

**DIAGNOSTIC ACCURACY OF FOCUSED ASSESSMENT
WITH SONOGRAPHY FOR TRAUMA (F.A.S.T) AT THE
KENYATTA NATIONAL HOSPITAL.**

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FOR THE DEGREE OF MASTERS IN MEDICINE IN GENERAL SURGERY, AT THE
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STUDENT'S DECLARATION

I, Dr. Kevin Wambugu, declare that this research proposal is my own original work and has not been presented anywhere else.

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Date.....

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LIST OF ABBREVIATIONS

ATLS	-Advanced Trauma and Life Support.
A&E	-Accident and Emergency.
DPL	-Diagnostic Peritoneal Lavage.
ERC	- Ethics and research committee.
FAST	-Focused Assessment with Sonography for Trauma.
G.E.	-General Electric.
KNH	- Kenyatta national hospital.
MHz	- Mega Hertz.
NPV	-Negative predictive value.
POD	- Post operative day.
PI	- Principal investigator.
PPV	-Positive predictive value.
RA	- Research Assistant.
ROC	-Receiver operator curve.
SHO	-Senior House Officer.
UON	- University of Nairobi.

ABSTRACT

Background

Focused assessment with sonography for trauma (FAST), is widely utilized in the diagnosis of abdominal injuries after traumatic accidents. Although useful, it does have shortcomings like missed injuries. A positive FAST ultrasound in a stable patient does not warrant emergency laparotomy, and sometimes further investigations are required to determine the full extent of the patient's injuries.

A false negative-FAST ultrasound can result in a patient missing timely surgery that could result in increased morbidity and mortality.

Worldwide, different centers report different statistics of their FAST results, with false positives approximately 0.23%, false negatives approximately 5.1%, with 28.1%--99% sensitivity in abdominal trauma patients.^[1]

There is no local data showing the diagnostic accuracy of FAST ultrasound in K.N.H., and its utilization in the management of a patient with abdominal injuries.

Objective

To determine the sensitivity and specificity, (diagnostic accuracy) of FAST in trauma patients admitted at the Kenyatta National Hospital.

Design

A cross-sectional analytical study

Methodology

All abdominal trauma patients, presenting at the K.N.H. emergency department, will undergo routine specialist management, and their F.A.S.T. investigation results will be compared against explorative laparotomy findings over a period of 6 months. Laparotomy findings will serve as the standard reference point in this study.

Secondary data will be generated to analyze FAST scans compared against Abdominal C.T. scans in patients who undergo non – operative management.

Data Management and Analysis

A structured data collection form will be used to collect the data ^[appendix 1]. Data collected will be entered in SPSS version. 17.0 For analysis and will be presented in pie charts, tables and graphs format. Fisher's exact test will be used to determine the level of significance. Specificity, sensitivity, negative predictive value, positive predictive values will be calculated, of FAST Ultrasound in K.N.H.

Results

At the end of this study the specificity and sensitivity of FAST ultrasound in K.N.H. will be determined, and how this can impact our management of abdominal trauma in patients presenting with abdominal trauma in K.N.H.

1.0 CHAPTER ONE: INTRODUCTION:

The abdomen extends from the tips of the scapulae to the gluteal skin crease posteriorly, and the fourth intercostal space to the groin crease anteriorly. Any injury to this area, should be assessed as a potential abdominal injury.^[2] Trauma is thus described as any structural alteration or physiologic imbalance that results when energy is imparted from an external source to a body part by physical or chemical agents^[3]

This study focuses on both blunt and penetrating trauma. Penetrating trauma is described as intrusion of the abdominal cavity by a gunshot or stab injury^[4]. Blunt abdominal trauma is the structural and physiologic injury that occurs when blunt force is applied to the abdominal wall without breaching the skin layers.^[5]

This study is designed to evaluate the diagnostic accuracy of FAST ultrasound scans at K.N.H. compared to Explorative laparotomy (and Abdominal C.T. scans in non- operative managed patients) to substantiate its continued use in the trauma setting of acute abdominal traumatic injuries.

1.1 Literature Review

1.1.1 Introduction to literature review

Trauma is the foremost cause of death in the 18-45 year age demographic^[6, 21].

Patients with pulse rate of >100 beats per minute and blood pressures below 90/60 mmHg are classified as being in shock^[7]. Those that do not respond or transiently respond to two liter fluid bolus are said to be unstable and require emergency laparotomy^[2]. Those that do respond are stable then proceed for further investigations.^[2]

Currently ultrasonography is the primary modality used in screening both blunt and penetrating abdominal trauma^[8], in the assessment of abdominal injuries.

History and physical examination lacks the specificity and sensitivity to detect accurately the surgical pathology ensuing after trauma.^[9] Diagnostic peritoneal lavage is overly sensitive, invasive, is not reproducible and can lead to high rates of negative laparotomy^[10]. Abdominal C.T. scan is expensive, not easily available in most parts of Kenya and cannot be accessed easily in an emergency^[11]. FAST was therefore developed to mitigate the above for its reproducibility, timeliness and can be utilised in the primary survey of an injured patient.^[12]

However, FAST is not without its limitations as injuries can be missed and also can have false positive or negative results that can lead to either mortality or negative laparotomy.^[13]

Focused Assessment with Sonography for Trauma (FAST), was established in the early 1990s as a reproducible way of assessing vital abdominal and thoracic organs, as well as pooling of blood in the most dependent regions.

Initially it was known as Focused Abdominal Sonography for trauma but after incorporation into, part of the Advanced Trauma Life Support (A.T.L.S.) examination in 1996, has been referred to as, Focused Assessment with Sonography for Trauma^[14].

1.2 Scanning examination

Four main areas are assessed during this ultrasound scan, where blood can pool during intra-abdominal bleeding. 1) Peri-splenic region 2) Hepatorenal recess (Morison pouch), 3) Subxiphoid pericardial window, 4) Suprapubic window (Doughlas pouch). Some centers examine for haemothorax and pneumothorax – in an extended FAST examination. (E-FAST). Any fluid accumulation greater than 200mls is deemed significant.^[15]

1.3 FAST in Trauma:

FAST ultrasound scan, has mainly been used in patients with suspected intra-abdominal injuries, but is rapidly being replaced by Abdominal C.T. scans as the preferred method of assessing intra-abdominal injuries in haemodynamically stable patients^[16].

Among the general population trauma is the third most frequent cause of death after cardiovascular disease and cancer^[17]. In adults between 18 – 45 years, trauma is the leading cause of morbidity and mortality^[18]

Abdominal trauma, following road traffic accidents, falls or assaults, constitutes 7-20% of all hospital admissions.^[19] And mortality is estimated to range between 10-30 % of all abdominal trauma patients.^[20] Haemorrhagic shock is thus considered a surgical emergency when it occurs following abdominal trauma.

