

**A VALIDATION OF THE “TWIST” SCORE IN DIAGNOSIS
OF ACUTE TESTICULAR TORSION IN THE ACUTE
SCROTUM IN KENYATTA NATIONAL HOSPITAL**

**A dissertation presented in part fulfillment of the requirements for the award of the
degree of Master of Medicine in General Surgery of the University of Nairobi.**

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DECLARATION

I declare that this research is my own original work and has not been presented for a degree in any other University.

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Sign..... Date.....

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ABBREVIATIONS

ERC: Ethics & Research Committee

KNH: Kenyatta National Hospital

UoN: University of Nairobi

TWIST: Testicular Workup for Ischemia and Suspected Torsion

ABSTRACT

Background

The acute scrotum is a common urological emergency. The differential diagnosis of the acute scrotum is broad. A focused history and physical examination can at most times make an accurate diagnosis. A common cause of acute scrotal pain is testicular torsion. Any delay in diagnosis results in poor outcomes such as testicular loss or sub-fertility. A timely diagnosis of testicular torsion can result in improved testicular salvage rates hence immediate recognition is vital to management. There is no clear consensus on a particular algorithm to be followed in the diagnosis of testicular torsion. Traditionally, clinical examination followed by surgical exploration was the norm, but this resulted in unnecessary surgeries and increased morbidity and overall costs. Imaging modalities have been frequently used to assist in formulating a diagnosis however this also results in delays to definitive management and increased costs. A clinical tool such as the TWIST Score, which is a risk scoring system based on signs and symptoms, can be invaluable in management of patients with acute scrotum, specifically testicular torsion, as it can guide clinicians on decisions towards timely management of the patient with an acute scrotum.

Study Objective

To validate the efficacy of the TWIST Score in diagnosing testicular torsion in patients presenting with an acute scrotum.

Methodology

This was a prospective cross sectional study on male patients with acute scrotum who presented at the Kenyatta National Hospital (KNH) Adult and Paediatric Accident and Emergency Department, Paediatric and Surgical Outpatient clinics, and Paediatric and Surgical wards, carried out over a duration of 9 months. The estimated sample size was 60 male patients.

Recruited patients signed informed consent voluntarily and data collected on a structured pretested questionnaire which included age at diagnosis, time of onset of pain, first point of contact, history and physical examination findings, any adjunct test done, intra-operative findings and follow up findings of patients at low risk.

Data was managed using MS Excel and analyzed using SPSS version 21.0. Continuous data was presented as means and categorical variables as summarized percentages. The efficacy of the TWIST score in diagnosing testicular torsion was determined by calculating its sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV) and accuracy. Receiver-operator characteristic (ROC) curve was drawn for sensitivity and specificity. All statistical tests were conducted at 5% level of significance. The data is presented in form of tables and graphs.

Results

From the 60 patients enrolled into the study, 44 patients (73.3%) had testicular torsion. The mean age was 23 years. With all patients enrolled, 45 patients were classified as high risk as per the TWIST Score with 3 patients being classified as low risk. The remaining 12 patients were classified in the intermediate group. Positive predictive value for the TWIST Score was 95.6%. Negative predictive value for the TWIST Score in this study was 100% however the number of patients enrolled in this group was low. A low testicular salvage rate of 9.1% was obtained.

Conclusions

The use of the TWIST Score in clinical practice is accurate in determining high risk patients who can proceed straight to the operating theatre without need of an ultrasound while low risk patients can be treated without the use of an ultrasound.

1.0 CHAPTER ONE: INTRODUCTION

The acute scrotum is a common urological emergency presenting to the urological surgeon or casualty. ⁽¹⁾ As per the American Urological Association, the differential diagnosis of acute scrotum is broad, but an accurate history and physical examination can at many occasions precisely make a conclusive diagnosis. A common cause of acute scrotal pain is testicular torsion. It accounts for acute scrotal pain in 90% of post-pubescent boys and 30% of pre-pubescent boys. ⁽²⁾ Testicular torsion has been described as early as 1840. ^(3,4) The annual incidence of testicular torsion is 3.8-4.5/100,000. 1 in every 4,000 males under the age of 25 years develops testicular torsion. ^(5,6)

The testis is contained within the scrotum and measures approximately 3.8cm x 2.5cm x 2cm. Its longitudinal axis is vertical within the scrotum. The testis is encircled by peritoneum which forms its mesentery, the mesorchium. The lower part of the peritoneum forms the main part of the gubernaculum and forms the attachment to the inner scrotum. The testis is suspended into the scrotum from the spermatic cord. Contents of the spermatic cord include the vas deferens and its artery, pampiniform plexus of veins, lymphatics and nerves. The blood supply of the testis is derived from the testicular artery, a branch of the aorta; the deferential artery from the inferior vesical artery and the cremasteric artery from the inferior epigastric artery. Venous drainage is through the pampiniform plexus of veins which becomes the testicular vein. ⁽³⁾

Testicular torsion can be either intravaginal or extravaginal. Extravaginal torsion occurs mainly in perinatal life as the tunica vaginalis is not completely fixed to the inner scrotum due to descent of the testis thus the spermatic cord twists proximal to the tunica vaginalis. The more common, intravaginal torsion occurs mainly in adolescents or puberty. The most common cause is the Bell Clapper deformity (faulty mesentery of the testis). Normally, the posterior part of the testis and epididymis are fixed to the tunica vaginalis, however when attached more proximally to the spermatic cord, this allows the hanging horizontally placed testicle to twist within the tunica vaginalis. Other proposed aetiological factors thought to increase risk to testicular torsion include a voluminous scrotum, thrombosis of the pampiniform plexus, hyperactive cremasteric reflexes, previous surgery and orchidopexy. However, aetiology is not very clear and risk factors such as physical activity such as cycling, swimming and weight-lifting have been reported to increase risk of torsion. The inheritance

of testicular torsion is also unclear. There are about 20 published reports of familial testicular torsion. Suspected genes include insulin-like 3 hormone and its receptor, RXIf 2. Their exact role is still not known. ^(3,4,7)

Torsion results when the spermatic cord and testis twist along their axis. This results in reduced blood supply leading to ischaemia, which causes swelling, degeneration, necrosis, and infarction which all depend on the duration and degree of twisting. The torsion range is between 180-1080 degrees which contributes in variations of presentation. Torsion blocks both the arterial and venous supplies. Hence resultant oedema causes an increase in arterial blockage, and thus hypoxia and gangrene of the testis. ^(3,4)

Immediate recognition and therapy are crucial to the management of testicular torsion. Irreversible changes occur to the testis when an acute vascular event occurs. These changes begin after 6 hours or after only 4 hours in cases of an extremely twisted spermatic cord. Thus, time is the most critical factor in increasing salvage rates and morbidity is mostly dependent on this. ⁽⁴⁾ It is believed that testicles that are torsed longer than 6 hours are considered outside the time frame for survival and such cases are managed less urgently; however, such assumptions put potentially viable testicles at risk of non-salvagibility. Longer periods of torsion and viability of testis have been described. Testicular survival in periods of 12-24 hours of torsion has been described in various areas. Survival of testis has been described in patients who present after 6 hours but also up to 48 hours after onset of symptoms. ^(8,9)

