A randomized trial to compare purse-string suture with occlusive absorbent dressing for the closure of tube thoracostomy incision at the Kenyatta National Hospital.

A DISSERTATION PRESENTED IN PARTIAL FULFILMENT FOR THE AWARD OF THE DEGREE OF MASTER OF MEDICINE IN THORACIC AND CARDIOVASCULAR SURGERY AT THE UNIVERSITY OF NAIROBI.

Principal Investigator.

Dr. Obed Morara

H58/7086/2017

DEDICATION

I dedicate this project to Jesus Christ, my Strong Anchor in the storm, source of all knowledge, wisdom and understanding. He has been the source of my strength throughout this Masters of Medicine in Thoracic and Cardiovascular surgery program.

I also dedicate this work to my wife; Gloria Atieno Ndegwa Morara, who has been supportive and encouraging throughout this MMED program. She has only tasted the life of being married to a registrar and has been by my side all through.

To my children Benaiah Echad Morara and Barry Atuya Morara who have been affected in every way possible by the journey of postgraduate education. Thank you. My love for you all can never be measured.

May God bless you abundantly.

UNIVERSITY OF NAIROBI

DECLARATION OF ORIGINALITY FORM

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Thesis Title
A randomized trial to compare purse-string suture with occlusive absorbent dressing for the closure of tube thoracostomy incision at the Kenyatta National Hospital

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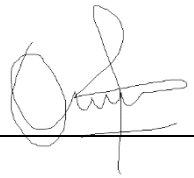
Signature: _  _____

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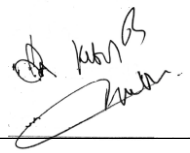
DEPARTMENT APPROVAL

This research dissertation has been presented at the surgical departmental meeting held on the **18th March 2021** and is hereby approved for presentation to the Kenyatta National Hospital Ethics and Research Committee.

Signed:  Date: _____7th September 2022_____

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LIST OF ABBREVIATIONS AND ACRONYMS

A&E – Accident and Emergency Department

ISI – Insertion site infection

KNH – Kenyatta National Hospital

Ref. No. – Reference number

SCAR – Scar Cosmesis Assessment and Rating

SPSS – statistical product and service solutions

SSI – Surgical Site Infection

UoN – University of Nairobi

UWSD – Underwater seal drainage

OPERATIONAL DEFINITIONS

Absorbent / Occlusive dressing – This is a type of dressing with absorption qualities and acts as a barrier to the entry of organisms into the wound.

Chest tube insertion – Placement of a drain into the pleural cavity to evacuate ectopic contents.

Dressing Arm – The group of participants where an occlusive absorbent dressing is used to close the thoracostomy incision.

Horizontal Mattress suture – A suture technique that everts skin edges.

Intercostal incision – An incision placed at the triangle of safety for access into the pleural cavity.

Leukomed T Plus – A type of absorbent occlusive dressing which has a waterproof feature. It will be used as the dressing of choice for the dressing arm.

Late Pneumothorax – Pneumothorax presenting more than 2 weeks after chest tube removal.

New Acute Pneumothorax – Pneumothorax presenting less than 2 weeks after chest tube removal.

Pain scale – An Index to measure the patient's perception of pain during removal of chest tube and closure of the incision. The Wong-Baker Faces Pain Scale will be used.

Persistent Drainage – Drainage from the thoracostomy incision for more than 7 days after removal of a chest drain.

Purse-string suture – This is a horizontal mattress suture placed at the thoracostomy incision to assist with closure of the incision after drain removal.

Purse-string Arm – The group of participants where the purse-string suture is used to close the thoracostomy incision.

Tube thoracostomy - synonymous with chest tube insertion.

Tube Thoracostomy incision – synonymous with the intercostal incision.

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ABSTRACT

Background

Tube thoracostomy incision has been closed in various ways. The purse-string closure has been the norm for the closure of the incision. New methods have been developed over time to address the shortcomings of the purse-string method. These methods include the use of absorbable sutures, staples, and occlusive absorbent dressings. Without a consensus on the closure method, this study compared the outcomes of two methods and provided scientific data to guide on best practice for the closure of the incision.

Objective

To compare purse-string suture with occlusive absorbent dressing for the closure of tube thoracostomy incision.

Methods

We randomized chest trauma patients at Kenyatta National Hospital who required tube thoracostomy incision into a dressing arm and suture arm. The rates of complications, pain scores and scar scores for incision closure using a dressing and purse-string method were compared. The overall outcome was to establish a non – inferiority comparison for dressing method to purse-string in order to promote its utilization in closure of chest tube incisions.

Results

From September 2021 till March 2022, 81 participants were enrolled into the study, of which 40 (49.4%) and 41 (50.6%) were randomized to the dressing and suture arms respectively. All of whom were included in the analysis. There were 55 (67.9%) males and 26 (32.1%) females, where the overall mean age was 35.8±13.9 years, of which the minimum observed age was 18.0 years and maximum was 67.0 years old. The mean age for dressing arm was

36.8±13.4 and 34.9±14.5 for the suture arm. Twenty-five (30.9%) patients had blunt chest trauma while 56 (69.1%) patients had penetrating chest trauma. Of the 25 patients, 14 (35.0%) were randomized into the dressing arm while 11 (26.8%) into the suture arm. Of the 56 patients, 26 (65%) were randomized into the dressing arm, while 30 (73.2%) into the suture arm.

For the dressing arm, 32 (80%) had Haemothorax, while 11 (27.5%) had pneumothorax. For the suture arm, 25 (61%) had Haemothorax while 23 (56.1%) had pneumothorax.

Overall pain scores were significantly less in the dressing arm. Median (IQR)2.0 (2.0 – 4.0) vs 8.0 (4.0 – 8.0) (P<0.001), Mean Rank 20.5 vs 61.0(P<0.001). Mean ± SD 3.0±1.8 vs 6.3±2.8 (P<0.001)

Overall Cosmesis was significantly better in the dressing arm. Scar scores Mean ± SD 3.3±1.0 vs 11.3±1.4 (P<0.001), Median (IQR) 3.0 (3.0 – 4.0) vs 11.0 (11.0 – 12.0) (P<0.001), Mean Rank 20.50 vs 61.00 (P<0.001).

There was no difference in the rates of SSI, recurrent acute and late pneumothoraces, and persistent drainage between the two arms.

Conclusions

Dressing method for closure of tube thoracostomy incision proved to have less pain and better Cosmesis outcomes with no difference in the complications rates.

CHAPTER ONE

1.0 INTRODUCTION

Chest tubes have been employed for a long period in thoracic conditions for the management of chest trauma to drain pneumothoraces, haemothoraces, and haemopneumothoraces. In thoracic surgeries and pleural conditions, chest tube is utilized as a drain for pleural effusions and empyema[1].

The practice of chest tube insertion dates back to 460BC when Hypocrates used metal tubes to manage empyema[2]. Playfair is credited with the modern improvement of chest drains and the use of underwater seal drainage (UWSD), for the management of empyema on a patient back in 1873[3]. An advancement in the use of chest tubes was noted during the 1918 Flu pandemic and World War II, for management of pleural effusions and haemo-pneumothoraces respectively[2]

More than 70 years have passed from the time of World war II to date, and still, there is no clear standard of care in regards to post chest tube management as evident from numerous papers. Consensus has not been reached on the mode of closure of the thoracostomy incision [4 – 5].

The general practice within many surgical thoracic centres has been the use of suture closure of thoracostomy incision after removal of the chest drain[6]. The rationale is to prevent air re-entry into the chest and reduce infection spread into the chest.

A horizontal mattress suture as a technique has been widely accepted and is used to close the thoracostomy incision. It has gained popularity in its simplicity and effectiveness in closing the wound and hence with time has become the routine method of closure of chest tube incisions[6].

Over time, different thoracic centres have encountered patient complaints of pain on tying the knot of the purse-string, suture granulomas, unsightly scars, and the need for clinic visits for removal of sutures[7]. This has warranted newer ways of closing the thoracostomy incision to address these issues.

The has led to the use of the knotless suture closing technique[7], staples, and absorbent occlusive dressings[8.]

Thus, the modern thoracic surgeon has options on the closure of tube thoracostomy incisions with the overall goal being the improvement in patient outcomes. Building on these choices currently and lack of consensus on the closure of the thoracostomy incision, has thus inspired scientific research to compare two methods, the purse-string with the use of absorbent occlusive dressing in the closure of the thoracostomy incision.

At the Kenyatta National Hospital, the current practise of closure of tube thoracostomy incisions is through purse-string method. This research compared one method, dressing method, to the current practise done at Kenyatta National hospital.

CHAPTER TWO

2.1 LITERATURE REVIEW

2.1.1 Background

The practice of tube thoracostomy has a rich history with significant improvement in modern-day thoracic surgery. There is an acceptable consensus in regards to indications for chest tube insertion, size of chest tubes, techniques of safe and proper insertion, monitoring, and removal of the chest tube. However, in regards to the closure of the intercostal incision used, no clear consensus has been reached with various centres using the techniques that have been passed down in time from when the departments commenced their practice. In literature, the following methods have been described concerning closure of the chest tube incision.

2.1.2 Purse-string suture for closure of tube thoracostomy incision

The purse-string suture is a horizontal mattress suture that is placed at the thoracostomy incision at the time of chest tube placement to assist with closure of the wound post-tube thoracostomy.

There are two variations to it.

The first is described as having two distinct non-absorbable sutures. One is placed at the edge of the incision that is used to purely anchor the chest tube, while the other is the horizontal mattress suture that will be used to close the incision at the point of chest tube removal. The diagram sketch below describes the technique;

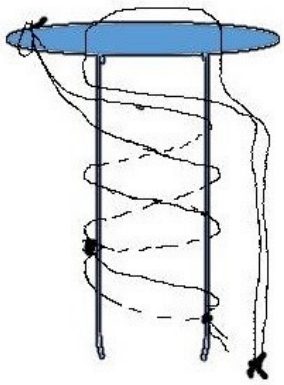

Figure 2.1.2 a: A simple suture for anchoring plus a horizontal mattress suture for closure

The second is a non-absorbable horizontal mattress suture that serves two purposes; to anchor the chest tube securely, and to close the incision at the time of chest tube removal. This is the practice at the cardiothoracic surgery department at the Kenyatta national hospital. The sketch diagram below demonstrates this technique;

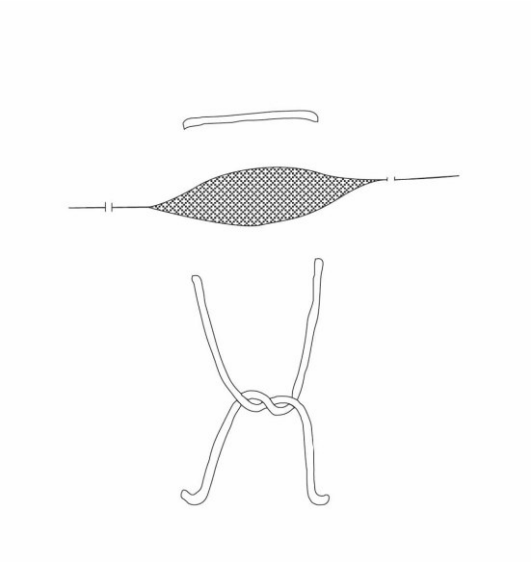

Figure 2.1.2 b: Closure of thoracostomy incision with a horizontal mattress suture

There has been diverse literature criticizing the use of this horizontal mattress suture to close the chest tube incisions due to the unsightly scar that it produces as a result of everting wound edges instead of proper apposition of wounds to propagate better healing [7 - 10].

The use of a non-absorbable suture also causes severe tissue reaction which further compounds on healing in addition to being a foreign body that hampers healing and propagates surgical site infections. This is worsened when there is a delay in removing the suture.

The purse-string technique has been associated with pain when doing the knot. It is routinely closed without a local anaesthetic.

There is the requirement to have a clinic visit for removal of the suture which may fail to happen when patients are lost to follow up. Hence, the sutures remain embedded in the wound[8]. With the various arguments against this methodology, several alternatives in literature have been described below.