Ultrasound use in medical practice begun in 1970, when assessing its effectiveness in detecting fluid injected into the abdominal cavity of a corpse.^[15] It has now advanced into the FAST ultrasound that is routinely used as a screening tool for abdominal trauma^[19,40]:

1.4 FAST replacing previous investigation modalities

FAST has quickly been adopted as a non-invasive and quick option for detecting peritoneal or pericardial fluid, rapidly substituting diagnostic peritoneal lavage (DPL) in many hospitals [20]. As an investigative modality FAST has proven, to be beneficial in screening abdominal trauma patients, and expedites faster treatment, compared to DPL, and Abdominal C.T. scanning [21]

FAST has been used to rapidly assess, potential sites of bleeding, in a hemodynamically unstable multiply injured patient with no readily apparent source of bleeding, as well as hemodynamically unstable blunt abdominal injuries [22]

Although FAST scans can be used to investigate hemodynamically unstable abdominal trauma patients, recent studies have shown that it should not interfere with the active resuscitation process, and acute surgical management, so as to better patient outcomes. [23]

In the emergency setting, FAST scans are advantageous, due to the fact that the patient can be assessed in the emergency department, and quickly continue with surgical intervention without having to move the patient to another area for scanning. [24]

When investigating abdominal trauma in pregnancy and children FAST ultrasound is preferred, as C.T. scans have high radiation dose, and D.P.L. is invasive, and not repeatable. [25]

1.5 Advancement of FAST Procedures

FAST ultrasound can be taught to different cadres of medical professionals, enabling them to carry out the ultrasound, in acute trauma, or in the emergency room, thus curbing the time to patient intervention. [26] Advancement in technology has resulted in portable hand-held ultrasound scanners that can be used to rapidly assess the abdominal cavity for bleeding even at the site of an accident. [27]

FAST scans, have been shown to reduce the number of patients referred for C.T. scans, when adequately utilized as a screening modality, within the emergency setting. [28]

1.6 Controversies in FAST

However abdominal C.T. scan is being performed more frequently in normotensive patients, as it is able to grade solid organ injuries as well as detect diaphragmatic injuries, and presents a more holistic representation of all the injuries within the abdomen. ^[22, 29]

In Southern Africa, a study by Smith et al reveals that FAST ultrasound scanning is useful in stable patients in the peripheral districts, where the patients may be timely managed and referred for further more accurate imaging, as well as surgical operations, but not necessarily useful in the major hospitals, in the larger cities, where helical C.T. scans give a more detailed description of abdominal injuries. ^[30]

Several recent studies have examined the use of FAST in the investigation of haemodynamically stable acute abdominal injuries, as several injuries were only detected after serial ultrasound scanning. ^[16, 31]

One drawback to the FAST ultrasound is that, if positive some patients may then require to have abdominal C.T. scans to grade the injury to determine whether the patient requires surgery or may be managed by supportive measures alone, as the patient recuperates. ^[32]

Furthermore, a positive FAST Ultrasound, in a patient with normal blood pressure does not warrant immediate laparotomy as Moylan et al, in a peripheral hospital in northern America, recorded only 37% of patients with a positive FAST required laparotomy, ^[33].

Rose et al at a leading level 1 trauma hospital in London, showed 41% of patients with a positive FAST ultrasound while haemodynamically stable, underwent unnecessary laparotomy^[34], thus exposing patients to unnecessary general anaesthesia, as well as morbidity in surgical scars as well as potential intestinal adhesions.

Systematic reviews of cross sectional studies performed in different centers reveal different results in terms of specificity and sensitivity with some reporting FAST ultrasound as having 28.1% - 99% sensitivity in invasive abdominal trauma. ^[1]

Consequently the type of radiological imaging used in the background of abdominal trauma is of the utmost importance, as when intra-abdominal hemorrhage is present the likelihood of death surges by 1 % for every 3 minutes that lapse devoid of intervention ^[35]

1.7 Local studies:

Locally, K.Mugambi in 1991 studied the pattern and treatment of trauma at K.N.H, and found that 15% of all trauma cases seen at the hospital were abdominal injuries.^[36]

R.K. Tenge in 1996, reported that diagnostic procedures were still rudimentary within K.N.H, whereby needle paracentesis was the most sensitive procedure, as C.T. scans and ultrasound were not employed during the assessment of children with blunt abdominal injuries being treated at the hospital.^[37]

J.W.Githaiga in 1996 in his appraisal of Diagnostic Peritoneal Lavage and paracentesis in invasive abdominal trauma patients seen in K.N.H., noted that there was little experience in acute Ultrasonography, and abdominal C.T. scans, at the time, and quite often they were unavailable for use in acute emergencies.^[38]

1.8 Summary:

Therefore with significant number of false negative FAST results in patients who require urgent laparotomies, a negative FAST outcome does not eliminate intra-abdominal injury. Consequently if its results cannot be wholly utilized, additional study is required in the role of FAST ultrasound, in the management of traumatic abdominal injuries^[40]

2.0 CHAPTER TWO: STUDY JUSTIFICATION

As seen from systematic reviews of several studies ^[1], different centers have different diagnostic accuracy of their FAST ultrasound scans, with some opting to fully utilize it in all trauma patients, and other centers skipping it altogether and going for more definitive imaging modalities. Newer models of C.T. scans have greatly reduced the procedural turnaround time, and radiation dose, which makes it advantageous to rapidly and definitively assess the critically injured patient.

FAST ultrasounds however, are more portable, cheaper, and safer to use in expectant mothers and pediatric age group. Currently there are no available studies, on the diagnostic accuracy of FAST ultrasound in the East African region, and thus the intention of this study is to deliver valuable feedback on this important imaging modality. More importantly, accurate descriptions of our specificity and sensitivity of FAST Ultrasound scans are required, to provide useful evidence to back up our practice, and know the true weight we should attach to the results of these scans, as we continue to manage the acutely injured patient.

2.1 Research Question

What is the specificity, sensitivity and accordingly diagnostic accuracy, of FAST ultrasound in blunt and penetrating abdominal injuries, in Kenyatta National Hospital?

2.2 Main Objective

- To define the diagnostic utility of FAST scans carried out at the Kenyatta National Hospital.

2.3 Specific Objectives

- To determine the specificity, sensitivity of FAST in blunt abdominal injuries
- To define the specificity, sensitivity of FAST in penetrating abdominal injuries
- To determine Positive Predictive Values (PPV), and Negative Predictive Values (NPV) of FAST.

3.0 CHAPTER THREE: METHODOLOGY

3.1 Study Area

1. Kenyatta National Hospital, accident and emergency casualty room 8,

Kenyatta National Hospital is Kenya's largest national referral hospital, located in Upper Hill, within the capital city of Nairobi. In the emergency department there is a surgical room 8, that triages all the surgical patients.

This room serves all the surgical specialties; orthopedics, general surgery, ear nose and throat surgery, neurosurgery, pediatric surgery, and plastic surgery. Here averages of 200 patients are screened every day by their respective registrars on call.

2. Kenyatta National Hospital -general surgery wards 5A, 5B, and 5D.

These three wards, located on the fifth floor of the hospital, admit all the general surgical patients, each having a bed capacity of 100 patients, and each served by 7 general surgery consultants, 8 surgical registrars, and a team of 20 nurses. At any one time the bed occupancy rate is 75 to 100%.

