

**ASSESSMENT OF THE PROGNOSTIC VALUE OF HELSINKI
COMPUTER TOMOGRAPHY SCORE IN SEVERE TRAUMATIC
BRAIN INJURY PATIENTS AT KENYATTA NATIONAL HOSPITAL**

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STUDENT'S DECLARATION

This dissertation is presented in partial fulfillment of the requirements for the award of the degree of Master of Medicine in Neurosurgery (MMed-Neurosurgery) at the University of Nairobi.

I, **Dr. Mangar Dave**, declare that this dissertation is my original work. No part of my work has been presented for the award of a degree at any other University.

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ABBREVIATIONS

| | |
|---------------|-----------------------------------|
| ASDH - | Acute subdural hematoma |
| BP - | Blood pressure |
| CT - | Computed tomography |
| DAI - | Diffuse axonal injury |
| EDH - | Epidural Hematoma |
| ERC - | Ethics & Research Committee |
| GCS - | Glasgow Coma Scale |
| GOS - | Glasgow Outcome Scale |
| GOSE - | Glasgow Outcome Scale Extended |
| KNH - | Kenyatta National Hospital |
| ICH - | Intracerebral hematoma |
| ICP - | Intracranial pressure |
| ICU - | Intensive care unit |
| IVH - | Intraventricular hemorrhage |
| tSAH - | Traumatic subarachnoid hemorrhage |
| TCDB - | Traumatic Coma Data Bank |
| TBI - | Traumatic brain injury |
| UoN - | University of Nairobi |
| WHO - | World Health Organisation |

ABSTRACT

Background: Head injury is usually considered as a silent epidemic and continues to exist as an everlasting consternation conferring high mortality and disability worldwide. In the early assessment of patients with injury to the head, the computer tomography(CT) is of utmost importance and millions of CT scans are conducted yearly. These CT scans contain information which can be used to determine the patient's prognosis and to form a baseline in identifying risk in clinical trials. The Helsinki computer tomography scoring classification was created in 2014 as a tool for determining outcomes in those patients with TBI. In Kenya, severe TBI accounts for 10.3% of all brain injuries seen at the Kenyatta National Hospital and 14.3% of all adults admitted at the Critical Care Unit. The Helsinki computer tomography score being the latest in the armamentarium of outcome predictors and having outperformed previous CT scoring system in the European and Asian subcontinent, it will be necessary to assess its capacity to predict outcome in the African subcontinent on severe traumatic brain injury patients and hence guide clinical decision making.

Objectives: This study assessed the prognostic value of the Helsinki Computer Tomography score among patients with severe traumatic brain injury.

Methodology: Following ethical approval, a prospective observational study involving forty two patients above 18 years of age with severe TBI were recruited by convenience sampling at the Kenyatta National Hospital Accident and Emergency Department and Critical care units over a period of four months(October 2019- January 2020). Clinical parameters of blood pressure, pupillary reactivity, random blood glucose, age, GCS and Helsinki computer tomography(CT) score were evaluated at admission and subsequent follow up done at 6 weeks for Glasgow outcome scoring. Data was collected using a structured questionnaire and recorded in excel sheets and analysis done using Statistical Package for Social Sciences version 23.0.

Results: A total of 42 patients were recruited with 90% males and mean age of 33 years old. Overall mortality was 64.3%. RTA was the commonest mode of injury at 64% followed by assault at 26% and falls at 10%. Patients with non reactive pupil had mortality of 67% while slow reacting pupil had 63%. Patients with systolic BP > 90 mmHg comprises 95% of the study population with a resultant mortality at 67.5%. The most common random blood glucose level was < 10 mmol/l at 80% with a mortality of 58.8%. Patients with GCS of 3-4 had the highest mortality of 100% while GCS of 7-8 lowest mortality of 60.9%. GCS of 3-4

had no favourable outcome at 6 weeks while GCS 7-8 had favourable outcome in 30.4%. The Helsinki CT score of 4 had mortality of 33.3% while Helsinki CT score of 11 had mortality of 100%. Patients with contusions and intracerebral hematomas had mortality of 80% while in ASDH and EDH the mortality were 53.8% and 44.4% respectively. In correlation analysis the Helsinki score was significantly associated with GOS at 6 weeks($p=0.004$), and death($p=0.009$). Age was significantly correlated with 6 weeks GOS($p=0.03$) and mortality($p=0.02$). Systolic BP was only associated with mortality at p value of 0.043. The other clinical parameters did not show any statistical significance with both 6 weeks GOS and mortality. The specificity, sensitivity and accuracy for Helsinki CT score for mortality were 88.9%, 53.3% and 71% respectively; and for an unfavourable outcome, these values were 81.8%, 55.6% and 69% respectively. After performing logistic regression analysis to determine the predictors of outcome, we found that the odds ratio(OR) for the Helsinki CT score to predict mortality to be 9.1(95% CI 1.9-44) and unfavourable outcome at 5.6(95% CI 1.2-27.4).

Conclusion: Severe TBI carries a high mortality and disability in Kenya. The age of patient, the systolic blood pressure on admission and the initial Helsinki CT score were significant predictors of outcome($p < 0.05$). The Helsinki CT score correlated well with the clinical parameters at predicting outcome.

Recommendations: A change to new computer tomography scoring system may be warranted and the Helsinki CT score can be used as a predictor of outcome in Kenyan hospitals and in our African population. Future studies comparing the different computer tomography scores available in correlation with clinical parameters on predicting outcome should be done as a multi-center study.

1.0 CHAPTER ONE: INTRODUCTION

Traumatic brain injury(TBI) is considered as a global burden hence it is important to determine a classification that correctly diagnoses and accurately predict its outcome. The ages mostly affected in traumatic brain injury are <5 years,15-24 years and >70 years with a mortality rate of up to 30% yearly¹. Masson et al² in his study on epidemiology of severe brain injury found an incidence of 17.3 per 100,000 population. Assessing the prognosis of patients is vital for doctors to make treatment strategies. The Glasgow coma scale(GCS) which explains the state of awareness, has been used as a modality of grading the gravity of TBI at the point of admission to the hospital. Even though the GCS provides clinical information, it is restricted in determining structural brain lesions. Moreover, the GCS can be error prone in patients with alcohol intoxication, sedation and intubation. Other modalities used in developed countries include the use of biochemical markers and ICP monitors¹ but these are expensive and not readily available in public hospitals in developing countries.

Computer tomography(CT) scan of the brain is a common mode of investigation used to evaluate structural brain pathologies during emergencies as it is readily available and less time-consuming. Currently, several CT classification system exists to predict prognosis and classify TBI patients. One of them is the Helsinki CT scoring system³ which was developed recently in 2014 and has been validated in the European and Asian subcontinent. Rahul et al³ proposed the Helsinki CT scoring system in 2014. They grouped the category of mass lesion into acute subdural hematoma (ASDH), intracerebral hematoma (ICH), extradural hematoma (EDH), highlighted the prognostic value of intraventricular hemorrhage (IVH), and mentioned the suprasellar cistern (SSC) status for the first time into a CT scoring system rather than using the term basal cistern. They showed that the Helsinki CT score has a greater discrimination in predicting outcome and performed better than other CT scoring systems. At present, no study has evaluated the use of the Helsinki CT scoring system in the African subcontinent. This study aims at assessing the prognostic value of the Helsinki CT scoring system in severe TBI patients presenting at Kenyatta National Hospital(KNH) and determining its correlation with clinical parameters including GCS, pupillary reaction, blood pressure, age and extra cranial injuries on their outcome at 6 weeks post injury. Resources in low income countries like Kenya are limited and few ICU beds are available in most public hospital, therefore, it is important to canalize the available resources to patients who are likely to do well.

2.0 CHAPTER TWO: LITERATURE REVIEW

Severe trauma to the brain is described as a patient having an admission Glasgow coma scale(GCS)of less than or equal to eight after resuscitation which is obtained before sedation and intubation. The global estimation of severe TBI is 5.48 million people per year(73 cases per 100,000 people)⁴. Around one-third to one-half of trauma related death is associated with TBI and occurs in low and middle income countries as per the latest WHO estimation⁴. A lot of resources and finances need to be mobilized in the management of severe TBI. In Kenya, severe traumatic brain injury accounts for 10.3% of all brain injuries seen at the Kenyatta National Hospital and 14.3% of all adults admitted at the Critical Care Unit⁵. Mortality associated with severe TBI at Kenyatta National Hospital was seen to be at 56% in 2001⁶, 54% in 2007⁵ and 51.5% in 2015⁷.

Clinical parameters and CT scan findings are reliable indicators in severe TBI⁸. There have been several large multicenter studies carried out in the European and American subcontinent for predictors of outcome in TBI and include the IMPACT trial (2007)⁸, European Brain Injury Consortium (1999)⁹, and CRASH trial (2008)¹⁰. It will be useful to employ modalities that can predict outcome so as to direct scarce resources to those who are certain to benefit from them.

2.1 Clinical Parameters

The IMPACT trial design quantified several clinical parameters that can be used as prognostic tools in traumatic brain injury⁸. These clinical parameters are easily available on the patient during admission and during care⁸.The strongest indicators at initial assessment are age, GCS score, and pupillary reactivity.

2.1.1 Age

Increasing age has been linked with a higher mortality and greater disability. The cause of this increased mortality has yet to be determined and is most likely dependent on many factors.

Scalea et al¹¹ have demonstrated that older patients who sustained trauma have reduced coronary hemodynamic and necessitate extensive observation and resuscitation.

Hukklelhoen et al¹² observed that the percentage of survivors with unfavourable outcome increased with age and that the percentage of patients with favourable outcome lessened.

They attributed it to the fact that the brain in older individuals has a diminished number of functional neurons that are able to promote repair and elderly patients are more prone to minor repetitive injury to the brain.

In KNH, the mortality was 44% for patients between 14-25 years and 56% in patients aged between 26-45 yrs⁵.

2.1.2 Glasgow Coma Scale

One of the major determinants of TBI severity is the level of consciousness which is determined by calculating the Glasgow coma score of the patient. Classification of TBI into different severities can be done by using the GCS score, into mild which is from 13 to 15, moderate which is from 9 to 12, and severe which is from 3 to 8. Teasdale and Jennet introduced the Glasgow Coma Scale in 1974 and suggested that it should be used to diagnose any change in the mental status of patients when assessing them regularly at the bedside and to measure the extent of coma period among neurosurgical patients during the initial 24 hours of neurological monitoring¹³.

The GCS has three constituents: eye response, best verbal response, best motor response that are summed conjointly to obtain a total score ranging from 3 to 15(Table1).

Table A: Glasgow Coma Scale

| Component | Response | Score |
|----------------------|------------------------|--------------|
| Eye response | Spontaneous | 4 |
| | To speech | 3 |
| | To pain | 2 |
| | None | 1 |
| Best Verbal response | Oriented | 5 |
| | Confused | 4 |
| | Inappropriate | 3 |
| | Incomprehensible | 2 |
| | None | 1 |
| Best Motor response | Obeys | 6 |
| | Localizes pain | 5 |
| | Withdraws to pain | 4 |
| | Flexion(decorticate) | 3 |
| | Extension(decerebrate) | 2 |
| | None | 1 |
| Total | | 3-15 |

GCS was never meant to be used in the acute settings of trauma or for any of its components to be summed into a score. Regardless of the developers' disapproval, it has been employed in these ways since its conception^{14,15}.

The motor score of the GCS has the greatest predictive value in patients with severe TBI as these patients are often intubated and may have facial injuries making determination of eye opening and verbal response difficult¹⁶. Assessment of the GCS should be done on admission after primary respiratory and hemodynamic resuscitation because the GCS often varies early after injury¹⁷. The GCS can still vary and be erroneous due to sedation, paralytic medication or intoxication e.g. by alcohol⁹.

Analysis of the Traumatic Coma Data Bank (TCDB) showed a mortality of 11% among patients with an initial GCS of 8 and a mortality of 78% among those with an initial GCS of 3¹⁸.

In KNH, patients with GCS 3-4 had a mortality of 88%, GCS of 5-6 had 60% mortality while 7-8 had 52%⁶.

2.1.3 Pupillary Reactivity

Determination of the pupil reaction is considered a vital clinical examination when assessing TBI patients. An unequal pupil reaction, especially in TBI patient, is considered as an emergency¹⁹. This is explained by the fact that due to brain edema or a lesion causing mass effect, there is herniation of the uncus leading to the oculomotor nerve being compressed resulting in pupillary dilatation²⁰. Concurrently there is diminished blood supply to the brain stem causing ischemic changes and is manifested as a dilated pupil¹⁹. Abnormal pupil reactivity is strongly associated with poor outcome²¹. In the early phases of severe head injury, pupil reactivity is a more stable variable than the GCS as it is less affected by sedation and paralytic effects of medication.

In the TCDB, 74% of patients with bilaterally unresponsive pupils after resuscitation died or were left vegetative¹⁸.

In KNH, patients with bilaterally dilated pupils not reacting to light had a mortality of 90%, patients with bilaterally constricted pupils had a mortality of 66% and only 20% mortality in patients with normally reacting pupils⁶.

2.1.4 Hypotension

Hypotension is a well known secondary systematic insult that worsens TBI. Chestnut et al²² in the analysis of patients from TCDB found that a combination of hypotension, systolic BP less than 90 mmHg, and hypoxia which was considered at a pO₂ below 60 mmHg or oxygen saturation less than 90% resulted in a 75% mortality rate.

In KNH, Mwangombe et al⁶ showed there is 85% mortality in severe TBI patients with blood pressure less than 90 mmHg and 60% mortality in patients with blood pressure more than 110mmHg. In 2007 another study showed hypotension in 32.2% of severe TBI patients with resultant mortality of 75%⁵.