2.1.3 Modifications of suture closure techniques for tube thoracostomy incision

Motivated by better cosmetic results of thoracostomy incision wounds, Vasseur described a method of using subcutaneous absorbable suture, Vicryl 2-0, to close the wound[9]. The suture is placed before chest tube insertion. A second non-absorbable suture is employed to secure the chest tube which is removed at the point of chest tube removal. Later the absorbable suture is tightened to seal the wound. It is removed at a later stage (usually 1 week after chest tube removal). A pictorial representation is presented below.

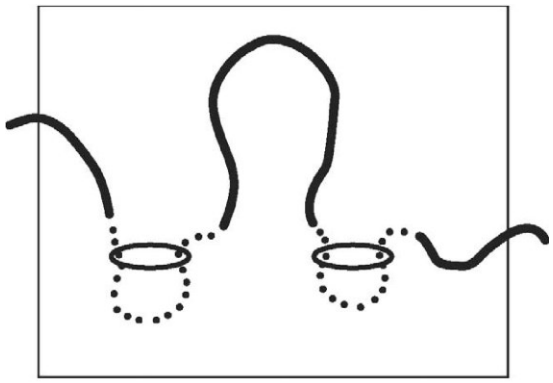

Figure 2.1.3 a: Placement of a subcutaneous suture before chest tube insertion[9]

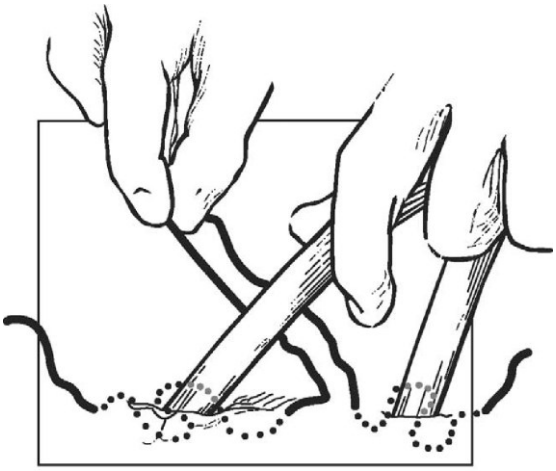

Figure 2.1.3 b: Chest tube placement with a suture in situ[9]

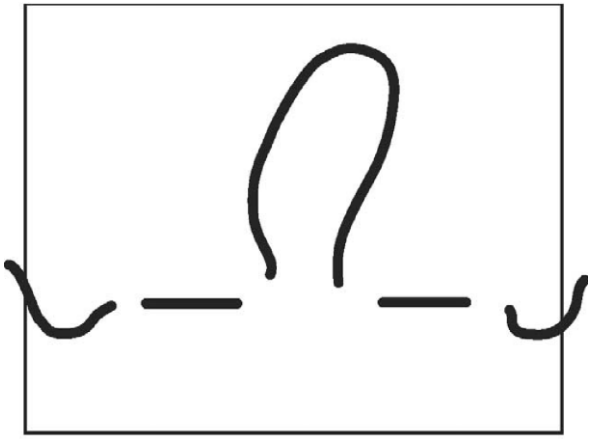

Figure 2.1.3 c: Closure of incision using the placed subcutaneous suture[9]

This closes the wound preventing air re-entry to enable tract closure. It provides better cosmetic results compared to the purse-string method via better apposition of skin as shown diagrammatically above[9.]

Yokohama et al, described the use of a two-layered Triclosan coated absorbable suture technique to close the thoracostomy incision without the need for removal of the suture and with better cosmetic results[10]. They described two-layered muscular and dermal layers placed before chest tube insertion which will be used to seal the wound. A pictorial representation is as shown below

Figure 2.1.3 d: Steps A – H: Placement of 1st layer of the absorbable suture on the muscular layer. I placement of 2nd layer of the suture on the epidermal segment. J suture secures the chest tube[10.]

Kim and Cho, in South Korea, proposed a subcutaneous running suture to close the incision with good cosmetic results[7]. A pictorial representation is as shown below

Figure 2.1.3 e: A - B. Placement of subcutaneous suture for later closure of incision [7]

In general, the subcutaneous methods of the closure of chest drain incision bear good cosmetic results and create a barrier to allow for tract closure[7, 9, 10].

However, the technical expertise involved in implementing it has come out as a challenge in addition to the extra sutures required. The cost-effectiveness is thus debatable in comparison to the use of the occlusive/absorbent dressing method.

2.1.4 Occlusive/Absorbent dressing for the closure of tube thoracostomy incision

In various centres in the world, the trend has shifted to the use of an adhesive absorbent dressing to close the intercostal wound after removal of a chest drain for indications that range from chest trauma-related causes, post thoracic surgeries to drainage of pleural effusion. Smelt et al[8] described a surgeon's experience over 2 years (2015 – 2017) at a facility in London, U.K, where they employed Tagederm plus a pad to close the intercostal wounds of 312 patients[8]. They had remarkable results in terms of reduced complications of

1.6% with SSI, 1.3% with acute pneumothoraces, and 0.3% requiring a suture for persistent drainage[8.]

The science entails the creation of a barrier to prevent the re-entry of air or microorganisms into the wound for a duration of time. This allows for the closure of the tract formed by the chest tube. A similar principle employed by suture methods but with the absence of a foreign body that acts as a risk factor for infection. Additional benefits are; better Cosmesis, reduced financial costs, and the need for further hospital visits[8.]

A simple non-absorbable suture is used purely to anchor the tube. This is removed during dressing closure after drain removal.

Figure 2.1.4: Occlusive/absorbent dressing placed on the incision post removal of the tube

No adverse events have been cited in literature for any of the above methods.

2.2 Markers of Indices for tube thoracostomy incision closure

The following section will cover the indicators used to compare the methods for closure of tube thoracostomy incision. These are; Degree of pain, Cosmesis, rates of pneumothoraces and rates of surgical site infection.

2.2.1 Assessment of pain

Donna Wong and Connie Baker described a pain scale from 0 to 10 to objectively assess a patient's pain perception. It has 6 faces represented by emoji. Each face emoji has a score difference of 2[11 – 12]. A pictorial representation is as shown below;

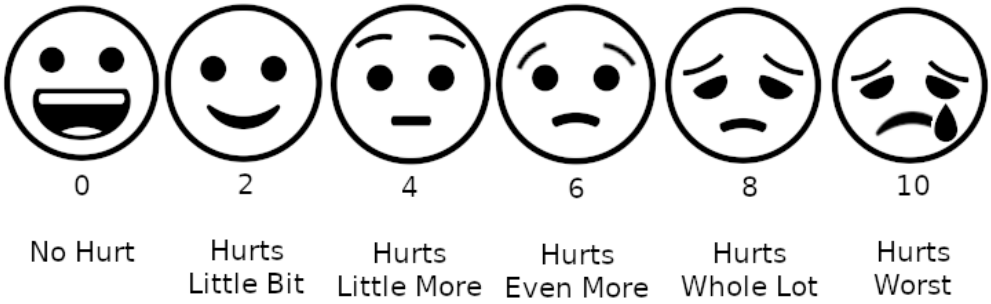

Figure 2.2 Wong – baker pain scale[11]

Scientifically this method has been shown to effectively quantify pain threshold in patients for purposes of rating[11]. This study aims to use this tool to assess the degree of pain during the closure of tube thoracostomy incision.

2.2.2 Cosmesis Assessment

The SCAR tool as proposed by Jonathan Kantor [13] comprises 2 sets of questions. It targets the clinician's responses and the patient's responses. The clinician's responses answer six parameters. These are; the scar spread, presence of erythema, presence of dyspigmentation, presence of suture marks, hypertrophy or atrophy status, and overall impression. The patient's

responses investigate the presence of itch or pain. The scores range from 0 to 15. This tool has demonstrated efficacy in the assessment of scars in various thoracic centers[14 -15]. The study intends to utilize this tool to assess the thoracostomy incision scars.

2.2.3 Post chest tube pneumothoraces

In literature[16], acute pneumothorax after chest tube placement is defined as the presence of air within the pleural cavity within 14 days after removal of a chest drain. Attributed from air re-entry due to breakdown of barrier, improper technique of chest tube removal, premature chest tube removal, or occult air leak[16.]

Late pneumothorax is described after 14 days of the removal of a chest drain. it is caused by barrier breakdown with associated SSIs or occult leak[16.]

2.2.4 Insertion Site infection

Insertion site infection (ISI) is a type of surgical site infection (SSI) associated with chest tube placement. It varies in the spectrum from erythema with swelling, discharging sinuses to necrotizing fasciitis[16 – 18]. Delay in the removal of suture, more than 14 days, can predispose the development of an ISI. The dressing technique of closure has been shown to have lower incidences of ISI[8]

2.6 THE PROBLEM, JUSTIFICATION, RESEARCH QUESTIONS, HYPOTHESIS, AND OBJECTIVES

2.6.1 Statement of the problem

The study compared the purse-string suture with occlusive absorbent dressing as a means of closure of tube thoracostomy incisions on chest trauma subset of patients at the Kenyatta National Hospital. This was a pioneer study in the Kenyan population that aimed to change practice should the outcomes be comparable or favour the occlusive absorbent dressing method. The dressing technique avoids the demerits associated with the purse-string technique which includes pain when closing the suture (routinely done without local anaesthetic). The need for removal of suture later, unsightly scars, infection, and suture granulomas for retained sutures[6-10]. The occlusive absorbent dressings are readily available, affordable, and easy to use at most public health facilities within the country.

The purse-string method is already in use at Kenyatta National hospital, while the dressing method has gained more popularity in comparison to the other closure methods highlighted in literature. Hence the decision to compare these two specific methods of closure of chest tube incision.

2.6.2 Study Justification

The purse-string suture presents with significant demerits that include; suture granuloma's, insertional site infection, unsightly scars and pain on closure. This study compared an alternative method to see its effectiveness in closure of the incision but with added benefits of avoidance of the demerits that presents from the purse-string technique

2.6.3 Research Design

The research design was a non-inferiority study to demonstrate the dressing method to be not worse to the purse-string method in closure of tube thoracostomy incision.

2.6.4 Research Questions

The following were the questions this research aimed to answer.

1. What are the complication rates (new acute pneumothoraces, late pneumothoraces, SSI) for the two techniques?
2. What are the aesthetics of the two techniques?
3. What is the degree of pain for patients during the closure of the incision in the two techniques?

2.6.5 Hypothesis

The null hypothesis was:

There is no difference in outcomes between the use of purse-string suture and absorbent occlusive dressing in the closure of thoracostomy incision.

The alternate hypothesis was:

There is a difference in outcomes between the use of purse-string suture and absorbent occlusive dressing in the closure of thoracostomy incision.