In the diagnosis of testicular torsion, there is no clear consensus on a particular algorithm to be followed. Traditionally, clinical examination followed by surgical exploration was the usual practice but this resulted in unnecessary surgery and hence increased costs and morbidity. ⁽¹⁰⁾ Thus many investigative methods have been introduced to assist in forming a diagnosis however, there is no gold standard investigation with 100% sensitivity, specificity and accuracy. ⁽³⁾

2.0 CHAPTER TWO: LITERATURE REVIEW

2.1 Incidence

The magnitude of testicular torsion is not known in the African continent as per Ewer Et al. Morbidity in Africa is related to both delays in surgery and referral of patients to definitive management at point of first contact with a healthcare provider. ⁽⁶⁾ In a study carried out at various government and private institutions in Nairobi, 86.36% of patients who underwent scrotal exploration had testicular torsion and the testicular salvage rate was low at 21%. ⁽¹¹⁾

2.2 History and Physical Examination

There exists a clinical overlap of signs and symptoms of various differential diagnosis of the acute scrotum. Also, physical exam in patients with acute scrotum may be difficult due to pain or an uncooperative patient in distress. This makes diagnosis of testicular torsion difficult. Thus, imaging is frequently necessary to assist in forming a diagnosis and guide management, and this could increase ischemic times and reduce salvage rates. ⁽¹²⁾

The classical presentation of patients with testicular torsion is an onset of one-sided testicular pain associated with nausea and vomiting. A sign considered to be specific to the diagnosis of testicular torsion is the absence of the cremasteric reflex, however some patients with testicular torsion may have presence of the reflex. Other signs include testicular swelling, tenderness and a high riding testis but these signs are usually non-specific and thus often make diagnosis of testicular torsion solely on physical examination findings difficult, thus the reliance of testicular ultrasound with Doppler to make or confirm the diagnosis. ⁽¹³⁾ Testicular Doppler ultrasound has resulted in many physicians relying on imaging to make the diagnosis of testicular torsion, rather than using clinical judgment on its own. ⁽⁴⁾

2.3 Use of Imaging Modalities

Most clinical providers are dependent on Doppler ultrasound in diagnosing testicular torsion. Other modalities available include Nuclear scintigraphy and magnetic resonance imaging. These tests are sensitive but are limited by the need for intravenous injection of contrast, a possible requirement for anaesthesia and a long period to perform the examination. A new approach to evaluation of testicular oxygen saturation with near-infrared spectroscopy (NIRS) has been investigated and is used as a diagnostic modality for testicular torsion

however, this modality still lacks proof of reliability and whether it is cost effective in management of testicular torsion.^(14, 15) These modalities are also not readily available and are expensive in many centres.⁽¹⁶⁾

Good clinical acumen is vital in arriving at a diagnosis of testicular torsion, however, if doubt exists, the use of Doppler ultrasound in good hands has shown to have a sensitivity of 89% and a specificity of 100% in arriving at a diagnosis. However, the outcome has been shown to be user dependent and as per expertise. A false Doppler ultrasound signal may be seen in prepubertal testis, or when there is an elevated volume of paratesticular blood flow from communicating vessels.^(4,17) The nature of testicular torsion introduces errors in ultrasound findings; such as in intermittent torsion or in cases of lower degrees and duration of torsion, Doppler flow may be maintained. Therefore, a negative result on imaging must be interpreted with caution in the face of suggestive history and physical exam findings.⁽¹⁸⁾ Doppler ultrasound has frequently been used to determine the presence and extent of testicular torsion over the last 20 years. It is helpful in determining when surgical exploration is unnecessary however user discrepancies occur, and thus history and physical examination should be compared to Doppler ultrasound findings. It is known that Doppler ultrasound complicates the diagnosis of testicular torsion and over diagnoses epididymo-orchitis.⁽¹⁹⁾

Availability of ultrasounds may be limited resulting in delays of transfer of patients to definitive care and thus results in higher orchidectomy rates. Where ultrasounds and urologic surgeons are readily available, the use of imaging on all patients who present with an acute scrotum may not be necessary. Imaging will reduce testicular salvage rates in patients with obvious signs and symptoms of testicular torsion. Time to presentation to the health care provider has been noted to be the most important factor in predicting testicular salvage in patients who present with testicular torsion.⁽²⁰⁾

2.4 The “TWIST” Score

Having a clinical tool to determine risk for testicular torsion is useful to determine urgency for referral, reduce overall costs and improve outcomes. Clinical features in history and physical examination alone can assist in differentiating patients with testicular torsion from other causes of an acute scrotum, as shown in retrospective studies and one smaller prospective study.^(20, 21)

Awaiting imaging results in a time delay to definitive management, hence risk-scoring systems based on signs and symptoms have been proposed. Such a scoring system is the TWIST (Testicular Workup for Ischemia and Suspected Torsion) score. The TWIST Score consists of a summed score ranging from 0 to 7 points based on the absence or presence of 5 variables derived from signs and symptoms. These include:

- Testicular swelling (2 points)
- Hard Testicle (2 points)
- Absent cremasteric reflex (1 point)
- Nausea or vomiting (1 point) and
- High riding testis (1 point)

As per initial validation of the score by Barbosa et al, who devised the score, patients were grouped into three; those with a high risk of torsion (a TWIST Score of ≥ 5 points), patients with an intermediate risk (TWIST Score of 3-4) and patients at a low risk for torsion (TWIST score ≤ 2). Patients at high risk could proceed directly to surgery without any imaging (positive predictive value of 100%), intermediate risk patients would require ultrasound for further evaluation, and low risk patients do not require scrotal ultrasound (negative predictive value of 100%).^(12,13,14) The TWIST score has also been validated by Sheth et al and found to be very useful for predicting testicular torsion. Patients with scrotal pain were prospectively evaluated. Their findings supported that the TWIST scoring system is accurate in predicting torsion. The score was found to be accurate in predicting torsion in adolescent patients with tanner stage 3-5. However, cut-off values for the score were low risk patients had a score of 0 and high risk patients had a score of ≥ 6 . They concluded that the scoring system enabled a more accurate triage of patients and hence could reduce the time to definitive management and expense of radiographic confirmation in more than 50% of cases.⁽¹³⁾ Shah et al derived a decision tool for children at low risk for testicular torsion, in which normal testicular lie, lack of nausea or vomiting, and age 0–10 years had no risk for testicular torsion, whereas, horizontal or inguinal testicular lie, an abnormal cremasteric reflex, nausea or vomiting, scrotal oedema, and age between 11–21 were found to have a significantly higher likelihood of testicular torsion.⁽²¹⁾ In a study by Afsalar et al, the three prior mentioned parameters were used to develop a scrotal pain checklist and a conclusion that using the checklist led to significantly reduced times from emergency department to the operating room.⁽²²⁾

2.5 Importance of a clinical tool such as the “TWIST” Score

When ruling out testicular torsion, it is imperative to integrate multiple pieces of patient data, with the knowledge that every piece of data may have inaccuracies. Keeping this in mind, Doppler ultrasound becomes an excellent adjunctive test in situations where clinical evaluation suggests an equivocal or low suspicion for testicular torsion. ⁽¹⁸⁾

The TWIST score’s purpose is not to substitute imaging tools in acute scrotum management but to better delineate their indications. ⁽¹²⁾

Delay in diagnosis may result in poor outcomes such as testicular loss or sub-fertility, therefore history and physical examination are appropriate enough for immediate intervention. ⁽⁴⁾ Hence a clinical scoring system such as the TWIST Score could be invaluable in management of testicular torsion.

