SURGICAL APGAR SCORE: A PREDICTOR OF POSTOPERATIVE COMPLICATION IN PATIENTS UNDERGOING SURGERY FOR TRAUMATIC BRAIN INJURY.

A PROSPECTIVE STUDY

A DISSERTATION SUBMITTED IN PART FULFILMENT OF THE REQUIREMENTS OF THE UNIVERSITY OF NAIROBI FOR AWARD OF THE DEGREE OF MASTER OF MEDICINE IN GENERAL SURGERY.

By

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2015

DECLARATION

I hereby certify that this study is my original work and has not been submitted for any degree in any institution.

Dr. Taha .S. Yusufali

Sign……Date…….

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LIST OF ABBREVIATIONS

AKI	Acute kidney injury
APACHE	Acute Physiological and Chronic Health Evaluation
ASA	American Society of Anesthesiologists
ASDH	Acute subdural hemorrhage
CRF	Chronic renal failure
EBL	Estimated Blood Loss
EDH	Extradural hemorrhage
ERC	Ethics Research Committee
GCS	Glasgow coma scale
HDU	High dependency unit
ICH	Intracerebral hemorrhage
ICU	Intensive care unit
IQ	Intelligence Quotient
KNH	Kenyatta National Hospital
MAP	Mean Arterial Pressure
MODS	Multiple organ dysfunction score
MPM	Mortality Probability Model
NSQIP	National Surgical Quality Improvement Program
POSSUM	Physiological and operative severity score for enumeration of mortality and morbidity
P-POSSUM	Portsmouth Physiological and operative severity score for enumeration of mortality and morbidity
SAPS	Simplified Acute Physiological Score
SAS	Surgical Apgar Score
SASDH	Subacute subdural hemorrhage
TBI	Traumatic Brain Injury
TRIOS	Three days recalibrated ICU outcome score
UON	University of Nairobi

DEFINITIONS:

Acute kidney injury (AKI): an abrupt or rapid decline in renal filtration function (emedicine).

Surgical Site Infection: an infection that occurs after surgery in the part of the body where the surgery took place (CDC; http://www.cdc.gov/hai/ssi/ssi.html).

Sepsis: presence of infection in conjunction with the systemic inflammatory response syndrome (SIRS) (Medscape).

Septic Shock: sepsis-induced acute circulatory failure characterized by persistent arterial hypotension despite adequate volume resuscitation and not explained by other causes. (Medscape).

Abstract:

Background: Health facilities strive to offer quality surgical care by minimizing postoperative complications. Predicting complications facilitates objective clinical decision making during recovery. Compared to existing morbidity and mortality predictive scores, the Surgical Apgar Score is simple and effective. Morbidity and mortality in neurotrauma patients are high; an effective scoring system can reduce these.

Objective: To determine the utility of the Surgical Apgar Score in predicting the 'thirty day major postoperative complications rates for patients with traumatic brain injury.

Study design: Prospective descriptive study.

Study population: Two hundred and three patients aged 13 years and above undergoing surgery for traumatic brain injury at Kenyatta National Hospital were selected by consecutive sampling until the desired sample size was achieved.

Study duration: Four months from 23rd December 2014 to 15th April 2015.

Material and methods:

Intra operative values of the lowest mean arterial pressure, the lowest heart rate and the blood loss were collected using a questionnaire immediately after surgery and the Surgical Apgar Score was derived for each patient. The occurrence of major complications and the mortality rate was determined during a thirty day period starting immediately after surgery. Data was obtained from the admitting ward, the ICU and neurosurgical outpatient clinic notes. Major complication definitions were according to American College of Surgeons' National Surgical Quality Improvement Program with inclusion of seizure.

Data collected was entered and analyzed using SPSS version 17software. P values were generated using t test for means, $x2$ for comparison of proportions, analysis of variance (ANOVA) and where applicable Fischer's exact test. Results were presented in graph, tables and charts.

Results

Two hundred and seven (207) patients were recruited of which six were lost on follow up. Mean age was 32.7 year with male to female ratio of 22:1. One hundred and sixteen(56%) of the patients developed one or more major complications during the 30 day period post surgery. Need for intensive care (43.1%) and development of neurological deficit (38.8%)

were the common post operative complications. While older age was associated with more complications, no significant difference in complication rates was found between male and female patients. Most patients 40(19%) had a SAS of 6 with a mean of 5.72. The mean SAS for patients without complications was 7.04(±0.29) while for patients with complications was 4.80(±0.30) (p-value < 0.001). High risk SAS category patients (78%) developed more major postoperative complications compared to medium and low risk SAS category patients. Thirty day mortality and need of intensive care were also linked with high risk SAS. SAS was found to have a strong correlation with occurrence of major complication during the 30 day post surgery period.

Conclusion

Surgery for neurotrauma is associated with significant morbidity and mortality. The SAS, despite using simple and widely available intra-operative parameters, is useful tool to predict occurrence of 30 day major complications and mortality following surgery in patients with traumatic brain injury.

1.0 INTRODUCTION

An ideal model to predict postoperative complications should be simple and readily applicable to almost all surgical patients. It should properly define the complications, accurately estimate their incidence and have a low threshold to detect them[1].

Intraoperative factors altering a patients' condition include extremes in blood pressure (hyper or hypotension), hypothermia, bradycardia / tachycardia and the amount of blood loss during surgery. A trend of increased complication is observed among patients whose intraoperative mean arterial pressure (MAP) decreases to less than 70mmHg [2]. Bradycardia and hypotension are also independently linked to poor outcomes in the recovery period[2,3,4,5]. A higher wound class and ASA class are also linked to an increase postoperative mortality and morbidity[6]. No consensus exists on how to directly evaluate performance and safety during an operation using these variables[7]. For the score to be a clinically useful predictor of postoperative complications, each component should independently and collectively contribute to outcome prediction.

In the operating room, the surgeon usually relies principally on his "gut feeling" instead of objective assessment to predict postoperative events[8]. Operative management contributes heavily to the overall outcome of the patient although there is no available quantitative measure of the operative care provided[1].

A simple surgical outcome score, which will allow a surgical team to collect data immediately on completion of an operation, regardless of available resources and technological capacity was derived by Gawande et al. This is the ten point Surgical Apgar score (SAS) which predicts postoperative complications (including mortality) and is applicable to all surgical specialties. The score was derived after collection of 28 parameters during surgery and after analyzing them. Only three intraoperative variables remained independent predictors of major postoperative complications and death. These were the lowest heart rate, the lowest mean arterial pressure and estimated blood loss during the surgery[9].

The Surgical Apgar Score, POSSUM and P-POSSUM have been validated at Kenyatta National Hospital in patients undergoing laparotomy and were found to be adequate in predicting major postoperative complication[10, 11].

In neurosurgery, there has been no comparative tool to quickly assess and objectively determine the status of patients using intraoperative physiological parameters. Previous

efforts have been made to validate the POSSUM and P-POSSUM scores in neurosurgical patients using perioperative parameters but due to their complexity, they have not gained widespread acceptance[12].

Local studies have mainly linked the admission clinical parameters with the outcomes of head injury but none of the intraoperative parameters has so far been evaluated for predicting mortality and morbidity in neurosurgical patients[13].

This study will help us to evaluate the utility of the SAS in patients who have undergone surgery for traumatic head injury at Kenyatta National Hospital. In particular, this study will determine the score ability to predict major postoperative complications common in our population. It will also facilitate objective decision making in regards to location for patients in immediate postoperative period.

1.1 LITERATURE REVIEW

Reduction of postoperative complications sets a benchmark for assessing quality of health care provided in a health institution. Both the hospital administration and the surgical team strive to offer surgical services with minimal major postoperative complications, thereby reducing the cost of healthcare to the patient and the hospital. Most of the major postoperative complications are linked to preoperative risk factors in the patient[1].

For health facilities to provide quality surgical care, installation and commission of all available resources is required to enable the most deserving patient to receive the optimum care. To accomplish this it is very important to identify the potential risks of developing complications after surgery[14].

Using the Medicare system, Lawson et al. demonstrated that patients with postoperative complications had a higher predicted probability of readmission and the cost of the readmission was greater than patients without a complication. The cost reduction by reducing postoperative complications was estimated at $620.3 million per year[15].

In a tertiary hospital, Khan et al. found that patients developing postoperative complications increased their hospital stay by 114% and hospital cost by 78%[16].

Predicting complications can help in predicting readmissions, step up or step down level of care depending on the probability of a complication occurring and also help in staffing medical personnel in a particular shift[17].

Therefore, adequate stratification and scoring of risk should be considered essential to aid clinical practice.

Surgical patients are assessed at various stations throughout their journey from admission to discharge and follow up in the outpatient clinics. This can generally be categorized in three groups:

1. Preoperative assessment; where planning an intervention and assessment of inbuilt physiological and acquired pathological comorbidity is carried out.
2. Perioperative assessment; where based on preoperative risk stratification the patient's most suitable setting for further care is determined (i.e. admission to general ward, ICU/HDU or daycare setup).
3. Postoperative assessment; where scores calculated from intraoperative variables can alter postoperative management in a patient.

Postoperative morbidity and mortality are associated with three major risk factors:

1. patient comorbitities
2. nature of surgical procedure and
3. anesthetic risk

The American society of anesthesiologists (ASA) classification is used by anesthetists to measure a patient's comorbidity preoperatively. A higher ASA score is associated with both a higher 30 and a higher 48 postoperative day mortality. Nearly 35% of ASA grade V patients die within 48 hours of surgery and nearly 50% of these patients die within the next 30 days[18.]

In the management of neurosurgical cases, no validated comparative tool was available until 2008 when the Physiological and Operative Severity Score for the enumeration of Mortality and Morbidity (POSSUM) and the Portsmouth-POSSUM (P-POSSUM) scoring systems were evaluated in Indian patients undergoing elective craniotomy and it was concluded that the P-POSSUM score was highly accurate in predicting overall mortality[12].

The existing scores to predict mortality and morbidity such as APACHE, POSSUM, P-POSSUM have not gained good acceptance in surgical practice due to complexity in calculating them at the bedside, need of numerous data which is not uniformly collected and existence of interdisciplinary disagreement on their interpretation[19, 20].