These outcomes were; rates of acute and late pneumothoraces development, rates of SSI, wound healing aesthetics and degree of pain

2.6.6 Study Objectives

2.6.6.1 Broad Objective

To compare outcomes between the purse-string suture and absorbent occlusive dressing in the closure of thoracostomy incisions in patients with chest trauma

2.6.6.2 Specific Objectives

1. To compare rates of acute and late pneumothoraces development between the two techniques

2. To compare rates of SSI between the two techniques.
3. To compare wound healing aesthetics between the two techniques.
4. To compare the degree of pain between the two techniques

2.7 Study Flow Chart

The following outline described the project concept framework

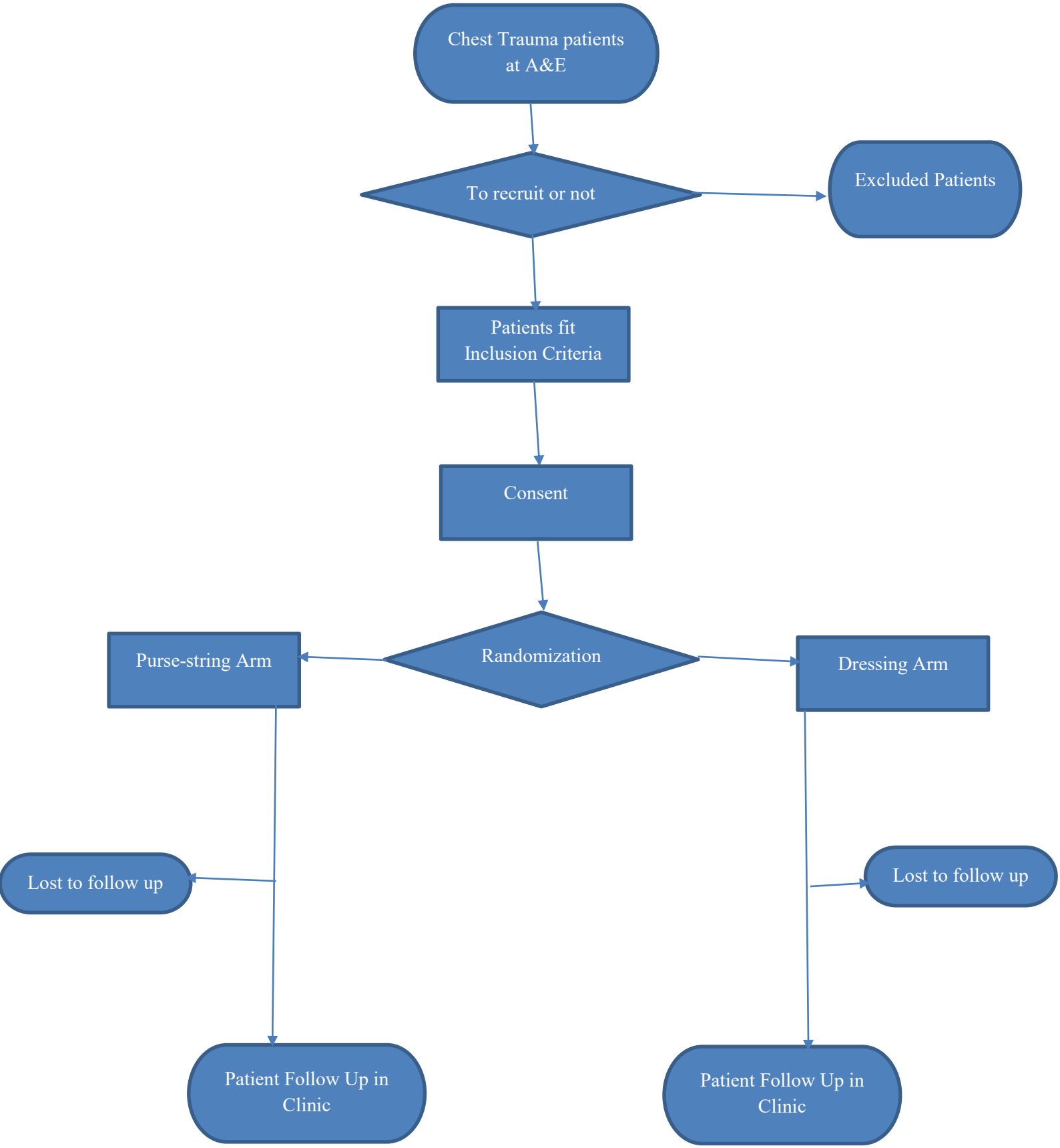

Figure 2.6: Flow chart

CHAPTER THREE

3.0 MATERIALS AND METHODS

3.1 Study Design

The study was an open-label randomized prospective study to compare outcomes between purse-string suture with occlusive absorbent dressing for the closure of tube thoracostomy incision.

3.2 Study Location

The study was carried out at the Kenyatta National Hospital, K.N.H, the largest referral hospital in Kenya. It receives chest trauma patients at the accident and emergency department (A&E).

3.3 Study Population

Chest trauma subset of patients who require tube thoracostomy and subsequent removal at KNH. The study was done over 6 months' period.

3.4 Inclusion and Exclusion Criteria

The inclusion criteria were;

- Patients 18 years of age and above
- Chest trauma patients with haemothoraces, pneumothoraces, or haemo-pneumothoraces presenting within 2 weeks of trauma – Acute phase.

The exclusion criteria were;

- Polytrauma patients; Severe injuries involving of 2 or more body systems.
- Chest trauma patients requiring thoracotomy
- Chest trauma patients with comorbidities
- Patients prone to keloid formation as documented in past medical history.

3.5 Sample size determination and formulae

The alpha for this study was at less than 0.05

The beta for this study was at 80 percent. The power of the study, p at 0.20.

This is a comparison of categorical variables;

Lehr's formula was applied in the determination of sample size for each arm.

$N = 16\ p\ (1 - p) / (p^0 - p^1)^2$ where $p = (p^0 + p^1) / 2$

$p^0 = 0.3$, while $p^1 = 0.1$, to achieve a p of $(0.3 + 0.1) / 2 = 0.20$

Hence $N = 16 \times 0.2\ (1 - 0.2) / (0.3 - 0.1)^2$

$N = 16 \times 0.2\ (0.8) / (0.2)^2$

$N = 16\ X\ 0.16 / 0.04$

N = 64 for each arm. 128 patients for both arms

10% more were to be recruited to factor in for potential loss to follow-up.

Hence 128 X 1.10 = 140.8 rounded to the nearest even whole number was 140.

A total of 140 patients were to be recruited for the study

3.6 Sampling procedure

A simple random sampling technique was used to recruit the participants into both arms to achieve a target of 70 patients in each arm.

Intending to randomize 140 participants for the study, 140 small papers were written. 70 papers for Purse-String arm represented as P and 70 for dressing arm represented as D.

The papers were folded, mixed, and picked at random to give the order of selection (lottery), that is whether suture or dressing. This was then filled into a predetermined table of numbers 1 – 140, with each number assigned randomly a P or D notation based on the papers picked and sequentially documented till all 140 papers were selected.

Each recruited participant had a predetermined random letter assignment into each arm.

The files were color-coded to further inform on their arms for follow-up after removal of chest tubes. The Purse-String arm was color-coded **Blue** while the dressing arm was color-coded **Yellow**.

3.7 Recruitment and consenting procedures

Study participants were screened and recruited through the A&E department of K.N.H after meeting the inclusion and exclusion criteria.

An informed consent form detailing the scope of the study, the benefits and effects of the study was explained to the patient, and recruitment was done after an informed decision had been made.

The key highlight of what the participants were consenting to is how the thoracostomy incision will be closed. Either via a suture (Purse-string arm) or a dressing (dressing arm).

The benefits and risks of both arms were explained to the patient (s) in details.

Attached in the appendix was the informed consent form used in English and Swahili versions.

3.8 Data Collection

An observational chart tool was used to capture the following key details: Participants' biodata and measured dependent variables.

This tool was filled on patient review in the ward and at the clinic after discharge. The observation chart tool was digitized into a google form document for ease of data collection and analysis during clinic follow-up for the patient.

Data was analysed using SPSS version 24.

See appendix for the observational chart tool

3.9 Variables

Independent Variables

These were;

1. Patient's age
2. Patient's Gender
3. Treatment Arm

Dependent Variables

These were;

1. Rates of acute pneumothoraces (Radiographically captured)
2. Rate of late pneumothoraces (Radiographically captured)
3. Rates of SSI
4. Incision cosmetics
5. Degree of Pain

3.10 Materials and Methods

Materials that were used during this study were;

- Absorbent Occlusive dressings – Leukomed T plus

- Nylon suture 2.0
- Observation chart tools

On recruitment and randomization of patients into the study. The biodata, diagnosis, and treatment arm details were filled in the observation chart tool at A&E and the chart placed into the participant's file.

At the time of removal of the chest tube, pain assessment was noted on the chart. A check chest x-ray was done as routine, and details filled in the observation complication section.

Two weeks at follow-up in the clinic, the complication checklist on the chart was filled after assessment of the patient. A second check chest x-ray was required at this stage. These chest x-rays were routinely done for patients post chest tube thoracotomy and patients cover for their costs. They were not new added costs for this research.

After 2 months from wound closure, scar assessment was noted on the chart during the clinic visit. This marked the end of the observational chart tool. The observation tool was then put on a google form document for data entry.

Summary of recruitment to follow up was demonstrated in the flow chart below

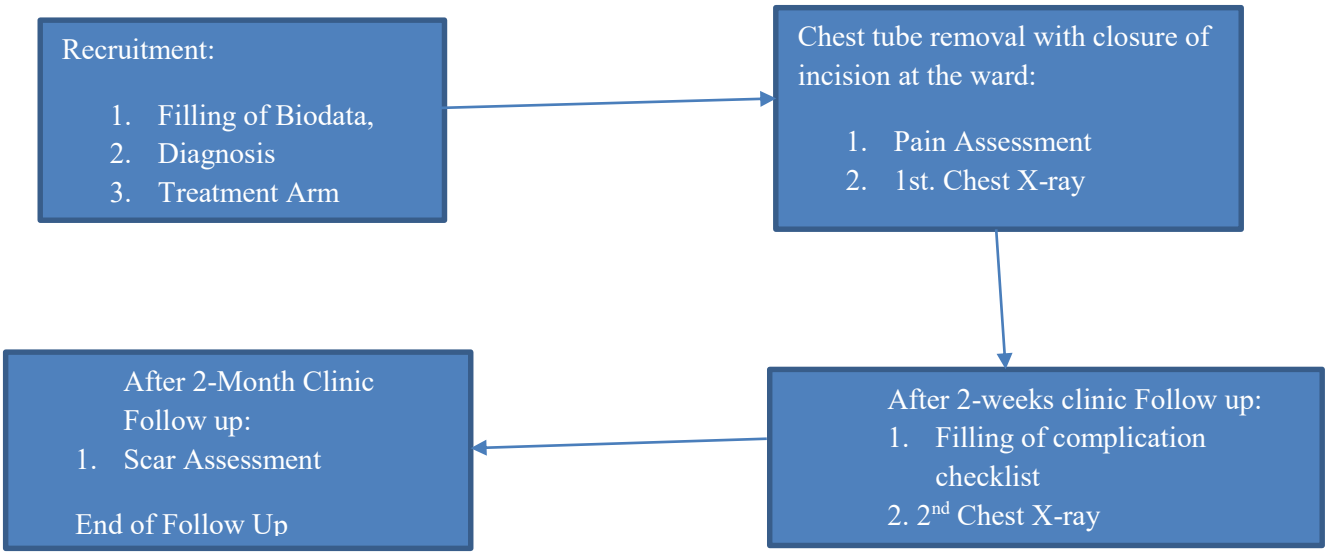

Figure 3.10: Recruited patients' Flow chart

3.11 Evidence of Good Clinical Practise

The principal investigator was a senior cardiothoracic registrar at the University of Nairobi/Kenyatta National Hospital department of cardiothoracic surgery. He has done over 500 tube thoracostomies with their removal and incision closure using the purse-string technique at the department. The research assistants were junior cardiothoracic registrars at the University of Nairobi/Kenyatta National Hospital department of cardiothoracic surgery. They have individually done over 200 tube thoracostomies with their removal and closure using the purse-string technique at the department.

3.12 Training procedures

At our facility, most tube thoracostomies' removal and incision closure were done by junior cardiothoracic residents. The principal investigator demonstrated the procedure for the removal of chest tubes and closure for both techniques. The training protocol included video demonstrations based on materials from internationally acceptable cardiothoracic centres on best practise for each method. This was further re-enforced by the current local protocols on the purse-string closure technique at the KNH cardiothoracic department.

Competence on each closure technique was assessed by the principal investigator which entailed sequence steps in performance of the two methods by the research assistants.

Repeat sessions of training were done for quality assurance.

3.13 Quality assurance

Routine inspection of techniques of chest tube removal and closure was done weekly to ascertain the techniques were within the specified standards to minimize confounders and user biases.

3.14 Ethical Consideration

The study commenced after approval by the UoN/K.N.H. Ethics committee and the KNH administration. The participants enrolled in the study were explained the objectives and goals of the study.

Informed consent was signed after participants understood the therapies under assessment and agreed to be randomized into either arm. The potential risks and benefits of each arm were highlighted to the participants.

The information of the participants was protected. Confidentiality and privacy was maintained throughout the entire study. Patient's name was coded with initials for anonymity.