To date, no systematic approach has been established for objective evaluation of the acute scrotum, hence a diagnostic tool such as the TWIST score can assist physicians and urologic surgeons in managing the acute scrotum, and thus reduce ischemic times in testicular torsion, reduce costs of treatment and increase salvage rates.

3.0 CHAPTER THREE: STUDY JUSTIFICATION

The acute scrotum is a common urological emergency which requires prompt assessment. Suspected testicular torsion requires emergency scrotal exploration. Many protocols in the management of the acute scrotum, in particular testicular torsion, are highly debated and there is no clear consensus. ⁽²³⁾ There is no clear protocol for the management of the acute scrotum in KNH. Prompt diagnosis of testicular torsion is essential to reduction of morbidity rates. Use of unnecessary imaging, results in delays to definitive management, increased costs and waste of resources. ^(10,21) A scoring system such as the TWIST score can assist in reducing time delays and overall costs and hence the importance to determine its efficacy in the management of the acute scrotum, in particular testicular torsion. This study will also assist in determining the testicular salvage rates at KNH. No such study has been undertaken in KNH before.

3.1 Research Question

Is the TWIST score an important clinical tool to assist in the diagnosis and management of testicular torsion in the patient who presents with an acute scrotum at KNH?

3.2 Broad Objective

To validate the efficacy of the TWIST score in diagnosing testicular torsion in patients presenting with an acute scrotum at KNH.

3.2.1 Specific Objectives

- I. To determine the rate of testicular torsion in patients with acute scrotum at KNH.
- II. To determine the positive and negative predictive values of the TWIST score.
- III. To determine the sensitivity and specificity of the TWIST score.
- IV. To determine the testicular salvage rates of patients with testicular torsion in the acute scrotum at KNH.

3.3 METHODOLOGY

3.3.1 Study design

Cross sectional descriptive study

3.3.2 Setting

Adult and Paediatric Accident and Emergency Department, Paediatric and Surgical Outpatient clinics, and Paediatric and Surgical wards, Kenyatta National Hospital.

3.3.3 Study population

All male patients who presented with an acute scrotum who met the inclusion criteria were recruited in the study.

3.3.4 Inclusion criteria

1. All male patients who presented to Adult or Paediatric Accident and Emergency Department or Paediatric and Surgical Outpatient clinics, and Paediatric and Surgical wards with a diagnosis of an acute scrotum.
2. Patient or parent/guardian of minors who consented to enroll into the study

3.3.5 Exclusion criteria

1. Patients with a prior history of torsion.
2. Patients with a prenatal diagnosis of testicular torsion.
3. Patients or parents/guardians who declined consent.

3.3.6 Sampling method

Consecutive sampling method was used to enroll patients who met the inclusion criteria for the study once ERC approval was obtained.

3.3.7 Sample size calculation

According to KNH data from hospital records, an estimated number of 95 patients with acute scrotum are seen annually. A representative sample was drawn from the population in the period and the sample size calculation was obtained using the formula for finite population (Daniel, 1999). The calculation was as follows:

$$n' = \frac{NZ^2P(1-P)}{d^2(N-1) + Z^2P(1-P)}$$

Where

n' = sample size with finite population correction,

N = size of the target population = 95

Z = Z statistic for 95% level of confidence = 1.96

P = Estimated prevalence of torsion in acute scrotum patients= 86%

d = margin of error = 5%

$$= \frac{95 \times 1.96^2 \times 0.86 \times 0.14}{0.05^2 (95-1) + 1.96^2 \times 0.86 \times 0.14}$$

= 60 patients were sampled

3.3.8 Data collection

Patients with a diagnosis of an acute scrotum and met the inclusion criteria were recruited. Recruitment was verbal and the participants were duly informed of the nature and purpose of the study. For the patients who agreed to participate in the study, informed consent/assent was obtained and they were subsequently enrolled into the study. Data collected included age at diagnosis, time of onset of pain, first point of contact, history and physical examination findings, any adjunct test done, pre-operative waiting time, intra-operative findings and follow up findings for patients categorized as low risk. This data was entered in a pretested data collection form partially adapted from the TWIST score. History and Physical examination of the external genitalia of the patient was conducted by the investigator and a trained research assistant, or surgical residents who were sensitized on this study. To ensure reproducibility of examination findings and interpretation of parameters, every patient was seen by a consultant or senior registrar in addition to the primary physician or principal investigator. This prevented bias and also ensured uniform performance of examinations and interpretation of parameters. In this way I as the principal investigator was calibrated. Sensitization of residents and surgeons was done through presentations at the Surgical Out-patient Clinic, The Tumour Board and Grand Round conferences and through notices in the Accident and Emergency departments and General Surgical and Paediatric Surgical wards. All patients were grouped into either low risk, intermediate risk or high risk of testicular torsion using the TWIST Score. Low risk patients were asked to do a Doppler ultrasound which was reviewed prior to discharge and appropriate management instituted and were followed up in one week at clinic. Intermediate risk patients were asked to do a Doppler ultrasound prior to discharge and management plan determined depending on the Doppler

ultrasound results and reviewed on follow up at clinic in one week if discharged. High risk patients were to proceed directly to theatre as the management plan.

3.3.9 Data entry

All the questionnaires were stored in a cabinet under lock and key by the investigator after checking for any errors. Data entry was done by the Principal investigator and his assistant onto an MS excel sheet and encrypted for safety. All the entered data was checked for consistency and validity by the investigator prior to analysis.

3.3.10 Variables

We collected data on the following variables: independent variables: Age, time from onset of pain, first point of contact, history of physical activity, morbidity and presenting signs and symptoms. Dependent variables: TWIST score and a diagnosis of torsion.

3.3.11 Study material and personnel

- Stationery
- Laptop

The Trained research assistant(s) was a doctor with minimum qualification of bachelor's degree in medicine.

3.3.12 Data management and statistical analysis

Data was entered into computerized data entry sheets. Cleaning and verification was done to ensure accuracy and completeness of the information. Statistical analysis was conducted using SPSS version 21.0 software. Patients' socio-demographic and clinical information was summarized percentages for categorical variables and means/medians for continuous variables. Rate of torsion was calculated and presented as a percentage with 95% confidence interval. TWIST score was analyzed and prevalence of torsion according to the score was calculated. Efficacy of TWIST score in diagnosing torsion was determined by calculating its sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV) and accuracy. Receiver-operator characteristic (ROC) curve was drawn for sensitivity and specificity. 95% confidence intervals calculated for sensitivity and specificity to determine their level of precision. Also, the level of agreement between the diagnostic methods was tested using Kappa statistic. Morbidity of patients and risk factors was analyzed and presented as proportions. Statistical tests were interpreted at 5% level of significance (p value less or equal to 0.05). Study findings are presented in tables and pie chart.

3.4 Quality Assurance

All patients were examined and managed in accordance with standard operation procedures (SOPs) laid down by hospital management. All laboratory tests carried out were processed using standard preparation protocols. Any ultrasounds done during the duration of the study were done by a radiology resident or Consultant radiologist to reduce bias and all were reported in the same format. All positive clinical and radiological examinations were randomly picked and re-examined by an independent Consultant. When disagreement arose in clinical examination then a consensus was reached between clinicians one of whom was an independent Consultant surgeon.