1.1.1 Surgical Apgar Score

In 1953, Virginia Apgar formulated a scoring system for evaluating the condition of newborns using basic physiological parameters. Its simplicity and effectiveness in predicting performance of the newborn after delivery led to its wide acceptance worldwide[21].

Gawande et al using the same principle came up with an intraoperative scoring system known as the Surgical Apgar score (SAS). The SAS is based on three easily calculated physiological parameters; estimated blood loss, lowest intraoperative heart rate and the lowest intra operative mean arterial blood pressure. Preoperative, intra operative and postoperative data was collected in three cohorts of patients, starting from a single type of procedure to a broader category of patients in general and vascular surgery, after which a score was derived. The outcomes database obtained from the National Surgical Quality Improvement Program (NSQIP) and 28 intraoperative variables from anesthetic data for each patient where analyzed. Two preoperative and nine intra operative variables were associated with major complications and death within 30 days of surgery. From these, lowest heart rate, estimated blood loss and lowest MAP where found to be independent predictors of post surgery outcomes [9].

The score derived from these parameters composes a predictive model for categorizing patients at risk of major postoperative complications in general and vascular surgical procedures. It was found that a lower score increased the chances of developing complications. Major complications occurred in 58.6% of patients with a score of less than four, while only 3.6% of patients with a score of 9 or 10 developed complications[9].

Cardiovascular performance and the degree of blood loss in surgery play a critical role in determining the postoperative course of a patient. The collective importance of heart rate, blood pressure and blood loss and their contribution towards gauging intraoperative performance can be easily recognized by the SAS[5, 22].

Data obtained from this scoring system can be used to plan an aggressive postoperative approach in patients with a low score and also guide clinicians in taking preventive measures such as optimizing blood pressure, heart rate and restoring intravascular volume. The surgeon, having an immediate score after surgery, is able to categorize the patients who need intense postoperative monitoring from those who are more likely to have an uneventful

course. This suggests that the SAS may be useful in neurosurgical patients who are prone to a high rate of postoperative morbidity and mortality. The score can also serve as a mode of communication between surgeons, residents and nursing staff about a patient's post operative status and assist in decision making. This includes decisions like when to discharge the patient after surgery, admission to ICU, frequency of postoperative visits, follow up at outpatient clinics and having a high index of suspicion to pick up a complication early[9].

Ghaferi et al noted that surgical mortality in different centers is not explained by postoperative complications but rather by the ability to "rescue" patients from these complications[23]. The score has also been used to grade health care institutions by comparing their predicted versus observed scores[24].

From the time Gawande introduced this scoring system it has gained interest in different fields of surgery like general surgery, vascular surgery, gynecology, urology and neurosurgery with promising predictive values [25]. There has been some critique on calculation of estimated blood loss and its subjectiveness. However studies done to evaluate the score, categorizes blood loss in categories of 0–100 ml, 101–600 ml, 600–1,000 ml, >1,000 ml which are easily within the observers' range of precision. Blood loss can also be calculated using a mathematical formula which uses a patient's hematological parameters and excludes biases [26, 27]. There is also a dispute over the influence of anesthetic manipulations and drugs on intra operative hemodynamic parameters which comprise the score. However, evidence shows that alteration in blood pressure and heart rate whether caused by the patients' pathology or influenced by the anesthetist during surgery will have a final impact on the outcomes of surgery[28, 29].

The score in all previous studies has been used across all groups of patients with different preoperative comorbidities. Regardless of the complexity of preoperative risks stratification, the score has been proven to be effective as a measure of the postoperative condition of the patient[24].

While it has been validated mostly in developed countries, more global studies in different populations need to be done before the SAS becomes as widely accepted as APACHE and P-POSSUM[24].

The SAS has been extensively used in general and vascular Surgery patients, its use in neurosurgery and in neurotrauma patients in particular has only been evaluated in few

centers. The results from these centers however show a strong correlation of the SAS with the occurrence of major postoperative complications[25,30].

The SAS for patients undergoing intracranial and spinal surgery has been validated in 918 patients where morbidity, mortality, ICU/HDU stay and hospital stay were found to have strong correlation with the SAS. This study was done in a developed country where we believe most of the patients are managed in neurosurgical units and are not resource restricted. It was a retrospective study and the author had recommended a prospective study to verify the findings in other institutions[30].

Another study to evaluate the SAS in all surgical specialties including 7,589 neurosurgery patients concluded that although it carries prognostication strength in neurosurgical patients, there exists variation across other specialties[25].

Table 1.The 10 point surgical Apgar score9.

	0 point	1 point	2 points	3 points	4 points
Estimated blood loss (ml)	> 1000	601 - 1000	101 - 600	≤ 100	-
Lowest mean arterial pressure (mmHg)	< 40	40 - 54	55 - 69	≥ 70	-
Lowest heart rate (beats/min)	> 85	76 - 85	66 - 75	56 - 65	≤ 55

* The score is a sum of the points for each category of a procedure

* Pathological bradyarrhythmia, sinus arrest, atrioventricular block or dissociation, junction or ventricular escape rhythms and asystole receive 0 points for lowest heart rate.

1.1.2Traumatic Brain Injury

Traumatic brain injury is a major cause of morbidity around the world with an estimate incidence of around 200 per 100,000 every year. Variation of the incidence, prevalence and duration of disability exists across the globe with preliminary reports from literature suggesting higher figures in developing countries[31].

TBI is defined as an injury to the head arising from blunt or penetrating trauma or from acceleration/ deceleration forces associated with one or more of the following: decreased level of consciousness, amnesia, objective neurologic or neuropsychological abnormality, skull fracture(s), diagnosed intracranial lesion(s), or head injury listed as a cause of death in

the death certificate. It is the most common cause of death and disability in children and young adults[32].

In the United States, there are 235,000 hospitalizations, 50,000 deaths and 90,000 people who are disabled for a long time every year from TBI alone. The economic burden for TBI alone in the United States was estimated at $9.2 billion in lifetime medical costs and $51.2 billion in productivity losses in the year 2000. The most common causes are attributed to motor vehicle crashes, falls and violence[33]. A short term follow up of soldiers with TBI, indicated mild TBI to be more associated with mental conditions while severe TBI was associated with increased morbidity and medical dependency[34]. Patients with severe TBI also had reduced quality of life, lower IQ, educational and employment problems in the long run[35].

In Africa, the predominant mechanism of injury for TBI is road traffic accidents and assault. The population affected most is children and young adults[36]. A study done in Kenyatta National Hospital found a patient's age, GCS on admission, systolic blood pressure on admission, presence of other associated injuries and absence of pupil reaction to light to be associated with poor outcomes in severe head injury patients. Mortality in patients with severe head injury was 56.2% of which 60% died within 48hours of admission[13].

1.1.3 Post operative complications:

Major postoperative complications according to the definitions used by the American College of Surgeons' National Surgical Quality Improvement Program are the following[37]:

Acute renal failure, bleeding requiring 4 units of red cell transfusion within 72 hours after operation, cardiac arrest requiring cardiopulmonary resuscitation, coma for 24 hours, deep venous thrombosis, myocardial infarction, unplanned intubation, ventilator use for 48 hours, pneumonia, pulmonary embolism, stroke, major wound disruption, surgical site infection, sepsis, septic shock, systemic inflammatory response syndrome, unplanned return to the operating room, and vascular graft failure.

2.0 JUSTIFICATION:

Surgeries for Traumatic brain Injury are one of the most common operations performed in Kenyatta National Hospital trauma theaters. Complications in these patients during their recovery period are not uncommon. The SAS is a simple and reliable tool which can be easily calculated by the surgeon when writing his operation notes. The parameters are easy to obtain without any additional cost to the hospital and the patient.

There has not been any comparative risk evaluating system using intraoperative parameters which has been actively used for neurotrauma patients in this Hospital. The SAS has been proven efficient in predicting major postoperative complications in general surgery but there has not been a local study to evaluate it efficacy in neurotrauma patients.

2.1 OBJECTIVE OF THE STUDY

2.1.1 Main objective:

To determine the utility of the SAS in predicting 'the thirty day' major postoperative complications rate in patients undergoing surgery for traumatic brain injury.

2.1.2 Specific objectives:

1. To determine percentage of patients undergoing surgery for traumatic brain injury who develop major postoperative complications.
2. To determine SAS in patients undergoing surgery for TBI.
3. To determine major post operative complications commonly found in patients undergoing surgery for TBI.

2.2 MATERIALS AND METHODS

2.2.1 Study area

The study was conducted at the Kenyatta National Hospital surgical wards, intensive care units, neurotrauma intensive care unit and the trauma and main theatres. Senior house officers in general surgery and neurosurgery provided pre and post operative care for acute neurotrauma patients and participate in surgical procedures when indicated. Anesthetists, apart from providing anesthesia during surgery, extended their care in the intensive care unit. The institution has a capacity to undertake major surgical procedures on a round the clock basis.

2.2.2 Study population

The target population was patients undergoing surgery for Traumatic Brain Injury admitted to the surgical wards, Neurosurgery ward and intensive and high dependency units who meet the eligibility criteria. Selection of patients was from the point first seen at KNH.

2.2.3 Study design

A hospital based, single centre prospective cohort study carried out from December 2014 to March 2015.

2.2.4 Inclusion criteria

All patients above 13 years of age scheduled for Traumatic Brain Injury surgery at KNH in whom appropriate consent to participate in the study had been obtained.

2.2.5 Exclusion criteria

Patients who underwent major surgical procedures on other body regions during or within thirty days of the TBI surgery under study.

Patients in whom appropriate consent had not been obtained.

Patients who underwent surgery under local anesthesia or in a setup where adequate monitoring of blood pressure and heart rate could not be carried out.

2.2.6 Study endpoint

Patients were followed up to the thirtieth post-operative days after surgery for traumatic brain injury. Discharged patients before thirty days were followed up at outpatient clinic with assigned dates.

2.3 SAMPLE SIZE

Using the formula:

$$n=\frac{z^2 \times p\,(1-p)}{d^2}$$

Where
z = score at 95% confidence interval (1.96)
p = 30 day mortality in acute neurotrauma patients undergoing surgery (15.7%) [38]
d = margin of error (0.05%)

n= 203

2.4 SAMPLING METHOD

Using non-probability convenience sampling all patients 13 years and above admitted to Kenyatta National Hospital and for whom surgery for Traumatic Brain Injury is scheduled and who met all inclusion and none of the exclusion criteria were recruited until the desired sample size of 203.