2.1.5 Extra cranial Injuries

The clinical severity in TBI relates to intracranial and extra cranial injuries. At present, there is no clear consensus on the prognostic value of major extra cranial injuries on TBI patients. Several studies show that the presence of extra cranial injuries does not influence the outcome in TBI patients as it depends on the severity of the primary brain damage²³. Sarrafzadeh et al²³ showed that the impact of extra cranial injuries is more significant in minor and moderate TBI and the outcome is more related to primary brain injury rather than the presence of extra cranial injuries in severe TBI. Other studies have shown that the presence of major injuries was related to poorer outcomes^{24,25}.

In KNH, extra cranial injuries were present in 91.6% of patients with severe TBI, of which 49.5% were maxillofacial injuries, 25.2% limb fractures⁵. Another study done in 2015⁷ showed that 31 patients (36%) had significant extra cranial injuries and of these, 17 patients died (54.8%). Chest injuries and cervical spine injuries had the highest mortality of 71.4% each. The most common extra cranial injury was fractures of limbs which constituted 54.8% among the 31 patients and 16.1% had facial fractures.

2.2 Computer Tomography(CT) and the Helsinki Computer Tomography Score

The gravity of TBI is often measured by utilizing the Glasgow Coma Scale which defines the level of consciousness. In spite of its clinical utility, the GCS is limited in describing any potential brain lesion. In the European Brain Injury Consortium study by Murray et al⁹ in 1998, GCS was reliable and accurate in only 56% of severe TBI patients. CT is a common mode of investigation used to evaluate structural brain lesions in acute settings as it is readily available and less time consuming. The findings provided in the admission CT scan enable

prompt diagnosis of likely brain lesions which can be treated by surgical means and can be used to prognosticate outcomes.

By using outcome predictors which are efficient and better, there is possibility of improving TBI research, grading patient's risk at presentation in clinical trials and efficiently optimizing standardization of patients' group in comparative research²⁶.

In 1991, Marshall et al²⁷ used CT characteristics to classify TBI as various types of diffuse pathologies based upon the characteristic of the basal cisterns, the value of the midline deviation and focal lesions morphology depending on whether the volume of the lesion was more than 25cm³. Although the different constituents in the Marshall CT classification have been found to predict outcome in trauma to the head, it was not meant to be used as a prognostic tool while it was being developed²⁸.

Hence the Rotterdam CT score was developed during 2005 to prognosticate outcome by revisiting constituents of the Marshall CT classification and including intraventricular hemorrhage and traumatic subarachnoid hemorrhage (tSAH) thereby establishing a numeral score²⁹. Constituents derived from the Rotterdam CT scoring system form part of the International Mission for Prognosis and Analysis of Clinical Trials in TBI (IMPACT) outcome model for TBI patients³⁰.

Currently, newer CT scoring classifications have been introduced including the Stockholm computer tomography scoring system in 2010³¹ and the Helsinki computer tomography scoring system in 2014³. The Stockholm CT scoring system utilizes the extent of midline deviation as a continuous variable and incorporates a discrete score for traumatic subarachnoid hemorrhage. It is the only radiological scoring classification which includes diffuse axonal injury (DAI) present on CT scan.

The Helsinki CT scoring system consists of components of the Marshall CT classification and the Rotterdam CT scoring system and emphasizes the types of structural brain injuries present.

Table B: Helsinki CT Scale

| | | |
|-----------------------------|--|--|
| Hematoma type | a) ASDH b) Contusion(s)/ICH c) EDH | a) 2 points b) 2 points c) -3 points |
| Hematoma >25 cc | a) Yes b) No | a) 2 points b) 0 point |
| IVH present | a) Yes b) No | a) 2 points b) 0 point |
| Suprasellar cisterns | a) Normal b) Compressed c) Obliterated | a) 0 point b) 1 point c) 5 points |

Rahul et al³ in 2014 designed a new radiological based model in a large trauma center in Helsinki, Finland. They analyzed 869 TBI patients' CT scan findings and correlated them to the Glasgow Outcome Score(GOS) hereby developing the Helsinki CT scoring classification which was able to prognosticate outcomes of mortality and disability at 6 months.

The Helsinki CT scoring classification comprises of six attributes ASDH, ICH, EDH, IVH, the volume of the lesion and the status of the suprasellar cisterns as shown in Table 2. The suprasellar cisterns(SSC), correlates with the "pentagonal cistern" and is distinct from the basal cistern, and was incorporated in this scoring classification in contrast with other radiological scoring systems. The status of the SSC is more weighted and the subcategory of obliterated SCC has been attributed to a score of five. The presence of IVH has been shown to have unfavourable outcomes in several studies^{3,30} and in the Helsinki CT scoring classification a score of three has been assigned. The total score range from -3 to 14.

The prognosis at 6 months for mortality ranges from 3% to 79% and for unfavourable neurological outcome from 7% to 94% when utilizing the Helsinki CT scoring system. The concordance between the predicted and observed outcome for the Helsinki CT score is shown in Figure 1.

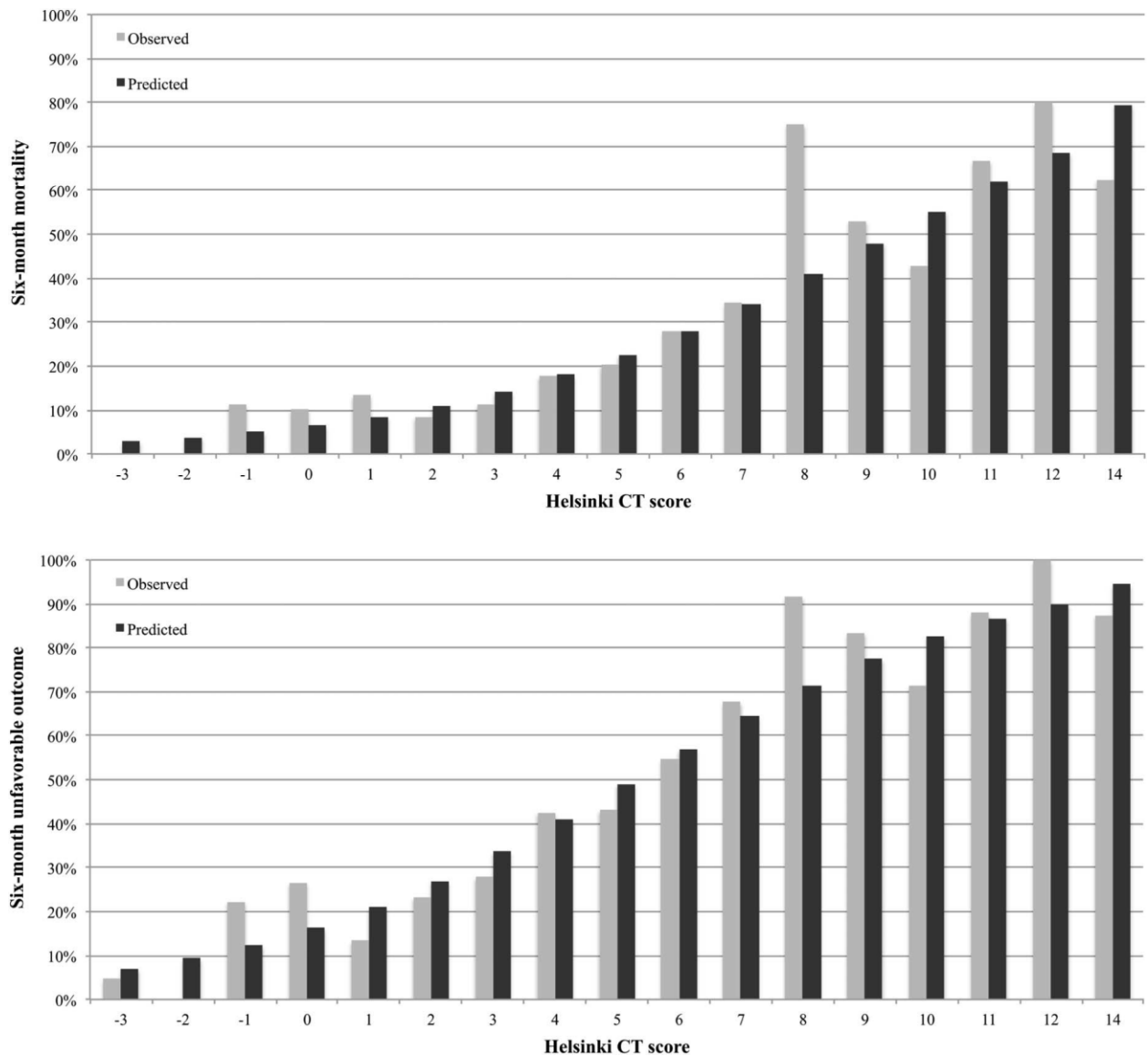


Figure A: Concordance between observed and predicted outcome for the Helsinki computerized tomography (CT) score. Top, concordance between observed and predicted 6-month mortality. Bottom, concordance between observed and predicted 6-month unfavourable outcome

Theilin et al²⁸ in 2017 evaluated both the Helsinki and Stockholm CT scoring systems by recruiting 1115 TBI patients in a combined cohort from two large centers in Europe. To determine the accuracy and to compare with past studies the Nagelkerke's pseudo- R^2 and the Area Under the Receiver Operating Characteristic curve(AUROC) methods were utilized. A Nagelkerke's pseudo- R^2 describes explained variance and is attributed a range between 0 to 1 whereby 1 implies the model which can accurately explain the observed outcome. The Area Under the Curve(AUC) is related to Nagelkerke's pseudo- R^2 in a nonlinear way and is given a

value of 0 which suggest a model whose predictions are 100% wrong and 1 which indicates a model which is perfect. A Nagelkerke's pseudo- R^2 value ranging from 0.20 to 0.25 were obtained for both Helsinki and Stockholm CT scoring systems, as compared to Marshall CT classification which yielded a value around 0.05 and compared to the Rotterdam CT scoring system a value in between 0.10 to 0.20. The AUCs results were similar to Nagelkerke's pseudo- R^2 . In conclusion of their analysis after dichotomizing all outcome, they found that the Helsinki and Stockholm CT classification systems to be better than the Rotterdam and Marshall CT scoring systems as predictors of outcome.

In 2017, another study was done by Yao et al³² who retrospectively analyzed the relationship between the initial Helsinki CT scores with the Glasgow Outcome Score(GOS) at 6 months following injury in a group of 302 consecutive patients with TBI. Among their cohort, there was a mortality of 17.9% and unfavourable outcome of 41.4%. In univariate analysis, the Helsinki CT score was notably related to 6-month outcome($p<0.05$). In multivariate regression analysis, the Helsinki CT score was considered as an independent predictor for mortality with an odds ratio of 1.22 and for unfavourable outcome with an odds ratio of 1.14. The area under the receiver operating characteristic curve(AUROC) analysis yielded an AUC value of 0.81 for mortality and 0.74 for unfavourable outcome thereby concluding the good ability to discriminate mortality and moderate ability to discriminate unfavourable outcome of the Helsinki CT scoring system. They also noted that the Helsinki CT score was deemed to be more precise in predicting mortality with an accuracy of 74.5% and unfavourable outcome with an accuracy of 71.5% when the patients presented to the hospital at 1.9 hours of the injury.

2.3 Glasgow Outcome Scale

In 1975, Jennet and Bond proposed and developed the Glasgow Outcome Scale(GOS) that describes the functional outcome following head injury in terms of the ability of a patient to take care of his/her own needs, his/her dependence on others as a consequence of neurological damage³³.

There are 5 outcomes in the GOS: death(scale I), persistent vegetative state, severe disability, moderate disability and good recovery(scale V) as shown in Table 3.

Table C: The Glasgow Outcome Score (GOS)

| SCALE VALUE | SCALE | DESCRIPTION |
|-------------|-----------------------------|---|
| 1 | Dead | Death |
| 2 | Persistent vegetative state | Severe damage with lack of higher mental functions and prolonged state of being unresponsive |
| 3 | Severe disability | Severe injury requiring constant assistance for help in daily activities |
| 4 | Moderate disability | Does not require assistance in daily activities but need special equipment to return to employment |
| 5 | Good recovery | Reintegrated and able to return to work but not necessarily at the same level; may have minor neurological or psychological impairments |

In 1981 the Glasgow Outcome Scale Extended(GOSE) was described by Jennett et al³⁴ as being a more sensitive measure of recovery. It divides good recovery, moderate disability, and severe disability into an upper and lower category.

Brooks et al³⁵ found that there is an increase in inter-observer variability when GOSE is used instead of GOS. In large multicenter studies e.g. IMPACT study, the GOS has been preferred over the GOSE.

King et al³⁶ showed that a 3 months GOS had a good correlation with long term outcomes. In the IMPACT study, GOS at 3 months and 6 months were accepted as correlation with long term outcomes for patients³⁷.

3.0 CHAPTER THREE: STUDY JUSTIFICATION AND METHODOLOGY

- Kenya being a developing country with limited intensive care facilities, it is necessary to incorporate new outcome predictors in severe TBI patients to canalize resources to patients who will benefit the most.
- The findings of the CT scan could be of use to assess prognosis as the clinical parameters like GCS and pupillary reactivity become cumbersome in severe TBI patients who are mostly intubated and sedated.
- The Helsinki computer tomography score being the latest in the armamentarium of outcome predictors and having outperformed previous CT scoring system in the European and Asian subcontinent, it will be necessary to assess its clinical utility in the African subcontinent.

3.1 Study Question

- What is the predictive value of Helsinki CT score in correlation with the clinical parameters on the 6 weeks functional outcome of patients with severe traumatic brain injury at Kenyatta National Hospital?