3.5 Results dissemination

Results of this study have been published as a dissertation in part fulfillment of the degree Masters in Medicine in General Surgery, and have been disseminated to the thematic head of department of General Surgery at KNH and to the overall head of surgery KNH. Copies have also been availed to the UoN department of surgery, College of Health Sciences library and to The Ethics and Research Committee of KNH/UON. The findings of this study will be disseminated in seminars, conferences and workshops. Manuscripts will be submitted for publication in peer reviewed journals within six months of its completion.

3.6 Ethical Consideration

This study commenced after approval from the Department of Surgery UoN and the UoN-KNH Ethics and Research Committee. An informed consent was obtained from all parents/guardians of patients, or patients over the age of 18yrs before being enrolled. Assent was sought from children aged between 12-18yrs.

Parents/guardians were not coerced to enroll the patients into the study. Non-participation did not affect such a patient's care in the hospital.

Participation in this study did not attract extra cost to the medical care of the participants.

All patients received appropriate aftercare following data collection upto their time of discharge and follow up.

Patients' hospital file number was included into the data sheet to facilitate easy tracing and capture missed information during data collection.

The data sheet was kept safely by the researcher and confidentiality maintained throughout. Electronic data file generated was encrypted with a password only availed to the research team. Any hard copy research data was kept in a safe locked cabinet only accessed by the research team. The collected data was destroyed after completion of this study.

4.0 RESULTS

During the study period of Oct 2016 – June 2017, 60 patients were evaluated with a diagnosis of acute scrotum. All patients were enrolled into the study having met the inclusion and exclusion criteria. The mean age of patients enrolled was 23 years. (Table 1 and figure 2)

44 patients (73.3%) were diagnosed with testicular torsion with a mean degree of torsion of 408 degrees and median of 390 degrees. 16 patients were diagnosed with other causes of acute scrotum (Figure 1).

66.7% of the patients enrolled presented after 24 hours with 5% of the patients presenting within 6 hours of time of onset of symptoms. (Figure 3)

KNH, being a tertiary referral facility, was the first point of contact for 33 patients (55%) while 27 patients (45%) presented at another health care facility prior to presenting to KNH.

There was no history of physical activity in 88.3% of the patients enrolled.

Figure 1 : Diagnosis of patients who presented with Acute Scrotum

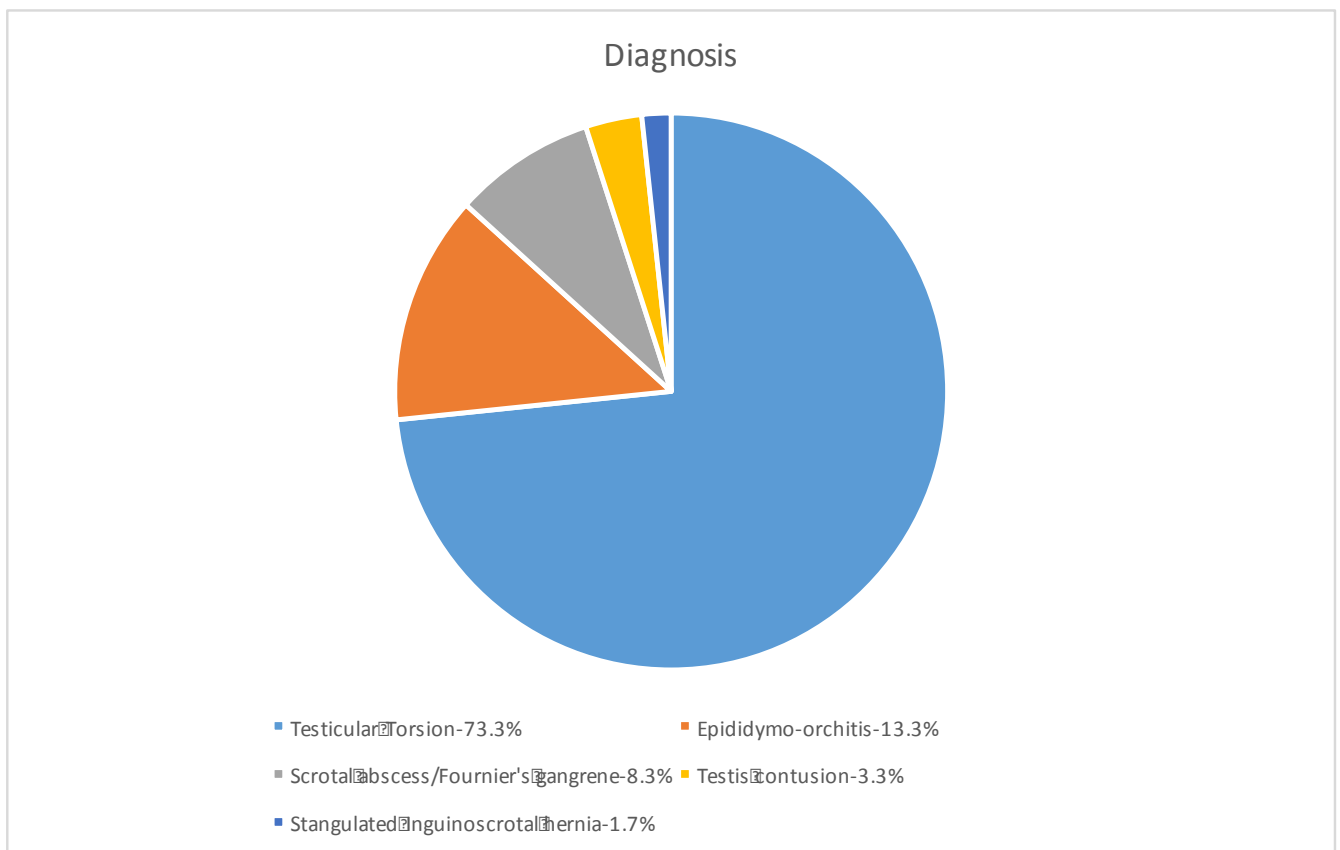
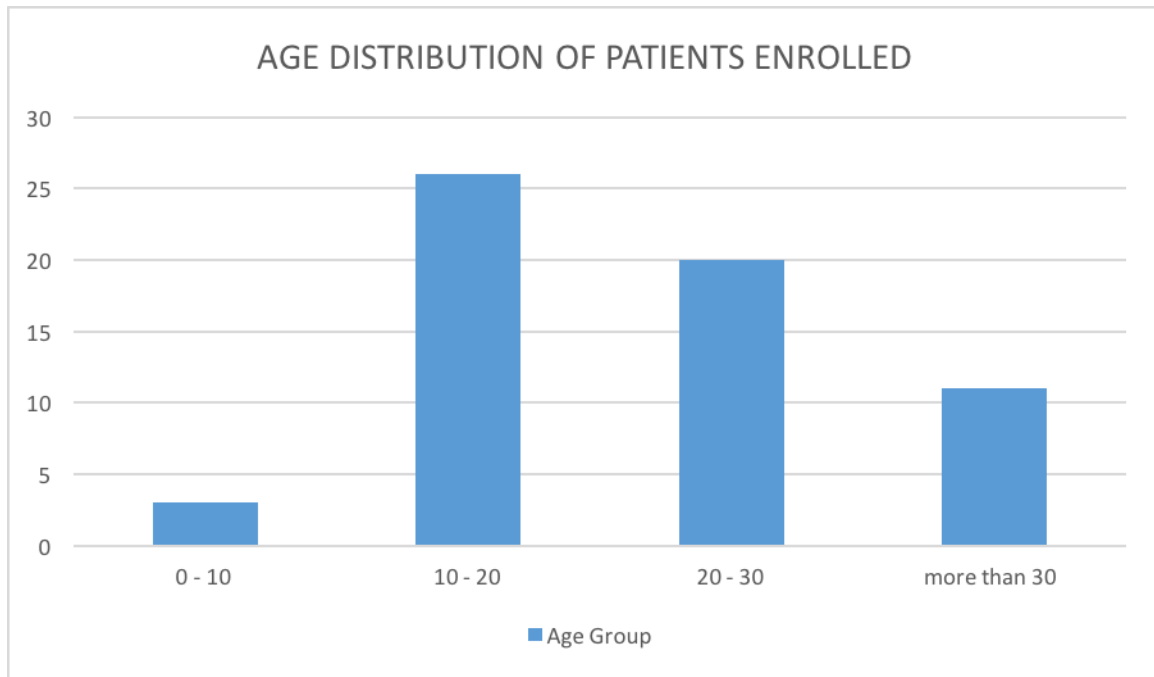