2.5 DATA COLLECTION

The primary researcher and a trained assistant recorded the required variables in the data collecting sheet. Data was collected after the surgery (within 24 hours) in the operating theater, recovery area, ICU/HDU or in the ward admitted. Anesthetic notes were used to collect blood pressure, heart rate parameters during the surgery. Blood pressure and heart rate were monitored every fifteen minutes from induction to reversal of general anesthesia. MAP was calculated by using a formula [(2 x diastolic pressure) + systolic pressure] / 3.

Pre and post operative hematocrit and hemoglobin levels to calculate blood loss was obtained from patient's pre and post surgery full hemogram results. Post operative follow up notes both as inpatient and outpatient for the next thirty days after surgery was used to determine occurrence of any major postoperative complications.

Data was collected using a standard questionnaire administered by the principal researcher and a trained assistant. The collected data was entered into a password-protected customized MS Access database with in-built checks to minimize on data entry error. Once data entry is complete, the principal researcher compared the entered data with the hard copy forms to check for errors, inconsistencies, missing entries and duplicate entries to ensure high quality data.

Personal identifying information like the patients telephone number which might be needed to remind patients on their due outpatient visit during the study period were coded with a key stored separately and known only to the investigators. Reference number was used instead of patients' inpatient file number for follow up purposes.

The 'trained assistant' was a medical doctor with a minimum qualification of bachelor's degree in medicine. He/she was familiarized with the study protocol and trained by the principle investigator on how to collect data from the anesthetic notes, pre and postoperative laboratory results and patients follow up notes from the file. He/she was also shown how to enter this data in the data collection sheet and calculate SAS.

Data collected included;

1. Age
2. Sex
3. Nature of operation; Craniotomy, Craniectomy, elevation of depressed skull fracture(s), cranialization of paranasal sinuses, burr holes.
4. Diagnosis
5. The SAS derived from blood loss, lowest recorded mean arterial pressure and lowest recorded pulse rate. Blood loss was calculated using a mathematical formula presented below.
6. The occurrence of major complications and mortality within 30 days (postoperatively) was based on follow-up data in the admitting ward and the surgical outpatient clinic notes.

Major complications definitions was according to American College of Surgeons' National Surgical Quality Improvement Program (6);

Patients were subsequently grouped into three categories based on their SAS for purposes of risk stratification.

High risk 0 to 4

Medium risk 5 to 7

Low risk 8 to 10

Blood loss was calculated using a mathematical formula[27]:

Blood loss = {EBV x (H (i) - H (f)) / ((Hct (i) + Hct (f))/2} + (500 x T (u))

Where:

1. Estimated blood volume (EBV) is assumed to be 70 cm^3/kg;
2. H(i) and H(f) represent pre and post operative hemoglobin
3. Hgb(i)and Hgb(f) represents pre and post operative hematocrit
4. T (u) is the sum of whole blood, packed red blood cells, and cell saver units transfused.

3.0 DATA MANAGEMENT AND ANALYSIS

Data collected was entered into and analyzed using SPSS (SPSS, Chicago, Illinois, USA) version 17 software. P values was generated using t test for means, Chi square (x2) for comparison of proportions, analysis of variance (ANOVA) and where applicable Fischer's exact test. Value of $p < 0.05$ was considered significant.

All raw data is stored in electronic form in a password protected hard drive which is known only to the principle investigator. Access to this data in future by any interested party for purposes of research or policy making will be after an official permission by the KNH/UON – ERC.

3.1 ETHICAL CONSIDERATIONS

Approval to conduct the study was sought from The Department of Surgery, University of Nairobi, the KNH Ethics and Research Committee.

Procedures for research with vulnerable population was followed according to KNH/UoN – ERC (APPENDIX 5).

Patients, Next of the kin or guardians received a briefing on the study title, its objectives and its rationale. There after an informed consent was obtained from the patient. In the event that the patient was found to have altered consciousness and found not to be competent to give an informed consent, consent was obtained from the next of kin. For patients under 18 years of age informed consent was obtained from their parents or guardians after obtaining an assent from the minor.

The participant or next of the kin were informed that participation is voluntary and they could withdraw from the study at any point without provision of services from the hospital being interrupted. Patients were not coerced to participate if they were unwilling. Non-participation did not affect patient care. Confidentiality and privacy was observed.

4.0 RESULTS

4.1 PATIENT CHARACTERISTICS

Two hundred and seven (207) patients were recruited of which six were lost on follow up. The age range was between 13 and 85 years with a mean of 32.7 (±1.86) years. Their ages were positively skewed (skeweness = 1.35) implying that most of the patients were below the mean age.

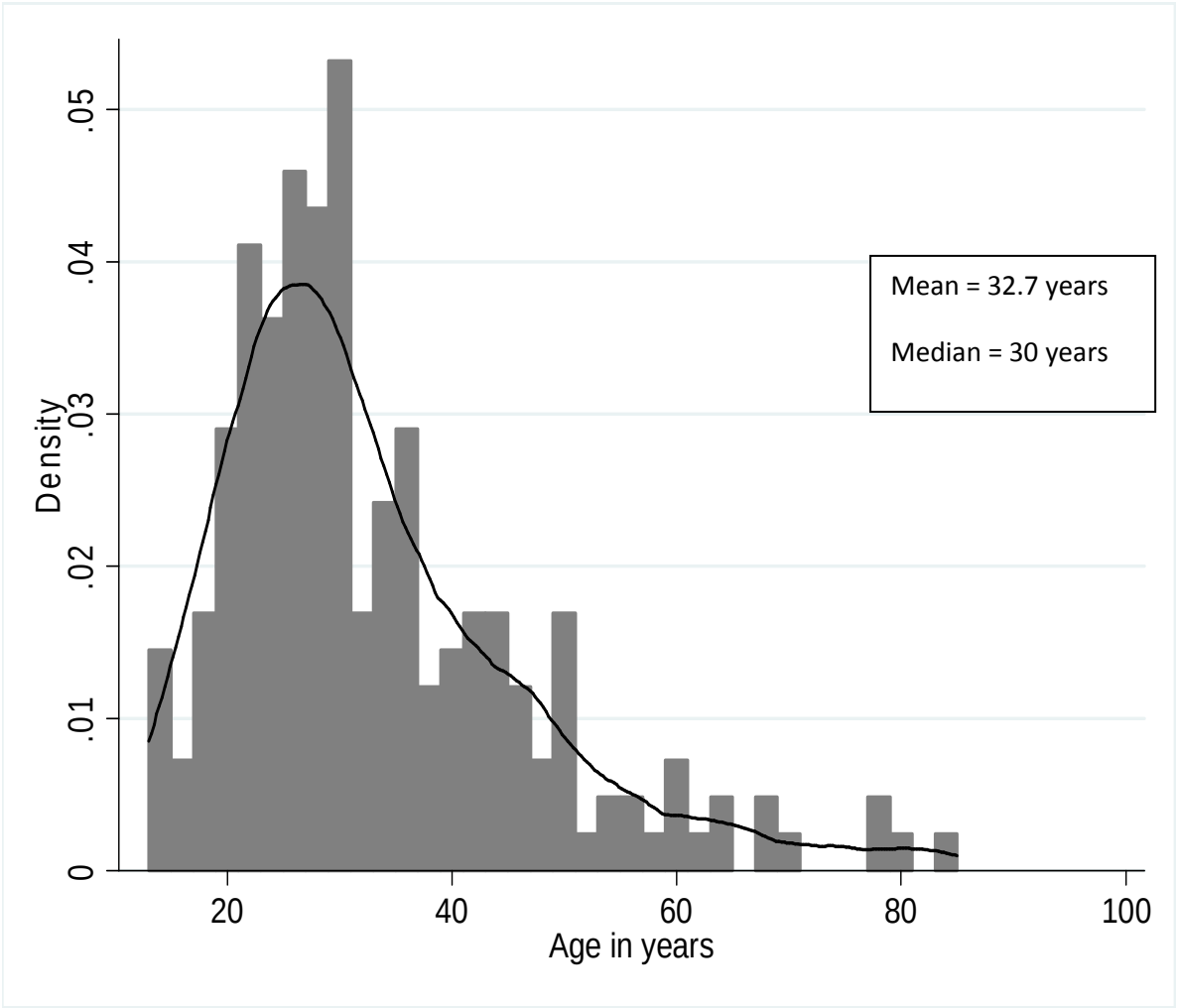

Figure 1: Distribution of patient's age

There were 198 (95.7%) male patients and 9 (4.3%) female patients resulting in a male: female ratio of 22:1(Figure 2).

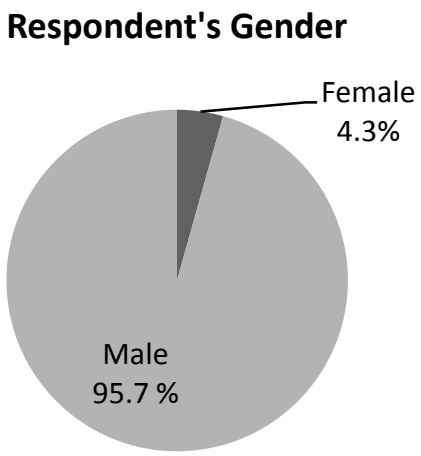

Figure 2: Distribution of patient's gender

4.3 DIAGNOSIS

The commonest diagnosis in patients undergoing surgery for TBI were EDH 82(39.6%) and skull fracture 81 (39.1%) while only 1 (0.5%) had intraventricular haemorrhage as shown in figure 3.

