade and SSI at KBTH following appendicectomy.

Regarding the ASA score the data showed the majority of patients classified as ASA score I experienced no SSIs (82.5%), while a smaller proportion of patients with ASA score II developed SSI (1.8%). Emergency appendectomies, being more frequent had all the SSI recorded.

In terms of the duration of surgery, while procedures lasting 1-2 hours had the highest number of SSIs, surgeries conducted in less than an hour demonstrated a lower SSI rate despite being more common. Surgeon grade did not appear to significantly influence SSI occurrence, with consistent SSI distributions across different surgeon grades, including consultants. **(Table 4.12)**

Table 4.12 ASA score, urgency of Surgery, duration of Surgery, surgeon's grade and SSI at KBTH following appendicectomy.

	SSI			
	Not present	**Present**	**Person Chi-square**	**P-Value**
Type of Intervention				0.047
Irrigation of subcutaneous tissue	55(52.8)	2(20.0)		
Non-irrigation of subcutaneous tissue	49(47.2)	8(80.0)		
ASA Score				.283
I	94(82.5)	8(7.0)		
II	10(8.8)	2(1.8)		
Type of Appendectomy 1			-	1.000*
Elective	1(0.9)	0(0.0)		
Emergency	103(90.4)	10(8.8)		
Type of Appendectomy 2				
Open	104(91.2)	10(8.8)		
Duration of Surgery			-	.215*

1-2 hours	43(37.7)	7(6.1)		
2-3 hours	1(0.9)	0(0.0)		
< 1 hour	60(52.6)	3(2.6)		
Grade of surgeon			.650	.722
Consultant	6(5.4)	0(0.0)		
Resident	41(36.6)	4(3.6)		
Senior Resident	55(49.1)	6(5.4)		
Prophylactic Antibiotics Given				
Yes	104(91.2)	10(8.8)	-	-

*= Fisher's exact

4.27 Duration on admission and wound class on SSI at KBTH following appendicectomy

The duration of admission, reveals a statistically significant association with SSI occurrence (Chi-Square = 6.415, p = .040). Patients with longer durations of admission, specifically those staying for 4-7 days or over 7 days, exhibit higher rates of SSI compared to those with shorter stays.

In terms of wound class, significant differences in SSI rates are observed (p = .005). Dirty wounds display a notably higher SSI rate (7.0%) compared to Contaminated wounds (1.8%), The presence of frank pus in wounds is significantly associated with SSI occurrence (p = .005). **Table 4.13**

Table 4.13 Duration of admission, wound class on SSI at KBTH following appendectomy

	SSI			
	Not present	**Present**	**Person Chi-Square**	**P-Value**
Duration of Admission			6.415	**.040**
2-3 days	78(68.4)	4(3.5)		
4-7 days	24(21.1)	5(4.4)		
>7 days	2(1.8)	1(0.9)		
Wound Class			-	**.012***
Clean contaminated	3(2.6)	0(0.0)		
Contaminated	67(58.8)	2(1.8)		
Dirty	34(29.8)	8(7.0)		

4.28 Summary of factors associated with the risk of developing an SSI at KBTH following appendicectomy

The analysis employed multivariate logistic regression to ascertain the impact of various variables on SSI occurrence.

Wound class was a significant predictor of SSI occurrence. Patients with dirty wounds had 2.1 times higher odds of developing an SSI compared to those with contaminated wounds (OR=2.1; p = 0.01). Conversely, the duration of hospital admission showed a statistically significant association with SSI occurrence, with odds ratios of -2.3 (p = 0.086) for 2-3 days and -0.9 (p = 0.507) for 4-7 days compared to admissions exceeding 7 days.