3.2 Study Population

All patients admitted with penetrating and/or blunt abdominal trauma, presenting at the Kenyatta National Hospital.

3.3 Study Design

A cross-sectional analytical study.

3.4 Sampling Technique

Sequential enrolment of patients who satisfy the inclusion criteria.

3.5 Inclusion Criteria

All patients above 12 years presenting with blunt or penetrating abdominal injury, who:

- Abdominal trauma patients who have FAST performed on them.
- Give consent or ascent by guardian/ relative.
- Have undergone Laparotomy OR Abdominal C.T. scan

3.6 Exclusion Criteria

- Patients who do not wish to participate in the study.
- Abdominal trauma patients who are haemodynamically unstable, have peritonitis, or evisceration of bowel from the abdominal wall during the time of presentation.

3.7 Sample Size Calculation

The sample size is arrived at using the formula for a descriptive study.

The proportion of abdominal trauma is 15 % as seen from the study of assault trauma in K.N.H. by Dr. K. Mugambi^[36]

$$n = \frac{Z^2 \times p(1-p)^{[41]}}{d^2}$$

Where Z = Z indicator for level of confidence

P = estimated prevalence of Abdominal trauma

n = sample size

d = precision

In ratio of One; if 5%, e = 0.05

For the expected confidence of 95%, Z value is 1.96

$$n = \frac{1.96^2 \times 0.15(1-0.15)}{0.05^2}$$

$$n = 195.921$$

$$n = 196$$

The study will be conducted for a period of 6 months, utilizing the finite population correction factor; the sample size is determined by:

$$N = \frac{n_0}{1 + \frac{n_0 - 1}{T}} \quad [42]$$

Where n0 = is the preliminary sample size (196)

T = the total target population during the study period

(Average annual FAST scans performed in K.N.H. is 120 scans)

(For 6 months the target population scanned will be on average 60).

Thus

$$N = \frac{196}{1 + \frac{196 - 1}{60}} = 46.1 = 46$$

A sample of 48 patients will be involved in the study inclusive of 4.3% attrition rate

Sample size = 48 patients

3.8 Patient Investigation

All haemodynamically stable patients with penetrating and/or blunt abdominal injury, as routine, have a FAST ultrasound performed once received in casualty surgical room 8. This test is requested by the medical officer in casualty or the surgical registrar on call at the time. No prior patient preparations are required as it is an investigation suitable for emergencies. The scan is requested on the standard radiological request forms available in casualty. Patient is transferred to the Ultrasound room, placed on the examining couch supine, with the chest and abdomen exposed.

A General Electric (G.E.) Logic 7 ultrasound scanner, utilizing a curvilinear 3.5 MHz (Mega Hertz) probe, after application of coupling gel, is used to scan the patient. The scan results are printed out on SONY thermal paper, and reported by the radiologist registrar on call, after confirmation by radiologist consultant on call. The FAST ultrasound results are placed in the patients file and this information is now available to the requesting doctor/surgeon, to make an informed decision on whether to operate or not, or whether further investigations (like abdominal C.T. scan) are warranted.

The principle investigator, after obtaining consent from the patient/guardian, during the post-operative period, will go through the file and compare the FAST scan results with the operative findings. If the patient was put under conservative (non-operative) management, and has an abdominal C.T. scan, then the FAST ultrasound will be compared to the abdominal C.T. scan.

3.9 Data Collection

Research Assistants (R.A), who are Senior House Officers (S.H.O.s), with MBChB as minimum qualification, will notify the Principle Investigator (P.I.) of all admitted abdominal trauma patients in each ward, and the Principle researcher will then gain consent from the patients/guardians, and fill in the data collection form.

Patients demographic data: age, sex, location, as well as results of FAST ultrasound, results of Abdominal C.T. scan, and results of intra-operative findings, will be entered in a pre-prepared data sheet ^[Appendix 1].

3.10 Data Analysis

The recorded data will be run in the Statistical Package for Social Sciences version 17.0 (SPSS 17.0). Graphic univariate analysis of data on socio- demographic characteristics will be analyzed and presented using percentages, frequencies tables, pie charts and graphs. Fisher's exact test will be utilized to determine the level of significance.

Univariate analysis on functional outcomes, will be analyzed and presented by use of measures of distribution, like frequency distribution tables, central tendency (mean, median and mode) dispersions (range and standard deviation).

3.11 Ethical Considerations

After approval from the University of Nairobi (UON), the study will be presented and analyzed by the Ethics and Research Committee of KNH. Informed consent shall be sought from the patients or parents/guardians of patients. Confidentiality and privacy shall be observed according to the KNH and University of Nairobi Ethics and Research committee regulations.

Participants will not incur any extra costs and will be unrestricted to withdraw from the study at any interval. All information and data acquired in the course of the study will be kept private. Any patient, who does not desire to partake in the study, will continue to receive the excellent standard of care accorded to all patients, being managed here in K.N.H.

The Principle Investigator is merely an observer in the standard tests and management that are carried out on a patient with penetrating and/or blunt abdominal injury. Thus the patient/patients' insurance cover will cater for the costs of the investigations, and surgery.

4.0 CHAPTER FOUR: RESULTS

50 patients were recruited into the study

4.1 Characteristics of Patients

Slightly over a third of the patients were aged between 22 and 26 years while on average the patients were aged 29.3 years.