3.2 Broad Objective

To investigate the prognostic value of the Helsinki Computer tomography (CT) score on the outcome of severe traumatic brain injury(TBI) patients at Kenyatta National Hospital at 6 weeks post-admission.

3.3 Specific Objectives

1. To establish the baseline GCS, physiological parameters, demographic characteristics and presenting extra cranial injuries among patients admitted at the KNH after sustaining severe TBI.
2. To evaluate the predictive value at 6 weeks of the Helsinki CT score among patients with severe TBI.
3. To evaluate the correlation between the admission Helsinki CT score and the clinical parameters on the outcome of severe TBI patients at 6 weeks post-admission.

3.4 Methodology

3.4.1 Study Design

This was a prospective observational study conducted for a period of 4 months at Kenyatta National Hospital.

3.4.2 Study Location

- Patients with severe traumatic brain injury were recruited at the Kenyatta National Hospital(KNH), Nairobi and following initial assessment and resuscitation at the Accident and Emergency department at KNH, admissions were done at the Critical care Unit/ Intensive Care Unit where they were further managed.
- Follow up of patients was done at the General surgical wards (ward 5A, 5D) and the neurosurgical ward (ward 4C) once the patients have improved clinically. Upon discharge patients were followed up at the outpatient department clinic no. 24 at 2 weeks and at 6 weeks. Patients and relatives were notified by phone.

3.4.3 Study Duration

The study was carried out over a period of four months.

3.4.4 Study Population

Patients above 18 years of age who presented at the Kenyatta National Hospital with severe traumatic brain injury with GCS of 8 and below, and had informed consent availed from guardian/ relatives.

3.4.5 Inclusion Criteria

- Severe traumatic brain injury patients with GCS <8
- Patients above the age of 18 years
- Patients who had informed consent availed from relatives/ guardians

3.4.6 Exclusion Criteria

- Patients without a CT scan done
- Mortality before 24 hours of admission
- Non – intubated, non – resuscitated patients

3.5 Sample Size Calculation

The formula below was used to calculate the sample size

$$n = \frac{Z^2 \times P (1 - P)}{d^2}$$

- n is the sample size required
- Z refers to the level of significance or confidence interval = 1.96 for 95% CI
- P is the estimated prevalence of severe head injury among Head injury patients = 0.0173(Masson et al² who found 17.3 patients per 100,000 had severe head injury)
- d is the desired margin of error = 5%

Substituting into the formula:

$$n = 26 \text{ patients round off to } 30$$

An addition of 20% of the calculation was used for errors for loss of follow-up of patients. Therefore, a sample size of 36 patients was obtained.

3.6 Sampling Procedure

A convenience sampling method was used to enroll patients who met the inclusion criteria until the desired sample size was achieved. At the point of presentation, the investigator interviewed the guardian to obtain the history of clinical presentation, physically examined the patient and recorded both the clinical parameters and radiological imaging findings using the data collection sheet provided in the appendices. At follow up the investigator recorded the Glasgow outcome scale score at two weeks and six weeks.

3.6.1 Quality Assurance Procedure

There was only one principal investigator who is a neurosurgical resident and 3 supervisors out of which 2 are consultant neurosurgeons and 1 is a consultant radiologist. The principal investigator was responsible for obtaining the clinical history, performing clinical examination and analyzing the radiological findings which was confirmed by the consultant neurosurgeon and radiologist on call on that day.

During major ward rounds all consultants neurosurgeons in the neurosurgical unit reviewed and confirmed the principal investigator's findings. Radiological findings was confirmed by the supervisor who is the consultant radiologist.

Clinical management including investigations and interventions was left to the discretion of the consultant on call on each day. The investigator did not interfere with patient management.

At the point of follow up the principal investigator was responsible to records all relevant findings pertaining to the study. The supervisors randomly reviewed 20% of the data collected and confirmed the findings. Data entry was done by the principal investigator and the supervisors randomly reviewed 20% of the data entered to ensure accurate data entry.

The scientific concept and general aims of the study was presented to the neurosurgical unit at a meeting organized by the principal investigator and was approved by the neurosurgery department which offered its full support.

3.7 Ethics and Confidentiality

- This study was approved by the Department of Surgery University of Nairobi and the UoN-KNH Ethics and Research Committee.
- Prior authorization from the administration offices at Kenyatta National Hospital was sought before commencement of this study.
- An informed consent was taken from all parents/guardians of patients by the principal investigator before being enrolled in the study.
- Participation in this study did not attract extra costs to the medical care of the participants. Participants had a right to withdraw from the study at any stage and continued to get standard medical care.
- All information collected about the patients were handled with confidentiality. No patient identifiers were published or disseminated. Information on the questionnaire was only be accessible to the investigators and statistician.

3.8 Data Collection Procedure

- Patients with a diagnosis of a severe traumatic brain injury and meeting the inclusion criteria were recruited.
- Data was collected using a standard questionnaire administered by the principal investigator at admission and at follow up.
- Consent to participate in the study was taken from the next of kin/ guardian of the patient by the principal investigator on the day of admission. Consent was provided by the consultant on call for patients who had no relatives and unable to give consent.
- The initial CT scan head was done on admission after intubation and resuscitation of the patient.
- The CT scan was then analyzed by the consultant radiologist or registrar who then evaluated the Helsinki score. The patients were followed up by the principal investigator.
- At 6 weeks follow up, the patient's guardian/relative were contacted by phone 1 week prior to their scheduled appointment and asked to attend the neurosurgical clinic with the patient at clinic no. 24 at the KNH to record the Glasgow outcome scores. The data was collected by the principal investigator and recorded in the data sheets/questionnaire of the patient. The patients who failed to attend that particular day were again contacted and given a day to attend within the week. Failure to attend within a 2 week period, the patient was deemed to have defaulted in his follow up and his data was withdrawn from the study. Mortality, favourable and unfavourable outcomes at 2 weeks and 6 weeks were recorded.

3.9 Data Management and Analysis

- The collected data was entered into MS excel spread sheet and analyzed using the Statistical Package for social sciences version 23.0 (SPSS 23.0).
- Patient characteristics were summarized using the clinical parameters of age, GCS, pupillary reactivity, blood pressure, blood glucose level and extra cranial injuries, and presented as means or proportioned for continuous and categorical variables respectively.

- Blood pressure was categorized into those with systolic blood pressure less than and greater than 90 mmHg.
- The pupillary reaction was categorized as a brisk, slow reaction, non-equal(anisocoria) and non-reactive.
- The GCS was classified as scores of 3-4, 5-6 and 7-8.
- The Glasgow outcome score was dichotomized as unfavourable (grade I – III) and favourable (IV and V).
- Association of Glasgow outcome score with extra cranial injuries, blood pressure, blood glucose level, pupillary reactivity, GCS and the initial Helsinki score were done using chi-square test of associations.
- Student's t-test was used to test the difference in numerical variables such as GCS and Helsinki score across different outcome groups.
- Logistic regression analysis was used to determine the independent predictors of outcome.
- Receiver-operator characteristic (ROC) curve was drawn for sensitivity and specificity and AUC values were calculated. Confidence interval was calculated at 95% for sensitivity and specificity to determine the level of precision.
- All statistical tests were conducted at a 5% level of significance.

4.0 CHAPTER FOUR: RESULTS

4.1 Sex

There were 42 patients in this study, 38 males(90%) and 4 females(10%). The male to female ratio was 9:1.

4.2 Age

Table 1 and figures 1 and 2 show the age distribution and mortality.

Table 1: Age Distribution and Mortality

| AGE | NUMBER OF PATIENTS | NO OF DEAD | % MORTALITY |
|--------------|--------------------|------------|---------------|
| 18-20 | 5 (12%) | 0 | 0 |
| 21-30 | 15 (36%) | 10 | 66.67 |
| 31-40 | 13 (31%) | 10 | 76.92 |
| 41-50 | 6 (14%) | 4 | 66.67 |
| 51-60 | 3 (7%) | 3 | 100.00 |
| 60+ | 0 (0%) | 0 | 0 |
| TOTAL | 42 (100%) | 27 | 64.29% |

The age range in the study was from 18 years to 100 years. The mean age was 33 years old. The overall mortality was 64.3%(27 patients out of 42).

Severe TBI was common in the age group between 21 to 50 years(Table 1 and Figure 1). The highest being at 21 to 30 years at 36%. These incorporated 34 patients out of a total 42 (81%).

Figure 1 shows that severe TBI was highest at age group between 21 and 50 years and the highest affected groups were between 21 and 40 years.

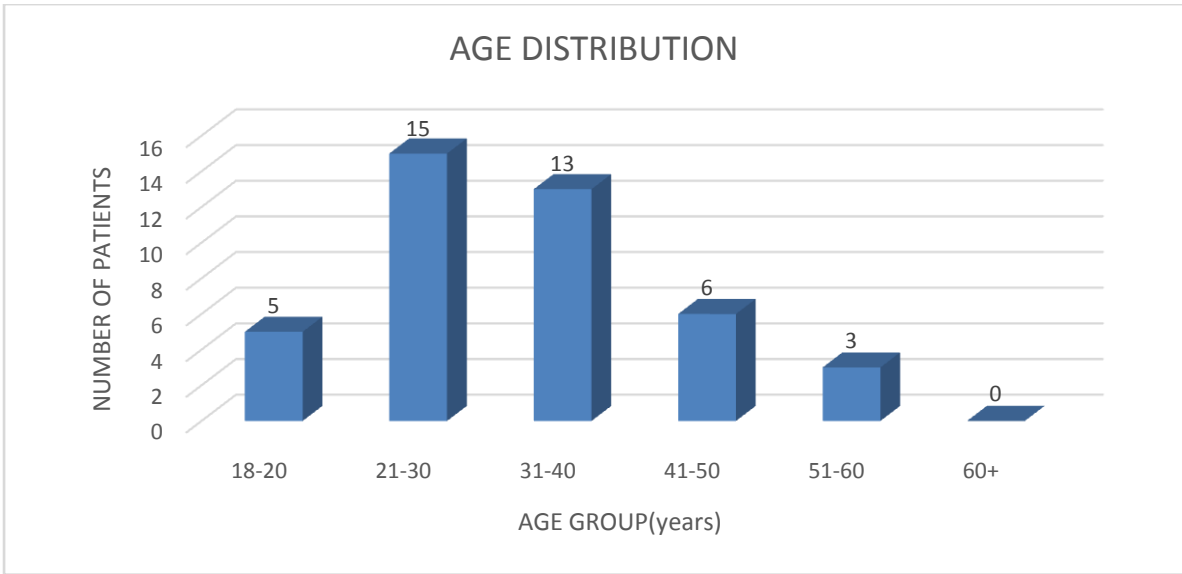


Figure 1: Distribution of Patients by Age Groups

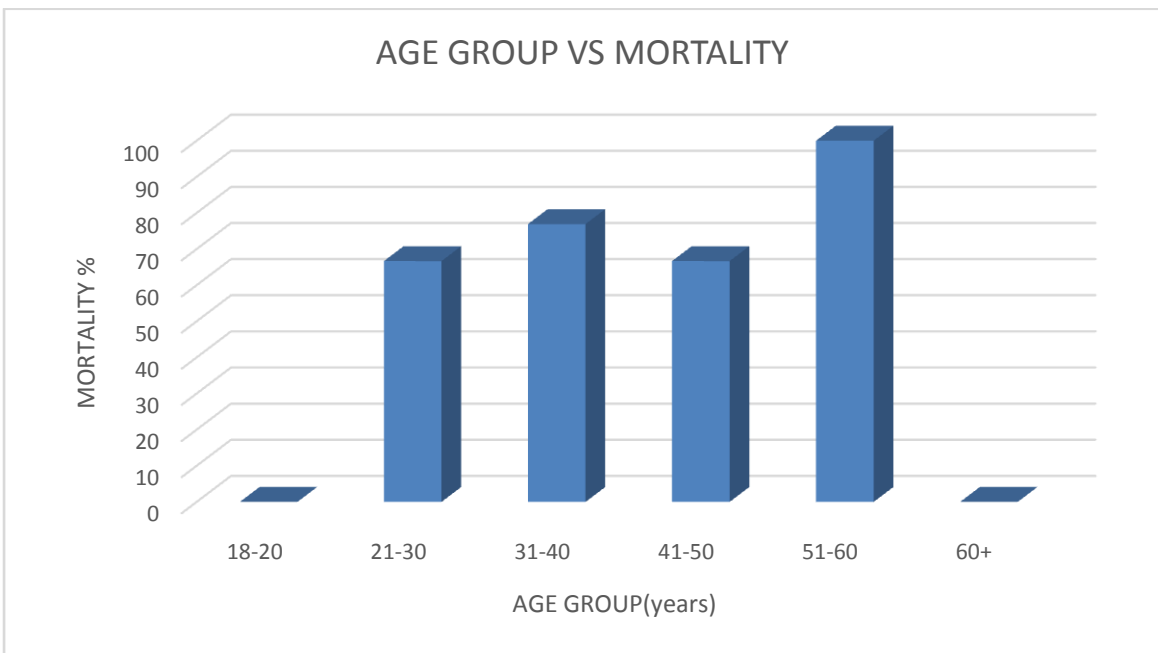


Figure 2: Age-Group Specific Mortality

Patients below age of 20 years, all survived with good outcomes whereas patients above 50 years of age all died (3 patients). Table 1 and figure 2 summarize the age group specific mortality. Mortality was recorded to be 66.7% and 100% in age group of 21-30 years and 51-60 years respectively. The histogram shows that mortality increased with increasing age.