Furthermore, patients within the age group 20 to 30 years had 0.6 times odds of developing an SSI compared to those less than 20 years. Male patients were 2.8 times more likely to develop an SSI compared to females; and patients with ASA score II were 2.4 times more likely to develop an SSI compared to patients with ASA score of I. Regarding the grade of the surgeon performing the surgery, the analysis showed that surgeries performed by residents had an odds 0.9 compared to

consultants. An assessment of the duration of surgery revealed odd ratio of 3.3 compared to durations less than an hour. Finally, obese patients were 2.1 times more likely to develop SSIs, and those overweight had odds of 1.4 as compared to those with normal weight. Lastly patients who did not have irrigation of wounds had 1.5 times higher odds of developing an SSI compared to those who underwent irrigation (OR=1.5; p = 0.065). These findings collectively contribute to understanding the risk factors and clinical practices influencing SSI rates post-appendicectomy. **(Table 4.14)**

Table 4.14 Logistic Regression of factors associated with the risk of developing an SSI at KBTH following appendectomy

			95% CI	
	O.R	**P-Value**	**Lower**	**Upper**
Age group				
< 20 years	Ref	-	-	-
20-30 years	0.6	0.590	0.116	3.395
31-40 years	1.1	0.954	0.212	5.179
41+ years	1.0	-	-	-
Sex				
Female	Ref			
Male	2.8	0.332	0.344	23.594
ASA Score				
I	Ref			
II	2.4	0.319	0.437	0.175
Grade of surgeon				
Consultant	Ref			
Resident	0.9	0.869	0.237	3.300
Senior Resident	1			
Smoking status				
Smoker	2.6	0.261	0.452	14.352
Non smoker	Ref			

Duration of Surgery				
1-2 hours	3.3	0.100	0.796	13.309
2-3 hours	1			
< 1 hour	Ref			
BMI Class				
Normal Weight	Ref			
Obesity	2.1	0.445	0.324	13.034
Overweight	1.4	0.642	0.296	7.280
Underweight	1			
Wound Class				
Clean contaminated	0			
Contaminated	Ref			
Dirty	2.1	0.012	0.506	3.711
Admission duration				
2-3 days	-2.3	0.086	-4.880	0.325
4-7 days	-0.9	0.507	-3.462	1.711
>7 days	Ref			

5.0 DISCUSSION

Intraoperative irrigation of surgical incision wounds have been thought to be an important part of wound management for years. Controversy however remains about its efficacy and type of agent to use.

This was a study done to ascertain if irrigation of subcutaneous tissue following appendicectomy will lower the surgical site infection rate at the Korle-Bu Teaching Hospital. Appendicectomy as earlier explained is one of the commonest surgeries performed worldwide and almost all surgeons and surgical trainees are able to carry it out.

Two groups of participants were recruited. Those who had the standard appendicectomy without irrigation of the subcutaneous tissue as practiced in the Korle-Bu Teaching Hospital, the control group in this case compared to those who had irrigation of the subcutaneous tissue with normal saline, the intervention group.

The study showed an overall surgical site infection rate of 8.8% in appendicectomy wounds, and 14% with non-irrigation only. These are lower than SSI rates after appendicectomy in an institution in Pakistan where Kattak et al. reported an SSI rate of 18.6%, again lower than the SSI rate in a teaching hospital in India with an SSI rate of 30.7%.where 114 patients were followed up for clinic bacteriological evidence of SSI. This was a prospective observational study with patients more than 12 years of age included in the study.[5,28] In a tertiary facility in Tamale, Ghana, a retrospective cross-sectional studies of 352 patients was done with age groups cutting across form more than 5 years to above 60 years. In this study the paediatric population was included in the study and the surgeries ranged from abdominal surgeries to orthopedic surgeries. An SSI rate was found to be 39%.[71]. At the Hawassa University Referral Hospital in Ethiopia an SSI rate of 19.1% was established when a prospective studies was conducted on 105 patients comprising of paediatric and adult patients. The surgeries they underwent included head and neck surgeries, abdominal surgeries and mastectomies.,[39] All SSI diagnosed was based on the CDC guidelines in all the studies.

The overall SSI rate of 8.8% is similar to a study conducted at public hospitals in Cameroun where the SSI rate was found to be 9.1% and that of Bowan et al. in Accra who saw an SSI rate of 10% at a tertiary institution.