Table 1: Patient characteristics

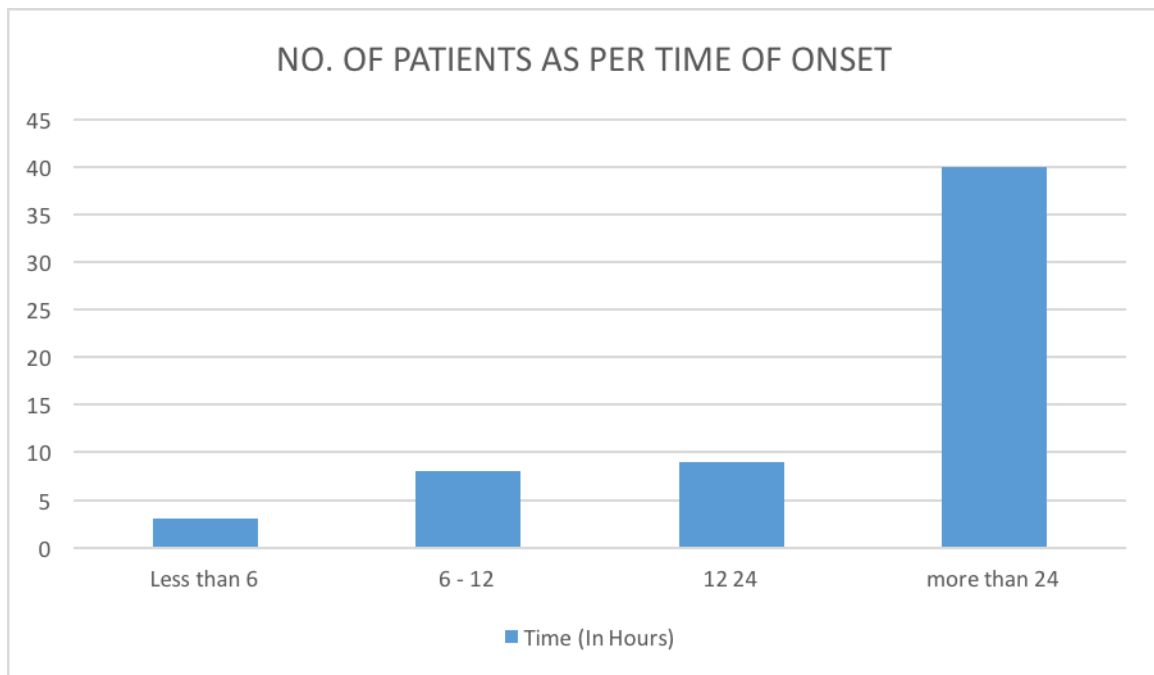
Variable	Frequency (%)
Age	
Mean (SD)	23.0 (9.0)
Min-Max	4-50
Time of onset in hours	
<6	3 (5.0)
6-12	8 (13.3)
12-24	9 (15.0)
>24	40 (66.7)
KNH the first point of contact	
Yes	33 (55.0)
No	27 (45.0)
If not KNH (n=27)	
Private physician/clinic	11 (40.7)
Dispensary	5 (18.5)
Hospital	11 (40.7)
History of physical activity	
Yes	11 (18.3)
No	53 (88.3)

Figure 2: Age distribution of patients enrolled



Fig

Figure 3 : Number of patients as per time of onset of symptoms



Of the 60 patients evaluated, 45 patients (75%) were categorized as high risk as per the TWIST Score. 43 patients had testicular torsion. The remaining 2 patients had epididymo-orchitis. Positive predictive value (PPV) was 95.6% and specificity was 87.5%. A total of 3 patients (5%) were categorized as low risk as per the TWIST Score. A total of 12 patients (20%) were categorized in the intermediate group of which 1 patient in this group had testicular torsion. (Tables 2 & 3)

Table 2: Diagnostic sensitivity and specificity of TWIST \geq 5

	Torsion (intraop findings)		Total
	Present	Absent	
TWIST			
(\geq 5)	43	2	45
(<5)	1	14	15
Total	44	16	60

	n/N	%
Sensitivity	43/44	97.7
Specificity	14/16	87.5
PPV	43/45	95.6

Table 3 : Diagnostic sensitivity and NPV of TWIST ≤ 2 score

	Torsion (intraop findings)		Total
	Yes	No	
TWIST ≤ 2	0	3	3

	n/N	%
Sensitivity	6/6	100.0
NPV	3/3	100.0

All patients grouped in the high risk category were operated on, with 43 patients confirming testicular torsion, and 2 patients being diagnosed with epididymo-orchitis. The 3 patients in the low risk category on follow up with Doppler scrotal ultrasound confirmed not to have testicular torsion. Of the 12 patients in the intermediate group, 9 patients were operated on. 1 patient had Testicular Torsion, 6 patients required operation for other causes and 2 patients had a diagnosis of epididymo-orchitis made intraoperatively. The remaining 3 patients were treated for epididymo-orchitis. (Table 4)

Table 4 : TWIST Score Results

Variable	Torsion	No torsion	P value
TWIST score			
0	0	1 (100.0)	<0.001
1	0	1 (100.0)	
2	0	1 (100.0)	
3	0	7 (100.0)	
4	1 (20.0)	4 (80.0)	
5	5 (71.4)	2 (28.6)	
6	28 (100.0)	0	
7	10 (100.0)	0	
TWIST			
≤ 2	0	3 (100.0)	<0.001
3,4	1 (20.0)	11 (80.0)	
≥ 5	43(95.6)	2(4.6)	

52 patients (86.7%) had a scrotal Doppler ultrasound done. In the group of patients who did not have an ultrasound done; 6 patients were in the high risk group and had testicular torsion confirmed intraoperatively while 2 patients required operation due to different diagnosis without need of an ultrasound. All patients had a haemogram and urea, creatinine and electrolytes done. (Table 5)

Table 5 : Investigations

Variable	Frequency (%)
Adjustment tests done and within reason CBC	
Routine	38 (63.3)
Investigative	22 (36.7)
U/E/C'S	
Routine	60 (100)
Scrotal Ultrasound	
Investigative	18 (30.0)
Confirmatory	34 (56.7)
No	8 (13.3)

Testicular salvage rates at KNH were found to be 9.1% (4patients). The average median preoperative waiting time was found to be 9 hours from the time of diagnosis at our facility. (Table 6)

Table 6 : Testicular Salvage

Variable	Frequency (%)
Testes Viability	
Yes	4 (9.1)
No	40 (90.9)

DISCUSSION

The acute scrotum is a urological emergency with testicular torsion a common cause.¹ Early recognition and treatment are prudent to the management of testicular Torsion.⁴

Assessing the TWIST score was hence important for application in our setup to reduce time to definitive management and reduce wastage of resources both to patients and the health providers.

