COMPARISON OF COMPUTED TOMOGRAPHY (CT) MODEL AND CLINICAL PARAMETERS AS PREDICTORS OF OUTCOME IN SEVERE TRAUMATIC BRAIN INJURY PATIENTS AT THE KENYATTA NATIONAL HOSPITAL

A DISSERTATION SUBMITTED IN PART FULFILLMENT FOR AWARD OF THE DEGREE OF MASTER OF MEDICINE (MMED) IN NEUROSURGERY OF THE UNIVERSITY OF NAIROBI

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DECLARATION

Candidate's declaration

I hereby declare that this study is my original work and has not been presented at any other university.

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H58/75970/2009

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DEDICATIONS

I dedicate this study to my parents who have always guided me in life and given me tremendous support throughout. Thanks to the late G.W. Griffin who taught me discipline and the path of duty during my younger years, your lessons are always remembered.

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ABBREVIATIONS

ASDH – Acute subdural hematoma

BP – blood pressure

CT – computed tomography

EDH – Epidural Hematoma

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

SD – standard deviation

tSAH – traumatic subarachnoid hemorrhage

TCDB - Traumatic Coma Data Bank

TBI – traumatic brain injury

SUMMARY

Severe traumatic brain injury is associated with a high mortality and morbidity in Kenya. Mortality rates in previous studies in Kenya reported at 51 - 56% in severe TBI patients. Ninety percent of severe TBI worldwide occur in low and middle – income countries. Many of these countries do not have resources for intensive care facilities and there is need to have predictors of outcome in such patients so as to channel resources to patients who are likely to have a better outcome. Use of clinical parameters like the Glasgow coma scale (GCS) is affected by sedation and paralysis of the patients since they are intubated and ventilated on admission. The CT Marshall score has been shown to be a reliable predictor of outcome in severe TBI patients in the western literature but no study done in Kenya to validate it for local data.

The aim of the study was to compare Computed tomography (CT) model by Marshall with other clinical parameters in severe TBI patients like age, GCS with outcome at three months.

Following ethical approval, a prospective study involving eighty six consenting patients above 16 years of age with severe TBI were recruited by random sampling at the Kenyatta National Hospital Accident and Emergency Department and Critical care units over a period of 8 months (May – December 2014) . Clinical parameters of Blood pressure, pupillary reactivity, age, GCS and CT scan Marshall Scoring were evaluated at admission and subsequent follow-up done for 3 month duration for Glasgow outcome scoring. Data was collected and recorded in excel sheets and analysis done using Statistical Package for Social Sciences (SPSS) version 21.0.

In our study of 86 patients, the male to female ratio was 9:1. Overall mortality rate of 52.3%. RTA was the commonest cause of injury at 63.9%, assault 31.1% and falls at 8.9%. Patients with bilateral mydriasis had mortality of 66.7% while patients with anisocoria had 57.5% and

associated with worse outcome. Patients with GCS of 3 had highest mortality of 85.7% while GCS of 8 lowest mortality of 35.3%. GCS of 3-4 had favourable outcome in only 11.7% at 3 months while GCS of 7-8 had favourable outcome in 52.3%. The CT marshall score of 1 had mortality of 30% while Marshall 3 and 4 at 83.3% and 100% respectively. Patients with tSAH and acute SDH had worse outcomes with mortality of 63% and 57.9% respectively

Severe TBI has high mortality and morbidity in Kenya. In our study, age, the GCS score and the Marshall score were significantly related to the 3 month outcome ($p<0.05$). GCS score was comparative to Marshall CT on outcome and there was no significant difference between the two parameters in analysis with outcome at 3 months. The CT Marshall score is therefore a reliable predictor of outcome in severe TBI patients.

INTRODUCTION

Severe traumatic brain injury (TBI) is a common cause of neurological disability and death. About 1.5 million people die worldwide due to TBI and 90% of these occur in low and middle-income countries[1]. It is one of the leading causes of mortality in the intensive care units worldwide and in the accident and emergency departments in major trauma centers[1]. Resources in low income countries like Kenya are limited and there is need to have a predictor on outcome of severe TBI patients. There are few ICU beds in most public hospitals and these are not available in many centres in the country. Therefore it is important to channel the available resources to patients who are likely to do well. A study done by Mwang'ombe and Kiboi[2] at Kenyatta National Hospital in 2001 showed a mortality of 56% in patients with severe head injury.

Severe TBI comprise 14.3% of all patients admitted at the KNH ICU[3]. Most of these patients are unconscious, intubated, anaesthetized and sedated. This makes the use of clinical evaluation of severity of intracranial injury like the Glasgow coma scale (GCS) less reliable[4]. Monitoring the course and estimating the degree of brain injury and its long-term consequences can therefore be difficult. The use of computed tomography (CT) may be useful adjuncts to the clinical evaluation to provide information on prognosis and outcome[5]. The features on CT may correlate with the intracranial pressure and it is a useful adjunct in resource poor setting[1]. CT scan is routinely done on admission at the Kenyatta National Hospital. Other modalities used in developed countries include use of biochemical markers and ICP monitors but these are expensive and not available readily in public hospitals in developing countries. The Computed Tomography (CT) classification is used as a major predictor based on Class I evidence[23].

This study correlated the CT head scan classification with clinical parameters of Severe TBI in patients admitted at KNH and their outcomes at three-months post trauma. The specific objectives were to characterize the CT classification by Marshall and correlate clinical parameters of GCS, age, pupils, extra-cranial injuries and outcomes. The study also aimed to evaluate the benefit and value of repeat CT scan in severe TBI patients.

LITERATURE REVIEW

Severe traumatic brain injury (TBI) has been defined by the national traumatic coma bank as Glasgow coma scale of less than or equal to eight[1]. In the United States (US), the incidence of head injury at the Emergency Department was recently reported to be 394 per 100,000 people, male: female ratio was 1.8:1 and mortality rate 19.3 per 100,000 people [1]. The management of severe TBI patients is expensive and needs a lot of resources. Mortality of severe TBI remains high in Kenya (over fifty percent) with 56% reported in KNH by Mwang'ombe et al.[2,3] Developing countries like Kenya have limited intensive care resources and these facilities are available in only five public hospitals in the country.

Clinical parameters and CT scan findings have been found to be reliable indicators in severe TBI[4]. Large multicenter studies carried out in the European and American population for predictors of outcome in TBI include the IMPACT trial (2007)[4], European Brain Injury Consortium (1999)[5], and CRASH (2008)[6]. Outcome prediction by use of modalities may be useful so as to channel the scarce resources to those who are likely to benefit[7].

CLINICAL PARAMETERS

The prognostic value of each clinical parameters used was quantified in the International Mission for Prognosis and Clinical Trial design in Traumatic Brain Injury(TBI) – IMPACT[4]. These clinical parameters are easily available on the patient on admission and during care[4]. The strongest indicators at initial assessment were age, GCS score and pupillary reactivity.

Age

Age is one of the strongest predictors of outcome with older age being associated with poor outcome[8.] The mortality rate was higher in the elderly (>65yrs) for all levels of injury[8]. In KNH, the mortality was 44% for patients between 14-25 years and 56% in patients aged between 26 – 45 yrs[3]. Although some increased mortality is explained by the complications or type of head injury, age is an independent predictor of mortality[8]. Elderly patients were more likely to have poor functional outcome than younger patients[9]. Older patients were also more likely to develop mass lesions[10].

Several studies did not find a relation between gender and outcome though it was more common that males were more involved due to more of them driving or alcohol intake than females[6].

Glasgow Coma Scale

In 1974, Teasdale and Jennett introduced the Glasgow Coma Scale. The Glasgow Coma Scale (GCS) is used as a clinical scoring for the severity of intracranial injury[11]. The score has three aspects which are the motor response, verbal performance and eye opening (Table A). In KNH, patients with GCS 3-4 had mortality of 88%, GCS of 5-6 had 60% mortality while 7-8 had 52%[2].In the Traumatic Coma Data Bank(TCDB), the mortality was 78% in patients with GCS of 3 and 11% in patients with GCS of 8[12]. The motor score of the GCS has the greatest predictive value in patients with severe TBI. This is because the patients are often intubated and may have facial injuries making eye opening and verbal responses difficult to assess[13].

TABLE A: THE GLASGOW COMA SCALE

points	Best eye opening	Best verbal	Best motor
6	-	-	Obeys
5	-	Oriented	Localizes pain
4	Spontaneous	Confused	Withdraws to pain
3	To speech	Inappropriate	Flexion(decorticate)
2	To pain	Incomprehensible	Extensor(decerebrate)
1	None	None	none

Assessment of the GCS should be done on admission after primary respiratory and hemodynamic resuscitation because the GCS often varies early after injury[14]. The GCS may still vary and be erroneous due to sedation, paralytic medication or intoxication e.g. by alcohol[5].

Pupillary reactivity

The pupillary reactivity is another key clinical assessment that has been shown to have significant prognostic value in TBI. Abnormal pupil reactivity is strongly associated with poor outcome[15].

In KNH, patients with bilaterally dilated pupils not reacting to light had mortality of 90%, patients with bilaterally constricted pupils had mortality of 66% and only 20% mortality in patients with normally reacting pupils[2].

In the TCDB, 74% of patients with bilaterally unresponsive pupils after resuscitation died or were left vegetative[12]. In the early phases of severe head injury, pupil reactivity is a more stable variable than the GCS because it is less prone to sedation and paralytic effects[15].

Hypotension

Hypotension is a major cause of secondary insult. In the analyses of patients from the TCDB, early hypotension (systolic blood pressure <90mmHg) was associated with doubling mortality[16]. The avoidance of hypotension has the highest likelihood of improving outcome. In maintenance of adequate cerebral perfusion pressure (CPP), it is critical to avoid hypotension[16].

In KNH, 85% of severe TBI patients who were admitted with systolic blood pressure of <90mmHg died. In contrast, there was 60% mortality in patients with blood pressure >120mmHg[2].

Extracranial injuries

The clinical severity in traumatic brain injury (TBI) relates to intracranial and extracranial injuries. There has not been any consensus on the prognostic value of major extracranial injuries on traumatic brain injury patients. Some studies show that the presence of extracranial injuries does not affect the outcome in TBI patients and this mainly depends on the severity of the primary cerebral damage[17]. In other studies, presence of major extracranial injuries was associated with poorer outcomes[18,19]. It has been shown that in patients with severe TBI, the effect of extracranial injury on functional outcome was small compared to mild to moderate injuries. In severe TBI at KNH, presence of extracranial injuries mainly increased early mortalities[3]. The clinical severity of extracranial injuries is assessed with the Injury Severity Score[20] and the Abbreviated Injury Score[21].

