DIAGNOSTIC VALUE OF ULTRASONOGRAPHY IN EVALUATION OF BLUNT ABDOMINAL TRAUMA BASED ON SURGICAL FINDINGS AT MTRH, ELDORET-KENYA.

BY

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A RESEARCH THESIS SUBMITTED TO THE SCHOOL OF MEDICINE COLLEGE OF HEALTH SCIENCES IN PARTIAL FULFILMENT OF THE AWARD OF THE DEGREE OF MASTER OF MEDICINE IN RADIOLOGY AND IMAGING OF MOI UNIVERSITY.

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DECLARATION

Student's Declaration

I declare that this is my original work and has not been presented in any other university or institution for an award of a degree or any academic credit. No part of this work may be reproduced or transmitted in any form without prior permission from the author or Moi University

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DEDICATION

To my loving wife Pauline for her overwhelming support. To my daughter Natalie who has been a source of inspiration. To my parents and my siblings for their unending encouragement, love and support, and above all the almighty God who has seen me through my entire life. I will always love you and am grateful for everything.

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LIST OF ABBREVIATIONS

BAT	Blunt Abdominal Trauma
CT	Computed Tomography
FAST	Focused Assessment with Sonography for Trauma
FN	False Negative
FP	False Positive
ICU	Intensive Care Unit
IREC	Institutional Research and Ethics Committee
KNH	Kenyatta National Hospital
MTRH	Moi Teaching and Referral Hospital
MVA	Motor Vehicle Accident.
NPV	Negative Predictive Value
PPV	Positive Predictive Value
RTA	Road Traffic Accident
TN	True Negative
TP	True Positive
US	Ultrasound

OPERATIONAL DEFINITIONS

Blunt abdominal trauma	Any injury sustained to the abdomen from a force without penetration into the abdominal cavity.
Diagnostic Value	Ability of a test to detect a condition when it is present and detect the absence of a condition when it is absent.
True Positive	Positive result on both ultrasound (test) and surgery (Gold standard)
True Negative	Negative result on both ultrasound (test) and surgery (Gold standard)
False Negative	Negative test result on ultrasound but positive result at surgery (Gold standard)
False Positive	Positive test result on ultrasound but negative result at surgery (Gold standard)
Negative Predictive Value	The probability of being disease free given a negative test result
Positive Predictive Value	The probability of disease given a positive test result
Sensitivity	Ability of a test to identify disease among those who have it.
Specificity	Ability of a test to exclude disease among those who do not have it.
Accuracy	Measure of validity that combines both sensitivity and specificity.

ABSTRACT

Background: Abdominal injuries rank third as a cause of traumatic death just after head and chest injuries. Rapid diagnosis and treatment is very vital. Evaluation of diagnostic value of ultrasonography is important to ascertain the reliability of ultrasound findings in blunt abdominal trauma in order to aid clinical decisions.

Objective: To determine ultrasound test findings and ascertain the diagnostic value of ultrasonography in evaluation of blunt abdominal trauma as confirmed by surgical findings at Moi Teaching and Referral Hospital, Eldoret, Kenya.

Methods: This was a cross -sectional study conducted at Moi Teaching and Referral Hospital between October 2016 and September 2017. A total of forty six patients who presented with blunt abdominal trauma and subjected to abdominal ultrasonography and subsequent surgery were enrolled. All the sonograms were performed by either the principal investigator or trained research assistant and images reviewed by two consultant radiologists. Ultrasound findings were documented and comparison done with surgical findings. Data was collected using structured questionnaire and analysis done using Stata/MP version 13 software. Categorical variables were summarized as frequencies and percentages while continuous variables as median and standard deviation. Association between categorical variables was assessed using Fisher exact test. A P-value of less than 0.05 was considered statistically significant. Results were presented using tables and charts.

Results: The mean age of participants was 30.3 years (SD 14.2). The most common ultrasound findings in blunt abdominal trauma was hemoperitoneum at 91.3 % followed by splenic injury and liver injury at 13.04 % and 10.87 % respectively. 8.7 % of participants had normal ultrasound findings. Ultrasound had a high sensitivity in detection of hemoperitoneum at 91.98 % with a specificity of 77.78 % and an overall diagnostic accuracy of 89.13%. Sonographic features of hemoperitoneum was significantly associated with surgical findings of organ injury ($p < 0.0001$, Fisher Exact test). Ultrasound had a low sensitivity of 37.5% in detection of parenchymal injuries with specificity of 78.57 % and an overall accuracy of 50 %.There was no significant association between sonographic features and surgical findings in detection of parenchymal injuries (p-value = 0.3306,Fisher Exact test**).**

Conclusion: Hemoperitoneum was the most common ultrasound finding in patients with blunt abdominal trauma. The diagnostic value of ultrasound was found to be high in the evaluation of hemoperitoneum with a sensitivity of 91.98% but low in evaluation of parenchymal injuries with a sensitivity of 37.5 %.

Recommendations: Routine use of sonography for evaluation of blunt abdominal trauma as part of primary survey. Use of additional diagnostic adjuncts in evaluation of parenchymal injuries.

CHAPTER ONE: INTRODUCTION

1.1 Background Information

Abdominal injuries rank third as a cause of trauma related death after head and chest injuries. Unrecognized abdominal injuries are frequently the cause of preventable death, which constitutes a significant diagnostic challenge to emergency physicians (Schneck, Koch et al. 2017)

Blunt Abdominal Trauma (BAT) accounts for about 80% of abdominal injuries seen in the Emergency Department (Nasr-Esfahani, Kolahdouzan et al. 2014) and is responsible for substantial morbidity and mortality.

The majority of BAT cases (75%) are due to Motor Vehicle Collisions or auto versus pedestrian accidents (Nasr-Esfahani, Kolahdouzan et al. 2014) .Blows to the abdomen and falls are responsible for 15% and 6-9% respectively. Occult BAT may occur with child abuse and domestic violence.

A study done in Nigeria (Oyinloye,2007) found that Road Traffic Accident (RTA) was the most common cause of BAT at 81.1 %. Others included assault (8%),sporting injuries(5.6%) and fall from heights at 4.4 %

A prospective study done in Uganda (Ruhinda, Kyamanywa et al. 2008) documented that abdominal trauma accounted for 14.23% of all trauma admissions and 4.8% of all admissions in Surgical department. BAT accounted for 85.7 % of abdominal trauma cases. Most injuries were as a result of RTA at 47.1 % and assault

In a study done at Kenyatta National Hospital (Musau, Jani et al. 2006), it was documented that the risk of dying from abdominal injury sustained from road traffic

accident was indeed fifteen times higher than that of dying from a stab wound on the abdomen (Musau, Jani et al. 2006)

In contrast to penetrating abdominal trauma, where management is largely determined clinically, the diagnosis of blunt abdominal injury by clinical examination cannot be relied upon, particularly in patients with a decreased level of consciousness (Myers 2007)

Confirmation of the presence or absence of injury therefore largely relies on the use of diagnostic adjuncts. Late diagnosis and missed injuries are associated with poor outcome. A large prospective observational study of patients with blunt polytrauma but with no clinical signs of injury found radiological evidence of abdominal injury in almost 10% of patients (Salim, Sangthong et al. 2006)

A recent American College of Radiologists consensus guideline suggest that there should be a low threshold for investigation of blunt abdominal trauma (ACR,2012)

Expeditious diagnosis of abdominal injury is a very important step in the treatment process to minimize /prevent morbidity or mortality in Blunt Abdominal Trauma cases. Rapid determination of patients in need of emergency surgery and the avoidance of unnecessary laparotomies with its invasiveness and complications should be considered appropriately (Mohammadi and Ghasemi-rad 2012).

In order to diagnose intra-abdominal injury from blunt trauma, Emergency Physicians and Trauma Surgeons have several options: Physical examination, laboratory tests, observation, Diagnostic Peritoneal Lavage, Ultrasound and Computed Tomography scan.

Physical examination and laboratory tests are not accurate in detecting intra-abdominal injuries. The presence of tenderness on palpation is neither sensitive nor specific for intra-abdominal injury; and cannot be relied upon in patients with loss of consciousness. Laboratory tests that indicate a fall in hematocrit levels more than 5% or abnormal liver function tests are questionable (Richards 1998)

Ultrasound is highly operator and technique dependent. Good multiplanar sonographic images rely on adequate understanding about the machine tributes, optimization of the image, and a precise transducer positioning (Checa 2018)

Skilled operators will be able in many instances to avoid or correct common artifacts and pitfalls. Also, profound knowledge about anatomy, anatomical variants, biomechanics, and elementary lesions are crucial in the interpretation of a sonogram.

Ultrasound is portable, non-invasive, rapid and relatively inexpensive. It is readily available in most facilities.

Some studies have criticized the rapid promotion of emergency FAST scanning, stating that there is insufficient evidence (Smith 2010)

However, other studies have shown it decreases time to disposition or operative intervention and reduces requirement for CT scanning (Melniker, Leibner et al. 2006)

This study seeks to describe the abdominal ultrasound findings in blunt abdominal trauma patients and perform a comparison of the ultrasound findings and intra operative findings in order to ascertain the diagnostic value at MTRH.

1.2 Problem Statement

Ultrasound is portable, non-invasive, rapid and relatively inexpensive. It is readily available in most facilities.

However, the extent to which ultrasound findings in BAT can be relied upon has been a subject of great controversy in literature, despite its advantages (Smith 2010).

This study aimed to ascertain the extent to which ultrasound findings in patients with BAT can be relied upon in planning the course of management for these patients in MTRH

1.3 Study Justification

Missed abdominal injuries are a frequent cause of morbidity and late mortality in patients who survive the early period after injury.

Some studies have criticized the rapid promotion of emergency Focused Assessment with Sonography for Trauma (FAST), stating that there is insufficient evidence to support the adoption of Ultrasonography based clinical pathways in the assessment BAT.

However, this has been contested by other studies which have shown FAST decreases time to disposition or operative intervention, reduces requirement for CT scanning and reduces complication rates and length of hospital stay.

Furthermore, there is paucity of local data on the diagnostic value of abdominal ultrasonography in evaluation of blunt abdominal trauma patients.

An established diagnostic value will inform the use of abdominal ultrasound in BAT and form baseline local data for future studies.

1.4. Research Questions

This study sought to answer the following questions

1. What are the ultrasound findings in patients with blunt abdominal trauma at MTRH?
2. What is the diagnostic value of abdominal ultrasound in evaluation of blunt abdominal trauma based on surgical findings at MTRH?