Figure 1: Age of Patients

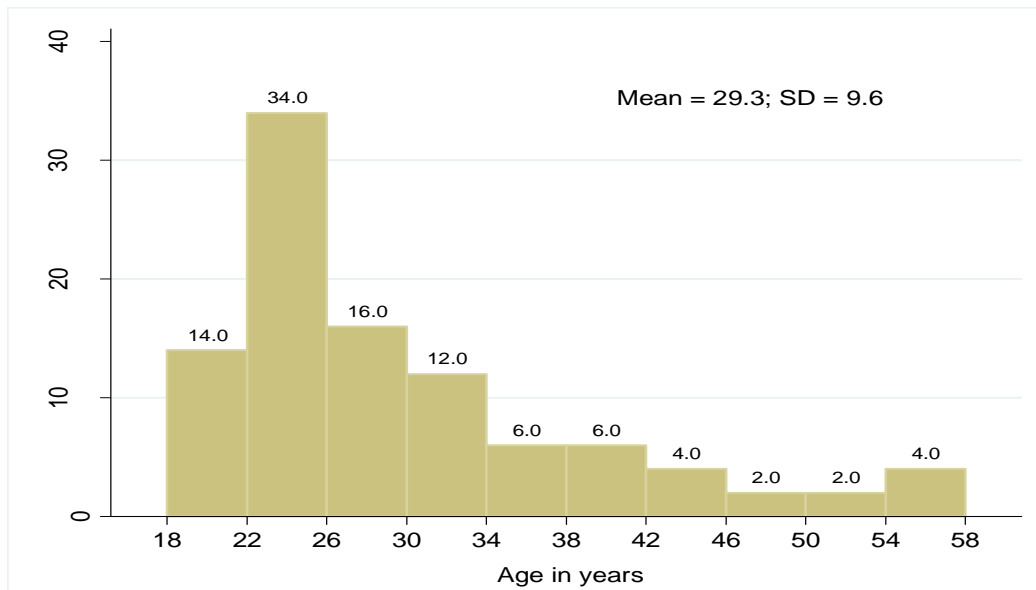
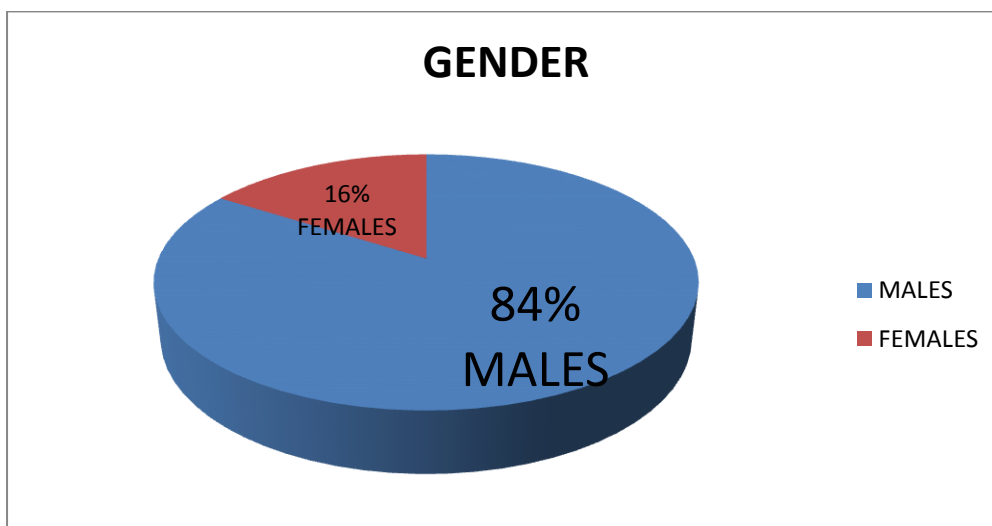


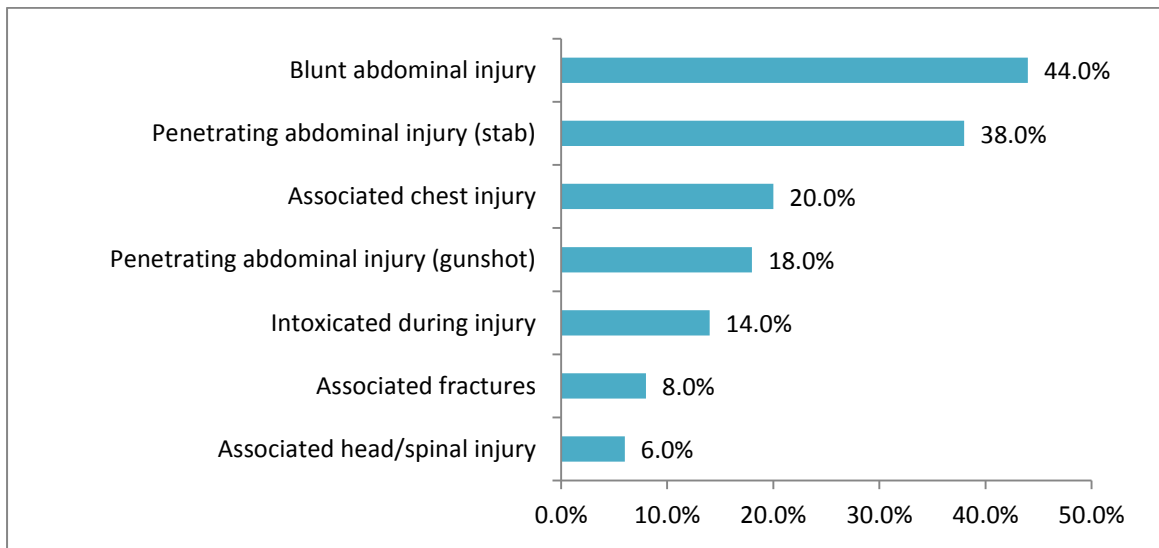
Figure 2 : Pie Chart illustrating Gender of Respondents



Majority 42(84%) of abdominal trauma victims were males, compared to 8(14%)

Being females

Figure 3: Bar chart illustrating types of injuries

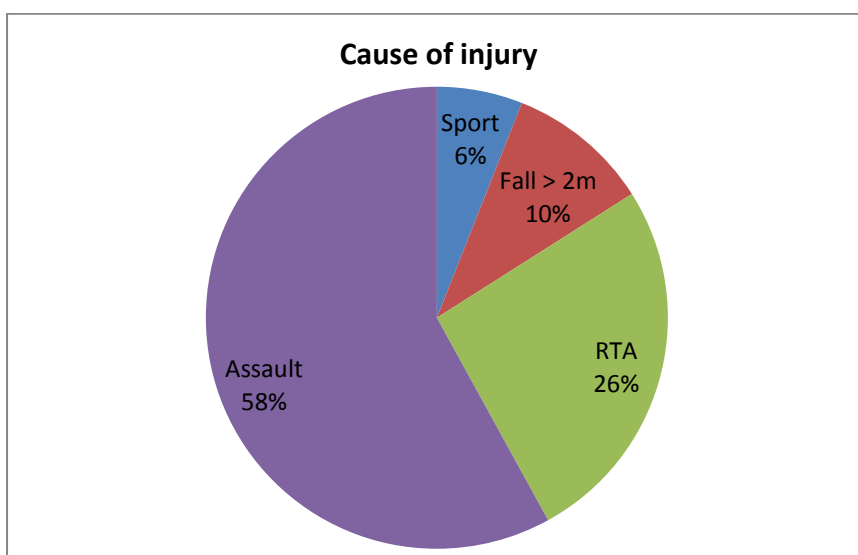


Most of the patients (56%) had penetrating abdominal injuries, with stab wounds being predominant at (38%) and gunshot wounds to the abdomen being (18%). Blunt abdominal injuries totaled (44%) of all the sampled patients.

The patients presenting with other associated injuries were (34%) of all the patients with abdominal trauma, majority (20%) suffered associated chest injuries, (8%) had associated fractures while (6%) had head and/or spinal injuries.