In KNH, extracranial injuries were present in 91.6% of patients with severe TBI, 49.5% of which were maxillofacial injuries, 25.2% limb fractures[3].

COMPUTED TOMOGRAPHY (CT) AND THE MARSHALL SCORE

Severe traumatic brain injury patients are often sedated, intubated and ventilated and this makes use of clinical examination for example the Glasgow coma scale less valuable in prediction of outcome[22]. In a survey by the European Brain Injury Consortium by Murray et al in 1998, GCS was reliable and accurate in only 56% of severe TBI patients[5].

Computed tomography is the recommended radiological investigation in acute phase of TBI. It provides information with implications for prognosis and intervention[14]. CT findings also give features of increased ICP[23] and these findings may be used as adjuncts to management in resource poor centres where routine ICP monitoring is not available in severe TBI patients.

Computed tomography scanners are available and accessible at major referral centres in developing countries and routinely done on severe traumatic brain injury patients on arrival at the hospital[1].

Several CT classifications have been made but the most widely studied and accepted is the Marshall CT classification[4]. International guidelines on prognosis in severe TBI include Marshall's CT classification as a predictor based on class I evidence[24].The Marshall CT classification has been shown to be a strong predictor in traumatic brain injury with high inter- and intra-observer reliability[25]

In 1991, Marshall et al [26] used the CT characteristics to classify traumatic brain injury (Table B). It mainly uses the following characteristics: - 1) presence or absence of mass lesion (2) signs of

raised intracranial pressure (3) presence or absence of intracranial abnormalities (4) planned evacuation of mass lesions. There are six different groups in the CT classification based on different findings on CT scan head. The first four categories classify diffuse injuries based on midline shift, compressed/absent basal cisterns as signs of increased ICP[23]

TABLE B: MARSHALL CT CLASSIFICATION

Diffuse Injury I	No visible intracranial pathological changes seen on CT scan
Diffuse Injury II	Cisterns are present with midline shift 0-5mm and/or lesions densities present; no high or mixed density lesion >25cm^3 may include bone fragments and foreign bodies
Diffuse Injury III	Cisterns compressed or absent with midline shift 0-5mm; no high or mixed density lesion >25 cm^3
Diffuse Injury IV	Midline shift >5mm; no high or mixed density lesion > 25cm^3
Evacuated Mass lesion	Any lesion surgically evacuated
Non-evacuated mass lesion	High or mixed lesion >25cm^3; not surgically evacuated

In the Marshall study of CTclassification[26], midline shift (class IV) had strong evidence of worse outcome. Compressed / obliterated basal cisterns were also shown to have poor outcome. Diffuse injury I had good recovery/moderate disability of 61.6%, severe disability/vegetative state of

28.8% and mortality of 9.6%. This was compared to diffuse injury IV who had only 6.2% having good recovery/ moderate disability, 37.6% had severe disability/vegetative state and 56.2% mortality rate[26].

The IMPACT database[27] of 5209 patients that combined seven studies showed that intracranial abnormalities were present in 93% of patients. The Marshall's CT classification was used to score patients and was shown to strongly relate with outcome[27]. 13-34% of patients were in class III (odds ratio 2.50) and class IV (odds ratio 3.03) and these patients had worse outcomes with severe disability and mortality[27]. Mass lesions were present in 24 - 47% of patients and of these, epidural hematomas (better outcomes) consisted 10 - 20% and acute subdural hematomas (worse outcomes) in 20 – 35%. It was also noted that presence of traumatic subarachnoid haemorrhage (tSAH) had worse outcome[27].

Obliteration of basal cisterns and the presence of subarachnoid haemorrhage are the strongest CT predictors of outcome[28]. The presence of traumatic subarachnoid haemorrhage is not included in the Marshall classification. A multicentre study by Maas et al[23]on 2269 patients showed that although the Marshall CT classification had a good prognostic value, tSAH and intraventricular haemorrhage were significant predictors of mortality.

Maas et al also showed that differentiation of lesions was not associated with differences in mortality[23]. However, differentiation between epidural and intradural lesion was highly relevant. Epidural hematomas have better outcome than acute subdural hematomas[23].

Lobato et al[29] studied effect of the type of intracranial lesion on the final outcome in 277 severe TBI patients using CT and had concurrent ICP monitoring. Patients with pure extracerebral hematoma, single brain contusion, general brain swelling, and normal CT scans had a

significantly better outcome than patients developing acute hemispheric swelling after operation for a large extracerebral hematoma, patients with multiple brain contusion, and patients with diffuse axonal injury. Characterising the different type of intracranial lesions had prognostic implications[29].

Patients in the ICU with severe TBI have serial CT scans performed to assess progress of the intracranial findings. This has cost implications and some are associated with complications. Lee et al[30] reported on follow-up scans in severe TBI patients and showed that scans of clinically stable patients may not provide additional information, but could potentially subject the patients to secondary injuries. Study included 94 patients who had a total of 319 follow up scans. When patients had unchanged or improved GCS, 73.1% had improved or the same CT appearance. When patients had a worse GCS, the CT was worse in 77.9%. A 16.9% (54/319) complication rate was documented during the follow-up scans (hemodynamic instability, increased intracranial pressure, desaturation, and agitation) [30]. This rate was higher in severe head trauma (GCS 3–8) patients than in moderate head injury (GCS 9–12) patients. Hemodynamic instability was the most common complication 42.6% (23/54).[30]

Lobato et al[29] analysed serial CT findings in severe TBI patients in order to assess the variability in gross intracranial pathology through the acute posttraumatic period and determine the most common patterns of CT change. The study also compared the prognostic significance of second CT scan from the initial scan in relation to outcome. 23.6% of 587 patients developed new diffuse injury on repeat scan and 20.9% new focal mass lesions most of which had to be evacuated. The final outcome was more accurately predicted by using the repeat CT scans (81.2% of the cases) than by using the initial CT scans (71.5% of the cases only). Since the majority of relevant CT changes developed within 48 hours after injury a pathological

categorization made by using an early control CT scan seems to be most useful for prognostic purposes[29].

Servadei et al[31] on a prospective study of 1005 patients in the European Brain injury Consortium studied value of initial scan and subsequent 'worst' scan. The initial CT findings were classified as a diffuse injury for 53% of patients, with 16% of these diffuse injuries demonstrating deterioration on a subsequent scans. In 74% of those showing deterioration, the change was from a diffuse injury to a mass lesion. It was concluded that evolution to a mass lesion when initial scan only demonstrated diffuse injury with no shift was associated with a statistically significant increase in the risk of an unfavorable outcome (62% versus 38%)[31].

OUTCOME MEASURE – THE GLASGOW OUTCOME SCALE

Described by Jennett and Bond[32] in 1975, the Glasgow Outcome Scale (GOS) is the most commonly used measure after traumatic brain injury. It describes the functional outcome after head injury. It describes the ability of a patient to take care of his/her own needs, his/her dependence on others as consequence of neurologic damage [32].

There are five outcomes in the GOS (table C): death (scale I), persistent vegetative state, severe disability, moderate disability and good recovery (scale V)[32]. Good recovery implies able to return to work. Severe disability patients cannot live independently[32].

The Glasgow Outcome Scale Extended (GOSE) was described by Jennett et al[33] in 1981so as to be a more sensitive measures of recovery. It divides good recovery, moderate disability and severe disability into upper and lower divisions. There is an increase in inter-observer variability when GOSE is used as opposed to GOS[34]. The GOS has been preferred to the GOSE in large multicentre studies e.g. IMPACT[14].

Comparison of the GOS and GOSE: using the GOS led to 92% agreement between observers but only 78% in the GOSE[35]. This showed that for observer reliability, the GOS was superior to the GOSE. The GOS can accurately be used in patients aged 16 years and above and is to be used when patient is discharge from the hospital. This questionnaire is based on (1) independence at home (2) independence outside home (3) employability (4) ability to engage in premorbid social and leisure activities (5) interpersonal relationships. Table C and table D show the GOS and the GOSE.

TABLE C: 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

TABLE D: GLASGOW OUTCOME SCORE AND EXTENDED (GOSE) SCORE

GOSE	GOS	DESCRIPTION
1	1	Dead
2	2	Vegetative state
3	3	Lower severe disability Completely dependent on others
4	3	Upper severe disability Dependent on others for some activities
5	4	Lower moderate disability Unable to return to work or participate in social activities
6	4	Upper moderate disability Return to work at reduced capacity, reduced participation in social activities
7	5	Lower good recovery Good recovery with minor social or mental deficits
8	5	Upper good recovery

King et al showed that at 3 month GOS shows good correlation with long-term outcome in patients with severe TBI[36]. The IMPACT database included 3 month and 6 month GOS based on data availed and were accepted as correlating with long-term outcome of patients[27].

RESEARCH QUESTION

What is the predictive value of Computed Tomography in correlation with the clinical parameters on the 3 month functional outcome of patients with severe traumatic brain injury at Kenyatta National Hospital?

JUSTIFICATION

Resources in low income countries like Kenya are limited and thus the need to have a predictor on outcome of severe traumatic brain injury patients in order to channel resources to patients who will do well.

Severe traumatic brain injury patients are intubated and sedated and use of clinical evaluation scoring of GCS and pupillary scoring may not be accurate and hence the need to study value of computed tomography in prognostication.

Several studies have shown relevance of racial differences in outcome of severe traumatic brain injury patients and most studies available are on European or American patients. It is also necessary to validate the Marshall CT Classification in our African population and its value in predicting outcome.

Serial CT scans of head are done in our ICU set up in patients who do not show clinical improvement and patients who worsen. These repeat scans have cost implications and the study would try to show which patients would benefit from repeat scanning, at what interval to repeat and hence save on resources.

Severe traumatic brain injury is a debilitating disease and many patients need long-term care, this study also aims to evaluate the outcome of the patients at 3 months which may have implications

on the socioeconomic effects of the disease to the society. Previous studies at KNH were only based on discharge findings from ICU.