1.5. Research Objectives

1.5.1. Broad Objective

To describe ultrasound findings and determine the diagnostic value of abdominal ultrasound in evaluation of blunt abdominal trauma based on surgical findings at MTRH.

1.5.2. Specific Objectives

1. To describe ultrasound findings in BAT patients at MTRH.
2. To determine the diagnostic value of ultrasound based on intraoperative findings in evaluation of BAT at MTRH

CHAPTER TWO: LITERATURE REVIEW

2.1 Epidemiology

Trauma is a leading cause of mortality worldwide; it is the leading cause of death in the young adults and accounts for 10% of all deaths among men and women. In the United States, more than 500 Million patients receive medical care for trauma annually and trauma accounts for approximately 30% of all Intensive Care Unit admissions (Kauvar and Wade 2005).

Blunt abdominal trauma accounts for the majority (80%) of abdominal injuries seen in the Emergency Department (Nasr-Esfahani, Kolahdouzan et al. 2014) and is responsible for substantial morbidity and mortality.

A study done in Nigeria (Oyinloye 2007) found that Road traffic Accident was the most common cause of Blunt abdominal injury at 81.1 %.Others included assault (8%),sporting injuries(5.6%) and fall from heights at 4.4 %.

A prospective study done in Uganda on abdominal injury at Mbarara Regional Referral Hospital (Ruhinda, Kyamanywa et al. 2008) found that Abdominal trauma accounted for 14.23% of all trauma admissions and 4.8% of all admissions in Surgical department. Blunt abdominal injury was the most common at 85.7 %.

The risk of dying from abdominal injury sustained from Road Traffic Accidents was fifteen times higher than that of dying from a stab wound on the abdomen.(Musau, Jani et al. 2006)

2.2 Diagnosis of Blunt Abdominal Trauma

Rapid diagnosis of abdominal injury is an important step in the treatment process to prevent morbidity or mortality in BAT cases. Rapid determination of cases in need of emergency laparotomy is crucial for life saving.

The avoidance of unnecessary surgeries with its invasiveness and complications should be considered (Mohammadi and Ghasemi-rad 2012).

2.2.1 Diagnostic Peritoneal Lavage (DPL)

Diagnostic peritoneal lavage was first described in 1965 and rapidly became the standard of care in blunt abdominal trauma. It has shown sensitivity for intraperitoneal hemorrhage, as great as 95%, almost equal to Ultrasound (Pathan 2005).

It is inappropriate for stable and awake patients; it is also an invasive procedure requiring substantial amount of time and effort (Biffl and Leppaniemi 2015)

The biggest limitation of diagnostic peritoneal lavage is the resulting high non-therapeutic laparotomy rate of up to 36% (Pathan 2005).

2.2.2 Abdominal CT scan.

There has been a doubling of patient exposure to ionizing radiation in the last two decades in the United States (de González, Mahesh et al. 2009) .

In abdominal CT effective radiation dose is the equivalent of 400 chest x-rays and the equivalent of 2.7 years' worth of natural radiation dose (Fleming, Bird et al. 2012)

Thus, in addition to increasing concerns about the rising cost of diagnostic imaging, there is growing and justifiable concern regarding health risks of radiation exposure.

Previous studies reported an incidence of missed abdominal injuries on Focused Abdominal CT for trauma between 0.06 – 15 % (Schneck, Koch et al. 2017)

In addition, the need to transfer the patient to the scanner from the emergency department, makes it unsuitable in unstable patients.

Pediatric patients often require sedation, which, means constant monitoring for risk of airway compromise.

Abdominal CT's are able to detect solid organ injury, however a large study by Fakhry et al in 2003 showed that nearly 15% of patients with perforated small bowel injury had a normal pre-operative CT scan ,so they are not without limitation (Fakhry, Watts et al. 2003)

The Food and Drug Administration has recently proposed a national initiative to reduce radiation exposure from unnecessary imaging. In developing countries, the cost implications of CT scans could be prohibitive to patients who might require it.

2.2.3 Abdominal Ultrasonography

Kristensen et al described the use of ultrasound scanning in the diagnosis of abdominal trauma (Kristensen, Buemann et al. 1971).

After that, the use of ultrasound in abdominal trauma grew gradually, and the term 'focused abdominal sonography for trauma' (FAST) scan has been used since the early 1990s

It is undertaken after the primary survey in order to identify the presence of free fluid in the peritoneal cavity, which may represent hemoperitoneum, and thus enable early referral for further imaging (CT), and/or surgery if necessary (Smith 2010).

Ultrasound has many qualities which make it an attractive initial screening method for intraabdominal injury. It is portable, non-invasive, rapid and relatively inexpensive, requires no oral or parenteral radio contrast. It can be performed during trauma resuscitation.

With appropriate training, Focused abdominal sonography for trauma can be performed by non-radiologists (Patelis, Theofanis et al. 2011)

Focused Abdominal Sonography for Trauma (FAST) is used and can be completed within 5 minutes and involve 5 views.

- Subxiphoid transverse view: assess for Left lobe liver injuries
- Longitudinal view of the right upper quadrant: assess for right liver injuries, right kidney injury, and Morison pouch
- Longitudinal view of the left upper quadrant: assess for splenic injury and left kidney injury
- Transverse and longitudinal views of the suprapubic region: assess the bladder and pouch of Douglas

(Adopted from the American Institute of Ultrasound in Medicine, 2014)

Extended FAST (E-FAST) in addition to standard FAST, evaluates for the presence of fluid in the pleural and pericardial cavity. This examination is also be used to evaluate the lungs for pneumothorax.

2.2.3.1 Ultrasound findings in blunt abdominal trauma.

Hemoperitoneum is the most common ultrasound finding in patients with intra-abdominal injury. Indeed, ultrasound is quite sensitive for detection of free fluid.

In a study done by Nnamonu et al in Nigeria, abdominal Ultrasound was able to detect intraperitoneal free fluid in 49 patients out of the studied 57 (86%) (Nnamonu, Ihezue *et al.* 2013)

In a similar study done by Boutros eta al in 2016,ultrasound was able to detect free fluid in all 15 patients with intra-abdominal injuries (Boutros, Nassef et al. 2016).

The amount of intraperitoneal fluid required for ultrasound detection remains unclear. Different studies have shown that a minimum of 100-600 cc of fluid is detectable by US exam (Gracias, Frankel et al. 1998) but is widely regarded as 500 cc.

The spleen is the most commonly injured organ in blunt abdominal trauma.

The most common pattern of laceration is diffuse heterogeneous appearance,

Other patterns include discrete hyperechoic or hypoechoic regions and hyperechoic or hypoechoic peri-splenic rim or crescent, representing a clot often surrounds the spleen (Pathan 2005)

Renal hematomas and lacerations can be identified and delineated on ultrasound, but are more likely to be picked on sonography with severe (grade II or greater) renal injuries (Miller and McAninch 1995).

Richards et al has observed that sonography may also reveal blunt hepatic injury with three distinct patterns (Richards, McGahan et al. 1999).

The most common US pattern observed was a discrete hyperechoic area. Other patterns included diffuse hyperechoic pattern and a discrete hypoechoic pattern. An echogenic clot often surrounds the liver, and hypoechoic fluid may be in other portions of the abdomen. Hepatic lacerations appear more hypoechoic or cystic when they are scanned days after the initial injury

It is fairly well established that a positive US result in a hemodynamically unstable patient can be effective in directing patients toward definitive care and reduce morbidity and mortality in such patients (Richards and McGahan 2017).

In the study by Holmes et al, the use of negative FAST examination results successfully reduced physician concern for intra-abdominal injury (Holmes, Kelley *et al*. 2017).

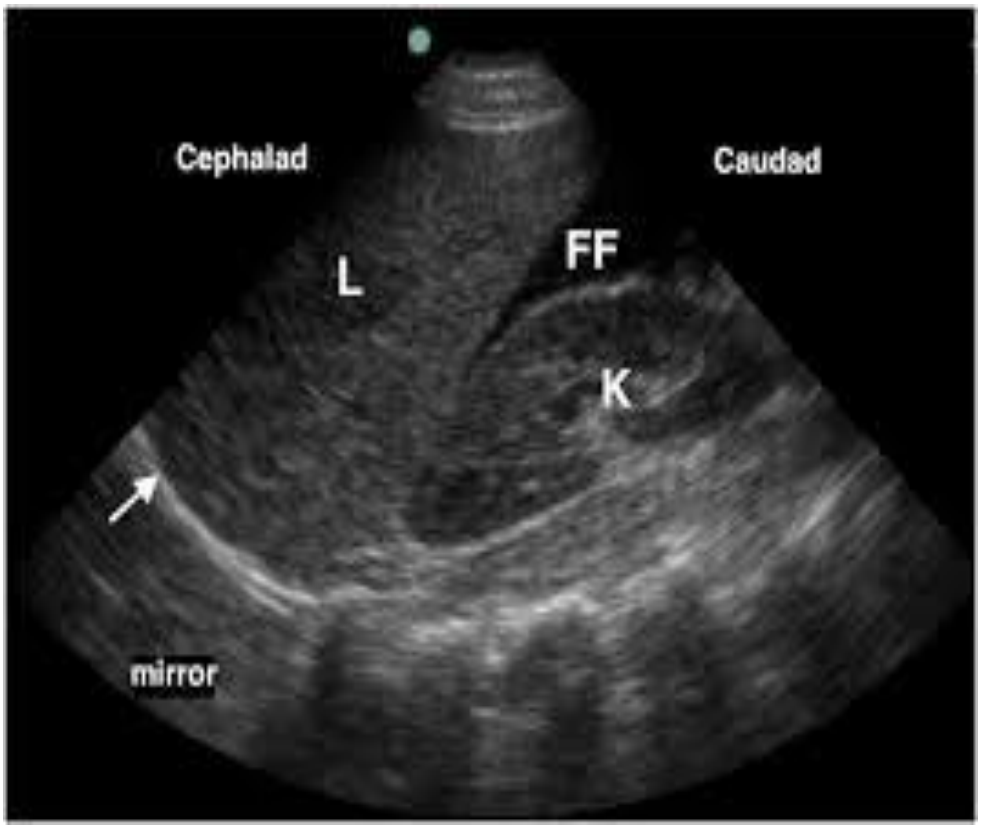

Figure 1: Right upper quadrant view depicting a positive FAST scan with free fluid visible in Morrison's pouch.
Source: www.radiopaedia.org