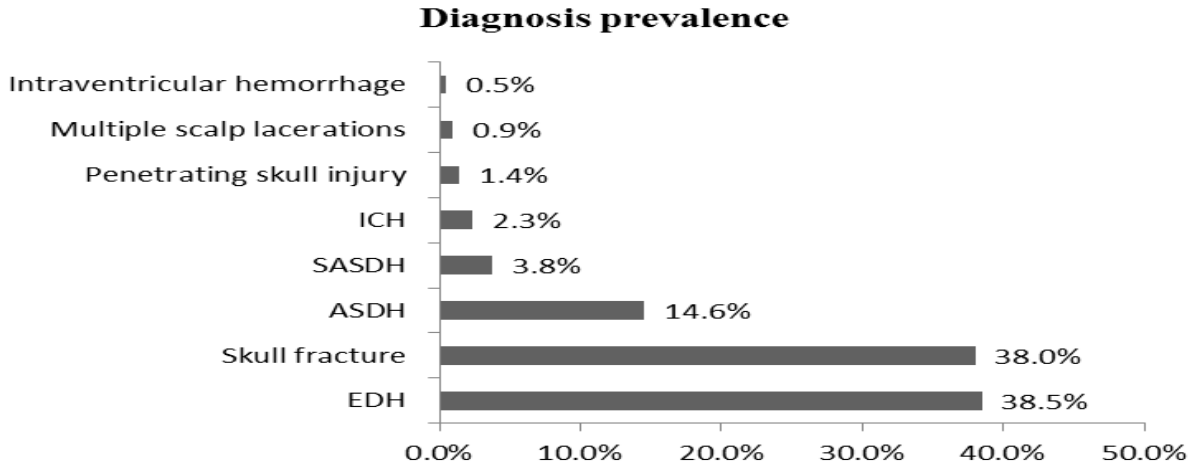

Figure 3: Intra-operative diagnosis prevalence in patients with TBI

Key to figure 3:

ASDH - Acute subdural haemorrhage

EDH - Extradural haemorrhage

ICH - Intracerebral haemorrhage

SASDH - Subacute subdural haemorrhage.

4.4 MAJOR POSTOPERATIVE COMPLICATIONS

Majority 116(56%) of the patients developed one or more major complication during the thirty day postoperative period.

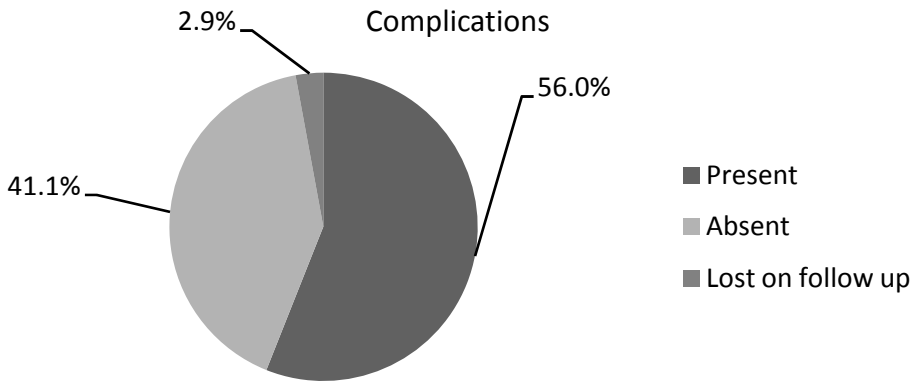

Figure 4 : Occurrence of complication in patients undergoing surgery for TBI

Number of complication developing in this group of patients were as follows; 76(37.6%) had 1 to 3 complications; 34(16.8%) had 4 to 6 complications while 7(3.5%) had 7 to 8 complications (Figure 5). Single tailed Chi-square test of multiple proportions (p-value < 0.001) indicated that the proportion of complications occurrence number significantly differed.

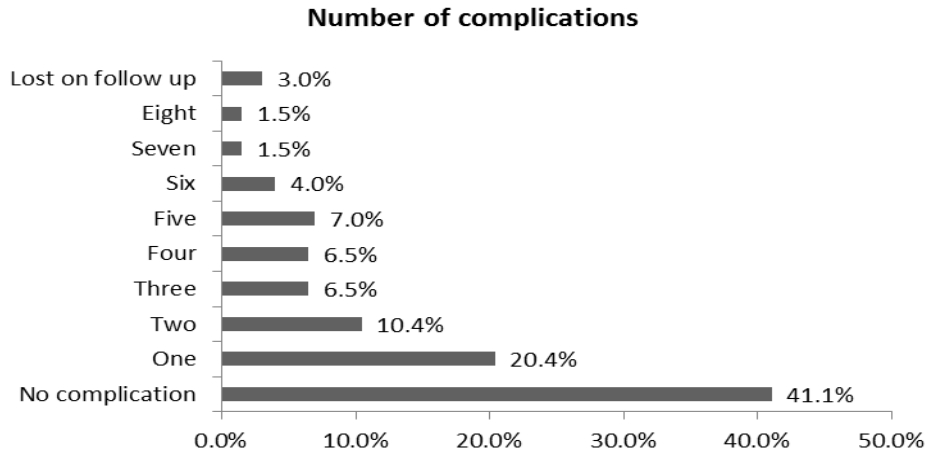

Figure 5: Number of major complication occurring in postoperative period.

To assess whether SAS scores differed between patients with complications and those without complications, their SAS scores were compared. The mean SAS score for patients without complications was 7.04(±0.29) while for patients with complications was 4.80(±0.30). Mann Whitney U test (p-value < 0.001) indicated that the SAS scores for patients without complications were significantly higher than the SAS scores for patients with complications as depicted in figure 6.

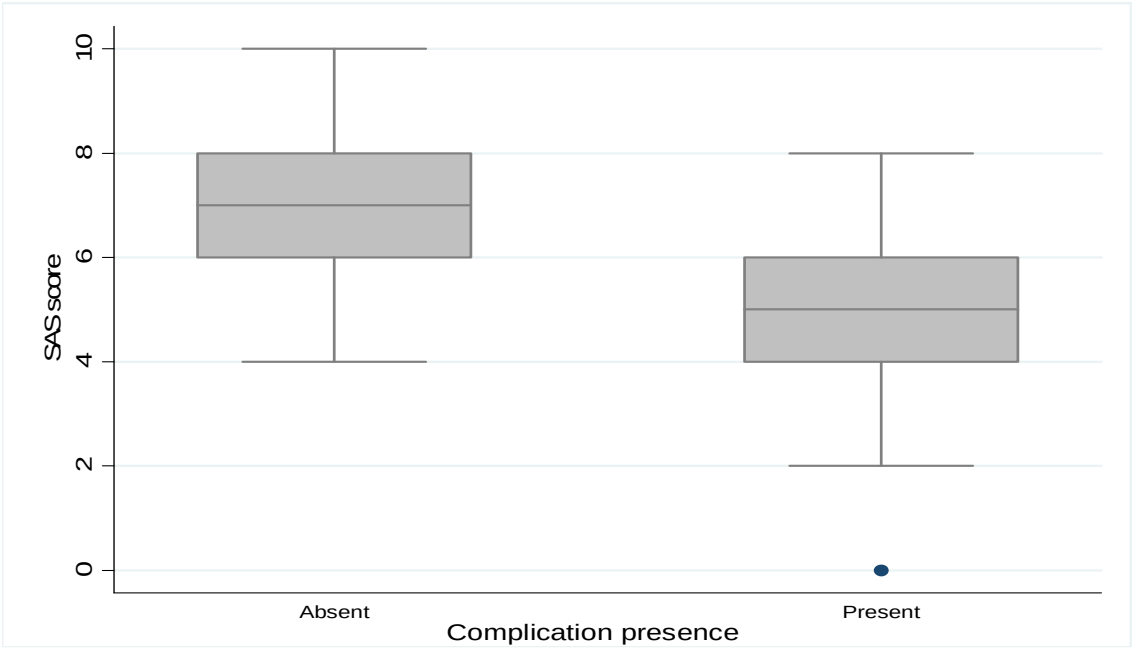

Figure 6: SAS scores by Complication presence

4.5 SURGICAL APGAR SCORE : RISK STRATIFICATION

SAS scores were categorized as follows [9] : High risk (0 to 4), Medium risk (5 to 7) and Low risk (8 to 10). Stratification based on SAS resulted in 115 (55.6%) of patients falling under the medium risk category while 53 (25.6%) and 39 (18.8%) were under high and low-risk respectively.

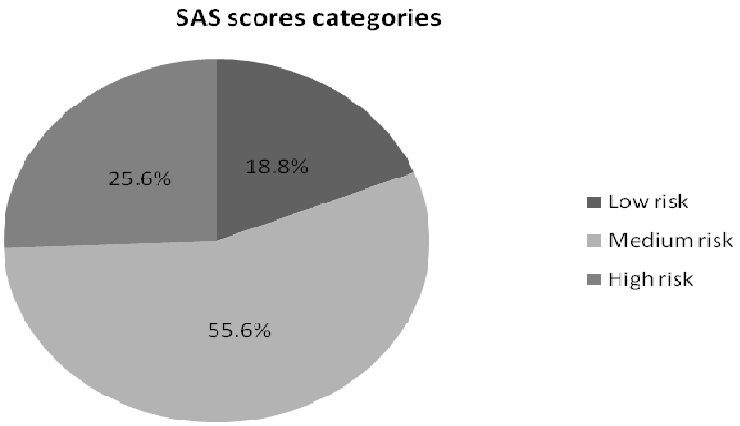

Figure 7: SAS Risk stratification

According to SAS stratification majority of the patients who had no complications and patients who had 1 to 3 complications (64.6%) were at medium risk category while majority of the patients who had more than 4 complications (78 %) were at high risk category. The mean number of complications of low risk patients was 0.4359(±0.3628), 1.0982(±0.2798) for medium risk patients and 3.94(±0.5923) for high risk patients (Figure 8). Kruskal Wallis test (p-value < 0.001) indicated that a higher risk stratum according to SAS was significantly associated with a higher number of complications and vice versa.

Comparing low risk versus medium risk category of SAS; low risk had significantly lower complication rate compared to medium risk group ($p < 0.001$).

Comparing medium risk category with high risk category of SAS; high risk category had significantly higher complication rate than medium risk category ($p < 0.001$).