With regards to SSI rates post appendicectomy specifically, our study is consistent with study's by Noorit et al. who had an SSI rate of 8.7 % after appendicectomy .[12,84] Our incidence is higher than SSI rate reported in the United States after appendicectomy of 3% according to Kelly et al., higher than in France where the SSI rate was also 3% and higher than in South America where the incidence rate was 1.8% post appendicectomy.[61,10,85] From the study we recorded higher infection rates than from systematic studies conducted by Danwang et al. who saw an SSI rate of 6.2% in developed countries post appendicectomy [20], again higher than post appendicectomy infections recorded by Giesen et al. in the Netherlands who reported an SSI rate of 6.6 post appendicectomy.[60]

Our infection rate was lower than that of systematic studies comprising of 35 studies across low to middle income countries conducted by Foster et al. on SSI post appendicectomy. They recorded an SSI rate of 17.9 % for open appendicectmies but very similar to their SSI rate following laparoscopic appendicectomy of 8.8%.[27]

Our rate again is lower that of Koumu et al. in Saudi Arabia who realized an SSI rate post appendicectomy of 17.9% over a 2 year period.[59]

With the use of normal saline in irrigating the wounds our study realized an SSI rate of 3.5%. Our findings are similar to those of Hassan A Hassan et al. They found irrigation of subcutaneous tissue with normal saline during appendicectomy resulted in decreased bacterial contamination when compared with povidone iodine.[19] Parcells et al., in their use of normal saline for irrigation after appendicectomy reported normal saline being superior to Dakin solution for irrigation. [79]Our study again is similar to that of Hayashi et al.'s who saw a reduction in bacterial infection after use of normal saline in wound irrigation and Lord et al. who also reported reduction in SSI rate using antibiotics dissolved in normal saline.[81,80] A study at the Emergency Department of a hospital in Mexico that used 300 ml normal saline for appendicectomy wound irrigation saw a great reduction in SSI of wounds in the irrigation group of about 50%.[35]

Our study differs from that of Dire et al. who reported no statistical difference in the wound infection rate for wound irrigated with normal saline, povidone iodine and pluronic F-58.[36]

Griffiths et al. in Australia saw no difference in using tap water for wound irrigation compared to normal saline.[86]

In comparing the use of normal saline irrigation on wounds to non-irrigation at the State University of New York, researchers did not find any significant difference in infection rate of wounds between the two.[87]

We can explain the reduction in SSI following irrigation with normal saline by reasoning that normal saline acts as a mechanical cleanser and so washes off bacteria, residue, debris and any other contaminates that may be in the wound. The bacterial load is reduced to an amount that can be destroyed by the hosts own defense system therefore decreasing infection risk. Also by irrigating the wound, skin, subcutaneous tissue and fascia the appendiceal contents are prevented from colonizing the wound and causing wound dehiscence.

The reduction in SSI when normal saline was used for the irrigation was statistically significant in this study with p- value of 0.047.

From this study the most common organism isolated from the wound was Escherichia coli (E-coli), followed by Staphylococcus aureus. Other organisms identified included Klebsiella pneumonia, Pseudomonas aeruginosa and Enterococcus.

Staphylococcus aureus and Enterococcus were the Gram positive organisms identified and the Gram negative organisms include Escherichia coli, Klebsiella pneumonia and Pseudomonas aureginosa .As in a lot of studies Escherichia coli is the most common organism isolated in wounds. This was similar to Bowan et al findings where Escherichia coli topped the organisms isolated in infected wounds at the Korle-Bu teaching hospital [11] and similar findings were found in Qatar.[25] However in the Northern part of Ghana, Staphylococcus aureus was the main organism isolated in infected surgical wounds[71] . E-coli was sensitive to amikacin, cefuroxime and ceftazidime. Klebsiella isolated was sensitive to amikacin and gentamicin but resistant to ceftazidime. Most of the organisms isolated however were sensitive to amikacin.