BROAD OBJECTIVE

To determine the predictive value of Computed tomography (CT) Marshall Classification model on the outcome of severe traumatic brain injury patients at Kenyatta National Hospital at 3 months post admission.

SPECIFIC OBJECTIVES

1. To determine the baseline GCS, demographic characteristics, presenting extracranial injuries and physiological parameters among patients admitted at the KNH after sustaining severe TBI
2. To determine the post – resuscitation predictive value at 3 months of CT scan according to the Marshall score among patients with severe TBI
3. To determine the correlation between the CT Marshall Classification model and the post resuscitation GCS on the outcome of severe TBI patients at 3 months post admission .

MATERIALS AND METHODS

STUDY DESIGN

This was a prospective cohort study conducted for a period of 8 months

STUDY LOCATION

Patients were recruited at the Kenyatta National Hospital (KNH), Nairobi in units which manage severe traumatic brain injury patients. Following arrival at the KNH, patients were assessed, resuscitated and intubated at the *Accident and Emergency department at the KNH (Acute Room and Emergency wards)* and subsequent admission done at the *Critical care Unit/ Intensive Care Unit or the Critical Care Unit at ward 4C.* These are units at KNH where mechanical ventilators are available.

Subsequent follow up of patients who improved was done at the General surgical wards (ward 5A, 5B, 5D), the neurosurgical ward (ward 4C) as inpatients. These patients were followed up upon discharge at the outpatient department at clinic no. 24 at the KNH at 2 weeks and at 3 month post admission. Patients and relatives were notified by phone.

STUDY DURATION

Eight months, from 8th May 2014 to end of December 2014. Patients were selected and followed up for total of 3 months.

STUDY POPULATION

Patients above 16 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.

SAMPLE SIZE CALCULATION

The formula below was used to calculate the sample size

$$n = \frac{2(Z_{1-\alpha/2}+Z_{1-\beta})^2 P_{av}(1-P_{av})}{(P_0-P_1)^2}$$

n is the sample size required in each group

$Z_{1-\alpha/2}$ refers to the level of significance or confidence interval – 1.96 for 95% CI

$Z_{1-\beta}$ refers to the power of obtaining difference between the two groups – 0.84 for 80% power

P_0 – Proportion of patients with good outcome associated with good GCS score – 70%

P_1 –Proportion of patients with good outcome associated with Marshall score of I (diffuse injury 1) – 90%

P_{av} – Average outcome in the two groups – 80%

Substituting into the formula:

n = 63 patients

An addition of 20% of the calculation was used for errors for loss of follow-up of patients. Therefore, a sample size of 74 patients obtained.

SAMPLING PROCEDURE

The study was conducted on severe traumatic brain injury patients with GCS 8 and below who were admitted at the Accident and Emergency Department, critical care units at the Kenyatta National Hospital. Random sampling procedure was used to select patients into the study. Patients who met the criteria were enrolled into the study until the desired sample size was achieved. The criteria below was used to select patients

INCLUSION CRITERIA

Severe traumatic brain injury patients with GCS $\leq$8

Patients above the age of 16 years

Patients who had informed consent availed from relatives/ guardians

EXCLUSION CRITERIA

Patients who did not have CT scan done

Mortality before 24 hours of admission

Non – intubated, non – resuscitated patients

Patients less than 16 years of age

Patients with no consent availed

ETHICS AND CONFIDENTIALITY

The study proposal was approved by the KNH ethics and research committee prior to commencement of the study and permission obtained from the director of Kenyatta National Hospital.

All data collected was handled with confidentiality. No patient identifiers were published or disseminated.

DATA COLLECTION PROCEDURE

Consent to participate in the study was taken from the legally authorized representative 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. Data collection was done using a structured questionnaire. The patients were assessed by the neurosurgery resident on call at admission. The principal investigator then re-evaluated the clinical parameters on all patients and where there was a discrepancy, the investigator's findings were used in the analysis. Pupil reaction and size, initial blood pressure, time and date of admission, GCS score done after resuscitation of patient were recorded in the data collection form. Presence and site of extra-cranial injuries were also recorded.

The initial head CT scan was done on admission after intubation and resuscitation of the patient. The CT scan was then analysed by the consultant radiologist who then did the Marshall score. Subsequent scans were done as judged by the physicians following up patient care and their Marshall score recorded with GCS at time of scan. A random sample of 10 CT scans were

selected and reviewed by a second consultant radiologist to assess the level of reproducibility of the Marshall's score. The patients were followed up by the principal investigator, mortality recorded, deaths before 2 weeks recorded as early mortality.

At 3 month follow up, the patient's guardian/relative were contacted by phone 1 week prior to their scheduled time 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 noted to have defaulted in his follow up and his data was withdrawn from the study.

DATA MANAGEMENT AND ANALYSIS

Data was entered into MS Excel spread sheet and analysed using SPSS version 21.0. Patient characteristics were summarized using the clinical parameters of age, GCS, pupillary reactivity, blood pressure and extra-cranial injuries presented as means or proportioned for continuous and categorical variables respectively. Blood pressure was categorized into those with systolic blood pressure less than 90 and greater than 90mmHg. Pupillary reaction was categorized as brisk, slow reaction, non-equal(anisocoria) and non-reactive. The GCS classified as scores of 3-4, 5-6 and 7-8. The Glasgow outcome Score dichotomized as unfavourable (grade I – III) and favourable (IV and V). Chi-square was used to test association between categorical variables such as between GOS, age and Blood pressure. Student t-test was used to test the difference in numerical variables such as GCS and Marshall score across different outcome groups. Logistic

regression analysis was used to determine the independent predictors of outcome. All statistical tests were conducted at 5% level of significance.

RESULTS

There were 86 patients with severe head injury in this study, 81 males (94.2%) and 5 females (5.8%), M: F ratio of 9:1. Table 1 and figures 1 and 2 show the age distribution and mortality

TABLE 1: AGE DISTRIBUTION AND MORTALITY

AGE (years)	NO. OF PATIENTS	% OF PATIENTS	NO. OF DEATHS	% MORTALITY
16 – 20	2	2.3%	0	0%
21 – 30	24	27.9%	9	37.5%
31 – 40	23	26.7%	11	47.8%
41 – 50	18	20.9%	12	66.7%
51 – 60	10	11.6%	6	60%
>60	3	3.5%	3	100%
TOTAL	86	100	45	52.3%

The age range in the study was 16 years to 100 years. The mean age was 38.5 years. The overall mortality was 52.3% (45 patients out of total of 86).

Severe TBI was common in the age group between 21– 50 years (table 1 and figure 1), the highest being at 21 -30 years at 27.9%. These encompassed 65 patients out of the total 86 (75.6%).

FIGURE 1: DISTRIBUTION OF PATIENTS BY AGE GROUPS

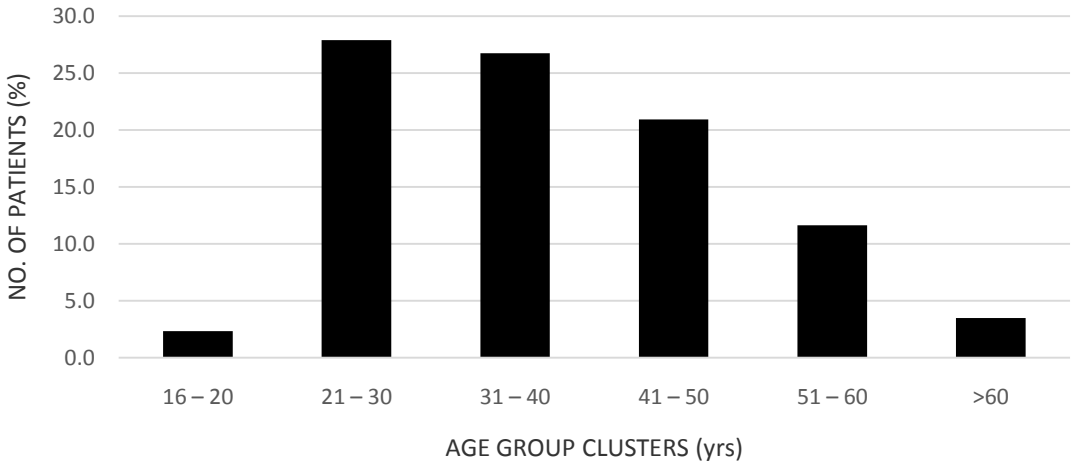
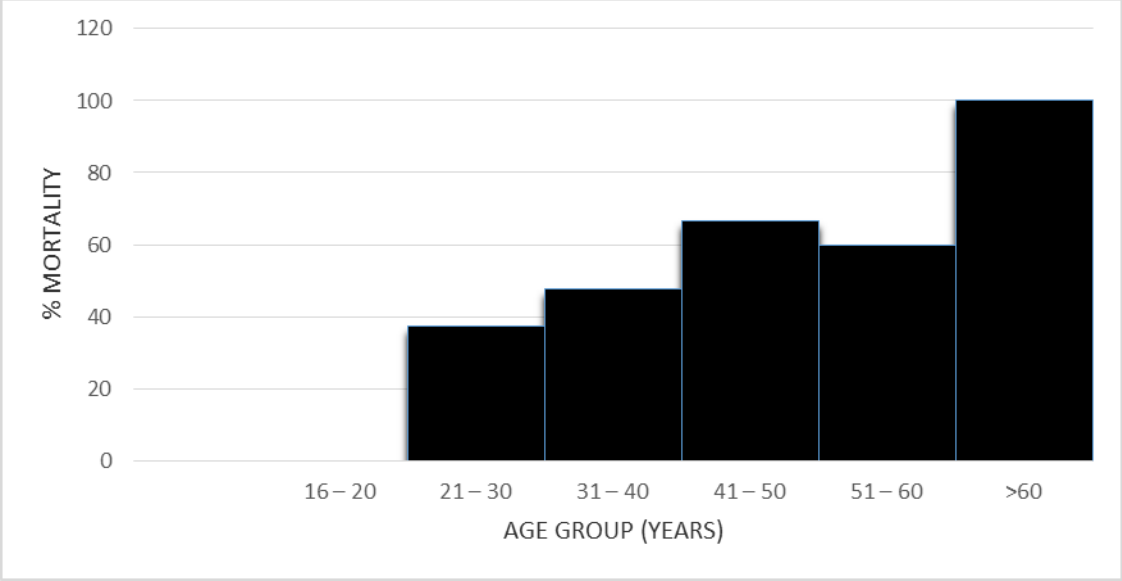