The patients were assigned a unique identifier that used to hide their identity and for reference purposes.

Patients were informed of their arm after randomization and were included in the arm after informed consent had been made.

For those who did not wish to participate in the study after randomization, they were entitled to care as per the hospital protocols on closure of chest tube incision. No patient was denied treatment due to refusal to participate in the study.

NHIF Medical insurance was provided for the participants in the dressing arm for 3 months' period.

3.15 Data management

Patient data was collected in the observational chart tool, digitized and later transferred to an excel sheet. This provided a platform for the migration of the data to the SPSS version 24.

The softcopy data was stored in a dedicated external hard disk which was password protected as a security measure.

The observation chart tools were placed in a secure drawer within Ward 4B for retrieval upon analysis. Upon completion of study, the observation chart tools were appended to the individual patient files and stored in the hospital information department as per hospital protocols and regulations

Privacy and data confidentiality was maintained.

Upon migration of the data to the SPSS tool, data cleaning was done. Analysis through Pearson's Chi square test for categorical variables and student T test for parametric variables were done.

3.16 Study Limitations/Bias Minimization

Bias was minimized through randomization as described in the earlier section.

Besides, doing intention to treat and per-protocol analysis reduced selection bias.

User bias was present on recruitment. This was handled through training of research assistants on the study protocols and weekly inspection of the recruitment process.

Research assistants consulted the principal investigator on patient's assignment arm during recruitment to minimize on user bias.

3.17 Covid-19 mitigation measures

The researcher and research assistants were protected against Covid-19 by adhering to the guidelines set by the Government of Kenya for mitigating the spread of the disease. They were expected to adhere to infection prevention measures which included; maintaining proper hand hygiene, wearing of face masks, observing cough etiquette, and using appropriate personal protective equipment (PPE).

Symptom free research assistants were allowed to collect data during the study. The participants were screened for Covid-19 symptoms. Suspects were attended to with

appropriate PPE to minimize spread to the researchers. They were referred to the Ministry of health designated isolation ward for specialised care after appropriate cardiothoracic intervention had been done. Upon discharge from the isolation facilities, they were followed up as routine in the surgical clinic. See appendix for the Covid 19 screening tool used.

3.18 Study Closure plan and procedure

During follow-up of patients at the clinic, the provisional results of the study were presented to them, and appreciation made for their contribution to the scientific information

CHAPTER FOUR

4.0 STUDY RESULTS

4.1 General results

From September 2021 to March 2022, 81 participants were enrolled into the study, of which 40 (49.4%) and 41 (50.6%) were randomized to the dressing and suture arms respectively. There were 55 (67.9%) males and 26 (32.1%) females, where the overall mean age was 35.8±13.9 years, of which the minimum observed age was 18.0 years and maximum was 67.0 years old. The other characteristics are as shown on Table 4.1

Table 4.1 General sample distribution and characteristics.

	Dressing	**Suture**	**Total**	**p-value**
Gender, *n (%)*				
Male	24 (60.0)	31 (75.6)	55 (67.9)	0.132
Female	16 (40.0)	10 (24.4)	26 (32.1)	
Age				
Mean ± SD	36.8±13.4	34.9±14.5	35.8±13.9	0.532
Median (IQR)	34.5 (24.5 – 47.0)	30.0 (24.0 – 42.0)	32.0 (24.0 – 46.0)	0.377
Diagnosis, *n (%)*				
Blunt chest trauma	14 (35.0)	11 (26.8)	25 (30.9)	0.426
Penetrating chest trauma	26 (65.0)	30 (73.2)	56 (69.1)	
Haemothorax, *n (%)*				
Yes	32 (80.0)	25 (61.0)	57 (70.4)	0.061
No	8 (20.0)	16 (39.0)	24 (29.6)	
Pneumothorax, *n (%)*				
Yes	11 (27.5)	23 (56.1)	34 (42.0)	**0.009**
No	29 (72.5)	18 (43.9)	47 (58.0)	

Gender distribution after randomization was as represented in the chart below.

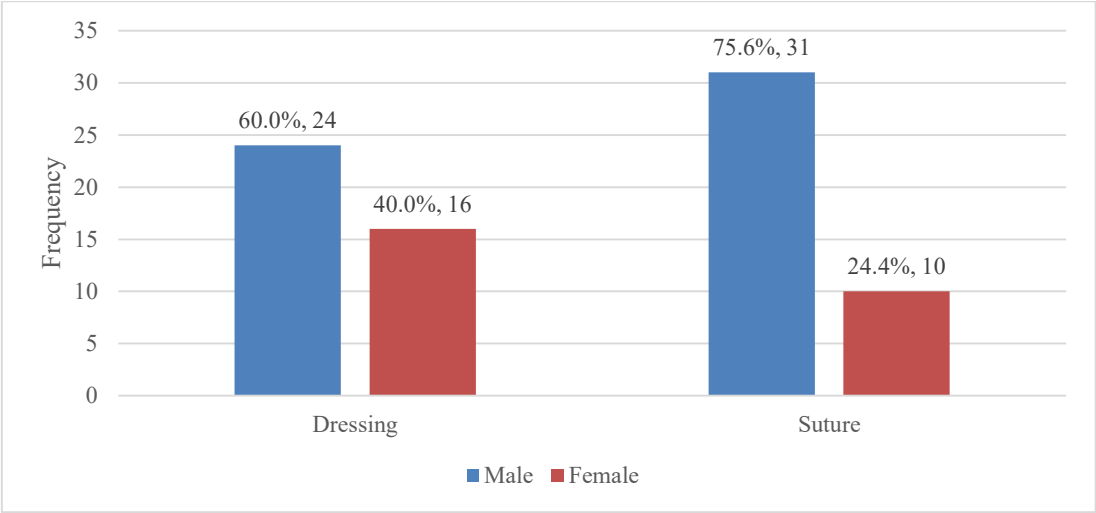

Figure 4.1.1 Gender distribution

The mean age for dressing arm was 36.8±13.4 and 34.9±14.5 for the suture arm. There was no statistical difference in the ages of the participants in the 2 arms (p=0.532), as assessed by the independent students t-test. This validates the randomization technique. The distribution is as demonstrated below

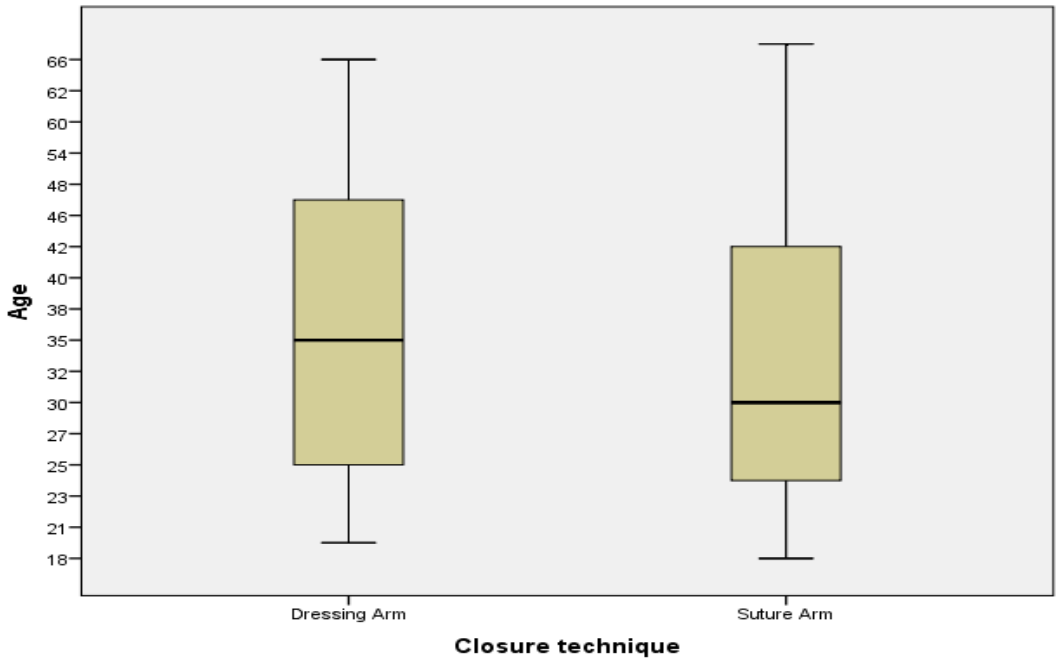

Figure 4.1.2 Age distribution following randomization

Twenty-five patients had blunt chest trauma while 56 patients had penetrating chest trauma. Of the 25 patients, 14 were randomized into the dressing arm while 11 into the suture arm. Of the 56 patients, 26 were randomized into the dressing arm, while 30 into the suture arm. This is demonstrated below

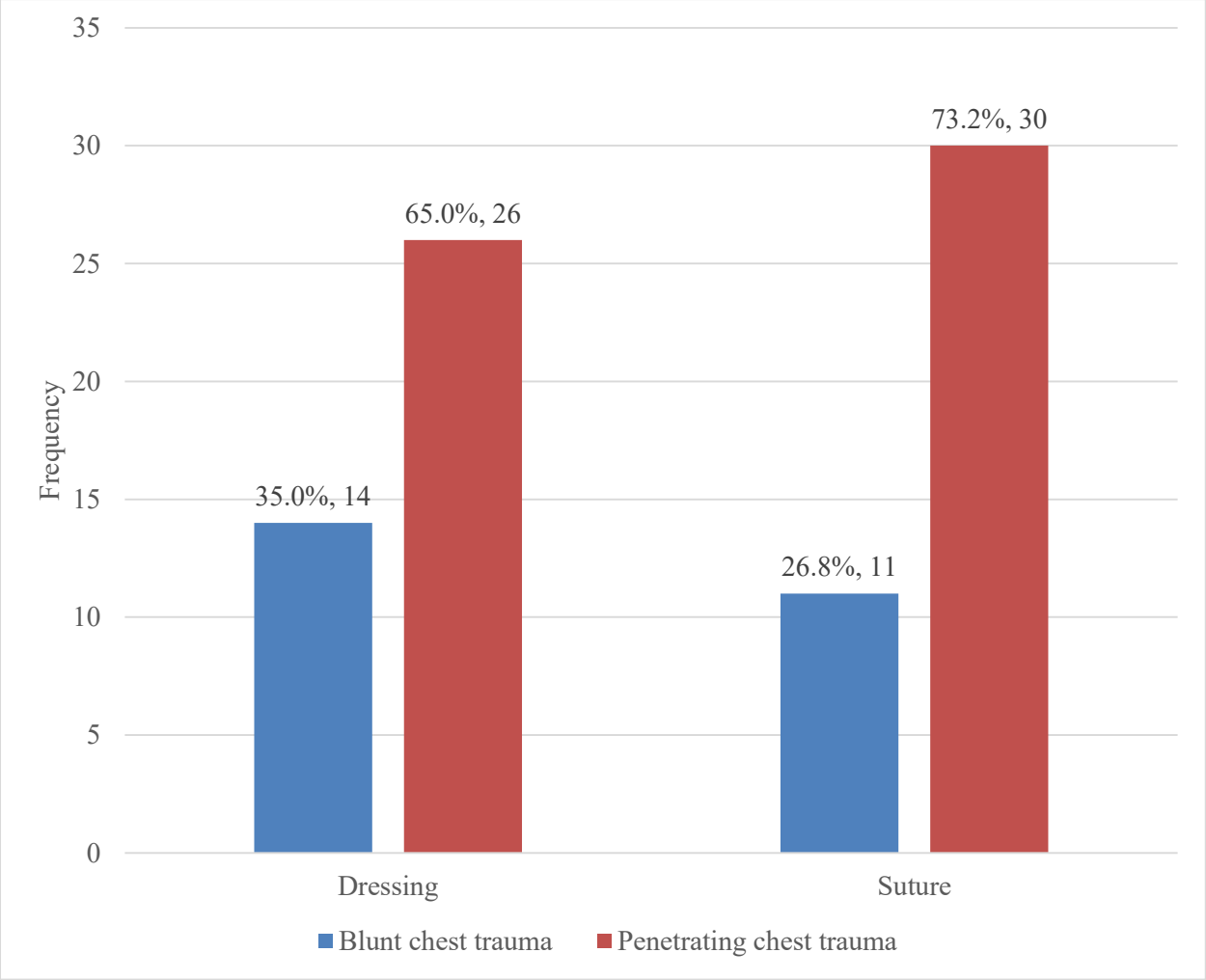

Figure 4.1.3. Diagnosis Distribution

For the dressing arm, 32 had Haemothorax, while 11 had pneumothorax. For the suture arm, 25 had Haemothorax while 23 had pneumothorax.