The TWIST score was performed on all patients enrolled by either the principal investigator or surgical residents with confirmation of physical findings by either a second senior surgical resident or consultant.

In this study the TWIST score was found to be an excellent diagnostic tool in the diagnosis of testicular torsion, which is comparable to other studies.^{12,13}

Currently there is a high reliance on ultrasound towards making a diagnosis of testicular torsion.^{16,24,25} In our study population, 86.7% of the patients received a testicular Doppler ultrasound with 56.7% of the patients receiving an ultrasound to confirm the diagnosis and 30% of patients for investigative purposes. The remaining patients who did not receive an ultrasound all required operation. This is comparable to studies showing many physicians relying on testicular Doppler ultrasound to make a diagnosis of testicular torsion rather than using clinical judgement alone.⁴

A move toward the use of history and physical examination findings to diagnose testicular torsion is generally increasing, hence reducing time delays, costs and reliance on imaging.^{1,26,27}

In this study, 43/44 (95.6%) of patients with testicular torsion were detected by a high risk TWIST score (≥ 5). Two patients had a diagnosis of epididymo-orchitis. This resulted in a Positive predictive value (PPV) of 95.6% and Sensitivity of 97.7%. 3/60 (5%) of patients were grouped as low risk with none being diagnosed with testicular torsion, resulting in a Negative predictive value (NPV) of 100% with 100% specificity. It must be noted however, that this number is low to make a definitive conclusion on NPV. In our study, a high risk group cut-off of 6 and above would result in a PPV of 100% with 100% specificity.

The purpose of the TWIST Score is to categorise patients who require an ultrasound. All low risk and high risk patients, a total of 80%, could have avoided use of an ultrasound scan. In

the study carried out by Barbosa et al, approximately 80% of patients had unnecessary ultrasounds.¹²

The rate of testicular torsion in patients with an acute scrotum at KNH was found to be 73.7% with an unacceptably low salvage rate of 9.1%. In comparison Magoha et al found a rate of 86.36% with salvage rates of 21% in patients seen in various government and private facilities within Nairobi, though we note that this included cases seen in both private and government sectors unlike our study which was in a government facility.¹¹ It must be noted that time to presentation to our facility and the average pre-operative waiting time(9hours) found in our study was quite high and this may also have contributed to poor testicular salvage rates.

STUDY LIMITATION

The main drawback in this study was the low number of patients enrolled and categorized as a low risk group as per the TWIST Score. This may have biased the high NPV and sensitivity values. This may have been due to the fact that many patients that would be low risk are probably seen in peripheral facilities and not referred to KNH. Another limitation in the study was that investigations ordered were left to the discretion of the first resident to see the patient and hence most patients received an ultrasound despite their TWIST Score category. Of note was also no patient had a urinalysis done, an important investigation in ruling out infection, which could assist in differential diagnosis of acute scrotum. Infective causes were noted to be made using clinical findings, haemogram and ultrasound, and 2 cases being diagnosed intraoperatively.

CONCLUSION

The study has demonstrated the TWIST score as an invaluable tool in the diagnosis of testicular torsion. With PPV of 95.6% our study, the TWIST Score can predict the presence testicular torsion with a high efficacy. Despite a NPV of 100%, as the number of patients enrolled in this group were very low it is difficult to conclude on the TWIST score accurately predicting the absence of testicular torsion. This scoring tool can assist attending physicians/residents/surgeons stratify patients who present with an acute scrotum easily. The TWIST Score as a tool can hence aid in reducing waiting times for patients requiring operation, by reducing the reliance on scrotal ultrasounds for making or confirming a diagnosis of testicular torsion, and hence may improve salvage rates. In addition, overall costs to both patients and health care facilities can be reduced with application of this clinical tool.

RECOMMENDATIONS

As noted in this study, the number of patients enrolled and grouped into the low risk group was very low. This may have been due to such patients presenting more often at smaller facilities and not being referred to our facility. Therefore, a similar study may be carried out incorporating smaller health facilities where patients are seen prior to referral.

It would also be important to study the sensitivity and specificity of the scrotal Doppler ultrasound in diagnosing testicular torsion in our set up, as this is an important adjunct test in managing the acute scrotum and in the application of the TWIST score in its need in intermediate risk patients.

STUDY TIME FRAME

ACTIVITY	Jul 2016	Aug 2016	Sept 2016	Oct 2016	Nov 2016	Dec 2016	Jan 2017	Feb 2017	Mar 2017	Apr 2017	May 2017	Jun 2017	Jul 2017	Aug 2017
Proposal development														
Ethical Approval														
Data Collection														
Data Analysis														
Dissertation Writing and presentation														

STUDY BUDGET

Budget Item	Amount (K.shs)
Research fee for KNH-ERC	2,000
Statistician consultation fee	20,000
Stationery; (a) Printing	15,000
(b) Photocopying	6,000
(c) Binding	32,000
(d) Pens	500
Research assistants fee @15000 each (two assistants)	30,000
Contingency fund	20,000
Total	125,000

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APPENDICES

Appendix I : Informed Consent (English version)

A VALIDATION OF “THE TWIST” SCORE IN DIAGNOSIS OF TESTICULAR TORSION IN THE ACUTE SCROTUM IN KNH

This informed consent is for patients with an Acute Scrotum presenting at the Adult and Paediatric Accident and Emergency Department, KNH. This consent will be administered to the parents/patient’s guardians/patients themselves. We are requesting these patients to participate in this research project whose title is “**A Validation of “The Twist” Score in diagnosis of Testicular Torsion in the Acute Scrotum in KNH.**”

Principal investigator:

Dr. Hussein Shabbir Moosajee.

School of Medicine, Department of surgery- University of Nairobi

Supervisors:

Dr. Francis Osawa.

MBChB (U.O.N), M.Med Surgery (U.O.N), F.C.S (ECSA)

Department of pediatrics Surgery, School of Medicine, University of Nairobi

Dr. Francis Owillah

M.B.ch.B, M.Med Surgery (U.O.N), FCS (ECSA), Cert Urology. (EA),

Department of Surgery, School of Medicine, University of Nairobi

Dr. Swaleh Shahbal

MBChB (U.O.N), M.Med Surgery (U.O.N)

Department of Surgery, School of Medicine, University of Nairobi

This informed consent has three parts:

- Information sheet (to share information about the research with you)
- Certificate of Consent (for signatures if you agree to take part)
- 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 Hussein Shabbir Moosajee; I am a post graduate student at the University Of Nairobi School Of Medicine, department of general surgery. I am carrying out a study to validate “the twist” score in diagnosis of testicular torsion in the acute scrotum in our hospital, KNH. The TWIST score is a clinical scoring system that uses various signs and symptoms. Depending on the total sum value of the score, patients can be categorized and their management path determined. This score can improve health outcomes for patients and reduce overall costs to both patients and health facilities. Information towards conducting this study will be obtained through data collection by filling in a data collection tool/questionnaire.

Purpose of the research

Information obtained from this study will reveal to the doctors the efficacy of using the TWIST Score in diagnosing testicular torsion in patients with an acute scrotum and further help in the management of this condition. This study is also a requirement for any doctor who aspires to graduate from our college as a surgeon.