Figure 1 shows that severe TBI was highest at age between 21 and 60 years and least in ages above 60 years. Highest affected age groups was between 21 and 40 years

FIGURE 2: AGE-GROUP SPECIFIC MORTALITY



Patients below 20 years all survived with good outcome while patients above 60 years all died (3 patients). Table 1 and figure 2 summarize the age group specific mortality. Mortality increased

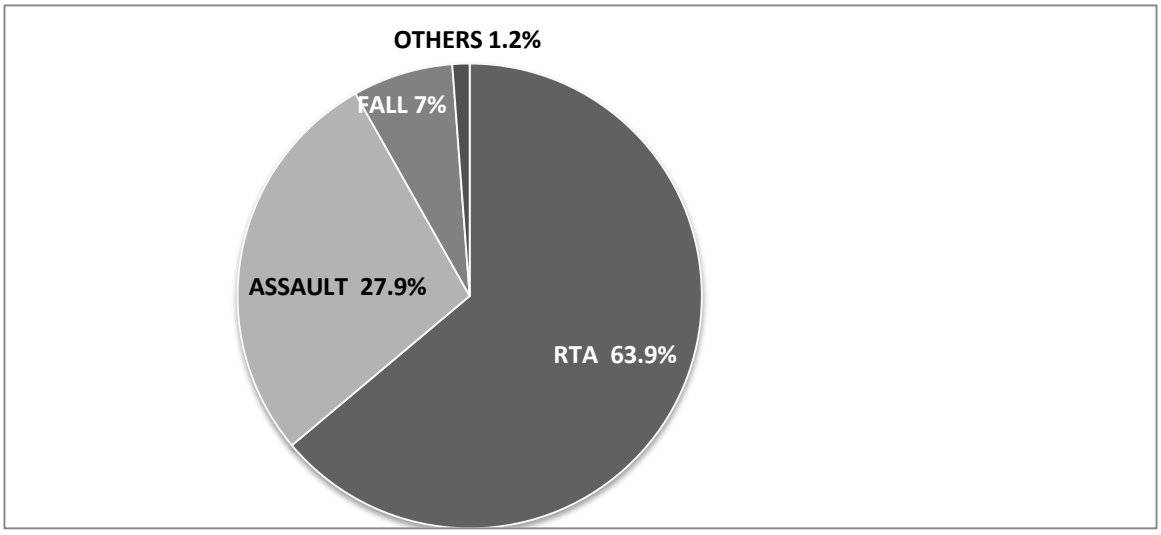
with increase in age as can be seen from the histogram. Mortality in age group between 21 – 30 yrs was 37.5% while 60% in age between 51-60 years.

TABLE 2: CAUSE OF INJURY

CAUSE	NO. OF PATIENTS	% OF PATIENTS
RTA	55	63.9%
ASSAULT	24	27.9%
FALL	6	7%
OTHERS (BLAST INJURY)	1	1.2%

Road traffic accidents was the commonest cause of severe TBI at 63.9%. The second commonest cause was assault at 27.9%. Falls and blast (high velocity) injuries caused 7% and 1.2% respectively (table 2 and figure 3).

FIGURE 3: DISTRIBUTION OF CAUSE OF INJURY



RTA was the most common cause of severe TBI accounting for 63.9% of injuries (55 patients out of 86). Assault was second most common accounting for 27.9% while fall from height at 7% and blast injury at 1.2% (1 patient) as shown in table 2 and figure 2.

TABLE 3: CAUSE OF INJURY AND MORTALITY

Cause	No. of Patients	Mortality (%)
RTA	26	57.8
Assault	14	31.1
Fall	4	8.9
Others (Blast Injury)	1	2.2
Total	45	100

Road traffic accidents was the commonest cause of death in severe TBI patients (57.8%) Assault caused death in 31.1% while falls (8.9%) and blast injuries (2.2%) were the least common. Only 1 patient had blast injury and died.

FIGURE 4: CAUSE OF INJURY AND MORTALITY

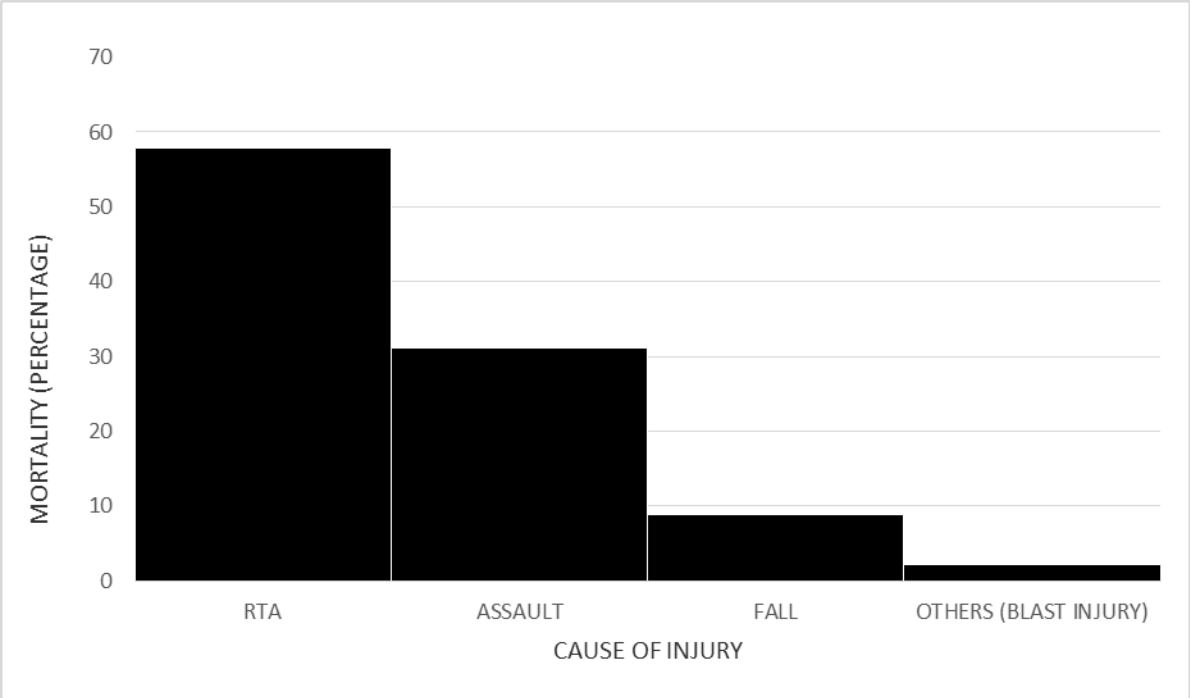


TABLE 4: RELATIONSHIP BETWEEN MORTALITY AND PUPILLARY REACTION TO LIGHT

	No. of Patients	**No. Dead (%)**
Brisk Reaction	11	3 (27.3)
Slow Reaction	72	40 (55.6)
Non-Reactive To Light	3	2 (66.7)
Anisocoria	40	23 (57.5)

Patients who had brisk pupillary reaction to light had better outcomes compared to patients with anisocoria and non-reactive pupils. 57.5% of patients with anisocoria and 66.7% of non-reactive pupils died while 27.3% of patients with brisk reactivity of pupils died. The most common pupillary finding was slow reactivity present in 72 patients (83.7%) and 55.6% of these patients died (table 4)

FIGURE 5: PUPILLARY REACTION Vs MORTALITY

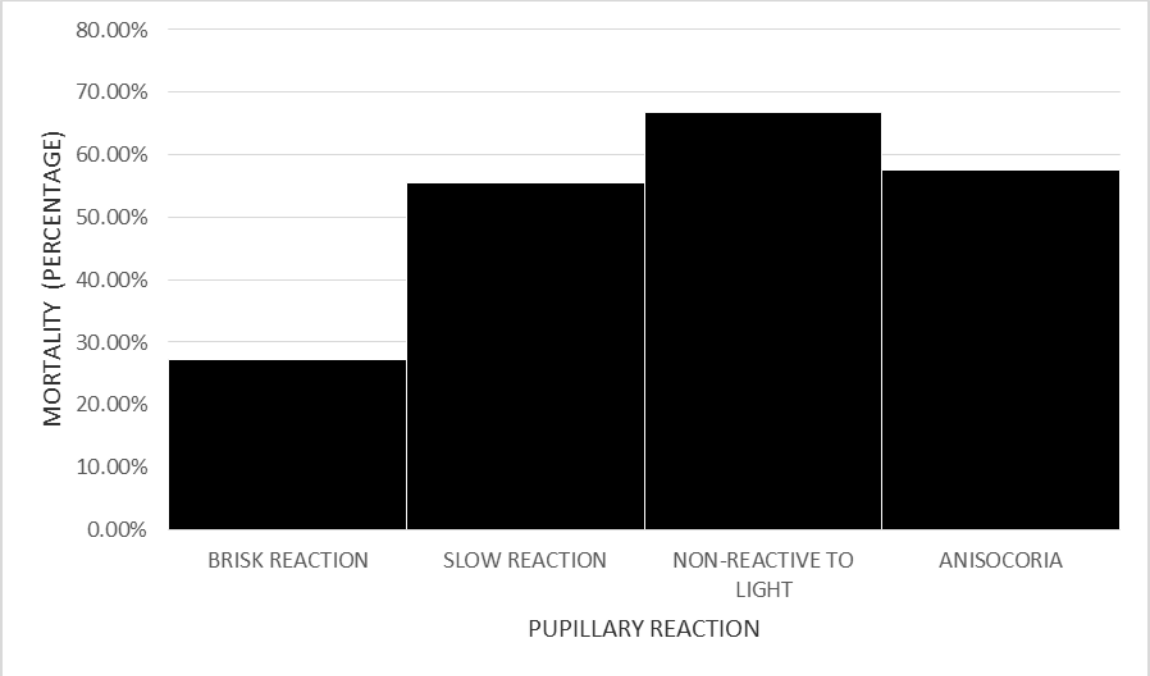


Figure 4 shows that patients with non-reactive pupils had highest mortality (66.7%) while those with brisk reaction to light had the least mortality at 27.3%