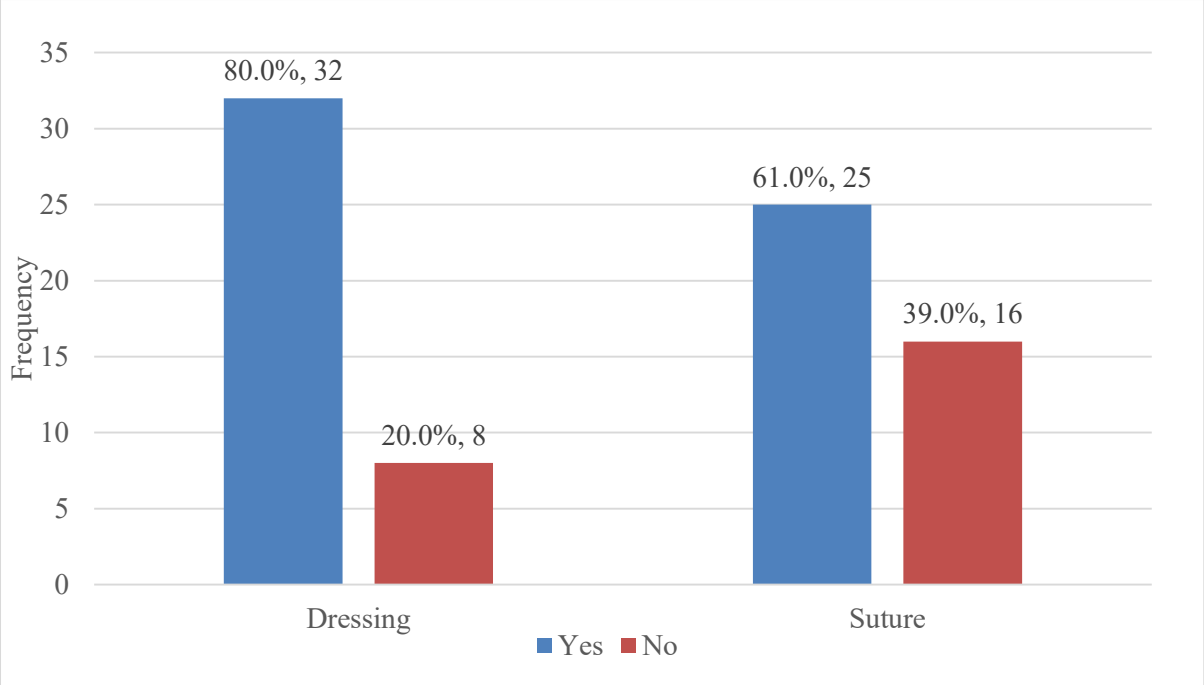

Figure 4.1.4 Haemothorax distribution

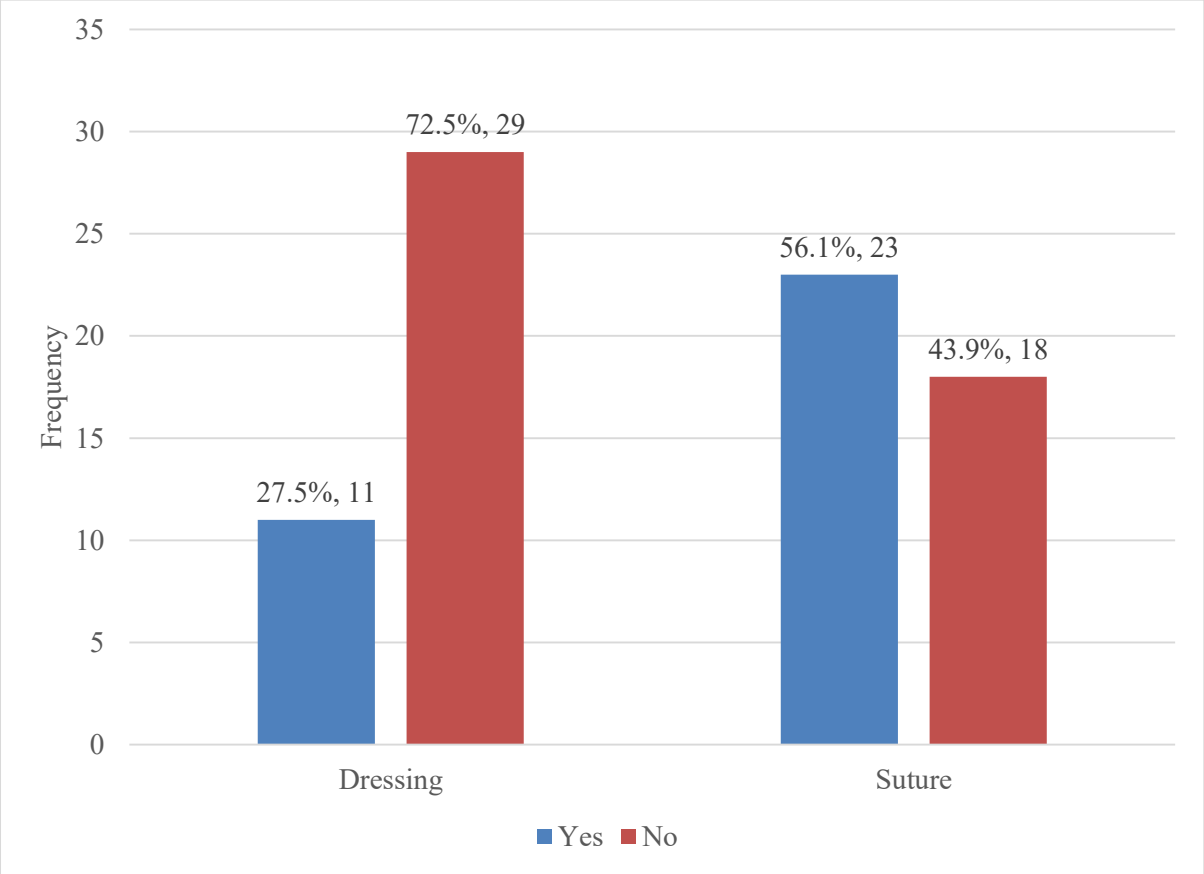

Figure 4.1.5 Pneumothorax distribution

4.2 Pain scores

The pain score results are shown in the table below

Table 4.2. Pain score results

	Dressing	Suture	P-Value
Pain score			
Mean ± SD	3.0±1.8	6.3±2.8	**<0.001**
Median (IQR)	2.0 (2.0 – 4.0)	8.0 (4.0 – 8.0)	**<0.001**
Mean Rank	20.5	61.0	**<0.001**

The pain scores distribution for both techniques is demonstrated below

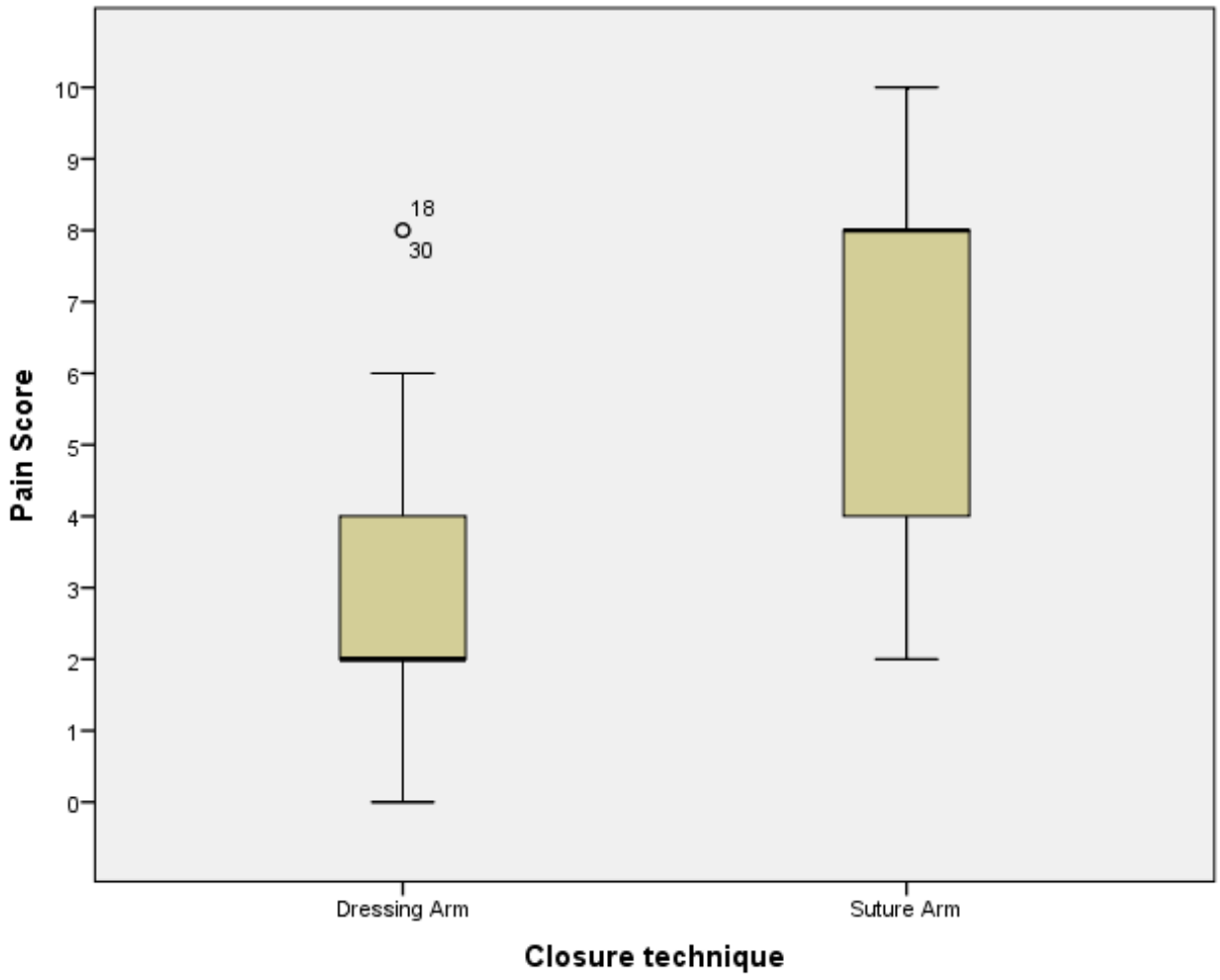

Figure 4.2. Pain scores distribution

A Kruskal-Wallis H test showed that there was a statistically significant difference in the pain score between the closure techniques, $\chi 2(1) = 23.036$, ($p < 0.001$), with a mean rank pain score of 28.56 for Dressing arm, and 53.13 for the Suture arm.