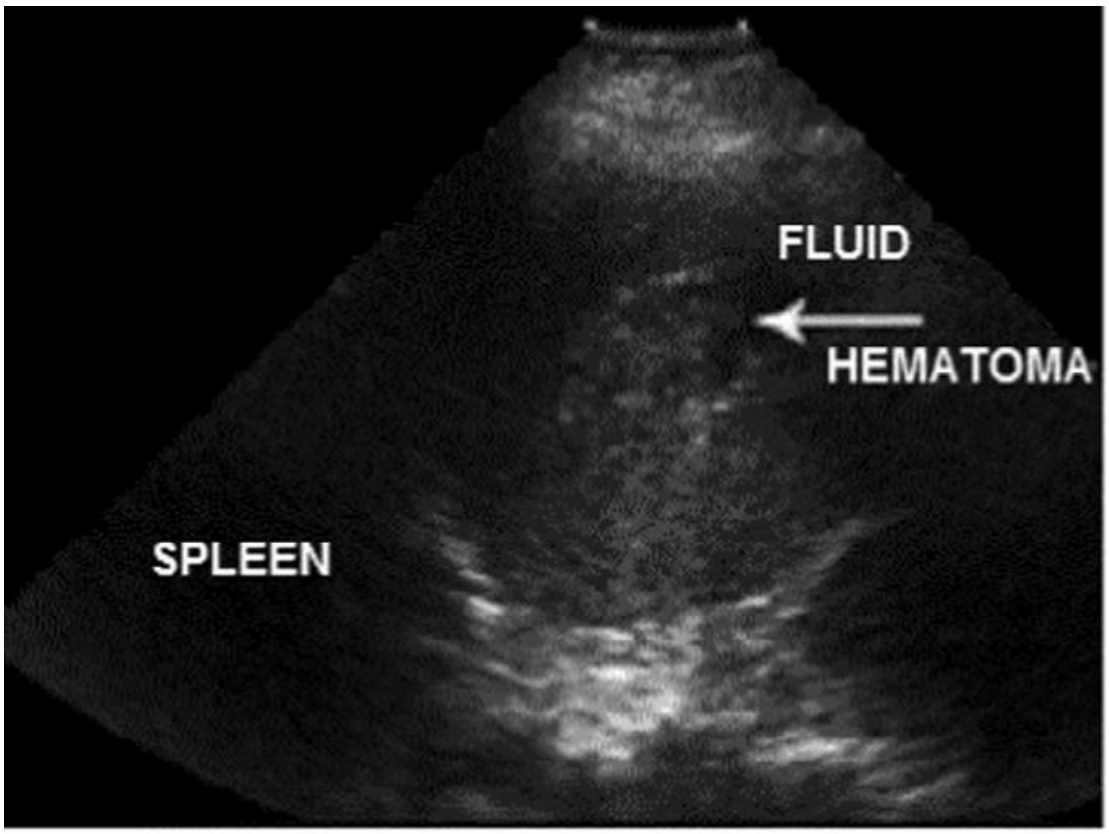

Figure 2: Male patient 26 years old presented to the ER with BAT following fight. FAST examination performed at the time of presentation showed Upper pole of the spleen iso to hypoechoic area measuring 1 cm in its maximum diameter (hematoma) and minimal free fluid at the splenorenal angle.
Source: (Boutros, Nassef et al. 2016)

2.2.3.2 Diagnostic value of ultrasound in evaluation of blunt abdominal trauma.

A study done in Nigeria showed ultrasound sensitivity of 95% in detecting hemoperitoneum following blunt abdominal trauma and a specificity of 98%, ruling out presence of intraperitoneal injuries arising from blunt abdominal trauma and prevent the need for unnecessary laparatomies (Oyinloye 2007).

In a study performed by Lingawi and Buckle on 1090 patients, the sensitivity, specificity, positive and Negative Predictive values for FAST were reported as 94%, 98%, 78% and 100% respectively (Lingawi and Buckley 2000). Similar results were

reported by Foo et al in 2001 showing sensitivity and specificity of 86% and 92% respectively and Positive and Negative Predictive values of 89% (Foo, Su et al. 2001)

Chiu et al raised valid concerns regarding the sensitivity of FAST. Their study showed 50 out of 196 patients with free fluid on CT did not have detectable fluid on FAST scan (Chiu, Cushing et al. 1997)

In addition, Natarajan et al could only report 41% sensitivity in a retrospective study of 2980 patients, specificity reported as 99% (Natarajan, Gupta et al. 2010)

McGahan et al in a study of 500 patients, compared ultrasound findings with laparotomy and abdominal CT scan in hemoperitoneum and organ injuries. They found ultrasound sensitivity of 63% and specificity of 95% in detecting these particular injuries (McGahan, Rose et al. 1997)

Smith argues that FAST is a limited triage tool, whose actual value in the diagnostic and treatment pathway of patients with BAT remains questionable, and more data are needed to justify its use in the light of recent developments (Smith 2010)

Rhea et al opines that if a BAT patient is unstable, US is beneficial in screening for certain injuries or large hemoperitoneum prior to an exploratory laparotomy.(Rhea, Garza et al. 2004)

In hemodynamically unstable blunt trauma patients, with clear physical findings on examination, the decision for exploratory laparotomy should not be distracted by a negative FAST (Carter, Falco et al. 2015)

Some posit that it has a limited diagnostic accuracy and could engender undue delay in intervention in some patients who turn out to be false negatives (Nnamonu, Ihezue et al. 2013)

However, this has been contested by others, which include a randomized controlled trial comparing the use of FAST scanning with clinical assessment alone (Melniker, Leibner et al. 2006) .Such studies have shown FAST decreases time to disposition or operative intervention by 64–76%, reduces the requirement for CT scanning and decreases complication rates and length of hospital stay.

For detection of visceral organ injuries, Simon Fleming et al found a sensitivity of abdominal ultrasound at 38.5% (Fleming, Bird et al. 2012)

However Catalano et al argue that detection of visceral organ injury (traditionally a weakness of the FAST examination) is also improving with better imaging technology and the method of contrast-enhanced ultrasound, which may be an important part of future algorithms (Catalano, Aiani et al. 2009)

Furthermore, a negative ultrasound examination cannot completely rule out the possibility of intra-abdominal injury. Up to 28 % of patients with intra-abdominal injury from BAT may have no hemoperitoneum identified on ultrasound (Benya, Lim-Dunham et al. 2000)

Shanmuganathan et al found that more than 25% of patients with visceral injuries did not have free fluid on FAST scan taken on admission (Shanmuganathan and Mirvis 1998)

These great controversies in literature and conflicting results brings into question the reliability of abdominal ultrasound results in evaluation of blunt abdominal trauma, which the study aims to address

CHAPTER THREE: MATERIALS AND METHODS

3.1 Study Design

A cross-sectional study was done within a period of one year from 1st October 2016 to 30th September 2017. Patients with blunt abdominal trauma who had undergone abdominal sonography and scheduled for subsequent surgery were recruited and their surgical findings followed up by the investigator.

To evaluate the reliability of sonography findings, surgical findings were used as the gold standard in assessment of hemoperitoneum and specific visceral organ injuries within twenty four hours from the time of injury.

3.2 Study Site

This study was conducted at Moi Teaching and Referral Hospital (MTRH) Casualty Departments, Surgical Wards in conjunction with Radiology and Imaging Departments.

The Hospital is located in Eldoret town, which is 350 Kilometers Northwest of the Capital Nairobi. MTRH is a tertiary (level 6) health facility serving as a teaching hospital for Moi University School of Medicine, Public health and Dentistry. Others include Kenya Medical Training Center (KMTC), Eldoret and University of Eastern Africa Baraton School of Nursing. MTRH is also a training center for medical, clinical and nursing officer interns. It is the referral hospital for the Western part of Kenya and North rift and has a catchment population of approximately 13 million people. The facility has several departments including Surgery, Pediatrics and Radiology and Imaging among others.

3.3 Study Population

The study population comprised patients presenting with Blunt abdominal trauma during the period 1st October 2016 to 30th September 2017 and subjected to abdominal Ultrasonography and laparotomy at Moi Teaching and Referral Hospital.

3.4 Eligibility criteria

3.4.1 Inclusion Criteria

1. Patients presenting with blunt abdominal trauma within twenty four hours after injury who were subjected to abdominal Ultrasonography, subsequent laparotomy and consented to be part of the study.

3.4.2 Exclusion Criteria

1. Patients referred to the hospital with definitive diagnosis of hemoperitoneum or specific solid organ injury.

2. Patients with known co-morbid conditions associated with ascites e.g. heart failure, cirrhosis, renal failure

3.Patients who declined to consent

4.Patients who present 24 hours after blunt abdominal trauma

3.5 Sampling Techniques

Sample size was calculated using the Buderer formula (Buderer 1996). According to Buderer, sample size is calculated using either sensitivity or specificity depending on which one gives the higher sample size.

Sample size (n):

$$= \frac{Z^2_{1-\alpha/2} \times S_N \times (1 - S_N)}{L^2 \times \text{Prevalence}}$$

Where n = sample size

$z_{1-\alpha/2}$ = standard normal deviation corresponding to the specified size of the critical region (α)

α = size of the critical region (1 – α is the confidence level),

S_N = anticipated sensitivity/ specificity, and

L = absolute precision desired on either side (half-width of the confidence interval) of sensitivity or specificity.

The confidence level was set at 95%, power at 80% and precision at 10%.

The sensitivity and specificity of ultrasound examination 95% and 98% respectively obtained from a similarly designed study was used (Oyinloye 2007).

A prevalence of 40.1 % was used; based on the prevalence of intra-abdominal injury on ultrasound in BAT from a Nigerian study (Oyinloye 2007).

A sample size of 46 was obtained.

Consecutive sampling method was be used in this study until the desired sample size is obtained.

This method has been chosen due to the number of cases seen in the previous year.

In the year 2015, a total number of 55 cases underwent abdominal ultrasonography and subsequent surgery for blunt abdominal trauma.