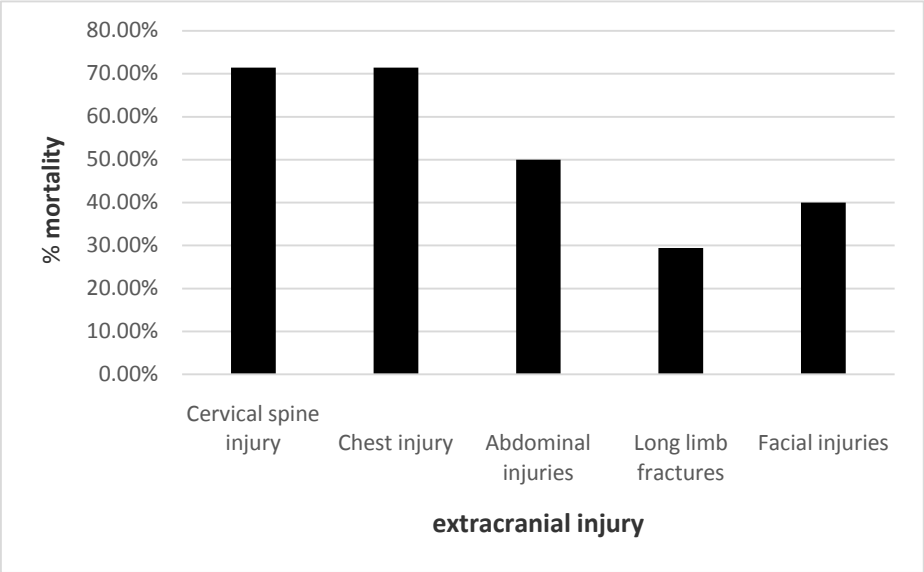
TABLE 5: SYSTOLIC BLOOD PRESSURE AND EXTRACRANIAL INJURIES

	FREQUENCY (%)	**MORTALITY (%)**
Extra cranial injury (significant)	31 (36%)	17 (54.8%)
Cervical spine injury	7 (22.5%)	5 (71.4%)
Chest injury	7 (22.5%)	5 (71.4%)
Abdominal injuries	2 (6.5%)	1 (50%)
Long limb fractures	17 (54.8%)	5 (29.4%)
Facial injuries	5 (16.1%)	2 (40%)
Systolic Blood pressure		
<90 mmHg	3 (3.5%)	1 (33.3%)
>120mmHg	58 (67.4%)	30 (51.7%)

Significant extracranial injuries were present in 36% of patients (table 5). These are patients who had radiologic evidence of injuries and fractures, minor injuries e.g. facial bruising, skin lacerations were not considered. The most common extracranial injury was long limb fractures (54.8%) followed by C-spine and chest injuries at 22.5% each. Least common was abdominal injuries (6.5%).

Hypotension (systolic blood pressure <90mmHg) was present in 3.5% of patients and 33.3% of these patients died. Out of the 86 patients, 58 patients had systolic BP >120mmHg and 51.7% of them died.

FIGURE 6: EXTRACRANIAL INJURY Vs MORTALITY



C-spine injuries and Chest injuries had the highest mortality of 71.4% within each group while fractures of long limbs had the least at 29.4%. 2 of the patients had combinations of major injuries and died (figure 6)

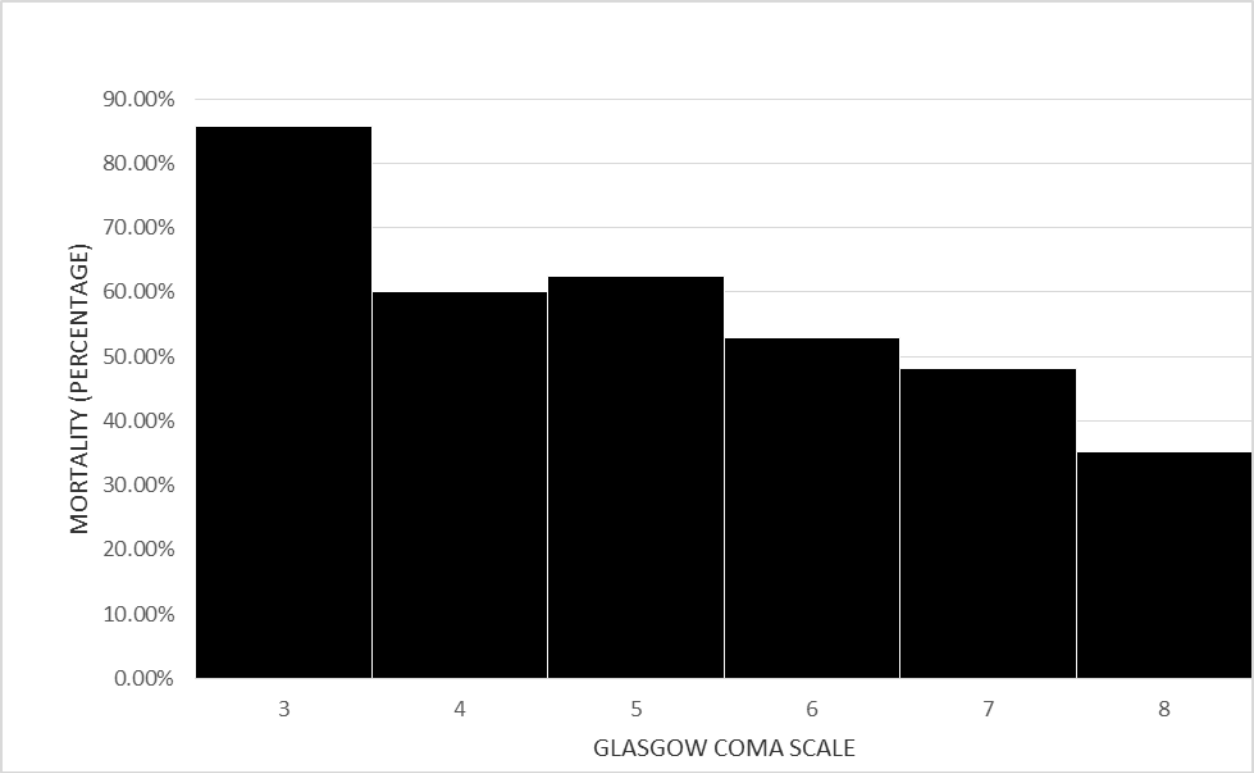
TABLE 6: GLASGOW COMA SCALE (GCS) AND MORTALITY

GCS on admission	No. of patients	No. of patients who died	MORTALITY (%)
3	7	6	85.7%
4	10	6	60%
5	8	5	62.5%
6	17	9	52.9%
7	27	13	48.1%
8	17	6	35.3%
TOTAL	86	45	52.3%

The post-resuscitation GCS correlated with mortality (table 6). Patients with GCS of 3 had mortality of 85.7% while patients with GCS of 7 and 8 had mortality of 48.1% and 35.3%

respectively. This showed that as GCS improved, the mortality reduced as shown in the graph below.

FIGURE 7: INITIAL GLASGOW COMA SCALE VS MORTALITY



A decline in GCS was associated with higher mortality as is seen in figure 7. GCS of 3 had highest mortality while GCS of 8 the least. GCS less than 6 had mortality >50%.

TABLE 7: MARSHALL SCORE AND MORTALITY

Marshall score	No. of patients	No. of patients who died	MORTALITY (%)
1	10	3	30%
2	22	10	45.5%
3	12	10	83.3%
4	2	2	100%
5	36	16	44.4%
6	4	4	100%
TOTAL	86	45	

Patients with CT scan Marshall score of 1 had mortality of 30% while Marshall scores of 4 and 6 had mortality of 100%. Patients who had surgical intervention (Marshall score of 5) had mortality of 44.4%. This constituted the largest group of patients (36 out of 86 patients). The graph below shows that from Marshall score of 1 to 6 there was increase in mortality except Marshall score 5 who had surgical intervention (table 7 and figure 8)

FIGURE 8: MARSHALL SCORE Vs MORTALITY

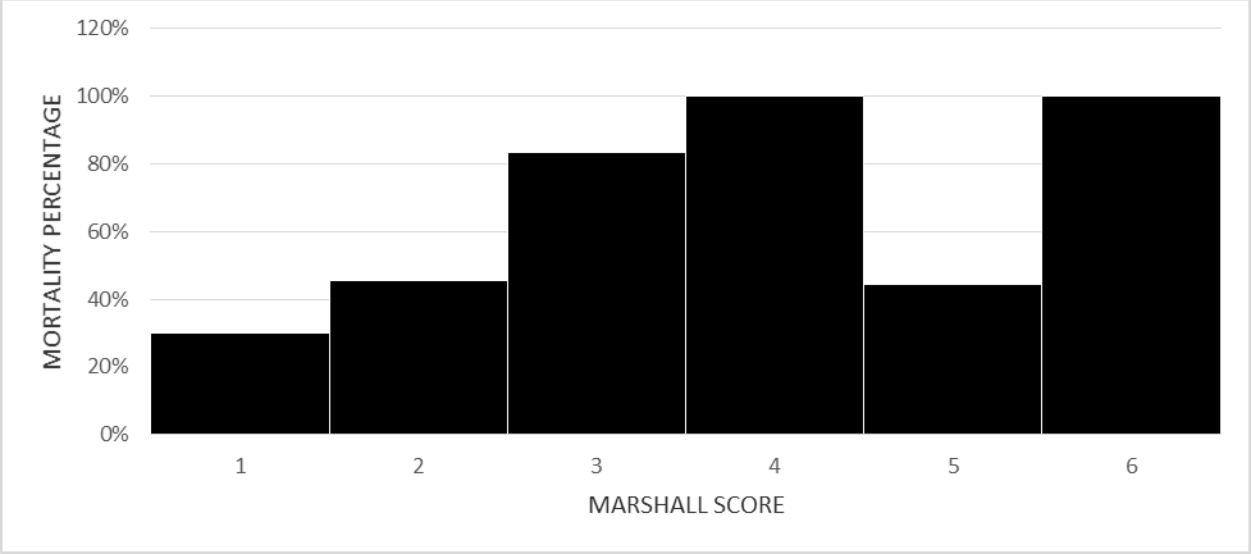
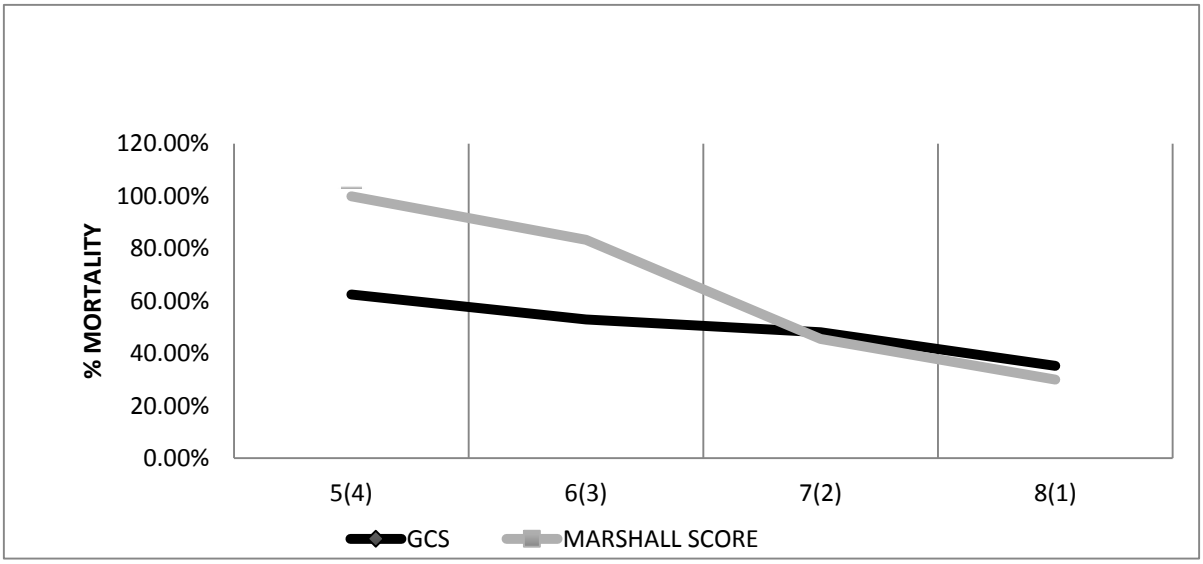