4.3 Scar scores

The scar score results are shown in the table below

Table 4.3. Scar score results

	Dressing	Suture	**P - Value**
Scare Score			
Mean ± SD	3.3±1.0	11.3±1.4	**<0.001**
Median (IQR)	3.0 (3.0 – 4.0)	11.0 (11.0 – 12.0)	**<0.001**
Mean Rank	20.50	61.00	**<0.001**

The scar score distribution for the two arms is depicted below

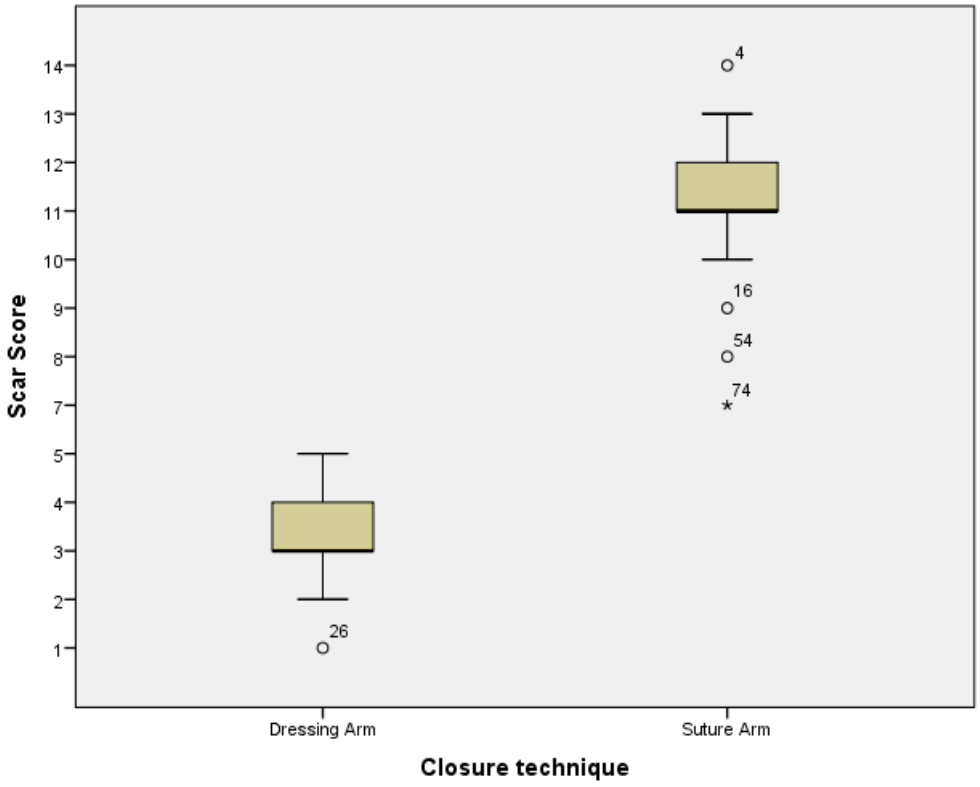

Figure 4.3. Scar scores distribution.

A Kruskal-Wallis H test showed that there was a statistically significant difference in scar score between the closure techniques, $\chi 2(1) = 61.219$, ($p < 0.001$), with a mean rank scar score of 20.50 for Dressing arm, and 61.00 for the Suture arm.

4.4 Complications results

The table below outline the observed complications in the two arms.

Table 4.4. Complications summary

Complications	Dressing	Suture	P-Value
Acute Pneumothoraces			
Yes	2 (5.0)	1 (2.4)	0.542
No	38 (95.0)	40 (97.6)	
Surgical site infection			
Yes	0 (0.0)	3 (7.3)	0.241
No	40 (100.0)	38 (92.7)	

There were 2 cases of recurrent acute pneumothorax in the dressing arm versus 1 in the suture arm. 5% vs 2.4%. However, this was not statistical significant. (P-Value 0.542)

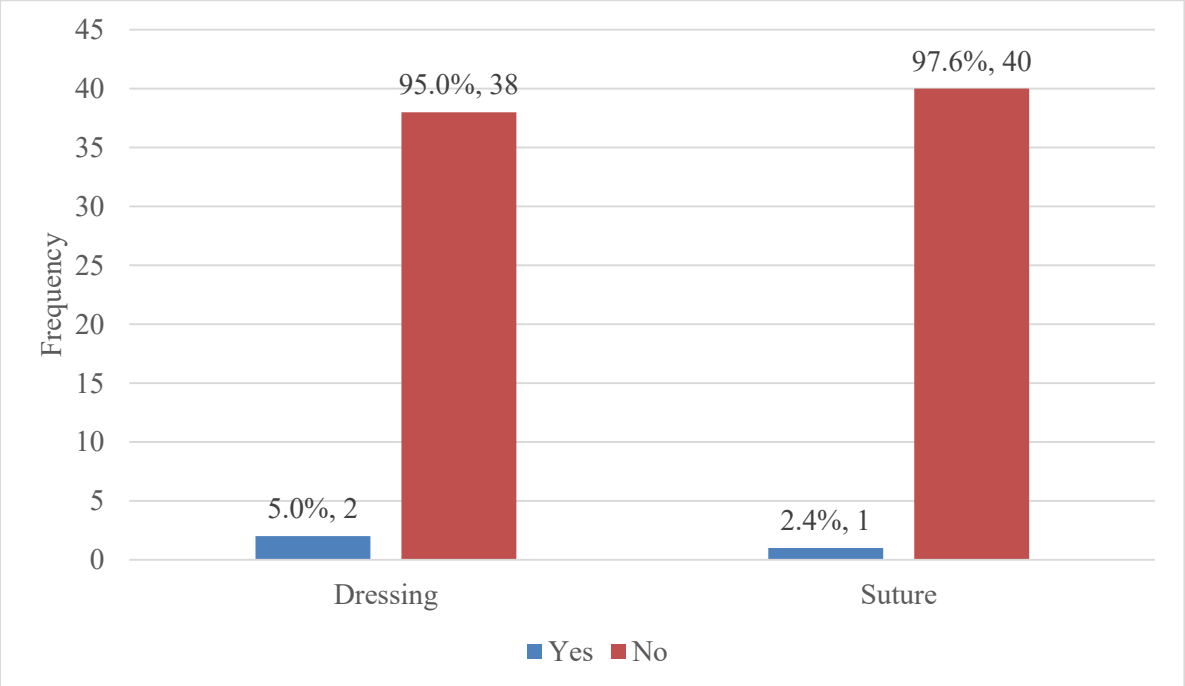

Figure 4.4.1 Acute pneumothorax

Three cases of SSI were noted in the suture arm (7.3%) vs (0.0%). However, this was not statistically significant. (P-Value 0.241)

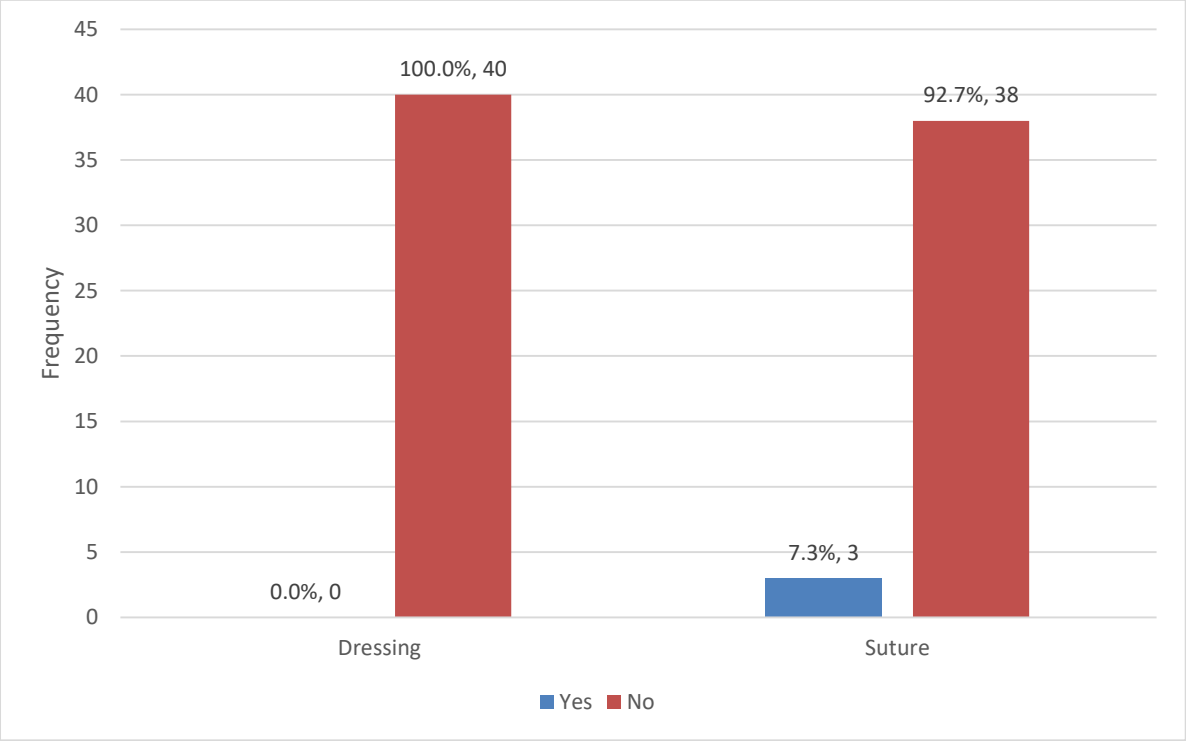

Figure 4.4.2. SSI distribution

Neither late pneumothoraces nor persistent drainage were observed in both arms

CHAPTER FIVE.

5.0 DISCUSSION

This randomized trial of dressing versus suture techniques of closure of chest tube incision in chest trauma patients demonstrated significantly better overall cosmesis with lesser pain scores in the dressing arm as compared to the suture arm.

The dressing arm showed lesser incidence of SSI which is comparable to outcomes reported by Smelt et al[8]. (0.0% vs 1.6%). Thus demonstrating reproducibility of the results giving credit to the methodology of study execution.

The recurrent acute pneumothoraces in the study was comparable to smelt et al[8] (5.0% vs 1.3%). This reinforces reproducibility of the results.

The dressing technique was designed to factor the availability of dressings within the KNH setup to provide alternatives to thoracostomy incision closure as demonstrated in literature though not widely used in our local setup.

The study was designed to detect a difference in the pain scores in favour of the dressing technique owing to the fact that absence of knot tying in this method theoretically should translate to better comfort for the patient when the method is applied during closure of the tube thoracostomy incision. The results demonstrated a statistical significant lower pain score for the dressing arm in comparison to the suture arm (Median 2.0 vs 8.0 ($P < 0.001$)). This suggests that this method may be a more patient friendly technique in respect to pain perception.

The study was designed to detect a difference in the scar score with respect to the dressing technique; the documented eversion of edges in literature for the suture technique[7-10]. On

subjecting the data to analytical tests, it was evident that the cosmesis results were superior in the dressing arm. (Mean Rank 20.50 vs 61.00 ($p<0.001$))

5.1 Study limitation

Due to KNH implementation of strict patient referral rules and regulation in the 2021 – 2022 calendar year, fewer chest trauma patients were reviewed in the KNH A&E hence the original sample size of 128 patients was not achieved.

Covid pandemic restriction further impacted on achieving the target sample size of 128 participants. This however doesn't affect the power of the study ($n>30$ for each arm).

Focus of the closure technique was only for chest trauma patient subset who have tube thoracostomies. Other patient types who have chest tube inserted and require closure were excluded in the study, so other studies to include these populations may be warranted in the future.

5.2 Conclusion

The dressing technique provided better cosmesis, was more patient friendly in pain perception with comparable complications rates as suture technique, thereby demonstrating the rejection of the null hypothesis of no difference in outcomes between the two techniques in favour of the alternate hypothesis.

5.3 Recommendation

We recommend adoption of the dressing technique as a protocol within KNH cardiothoracic department for closure of tube thoracostomy incision in chest trauma patients.

5.4 Disclosure

This study was funded by the Kenyatta National Hospital Research Grant.

The principal investigator did not prefer to use any particular occlusive absorbent dressing brands to promote any product. The dressings used for the study were those already available in KNH wards.