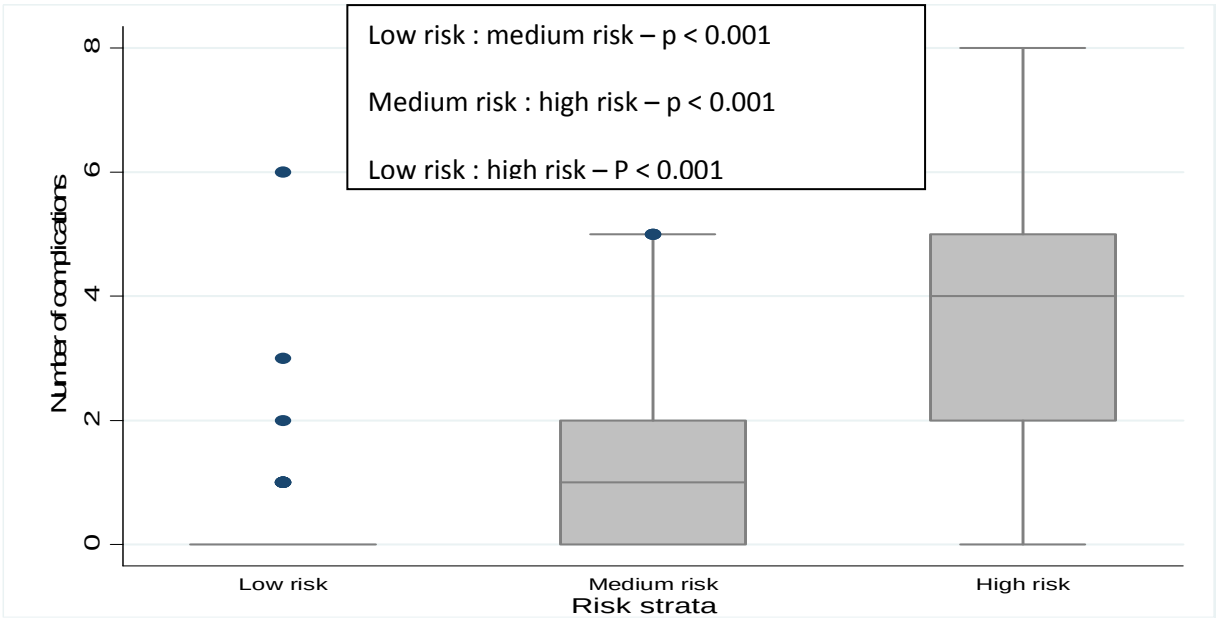

Figure 8: SAS risk strata by number of complications

Majority 19(82.6%) of the patients who died had high risk SAS category while majority 108(60.3%) of the patients who did not die had medium risk SAS strata. Mann Whitney U test (p-value < .001) indicated that patients who did not die had a lower risk category as compared to patients who died.

Majority 34(68%) of the patients who underwent ICU care had high risk SAS category while majority 98(64.9%) of patients who did not undergo ICU care had medium risk SAS category. Mann Whitney U test (p-value < .001) indicated that patients who did not undergo ICU care had a lower risk stratum as compared to patients who underwent ICU care.

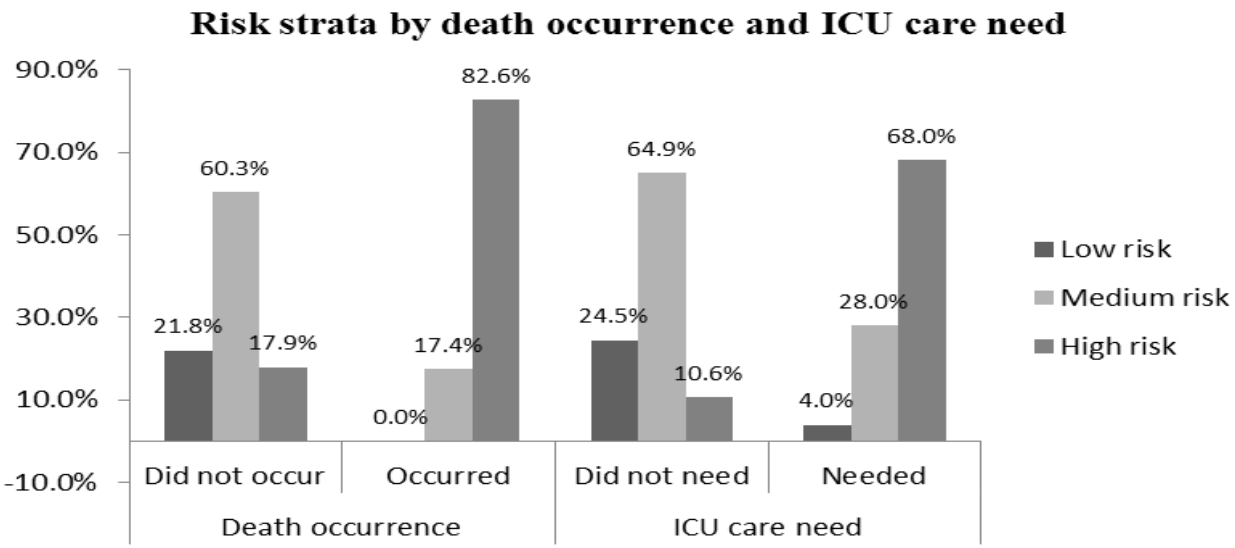

Figure 9: Risk stratification by Death occurrence and ICU care need

Majority 50(43.1%) of the patients who developed major postoperative complications were admitted in ICU immediately after surgery, 45(38.8%) developed neurological deficit as a sequel of head injury, 43(37.1%) had to be on ventilator support for more than 48 hours after surgery and 20(17.2%) died within 30 days after surgery; as shown in table 2.

Table 2: Distribution of major postoperative complications

Complications	Frequency	Percent (N=116)
Intensive unit care	50	43.1%
Neurological deficit	45	38.8%
Ventilator use for 48 hours	43	37.1%
Coma for 24 hours after surgery	32	27.6%
Haemorrhage requiring transfusion	30	25.9%
Surgical site infection	24	20.7%
Death	20	17.2%
Pneumonia	18	15.5%
Convulsions (seizures)	16	13.8%
Sepsis or Septic shock	15	12.9%
Acute kidney injury	11	9.5%
Unplanned Intubation	9	7.8%
Unplanned return to the operating room	8	6.9%
Prolonged confusion	6	5.2%
Others	6	5.2%
Cardiac arrest requiring cardiopulmonary resuscitation	1	0.9%
Pulmonary embolism	0	0.0%
Myocardinal infarction	0	0.0%
Deep venous thrombosis	0	0.0%
Myocardinal infarction	0	0.0%
Deep venous thrombosis	0	0.0%

*Percentages add up to more than 100% because of multiple complications.

*Others include hypertension (2), tracheostomy (3) and empyema (1)

The most prevalent complication was ICU care (15.0%), neurological deficit (13.5%), and ventilator use for 48 hours (12.9%) among others. One sample Chi-square test (p-value < .001) indicated that occurrence of complications significantly varied among patients.

Table 3: Prevalence of major complications in postoperative period

Complications	Frequency	Percent (N=334)
Intensive unit care	50	15.0%
Neurological deficit	45	13.5%
Ventilator use for 48 hours	43	12.9%
Coma for 24 hours after surgery	32	9.6%
Hemorrhage requiring transfusion	30	9.0%
Surgical site infection	24	7.2%
Death	20	6.0%
Pneumonia	18	5.4%
Convulsions (seizures)	16	4.8%
Sepsis or Septic shock	15	4.5%
AKI	11	3.3%
Unplanned Intubation	9	2.7%
Unplanned return to the operating room	8	2.4%
Prolonged confusion	6	1.8%
Others	6	1.8%
Cardiac arrest requiring cardiopulmonary resuscitation	1	0.3%
Pulmonary embolism	0	0.0%
Myocardinal infarction	0	0.0%
Deep venous thrombosis	0	0.0%

Majority of female patients 5(55.6%) and male patients 80(41.5%) did not have complications. The mean number of complications among female patients was 0.7778(±0.8401) while mean number of complications among male respondents was 1.7188(±0.2994). Mann Whitney U test (p-value = 0.234) indicated that the number of complications did not significantly vary with gender.

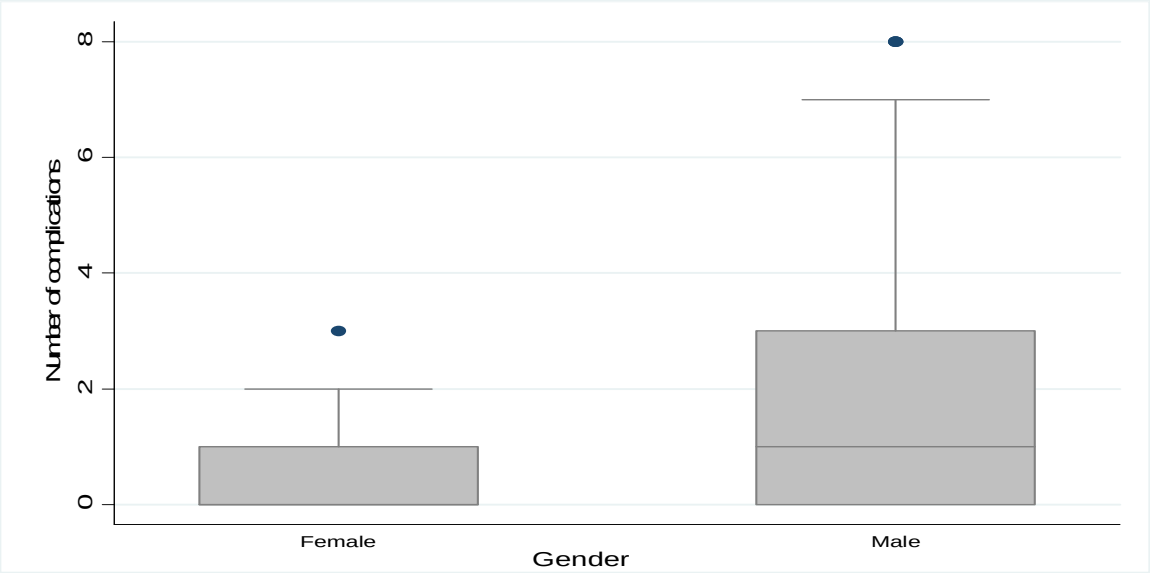

Figure 10: Occurrence of complications among gender

The mean age of patients with 3 complications 29.62(±5.16) years was the least while the mean age of patients with 7 complications 42.67(±24.85) years was the highest. There was a significant (p-value = 0.007) positive correlation (Pearson r = 0.190) between age of patient and number of complications. This implied that older patients were associated with a higher number of complications.