TABLE 8: COMPARISON OF INITIAL GCS, MARSHALL SCORE Vs MORTALITY

GCS	% MORTALITY	MARSHALL SCORE	% MORTALITY
3	85.70%	6	100%
4	60%	5	44.40%
5	62.50%	4	100.00%
6	52.90%	3	83%
7	48.10%	2	45.50%
8	35.30%	1	30%

Comparison between GCS and Marshall score done as on the table 8 above. Marshall score with worst outcome (Marshall 6) compared with GCS with worst outcome (GCS 3) and similarly GCS 8 compared with Marshall 1.

FIGURE 9: GCS, MARSHALL SCORE Vs MORTALITY



The line graph above (Figure 9) compares GCS and Marshall score. GCS of 5 is compared with Marshall score of 4 as 5(4) on the X-axis while GCS of 8 compared with Marshall score of 1 as 8(1). There is decrease in mortality from GCS of 5 to GCS of 8 with mortality of 62.5% and 35.3% respectively. The comparison of Marshall score with mortality also shows decline from

Marshall score of 4 to 1 as mortality of 100% to 30% respectively. The Marshall score 5 and 6 were excluded from the analysis of comparison as these had intervention in Marshall 5.

TABLE 9: ANALYSIS OF GCS, MARSHALL SCORE AND MORTALITY

GCS		MARSHALL SCORE	
Score	**95% CI**	**Score**	**95% CI**
5	36.3, 100.0	4	-
6	26.4, 79.4	3	49.8, 100.0
7	28.0, 68.2	2	19.8, 65.9
8	10.0, 60.6	1	0.0, 64.6

There was no significant difference in mortality between GCS and Marshall score I - IV (all the 95% confidence intervals are overlapping). This indicates that the Marshall score can be used as a predictor of mortality as compared to the GCS (Table 9)

TABLE 10: PATTERNS OF INTRACRANIAL BLEED

TYPE OF INTRACRANIAL BLEED				MARSHALL SCORE
EDH	**SDH**	**ICH**	**tSAH**	
-	-	-	-	1
-	-	9	14	2
-	1	6	9	3
-	1	1	2	4
16	16	18	14	5
-	1	4	4	6
16 (18.6%)	**19 (22.1%)**	**38 (44.2%)**	**43 (50%)**	**Total**

The most common intracranial bleed among severe TBI patients was traumatic subarachnoid bleeds at 50% of patients while intracerebral haemorrhages and contusions (44.2% of patients) being second. Acute subdural hematomas and epidural hematomas accounted for 22.1% and

18.6% respectively (table 10). This is compared with the Marshall score and most patients with bleeds underwent surgery (Marshall score 5).

TABLE 11: PATTERNS OF INTRACRANIAL BLEED AND MORTALITY

	Total no. of patients	**Dead patients**	**% mortality**
EDH	16	6	37.5%
SDH	19	11	57.9%
ICH	40	22	55%
tSAH	46	29	63%

63% of patients with traumatic subarachnoid hemorrhage (tSAH) died while 57.9% of patients with acute subdural died. Of the patients with tSAH, patients with intraventricular bleeds (2 patients) all died. 37.5% of patients with epidural hematomas died and had the least mortality (table 11 and figure 10).

FIGURE 10: PATTERN OF INTRACRANIAL HEMORRHAGE AND MORTALITY

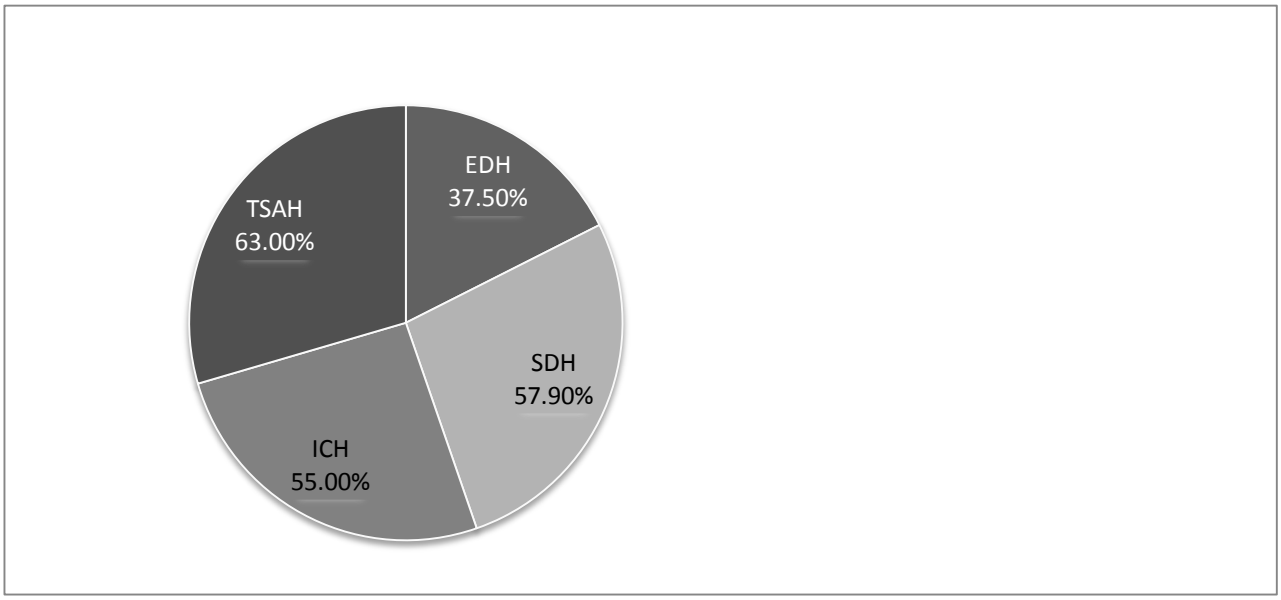
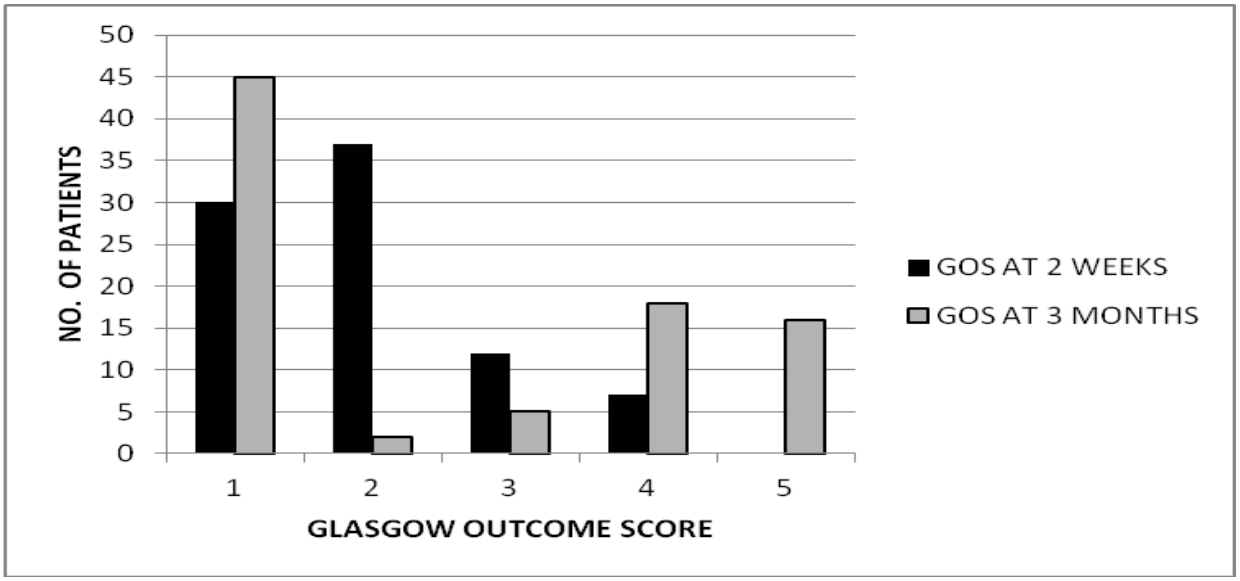


TABLE 12: GLASGOW OUTCOME SCORE AT 2 WEEKS AND 3 MONTHS

GLASGOW OUTCOME SCORE(GOS)	GOS AT 2 WEEKS (number of patients)	GOS AT 3 MONTHS (number of patients)
1	30	45
2	37	2
3	12	5
4	7	18
5	0	16
TOTAL	86	86

Table 12 and figure 11 show that majority of mortality (30 out of 45 i.e. 66.7%) occurred before 2 week period and only 2 patients died after 60 day period (one at 60 days and other at 85 days). At 2 week period, only 7 patients (8.1%) had favourable outcome (GOS 4 and 5) while at 3 months, 34 patients (39.5%) had favourable outcomes.