4.2 Causes of Injury

Figure 4: Pie Chart Showing Causative factors in Abdominal Injury



The study shows that (58%) of all the abdominal trauma cases were due to altercative assault, with the next major cause being road traffic accidents at (26%). Fall from a height greater than two meters was (10%) and mostly seen in construction workers. Those who suffered abdominal injuries during sporting activity were (6%). Interesting to note was that there were no sampled patients with abdominal injuries after fall from less than two meters (0%)

4.3 Test results for FAST, Laparotomy and CT scan

Table 1: Showing results for FAST, Laparotomy and CT scan

Ailment	FAST		Laparotomy		CT scan	
	Negative	Positive	Negative	Positive	Negative	Positive
Hepatorenal recess bleeding	36	9	39	9	8	11
Peri-splenic bleeding	36	9	43	5	17	2
Peri-cardiac haemorrhage	45	0	47	1	18	1
Pelvic fluid accumulation	20	25	22	26	13	6
Liver injury	42	3	39	9	11	8
Splenic injury	43	2	42	6	18	1
Renal injury	44	1	48	0	18	1
Bladder injury	42	3	39	9	18	1
Bowel injury	40	5	22	26	13	6
Mesenteric injury	45	0	40	8	19	0
Diaphragmatic injury	45	0	45	3	19	0
Abdominal wall injury only	45	0	47	1	19	0

The above table shows the results of all the parameters examined under the data collection sheet as compared to laparotomy findings, depending on whether FAST or CT scan was carried out prior to operation.

Majority of the positive FAST scans did show Pelvic fluid accumulation (62%) with only (25%) being positive for both hepato-renal recess fluid accumulation and peri – Splenic fluid

accumulation. FAST scans were only able to detect (19%) of bowel injuries and (33%) of bladder injuries

Most of the CT scans showed positive hepato-renal recess fluid accumulation (57%) with positively identified liver injuries at (72%). The Ct scans were able to detect bowel injury in (46%) of those with positive identified bowel injury during laparotomy.

4.4 FAST

Table 2 : Comparison of FAST against Laparotomy findings

		Laparotomy		Total
		Negative	Positive	
FAST	Negative	410	50	460
	Positive	15	41	56
Total		425	91	516

To test for sensitivity and specificity FAST, each patient was assessed for the 12 conditions under the study (pooling of fluid in the hepato-renal recess, splenic recess, pelvis, peri-cardiac, haemorrhage, liver, splenic, renal, bladder, bowel, mesenteric, diaphragmatic and anterior abdominal wall injuries) and for each condition the FAST results and Laparotomy was recorded. According to FAST, 89.1% (460) tested negative for abdominal injury while 10.9% (56) tested positive for abdominal injuries. Therefore the sensitivity of FAST is 45.1% (41 out of 91), FAST specificity is 96.5% (410 out of 425), FAST Positive Predictive Value is 73.2% (41 out of 56) while Negative Predictive Value 89.1% (410 out of 460)

4.5 CT scan

Table 3 : Comparison of CT scan against Laparotomy findings

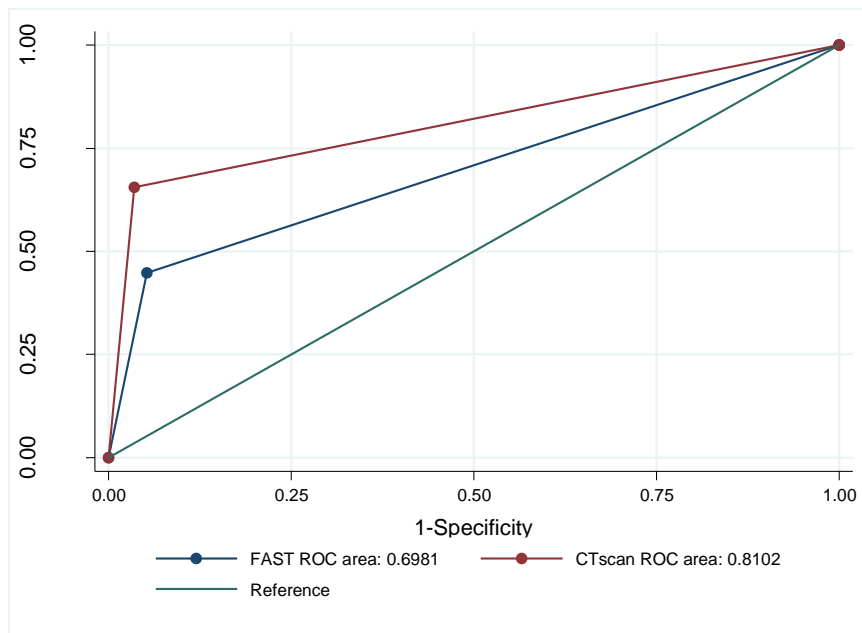
		Laparotomy		Total
		Negative	Positive	
CT scan	Negative	159	12	171
	Positive	4	29	33
Total		163	41	204

To test for sensitivity and specificity CT scan, each patient was assessed for the 12 conditions under the study and for each condition the CT scan results and Laparotomy was recorded. According to CT scan, 83.8% (171) tested negative for abdominal injury while 16.2% (33) tested positive for abdominal injuries. Therefore the sensitivity of CT scan is 70.7 % (29 out of 41), CT scan specificity is 97.5% (159 out of 163), CT scan Positive Predictive Value is 87.8% (29 out of 33) while Negative Predictive Value 93.0% (159 out of 171).

4.6 ROC comparison between FAST and CT scan

The study also sought to determine the ROC under the FAST and CT scan and compare it against the gold standard (Laparotomy). The results showed that ROC under FAST was 0.6981 thus a poor test while under CT scan the ROC was 0.8102 thus a good test. Further there was significant difference (p-value = 0.0332) in ROC curves under FAST and CT scan. This shows that FAST was less accurate than CT scan.

Figure 5: ROC under FAST and CT Scan



5.0 CHAPTER FIVE: DISCUSSION

5.1 Introduction

The intention of this study was to establish the efficacy and diagnostic precision of FAST as practiced at the Kenyatta National Hospital. FAST scans are routinely used to diagnose intra-abdominal injuries in patients who present at the hospital, but newer and faster CT scans are being increasingly utilized to diagnose and further classify intra-abdominal injuries. Determining its accuracy would further elucidate its role in the care of acutely incapacitated patients with abdominal injuries.

This study was carried out on 50 patients above 14 years old with primary history of abdominal trauma with or without other associated injuries, in the K.N.H., A&E department as well as within the surgical wards. The patients studied had a range of ages from 18 years to 58 years, with a mean age of 29.3 (+/- 9.6) of all the patients sampled. This is in keeping with a study performed by Mohammad et al; "Incidence, patterns and factors predicting mortality of abdominal injuries in trauma patients", where he found most abdominal trauma victims age range from (20) to (30) years.^[43]

There was an overwhelming preponderance of male patients (84%), during the study, but this is seen to be a similar pattern in other studies as males are more involved in violent and traumatic experiences, involving abdominal injuries^[43]. Ozpek et al implemented a multivariate inquiry of patients with abdominal injuries and the conceivable factors affecting mortality and in his study he had (78.9%) being males and (21.1%) being females with a mean age of 36.7 +/- 16.97 years (3-80 years).^[44] In America census and statistics of 2011 they report that roughly (90%) of patients with invasive trauma are males.^[45]

As the study shows over half (58%) of abdominal injuries in our region are due to assault and slightly less than a third (26%) being due to road traffic accidents. This is in keeping with other regions data and studies which show similar patterns of trauma. Smith et al in South Africa when performing their study," FAST scanning in the developing world emergency department" show (64%) of abdominal trauma was due to assault.^[30] Locally Kinoti Mugambi in his study in K.N.H in 1993- evaluating the pattern and management of assault trauma showed that (62%) of all trauma admitted to the general surgery wards was due to assault.