4.3 Cause of Injury

Table 2: Cause of Injury with Mortality

| CAUSE OF INJURY | NUMBER OF PATIENTS | NO OF DEAD | % MORTALITY |
|-----------------|--------------------|------------|--------------|
| ASSAULT | 11 (26%) | 5 | 45.45 |
| OTHERS (FALL) | 4 (10%) | 4 | 100.00 |
| RTA | 27 (64%) | 18 | 66.67 |
| TOTAL | 42 (100%) | 27 | 64.29 |

Road traffic accident was the commonest mode of severe TBI at 64%. The second commonest cause was assault at 26%. Injuries resulting from falls was 10% (Table 2 and Figure 3).

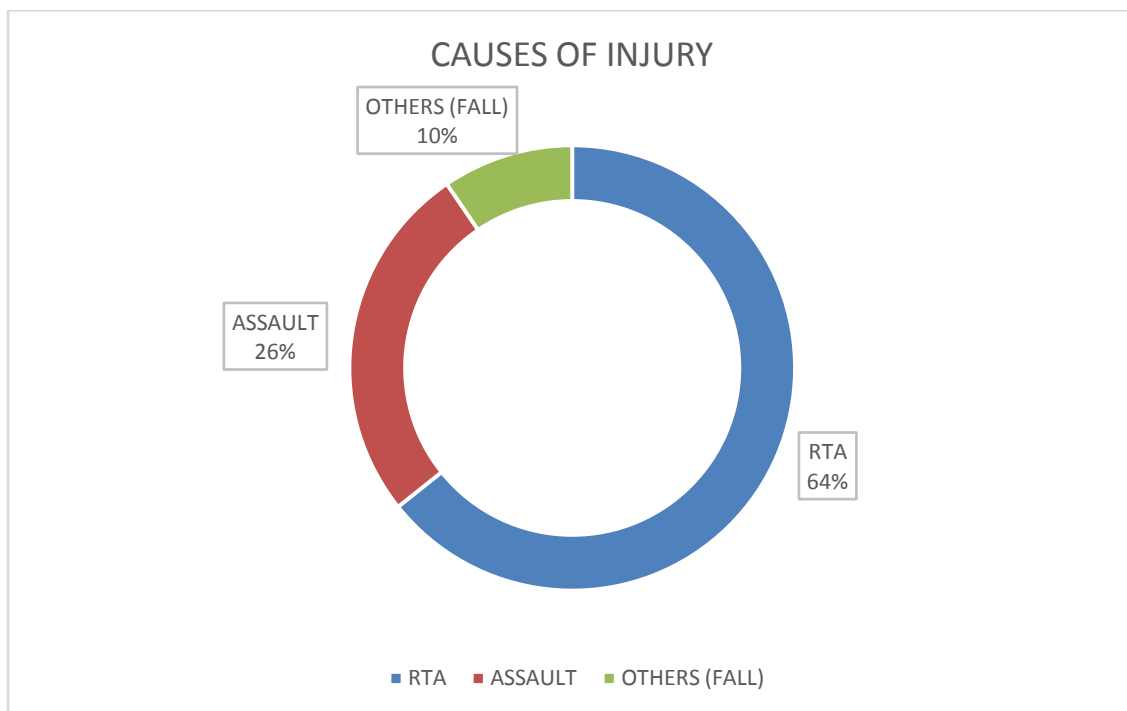


Figure 3: Distribution of Cause of Injury

The mortality among those involved in falls from height was the highest at 100% followed by road traffic accident at 66.7%. Patients with cause of injury due to assault had a mortality of 45.4% (Table 2 and Figure 4).

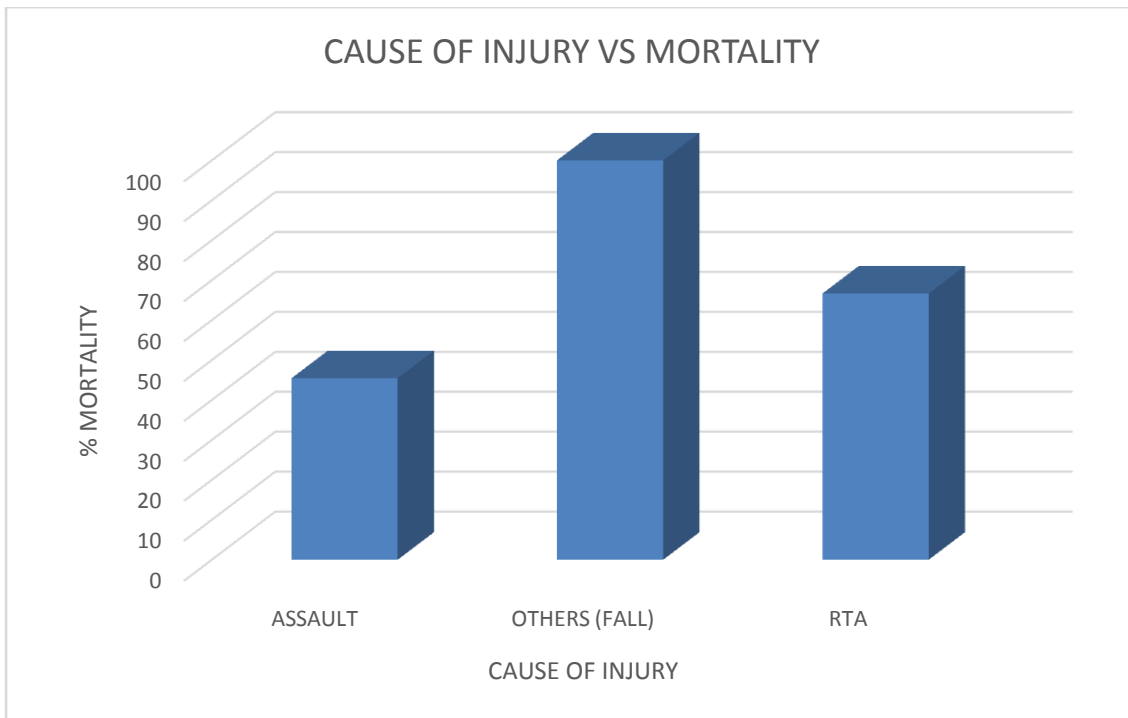


Figure 4: Cause of Injury and Mortality

4.4 Pupillary Reaction

Table 3: Pupillary Reactivity and Mortality

| PUPILLARY REACTIVITY | NO OF PATIENTS | NO OF DEAD | % OF MORTALITY |
|-----------------------|------------------|------------|----------------|
| Brisk Reaction | 0 | 0 | 0 |
| Slow Reaction | 27 (64%) | 17 | 62.96 |
| Non-Reactive To Light | 15 (36%) | 10 | 66.67 |
| TOTAL | 42 (100%) | 27 | |

The most common pupillary finding was slow reacting pupil present in 27 patients(64%) followed by non reactive pupil in 15 patients(36%). There was also 19 patients(45%) who had anisocoria. The highest mortality was associated with non reactive pupil group followed by the slow reacting pupil group at 67% and 63% respectively(Table 3 and Figure 5). Among those with anisocoria there was 11 patients(57.9%) who died.

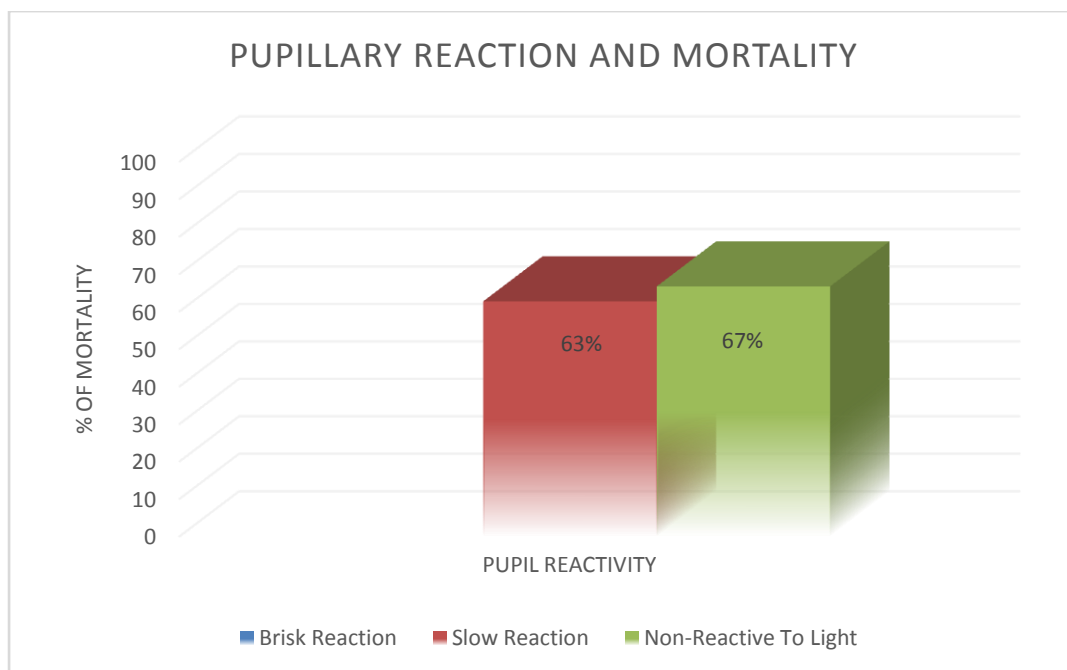


Figure 5: Pupillary Reaction and Mortality

4.5 Systolic Blood Pressure

Table 4: Systolic Blood Pressure and Mortality

| SYSTOLIC BLOOD PRESSURE/ mmHg | NUMBER OF PATIENTS | NO OF DEAD | % MORTALITY |
|----------------------------------|-----------------------|------------|-------------|
| < 90 | 2 (5%) | 0 | 0.00 |
| >90 | 40 (95%) | 27 | 67.50 |
| TOTAL | 42 (100%) | 27 | |

Out of 42 patients, 40 patients had systolic BP >90 mmHg and 67.5% of them died. Hypotension(systolic blood pressure <90 mmHg) was present in 5% of patients and none of them had any mortality(Table 4 and Figure 6).

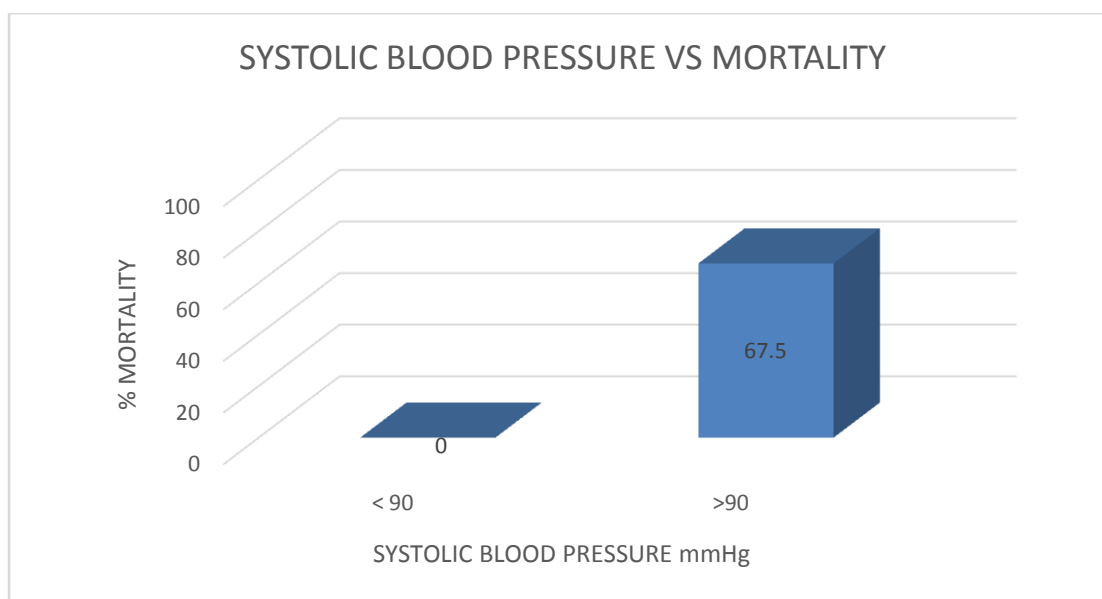


Figure 6: Systolic Blood Pressure and Mortality

4.6 Extra Cranial Injury

Table 5: Extra cranial Injuries and Mortality

| EXTRACRANIAL INJURY | NUMBER OF PATIENTS | NO OF DEAD | % MORTALITY |
|---------------------|--------------------|------------|--------------|
| ABDOMINAL | 2 (11.1%) | 2 | 100.00 |
| CHEST | 2 (11.1%) | 1 | 50.00 |
| CERVICAL | 2 (11.1%) | 1 | 50.00 |
| LIMB | 8 (44.4%) | 5 | 62.50 |
| FACIAL | 4 (22.2%) | 3 | 75.00 |
| TOTAL | 18 (100%) | 12 | 66.67 |

Extra cranial injuries were present in 18 patients(43%) in our study of which 66.7% did not survived. The most frequent extra cranial injury was limb fractures (44.4%) followed by facial injuries at 22.1% and cervical spine, chest injuries and abdominal injuries at 11.1% each(Table 5 and Figure 7). The highest mortality was in those patients with abdominal injuries(100%) and the least mortality was in both cervical spine and chest injuries group at 50%(Table 5 and Figure 8).