FIGURE 11: COMPARISON OF GLASGOW OUTCOME SCORE AT 2 WEEKS AND 3 MONTHS



The graph above (figure 11) shows that at 2 week period, 30 patients had died (GOS 1), 37 had persistent vegetative state (GOS 2) and 12 had severe disability (GOS 3). These represented 91.8% of patients with unfavourable outcome (GOS 1 – 3). Only 8.2% of patients had favourable outcomes (GOS 4-5) at 2 weeks

This is in comparison with GOS at 3 months. 15 patients died after 2 week period with mortality total of 45 (GOS 1). 52 patients (60.5%) had unfavourable outcome (GOS 1 – 3) while 34 patients (39.5%) had favourable outcomes (GOS 4 – 5) at 3 months.

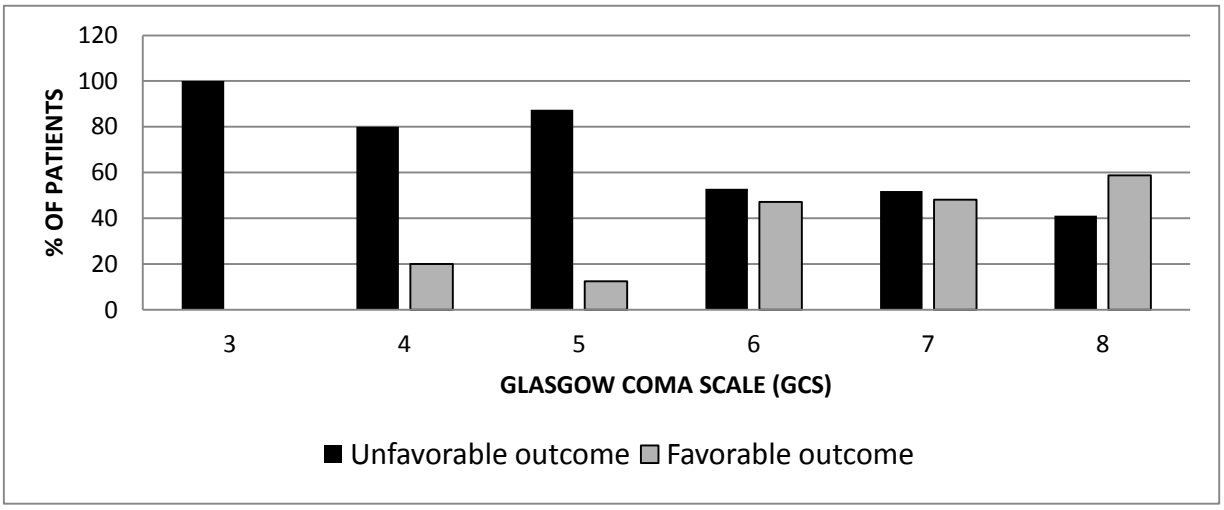
TABLE 13: COMPARISON OF GCS AND GLASGOW OUTCOME SCORE (GOS) AT 3 MONTHS

GCS	**GLASGOW OUTCOME SCORE (GOS)**	
	Unfavorable	**Favorable**
3	7 (100.0%)	0 (0.0%)
4	8 (80.0%)	2 (20.0%)
5	7 (87.5%)	1 (12.5%)
6	9 (52.9%)	8 (47.1%)
7	14 (51.9%)	13 (48.1%)
8	7 (41.2%)	10 (58.8%)

Glasgow outcome score of 1 – 3 (unfavourable); GCS 4 – 5 (favourable) outcome.

Table 13 compares the Glasgow coma scale and the GOS at 3 month duration which showed that as the GCS score increased, the proportion of patients with favourable outcomes increased. GCS of 3 had patients with favourable outcomes of 0% while GCS of 8 had favourable outcomes of 58.8%.

FIGURE 12: COMPARISON OF GCS WITH GOS AT 3 MONTHS



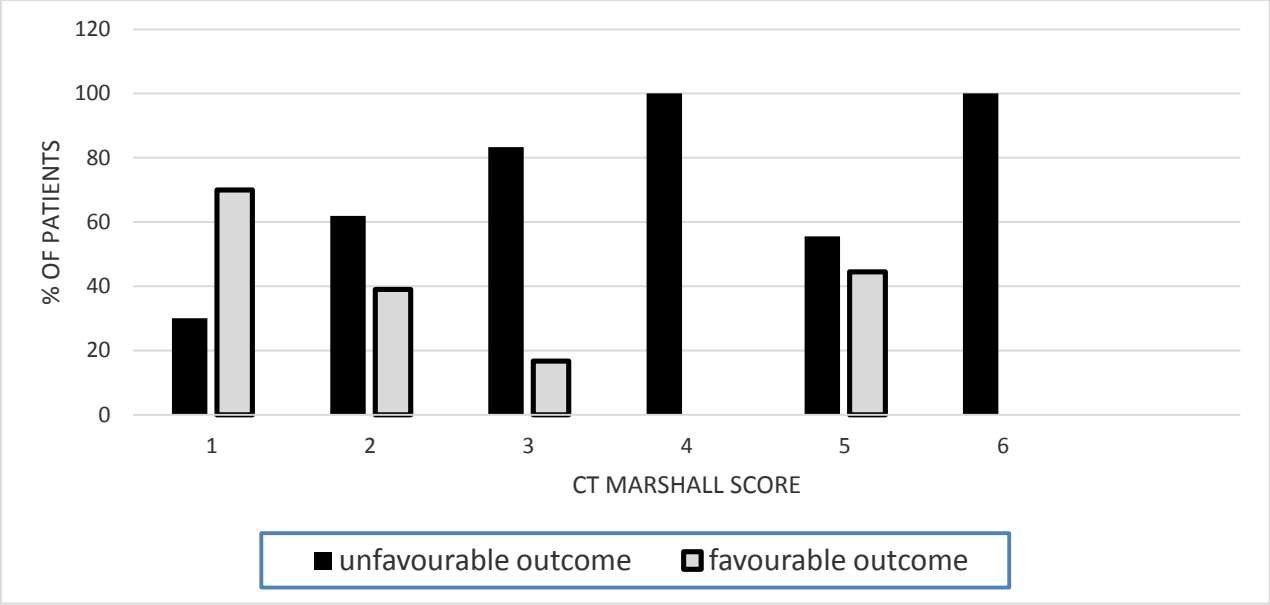
The graph above shows the correlation between GCS and GOS at 3 month period. GCS of 3, 4 and 5 had unfavourable outcomes of 100%, 80% and 87.5% respectively. Only 3 patients out of 23 patients in this group had a favourable outcome. GCS of 6, 7 and 8 had more favourable outcomes of 47.1%, 48.1% and 58.8% at 3 month period.

TABLE 14: COMPARISON OF CT MARSHALL SCORE AND GLASGOW OUTCOME SCORE AT 3 MONTHS

Marshall score	**GLASGOW OUTCOME SCORE (GOS)**	
	unfavourable	**favourable**
1	3 (30.0%)	7 (70.0%)
2	13 (61.9%)	9 (39.1%)
3	10 (83.3%)	2 (16.7%)
4	2 (100.0%)	0 (0.0%)
5	20 (55.5%)	16 (44.5%)
6	4 (100.0%)	0 (0.0%)

Patients with Marshall score of 1 had 70% of patients with favourable outcomes while Marshall scores of 4 and 6 had no favourable outcomes at 3 month duration. Marshall score 5 (patients who underwent surgical intervention) had 44.5% of patients with favourable outcomes. (table 14)

FIGURE 13: COMPARISON OF CT MARSHALL SCORE AND GOS AT 3 MONTHS



The graph (figure 13) above compares the GOS at 3 month and admission CT Marshall score. As the Marshall score increased from 1 to 4, the outcome worsened form 30% (Marshall 1) to 100% (Marshall 4 and Marshall 6). Patients who had surgical evacuation for intracranial hematomas (Marshall 5) had a favourable outcome of 44.5% at 3 months.

TABLE 15: ANALYSIS OF MARSHALL SCORE, GCS SCORE AND OUTCOME

	P value		
	GOS (2 weeks)	**GOS (3 months)**	**Death**
Marshall score	0.127	0.003*	0.003*
GCS	0.001*	0.005*	0.032*

*. Significant association (p value < 0.05)

As shown in table 15 using Spearman's correlation analysis shows that the Marshall score is significantly associated with GOS-3 months (p = 0.003), and death (p=0.003) in table 14. There's no significant association between the Marshall and GOS-2 weeks (p = 0.127). The GCS is significantly associated with GOS at 2 weeks (p=0.001), GOS at 3 months (p=0.005) and death (p=0.032).

TABLE 16: SUMMARY OF P VALUES FOR VARIABLES AND OUTCOME

	SEX	**AGE**	**SYSTOLIC BP**	**ANISOCORIA**	**GCS**	**MARSHALL**
GOS (3 months)	0.199	**0.002**	0.152	0.459	**0.005**	**0.003**
Mortality	0.207	**0.007**	0.278	0.376	**0.032**	**0.003**

The other variables that were analysed are sex, age, systolic blood pressure and pupillary reflexes (Table 16) and showed that only age had significantly correlated (p value <0.05) with the 3 month GOS and mortality. Systolic blood pressure, sex, pupillary reactivity to light were not significant (p value >0.05)

DISCUSSION

Severe traumatic brain injury has a high mortality and morbidity. Several studies have been carried out so as to investigate variables which could predict outcome[6,14,23,24]. In our study, majority of the patients were male (94.2%) and only 5.8% were female with a male to female ratio of 9:1. This has been attributed due to more men being drivers and being involved in assault in Kenya[6]. Opondo and Mwang'ombe had reported a male to female ratio of 5.2:1[3]. This has shown an increase in number of men as compared to women sustaining severe TBI. Sex has been analysed in prior studies and does not have statistical significance in predicting outcome[5,6,14]

The commonest cause of severe TBI was road traffic accident at 64% and assault at 28%. Other causes e.g. falls and blast injury accounted for 8%. Opondo and Mwang'ombe[3] reported similar results of RTA 59% and assault 32%. Andriessen et al[37], RTA was reported among 51% of patients and falls in 38%, a third were from stairs. This shows a different pattern in Kenya compared to developed countries. RTA was the highest cause of mortality at 57.8%. This emphasizes the need to have traffic regulations that are enforced in the country.