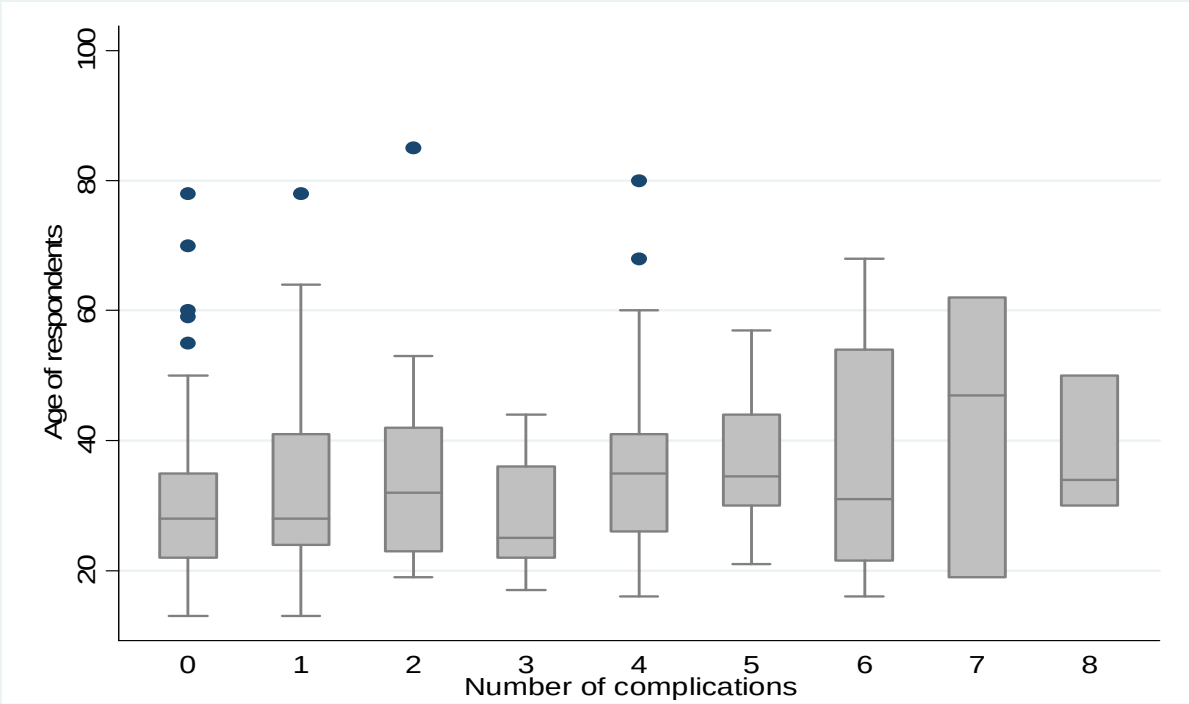

Figure 11: Number of complications by age of patients

SURGICAL APGAR SCORE IN PATIENTS WITH TBI

To obtain SAS following data was obtained and recorded:

	0 point	**1 point**	**2 points**	**3 points**	**4 points**
Estimated blood loss (ml)	> 1000	601 - 1000	101 - 600	≤ 100	-
Lowest mean arterial pressure (mmHg)	< 40	40 - 54	55 - 69	≥ 70	-
Lowest heart rate (beats/min)	> 85	76 - 85	66 - 75	56 - 65	≤ 55

Table 4 shows distribution of SAS points in our study group, majority 101(48.8%) of the patients had lowest mean arterial pressure of between 55mmHg and 69mmHg. Most 69(33.3%) of the patients had lowest heart rate of 85 beats per minute and above. Majority 105(50.7%) of the patients also had an estimated blood loss of between 101ml and 600ml.

Table 4: SAS components scores

SAS component (N = 207)		Lowest mean arterial pressure	Lowest heart rate	Estimated blood loss
Points	0	5(2.4%)	69(33.3%)	11(5.3%)
	1	18(8.7%)	46(22.2%)	29(14.0%)
	2	101(48.8%)	46(22.2%)	105(50.7%)
	3	82(39.6%)	28(13.5%)	62(30.0%)
	4	-	17(8.2%)	-

The mean SAS score was 5.72(±0.26). The SAS scores ranged from 0 to 10 with a standard deviation of 3.523 and skeweness of - 0.161 implying that the SAS scores was dispersed and relatively skewed negatively. Most patients 40(19.32%) had a SAS score of 6. Only 1 (0.4831%) patient had a SAS score of 0.

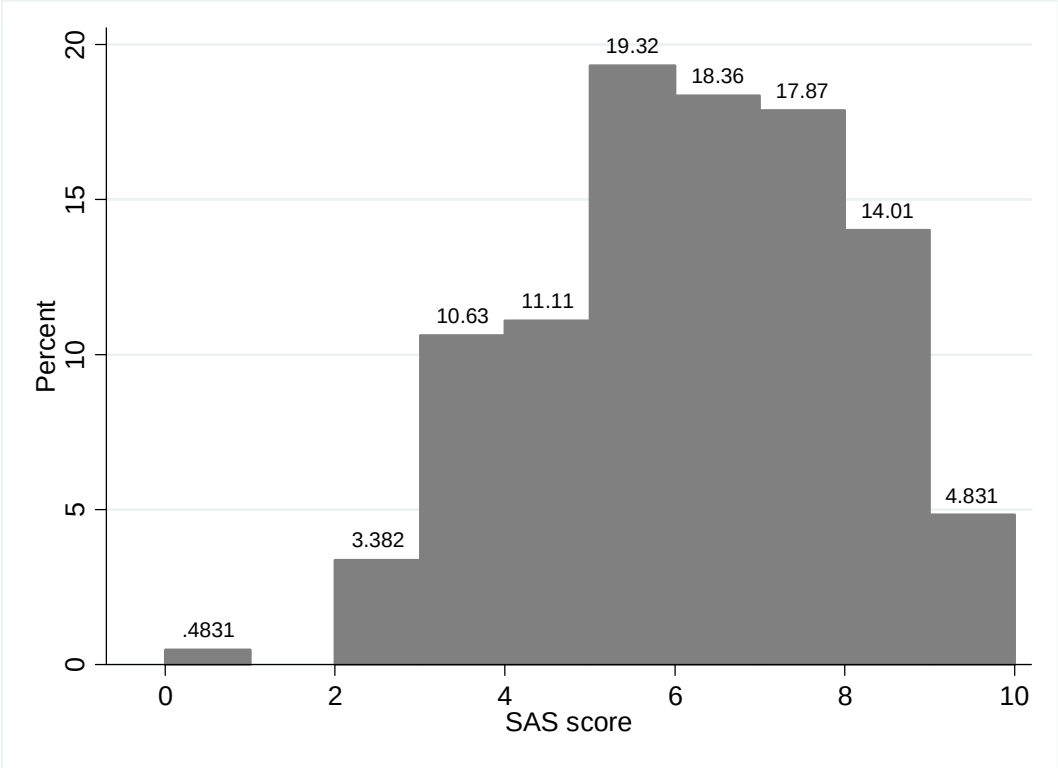

Figure 12: Distribution of SAS among patients in the study

To assess the difference in SAS scores between complications, the SAS scores of patients with the respective complication was compared. Prolonged confusion patients had the highest SAS score of 5.38(±0.55) while patients who died had the least mean SAS scores of 3.39(±0.52). Kruskal Wallis test (p-value < .001) indicated that the distribution of SAS scores was significantly different between complications.

To visually examine the differences in SAS score distribution across complications a box plot was drawn. The results were as shown in figure 13.

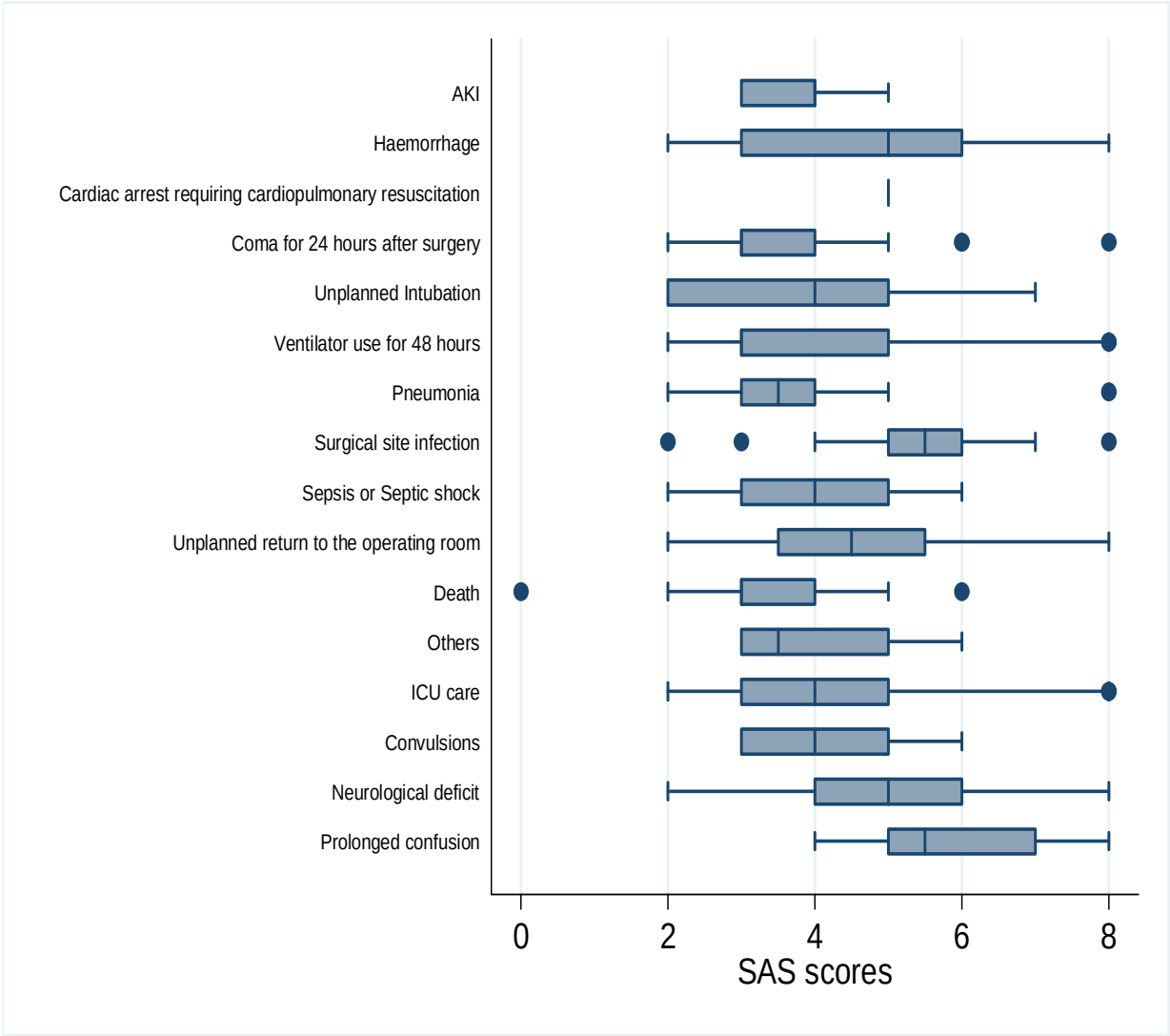

Figure 13 : Mean SAS scores by complication

5.0 DISCUSSION

The purpose of this study was to determine the utility of the SAS in predicting 'the thirty day' major postoperative complications rate in patients undergoing surgery for traumatic brain injury. The SAS was developed as a simple and objective tool that could identify patients at higher than average risk of postoperative complication. Craniotomy for traumatic brain injury is one of the common surgeries at KNH and previous studies have demonstrated the significant morbidity and mortality associated with this surgery.