The study used multivariate logistic regression to ascertain the risk of developing SSI following appendicectomy.

Wound class was a significant predictor of SSI. Patients with dirty wounds were 2.1 times more likely to develop SSI compared to those with contaminated and clean contaminated wounds. (OR=2.1; p=0.005)

According to our study, patients with dirty wounds were more at risk of SSI compared to those with contaminated and clean contaminated.

Our findings were similar to a studies by Giesen et al. who found that in Europe, SSI after appendicectomy was more common in patients with dirty wounds. [60]

Kelly et al. reported the disease severity was associated with SSI after appendicectomy in that patients with wound classes III and IV were more at risk of developing SSI after appendicectomy.[52]
It is a well-documented fact that dirty wounds have a higher chance of getting infected and so our study is consistent with several studies in literature.[17,23,61]
With dirty wounds and especially with the presence of pus, tissue, tend to be ischemic and non-viable which all increases the chances of developing SSI.
It is well documented that diabetes is a risk factor for a patient developing SSI.[71,84] However in our study the patient with diabetes did not develop SSI. This can be attributed to the small sample size, perhaps by studying only diabetics and SSI this theory could be further explored.

Patients who spent more days on admission at the hospital were found to be at risk of SSI. (Chi-square-6.415, p=0.040) The findings are consistent with some work done by Bowan et al. and Benedeta et al. They reported that the longer the patient spent time on the wards the more the patient was at risk of SSI.[2,12] It will be assumed that patients who spend more days in the hospital maybe exposed to more pathogens which can affect their healing rate and to an extent cause SSI. Another school of thought that can be entertained will be that some of the patients may have comorbidities that were being managed concurrently, after surgery and this prolonged their stay on the wards, and that they may have developed SSI anyway but not necessarily because of their prolonged stay on the wards.

Patients with ASA score of II were 2.4 times more likely to develop SSI compared to patients with ASA score of I per our study.

This is consistent with studies in which the higher the ASA score the more likely patients developed SSI so this is used as a predictive marker for SSI in some settings. In most of the studies however ASA of III or more was recognized as significant. [23,88,89]Increasing ASA score suggests decrease in immunity with patients having comorbidities and other conditions which can result in

poor healing and recovery rates leading to SSI. Surgeons therefore have to be more alert with patients whose ASA scores are high and set preventive measures against SSI.

In our study most patients were had normal BMI but the patients with BMI higher than normal were more at risk of SSI than patients with normal BMI. Per our study, obese patients were 2.1 times more likely to develop SSI and opatients 1.4 times more likely to develop SSI making increased weight a risk factor for SSI.

Obesity is deemed a risk factor for SSI, it is said to cause reduced immunity, and obesity also puts one at risk of having other chronic illnesses like diabetes mellitus which further reduces ones immunity. Access to operation site takes a longer time in the obese and so tissues are exposed to the environment and pathogens for a longer time, this prolongs surgery time.[90]

The adipose tissue is poorly perfused therefore oxygenation of tissues are reduced causing impaired healing and resulting in increased risk of SSI.[91]

Diabetes is a risk factor for SSI, and this cuts across all types of surgeries being well documented in several studies. Contributing factor includes the hyperglycaemic state which poses a resistance to healing. In cases of uncontrolled diabetes patients are often than not more likely to develop surgical site infections.[71,84,92].However in our study diabetes was not found to be a risk factor for SSI. There was just one patient with diabetes who did not develop SSI. This can be attributed to a small sample size perhaps if studying only diabetics for SSI that theory could be proven. Overall, in open with appendicectomy at the Korle-Bu Teaching Hospital people who did not have irrigation of their wound were1.5 times odds higher to develop SSI compared to those who had irrigation (OR=1.5)

The surgeons' grade did not significantly influence SSI rate, be it a resident, senior resident or consultant who performed the surgery.