6.0 BUDGET AND BUDGET JUSTIFICATION

The proposed budgetary allocations are outlined below;

Table 6.0

Components	Unit of Measure	Duration/ Number	Unit Cost(Kshs)	Total Cost(Kshs)
Personnel				
Research Assistant	**2**	**26**	**1,500.00**	**78,000.00**
Statistician	**1**	**1**	**30,000.00**	**30,000.00**
Participants' Insurance	**1**	**70**	**1,500.00**	**105,000.00**
Printing				
Consent Form	**1**	**12**	**10.00**	**120.00**
Questionnaires	**1**	**2**	**10.00**	**20.00**
Final Report	**1**	**100**	**10.00**	**1,000.00**
Photocopying				
Consent Form	**155**	**6**	**5.00**	**4,650.00**
Questionnaires	**155**	**2**	**5.00**	**1,550.00**
Interview Guide				
Final Report	**5**	**100**	**5.00**	**2,500.00**
Final Report Binding	**6**	**1**	**800.00**	**4,800.00**
Other costs				
ERC Fees	**1**	**1**	**2,000.00**	**2,000.00**
Poster Printing	**1**	**1**	**3,000.00**	**3,000.00**
Total				**232,640.00**

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6.0 APPENDICES

APPENDIX 1: DATA COLLECTION TOOL

THORACOSTOMY INCISION CLOSURE OBSERVATION FORM

1. Biodata

Name_____

Ref. No: _____

DoB: _____ **Age:** ☐

Phone No: _____

Email: _____

Gender: **Male:** ☐

Female: ☐

2. Clinical Outcomes

Diagnosis:	**Blunt Chest Trauma**	☐	**Penetrating Chest Trauma**	☐
Chest Tube Indication:	**Haemothorax**	☐	**Pneumothorax**	☐
Closure Technique:	**Suture Arm**	☐	**Dressing Arm**	☐

3. Pain Assessment

Pain scale during removal of drain and closure of the incision
Chart based on the Wong-Baker Pain Scale (Rated 0 to 10)

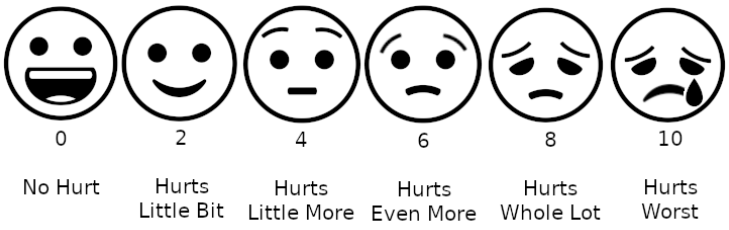

Figure 2.2[11]

Pain Score ☐

4. Complication's checklist

Acute pneumothorax:	**Yes**	☐	**No**	☐
Late Pneumothorax:	**Yes**	☐	**No**	☐
Surgical Site infection:	**Yes**	☐	**No**	☐
Persistent Drainage:	**Yes**	☐	**No**	☐
Requirement for Suture placement (for dressing arm only):	**Yes**	☐	**No**	☐

5. Incision Cosmetic Level assessment using the SCAR tool. [13-15]

Parameter	Descriptor	Score
Clinician questions		
Scar spread	None/near invisible	**0**
	Pencil-thin line	**1**
	Mild spread, noticeable on close inspection	**2**
	Moderate spread, obvious scarring	**3**
	Severe spread	**4**
Erythema	None	**0**
	Light pink, some telangiectasia may be present	**1**
	Red, many telangiectasias may be present	**2**
	Deep red or purple	**3**
Dyspigmentation	Absent	**0**
	Present	**1**
Suture marks	Absent	**0**
	Present	**1**
Hypertrophy/atrophy	None	**0**
	Mild: palpable, barely visible hypertrophy or atrophy	**1**
	Moderate: visible hypertrophy or atrophy	**2**
	Severe: marked hypertrophy or atrophy or keloid formation	**3**
Overall impression	Desirable scar	**0**
	Undesirable scar	**1**
Patient questions		
Itch	No	**0**
	Yes	**1**
Pain	No	**0**
	Yes	**1**
Total Score	**(Max. score: 15 Min. score: 0)**	

APPENDIX 2: DUMMY TABLES

Table 6.1a

Participant Characteristics	**Dressing Arm (N)**	**Suture Arm (N)**	**Totals (N)**
Gender ● Male ● Female			

Table 6.1 b

Participants Characteristics	**Mean Age**	**Median Age**	**Standard Deviation**	**Student T-Test**
Treatment ● Dressing ● Suture				

Table 6.1 c

Treatment Arm	**Mean of Pain Score**	**Standard Deviation**	**Student T-Test**
Dressing Arm			
Suture Arm			

Table 6.1 d

Treatment Arm	**Acute Pneumothoraces present**	**Acute Pneumothoraces Absent**	**Totals**
Dressing Arm			
Suture Arm			
Totals			

Table 6.1 e

Treatment Arm	Late Pneumothoraces present	Late Pneumothoraces Absent	Totals
Dressing Arm			
Suture Arm			
Totals			

Table 6.1 f

Treatment Arm	ISI present	ISI Absent	Totals
Dressing Arm			
Suture Arm			
Totals			

Table 6.1 g

Treatment Arm	Mean of Cosmesis	Standard Deviation	Student T-Test
Dressing Arm			
Suture Arm			

APPENDIX 3: COVID-19 PATIENT SCREENING FORM

Name_____
Ref. No: _____
DoB: _____ Age:

Checklist	Before Recruitment	Response
Are you over 60 years of age?	YES/NO	
Do you have a pre-existing condition such as lung disease, heart disease, diabetes, kidney disease or an autoimmune disorder?	YES/NO	
Are you experiencing shortness of breath or trouble breathing?	YES/NO	
Do you have a temperature of 37.5° C or higher?	YES/NO	
Are you experiencing a sore throat?	YES/NO	
Are you coughing?	YES/NO	
Are you experiencing repeated shaking with chills?	YES/NO	
Do you have muscle aches?	YES/NO	
Are you experiencing gastrointestinal changes?	YES/NO	
Have you noticed a loss of smell or taste?	YES/NO	
Have you had contact with a known or suspected COVID-19-positive person?	YES/NO	
In the last 14 days, have you travelled to an area that has a high incidence of COVID-19?	YES/NO	
If yes to the question above, please specify:		

APPENDIX 4: Research Screening and Consent Form (English Version)

Pre-screening form to participate in a randomized trial to compare suture with dressing for the closure of chest tube wound at the Kenyatta National Hospital

This is a screening and consent form for chest trauma patients who require chest tube insertion and later removal at Kenyatta National Hospital (KNH).

Principal Investigator: Dr. Obed Morara

Institution: Department of Surgery, School of Medicine, University of Nairobi

Supervisors: Dr. Mark Nelson Awori and Dr. Nikita Mehta

You are invited to participate in this research that will entail assessing outcomes in two methods for closing chest tube wounds after their removal. You will be randomly put into either of the methods should you consent. Before signing the consent, kindly understand the details of the research and ask any questions you may have.

The research will be conducted at the Kenyatta national hospital by the principal investigator, Dr. Obed Morara, a senior fellow at the cardiothoracic department. The study will be conducted to compare a dressing method to a suture method in closing chest tube wounds. Both methods have been found to be effective in closure of chest tube wounds.

To participate in this study, you must be a person aged above 18 years who has an indication for a chest tube placement.

After you sign this form, your biodata details will be recorded by the investigator.

Statement of consent by the patient

By signing this document, I freely give my consent to the medical team of Kenyatta National hospital to examine me for possible participation in the research study "**A randomized trial to compare suture with dressing for the closure of chest tube wound at the Kenyatta National Hospital**."

I understand that giving false, incomplete, or misleading information about my medical history could have very serious consequences. I understand that in the event I am not selected for inclusion in the study, I will still receive the treatment that I require.

Participant's Name (PRINT): _____

Participant's Initials: ___ ___ ___

Participant's date of birth, __ __ / __ __ __ / __ __ __ __,

Age: _____

Screening Number: _____

Sign and Date: _____

Researcher's Name: _____

Sign and Date: _____

APPENDIX 5: Research Screening and Consent Form (Kiswahili Version)

Fomu ya uchunguzi wa mapema kushiriki katika utafiti kwa jina ya "**A randomized trial to compare suture with dressing for the closure of chest tube wound at the Kenyatta National Hospital**"

Mtafiti Mkuu: Dkt Obed Morara

Kituo: Idara ya Upasuaji, Kitivo cha Afya - Chuo Kikuu cha Nairobi

Wakufunzi Wakuu: Dkt. Mark Nelson Awori na Dkt. Nikita Mehta.

Unaalikwa kushiriki katika utafiti huu ambao utajumuisha kutathmini matokeo katika njia mbili za kufunga vidonda vya kifua baada ya kuondolewa bomba la kifua. Utawekwa kwa nasibu katika njia yoyote ikiwa utakubali. Kabla ya kusaini idhini, elewa kwa fadhili maelezo ya utafiti na uulize maswali yoyote unayoweza kuwa nayo

Utafiti huo utafanywa katika hospitali ya kitaifa ya Kenyatta na mpelelezi mkuu, Daktari Obed Morara, mwenzake mwandamizi katika idara ya magonjwa ya moyo. Utafiti huo utafanywa kulinganisha njia ya kuvaa na njia ya mshono katika kufunga vidonda vya bomba la kifua. Njia zote mbili zimepatikana kuwa na ufanisi katika kufungwa kwa vidonda vya bomba la kifua

Ili kushiriki katika utafiti huu, lazima uwe mtu mwenye umri wa zaidi ya miaka 18 ambaye ana dalili ya kuwekwa kwa bomba la kifua.

Baada ya kusaini fomu hii, maelezo yako ya biodata yatarekodiwa na mpelelezi

Taarifa ya idhini na mgonjwa

Kwa kusaini waraka huu, ninatoa idhini yangu kwa hiari kwa timu ya matibabu ya hospitali ya kitaifa ya Kenyatta kunichunguza kuhusu uwezekano wa kushiriki katika utafiti wa jina "**A randomized trial to compare suture with dressing for the closure of chest tube wound at the Kenyatta National Hospital**."

Ninaelewa kuwa kutoa habari ya uwongo, isiyo kamili, au ya kupotosha juu ya historia yangu ya matibabu inaweza kuwa na athari mbaya sana. Ninaelewa kuwa ikiwa sikuchaguliwa kuingizwa kwenye utafiti, bado nitapokea matibabu ambayo ninahitaji.

Jina la mshiriki: _____

Mwanzo wa mshiriki: ___ ___ ___

Tarehe ya kuzaliwa ya mshiriki, __ __ / __ __ __ / __ __ __ __,

Umri: _____

Nambari ya Uchunguzi: _____

Ishara na Tarehe: _____

Jina la Mtafiti: _____

Saini na Tarehe _: _____

APPENDIX 6: INFORMED CONSENT FORM: (English Version)

A randomized trial to compare suture with dressing for the closure of chest tube wound at the Kenyatta National Hospital

This informed consent is for chest trauma patients who require chest tube insertion and later removal at Kenyatta National Hospital (KNH). We are requesting patients to participate in the study whose title is "**A randomized trial to compare suture with dressing for the closure of chest tube wound at the Kenyatta National Hospital**

"

Principal Investigator: Dr. Obed Morara

Institution: Department of Surgery, School of Medicine, University of Nairobi

Supervisors: Dr. Mark Nelson Awori and Dr. Nikita Mehta

This informed consent has three sections:

1. Information about the research
2. Certificate of consent
3. Statement by the Researcher

You will be issued with a copy of the full informed consent form.

SECTION 1: INFORMATION ABOUT THE RESEARCH

Introduction

My name is Dr. Obed Morara, a postgraduate student in Thoracic and cardiovascular surgery at the University of Nairobi. I am conducting a study to compare outcomes between suture with dressing in the closure of chest-tube wounds at KNH.

Purpose of the study

Due to lack of consensus in the closure of tube thoracostomy incision, the study proposes to compare two techniques' outcomes to provide information to enable the development of protocols for the closure of chest tube incisions.

Study participation

I am inviting you, as a chest trauma patient who requires chest tube placement, to participate in my study. You will be allowed to ask questions before you decide. Your participation is voluntary. Should you agree to participate, you will be requested to sign a consent form. No monetary payment will be made due to your participation in the study.

Benefits of participation

Your participation in this study will help us assess two techniques in the closure of the incision after your chest tube has been removed. This will enable us to get information to guide us on the technique to recommend in our future protocols.