In this prospective study, 207 patients were evaluated of which 6 patients where lost to follow up due to absconding from the ward / outpatient clinic or inability to reach the patient using the given contacts. The median age was 30 years (mean of 32.7 years) with most of the patients below the mean age. Males accounted for 95.7% of patients. This is comparable to the local study by Kithikii et al [38] that had a male preponderance of 89.3% with a mean age of 35.33 years. The two major studies done in the western countries were mainly retrospective studies giving them an advantage of comparing equal number of male and female patients and their median age was 51years. They also did not restrict themselves to traumatic indications for surgery [25,30].

In this study, EDH and skull fractures were the most common reasons for craniotomy; 38.5% and 38.0% respectively. Intraventricular hemorrhage requiring external ventricular drainage occurred only in one patient (0.5%). Kithikii et al [38] also found EDH (47.7%) to be the most common intracranial hemorrhage in patients with traumatic brain injury at the Kenyatta National Hospital.

Major postoperative complications occurring in this study where classified according to the American College of Surgeons' National Surgical Quality Improvement Program[6]. Need of intensive care unit (43.1%) and development of neurological deficit (38.8%) were found to be the common major complications occurring within 30 day period post surgery. Other common major complications occurring in this study were ventilator use and coma for more than 48 hours.

Patients who developed major postoperative complications (56%) were more than those who didn't (41.1%) (P-value = 0.029). Older patients were prone to develop more complication as compared to younger age group (Pearson r = 0.190). Although occurrence of complication did not significantly vary with gender (p-value = 0.234). Reynolds et al [25]observed similar to

us complication rates in patients who underwent craniotomies for trauma (51%) and a positive correlation of old age with higher complication rates. However, in their study male patients were prone to higher complication rates as compared to ours where difference between the two genders non significant. This can be explained by the equal number of male and female patients evaluated by Reynolds which might have influenced the outcome.

The observed 30-day mortality in our study was 17.2%. This is slightly higher than that observed by Kithikii et al [38] that was 15.7%. In studies done by Reynolds and John [25,30] mortality is quoted as low as 2.6% [25,30]. Surgical mortality is frequently used as a surrogate marker for performance to enable comparisons between individual surgeons and units. This can sometimes be misleading due to differences in case mix as can be seen in differences between patients in our study and that from Reynolds and Johns study in which both trauma and non trauma neurosurgery patients were evaluated.

After SAS was categorized into High risk (0 to 4), Medium risk (5 to 7) and Low risk (8 to 10) [9], Majority of patients who did not develop major complication or developed one to three complications (64.6%) fell into medium risk category of SAS. The high risk category mainly comprised patients who developed four to eight major complications (78%). Mortality and postoperatively need of ICU care was also associated with high risk SAS category (p-value < 0 .001). This demonstrates the ability of the SAS in identifying patients at a higher than average risk of major post-operative complications. It also shows that mortality, being the worst outcome, can be prognosticated using the SAS. Reynolds and John [25,30] showed that surgical apgar scores of 3–4, 5–6, 7–8 and 9–10, were correlated with complication rates of 29.3%, 18.1%, 10.8% and 5.3%, respectively. Further, patients scoring 0–2, 3–4, 5–6,7–8, and 9–10 had 30-day mortality rates of 12.5%, 7.5%,6.0%, 1.2%, and 1.7%, respectively ($p = 0.002$) which shows a similar relationship to our study where poor scores correlate with higher morbidity and mortality.

In a developing country like Kenya, a simple tool like the SAS would be useful in routine post-operative risk stratification thereby facilitating easier identification of high-risk patients. This would allow for prudent allocation of our limited resources for post-operative monitoring and follow up. Studies indicating a link between intra-operative anesthetic and surgical performance and SAS suggest possibility of its use in surgical audit [9,24]. Serial monitoring of SAS within a unit may be used as a tool for improving performance. However, more studies in other surgical specialties on this aspect are required.

5.1CONCLUSION

This study demonstrates that,

i) In our setting surgery for neurotrauma is still associated with significant morbidity and mortality.

ii) Major complications commonly occurring in patients undergoing surgery for traumatic brain injury were the need of intensive care unit admission and development of neurological deficit during their recovery period.

iii) The SAS, despite using simple and widely available intra-operative parameters, is useful tool to predict occurrence of 30 day major complications and mortality following surgery in patients with traumatic brain injury.

5.2 RECOMMENDATIONS

Surgical apgar score can be used as a tool for triaging patients after surgery for traumatic brain injury in all levels of health care facilities due to its simplicity and accuracy.

The score can guide the hospitals with limited facilities (lack of intensive care unit) to facilitate early referrals of patients with poor score.

Further research is recommended in evaluating the use of this score in other surgical specialities.

TIME FRAME

	Aug 2014	Sept 2014	Oct 2014	Nov 2014	Dec 2015	Jan 2015	Feb 2015	March 2015	April 2015	May 2015	June 2015
Proposal development / presentation											
Ethical approval											
Data collection											
Data analysis											
Submission of Dissertation											

BUDGET

ITEM	COST (KSH)
Research fee for KNH/ Uno ERC	2000
Stationery, printing, binding	10,000
Statistician fee	30,000
Research Assistant	10,000
Contingencies	10,000
Total	**62,000**

The research will be funded by the principal researcher.

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APPENDICES

APPENDIX 1: QUESTIONNAIRE

SURGICAL APGAR SCORE: A PREDICTOR OF POSTOPERATIVE COMPLICATION IN PATIENTS UNDERGOING SURGERY FOR TRAUMATIC BRAIN INJURY.

Date: _____

Reference Number: _____

Age: _____

Sex: _____

Telephone Code: _____

Final Diagnosis: _____

Type of Surgical Intervention _____

Surgical Apgar Score:

Measured Parameter	0 point	1 point	2 points	3 points	4 points	Awarded points
Estimated blood loss (ml)	> 1000	601 - 1000	101 - 600	≤ 100	-	
Lowest mean arterial pressure (mmHg)	< 40	40 - 54	55 - 69	≥ 70	-	
Lowest heart rate (beats/min)	> 85	76 - 85	66 - 75	56 - 65	≤ 55	

Final SAS score _____

Major complications: (tick if present)

1. Acute renal failure	
2. Haemorrhage (within 72 hours after operation) No. of blood pints transfused	
3. Cardiac arrest requiring cardiopulmonary resuscitation	
4. Coma for 24 hours after surgery	
5. Deep venous thrombosis	
6. Myocardial infarction	
7. Unplanned intubation	
8. Ventilator use for 48 hours	
9. Pneumonia	
10. Pulmonary embolism	
11. Stroke	
12. Surgical site infection	
13. Sepsis or Septic shock	
14. Unplanned return to the operating room	
15. Seizures	
16. Death	
17. others; specify ( )	

APPENDIX 2: INFORMED CONSENT FORM

SURGICAL APGAR SCORE: A PREDICTOR OF POSTOPERATIVE COMPLICATION IN PATIENTS UNDERGOING SURGERY FOR TRAUMATIC BRAIN INJURY.

This informed consent form is for patients attended at KNH and has been invited to participate in the research whose title is **"Surgical Apgar Score: a predictor of postoperative complication in patients undergoing surgery for Traumatic Brain Injury".** This consent will be administered to the guardians or patient's next of kin.

Principal Investigator: Dr. Taha Shabberali Yusufali

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. Taha Shabberali Yusufali, a post graduate student studying General Surgery at the University of Nairobi. I am carrying out a research to find out if the "Surgical Apgar score" (SAS) can help in predicting complications arising in patients undergoing surgery for injuries sustained in their head.

Purpose of the research

Injuries to the head are a major cause of disability and death among trauma patients in Kenya. Surgery is one of the options used to treat injuries to the head. An effective and simple scoring system to predict complications occurring after surgery can guide the clinician to take timely measures to prevent them. Physiological parameters like the blood pressure, heart rate and blood loss during surgery have been shown to influence the outcomes after surgery. The purpose of this study is to find out whether SAS which uses lowest mean arterial pressure, lowest heart rate and blood loss during an operation for injuries to the head can predict occurrence of major complications after surgery. Findings from this research can help clinicians make decision on where and how the patient should be managed after the surgery.

I am going to give you information and invite your child or next of kin to be a participant in this research. There may be some words that you do not understand. Please ask me to stop as we go through the information and I will explain. After receiving the information concerning the study, you are encouraged to seek clarification in case of any doubt.

Type of Research Intervention

This research will involve taking record of blood pressure, heart rate and calculating blood loss during the operation. These parameters are routinely monitored during most of the surgeries under general anaesthesia. Your child or next of keen will be followed up for thirty days after the operation. This will include the time he will be in the hospital and also after discharge in the outpatient neurosurgical clinic. During the follow up period we will be looking for any complications which might arise. You can opt to give us your telephone number which will be coded to protect your identity and it will be used to remind you of any due outpatient visit.