Per our findings more males presented with appendicitis than females.
Similar to our findings in the United States of America, data collected by Addis et al. saw a male preponderance for appendicitis.[28] Ceresoli et al. in Italy on their epidemiology study of acute appendicitis also resulted in more males presenting with the disease than females. Again similar to Ohene Yeboah et al'.'s findings at the Komfo Anokye teaching hospital, where more males

presented with acute appendicitis than females and with works of Debrah et al. where more males predominately presented with acute appendicitis. [52,56,55.]Our findings are also in line with that of Clegg-Lamptey and Naaeder, who reported males are twice affected by appendicitis compared to females.[29]

This is in contrast with a prospective descriptive study by Nwashilli et al. in Benin State, Nigeria which saw acute appendicitis being more common in females than in males with an incidence of acute appendicectomy of female to male ratio of 2:1,also in Port Harcourt acute appendicitis was found to be more common in females than males.[24]

In our study we discovered male patients were 2.8 times more likely to develop SSI than their female counterparts following appendicectomy. This can also be explained with reasoning that males presented more with appendicitis than females and so have higher chances of developing SSI than their female counterparts.

With regards to the age group, we found out acute appendicitis was more common in patients in their 3rd decade of life. This is similar to a study conducted in Benin state, Nigeria where acute appendicitis occurred in the age ranges of 21-30 years [24].In contrast, data collected over 15 years on appendicitis gathered by Addis et al. in the United states saw a higher incidence in patients in the 2nd decade of life rather than the 3rd in our case.[55]

However age range for acute appendicitis is a bit wide spread in a Coastal town in Ghana where the incidence of acute appendicitis was in patients in their 2nd and 3rd decades of life.[56]

5.1 LIMITATIONS

It was difficult reaching some of the participants on phone however they did present at the clinic for review and their wounds were assessed.

There is a possibility some patients followed up on phone developed SSI but this may have been missed as they are not medical personnel and so may not be able to describe the wound accurately.

One center study and therefore generalization or extrapolation of results onto the entire Ghanaian and West African population may be difficult.

6.0 CONCLUSION AND RECOMMENDATIONS

6.1 CONCLUSION

From the study wound irrigation with normal saline following appendicectomy at the Korle-Bu Teaching Hospital is effective in reducing surgical site infections.

Escherichia coli was the commonest organism isolated in the wounds that were infected.

Wound class, male gender, high BMI and duration of hospital stay were some of the key factors identified that increases ones' chances of developing SSI following appendicectomy at the Korle-Bu Teaching Hospital.

6.2 RECOMMENDATIONS

Normal saline is cheap, non-allergic, non-toxic to tissues and readily available. We recommend the use of normal saline for wound irrigation after appendicectomy.

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TIMELINES

S/N	MONTH/ ACTIVITY	LITERATURE SEARCH	PROPOSAL WRITING	SUBMISSION OF PROPOSAL	ETHICAL CLEARANCE	DATA COLLECTION	DATA ENTRY/ ANALYSIS	FINAL WRITE UP	SUBMISSION OF FINAL WORK
1	DEC' 2021								
2	JAN' 2022								
3	FEB' 2022								
4	MAR' 2022								
5	APR' 2022								
6	MAY' 2022								
7	JUNE'2022								
8	JUL' 2022								
9	AUG' 2022								
10	SEP' 2022								
11	OCT' 2022								
12	NOV' 2022								
13	DEC' 2022								
14	JAN '2023								
15	FEB' 2023								

16	**MAR’ 2023**								
17	**APR’ 2023**								
18	**MAY 2023**								
19	**NOV. 2023**								
20	**JAN. 2024**								
21	**FEB.2024**								
22	**MAR. 2024**								

BUDGET

SOLELY FUNDED BY

THE PRINCIPAL INVESTIGATOR

BUDGET			
S/N	**ITEM**	**AMOUNT (GH₵)**	**JUSTIFICATION**
1.	RESEARCH ASSISTANT'S STIPEND	1000.00	Stipend for research assistant covering the period of study
2.	TELEPHONE CREDITS	500.00	For follow up calls
3.	STATISTICIAN	2000.00	Token for Data analysis
4.	ETHICAL CLEARANCE	200.00	IRB submission fee
5.	PRINTING/ PHOTOCOPY	1000.00	Printing and photocopy of material
6.	LABORATORY CHARGES	700.00	Estimate for culture and sensitivity
7.	MICELLANEOUS	500.00	
TOTAL		**GH₵6,900.00**	

CONSENT FORM

My name is Dr Victoria Sena Gawu. I am a Senior Resident in General Surgery at the Korle Bu Teaching Hospital.