3.6 Study Procedure

Figure 3 below presents the patient recruitment schema. Patients with blunt abdominal trauma and referred for ultrasound evaluation were scanned. Thereafter, potential study participants who had undergone scanning and were admitted for surgery were identified in the surgical ward. Verbal consent was obtained to review clinical records for surgical and sonography findings. If the patient met the eligibility criteria, informed consent to be recruited into the study was obtained

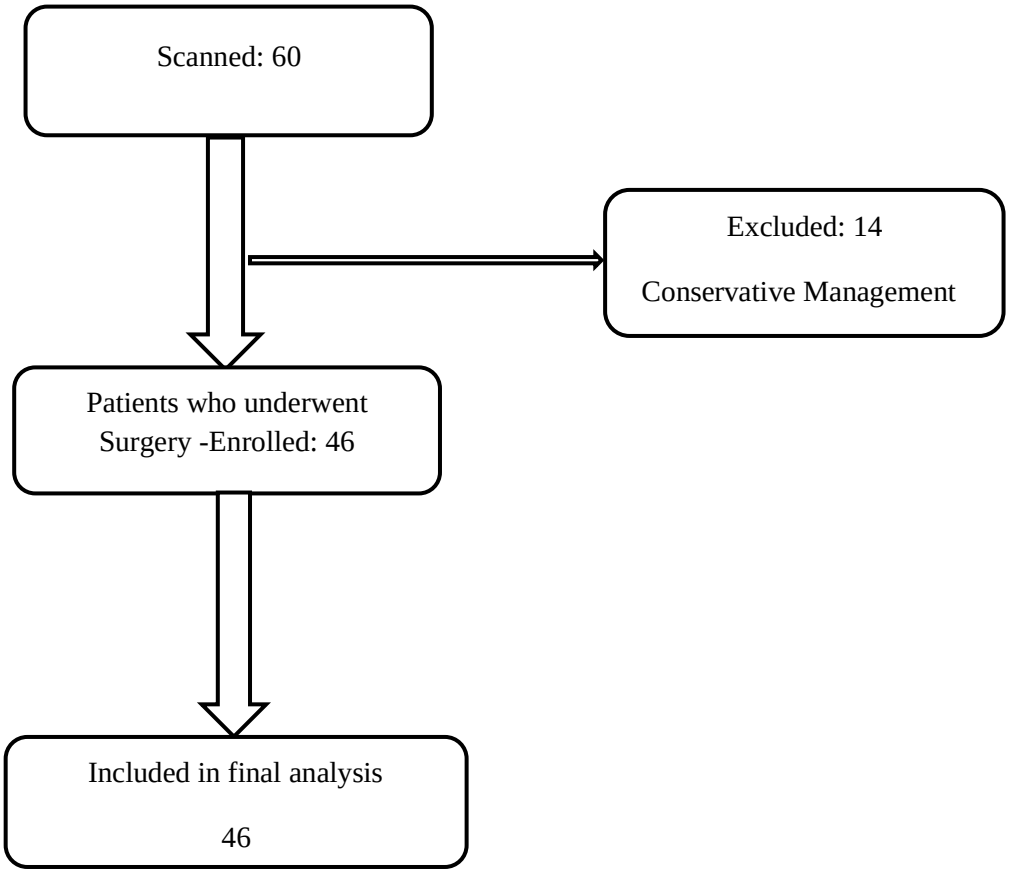

Figure 3: Study Recruitment Schema

3.7 Sonographic Examination Procedure

All the examinations were performed by the principal investigator or by a trained assistant on duty using Mind Ray M7 Portable Ultrasound machine model 2014 with 3.5-5.0 MHz convex transducer.

The examinations were performed in supine position, in an enclosed room that afforded privacy.

- Five regions of the abdomen were scanned ((*Adopted from the American Institute of Ultrasound in Medicine, 2014)*

- subxiphoid transverse view: assess for left lobe liver injuries
- longitudinal view of the right upper quadrant: assess for right liver injuries, right kidney injury, and Morison pouch
- longitudinal view of the left upper quadrant: assess for splenic injury and left kidney injury
- transverse view of the suprapubic region: assess the bladder and pouch of Douglas
- Longitudinal views of the suprapubic region: assess the bladder and pouch of Douglas.

The aim was to identify intra-abdominal free fluid (assumed to be haemoperitoneum in the context of trauma) and document any subcapsular fluid collection together with solid organ injuries identified..

All positive results were compared with intra-operative findings.

Negative results were followed up in the wards and laparotomy findings documented for those who underwent subsequent surgery.

3.8 Data Collection and Management

3.8.1 Data Collection.

Data was collected between October 2016 and November 2017. Entry was made in the questionnaires and later transferred to a computer database. Double entry was used to ensure accuracy of the data. All patient details were kept confidential and data was only available to the investigator and the supervisors via password access. Patients had a copy of their results and had autonomy over who else can view their scan result(s). Serial numbers were used in order to protect patients' identity. At the end of each day data collection forms were verified for completeness and coded (assigning numerical meanings).

3.8.2 Quality Control

All Ultrasound scans were done at MTRH Ultrasound room that has internal quality controls. The internal controls encompass purchase of ultrasound machines, setting up, service , and regular calibration to achieve desired resolution at all times.. The scans were done by the Principal Investigator conducting the study plus two other trained assistants based on a standardized evaluation criteria. Images were then reviewed by two consultant radiologists.

The findings of the surgical procedures were obtained from the Surgery department from the theatre notes and clarity sought from the lead surgeon when the findings are not clear. These were recorded accordingly. The comparison between the two was then done and recorded appropriately.

3.8.3 Data Analysis and Presentation

Data analysis was conducted using STATA/Multiprocessing Version 13 software.

The results of abdominal scans were analyzed and compared with intra operative findings. Descriptive statistics and sensitivity, specificity, and accuracy were calculated.

Frequency tables were generated for categorical variables.

Fisher's exact test was used to test for strength of association between ultrasound findings and laparotomy findings.

P-value less than 0.05 was considered significant at the 95 % confidence.

Data was presented in terms of graphs and tables.

3.9 Ethical Considerations

Approval of this study was granted by the hospital's Institutional Research and Ethics Committee (IREC) Board.

All patients/guardians were informed about the study and the procedures involved in the study and the possible benefits and harm to them and that the procedure is generally safe.

Regarding the necessity of the investigation for management of the patient, consent was sought from the hospital management and IREC to allow studying of the sonograms of the patients who have undergone evaluation. All patients received medical attention as necessary regardless of their willingness/unwillingness to participate in the study. No incentives or inducements were used to convince patients to participate in the study.

Patients were informed of their results and appropriate standard treatment given. Confidentiality was maintained throughout the study.

The data collection forms used neither contained the names of the patients nor their personal identification numbers. Data collecting material were kept in a locked cabinet during the study period.

The results of the research will be presented to the Hospital's management and the university's department of Radiology and Imaging and department of Surgery for use as necessary.

It will also be available for academic reference in the College of Health Sciences Resource Centre. The results of this research shall be published in a reputable journal of medicine for use by the wider population in the general improvement of patient management and as a reference for future studies.

CHAPTER FOUR: RESULTS

4.1 Demographics of the Participants

A total of 60 participants were screened for eligibility into the study. Of these, 46 were successfully consented and enrolled. The remaining 14 were excluded after undergoing conservative management successfully.

The ratio of males to females was 4.7:1 (females 17.4%, males 82.6%). The age of the patients ranged from 12 years to 72 years with mean of 30.3 (SD 14.2) years, 50% of the patients were aged above 27years.

Table 1: Demographic characteristics of participants

Age	Frequency	Percent
<16yrs	4	8.7
16-30yrs	21	45.65
31-45yrs	17	36.96
46-60yrs	2	4.35
	2	4.35
Total	46	100

4.2 Cause of injury

The various causes of injury are summarized in Figure 3.As illustrated, road traffic accidents were the most common cause at 56.5%, followed by assault at 26 %.The other causes were sporting and fall from height.

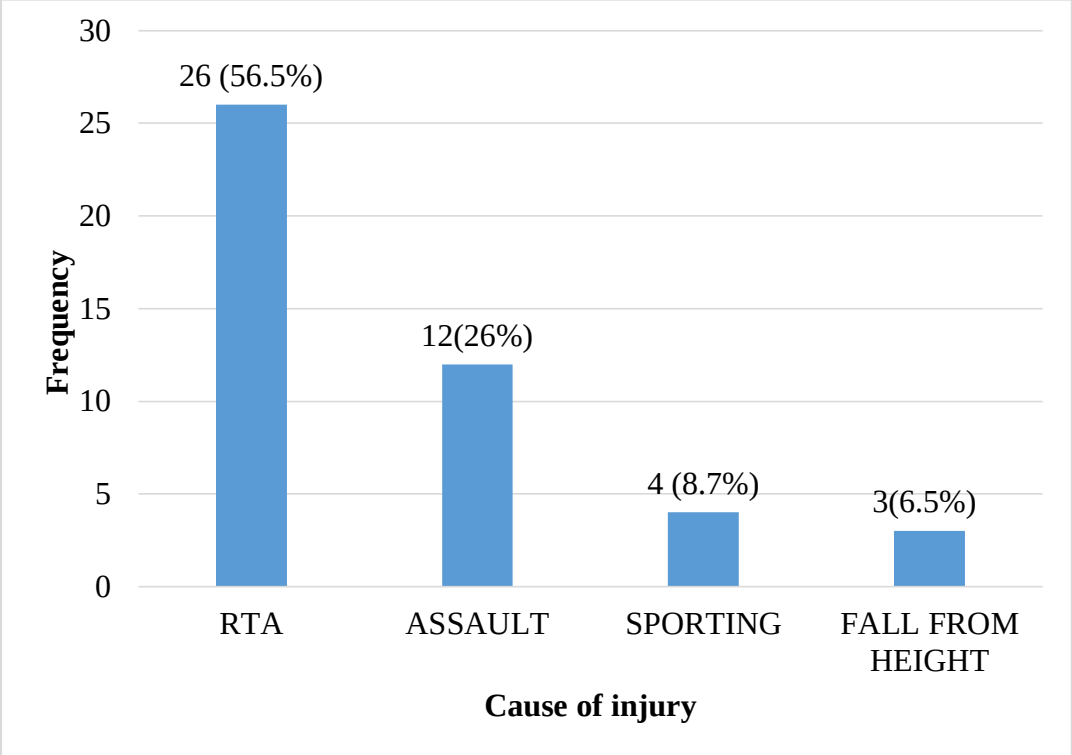

Figure 4: Bar chart showing cause of Injury

4.3 Ultrasound findings

Table 2 shows the various ultrasound diagnoses made. The most common ultrasound finding was hemoperitoneum at 91.3 %.

The most common solid organ injury diagnosed on ultrasound was splenic injury at 13% followed by liver injury.

Four patients (4.8 %) had normal ultrasound findings.