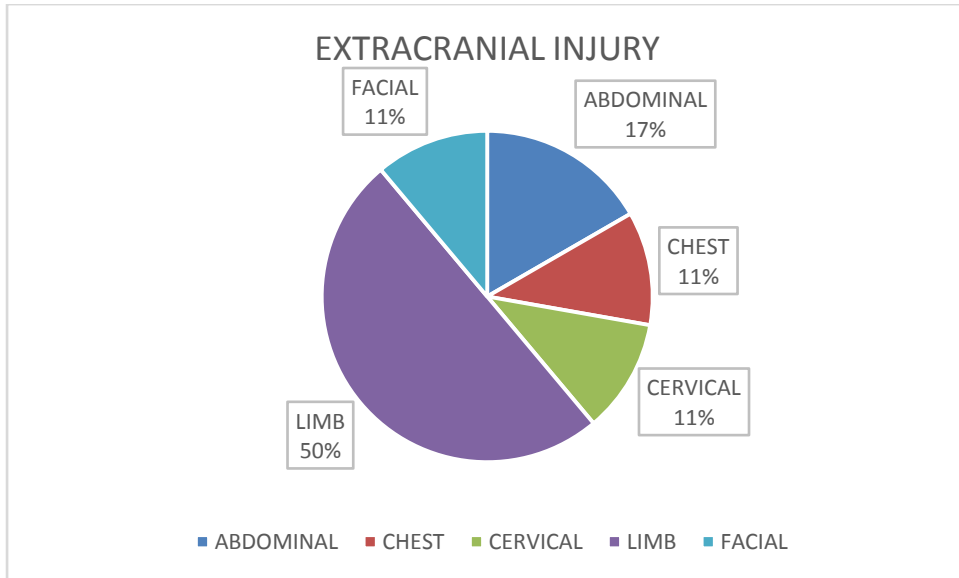


Figure 7: Extra cranial Injury Distribution

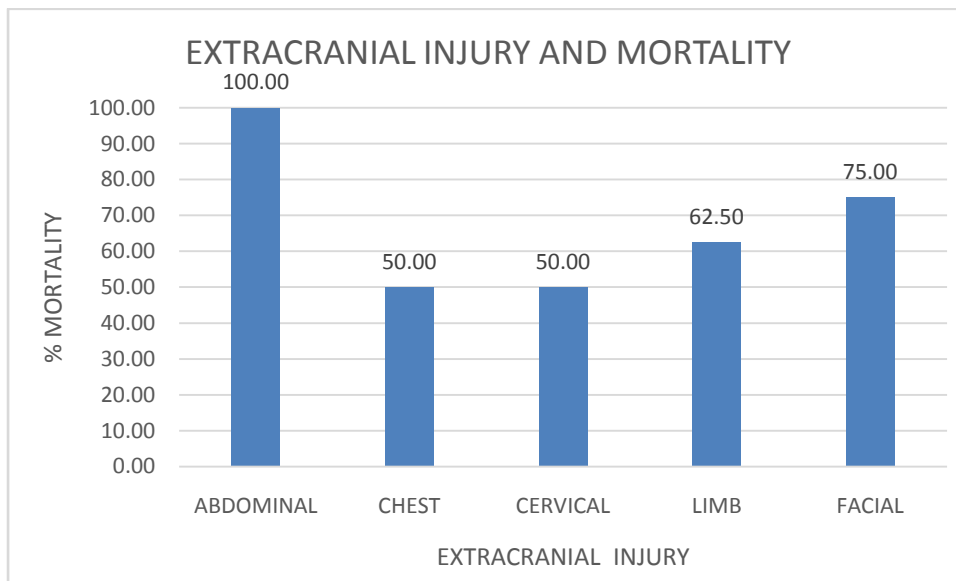


Figure 8: Extra cranial Injury and Mortality

4.7 Random Blood Sugar

Table 6: Random Blood Sugar with Mortality

| RBS | NUMBER OF PATIENTS | NO OF DEAD | % MORTALITY |
|--------------|--------------------|------------|-------------|
| A>10 | 8 (20%) | 7 | 87.50 |
| B<10 | 34 (80%) | 20 | 58.82 |
| TOTAL | 42 (100%) | 27 | |

The most common random blood sugar at admission was < 10 mmol/l which was found in 34 patients(80%) and a mortality of 58.8 % was seen in this group of patient. Those patients who presented with random blood sugar > 10 mmol/l were 8(20%) and their mortality accounted at 87.5%(Table 6 and Figure 9).

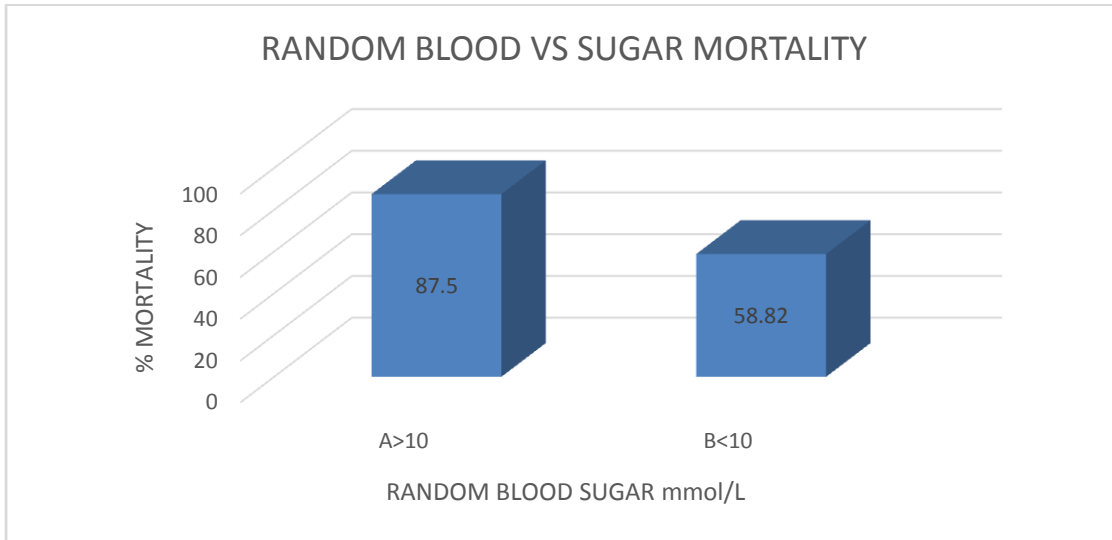


Figure 9: Random Blood Sugar and Mortality

4.8 Glasgow Coma Score

The post-resuscitation GCS was grouped into 3 groups and correlated with mortality. Patients with GCS 7-8 accounted for 23 patients(55%), GCS 5-6 for 16 patients(33%) and GCS 3-4 for 3 patients(7%) as shown in table 7. This showed that as GCS improved, the mortality reduced as shown in figure 10.

Table 7: Glasgow Coma Scale(GCS) and Mortality

| GCS ON ADMISSION | NO OF PATIENTS | NUMBER OF DEATH | MORTALITY % |
|------------------|------------------|-----------------|-------------|
| 3-4 | 3 (7%) | 3 | 100.00 |
| 5-6 | 16 (39%) | 10 | 62.50 |
| 7-8 | 23 (55%) | 14 | 60.87 |
| TOTAL | 42 (100%) | 27 | |

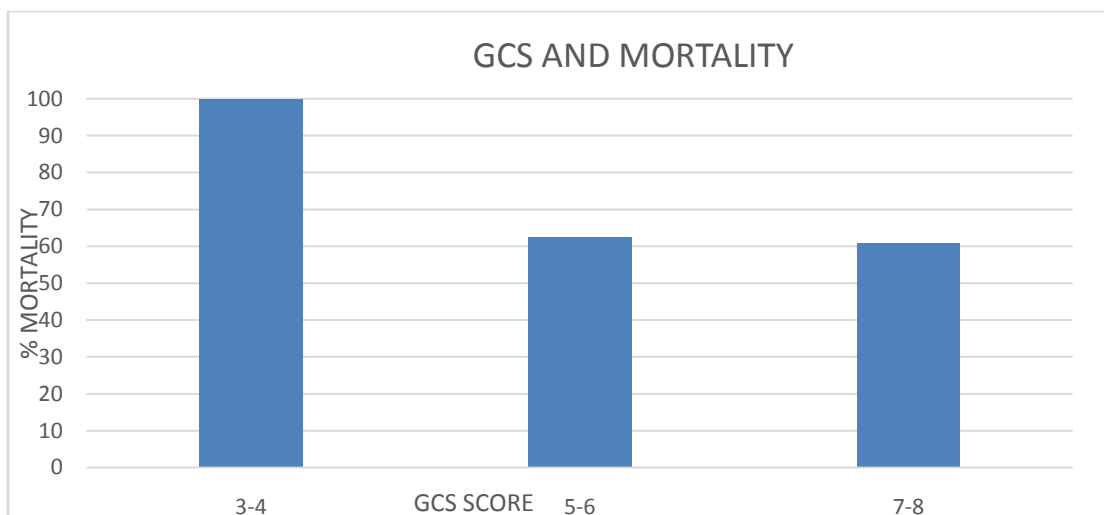


Figure 10: Post-Resuscitation Glasgow Coma Scale and Mortality

A decline in GCS was associated with higher mortality as seen in figure 10. GCS 3-4 had the highest mortality whereas GCS 7-8 the least.

4.9 Helsinki Computer Tomography Score

Table 8: Helsinki Score and Mortality

| HELSENKI SCORE | NO OF PATIENTS | NO OF PATIENTS WHO DIED | MORTALITY (%) |
|----------------|----------------|-------------------------|---------------|
| -3 | | | |
| -2 | | | |
| -1 | | | |
| 0 | | | |
| 1 | | | |
| 2 | 1 | | |
| 3 | 4 | 2 | 50.00 |
| 4 | 3 | 1 | 33.33 |
| 5 | 3 | | |
| 6 | 5 | 4 | 80.00 |
| 7 | 9 | 8 | 88.89 |
| 8 | | | |
| 9 | 15 | 10 | 66.67 |
| 10 | | | |
| 11 | 2 | 2 | 100.00 |
| 12 | | | |
| 13 | | | |
| 14 | | | |
| TOTAL | 42 | 27 | 64.29 |

Patients with a Helsinki score of 4 had mortality of 33.3% while Helsinki score of 11 had mortality of 100%. The largest group constituted patients with Helsinki score of 9(15 out of 42 patients) with mortality of 66.7%. The graph below shows that an increasing Helsinki score conferred a higher mortality(Table 8 and Figure 11).



Figure 11: Helsinki Score and Mortality

4.10 Patterns of Intracranial Bleed

Table 9: Patterns of Intracranial Bleed

| HELSINKI SCORE | ASDH | CONTUSION/ICH | EDH | TOTAL |
|-----------------|-----------------|-----------------|----------------|----------------|
| -3 | | | | |
| -2 | | | | |
| -1 | | | | |
| 0 | | | | |
| 1 | | | | |
| 2 | | | 1 | 1 |
| 3 | | 4 | | 4 |
| 4 | | | 3 | 3 |
| 5 | 2 | | 1 | 3 |
| 6 | | 1 | 4 | 5 |
| 7 | 1 | 8 | | 9 |
| 8 | | | | |
| 9 | 8 | 7 | | 15 |
| 10 | | | | |
| 11 | 2 | | | 2 |
| 12 | | | | |
| 13 | | | | |
| 14 | | | | |
| TOTAL(%) | 13(30.9) | 20(47.6) | 9(21.4) | 42(100) |

The most common intracranial bleed among severe TBI patients was contusions and intracerebral hemorrhage(ICH) at 47.6% of patients while acute subdural hematomas(ASDH) and acute epidural hematomas(EDH) were 30.9% and 21.4% respectively(Table 9). This is compared with Helsinki score and most patients with Helsinki score between 7 and 9 had either ASDH or contusions and intracerebral hematomas.

Table 10:Patterns of Intracranial Bleed and Mortality

| TYPE OF LESION | NO OF PATIENTS | NO OF DEAD | % MORTALITY |
|----------------|----------------|------------|-------------|
| ASDH | 13 (31%) | 7 | 53.85 |
| CONTUSION/ICH | 20 (48%) | 16 | 80.00 |
| EDH | 9 (21%) | 4 | 44.44 |
| TOTAL | 42 | 27 | |

The highest mortality was recorded in the group of contusions and intracerebral hematomas at 80% while in acute subdural hematomas and acute epidural hematomas the mortality were 53.8% and 44.4% respectively(Table 10).

4.11 Glasgow Outcome Score

Table 11: Glasgow Outcome Score (GOS) At 2 Weeks and 6 Weeks

| GOS | GOS 2 WEEKS | GOS 6 WEEKS |
|--------------|-------------|-------------|
| 1 | 25 | 27 |
| 2 | 7 | 4 |
| 3 | 9 | 2 |
| 4 | 1 | 9 |
| 5 | | |
| TOTAL | 42 | 42 |

Table 11 and figure 12 show that most mortality(25 out of 27,i.e 92.6%) occurred before 2 weeks period and only 2 patients died after 6 weeks period. At 2 week period, only 1 patient(2.4%) had favourable outcome(GOS 4 and 5) while at 6 weeks, 9 patients(21.4%) had favourable outcomes.