Voluntary Participation/Right to Decline or Withdraw

An invitation to participate in this study is hereby extended to you. You will have the opportunity to ask questions before you decide on your/ your Child’s enrollment into the study. You may seek clarification regarding any bit of the study from my assistant(s) or me should any part be unclear. The decision to participate in this study will be entirely voluntary after you have comprehensively understood the details herein. By refusing to participate in the study, you (or your kin) will not be denied medical care. Furthermore, you may stop participating at any time with no consequences whatsoever.

Confidentiality

All the information which you provide regarding yourself/your child/kin will be kept confidential; only the researchers will access this information. They will be identified by a number and only the researchers can relate the number to the patient. The information will not be shared with anyone else unless authorized by the Kenyatta National Hospital/University of Nairobi – Ethics and Research Committee (KNH/UoN-ERC).

Risks

Your/your child's or kin's involvement in this research will be through an interview and clinical evaluation and they will not expose themselves to any risks if you consent, to participate.

Cost and Compensation

There will be no extra cost incurred by you (or your kin) from participation in this study, and there is also no compensation.

Sharing of information

Following authorization by the Kenyatta National Hospital/University of Nairobi – Ethics and Research Committee (KNH/UoN-ERC), which is a committee whose work is to make sure research participants are protected from harm, relevant medical information yielded from this study may be shared with fellow doctors through scientific seminars, workshops and publications. Personal information will not be disclosed whatsoever.

Part ii: Consent certificate by patient’s guardian.

I.....freely give consent for myself/my child/kin (Name.....) to take part in the study conducted by Dr. Hussein Shabbir Moosajee, the nature of which has been explained to me by him/his research assistant. I have been informed and have understood that my participation is entirely voluntary and I understand that I am free to withdraw my consent at any time if I so wish and this will not in any way alter the care being given to me/my child or my proxy. The results of the study may directly be of benefit to me/my child or my kin and other patients.

.....
Signature/left thumb print (Patient/Guardian/Next of kin)
Date.....

Thumb print of participant if
Unable to sign due to illiteracy

Statement by the witness if patient/ guardian or proxy is illiterate.

I have witnessed the accurate reading of the consent form to the participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Name of witness.....

Signature of witness.....

Date.....

Who to contact

Secretary, KNH/UoN-ERC

P.O. Box 20723 KNH, Nairobi 00202

Tel +254-020-2726300-9 Ext 44355

Email: KNHplan@Ken.Healthnet.org

University of Nairobi research supervisors:**Dr. Francis Osawa**

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Principal researcher:**Dr. Hussein Shabbir Moosajee**

Department of Surgery, School of Medicine, University of Nairobi

P.O. Box 19676 KNH, Nairobi 00202

Mobile phone 0722526069

Part iii: Statement by the researcher

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

- Refusal to participate or withdrawal from the study will not compromise the quality of care and treatment given to the patient.
- All information given to us will be treated with confidentiality.
- The results of this study may be published to enhance knowledge and to help improve management of acute scrotum.

I confirm that the participant was given the chance to ask questions about the study, and all such questions 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 taking consent.....

Signature of researcher taking the consent.....

Date.....

Appendix II: Fomu ya Makubaliano ya Kujiunga na Utafiti

A VALIDATION OF “THE TWIST” SCORE IN DIAGNOSIS OF TESTICULAR TORSION IN THE ACUTE SCROTUM IN KNH

Fomu hii ya makubaliano ni kwa wagonjwa na “Acute scrotum” ambao wanahudumiwa kwenye Idara ya Ajali na Dharura katika hospitali ya KNH na wamealikwa kujiunga na utafiti, **“A Validation “The Twist” Score in diagnosis of Testicular Torsion in the Acute Scrotum in KNH”**

Mtafiti mkuu:

Daktari Hussein Shabbir Moosajee

Kituo:

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

Fomu hii ya makubaliano ina sehemu tatu:

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

Utapewa nakala ya fomu hii.

SEHEMU YA KWANZA: Ukurasa wa habari

Kitambulizi

Jina langu ni Daktari Hussein Shabbir Moosajee. Mimi ni daktari ninayesomea upasuaji katika Chuo Kikuu cha Nairobi. Ninafanya utafiti kwa anwani ya, **“A Validation of “The Twist” Score in diagnosis of Testicular Torsion in the Acute Scrotum in KNH”**

Lengo kuu la utafiti

Habari zilizopatikana kutoka utafiti huu itaonyesha kwa madaktari ufanisi wa kutumia TWIST Score katika kupima testicular torsion kwa wagonjwa na “acute scrotum” na msaada zaidi katika usimamizi wa hali hii. Utafiti huu pia ni mojawapo wa mahitaji ya kuhitimu kwa stashada ya upasuaji.

Ushiriki wa Hiari/Haki ya Kukataa

Ningependa kukualika ushiriki katika utafiti huu. Utapata nafasi ya kuuliza maswali kuhusu utafiti huu, aidha kutoka kwangu au kutoka kwa wasaidizi wangu. Baada ya kuelewa kabisa undani wa maelezo ya utafiti, ushiriki wako utakuwa wa hiari. Iwapo utaamua kutoshiriki katika utafiti, hautanyimwa matibabu. Isitoshe, ukishaamua kushiriki, ni haki yako kukataa kuendelea na ushiriki huo wakati wowote ule bila madhara yoyote.

Taadhima ya Siri

Ujumbe wote utakaotokana nawe utahifadhiwa kwa siri, na utatumika tu na wahusika wa utafiti kwa malengo ya utafiti pekee. Jina lako au la mtoto yako halitaorodheshwa popote katika utafiti huu; nambari spesheli itatumika katika utambulizi wako.

Utumizi wa Matokeo ya Utafiti

Nakala za matokeo ya utafiti huu zitahifadhiwa kwa siri katika maktaba ya Idara ya Upasuaji, Chuo Kikuu cha Nairobi. Kwa minajili ya kuendeleza ujuzi wa Sayansi ya Utabibu, huenda haja ya kuarifu matabibu wengine kuhusu utafiti huu itokee. Cha muhimu ni kwamba, ruhusa itaombwa kutoka kwa Afisi ya Maadili ya Utafiti inayosimamia utafiti katika Hospitali kuu ya Kenyatta na Chuo Kikuu cha Nairobi, kabla ya kutumia matokeo ya utafiti huu katika warsha za Sayansi au kuyachapisha katika majarida ya Sayansi. Nyakati hizo, ujumbe wa kibinafsi hautafichuliwa kamwe.

Madhara

Utafiti huu hauna madhara yoyote kwako.

Gharama/Malipo

Hakuna gharama ya ziada wala malipo utakayopata kutokana na kushiriki kwako katika utafiti

SEHEMU YA PILI: Fomu ya makubaliano

Nimeelezwa utafiti huu kwa kina. Nakubali kushiriki utafiti huu kwa hiari yangu. Nimepata wakati wa kuuliza maswali na nimeelewa kuwa iwapo nina maswali zaidi, ninaweza kumwuliza mtafiti mkuu au watafiti waliotajwa hapa juu.

Jina la Mshiriki:.....

Sahihi ya mshiriki:.....

Tarehe:.....