Table 2: Ultra Sound Findings (n=46)

Diagnosis	**Frequency**	**Percentage**
Normal	4	8.70
Hemoperitoneum	42	91.30
Splenic hematoma	3	6.52
Splenic contusions	3	6.52
Liver subcapsular hematoma	3	6.52
Liver contusions	2	4.35
Renal Lacerations	2	4.35
Renal hematoma	2	4.35
Bladder rapture	1	2.17
Bladder hematoma	2	4.35

4.5 Comparison of ultrasound findings and surgical findings-hemoperitoneum

Ultrasound reported a high sensitivity in detection of hemoperitoneum at 91.98 %. Specificity was at 77.78 % with an overall diagnostic accuracy of 89.13%.

In this study False Negatives in evaluation of hemoperitoneum were at **6.5%** (n= 3) while False positives were **4.3%** (n=2).

Table 3: 2x2 Table showing Ultra Sound test result against Intra-op findings (Gold standard) in relation to Hemoperitoneum.

US FINDINGS (TEST)		**SURGICAL FINDINGS (GOLD STANDARD)**	
		YES	NO
	YES	34 (TRUE POSITIVES)	2 (FALSE POSITIVES)
	NO	3 (FALSE NEGATIVE)	7 (TRUE NEGATIVES)

Table 4: Comparison of Ultra Sound and Intra-op (Hemoperitoneum).

TP	**FN**	**FP**	**TN**	**Sensitivity**	**Specificity**	**PPV**	**NPV**	**Accuracy**	**P-Value**
34	**3**	**2**	**7**	**91.89%**	**77.78%**	**94.4%**	**70%**	**89.13%**	**<0.001**

Fisher's exact test shows that Ultrasound test result of hemoperitoneum is significantly associated with hemoperitoneum finding at surgery. The two-tailed P value is less than **0.0001** . This is considered to be statistically significant.

4.6 Comparison of ultrasound findings and surgical findings-Visceral organ injuries

Ultrasound reported a low sensitivity of 37.5% in detection of visceral parenchymal injuries. Specificity was at 78.57 % with an overall accuracy of 50 %. This was not statistically significant, with a p-value of 0.3306

In our study 20 patients (43.6%) had False Negative results on evaluation of visceral parenchymal injuries.

Out of these 4 patients had normal ultrasound findings, later discovered to have intestinal lacerations (2) and mesenteric hematomas (2).

The remaining 16 patients had hemoperitoneum as the ultrasound diagnosis, with no specific visceral organ injuries identified.

Table 5: 2x2 table showing Ultra Sound test results against Surgical findings (Gold standard) in relation to Visceral Organ Injuries.

US FINDINGS (TEST)		**SURGICAL FINDINGS (GOLD STANDARD)**	
		YES	NO
	YES	12 (TRUE POSITIVES)	3 (FALSE POSITIVES)
	NO	20 (FALSE NEGATIVE)	11 (TRUE NEGATIVES)

Table 6: Comparison of Ultra Sound and Surgical findings (Visceral Parenchymal Injuries).

TP	FN	FP	TN	Sensitivity	Specificity	PPV	NPV	Accuracy	P-Value
12	**20**	**3**	**11**	**37.5%**	**78.57%**	**80%**	**47.83%**	**50%**	**0.336**

The two-tailed **P value equals 0.3306** .This is considered to be not statistically significant.

SONOGRAPHIC SAMPLE IMAGES

Figure 5: Case of a 28 year male with history of abdominal pain following MVA. There is significant free fluid in the Morrison's pouch, diagnosed as hemoperitoneum.

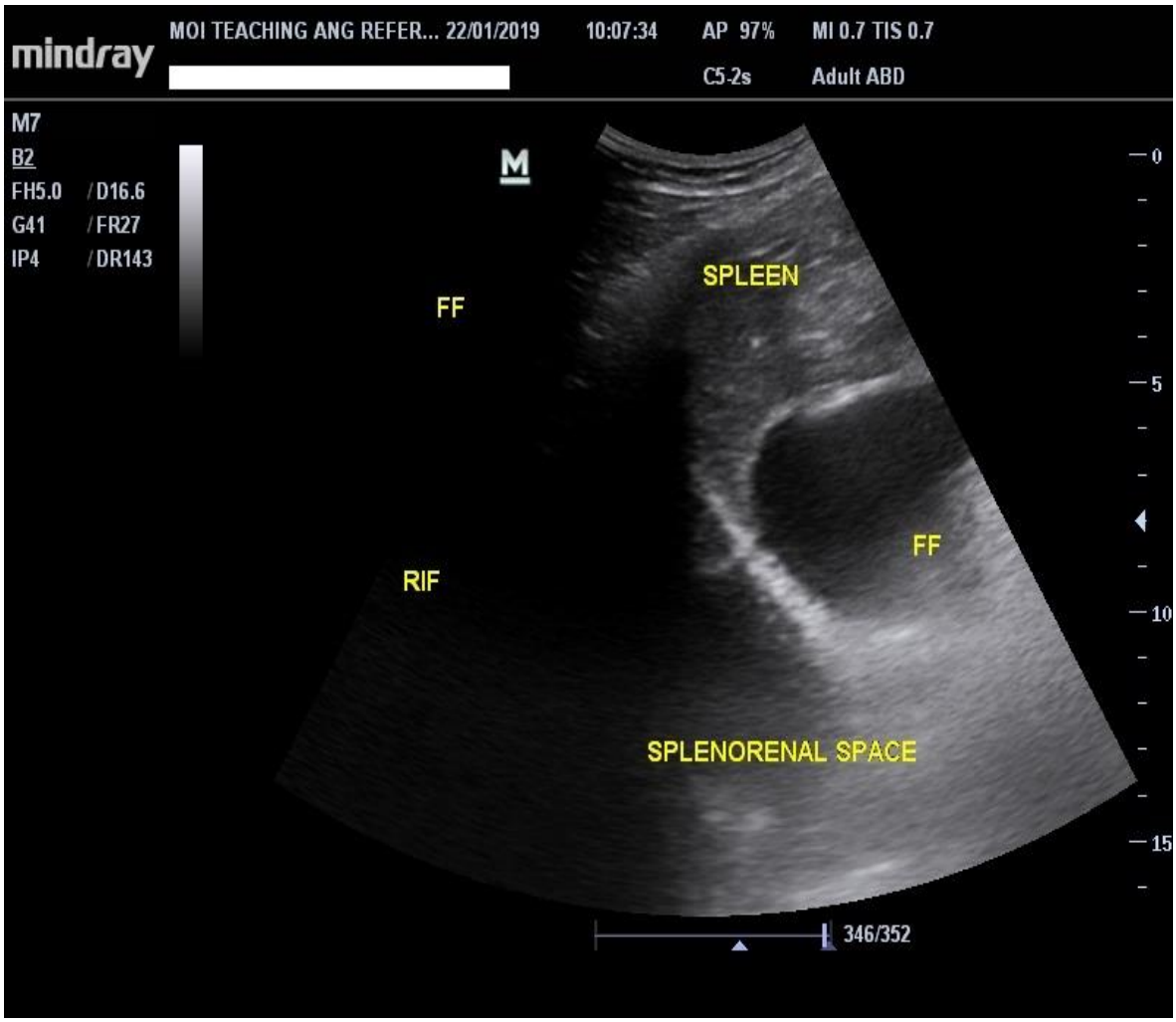

Figure 6: Case of a 36 year male with history of abdominal pain following MVA. There is significant free fluid in the Splenorenal space, diagnosed as hemoperitoneum.

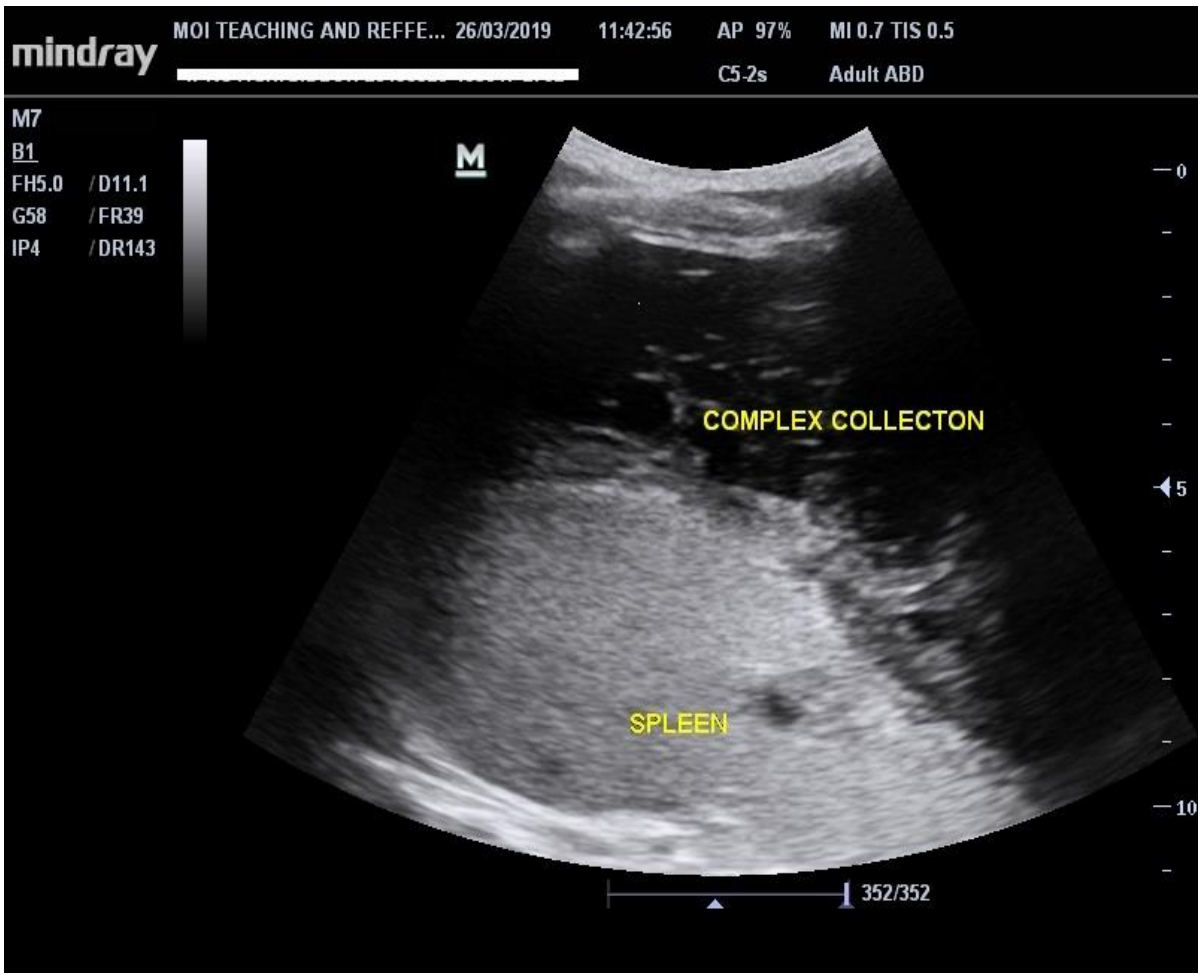

Figure 7: Case of a 36-year male with history of fall from height. There is peri-splenic fluid collection with splenic hematoma.