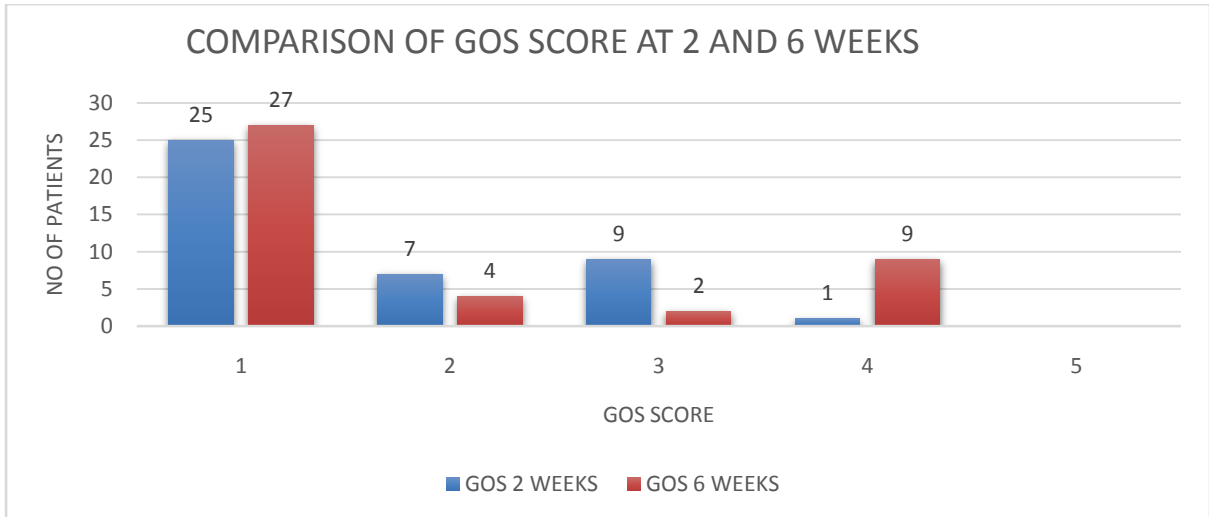


Figure 12: Comparison of Glasgow Outcome Score at 2 Weeks and 6 Weeks

The graph (Figure 12) shows that at 2 weeks, 25 patients had died(GOS1), 7 patients had persistent vegetative state(GOS 2) and 9 patients had severe disability(GOS 3). This constituted 97.6% of patients with unfavourable outcome(GOS 1-3) and 2.4% of patients with favourable outcomes at 2 weeks.

This in comparison with GOS at 6 weeks. 2 patients died after 2 week period with mortality total of 27(GOS 1), 33 patients(78.6%) had unfavourable outcomes(GOS 1-3) while 9 patients(21.4%) had favourable outcomes(GOS 4-5) at 6 weeks.

4.12 Correlation Analysis of GCS, Helsinki Score on Outcome

Table 12: Comparison Of GCS And Glasgow Outcome Score (GOS) At 6 Weeks

| GCS | GLASGOW OUTCOME SCORE (GOS) | |
|-----|-----------------------------|------------|
| | UNFAVOURABLE | FAVOURABLE |
| 3-4 | 3 (100%) | 0(0%) |
| 5-6 | 14 (87.50%) | 2 (12.50%) |
| 7-8 | 16 (69.57%) | 7 (30.43%) |

Table 12 compares Glasgow coma scale and the GOS at 6 weeks duration and showed that as the GCS score increased, the number of patients with favourable outcomes increased. GCS between 3-4 had favourable outcome of 0% while GCS of 7-8 had favourable outcomes of 30.4%.

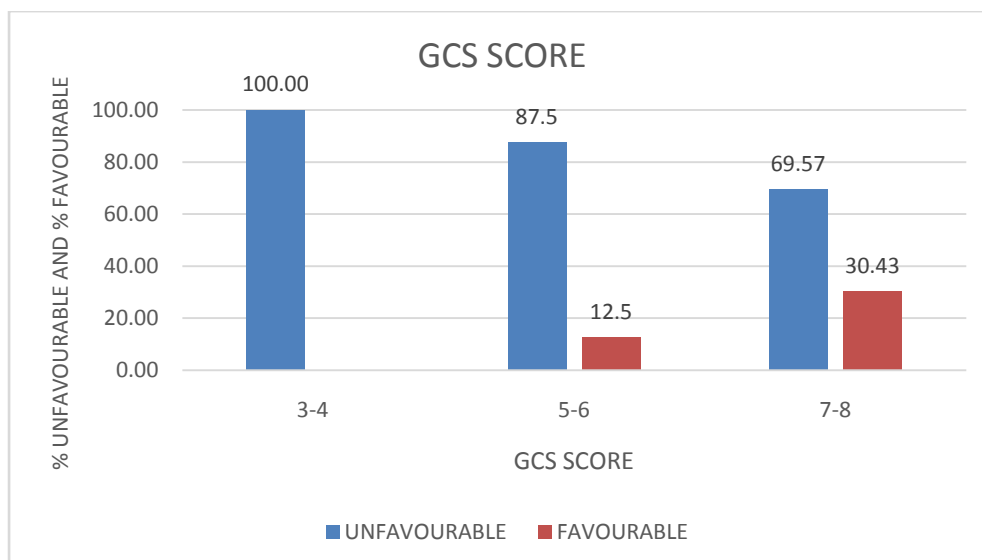


Figure 13: Comparison of GCS with GOS at 6 Weeks

The graph(Figure 13) shows the correlation between the GCS and GOS at 6 weeks period. GCS 3-4, 5-6 and 7-8 had unfavourable outcomes of 100%, 87.5% and 69.6% respectively. Favourable outcomes were present only in GCS 5-6 and 7-8 at 12.5% and 30.4% respectively at 6 weeks period.

Table 13 : Comparison of Helsinki Score and Glasgow Outcome Score at 6 Weeks

| HELSINKI SCORE | GLASGOW OUTCOME SCORE (GOS) | |
|----------------|-----------------------------|------------|
| | UNFAVOURABLE | FAVOURABLE |
| -3 | | |
| -2 | | |
| -1 | | |
| 0 | | |
| 1 | | |
| 2 | | 1 (100%) |
| 3 | 4 (100%) | |
| 4 | 1 (33%) | 2 (66.67%) |
| 5 | 1 (33%) | 2 (66.67%) |
| 6 | 4 (80%) | 1 (20%) |
| 7 | 7 (88.89%) | 1 (11.11%) |
| 8 | | |
| 9 | 13 (86.67%) | 2 (13.33%) |
| 10 | | |
| 11 | 2 (100%) | |
| 12 | | |
| 13 | | |
| 14 | | |

Patients with Helsinki score of 2 had 100% of favourable outcomes while Helsinki score of 11 had no favourable outcomes at 6 weeks duration. As the Helsinki score increase the proportion of patients with favourable outcomes decrease(table 13).

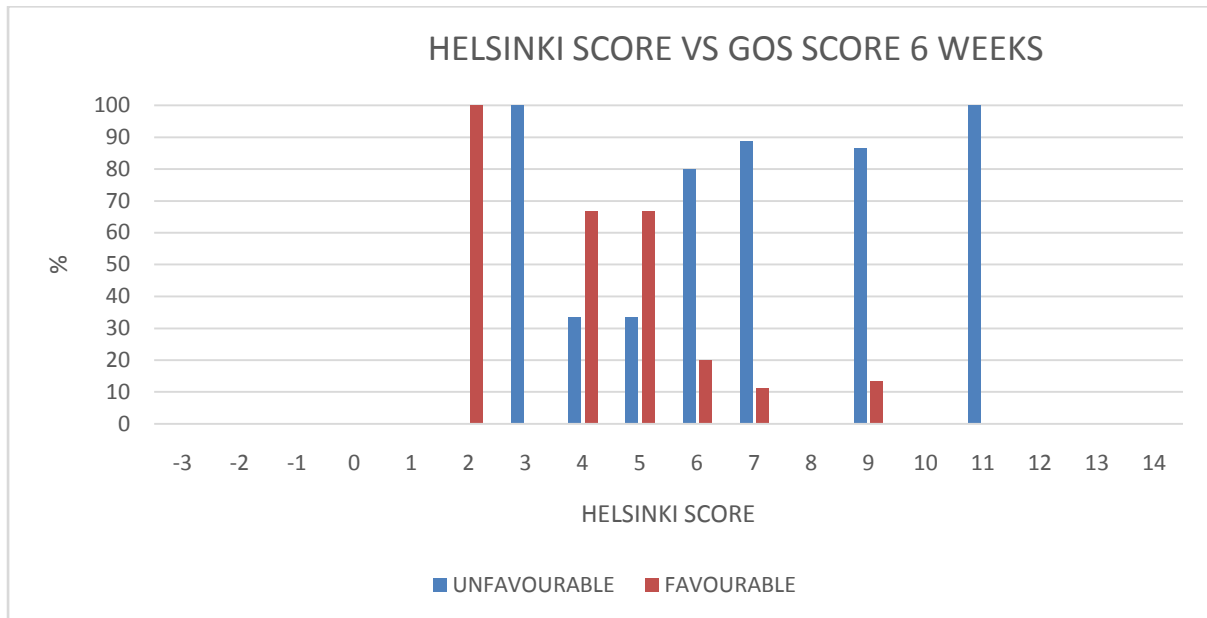


Figure 14: Comparison of Helsinki Score and GOS At 6 Weeks

The graph(Figure 14) above compares the GOS at 6 weeks and admission Helsinki score. As the Helsinki score increase from 4 to 11, the outcome worsened from 33% to 100%. All patients with Helsinki score of 3 had unfavourable outcomes and all patients with Helsinki score of 2 had favourable outcomes at 6 weeks duration.

Table 14: Analysis of Helsinki Score, GCS Score and Outcome

| | P value | | |
|----------------|--------------|---------------|---------------|
| | GOS(2 WEEKS) | GOS(6 WEEKS) | DEATH |
| HELSINKI SCORE | 1.000 | 0.004* | 0.009* |
| GCS | 1.000 | 0.332 | 0.687 |

*. Significant association(p value < 0.05)

As shown in table 14 after doing the Spearman's correlation analysis, it was found that the Helsinki score is significantly associated with GOS at 6 weeks(p=0.004), and death(p=0.009). There is no significant association between the Helsinki score and GOS at 2 weeks(p=1.000). The GCS is not significantly associated with GOS at 2 weeks(p=1.000), GOS at 6 weeks(p=0.332) and death(p=0.687).

Table 15: Summary of P Values For Variables And Outcome

| | SEX | AGE | SYSTOLIC BP | RANDOM BLOOD SUGAR | ANISOCORIA | GCS | HELSINKI SCORE |
|---------------------|-------|--------------|--------------|--------------------|------------|-------|----------------|
| GOS(6 WEEKS) | 1.000 | 0.030 | 0.210 | 0.210 | 0.362 | 0.332 | 0.004 |
| MORTALITY | 1.000 | 0.020 | 0.043 | 0.234 | 0.432 | 0.687 | 0.009 |

The other variables that were analyzed are sex, age, systolic blood pressure, random blood sugar, and pupillary reflexes (Table 15) and showed that age had significantly correlated (p value <0.05) with 6 weeks GOS and mortality. Systolic blood pressure was only significantly associated with mortality (p=0.043). The other clinical parameters like sex, random blood sugar, pupillary reactivity to light and GCS were not statistically significant (p value >0.05).

Receiver-operating characteristics (ROC) curve analysis was done to evaluate the performance of the Helsinki score by determining the area under the curve (AUC) value. This yielded AUC value of 0.69 for unfavourable outcome (moderate discrimination power) and AUC value of 0.71 for mortality (moderate discrimination power) at Helsinki score between 6 to 14. The specificity, sensitivity and accuracy for Helsinki score for mortality were 88.9%, 53.3% and 71% respectively; and for an unfavourable outcome, these values were 81.8%, 55.6% and 69% respectively (table 16). After performing logistic regression analysis to determine the predictors of outcome, we found that the odds ratio (OR) for the Helsinki score to predict mortality to be 9.1 (95% CI 1.9-44) and unfavourable outcome at 5.6 (95% CI 1.2-27.4).

Table 16: Summary of Analysis of Helsinki Score

| | SPECIFICITY | SENSITIVITY | AUC | ODDS RATIO | P VALUE |
|-----------------------------|-------------|-------------|------|------------|---------|
| MORTALITY | 88.9% | 53.3% | 0.71 | 9.1 | 0.009 |
| UNFAVOURABLE OUTCOME | 81.8% | 55.6% | 0.69 | 5.6 | 0.038 |

5.0 CHAPTER FIVE: DISCUSSION

Severe traumatic brain injury is a debilitating disease that carries a high mortality and disability. Many studies have been carried out to determine variables that could predict outcome^{10,17,29,38}. In our study majority of patients were male(90%) and only 10 % were female with a male to female ratio of 9:1. Mwangombe et al in 2007 reported a male to female ratio of 5.2:1⁵. There is a rise in the number of male sustaining severe traumatic brain injury in the last decade. This could be attributed to more men being involved in assault and being drivers in Kenya. Analysis of the p values for 6 weeks GOS and mortality with sex were not statistically significant which was similar to previous studies^{9,10,17}.

The most frequent cause of severe TBI was road traffic accident at 64% and assault at 26%. Other causes like fall accounted for 10%. Mohan et al⁷ reported similar findings of RTA 64% and assault 28%. Andriessen et al³⁹ in their study reported RTA among 51% of patients and falls in 38%, a third from stairs. In Kenya compared to developed countries this shows a different pattern of cause of severe TBI. Falls carried a highest mortality of 100% followed by RTA at 66.7%. This underlines the need to sensitize the population on following traffic regulations throughout the country.

The overall mortality rate in the study is 64.2%. This rate is higher to the local study done by Mohan et al in 2015 with mortality of 51.3%⁷. Andriessen et al found mortality of 46% at 6 months³⁹. In other multicenter studies mortality rate had been reported to be between 32-49%^{9,34}. The average number of days of mortality from time of injury was 3.7 days as compared to the study of Mohan et al which was 13.7 days⁷. Although 92.6%(25 patients) of deaths occurred before 2 weeks, 2 patients (7.4%) died after 2 weeks. This shows that in Kenya the mortality attributed to severe TBI is on the rise and is occurring earlier which could be attributed to the lack of neurosurgical centres with qualified staff to take care of these patients.

Severe TBI was found to be more prevalent in the age group between 21 and 40 years(67% of total), only 3 patients were above 50 years. Patients below 40 years constituted 79% of the total. The mean age was 33 years while in the study by Andriessen et al³⁹ the mean age was reported to be 46 years. This could be related to the age distribution in Kenya compared to the developed countries²⁹. All patients above 50 years (3 patients) died, followed by the age group of 31 to 40 years which had a mortality of 76.9%. Older patients have worse outcomes.