I am conducting a research on '**THE ROLE OF SUBCUTANEOUS TISSUE IRRIGATION WITH NORMAL SALINE IN DECREASING SURGICAL SITE INFECTION IN APPENDICECTOMY'**

My supervisors are Prof J.N.A Clegg Lamptey and Dr Joachim Amoaku.

The aim of the study is to find out if irrigating the subcutaneous tissue during appendicectomy at the Korle Bu Teaching hospital will reduce surgical site infection. Some questions will be asked, including your age, phone number, your level of education and so forth. You will be randomized into a group, you will either belong to the group for irrigation of the subcutaneous tissue or not. You will be followed up subsequently post operatively for signs of surgical site infection while on admission and discharge which may be done through a phone call. The findings of the study will be presented to the Hospital management and to the Ghana College which may inform development of protocols. There are no potential risks to this study. If your wound is infected a wound swap will be taken of which the cost will be borne by me the principal investigator. You are not obliged to answer some of the questions you are not comfortable with. Information gathered from you will be kept confidential and no 3rd party will have access to it. You can leave the study at any time if you so wish. You will not benefit from participating in this study however this study may help in policy making in the future. The study has been reviewed and approved by the Institutional Review Board (IRB) of the KBTH. If you have any further questions you can contact me, Dr Victoria Sena Gawu, Department of Surgery, KBTH or the IRB office between the hours of 8am to 5pm on working days on the telephone number 0302666766.

Thank you.

VOLUNTEER AGREEMENT

This above document describing the purpose, procedure, benefits for the research title 'The role of subcutaneous tissue irrigation with normal saline in decreasing surgical site infection in appendicectomy' has been explained to me in a language I understand to my satisfaction

I agree to be a participant in this study.

Name……...

Signature/Thumbprint…….

Date (DD/MM/YY) …….

Time (HH:MM)……

QUESTIONNAIRE

THE ROLE OF SUBCUTANEOUS TISSUE IRRIGATION WITH NORMAL SALINE IN DECREASING SURGICAL SITE INFECTION IN APPENDICECTOMY

DATE……/……/2023……

1. Patient ID: ……. **2.** Study ID: ……
3. Age: …… **4.** Gender: i) Male☐ ii) Female☐
5. Weight: [ ] kg **6.** Height: [ ] m **7.**BMI: [ ] kg/m^2
8. Marital Status: i) Married☐ ii) Single☐ iii) Divorced☐
9. Level of Education: i) None☐ iii) Primary☐ iii) JHS☐
   iv)SHS v) Tertiary☐
10. Phone No……
11. Person to notify in case of emergency- …..... Phone number……
12. Religion
13. Immunosuppression?
    i) Uncontrolled Diabetes ☐
    ii) Chemotherapy☐
        a) Last Chemotherapy Session?
            - within Last 3 Weeks of Operation☐
            - currently on Chemotherapy☐
    iii) Kidney Disease☐
    iv) Liver Disease☐
    v) Chronic Steroid Use☐
    vi) HIV☐
    vii) Others☐
    Please specify ……
14. Alcohol? i) Yes☐ number of years of consumption ☐ ii) No☐
15. Smoking? i) Non-Smoker☐ ii) Smoker☐ Number of pack years ☐
16. Randomization Number: [ ]