There were no patients admitted during the study period with abdominal injuries after fall from height less than 2 meters, but (10%) presented with blunt abdominal injuries after fall from a height of greater than 2 meters. This is in tandem with Kennedy et al study in 2001 where he studied, "low impact falls: demands on a system of trauma management, prediction of outcome, and influence of comorbidities". His research shows that falls from a height of greater than 2 meters resulted in severe injuries that resulted in hospitalization, with some requiring surgery, as opposed to those who fell from a height of less than 2 meters. ^[46]

Alcohol abuse has also been identified as a factor in blunt and penetrating injuries especially in tumbles from a height. His study shows that (14%) of the appraised patients were intoxicated at the time of injury. A study by Alleyne B. et al. "Alcohol and other drug use in occupational fatalities" show that more than half of non-industrial falls in adults and seventeen percent (17%) of industrial falls are concomitant with alcohol abuse. ^[47]

The sensitivity of FAST in our hospital is (45.1%) with a specificity of (96.5%). This study has determined that FAST performed in K.N.H. to have a Positive Predictive Value of (73.2%) while a negative predictive value of (89.1%). This tells us that when positive it is very likely that the patient has substantial intra-abdominal trauma, but conversely a sensitivity of (45.1%) it shows it is very poor at detecting the above mentioned abdominal injuries. However with a specificity of (96.5%) it does tell us that when the FAST is negative, the likelihood of a patient having intra-abdominal injuries is very low.

Our data is comparable to systematic reviews of various cross sectional studies from different centers that show FAST having sensitivities between (28.1% and 99%)^[11] Smith et al in his study performed from South Africa "FAST scanning in the developing world Emergency department", shows a sensitivity of (62%) and (100%) specificity^[30]

A sub set of statistics was used to evaluate the sensitivity and specificity of CT scans performed in K.N.H. This study shows CT scan sensitivity to be (70.7%) while a specificity of (97.5%) and a positive predictive value of (87.8%) accompanied with a negative predictive value of (93%) This tells us that the CT scan is an enhanced diagnostic tool comparatively and coupled to the fact that the surgeon can further classify the abdominal injuries is an added bonus.

A similar study performed by Sriussadaporn in Greece in his study of CT scan in blunt abdominal injuries, discloses a sensitivity of (92%) and a positive predictive value of (82%) while reporting a negative predictive value of (100%)^[48]. A subsequent study performed by

Shanmuganathan et al in 2004, this time assessing – “Penetrating torso trauma, triple contrast CT in peritoneal violation and organ injury”, he found that CT scan had a (97%) sensitivity, while maintaining a (98%) specificity for peritoneal injury.^[49]

The receiver operated curves do visually compare the performance of the CT scans and FAST against the gold standard (Laparotomy) when both their sensitivities and specificities evaluated and the area under the curve for FAST was (0.6981) while that under CT scan was (0.8102) thus depicting at this point in time CT scan is a more accurate test than FAST.

5.2 Conclusion

Acute abdominal trauma is a common presenting complaint in all general surgery wards. Resuscitative management, accurate diagnosis and timely intervention are the cornerstones of good surgical outcomes. The accurate diagnosis of intra- abdominal injuries have been a challenge, with multiple investigations all having their advantages and disadvantages, in assessing an acutely injured abdomen. FAST has been used extensively in the diagnosis of acute abdominal injuries but is slowly being replaced by CT scans in some centers.^[12,22] This study demonstrates that FAST has good positive predictive values that can assist in decision making on whether to operate on a patient with abdominal injuries, as well as having a high specificity, that if negative has a high prospect of no injury within the abdomen.

The down side of FAST has shown to be poor in detecting solid organ injuries as well as perforations of hollow viscous without intra-abdominal spillage. Thus it is not recommended for use in patients with right or left upper quadrant injuries, where if resources permit are better examined by CT scan. As thus it remains a very useful screening tool, in our setup but its use has to direct judiciously to patients with suspected intra-abdominal spillage.

With further advances in the technology of FAST scans as well as CT scans, with improved imaging and diagnostic capabilities, as well as reducing turnaround times, this study lays ground for further studies in the future as well as in other centers that will shed more light in determining the best imaging modality for the acutely injured abdomen.

5.3 Recommendations

- FAST is still a useful screening investigation, as it can be used quickly during the physical examination as per the A.T.L.S. management guidelines.
- FAST is better utilized in penetrating abdominal trauma that does not involve the right or left upper quadrants, where solid organs are positioned.
- CT scan is a better evaluation of blunt abdominal injury, as it better detects hollow viscus perforation, and solid organ injuries that are common during blunt abdominal trauma.
- CT scan is preferred in penetrating abdominal injuries to the left and right upper quadrants, as it is able to detect, classify and grade the solid organ traumatic injuries to the liver and spleen.

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APPENDICES

Appendix I: Data Collection Form.

SERIAL NUMBER	
AGE	
SEX	
LOCATION	
DESIGNATION OF SONOGRAPHER	

TYPE OF INJURY (TICK)

BLUNT ABDOMINAL INJURY	
PENETRATING ABDOMINAL INJURY (GUNSHOT)	
PENETRATING ABDOMINAL INJURY STAB	
ASSOCIATED CHEST INJURY	
ASSOCIATED HEAD/SPINAL INJURY	
ASSOCIATED FRACTURES (LIST)	
INTOXICATED DURING INJURY (Y/N)	

CAUSE (TICK)

RTA	
ASSAULT	
SPORT	
FALL < 2M	
FALL > 2M	
OTHER (SPECIFY)	

Tick where appropriate :

	<u>FAST U/S</u>	<u>ABDOMINAL C.T. SCAN</u>	<u>LAPAROTOMY</u>
Hepatorenal recess bleeding			
Peri-splenic bleeding			
Peri -cardiac hemorrhage			
Pelvic fluid accumulation (Pelvis)			
Liver injury			
Splenic injury			
Renal injury			
Bladder injury			
Bowel injury			
Mesenteric injury			
Diaphragmatic injury			
Abdominal wall injury only			

Appendix II: Informed Consent Form (English Version)

DIAGNOSTIC ACCURACY OF FOCUSED ASSESSMENT WITH SONOGRAPHY FOR TRAUMA (F.A.S.T.) AT KENYATTA NATIONAL HOSPITAL

This informed consent form is for patients seen at KNH and has been invited to participate in the research whose title is “**Diagnostic accuracy of focused assessment with sonography for trauma (F.A.S.T.) at Kenyatta National Hospital**”. This consent will be administered to the patients, or guardians.

Principal Investigator: Dr. Kevin B.Wambugu

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

This Informed Consent Form has three parts:

- 1) Information Sheet (to share information about the research with you).
- 2) Certificate of Consent (for signatures if you agree to take part).
- 3) Statement by the researcher

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

PART I: Information Sheet

Introduction

My name is Dr. Kevin B.Wambugu, a post graduate student in General Surgery at the University of Nairobi. I am carrying out a research to determine the “Diagnostic accuracy of focused assessment with sonography for trauma (F.A.S.T.) at Kenyatta National Hospital”.