Risk of participation

There is a risk of a recurrent pneumothorax after the chest tube has been removed. This probability is low with the right technique. In the event of pneumothorax, a second chest tube may be placed. You may have an unpleasant scar at the incision site. You may have an infection at the site. You may experience pain at the closure of the wound. These risks have been documented as low from the literature. In case of any complication for those in the dressing arm, the NHIF medical insurance provided will cover for the accrued medical costs.

Right to decline or withdraw

You are free to withdraw from the study at any time. The refusal to participate or withdraw will not deny you treatment.

Confidentiality

Any information that is obtained from you in this study will be confidential. Your names will be coded for anonymity.

Sharing of results

Knowledge obtained from this study will be shared with other professionals in conferences and publications while maintaining confidentiality.

Cost and compensation

No extra cost shall be incurred from your participation in the study. There will be no compensation

Contacts of relevant parties

1. **Principal investigator**

Dr. Obed Morara

Resident, Department of Surgery,
University of Nairobi

P.O. Box 19676 – 00202, KNH, Nairobi

Cell Phone: +254 725 569 168

Dr. George Kinyanjui

Resident, Department of Surgery,
University of Nairobi

P.O Box 19676 – 00202 KNH, Nairobi

Cell Phone +254 721 241 842

2. **Research Assistant**

3. **Research Assistant**

Dr. Gilbert Lagat

Resident, Department of Surgery,
University of Nairobi

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Cell Phone +254 734 497 711

4. **Research Assistant**

Dr. Hasan Mohammud

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5. **Research Assistant**

Dr. Pravin Mokaya

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6. **Research Assistant**

Dr. Jedidah Kimutai

Resident, Department of Surgery,
University of Nairobi

P.O Box 19676 – 00202 KNH, Nairobi

Cell Phone +254 720 559 758

7. **Secretary**

KNH/UON ERC

P.O Box 20723-00202, Nairobi

Tel: 0202726300 Ext 44355

Email: KNHplan@Ken.Healthnet.org

8. **Research Supervisors**

Dr. Mark Nelson Awori

Senior Lecturer in Thoracic and
Cardiovascular Surgery

Department of Surgery

University of Nairobi

P.O Box 19676-00202 KNH, Nairobi

Tel: 0202726300

9. Dr. Nikita Mehta

Lecturer in Thoracic and Cardiovascular
Surgery

Department of Surgery

University of Nairobi

P.O Box 19676 – 00202 KNH, Nairobi

Tel: 0202726300

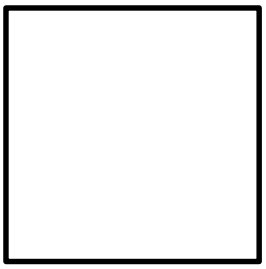
SECTION 2: CONSENT FORM

Statement of consent by the patient

I, _____ freely give consent to participate in the study "**A randomized trial to compare suture with dressing for the closure of chest tube wound at the Kenyatta National Hospital**"

I have been informed and have understood that my participation is voluntary. I understand the information about the study and I have had an opportunity to ask questions

I have the freedom to withdraw from the study at any particular time



Signature or Left Thumb Print (Patient)_____

Date_____

Statement by a witness (For illiterate patients)

I have witnessed the reading of the consent form to the patient and he/she has had the opportunity to ask questions. I confirm that he/she has given the consent freely.

Name of Witness_____

Signature: _____

Date: _____

SECTION 3: STATEMENT OF RESEARCHER

I have read out the information in **section one** to the participant and ascertained the following;

- The participant consent is voluntary.
- Refusal to participate or withdraw from the study will not deny the patient care as required.
- Information will be confidential.
- The results of the study will be published to share knowledge of the subject of research
- I have responded to all the questions of the participant to my best of my ability
- I have provided a copy of the consent form to the participant

Name of Researcher / Research Assistant _____

Signature of researcher / Research assistant_____

Date _____

APPENDIX 7: INFORMED CONSENT FORM (Kiswahili version)

FOMU YA MAKUBALIANO YA KUJIUNGA NA UTAFITI

A randomized trial to compare suture with dressing for the closure of chest tube wound at the Kenyatta National Hospital

Idhini hii ya habari ni kwa wagonjwa wa kiwewe cha kifua ambao wanahitaji kuingizwa kwa bomba la kifua na baadaye kuondolewa katika Hospitali ya Kitaifa ya Kenyatta (KNH). Tunaomba wagonjwa washiriki katika utafiti ambao jina lake ni "**A randomized trial to compare suture with dressing for the closure of chest tube wound at the Kenyatta National Hospital**"

Mtafiti Mkuu: Dkt Obed Morara

Kituo: Idara ya Upasuaji, Kitivo cha Afya - Chuo Kikuu cha Nairobi

Wakufunzi Wakuu: Dkt. Mark Nelson Awori na Dkt. Nikita Mehta.

Fomu hii ya makubaliano ina sehemu tatu

1. Habari itakayo saidia kukata kauli
2. Sehemu ya makubaliano (pa kuweka sahihi)
3. Ujumbe kutoka kwa Mtafiti

SEHEMU YA KWANZA: HABARI KUHUSU UTAFITI

Utangulizi

Jina langu ni Dkt. Obed Morara, mwanafunzi wa shahada ya juu katika upasuaji wa Kifua, Moyo na Mishipa katika Chuo Kikuu cha Nairobi. Ninafanya utafiti ili kulinganisha matokeo kati ya mshono wa mikoba ya jadi, na mavazi ya jeraha katika kufungwa kwa njia ya shimo ya bomba la kifua huko KNH.

Kusudi la utafiti

Kwa sababu ya ukosefu wa makubaliano katika kufungwa kwa mkato wa bomba la kifua, malengo ya utafiti ni kulinganisha kwa matokeo ya mbinu mbili ili kutoa habari kuwezesha ukuzaji wa itifaki za kufungwa kwa mkato huu wa kifua.

Ushiriki wa masomo

Ninakualika kama mgonjwa wa shida ya kifua ambaye anahitaji uwekaji wa bomba la kifua kushiriki katika somo langu. Unapewa nafasi ya kuuliza maswali kabla ya kuamua. Ushiriki wako ni kwa hiari yako. Ukikubali kushiriki, utaombwa kutia saini fomu ya idhini. Hakuna malipo ya fedha yatakayofanywa kwa sababu ya ushiriki wako katika utafiti.

Faida za kushiriki

Kushiriki kwako katika utafiti huu kutatusaidia kutathmini mbinu mbili katika kufungwa kwa chale baada ya bomba la kifua chako kuondolewa. Hii itatuwezesha kupata habari ya kutuongoza juu ya mbinu ya kupendekeza katika itifaki zetu za baadaye.

Hatari za kushiriki

Kuna hatari ya hewa kuingia kifuani baada ya bomba la kifua kuondolewa. Uwezekano huu ni mdogo ikiwa mbinu sahihi imetumika. Katika tukio la hewa kuingia kifuani, bomba la pili la kifua linaweza kuwekwa. Unaweza kuwa na kovu lisilofurahisha kwenye chale. Unaweza kuwa na maambukizo kwenye chale. Unaweza kupata maumivu wakati wa kufungwa kwa jeraha. Hatari hizi zimeandikwa kuwa za chini kutoka kwa fasihi. Ikiwa kuna shida yoyote kwa wale walio kwenye mkono wa kuvaa, bima ya matibabu ya NHIF itafikia gharama za matibabu.

Haki ya kukataa au kujiondoa

Uko huru kujiondoa kwenye utafiti wakati wowote. Kukataa kushiriki au kujiondoa hakutasababishwa kunyimwa matibabu.

Usiri

Habari yoyote ambayo itapatikana kutoka kwako katika utafiti huu itakuwa ya siri. Majina yako yatafichwa.

Kushiriki matokeo

Maarifa yaliyopatikana kutoka kwa utafiti huu yatasambazwa kwa wataalamu wengine katika mikutano na machapisho. Wakati wote usiri utadumishwa.

Gharama na fidia

Hakuna gharama ya ziada itakayopatikana kutokana na ushiriki wako katika utafiti. Hakutakuwa na fidia.

Mawasiliano ya vyama husika

1. Mtafiti Mkuu

Dkt Obed Morara

Idara ya Upasuaji, Chuo Kikuu cha Nairobi

Sanduku la Posta 19676 - 00202, KNH, Nairobi

Simu ya Rununu: +254 725 569 168

2. Mtafiti Msaidizi

Dkt George Kinyanjui

Idara ya Upasuaji, Chuo Kikuu cha Nairobi

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Simu ya Rununu: +254 721 241 842

3. Mtafiti Msaidizi

Dkt Gilbert Lagat

Idara ya Upasuaji, Chuo Kikuu cha Nairobi

Sanduku la Posta 19676 - 00202, KNH, Nairobi

Simu ya Rununu: +254 734 497 711

4. Mtafiti Msaidizi

Dkt Hasan Mohammud

Idara ya Upasuaji, Chuo Kikuu cha Nairobi

Sanduku la Posta 19676 - 00202, KNH, Nairobi

Simu ya Rununu: +254 713 046 799

5. Mtafiti Msaidizi

Dkt Pravin Mokaya

Idara ya Upasuaji, Chuo Kikuu cha Nairobi

Sanduku la Posta 19676 - 00202, KNH, Nairobi

Simu ya Rununu: +254 721 925 646

6. Mtafiti Msaidizi

Dkt Jedidah Kimutai

Idara ya Upasuaji, Chuo Kikuu cha Nairobi

Sanduku la Posta 19676 - 00202, KNH, Nairobi

Simu ya Rununu: +254 720 559 758

7. Karani

KNH/UON ERC

Sanduku La Posta 20723-00202, Nairobi

Simu: 0202726300 Ext 44355

Barua Pepe: KNHplan@Ken.Healthnet.org

Wahadhiri Wasimamizi wa Utafiti

8. Dr. Mark Nelson Awori

Mhadhiri katika Kitengo cha Upasuaji wa Kifua na Moyo

Idara ya Upasuaji, Shule ya Afya, Chuo Kikuu cha Nairobi,

Sanduku la Posta 19676 KNH, Nairobi 00202.

Simu: 0202726300

9. Dr. Nikita Mehta

Mhadhiri katika Kitengo cha Upasuaji wa Kifua na Moyo

Idara ya Upasuaji, Shule ya Afya, Chuo Kikuu cha Nairobi,

Sanduku la Posta 19676 KNH, Nairobi 00202.

Simu: 0202726300

SEHEMU YA PILI: Fomu ya makubaliano

Mimi_____ kwa hiari yangu nimekubali kushiriki katika utafiti huu wenye mada "**A randomized trial to compare suture with dressing for the closure of chest tube wound at the Kenyatta National Hospital**"

Nimearifiwa na nimeelewa kuwa ushiriki wangu ni kwa hiari. Ninaelewa habari kuhusu utafiti na nimepata nafasi ya kuuliza maswali

Nina uhuru wa kujiondoa katika utafiti wakati wowote

Saini au Chapisha kidole gumba cha kushoto (Mgonjwa)

Tarehe _____

Taarifa ya shahidi (Kwa wagonjwa wasiojua kusoma na kuandika)

Nimeshuhudia usomaji wa fomu ya idhini kwa mgonjwa na amepata nafasi ya kuuliza maswali. Ninathibitisha kwamba ametoa idhini hiyo kwa uhuru

Jina la Shahidi _____

Saini _____ Tarehe_____

SEHEMU YA TATU: Ujumbe kutoka kwa Mtafiti

Nimesoma habari hiyo katika sehemu ya kwanza kwa mshiriki na kwa uwezo wangu nilibaini yafuatayo;

- Idhini ya mshiriki ni ya hiari.
- Kukataa kushiriki au kujiondoa kwenye utafiti hakutanyima utunzaji wa mgonjwa kama inavyotakiwa.
- Habari itakuwa siri.
- Matokeo ya utafiti yatachapishwa ili kushiriki maarifa ya mada ya utafiti
- Nimejibu maswali yote ya mshiriki kwa uwezo wangu wote
- Nimetoa nakala ya fomu ya idhini kwa mshiriki

Jina la Mtafiti / Jina la Mtafiti Msaidizi _____

Saini _____ Tarehe _____