Voluntary participation/right to refuse or withdraw

It is your choice whether to participate or not. Whether you choose to participate or not, all the services your child or next of kin will receive at this hospital will continue and nothing will change. If you choose not to participate in this research project, your child or next of kin will be offered the treatment that is routinely offered in this hospital for the particular condition. You have a right to refuse or withdraw your child or next of kin participations in this study at any point.

Confidentiality

Your child or next of 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 on their behalf, to participate. The information obtained will be treated with confidentiality and only be available to the principal investigator. Your child or next of kin's name will not be used. Any information about your child or next of kin will have a number on it instead of his/her name. We will not be sharing the identity of those 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 and conferences. Confidential information will not be shared.

Risks

There are no risks in this study, the parameters are measured using methods which are not harmful and your child or next of kin won't be subjected to any extra procedure during the surgery to obtain required information.

Cost and compensation

There will be no extra cost incurred for participating in this study nor is there any compensation offered.

This proposal has been reviewed and approved by the University of Nairobi and Kenyatta National Hospital ethics committee whose work is to make sure participant like your child or next of kin are protected from harm. It was 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;

Dr. AWORI, MARK NELSON,

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

Tel: 020-2726300

Dr. OJUKA, KINYURU DANIEL

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

Tel: 020-2726300

Dr. WEKESA,VINCENT DISMAS

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

Tel: 020-2726300

Principle researcher:

Dr. Taha Shabberali Yusufali,

Department of Surgery, School of Medicine, University of Nairobi

P.O. Box 19676-00202,

KNH, Nairobi.

Mobile phone: 0788262660

PART II: Certificate of Consent

I……..voluntarily give consent for my child or my Next of kin (Name…….)

I have read the above information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction.

Signature of the Next of Kin ……..

Date ……..

If Non -literate:

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

Print Name of witness_____

Signature of witness _____

Date _____

Thumb print of Next of Kin

PART III: Statement by the researcher

I have accurately read out the information sheet to Next of kin, and to the best of my ability made sure that the Next of Kin 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 utility of Surgical Apgar score in predicting postoperative complications in patients undergoing surgery for traumatic brain injury.

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_____

ASSENT FORM FOR MINORS (FOR PATIENTS BELOW 18 YEARS)

I …… freely agree to participate in the research being done by Dr. Taha Shabberali Yusufali on finding out the ability of "Surgical Apgar Score" to predict complications which might occur after surgery for injuries to the head. I have been given adequate explanation on how they will collect information during and after the operation and that I will be followed up for thirty days after the surgery. I have allowed my parent / guardian to sign on my behalf. I understand that I can opt out of the research at any time without my treatment being effected in any way. The outcome of the research may help the doctors to take necessary measures in patients with condition similar to mine to prevent complication with the help of this score.

APPENDIX 3: STUDY CONSENT FORM IN SWAHILI

FOMU YA MAKUBALIANO YA KUJIUNGA NA UTAFITI

SURGICAL APGAR SCORE: A PREDICTOR OF POSTOPERATIVE COMPLICATION IN PATIENTS UNDERGOING SURGERY FOR TRAUMATIC BRAIN INJURY.

Fomu hii ya makubaliano ni ya wale wagonjwa ambao wanahudumiwa katika hospitali kuu ya KNH na wamealikwa kujiunga na utafiti kwa anwani ya "Matumizi ya Surgical Apgar Score kwa kuhubiri matatizo ambayo zinatokea baada ya upasuaji wa kichwa kwa wagonjwa waliopatwa na ajali.

Mtafiti mkuu: Dr. Taha Shabberali Yusufali

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

Fomu hii ya makubaliano 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 Dr. Taha Shabberali Yusufali. Mimi ni daktari ninaesomea upasuaji katika Chuo Kikuu cha Nairobi. Ninafanya utafiti kwa anwani ya, "Matumizi ya Surgical Apgar Score kwa kuhubiri matatizo ambayo zinatokea baada ya upasuaji wa kichwa kwa wagonjwa waliopatwa na ajali.

Lengo la utafiti

Lengo la utafiti huu ni kuchunguza matumizi ya Surgical Apgar Score kwa kuhubiri matatizo ambayo zinatokea baada ya upasuaji wa kichwa kwa wagonjwa waliopatwa na ajali. Surgical Apgar Score inahesabiwa kutoka shinikizo la damu ya wagonjwa , kasi ya moyo na kiasi cha kupoteza damu wakati wa upasuaji. Baada ya upasuaji utafuatiliwa kwa muda wa siku 30 hospitalini ama kwa kliniki ya upasuaji na mtafiti kuu ama msaidizi wake ili kujua kama

kuna matatizo yeyote iliyotokea. Matokeo ya utafiti itakuwa muhimu katika kuboresha kufuatiliwa kwa wagonjwa hawa baada ya upasuaji.

Hatari na faida

Hakuna madhara au hatari inayotarajiwa kwa kushiriki katika utafiti huu. Hakuna vipimo vya ziada nje ya yale kawaida kwa matibabu itafanywa, na hakuna gharama yeyote ya ziada utatokana kwa ajili ya kushiriki katika utafiti.

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 kuondoa ushiriki ya mwanawe au jamaa wako wakati wowote na hakuna madhara utatokeza kwa sababu ya kufanya hivyo.

Tandhima ya siri

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

Anwani za Wahusika

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

1. Mtafiti Mkuu:
   Dr. Taha Shabberali Yusufali,
   Kitengo cha Upasuaji, Shule ya Afya, Chuo Kikuu cha Nairobi,
   SLP 19676 KNH, Nairobi 00202.
   Simu: 0788262660

2. Wahadhiri wahusika:

   Dr. Daniel Kinyuru Ojuka,
   Mhadhiri, Kitengo cha Upasuaji, Shule ya Afya, Chuo Kikuu cha Nairobi,
   Sanduku la Posta 19676 KNH, Nairobi 00202.
   Nambari ya simu: 0202726300

Dr Mark Nelson Awori,
Mhadhiri, Kitengo cha Upasuaji, Shule ya Afya, Chuo Kikuu cha Nairobi,
Sanduku la Posta 19676 KNH, Nairobi 00202.
Nambari ya simu: 0202726300.

Dr. Wekesa,Vincent Dismas,
Mhadhiri, Kitengo cha Upasuaji, Shule ya Afya, Chuo Kikuu cha Nairobi,
Sanduku la Posta 19676 KNH, Nairobi 00202.
Nambari ya simu: 0202726300.

Wahusika wa maslahi yako katika Utafiti:

Secretary,
KNH/UoN-ERC
SLP 20723 KNH, Nairobi 00202
Simu: +254-020-2726300-9 Ext 44355
Barua pepe: KNHplan@Ken.Healthnet.org

SEHEMU YA PILI: Fomu ya makubaliano

Mimi (Jina)……kwa niaba ya mgonjwa wangu (mtoto au jamaa wangu) (Jina la Mgonjwa.....).
Nimeelezewa utafiti huu kwa kina. NakubaIi kwa niaba ya mototo / 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 ya kulazimishwa.

Jina la shahidi_____ Alama ya kidole cha mzazi / Jamaa

Sahihi la shahidi_____

Tarehe _____

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 inaweza chapishwa kusaidia mataktari kuhubiri matatizo zinayoweza kutokea baada ya upasuaji wa kichwa kwa wagonjwa waliyo patwa na ajali.

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_____

FOMU YA IDHINI WAGONJWA WA MIAKA 13-17

Mimi …… natoa idhini kwa hiari yangu kushiriki katika utafiti ambayo inafanywa na daktari Taha Shabberali Yusufali. Utafiti hii ni juu ya Matumizi ya Surgical Apgar Score kwa kuhubiri matatizo ambayo zinaweza zinatokea baada ya upasuaji wa kichwa kwa wagonjwa waliopatwa na ajali. Nimeelezwa vizuri sana vile mapimo zitachukuliwa wakati ya upasuaji na kwamba nitafuatiliwa kwa muda ya siku 30 baada ya upasuaji. Ninaruhusu mazazi / mlezi wangu kuweka sahihi kwa niaba yangu. Ninafahamu kuwa naweza kuondoa ushiriki yangu wakati wowote na hakuna madhara utatokeza kwa sababu ya kufanya hivyo. Matokeo ya utafiti huu inaweza isaidie madaktari kuchukua hatua kabla ya matatizo kutokea baada ya upasuaji kwa kutumia kipimo ya “ Surgical Apgar Score”.

APPENDIX4: DEFINITIONS OF MAJOR COMPLICATIONS

Major postoperative complications according to the definitions used in the American College of Surgeons' National Surgical Quality Improvement Program: (6)

Acute renal failure, bleeding requiring 4 units of red cell transfusion within 72 hours after operation, cardiac arrest requiring cardiopulmonary resuscitation, coma for 24 hours, deep venous thrombosis, myocardial infarction, unplanned intubation, ventilator use for 48 hours, pneumonia, pulmonary embolism, stroke, major wound disruption, surgical site infection, sepsis, septic shock, systemic inflammatory response syndrome, unplanned return to the operating room, and vascular graft failure.

APPENDIX 5: INCLUSION OF ADULTS WHO LACK DECISION-MAKING CAPACITY IN RESEARCH

Special procedures for IRB review and approval apply to research activities involving potential research subjects who, for a wide variety of reasons, are incapacitated to the extent that their decision-making capabilities are diminished or absent. Impaired capacity is not limited to individuals with neurologic, psychiatric, or substance abuse problems. Conversely, individuals with these problems should not be presumed to be cognitively impaired.

Generally, cognitively impaired potential or actual research subjects may not understand the difference between research and treatment or the dual role of the researcher. Therefore, when appropriate, it is essential that the consent / assent process clearly indicate the differences between individualized treatment (e.g., special education in classroom settings) and research. PI should also consider implementing DSMP to review the consent / assent process. PIs may want to consider using an independent expert to assess the participant's capacity to consent or assent. PIs need to specify in the research proposal consent, assent, and LAR procedures. Participants unable to consent must have consent of their LAR. The IRB will evaluate whether participants unable to consent should be required to assent to participation. In some circumstances consent may need at appropriate intervals to be reviewed with participants. The University of Texas at Austin IRB will only approve research involving adults that cannot consent provided the following criteria are met

1. The research question cannot be answered by using adults able to consent;
2. The research is of minimal risk or more than minimal risk with the prospect of direct benefit to each individual participant.