Kwa wasioweza kusoma na kuandika:

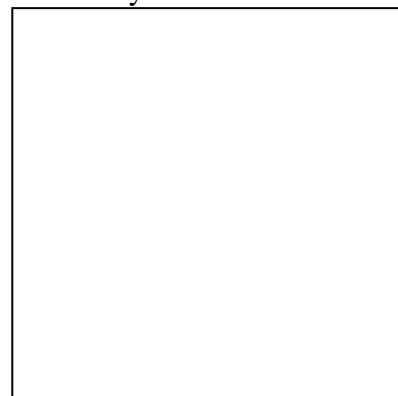
Nimeshuhudia usomaji na maelezo ya utafiti huu kwa mshiriki. Mshiriki amepewa nafasi ya kuuliza maswali. Nathibitisha kuwa mshiriki alipeana ruhusa ya kushiriki bila ya kulazimishwa.

Jina la shahidi.....

Alama ya kidole cha mshiriki

Sahihi la shahidi:.....

Tarehe:.....



Anwani za Wahusika

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

1. Mtafiti Mkuu:

Daktari Hussein Shabbir Moosajee,

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

SLP 19676 KNH, Nairobi 00202.

Simu: 0722526069.

2. Wahadhiri wahusika:

Daktari Francis Osawa,

MBCh.B, M.MED (Gen Surg.), F.C.S (ECSA),

Consultant paediatric surgeon/Mhadhiri,

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

SLP 19676 KNH, Nairobi 00202.

Daktari Francis Owillah

MBCHB, MMED (UON), FCS (ECSA), Cert Urology. (EA)

Daktari wa upasuaji / Urology

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

SLP 19676 KNH, Nairobi 00202.

Daktari Swaleh Shahbal

MBChB (U.O.N), M.Med Surgery (U.O.N)

Daktari wa upasuaji

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

SLP 19676 KNH, Nairobi 00202.

Wahusika wa maslahi yako katika Utafiti:

Karani,

KNH/UoN-ERC

SLP 20723 KNH, Nairobi 00202

Simu: +254-020-2726300-9 Ext 44355

Barua pepe: KNHplan@Ken.Healthnet.org

SEHEMU YA TATU: Ujumbe kutoka kwa mtafiti

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

- Kutoshiriki au kujitoa kwenye utafiti huu hautadhuru kupata kwake kwa matibabu.
- Ujumbe kuhusu majibu yake yatahifadhiwa kwa siri.
- Matokeo ya utafiti huu yanaweza chapishwa ili kuwezesha kutibu ugonjwa wa acute scrotum.

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 III: Assent Form for children 12 years to 18 years

My name is Dr Hussein Shabbir Moosajee; I am doing a study about **“A Validation of “The Twist” Score in diagnosis of Testicular Torsion in the Acute Scrotum in KNH.”**

We will be looking at the efficacy of the twist (testicular workup for ischemia and suspected torsion) score in diagnosis of testicular torsion in patients who present with an acute scrotum in our hospital, KNH.

This may help us improve management of this condition, reduce overall costs and improve resource utilization, and hence advise our patients accordingly. If you would like, you can participate in this study.

If you decide you want to participate in my study, your parent will be asked some personal questions, and required to go through a data collection tool with me or my research assistant. You will also undergo a physical examination.

There are no risks involved in this study; you will not incur any extra costs for participating in this study.

Other people will not know if you are participating in this study. Your answers and your progress will be kept private. When I tell other people about my research, I will not use your name, so no one can tell who I am talking about.

Your parents or guardian have to say it is okay for you to be in the study. After they decide, you get to choose if you want to do it too. If you don't want to be in the study, you will not get into any trouble. You can stop being in the study at any time.

My telephone number is 0722526069. You can call me if you have questions about the study or if you decide you do not want to be in the study any more.

I will give you a copy of this form in case you want to ask questions later.

Sign this form only if you:

- Have understood what you will be doing for this study,
- Have had all your questions answered,
- Have talked to your parent(s)/legal guardian about this project, and
- agree to take part in this research

.....

Your Signature

Name

Date

.....

Name of Parent(s) or Legal Guardian(s)

.....

Researcher explaining study

Signature

Name

Date

Appendix IV: Acute Scrotum Data Collection Tool

Patient Hospital Number

Study Number

1. Age :

2. Time from onset of pain:

- < 6 hrs
- 6-12 hrs
- 12 – 24 hrs
- > 24 hrs

3. Is this (KNH) the first point of contact?

Yes

No

If No, State the first point of contact:

- Private Physician / Clinic
- Dispensary
- Hospital (Specify level)
- Others (Specify)

4. History of Physical Activity?

Yes

No

If Yes, state activity (for example, swimming, cycling, weight lifting, etc.)

.....

5. History and Physical examination:

(Please tick appropriate box and add sum total of points)

- | | | |
|-------------------------------|--------------------------|------------|
| Testicular Swelling | <input type="checkbox"/> | (2 points) |
| Hard Testicle | <input type="checkbox"/> | (2 points) |
| Absence of cremasteric reflex | <input type="checkbox"/> | (1 point) |
| Nausea / Vomiting | <input type="checkbox"/> | (1 point) |
| High riding testis | <input type="checkbox"/> | (1point) |
| Sum Total | | |

(NB: Highest Score available is 7)

This is the TWIST (Testicular Workup For Ischemia And Suspected Torsion) Score.

- ≤ 2 Points – Low risk for Testicular Torsion
(Do Doppler Ultrasound for review on follow up visit in 1 week)
- 3 -4 Points – Intermediate risk for Testicular Torsion
(Do Doppler Ultrasound for further evaluation)
- ≥ 5 Points – High risk for Testicular Torsion
(Proceed to theatre)

6. Adjunct Tests done: (Please Tick)

- CBC
- U/E/C's
- Urinalysis
- Scrotal Ultrasound

(if done and TWIST Score < 2 Points / > 5 Points give reason)

.....

7. Pre-operative waiting period (if applicable):

.....

8. Intraoperative Findings:

- Testicular torsion – Yes No
- If Yes, is testis viable? Yes No

Degree of torsion:

.....

If No, Give Findings:

.....

9. For low risk Patients:

- Doppler Ultrasound findings:
 - Testicular Torsion
 - Epididymo-orchitis
 - Other Please state:.....

- Any change in symptoms? Yes No
(If Yes, please state change – Better/Worse:

Turnitin Originality Report

A VALIDATION OF THE "TWIST" SCORE IN DIAGNOSIS OF ACUTE TESTICULAR TORSION IN THE ACUTE SCROTUM IN KENYATTA NATIONAL HOSPITAL

by Hussein Moosaj

From Surgery (Medicine)

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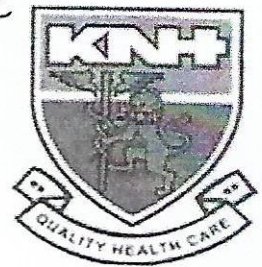
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3rd October 2016

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Dear Dr. Moosajee

REVISED RESEARCH PROPOSAL; A VALIDATION OF THE "TWIST" SCORE IN DIAGNOSIS OF ACUTE TESTICULAR TORSION IN THE ACUTE SCROTUM IN KENYATTA NATIONAL HOSPITAL (P457/06/2016)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and **approved** your above revised proposal. The approval period is from 3rd October 2016 – 2nd October 2017.

This approval is subject to compliance with the following requirements:

- a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
 - b) All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH-UoN ERC before implementation.
 - c) 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.
 - d) 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.
 - e) Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
 - f) Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
 - g) 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>