17. Asa Score: i) [ ] ii) [ ] iii) [ ] iv) [ ] v) [ ]

18. Type of Appendicectomy: i) Emergency☐ ii) Interval☐

19. Type of Appendicectomy: i) Open☐ ii) Laparoscopic☐

20. Antibiotics Given: i) Yes☐ ii) No☐

21. State of the Appendix: i) Inflamed☐ ii) Perforated☐ iii) Necrotic☐
iv) Presence of Frank Pus☐ v) Normal☐

22. Wound Class: i) Clean☐ ii) Clean Contaminated☐ iii) Contaminated☐
v) Dirty☐

23. Duration of Surgery: i) Less than 1hour☐ ii) 1-2hours☐ iii)2-3hours☐
iv) More than 3hours☐

24. Type of Intervention: i) Irrigation of Subcutaneous Tissue☐
ii) Non-Irrigation of Subcutaneous Tissue☐

25. Grade of Surgeon: Resident ☐ Senior Resident ☐ Consultant ☐

26. Duration of Admission: i) 2-3 days☐ii) 3-5 days☐ iii)5-7 days☐
iv) More than 7 days☐

27. Assessment of Wound:

S/N	Wound Assessment	Pod 3	Pod 7	Pod 14	Pod 30
1	Purulent Discharge from Wound				
2	localized Swelling				
3	Localized Pain or Tenderness				
4	Localized Redness or Heat				
5	Fever - Temp More Than 38.5^{o} C				
6	Wound Opened by Surgeon or Spontaneously Gapped				
7	None				

28. Swap for Culture and Sensitivity: i) Yes☐ ii) No☐

29. Organism Cultured……
……

30. Antimicrobial

Sensitivity………………………………………………..…………………………

………………………………………………………………………………………

APPENDIX

RANDOMIZATION TABLE

Research Randomizer	
2 Sets of 61 Yes Numb	
Range: From 1 to 132	
Irrigation	Non-Irriga
122	83
61	8
62	102
47	67
20	61
25	31
87	14
128	28
19	19
104	70
92	69
95	22
3	42
34	120
40	80
16	114
31	4
30	82
12	103
76	87
38	49
90	40
80	90
119	115
57	63
49	38
44	122
10	32
101	33
125	99
98	50
83	64
99	30
75	74
113	12
85	126
117	34
97	97
22	41
68	110
127	59
124	56
112	44
81	2
9	65
94	21
28	52
15	29
48	107
89	117
46	113
39	105
32	96
129	130
35	37
2	60
66	73
103	66
73	68
33	118
1	89

INSTITUTIONAL APPROVALS

In case of reply the number
And the date of this
Letter should be quoted
My Ref. No. KBTH/MS/G3/23
Your Ref. No......

KORLE BU TEACHING HOSPITAL
P. O. BOX KB 77,
KORLE BU, ACCRA.

Tel: +233 302 667759/673034-6
Fax: +233 302 667759
Email: Info@kbth.gov.gh
pr@kbth.gov.gh
Website: www.kbth.gov.gh

14th February, 2023

DR. VICTORIA SENA GAWU
DEPARTMENT OF SURGERY
KORLE BU TEACHING HOSPITAL
KORLE BU

INSTITUTIONAL APPROVAL: KORLE BU TEACHING HOSPITAL-SCIENTIFIC AND TECHNICAL COMMITTEE/INSTITUTIONAL REVIEW BOARD (KBTH-STC/IRB/000126/2022

Following approval of your study entitled "The Role of Subcutaneous Tissue Irrigation with Normal Saine in Decreasing Surgical Site Infection Following Appendectomies at the Korle Bu Teaching Hospital" by the Korle Bu Teaching Hospital-Scientific and Technical Committee/Institutional Review Board.

I am pleased to inform you that institutional approval has been granted for the conduct of your study in Korle Bu Teaching Hospital.

Please contact the Head of Department to discuss the commencement date of the study.

Please note that, this institutional approval is rendered invalid if the terms of the Institutional Reviewed Board/Scientific and Technical Committee approval are violated.

Sincere regards,

Dr. Harry Akoto
Ag. Director of Medical Affairs
For: Chief Executive

In case of reply the number
And the date of this
Letter should be quoted

My Ref. No. KBTH/MD/G3/20

Your Ref. No......