Purpose of the research

Acute Abdominal trauma is one of the most common causes of admissions, in a surgical unit, and one of the leading causes of morbidity and mortality in the world. Various investigations are carried out after stabilizing a patient, to determine the full extent of the patient’s injuries. All investigations have their advantages and disadvantages, but this study seeks in particular to examine the role of an Abdominal Ultrasound scan, that is frequently used in investigations of patients who have been acutely injured in the abdomen.

Research Method

Any stable patient who has had an abdominal ultrasound performed (F.A.S.T), will be eligible to participate in the study. This result will be compared to findings that were visualised in the operating theatre. If you have not been operated on, the findings of the F.A.S.T. scan will be compared to Abdominal C.T. scan findings.

Voluntary participation/right to refuse or withdraw

You are free to participate or decline participation in this study. Whether you choose to participate or not, will not change your current management and treatment, that is routinely offered in this hospital for your particular condition. You have a right to refuse or withdraw from this study at any point.

Confidentiality

The information obtained will be treated with utmost confidentiality and only be available to the principal investigator and his research team. Your name will not be used. We will not be sharing the identity of anyone participating in this research.

Sharing the results

The knowledge that we get from this study will be shared with the policy makers in the Ministry of Health and doctors through publications, conferences, journals and presentations. Confidential information will not be shared with any third party.

Risks

There are no risks in this study. All parameters are merely observations of your current treatment investigations and treatment; no invasive investigations will be used during the course of this study.

Cost and compensation

There will be no extra cost incurred for participating in this study. This proposal has been reviewed and approved by the UON/KNH-ERC which is a committee whose mandate is to ensure a research participant like yourself or next of kin is protected from harm. It will be submitted to them through the Chairman, Department of Surgery, School of Medicine, at the University of Nairobi with the approval of university supervisors. The contact information of these people is given below if you wish to contact any of them for whatever reason:

Secretary, UON/KNH-ERC,

P.O. Box 20723- 00202,

KNH, Nairobi.

Tel: 020-726300-9

Email: KNHplan@Ken.Healthnet.org

University of Nairobi research supervisors;

Prof. Peter Ndaguatha,

Consultant Urologist, General Surgeon and Lecturer,

Department of Surgery, School of Medicine, University of Nairobi

P.O. Box 19676-00202,

KNH, Nairobi.

Tel: 020-2726300

Dr. Ojuka, Daniel

Consultant General Surgeon and Lecturer,

Department of Surgery, School of Medicine, University of Nairobi

P.O. Box 19676-00202,

KNH, Nairobi.

Tel: 020-2726300

Dr. Elly O. Nyaim

Consultant General Surgeon and Lecturer,

Department of Surgery, School of Medicine, University of Nairobi

P.O. Box 19676-00202,

KNH, Nairobi.

Tel: 020-2726300

Principle researcher:

Dr. Kevin B. Wambugu,

Department of Surgery, School of Medicine, University of Nairobi

P.O. Box 19676-00202,

KNH, Nairobi.

Mobile phone: 0722610781

PART II: Certificate of Consent

I, acknowledge that the researcher has explained to me the nature, purpose and procedure, and the terms and conditions of the study.

I appreciate that my participation is voluntary and that in case I do not participate in, or withdraw from, the study my health will not be compromised.

I hereunder impress my signature / thumbprint as proof of my consent to participate in this study.

Date:Signature.....

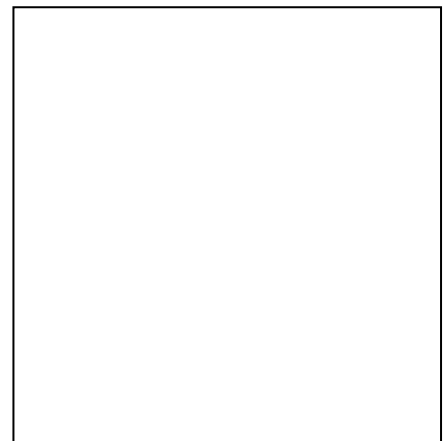
If Non -literate :

I have heard the accurate reading of the consent form, and the patient has had the opportunity to ask questions. I confirm that consent has been given freely.

Print Name of witness (S.H.O.) _____

Signature of witness _____

Date _____



Thumb print of Patient (Dominant hand)

PART III: Statement by the researcher

I have accurately read out the information sheet to the patient and/or guardian(s), and to the best of my ability made sure that the patient or guardian understands that the following will be done:

- Refusal to participate or withdrawal from the study will not in any way compromise the care of treatment.
- All information given will be treated with confidentiality.
- The results of this study might be published to highlight the sensitivity ,and specificity of FAST scans, performed on abdominal trauma patients, seen and managed in K.N.H.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this Informed Consent Form has been provided to the participant.

Name of researcher _____

Signature of researcher _____

Date_____

Appendix III: Study Consent Form (Swahili Version)

FOMU YA HABARI NA IDHINI

UCHUNGUZI TATHMINI NA SONOGRAFIA KWA MAJERAHA YA TUMBO (FAST) KATIKA HOSPITALI KUU YA TAIFA, KENYATTA

Hii fomu ni kwa ajili ya wagonjwa wanao hudumiwa katika Hospitali kuu ya Kenyatta, na walioalikwa kushiriki katika utafiti ambao anwani ni " **uchunguzi tathmini na sonografia kwa majeraha ya tumbo (FAST) katika hospitali kuu ya taifa, Kenyatta**".

Ridhaa hii ambayo itasimamiwa kwa wagonjwa, au walezi.

Mtafiti Mkuu: Dk Kevin B.Wambugu

Taasisi: Idara ya upasuaji, Shule ya Afya, Chuo Kikuu cha Nairobi.

Fomu hii ina sehemu tatu:

- 1) Habari itakayo kusaidia kukata kauli
- 2) Fomu ya makubaliano (utakapo weka sahihi)
- 3) Ujumbe kutoka kwa mtafiti

Utapewa nakala ya fomu hii,

SEHEMU YA KWANZA: Ukurasa wa habari

Kitambulizi

Jina langu ni Daktari Kevin B.Wambugu, Mimi ni daktari ninayesomea upasuaji katika Chuo Kikuu cha Nairobi. Ninafanya utafiti kwa anwani ya, " **uchunguzi tathmini na sonografia kwa majeraha ya tumbo (fast) katika hospitali kuu ya taifa Kenyatta**".

Madhumuni ya utafiti

Majeraha ya tumbo ni moja ya sababu ya kawaida ya uandikishaji, katika kitengo cha upasuaji, na moja ya sababu zinazoongoza maradhi na vifo duniani. Uchunguzi mbalimbali unafanywa baada ya mgonjwa kuumia, kuamua kiasi kamili cha majeraha ya mgonjwa. Chunguzi zote zina faida na hasara zao, lakini utafiti huu unalenga haswa kuchunguza jukumu la sonografia ya tumbo, kwa vile hutumika katika uchunguzi wa wagonjwa ambao wamejeruhiwa tumbo.