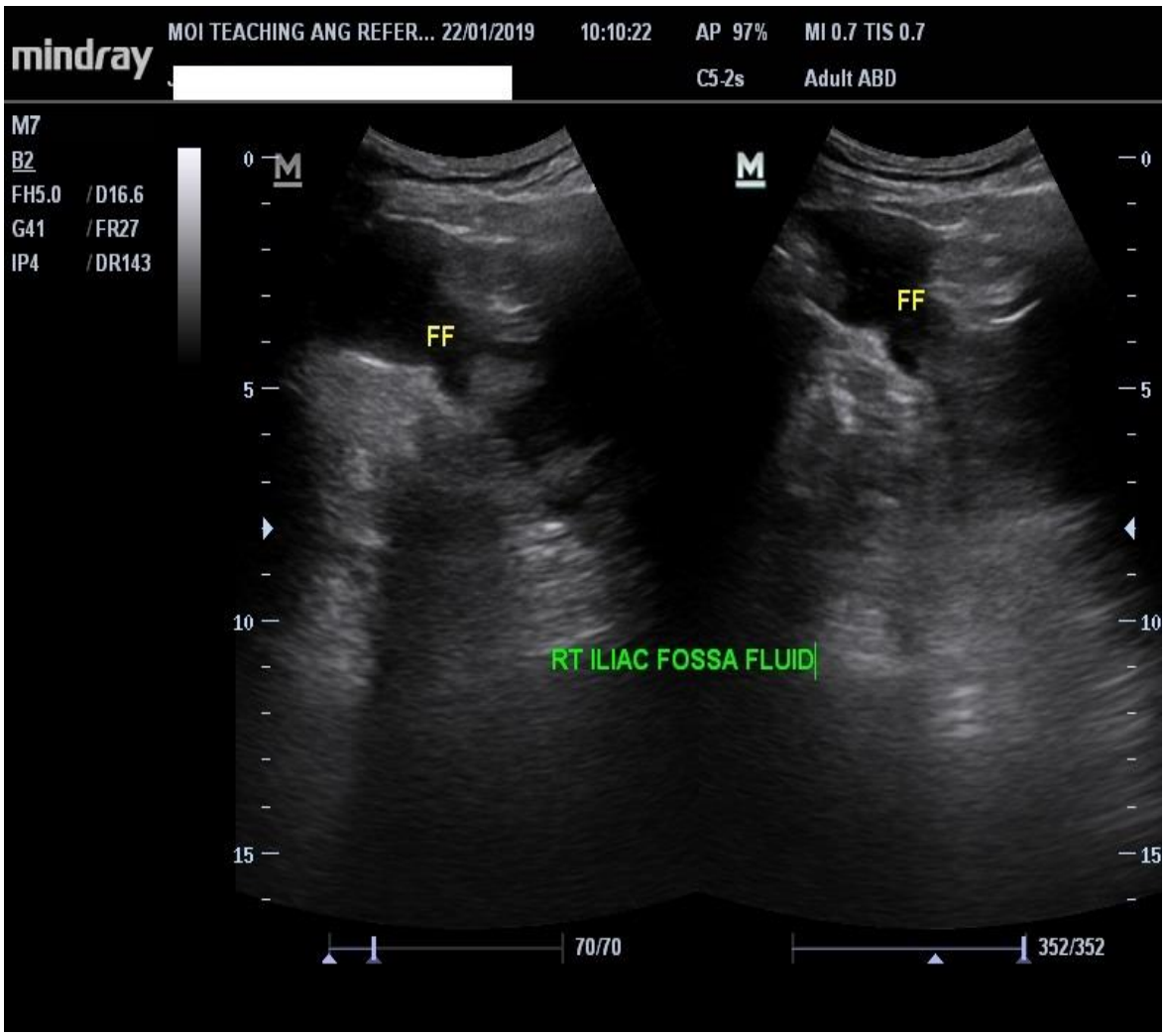

Figure 8: Case of a 43-year male with history of MVA. There is right iliac fossa fluid collection diagnosed as hemoperitoneum.

CHAPTER FIVE: DISCUSSION

5.1 Introduction

The purpose of this study was to determine the diagnostic value of abdominal sonography in comparison to surgical findings in the evaluation of blunt abdominal trauma.

Ultrasound has been found to be a fast, portable, non-invasive and cost effective modality that if clinically indicated, at regular can be used at the bedside to detect hemoperitoneum (Smith 2010)

Organ injury can be diagnosed by abdominal ultrasound in addition to identification of free fluid which could be blood, intestinal secretions or urine, that provides indirect evidence of these injuries (Boutros, Nassef et al. 2016)

5.2 Socio-demographic Characteristics

In this study, there is a male predominance (76.2 %) compared to females (23.8%).This compares well with other studies where male predominance has stood out.

McFarlane in Kingston, Jamaica, found a male predominance of 90 % (Creamer, McFarlane et al. 2005)

A study done by Oyinloye in Nigeria found a male predominance of 58.2% (Oyinloye 2007)

A study done by P.Musau in KNH found a male predominance of 94 % (Musau, Jani et al. 2006)

While the actual ratios may vary from study to study, male dominance stands out.

These finding can be explained by the fact that males are more involved in travelling and sporting activities, which are major causes of blunt abdominal trauma, than females.

The majority of patients with suspected blunt abdominal trauma fall in the age group of 16-30 years.

This is the most active age group involved in frequent travel and sporting activities and hence are at a higher risk of sustaining abdominal trauma compared to other age brackets.

Road Traffic accidents were the leading cause of blunt abdominal trauma.

This compares well with other studies, Oyinloye in Nigeria reported 74.4 % of BAT cases caused by RTA (Oyinloye 2007)

5.3 Ultrasound findings in blunt abdominal trauma

The most common ultrasound finding was hemoperitoneum in 42 patients (91.3 %). Indeed, ultrasound has been found to be highly sensitive in detection of intraperitoneal free fluid.

In a study done by Nnamonu et al in Nigeria, abdominal Ultrasound was able to detect intraperitoneal free fluid in 49 patients out of the studied 57 (86%) (Nnamonu, Ihezue et al. 2013)

In a similar study done by Boutros eta al in 2016,ultrasound was able to detect free fluid in all 15 patients with intra-abdominal injuries (Boutros, Nassef et al. 2016)

The free fluid not detected on ultrasound could be explained by the volume required for ultrasound detection.

The amount of intraperitoneal fluid required for ultrasound detection remains unclear. Different studies have shown that a minimum of 100-600 cc of fluid is detectable by US exam (Gracias, Frankel et al. 1998) but is widely regarded as 500 cc.

The time taken between Initial assessment and abdominal ultrasound scan may have been a source of potential bias. There is suggestion that detectable quantities of free fluid may develop during the time between initial clinical assessment and later imaging.

A similar bias may occur when comparing ultrasound to laparotomy; free fluid may also have developed in the interim period between admission and operation. This will result in a bias towards more false negatives results.

False negative test results in this study demonstrates that the reliance of detecting free fluid by US does have its limitations and the clinicians should be clearly aware of this and must use it within the context of a full clinical assessment. Indeed Up to 28 % of patients with intra-abdominal injury from BAT may have no hemoperitoneum identified on ultrasound (Benya, Lim-Dunham et al. 2000).

In patients with single visceral injuries, the spleen and liver were found to be the most commonly injured organs and this is often the finding in blunt abdominal trauma.

The spleen was the most common visceral injury on ultrasound in 6 patients (13.04%) followed by the liver.

At surgery 18 patients had splenic injuries followed by 13 patients with liver injuries

Similar findings were reported by EA Ameh et al in Nigeria 1999 where they found 34 splenic injuries out of 57 study participants with confirmed visceral injuries (Ameh, Chirdan et al. 2000)

5.4 Sensitivity and Specificity of Sonography for detection of Hemoperitoneum.

In this study, the sensitivity of US for detecting intra-abdominal injury when scanning for hemoperitoneum is 91.9%, with overall accuracy of 89.1 %. Specificity was found to be 77.7%

Fisher's exact test shows that Ultrasound test result of hemoperitoneum is significantly associated with the Intra-abdominal pathology. The two-tailed P value is less than **0.0001**. This is considered to be statistically significant

These findings are similar to Oyinloye study in Nigeria which found sensitivity of 95% (Oyinloye 2007)

Similar findings were reported by Yoshii et al who reported a sensitivity of 94.6% (Yoshii, Sato et al. 1998)

McGahan et al in a study of 500 patients, compared ultrasound findings with laparotomy and abdominal CT scan in hemoperitoneum .They found ultrasound sensitivity of 63% and specificity of 95% in detecting these particular injuries (McGahan, Rose et al. 1997)

McGahan's reported low sensitivity could be partly be attributed to the difference in methodology whereby he used both CT scan and surgery as gold standard.

Natarajan et al could only report 41% sensitivity in a retrospective study of 2980 patients, specificity reported as 99% (Natarajan, Gupta et al. 2010)

The variation in the sensitivity could be explained by operator and technique - dependent nature of US and the size of the sample evaluated.

The specificity of US when scanning for hemoperitoneum in this study was 77.78 %. Out of 9 patients (19.57%) who had no intra-abdominal fluid collection, 7 (15.2%) were correctly identified sonographically, while in 2 patients (4.3%), collections were reported to have been present at US, but hemoperitoneum was not demonstrated at surgery.

In a study performed by Lingawi and Buckle on 1090 patients, the reported specificity was 98% (Lingawi and Buckley 2000)

Natarajan et al reported specificity of 99% (Natarajan, Gupta et al. 2010)

It is apparent that the specificity of our study is lower than other studies, which could be attributed to the number of false positive cases of our study; sonography is not able to differentiate peritoneal fluid, blood, serosal secretion, lymph and urine from each other.