KORLE BU TEACHING HOSPITAL
P. O. BOX KB 77,
KORLE BU, ACCRA.

Tel: +233 302 667759/673034-6
Fax: +233 302 667759
Email: Info@kbth.gov.gh
pr@kbth.gov.gh
Website: www.kbth.gov.gh

9th February, 2023

DR. VICTORIA SENA GAWU
DEPARTMENT OF SURGERY
KORLE BU TEACHING HOSPITAL
KORLE BU

THE ROLE OF SUBCUTANEOUS TISSUE IRRIGATION WITH NORMAL SAINE IN DECREASING SURGICAL SITE INFECTION FOLLOWING APPENDECTOMIES AT THE KORLE BU TEACHING HOSPITAL

KBTH-IRB 000126/2022

Investigator**: DR. VICTORIA SENA GAWU**

The Korle Bu Teaching Hospital Institutional Review Board (KBTH IRB) reviewed and granted approval to the study entitled: "The Role of Subcutaneous Tissue Irrigation with Normal Saine in Decreasing Surgical Site Infection Following Appendectomies at the Korle Bu Teaching Hospital"

Please note that the Board requires you to submit a final review report on completion of this study to the KBTH-IRB.

Kindly, note that, any modification/amendment to the approved study protocol without approval from KBTH-IRB renders this certificate invalid.

Please report all serious adverse events related to this study to KBTH-IRB within seven days verbally and fourteen days in writing.

This IRB approval is valid till 31st January, 2024. You are to submit annual report for continuing review.

Sincere regards,

DR. DANIEL ANKRAH
VICE CHAIR (KBTH-IRB)
FOR: CHAIR (KBTH-IRB)

Cc: The Chief Executive Officer, KBTH
The Director of Medical Affairs, KBTH

In case of reply the number
And the date of this
Letter should be quoted

My Ref. No. KBTH/MS/C3/22

Your Ref. No......

KORLE BU TEACHING HOS
P. O. BOX KB 77,
KORLE BU, ACCRA.

Tel: +233 302 667759/673034-
Fax: +233 302 667759
Email: Info@kbth.gov.gh
pr@kbth.gov.gh
Website: www.kbth.gov.gh

30th October, 2022

DR VICTORIA SENA GAWU
DEPARTMENT OF SURGERY
KORLE BU TEACHING HOSPITAL
ACCRA, GHANA

SCIENTIFIC AND TECHNICAL COMMITTEE APPROVAL
PROTOCOL IDENTIFICATION NUMBER: KBTH-STC 000126/2022

The Korle Bu Teaching Hospital Scientific and Technical Committee (KBTH-STC), on 30th October, 2022, approved your submitted study protocol.

TITLE OF PROTOCOL: "The Role of Subcutaneous Tissue Irrigation with Normal Saine in Decreasing Surgical Site Infection Following Appendicectomies at The Korle-Bu Teaching Hospital"

This approval requires that you **forward your approved document to Korle Bu Teaching Hospital –Institutional Review Board (KBTH-IRB) for the ethical aspect of the proposal to be assessed before the project can be initiated.**

PRINCIPAL INVESTIGATOR: Victoria Sena Gawu

This STC approval is valid till 30th March, 2023

You may, however, request extension of the approval period, or renewal as the case may be, should the study extend beyond the stated period.

Upon completion, you are required to submit a final report on the study to the STC. This is to enable the STC ensure among others that, the project has been implemented as per the approved protocol. You are also required to inform the KBTH-STC and Research Directorate of any publications that may emanate from the research findings.

Kindly note that, should the need arise, the KBTH-STC or IRB may institute appropriate measures to satisfy itself that study is being conducted according to the highest scientific and ethical standards.

Please note that any modification to the study protocol without Scientific Technical Committee (STC) approval renders this approval invalid.

Prof. G. Obeng Adjei
Chairman, KBTH-STC

Cc: The Chairman, KBTH-IRB