Njia ya Utafiti

Mgonjwa yeyote ambaye amekuwa na uchunguzi wa sonografia ya tumbo (FAST), atakuwa na uwezo wa kushiriki katika utafiti. Matokeo haya yatalinganishwa na matokeo yatakaopatikana katika chumba cha upasuaji. Kama hujashiriki katika upasuaji, matokeo ya sonografia ya tumbo yatalinganishwa na picha ya C.T.scan ya tumbo..

Ushiriki wa hiari

Kushiriki katika utafiti huu ni kwa hiari yako mwenyewe. Mwanawe au Jamaa wako atapata huduma ya matibabu japo utakataa kushiriki katika utafiti. Unaweza kujiondoa kushiriki au mwanawe au jamaa wako wakati wowote na hakuna madhara utatokeza kwa sababu ya kufanya hivyo.

Taadhima ya siri

Ujumbe kuhusu majibu yako yatahifadhiwa . Ujumbe kuhusu ushiriki wako katika utafiti huu utaweza kupatikana na wewe na wanaoandaa utafiti na wala si yeyote mwingine. Jina lako halitatumika bali ujumbe wowote kukuhusu utapewa nambari badili ya jina lako.

Matokeo

Maarifa ya utafiti huu ,yataonekana na watunga sera katika wizara ya afya na madaktari kupitia machapisho, mikutano,na majarida ya maonyesho.

Hatari

Hakuna hatari katika utafiti huu. Vigezo vyote ni vya uchunguzi wa matibabu yako ya kawaida.

Gharama

Hakutakuwa na gharama za ziada zitakao tumika kwa kushiriki katika utafiti huu.

Anwani za Wahusika

Ikiwa uko na maswali ungependa kuuliza baadaye, unaweza kuwasiliana na:

Katibu Mkuu, UON / KNH-ERC,

Sanduku la Posta 20723 KNH, Nairobi 00202.

Nambari ya simu: 020-726300-9

Barua pepe: KNHplan@Ken.Healthnet.org

Chuo Kikuu cha Nairobi

wasimamizi utafiti:

Profesa.Peter Ndaguatha,

Mhadhiri mkuu, Kitengo cha Upasuaji, Shule ya Afya, Chuo Kikuu cha Nairobi,

Sanduku la Posta 19676 KNH, Nairobi 00202.

Nambari ya simu: 020-2726300

Dk Ojuka, Daniel

Mhadhiri, Kitengo cha Upasuaji, Shule ya Afya, Chuo Kikuu cha Nairobi,

Sanduku la Posta 19676 KNH, Nairobi 00202.

Nambari ya simu: 020-2726300

Dk Elly O.Nyaim

Mhadhiri, Kitengo cha Upasuaji, Shule ya Afya, Chuo Kikuu cha Nairobi,

Sanduku la Posta 19676 KNH, Nairobi 00202.

Nambari ya simu: 020-2726300

Mtafiti kanuni:

Dk Kevin B Wambugu,

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

Sanduku la Posta 19676 KNH, Nairobi 00202.

Simu ya mkononi: 0722610781

SEHEMU YA II: Fomu ya makubaliano

Mimi (Jina).....au kwa niamba ya mgonjwa wangu (mtoto au jamaa wangu) Jina la Mgonjwa.....).

Nimeelezwa utafiti huu kwa kina. Nakubali kwa niaba yangu au ya mtoto / jamaa wangu utafiti huu kwa hiari yangu. Nimepata wakati wa kuuliza maswali na nime elewa kuwa iwapo nina maswali zaidi, ninaweza kumwuliza mtafiti mkuu au watafiti waliotajwa hapa juu.

Sahihi ya mshiriki _____

Tarehe _____

Kwa wasioweza kusoma na kuandika:

Nimeshuhudia usomaji na maelezo ya utafiti huu kwa mshiriki. Mshiriki amepewa nafasi ya kuuliza maswali. Nathibitisha kuwa mshiriki alipeana ruhusa ya kushiriki bila kulazimishwa.

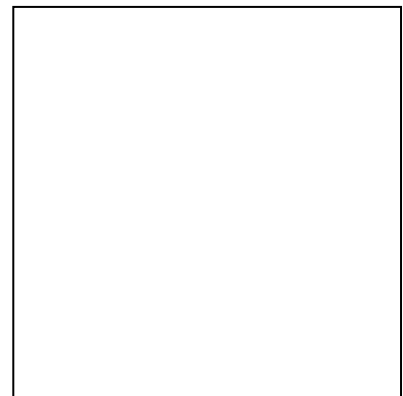
Jina la shahidi(Daktari) _____

Alama ya mgonjwa _____

Kidole cha mgonjwa

Sahihi la shahidi _____

Tarehe _____



SEHEMU YA III: Ujumbe kutoka kwa mtafiti

Nimemsomea mshiriki ujumbe kiwango ninavyoweza na kuhakikisha kuwa mshiriki amefahamu yafuatayo:

- Kutoshiriki au kujitoa kwenye utafiti huu hakutadhuru kupata kwake kwa matibabu.
- Ujumbe kuhusu majibu yake yatahifadhiwa kwa siri.
- Matokeo ya utafiti huu yanaweza chapishwa kusaidia madaktari kuhubiri aina manufaa wa uchunguzi kwa wagonjwa wanaopata majeraha ya tumbo.

Ninathibitisha kuwa mshiriki alipewa nafasi ya kuuliza maswali na yote yakajibiwa vilivyo. Ninahakikisha kuwa mshiriki alitoa ruhusa bila ya kulazimishwa.


Mshiriki amepewa nakala ya hii fomu ya makubaliano.

Jina la mtafiti _____


Sahihi ya Mtafiti _____

Tarehe _____

Appendix IV: KNH/UON-ERC letter of Approval



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KNH-UON ERC
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Website: <http://www.erc.uonbi.ac.ke>
Facebook: <https://www.facebook.com/uonknh.erc>
Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERC

Ref: KNH-ERC/AM/04

Dr. Kevin Wambugu
H-58/68052/2011
Dept of Surgery
School of Medicine
College of Health Sciences
University of Nairobi

18th March, 2016

Dear Dr. Wambugu

Revised Research Proposal: Diagnostic accuracy of focused assessment with sonography for trauma (F.A.S.T) at the Kenyatta National Hospital (P687/10/2015)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH-UoN ERC) has reviewed and approved your above proposal. The approval period is from 18th March 2016 – 17th March 2017.

This approval is subject to compliance with the following requirements:

- Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
- All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH UoN ERC before implementation.
- Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.
- Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH - UoN ERC within 72 hours.
- Submission of a request for renewal of approval at least 30 days prior to expiry of the approval period. (Attach a comprehensive progress report to support the renewal.)
- Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
- Submission of an executive summary report within 90 days upon completion of the study. This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/or plagiarism.

For more details consult the KNH- UoN ERC website <http://www.erc.uonbi.ac.ke>

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