Furthermore, although we excluded patients with liver cirrhosis and congestive cardiac failure, we could have possibly not excluded everyone since we were relying on diagnosis already made. Therefore, such patients with preexisting free fluid in their peritoneal recesses, sonography could not accurately confirm or rule out the presence of intra-abdominal injury.

One of the two False positive patients was a 30-year-old female with a sonographic diagnosis of hemoperitoneum and liver hematoma. At laparotomy, fluid collection in the pouch of Douglas was encountered which was not hemoperitoneum.

In our Study, False Negative rate was at 6.5%. These are cases which were negative on ultrasound but later proceeded to have laparotomy after admission in the wards.

Indeed, a negative ultrasound examination cannot completely rule out the possibility of intra-abdominal injury.

Shanmuganathan et al found that more than 25% of patients with visceral injuries did not have free fluid on US scan taken on admission (Shanmuganathan and Mirvis 1998)

This can be explained by the fact that contained parenchymal injuries which may not be accompanied by hemoperitoneum and some bowel and mesenteric injuries may go undetected by US (Pathan 2005)

In evaluating blunt abdominal trauma patients with ultrasound, the False Negative cases have far reaching management consequences in cases of failure to explore based on the ultrasound results.

Thus, continuous clinical evaluation is indispensable.

5.5 Predictive values of ultrasonography in detection of hemoperitoneum and solid organ injuries.

In our study, the positive and negative predictive values for detection of hemoperitoneum was 94.4% and 70% respectively. The results are comparable with Fleming et al study who found a PPV of 96% and a NPV of 39% (Fleming, Bird et al. 2012).

The PPV and NPV for ultrasound detection of solid organ injuries was 80% and 47.3% respectively. However, the low specificity ultrasound in detection of these injuries warrants further imaging for detection of these injuries.

PPV values provided in this study, therefore, provide important statistics to consider in making decisions about the plan of treatment. They are also useful in counseling

patients on the probability of having a disease based on clinical and sonography findings.

5.6 Sensitivity and specificity of ultrasonography in detection of visceral organ injuries

In our study, evaluation of visceral organ injuries by ultrasound was found to have a low sensitivity of 37.5 % and specificity of 78.57%, with an overall accuracy of 50 %.

In our study 20 patients (43.6%) had False Negative results on evaluation of visceral organ injuries. Out of these 4 patients had normal ultrasound findings, later discovered to have intestinal lacerations (2) and mesenteric hematomas (2).

The remaining 16 patients had hemoperitoneum as the ultrasound diagnosis. No visceral organ injuries had been detected on ultrasound among these patients

Michael et al in Nigeria could only report a sensitivity of 56 % (Nnamonu, Ihezue et al. 2013)

In Fleming et al study, they reported ultrasound sensitivity of solid organ injury at 38.5% (Fleming, Bird et al. 2012)

The reason for such low detection rates could be that a significant proportion of these injuries do not produce hemoperitoneum, or any free fluid in the abdomen.

Visceral organ injury accounts for a significant proportion of intra-abdominal injury in blunt trauma and even though most are managed conservatively, the detection of such injury is imperative in allowing the clinician to make an informed decision as to whether to initiate conservative, medical or surgical management.

Indeed Fleming argues that the lack of vital information in relation to an occult organ injury can be dangerous for the patient especially if the injury is significant and causes

rapid or sudden deterioration, requiring rapid decisions to be made (Fleming, Bird et al. 2012)

Pathan in 2005 concluded that US alone if used to evaluate blunt trauma victims, contained parenchymal injuries which may not be accompanied by hemoperitoneum and some bowel and mesenteric injuries may go undetected (Pathan 2005) .

5.7 Study Limitations

1. Potential bias from the time of ultrasonography to surgical intervention since free fluid may accumulate during this period.
2. The assumption that any free fluid was considered as hemoperitoneum in the context of trauma might have been affected by women of child bearing age with physiological fluid in the pouch of Douglas. To minimize this limitation, specific visceral organ injuries were also sought where possible in addition to hemoperitoneum.

CHAPTER SIX: RECOMMENDATIONS AND CONCLUSIONS

6.1 Conclusions

1. Hemoperitoneum was the most common ultrasound finding in patients with BAT. Among solid organ injuries, the spleen was the most common injured organ.
2. A negative ultrasound examination did not completely rule out the possibility of intra-abdominal injury
3. The diagnostic value of ultrasound was found to be high in the evaluation of presence of hemoperitoneum with a high sensitivity and accuracy. In evaluation of visceral parenchymal injuries, ultrasound had a low diagnostic value with low sensitivity and accuracy.

6.2 Recommendations

1. Routine use of ultrasonography for evaluation of BAT patients as part of primary survey for detection of hemoperitoneum.
2. High index of suspicion in patients with negative scans for clinical observation and further imaging to assess for delayed hemoperitoneum, contained parenchymal injuries and bowel/mesenteric injuries.
3. Use of additional diagnostic adjuncts, for example CT Scan in evaluation of visceral parenchymal injuries

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APPENDICES

Appendix I: Consent Form

English Version

Investigator: My name is Dr. WABOMBA S. Hudson. I am a qualified doctor, registered by the Kenya Medical Practitioners and Dentists Board. I am currently pursuing a Masters degree in Radiology and Imaging at Moi University. I would like to recruit you into my research which is to study the diagnostic value of ultrasonography in evaluation of blunt abdominal trauma based on surgical findings at Moi teaching and referral hospital.

Purpose: This study will seek to describe and compare the ultrasound findings and surgical findings in patients with Blunt abdominal trauma in MTRH.

Procedure: 46 Patients with blunt abdominal trauma will be recruited into the study after consent is sought. Consent will be sought from the close relative/guardian for those patients with decreased levels of consciousness. Informed assent will be sought from patients between 7-17 years. They will undergo abdominal ultrasound after proper history taking and physical examination is done. The patient is handed over to the surgical team once diagnosis is confirmed and those who will undergo surgery will be noted and findings of the surgical treatment obtained and recorded. Data collection will be done by interviewing and filling of questionnaires. Data collecting material will be kept in a locked cabinet in the office of the principal investigator during the study period.

Benefits: There will be no direct benefits of participating in this study. Study subjects will be accorded same quality of management as non-study subjects

Risks: There are no anticipated risks to the participants attributable to this study.

Confidentiality: All information obtained in this study will be treated with utmost confidentiality and shall not be divulged to any unauthorized person

Rights to Refuse: Participation in this study is voluntary, there is freedom to refuse to take part or withdraw at any time. This study has been approved by the Institutional Research and Ethics Committee (IREC) of Moi University/Moi Teaching and Referral Hospital.

Sign or make a mark if you agree to take part in the study

Patient: …… Investigator: …….. Date…….

Kiswahili Version

Mpelelezi: jina langu ni Dr.WABOMBA S.Hudson. Mimi ni daktari aliohitimu, kusajiliwa na bodi ya Kenya ya Madaktari na Madaktari wa meno. Mimi sasa natafuta shahada ya uzamili katika Radiology na Imaging katika Chuo Kikuu cha Moi. Ningependa kukuajiri wewe katika utafiti wangu ambao ni wa kujifunza uhusiano wa picha ya ultrasound ya tumbo na matokeo ya upasuaji kwa wagonjwa wanaopatikana na majeraha butu ya tumbo katika hospitali ya rufaa na mafunzo ya Moi.

Kusudi: Utafiti huu itajaribu kueleza uhusiano ya picha ya ultrasound na matokeo ya upasuaji kwa wagonjwa wanaopatikana na majeraha butu ya tumbo

Utaratibu: Wangojwa wanao majeraha butu ya tumbo wataelezwa na kuombwa wafanyiwe uchunguzi na baadaye utafiti.Kama mgonjwa atakuwa amepoteza fahamu,ruhusa itaombwa kutoka kwa mtu wake wa karibu kwa ukoo au yule anayemtunza.Picha ya ultrasound itafanywa,historia na physical examination pia.Baada ya shida hii kujulikana kikamilifu daktari wa upasuaji atamwona na wote watakaopelekwa kwa matibabu ya upasuaji wataandikishwa na matokeo yao kuandikwa .

Data zitakusanywa kwenye fomu za ukusanyaji data. Hifadhi zitakazo tumika katika ukusanyaji wa data zitawekwa katika kabati iliyofungwa katika nyumba ya mpelelezi mkuu katika kipindi cha utafiti.

Faida: Hakutakuwa na faida moja kwa moja ya kushiriki katika utafiti huu. Wanaofanyiwa utafiti watakuwa na haki ya kupewa matibabu bora sawa na wale ambao hawatofanyiwa utafiti huo.

Hatari: Hakuna hatari ya kutarajia kwa washiriki inatokana na utafiti huu.

Usiri: habari zote zilizopatikana katika utafiti huu wa kutibiwa zitawekwa kwa usiri mkubwa na wala haitaolewa kwa mtu yeyote asiye husika na utafiti.

Haki ya kukataa: Kushiriki katika utafiti huu ni hiari yako, kuna uhuru wa kukataa kuchukua sehemu au kutoka wakati wowote. Utafiti huu umepitishwa na Utafiti wa Taasisi na Kamati ya Maadili (IREC) ya Chuo Kikuu cha Moi na Hospitali ya Rufaa.

Kusaini au kufanya alama kama unakubali kushiriki katika utafiti

Mgonjwa: ..... Mpelelezi: .....

Tarehe: .....

Appendix II: Assent Form
English version

Information

This informed assent form is for children above 7 years of age who have blunt abdominal trauma and subjected to abdominal ultrasonography and are scheduled to undergo surgery.

What is medical research?

Medical research is when doctors collect information to get new knowledge about disease or illness. This helps doctors find better ways of treating diseases and helping children or people who are sick.

What is this research study about?

This research study is on patients with blunt abdominal trauma. Ultrasound is used by doctors to see how severe the abdominal injuries are. In this study, ultrasound findings will be compared to the surgical findings after operation to decide whether the ultrasound findings were helpful in managing the patient. This will help the patients who sustain blunt abdominal trauma.

Who is doing this research?

My name is Dr. Wabomba S. Hudson and I'm a medical doctor. I'm currently studying for my second degree (Masters in Medicine) in Radiology & Imaging at Moi University.

What will happen to me in this study?

I will invite you to be part of this study. If you agree to participate in this study, abdominal ultrasound findings will be reviewed, and compared with surgical findings. There are no risks or benefits of participating in this study and you will be given the same medical care as the children who are not in the study. You can choose whether or not you would like to participate in the study. I have discussed this with your

parent(s)/ guardian(s) and they know we are asking for your permission to be part of the study. In case you refuse to be part of the study you will not be forced to even if your parents agreed for you to participate.