Age was statistically significant on mortality for age above 25 years($p=0.02$) and on 6 weeks GOS for age below 25 years($p=0.03$).

The Glasgow Coma Scale (GCS) developed in 1974 by Teasdale and Jennet is a globally used validation tool in the assessment of the level of consciousness and for detection of changing neurological status in patients with TBI¹⁵. Several studies have shown that the GCS can be used as a strong outcome predictor in TBI^{17,24}. However it may be affected by presence of facial swelling, alcohol intoxication, sedation and paralysis^{9,16}. Our study demonstrated that GCS of 3-4 had 100 % mortality, 5-6 at 62.5 % and 7-8 with mortality of 60.8 %. In 2001, Mwangombe and Kiboi⁶ reported a mortality of 88%, 60% and 52% among patients with GCS 3-4, 5-6 and 7-8 respectively. In 2007 Mwangombe and Opondo⁵ found mortality of 76.7% in patients with GCS 3-5 and 29.5% in patients with GCS 6-8. In 2015 Mohan et al⁷ study showed a mortality of 70.6%, 56% and 43% for patients with GCS 3-4, 5-6 and 7-8 respectively. This shows that an improving GCS was associated with a reduction in mortality. In the study by Quigley et al⁴⁰, high mortality was found between GCS of 3-4 and only 12.5% survived. Patients above age of 60 years old also had high mortality and they concluded that a combination of age and GCS could predict outcome. In our study GCS 3-4, 5-6 and 7-8 had unfavourable outcomes of 100%, 87.5% and 69.6% respectively. Favourable outcomes were present only in GCS 5-6 and 7-8 at 12.5% and 30.4% respectively at 6 weeks period. The p values when analyzed with GCS were 0.332 and 0.687 for 6 weeks GOS and mortality respectively which were not significant statistically. This could be attributed to our smaller sample size.

Hyperglycemia in this study was defined as a serum glucose level of 10 mmol/l or higher. The major causes of hyperglycemia after TBI are elevated stress and inflammatory response. Several studies have shown that hyperglycemia is commonly present in the early phase following TBI and is associated with poor outcome^{41,42,43,44}. Khajavikhan et al showed that the mortality rate among patients with RBS>11 mmol/l was 88.2% together with a greater length of ICU stay and hospital stay⁴⁴. In previous study at KNH, mortality was found to be 47.8% among severe TBI patients with RBS>10 mmol/l⁵. In our study, 8 patients(20%) had hyperglycemia of which 7 died(87.5%).

Hypotension have an impact on the outcome of patients with severe TBI. In the study by Chestnut et al, hypotension was associated with a mortality of 75%²². Previous study at KNH showed hypotension in 32% of patients of which 75% died⁵. In our study, 2 patients had

hypotension of which no mortality was recorded. This may have been due to selection criteria because we excluded patients who died within 24 hours from our study. Early hypertension characterised by systolic blood pressure of 100 mmHg or higher, following TBI may also be harmful⁴⁵. Barmparas et al in 2014 found a mortality rate of 55% among patients with SBP>100 mmHg⁴⁵. Our study population had 40 patients with SBP>100 mmHg of which the mortality was 67.5%. The mean systolic blood pressure shown to predict mortality was 136 mmHg(p value 0.004). The p values were 0.210 and 0.004 for 6 weeks GOS and mortality respectively when analysed with systolic blood pressure and were only statistically significant for predicting mortality.

Extra cranial injury is an independent prognostic factor for mortality in TBI patients. In the study by Sarrafzadeh et al the impact of extra cranial injuries was seen to be more pronounced in minor and moderate TBI and the outcome to be more attributed to the primary brain injury rather than the presence of extra cranial injuries in severe TBI²³. In our study 18(43%) patients had significant extra cranial injuries and among them, 12 patients died(66.7%). The most common extra cranial injury was limb fractures which accounted for 44.4% of the patients followed by facial fractures which was 22.2%. The highest mortality was observed in the abdominal trauma patient at 100% followed by facial trauma and limb fractures at 75% and 62.5% respectively. Local study done by Mwangombe et al showed extra cranial injuries to be present in 91.6% patients with severe TBI of which 49.5% were facial trauma and 25.2% limb fractures⁵. The reason for this could be our selection criteria as we selected patients with significant extra cranial injuries with radiologic evidence and patients with soft tissue injuries were excluded.

Pupillary reaction is considered to be a useful outcome predictor in traumatic brain injury. Out of 42 patients, 45.2% of patients had anisocoria, 64% had slow reacting pupil of which 63 % of patients succumbed and 36 % of patients had non reactive pupil with a resultant mortality of 67%. Previous study at KNH in 2015 by Mohan et al showed 55.7% with anisocoria of which 66.7% of non reactive pupils died and 27.3% with brisk reactivity died⁷. The p values were 0.43 and 0.36 for mortality and 6 weeks GOS respectively when analyzed with anisocoria and were not statistically significant.

The patterns of intracranial hemorrhage have been found to have prognostic impact on outcome as highlighted by Mass et al²⁹. In our study, the types of intracranial hemorrhage findings in the initial CT scan were contusions and intracerebral hemorrhage 48%, ASDH

31% and EDH 21%. The highest mortality was recorded in the group of contusions and intracerebral hematomas at 80% while in acute subdural hematomas and acute epidural hematomas the mortality were 53.8% and 44.4% respectively. In the IMPACT study³⁷, the ASDH and traumatic subarachnoid hemorrhage carried the worst outcomes and mortality of 20-35% and the presence of 2 lesions predicted worse outcomes. Mass et al²⁹ also reported better outcomes among patients with EDH as compared to ASDH ones.

The Helsinki computer tomography(CT) score was described by Raj et al in 2014² and has been validated in the European and Asian subcontinent as a predictor of outcome in TBI patients. The Helsinki CT scoring classification comprises of six attributes ASDH, ICH, EDH, IVH, the volume of the lesion and the status of the suprasellar cisterns. The total score range from -3 to 14. The prognosis at 6 months for mortality ranges from 3% to 79% and for unfavourable neurological outcome from 7% to 94% when utilizing the Helsinki CT scoring system in TBI patients². In our study we used the Helsinki CT score among severe TBI patients admitted in the intensive care unit and found the prognosis at 6 weeks for mortality and unfavourable outcomes ranging from 33% to 100% and that for favourable outcomes from 11% to 100%. Patients with a Helsinki score of 4 had mortality of 33.3% while Helsinki score of 11 had mortality of 100%. The largest group constituted patients with Helsinki score of 9(15 out of 42 patients) with mortality of 66.7%. An increasing Helsinki score conferred a higher mortality. Patients with Helsinki score of 2 had 100% of favourable outcomes while Helsinki score of 11 had no favourable outcomes at 6 weeks duration. As the Helsinki score increase the proportion of patients with favourable outcomes decrease. After correlation analysis, it was found that the Helsinki score is significantly associated with GOS at 6 weeks($p=0.004$), and death($p=0.009$) as compared to the GCS. There is no significant association between the Helsinki score and GOS at 2 weeks($p=1.000$). In multivariate logistic regression analysis, we found that the Helsinki CT score can predict mortality with an odds ratio(OR) of 9.1(95% CI 1.9-44) and unfavourable outcome with an odds ratio of 5.6(95% CI 1.2-27.4). This implies that the Helsinki CT score can be used as an independent predictor of outcome when determining mortality and unfavourable outcome. The area under the receiver operating characteristic curve analysis yielded an AUC value of 0.71 for mortality and 0.69 for unfavourable outcome. Our study results for AUC were consistent with the studies by Yao et al³² who found AUC for mortality at 0.81 and for unfavourable outcome at 0.74, and by Raj et al² AUC for mortality at 0.75 and for unfavourable outcome at 0.74. This shows that the Helsinki CT score has moderate discrimination ability to predict

mortality and unfavourable outcome at 6 weeks period for a value between 6 to 14 of total score. Moreover we also found that the Helsinki CT score has a specificity, sensitivity and accuracy for mortality at 88.9%, 53.3% and 71% respectively; and for unfavourable outcome at 81.8%, 55.6% and 69% respectively. This shows that the Helsinki CT score can be used as a predictor of mortality and unfavourable outcome as compared to the GCS.

Delays between time of injury to undergo surgical intervention for severe TBI are highly correlated with poor outcomes. Seelig et al⁴⁶ in their study found an increasing mortality from 30% to 90% if surgery took place after 4 hours after the initial trauma. In another study by Haselsberger et al⁴⁷ showed that in 171 severe TBI patients mortality was doubled to 65% for EDH and tripled to 80% for ASDH if surgery was done after 2 hours. In our study, we found that average time to surgery from time of injury was 12 hours and among those who underwent surgery which was 45%, the mortality was 60%. This shows the need to expedite patients with severe TBI to the nearest available neurosurgical facility in a lesser time period to prevent mortality.

Previous local studies have demonstrated a significant delay between the time of injury and the time of arrival to the hospital^{5,6}. In our study the number of patient who came in referred were 24 (57%) and among them 23 out of 24 were not intubated at time referral and 18 (75%) of them presented 8 hours after the injury. This is in comparison with 18 (43%) of patients who came to the hospital without referral of which 2 patients (11%) presented after 8 hours of injury. This could be attributed to the fact that KNH being the only major public neurosurgical referral hospital in the Central and Eastern part of Kenya and its long distance from peripheral health facilities lacking proper infrastructure and trained medical personnel to deal with severe TBI patients.

In developed countries, patients with severe TBI are promptly intubated and sedated at the site of injury before transfer to the hospital. In the study done by Andriessen et al³⁹, 69% of patient were intubated at the site of trauma and thus had a better outcome to prevent secondary brain injury. This is comparable to our study where 2.3% of patients came in intubated and in previous local study by Mwangombe and Opondo⁵, none of their patients were intubated on referral. This shows a lack in the pre-hospital management of severe TBI patients and delay in referral of these patients.

The Glasgow outcome score was described by Jennet and Bond³³ and is one of the most reliable score to measure functional outcome among patients with TBI¹⁷. There are 5

outcomes in the GOS: death(scale I), persistent vegetative state, severe disability, moderate disability and good recovery(scale V). In our study, at 2 week period, only 2.4% of patients had favourable outcomes(GOS 4 and 5) and were functionally independent compared to at 6 weeks period where 21.4% had favourable outcome. This shows the need to follow up patients for a longer period to determine outcomes more precisely.

This study has shown the clinical utility of the Helsinki CT score to the clinical parameters in predicting outcome in severe TBI and has correlated with outcome at 6 weeks duration.

5.1 Study Limitations

The ideal would have been to do a multi-center study whereby a larger sample size could be obtained.

5.2 Conclusion

Severe traumatic brain injury is a frequent source of mortality and acquired persistent disability among young individuals. It affects more than just the injured person and robs the person of his income per year to sustain a family. The patients often require neuro-intensive care which is expensive in developing countries and burdens the health care resources. A significant proportion of patients (35.7%) were still dependent for care at 6 weeks post-injury.

The age of patient, the systolic blood pressure on admission and the initial Helsinki CT score are significant predictors of outcome($p < 0.05$). The Helsinki CT score correlates well with the clinical parameters at predicting outcome. Hence, a change to new computer tomography scoring system may be warranted and the Helsinki CT score can be used as a predictor of outcome in Kenyan hospitals and in our African population.

5.3 Recommendations

We recommend the following:

1. Guidelines for the management of severe TBI should be made readily available and should constitute the main background and cornerstone for the development of institutional clinical practice guidelines-based management protocols.
2. Usage of the Helsinki CT score routinely at admission and clinicians should be trained on its applicability.
3. Set up of an emergency response team in each major health facility which could initiate pre-hospital management at the trauma site and transfer patients to the nearest neurosurgical facility in a lesser time period.
4. Repeat scans should be performed in patients who are intubated and are worsening clinically and their Helsinki CT score should be recorded.
5. Exigency to prevent head trauma in our society is paramount in reducing the incidence of traumatic brain injury related mortality. With the increase motorization in developing countries, traffic rules should be customarily taught and responsible drinking advocated.
6. More neurosurgical centers with intensive care facilities should be built with qualified staff to care for the management of traumatic brain injury patients.
7. Future studies comparing the different computer tomography scores available in correlation with clinical parameters on predicting outcome should be done as a multi-center study.

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APPENDICES

Appendix I: Informed Consent (English version)

ASSESSMENT OF THE PROGNOSTIC VALUE OF HELSINKI COMPUTER TOMOGRAPHY SCORE IN SEVERE TRAUMATIC BRAIN INJURY PATIENTS AT KENYATTA NATIONAL HOSPITAL

Study No..... Date.....

Principal Investigator: Dr. Dave Mangar

Supervisors:

- 1) Dr. C.K MUSAU, MBChB, MMED, Consultant Neurosurgeon, Lecturer, Division of Neurosurgery, Department of Surgery, University of Nairobi.
- 2) Dr. A.ODHIAMBO, MBChB, MMED Diagnostic Radiology, Diagnostic Radiology Fellow in Neuroradiology (USA), Consultant Radiologist and Neuroradiologist, Senior Lecturer, Department of Diagnostic Imaging and Radiation Medicine, University of Nairobi.
- 3) Dr. G. MWANGI, MBChB, MMED, Consultant Neurosurgeon, Head of Neurosurgery unit, Kenyatta National Hospital.

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 Next of kin approval
3. Statement by the researcher/person taking consent.

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

Part I: Information sheet

Introduction

- My name is Dr. Dave Mangar; I am a post-graduate student at the University Of Nairobi, School Of Medicine, Department of Surgery. I am carrying out a study to validate the Helsinki CT score at predicting outcome in severe traumatic brain injury patients at Kenyatta National Hospital. This would be possible through data collection by filling in a questionnaire and regular examination of the patient during admission and at follow up appointments. The purpose of this consent form is to give you the information you will need to help you decide whether or not to be a participant in the study. Feel free to ask any questions about the purpose of the research, what happens if you participate in the study, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions to your satisfaction, you may decide to be in the study or not.

Purpose of the research

The researchers listed above are interviewing individuals who have severe head injuries. Information obtained from this study will reveal to the doctors the role of CT scan findings in correlation with clinical parameters at predicting outcome in severe traumatic brain injury patients. The information from the study will also assist clinicians in knowing what to emphasize when reviewing a patient with severe brain injury. This study is also a requirement for any doctor who aspires to graduate from our college as a neurosurgeon.

Procedure

After you have accepted to participate in the study and signed this consent form, I will ask you some questions to confirm or clarify where necessary information in the patient's file regarding the history of the patient. I may do a physical and neurological examination and read the CT scan. We will not alter or interfere in the management of the patient. We will follow up on the records of the patient at 2 weeks and 6 weeks. This follow-up will be done at our hospital or when discharged at our outpatient clinic number 24 at KNH.

Risks and benefits

- This is to assure you that there is no harm or risk to the patient or you for participating in this study. No additional tests will be requested other than routine for treatment and there will be no extra cost to you/patient for participating in the study. If there are any questions you do not want to answer, you can skip them. You have the right to refuse the interview or any questions asked during the interview.

Confidentiality

- All information will be treated with confidentiality and all information collected will be destroyed at the end of the study. No records of the names of the patient/relatives will be kept in the data collection.

Right to withdrawal

- Participation in this study is voluntary and the patient will not be denied medical care in case you refuse to participate in the study. You may withdraw from participating in the study at any time with no consequences whatsoever.

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.

Who to contact

If you have further questions or concerns about participating in this study, please call or send a text message to the study staff at the number provided below.

The study staff will pay you back for your charges to these numbers if the call is for study-related communication.

1.The Principal Researcher: Dr. Dave Mangar, Department of Surgery, School of Medicine, University of Nairobi, P.O. Box 19676 KNH, Nairobi 00202.

Mobile number: 0700015918

2. University of Nairobi Supervisors:

Dr. C.K MUSAU, MBChB, MMED, Consultant Neurosurgeon

Department of Surgery, School of Medicine, University of Nairobi, P.O. Box 19676-00202
KNH, Nairobi

Tel: 0202726300

Dr. A. ODHIAMBO, MBChB, MMED Diagnostic Radiology

Department of Diagnostic Imaging and Radiation Medicine, University of Nairobi

Mobile number: 0733870957

Dr. G. MWANGI, MBChB, MMED, Consultant Neurosurgeon, Head of Neurosurgery unit,
Kenyatta National Hospital. Mobile number: 0722779624

If any queries arise regarding your rights as a research participant you can contact the
Kenyatta National Hospital Ethics and Research Committee (KNH- ESRC) on Tel: 020-
2726300 Ext. 44355 email uonknh_erc@uonbi.ac.ke.

NEXT OF KIN APPROVAL.

- I Being the next of kin to (patient’s initials)..... do hereby give consent for my patient to participate in the above study. This is due to the patient being unconscious and not of sound mind. The procedure, benefits, and risks have been explained to me by the principal investigator to the best of my knowledge and I have no concerns whatsoever.
- NEXT OF KIN.....
- TELEPHONE No.
- DATE
- SIGNATURE/THUMBPRINT.....

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 outcome in severe traumatic brain injury.
- I confirm that the next of kin 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 Consent Form will be provided to the participant.

Name of researcher taking consent.....

Signature of researcher taking the consent

Date.....

Appendix II: Informed Consent (Swahili version)

IDHINI YA KUJIHUSISHA NA UTAFITI

Namba ya utafiti: _____ **Tarehe:** _____

Jina la utafiti:

ASSESSMENT OF THE PROGNOSTIC VALUE OF HELSINKI COMPUTER TOMOGRAPHY SCORE IN SEVERE TRAUMATIC BRAIN INJURY PATIENTS AT KENYATTA NATIONAL HOSPITAL

Kanunimpelelezi:

Dr. Dave Mangar

Wasimamizi:

1. Dkt. C.K MUSAU, Mhadhiri, Chuo Kikuu Cha Nairobi – Kitengo cha upasuaji.
2. Dkt. A. ODHIAMBO, Mhadhiri, Chuo Kikuu Cha Nairobi.
3. Dkt. G. MWANGI, Hospitali Kuuya Kenyatta - Kitengo cha upasuaji.

Sehemu la kwanza: Habari kuhusu utafiti

Utangulizi: Jina langu ni Dkt. Dave Mangar, wa Neurosurgery katika Chuo Kikuu cha Nairobi. Ninafanya utafiti kuhusu "ASSESSMENT OF THE PROGNOSTIC VALUE OF HELSINKI COMPUTER TOMOGRAPHY SCORE IN SEVERE TRAUMATIC BRAIN INJURY PATIENTS AT KENYATTA NATIONAL HOSPITAL"

Kusudi la utafiti: Kujeruhiwa kwa ubongo ni ugonjwa wa kudhoofisha na unaosababisha ulemavu mkubwa. Utafiti huu unalenga kutoa taarifa ambayo itasaidia maendeleo ya mikakati ambayo itasaidia kuzuia na kutibu kuumia kwa ubongo katika kanda letu kwa mtazamo wa kuboresha matibabu na matokeo.

Nitawapa taarifa na kukualika uwe mshiriki katika utafiti huu. Kunaweza kuwa na maneno ambayo hujui au kwamba unahitaji ufafanuzi. Tafadhali niulize kuacha tunapopitia maelezo na nitasema au kufafanua.

Ushiriki wa hiari: Wewe ni huru kushiriki au la. Ikiwa unachagua kushiriki au la, huduma zote unazopata katika hospitali hii itaendelea na hakuna kitu kitakachobadilika. Ikiwa unachagua kushiriki katika mradi huu wa utafiti, utapewa matibabu ambayo hutolewa mara kwa mara katika hospitali hii kwa hali yako. Una haki ya kukataa au kuondoa ushiriki wako katika utafiti huu wakati wowote.

Usiri: Taarifa unayejitolea au tunayopata itachukuliwa kwa siri na inapatikana kwa uchunguzi mkuu na timu ya utafiti pekee yao. Jina lako halitatumikiwa kamwe. Taarifa yoyote

kuhusu wewe itakuwa nayo nambari badala ya jina lako. Hatuwezi kugawana utambulisho wa wale wanaoshiriki katika utafiti huu.

Kushiriki matokeo: Maarifa tunayopata kutokana na utafiti huu yatashirikiwa na watunga sera katika Wizara ya Afya, KNH na madaktari kupitia machapisho na mikutano. Maelezo ya siri hayatashirikiwa.

Hatari: Hakuna hatari moja kwa moja kutokana na ushiriki wako katika utafiti.

Gharama na fidia: Hakutakuwa na gharama ya ziada iliyopatikana kwa kushiriki katika utafiti huu wala kuna fidia inayotolewa. Hata hivyo, wakati wako utahitaji kushiriki katika mahojiano.

Pendekezo hili limepitiwa na kupitishwa na Kamati ya Maadili ya UoN / KNH, ambayo ni Kamati ambayo kazi yake ni kuhakikisha kuwa washiriki wa utafiti wanalindwa dhidi ya madhara.

Matatizo au Maswali: Ikiwa una maswali yoyote kuhusu utafiti au juu yamatumizi ya matokeo unaweza kuwasiliana na mpelelezi mkuu, Dkt. DAVE MANGAR, Tel.0700015918, au wasimamizi wake, Dkt. MUSAU, Tel.0202726300, au Dkt. MWANGI, Tel.0722779624. Ikiwa una maswali yoyote kuhusu haki zako kama mshiriki wa utafiti unaweza kuwasiliana na **Kenyatta National Hospital Ethics and Research Committee (KNH- ESRC)** kwakupiga 2726300 Ext. 44355.

Sehemuyapili – Idhini ya mgonjwa

Nimeisoma habari hapo juu, au imesomewa. Nimekuwa na fursa ya kuuliza maswali kuhusu hilo na maswali yoyote niliyoyaomba yamejibiwa kwa kuridhika kwangu. Ninakubali kwa hiari kushiriki kama mshiriki katika utafiti huu.

Jina la Mshiriki: _____

Sahihi la Mshiriki: _____

Tarehe _____

Nimeona usomaji sahihi wa fomu ya kibali kwa mshiriki mwenye uwezo, na mtu huyo amepata fursa ya kuuliza maswali. Ninathibitisha kwamba mtu huyo ametoa ridhaa kwa uhuru.

Jina la Mshiriki: _____

Thumb print of participant

Sahihi la Mshiriki: _____

Tarehe: _____

Sehemuyatatu : Dhibitisho la mtafiti

Nimesoma kwa usahihi karatasi ya habari kwa mshiriki, na kwa uwezo wangu bora kuhakikisha kwamba mshiriki anaelewa kuwa zifuatazo zitafanywa:

- Kukataa kushiriki au kujiondoa kutoka kwenye utafiti hakutapoteza huduma ya matibabu kwa namna yoyote.
- Taarifa zote zilizotolewa zitashughulikiwa kwa siri.
- Matokeo ya utafiti huu yanaweza kuchapishwa ili kuwezesha matibabu na uchunguzi wa kuumia kichwa.

Ninathibitisha kwamba mshiriki huyo alitolewa fursa ya kuuliza maswali kuhusu utafiti huo, na maswali yote aliyoulizwa na mshiriki amejibu kwa usahihi na kwa uwezo wangu mkubwa. Ninathibitisha kwamba mtu huyo hakujazimishwa kutoa idhini, na ridhaa imetolewa kwa uhuru na kwa hiari.

Fomu ya Fomu hii ya Ruhusa ya Ruhusa imetolewa kwa mshiriki.

Jina la mtafiti: _____

Sahihi la mtafiti: _____

Tarehe: _____

Appendix III: Questionnaire

1. BIODATA

- a) STUDY NO.....
- b) SEX.....
- c) AGE (yrs).....
- d) DATE AND TIME OF ADMISSION.....
- e) Tel. no.....

2. CAUSE OF INJURY(TICK)

- a) RTA.....
- b) ASSAULT.....
- c) FALL FROM HEIGHT.....
- d) OTHERS.....

3. CLINICAL PARAMETERS

- a) ADMISSION BLOOD PRESSURE(mmHg).....
 - i. SYSTOLIC BLOOD PRESSURE > 90 mmHg
 - ii. SYSTOLIC BLOOD PRESSURE < 90 mmHg
- b) ADMISSION BLOOD GLUCOSE LEVEL(mmol/L).....
 - i. BLOOD GLUCOSE LEVEL > 10 mmol/L
 - ii. BLOOD GLUCOSE LEVEL < 10 mmol/L
- c) GLASGOW COMA SCALE ON ADMISSION(after resuscitation)
M.....E.....V.....TOTAL.....
- d) PUPIL REACTIVITY
 - i. ANISOCORIA(Y/N).....SIZE(MM).....
 - ii. BRISK/SLOW/NON-REACTIVE.....

e) PRESENCE OF EXTRACRANIAL INJURY.....Y.....N.....(tick)

i. State if MAJOR.....MINOR.....(tick)

ii. Specify injuries sites if major(limb/chest/abdominal etc).....
.....
.....
.....

4. DATE AND TIME OF INJURY

a) <8hrs from injury

b) >8hrs from injury

5. REFERRAL(YES/NO).....INTUBATED PREADMISSION(YES/NO).....

6. ADMISSION CT SCAN FINDINGS

a) Report done by consultant radiologist.....resident.....(tick)

b) Time interval of 1st CT scan from time of injury(hrs. minutes).....

c) HELSINKI CT SCAN SCORE:

d) Surgical intervention done based on CT scan
.....

7. TIME FROM TRAUMA TO SURGERY

8. REPEAT CT DONE DURING 6-WEEK PERIOD

a) Reason for repeat Scan.....

b) Interval of CT scan from time of injury (days/ hrs).....

c) GCS at the time of scan.....

d) Helsinki CT SCORE of repeat scan.....

9. OUTCOME

a) DEATH (DATE AND NO. OF DAYS FROM TIME OF TBI).....

b) GLASGOW OUTCOME SCORE

i. AT TWO WEEKS.....

ii. AT SIX WEEKS.....

TABLE 1

HELSINKI CT SCAN SCALE

| | | |
|-----------------------------|--|--|
| Hematoma type | c) ASDH d) Contusion(s)/ICH e) EDH | d) 2 points e) 2 points f) -3 points |
| Hematoma >25 cc | c) Yes d) No | c) 2 points d) 0 point |
| IVH present | c) Yes d) No | c) 2 points d) 0 point |
| Suprasellar cisterns | d) Normal e) Compressed f) Obliterated | d) 0 point e) 1 point f) 5 points |

TABLE 2

THE GLASGOW OUTCOME SCORE (GOS)

| SCALE VALUE | SCALE | DESCRIPTION |
|--------------------|-----------------------------|--|
| 1 | Dead | Dead |
| 2 | Persistent vegetative state | Wakefulness without awareness; absence of speech or evidence of mental function in a patient who appears awake with spontaneous eye-opening |
| 3 | Severe disability | Conscious but dependent: patient requires assistance to perform daily activities and cannot live independently |
| 4 | Moderate disability | Independent but disabled; patient unable to return to work but otherwise able to independently perform the activities of daily living |
| 5 | Good recovery | Reintegrated but may have non-disabling sequelae; able to return to work but not necessarily at the same level; may have minor neurological or psychological impairments |

GOS of I – III (unfavourable)

GOS of IV and V (favourable)