In case of any questions, feel free to ask, I will be happy to assist.

Certificate of assent

Do you understand this research study and are willing to take part in it?

Yes: …….. No: ……..

Has the researcher answered all your questions?

Yes: ……... No: ……..

Do you understand that you can pull out of the study at any time?

Yes: ……. No: …….

I agree to take part in the study _____

OR

I do not wish to take part in the study, and I have not signed the assent below_____.

Only if child assents:

Name of child _____

Child's thumb print: 

Date: _____

Kiswahili version

Fomu hii ya idhini ni ya watoto walio umri wa zaidi ya miaka saba ambao walio na majeraha butu ya tumbo na ambao wanatarajiwa kufanyiwa upasuaji.

Utafiti wa matibabu ni nini?

Utafiti wa matibabu ni wakati madaktari wanapopata taarifa ili kupata ujuzi mpya kuhusu magonjwa. Hii husaidia madaktari kupata njia bora za kutibu magonjwa na kusaidia watoto au watu ambao ni wagonjwa.

Utafiti huu unahusu nini?

Utafiti huu unahusisha wagonjwa walio na majeraha butu ya tumbo. Ultrasound hutumiwa na madaktari kuona majeraha ya ndani ya tumbo kwa wagonjwa wenye historia ya majeraha butu.. Katika utafiti huu, picha ya ultrasound itafanywa na matokeo yake kulinganishwa na yale ya upasuaji. Hii itakuwa ya manufaa kwa watoto wenye majeraha butu ya tumbo.

Nani anafanya utafiti huu?

Jina langu ni Dkt. Wabomba S.Hudson na mimi ni daktari aliyehitimu. Kwa sasa ninajifunza kwa shahada yangu ya pili (Masters in Medicine) katika Radiologia & Imaging katika Chuo Kikuu cha Moi.

Nini kitatokea kwangu katika utafiti huu?

Nitakualika kushiriki katika utafiti huu. Iwapo utakubali, matokeo yako ya picha Ultrasound ya tumbo yataangaliwa tena na kiwango cha majeraha kurekodiwa.. Baada ya upasuaji, kiwango cha majeraha ya tumbo yatarekodiwa na kulinganishwa nay ale ya picha ya ultrasound.

Hakuna hatari au faida za kushiriki katika utafiti huu na utapewa huduma sawa ya matibabu kama watoto ambao hawatashiriki kwenye utafiti. Unaweza kuchagua kama ungependa kushiriki katika utafiti huu. Nimezungumza na mzazi na/au mlezi wako na anajua tunaomba ruhusa yako kushiriki katika utafiti. Ikiwa unakataa kuwa sehemu ya utafiti huwezi kulazimishwa hata kama wazazi wako walikubali kushiriki.

Ikiwa kuna maswali yoyote, jisikie huru kuuliza, nitafurahia kusaidia.

Hati ya kukubali

Je unaelewa utafiti huu na uko tayari kushiriki?

Ndio: ..... La: .....

Je, mtafiti alijibu maswali yako yote?

Ndio: ..... La: .....

Je unaelewa kwamba unaweza kuondoka kwa utafiti huu wakati wowote?

Ndio: ……. La: ……

Nakubali kushiriki katika utafiti huu _____

AU

Sitaki kushiriki katika utafiti huu na sijasaini idhini hii _____

Ikiwa tu mtoto ataidhinisha:

Jina la mtoto: ……..

Alama ya kidole cha mtoto:

Tarehe: ……

Appendix III: Data Collection Form

DEMOGRAPHICS

Date: ……. Medical Record Number: ……

Age: …… Serial Number…….

County of residence.....

Presentation

Abdominal pain Yes ☐ No ☐

Abdominal Swelling Yes ☐ No ☐

Loss of Consciousness Yes ☐ No ☐

History

Is there any history of blunt abdominal trauma? Yes…… No……..

What is the Mode of injury?

Involvement in RTA ☐

Assault ☐

Sporting Injury ☐

Fall from Height ☐

Others ☐

EXAMINATION

General:

Pallor ☐ Jaundice ☐ Edema ☐

Dehydration ☐ Glascow Coma Scale ☐

Vital signs:

BP: ……/……mmHg Pulse: ……../min

Temp: ……^{o}C $SPO_{2:}$ ……..%

Chest examination:

Normal ☐ Abnormal ☐

Heart examination:

Normal ☐ Abnormal ☐

Abdominal examination:

Normal ☐ Abnormal ☐

Nervous system examination:

Normal ☐ Abnormal ☐

Other findings

UltraSound Examination Findings.

Presence of haemoperitoneum Yes ☐ No ☐

Solid Organ Injury

Liver ☐ → Hematoma ◯ Contusion ◯ Laceration ◯

Kidney → Hematoma ◯ Contusion ◯ Laceration ◯

Spleen → Hematoma ◯ Contusion ◯ Laceration ◯

Rapture

Bladder → Hematoma ◯ Contusion ◯ Laceration ◯

Rapture ◯

Pancreas → Hematoma Contusion ◯ aceration ◯

Mesentry ☐ → Hematoma ◯ Contusion ◯ aceration ◯

Bowel ☐ → Hematoma ◯ Contusion ◯ aceration ◯

Diaphragm ☐ → Hematoma ◯ Contusion ◯ aceration ◯

Others ☐

Surgical findings

Presence of haemoperitoneum Yes ☐ No ☐

Solid Organ Injury

Liver ☐ → Hematoma ◯ Contusion ◯ Laceration ◯

Kidney → Hematoma ◯ Contusion ◯ Laceration ◯

Spleen → Hematoma ◯ Contusion ◯ Laceration ◯

Rapture

Bladder → Hematoma ◯ Contusi◯ Laceration ◯

Rapture ◯

Pancreas → Hematoma Contusion ◯ Laceration ◯

Mesentry ☐ → Hematoma ◯ Contusion ◯ Laceration ◯

Bowel ☐ → Hematoma ◯ Contusion ◯ Laceration ◯

Diaphragm ☐ → Hematoma ◯ Contusion ◯ ceration ◯

Others ☐

Appendix IV: Hospital Approval

IREC/2016/132

MOI TEACHING AND REFERRAL HOSPITAL

Telephone: 2033471/2/3/4
Fax: 61749
Email: director@mtrh.or.ke
P. O. Box 3
ELDORET

Ref: ELD/MTRH/R.6/VOL.II/2008

30th September, 2016

Dr. Wabomba Hudson Simiyu,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.

RE: APPROVAL TO CONDUCT RESEARCH AT MTRH

Upon obtaining approval from the Institutional Research and Ethics Committee (IREC) to conduct your research proposal titled:-

"Validity of Ultrasonography in Evaluation of Blunt Abdominal Trauma in Eldoret".

You are hereby permitted to commence your investigation at Moi Teaching and Referral Hospital.

30/09/2016

DR. WILSON ARUASA
CHIEF EXECUTIVE OFFICER
MOI TEACHING AND REFERRAL HOSPITAL

CC - Deputy Director (CS)
- Chief Nurse
- HOD, HRISM

Appendix V: IREC Approval of Amendment

INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

MOI TEACHING AND REFERRAL HOSPITAL
P.O. BOX 3
ELDORET
Tel: 33471//2/3

MOI UNIVERSITY
COLLEGE OF HEALTH SCIENCES
P.O. BOX 4606
ELDORET
Tel: 33471/2/3

Reference IREC/2016/122
Approval Number: 0001768

11th December, 2018

Dr. Wabomba Hudson Simiyu,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.

INSTITUTIONAL RESEARCH & ETHICS COMMITTEE
11 DEC 2018
APPROVED
P.O. Box 4606-30100 ELDORET

Dear Dr. Wabomba,

RE: APPROVAL OF AMENDMENT

The Institutional Research and Ethics Committee has reviewed the amendment made to your proposal titled:-

"Diagnostic Value of Ultrasonography in Evaluation of Blunt Abdominal Trauma Based on Surgical Findings at Moi Teaching and Referral Hospital".

We note that you are seeking to make an amendment as follows:-

- To change the title to above from ***"Validity of Ultrasound in Evaluation of Blunt Abdominal Trauma in Eldoret".***

The amendment has been approved on 11th December, 2018 according to SOP's of IREC. You are therefore permitted to continue with your research.

You are required to submit progress(s) regularly as dictated by your proposal. Furthermore, you must notify the Committee of any proposal change(s) or amendment(s), serious or unexpected outcomes related to the conduct of the study, or study termination for any reason. The Committee expects to receive a final report at the end of the study.

Sincerely,

PROF. E. WERE
CHAIRMAN
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

cc: CEO - MTRH Dean - SPH Dean - SOM
Principal - CHS Dean - SOD Dean - SON

Appendix VI: Formal IREC Approval

INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

MOI TEACHING AND REFERRAL HOSPITAL
P.O. BOX 3
ELDORET
Tel: 33471//2/3

MOI UNIVERSITY
SCHOOL OF MEDICINE
P.O. BOX 4606
ELDORET

Reference: IREC/2016/122
Approval Number: 0001768

28th September, 2016

Dr. Wabomba Hudson Simiyu,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.

INSTITUTIONAL RESEARCH & ETHICS COMMITTEE
28 SEP 2016
APPROVED
P. O. Box 4606-30100 ELDORET

Dear Dr. Wabomba,

RE: FORMAL APPROVAL

The Institutional Research and Ethics Committee has reviewed your research proposal titled:-

"Validity of Ultrasonography in Evaluation of Blunt Abdominal Trauma in Eldoret".

Your proposal has been granted a Formal Approval Number: ***FAN: IREC 1768*** on 28th September, 2016. You are therefore permitted to begin your investigations.

Note that this approval is for 1 year; it will thus expire on 27th September, 2017. If it is necessary to continue with this research beyond the expiry date, a request for continuation should be made in writing to IREC Secretariat two months prior to the expiry date.

You are required to submit progress report(s) regularly as dictated by your proposal. Furthermore, you must notify the Committee of any proposal change (s) or amendment (s), serious or unexpected outcomes related to the conduct of the study, or study termination for any reason. The Committee expects to receive a final report at the end of the study.

Sincerely,

for

PROF. E. WERE
CHAIRMAN
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

cc	CEO	-	MTRH	Dean	-	SOP	Dean	-	SOM
	Principal	-	CHS	Dean	-	SON	Dean	-	SOD