The overall mortality rate in the study is 51.3%. This rate is similar to local reports by Kiboi et al in 2001 with mortality of 56%[2]. Andriessen et al reported mortality of 46% at 6 months[37]. Mortality rates of between 32 – 49% reported in other multicentre studies[5, 33]. This shows the high mortality still present in severe TBI. The average number of days of mortality from admission was 13.7 days and only 2 patients died after 2 months (one at 60 and another at 85 days). Although 66.7% (30 patients) of deaths occurred before 2 weeks, 15 patients (33.3%) died after 2 weeks. This shows the need to follow up patients for longer periods so as to report the actual mortality due to severe TBI.

Majority of patients sustaining severe TBI were between 21 and 50 years (75.6% of total), only 3 patients were above 60 years. Patients below 40 years constituted 56.9% of the total. The mean age was 38.5 years while in western literature by Adriessen et al[37], reported mean age of 46years. This is related to the age distribution in Kenya compared to the western countries[23].This also shows the impact of severe TBI affecting more commonly the young population. Age had a significant impact on outcome, patients below 40 years having mortality of 40.8% while above 40 years mortality of 67.7%, and all patients above 60yrs (3 patients) died. Older patients have worse outcomes. Statistically, age had significant effect on outcome and mortality at 2 weeks and 3 months (p=0.002).

The Glasgow coma scale score was described in 1974 by Teasdale and Jennet and was introduced to assess the degree of unconsciousness in patients with traumatic brain injury[11]. Evidence shows that GCS is a strong predictor of outcome in TBI[14,18]. It may however be affected by sedation, paralysis or intoxication with alcohol and affected by presence of facial swelling[5,13]. Our study showed that patients with GCS of 3-4 had 70.6% mortality, 5-6 at 56% and 7-8 with mortality of 43%. Mwang'ombe and Kiboi[2] in 2001 reported mortality of 88%, 60% and 52% in GCS 3-4, 5-6 and 7-8 respectively. Opondo et al3 reported a mortality of 76.7% in patients with GCS between 3 and 5 while only 29.5% in patients with GCS 6-8. This shows that as GCS improved, mortality reduced. Quigley et al[38] found high mortality in patients between GCS of 3-4 and only 12.5% survived. Elderly patients above sixty years also had high mortality. In their study, GCS and age combination could predict outcome. In our study, GCS has shown to predict outcome at 2 weeks, 3 months (p values 0.001 and 0.005 respectively). GCS also correlated with outcome and at 3 months, only 11.8% of patients with GCS of 3-4 had favourable outcome while 50% of patients with GCS 7-8 had favourable outcomes. There is

difference in outcome at 2 weeks (early) and at 3 months. This shows benefit of following up patients for longer periods as a stronger predictor of outcome than follow up at discharge from critical care unit or hospital.

The CT scan Marshall score was described in 1991 and has been studied in multicenter prospective studies in Europe and America and has been shown to predict outcome in severe TBI[12]. The CT scan Marshall score has been validated as a predictor of outcome based on class I evidence[4,24,25]. The Marshall score was useful adjunct as Murray et al[5] described GCS reliable and accurate in only 56% with severe TBI since these patients sedated, intubated and ventilated[22]. The Marshall score and CT findings give indications for increased ICP[23] and maybe used as an adjunct in resource poor settings where ICP monitoring is not readily available. Marshall et al[12]described Diffuse injury I as no abnormal findings on CT, Diffuse injury II as basal cisterns present with midline shift <5mm, Diffuse III as cisterns compressed/absent with shift <5mm, Diffuse injury IV as midline shift >5mm. In scores I – IV, there is absence of high/mixed density >25cm^3. Any lesion surgically evacuated or not evacuated but >25cm^3 was also indicated in the score. In his study, Marshall et al[12] reported patients with Diffuse injury I had a mortality of 9.6% and good recovery in 61.6% while diffuse IV having mortality of 56.2% and good recovery in only 6.2%. This is in contrast to our study where patients with diffuse injury I had mortality of 30% and good recovery in 70%, Diffuse injury II and III having mortality of 45.5% and 83.3% respectively. Diffuse injury IV and VI had 100% mortality. This showed that as Marshall score increased, mortality increased and outcome worsened. Surgical intervention had better outcome and mortality rate being 44.4% which was comparable with diffuse injury II (45.5%). 44.5% of patients who had surgery also had favourable outcomes at 3

months comparing with 39% and 16.7% of patients with diffuse injury II and III respectively. Statistically these results were significant at 3 months GOS comparison (p=0.003) but not at 2 weeks (p=0.127) though relation with mortality showed p=0.003. When comparing between GCS, Marshall score and mortality, there was no significant difference in between GCS and Marshall score I - IV (all the 95% confidence intervals were overlapping). This indicates that the Marshall score can be used as a predictor of mortality as compared to the GCS.

Differentiating the different mass lesions on CT scan had prognostic influence on outcome as described by Maas et al[23]. In our study, the patterns of intracranial bleed findings in the CT scan were tSAH 50%, ICH 44.2%, ASDH 22% and EDH at 18.6%. tSAH had highest mortality at 63% while ASDH 57.9% and EDH having mortality of 37.5%. The IMPACT study[27] showed worse outcomes and mortality of 20-35% in patients with ASDH and tSAH and presence of the 2 findings predicted worse outcomes. Maas et al[23] also demonstrated that EDH had better outcomes than ASDH.

Presence of hypotension and extracranial injuries also have impact on outcome of patients with severe TBI. Sarrafzadeh et al[17] showed that the impact of extracranial injuries is more signicant in minor and moderate TBI and outcome is more related to primary brain injury than the presence of extracranial injuries in severe TBI. Chestnut et al showed that hypotension resulted in 75% mortality rate[16]. In previous study at KNH, hypotension was in 32.2% of patients and had mortality of 75% in these patients[3]. In our study, 3 patients had hypotension of which one died (33.3%). This may have been due to selection criteria because we excluded patients who died within 24 hours from our study. 31 patients (36%) had significant extracranial 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 extracranial injury was fractures of limbs which

constituted 54.8% of the patients of the 31 patients. 16.1% had facial fractures. This data is different from local study by Opondo and Mwango'mbe[3] in which extracranial injuries were present in 91.6% of patients with severe TBI, 49.5% of which were maxillofacial injuries, 25.2% limb fractures[3]. The reason for this is due to selection of patients and we selected patients with significant extracranial injuries with radiologic evidence of fractures, patients with soft tissue injuries excluded.

The delay between injury and arrival to hospital has been shown to be common in previous local studies[2,3]. A significant number of patients came in referred (72% of patients). Nearly all patients referred to KNH were not intubated (2 out of 62 patients). Of the referred patients, 15 (24.2%) presented 8 hours after injury. This is in comparison with 24 (28%) of patients who came to the hospital without referral of which only 4 (17%) patients had delayed more than 8 hours. This is due to KNH being the major referral neurosurgical hospital in Kenya and long distances from other hospitals and poor infrastructure. In developed countries, patients with severe TBI are intubated and sedated before transfer to hospital and Andriessen et al[37]reported 69% of patients being intubated at site and this had better outcomes to prevent hypoxia. This is comparable to only 2.3% of patients who came in intubated and previous report by Opondo et al, none of their patients were received intubated. This shows a deficiency in the pre-hospital management of severe TBI patients and delay in referral of these patients.

Pupillary reflex has been shown to be a useful predictor of outcome. Out of the 86 patients, 55.7% of patients with anisocoria and 66.7% of non-reactive pupils died while 27.3% of patients with brisk reactivity of pupils died. Opondo et al[3] showed that 36.8% of patients had anisocoria

and 35.4% of these patients had poor outcomes. This showed that patients with brisk reacting pupils had better outcomes than patients with bilaterally dilated unreactive pupils and patients with anisocoria. The p values were 0.46 and 0.38 for 3 month GOS and mortality respectively when analysed with anisocoria and statistically was not significant.

The Glasgow outcome score described by Jennet and Bond[32] is the most reliable score to measure functional outcome in patients with TBI[14]. The 3 month and 6 month GOS shown to predict long-term functional outcomes[27,36]. In our study, at 2 week period, only 8.1% of patients had favourable outcomes (GOS 4 and 5) and were functionally independent compared to at 3 month period where 39.5% had favourable outcome. This shows the need to follow up patients longer at 3 or 6 month period to report outcomes more accurately.

This study has shown the additional value of the Marshall score to the clinical parameters in prediction of outcome in severe TBI and has correlated outcome at 3 months duration. Previous studies done in Kenya were based on discharge from ICU and had shorter follow-up.

STUDY LIMITATIONS

There was loss of follow up for five patients at 3 months period and outcome could not be assessed. These patients were hence excluded from the total number.

CONCLUSION

Severe TBI has a high mortality and morbidity in our society. It has a high impact on young people especially men in the society. These patients need intensive care which is expensive and strains the health care resources in the country. A significant proportion of patients (17%) were still dependent for care at 3 months post-admission.

The age of the patient, Glasgow coma scale at admission and the CT Marshall score are significant predictors of outcome ($p = <0.05$). The CT Marshall score correlates well with the GCS score at predicting outcome. Therefore, the Marshall score can be used as a predictor of outcome in Kenyan hospitals and in our African populations.

RECOMMENDATIONS

We recommend the following:

1. Routine use of CT scan Marshall score at admission in severe TBI patients and be recorded by clinicians routinely. Charts should be provided at the accident and emergency department that give a basic guide on how to score CT scan findings. The CT scan findings should be used together with the clinical findings e.g. GCS, pupillary findings when prognosticating patients with severe TBI.
2. Repeat scans should be done in patients who are intubated and are worsening clinically and not improving. Marshall scores of these should also be recorded.
3. Training on pre-hospital management of severe TBI should be done countrywide. Early intubation at site of injury, if possible, and resuscitation key to prevent further brain damage

4. Need to prevent head trauma in our society is key to reduce incidence of traumatic brain injury related mortality. Traffic rules should be frequently taught to the society and responsible drinking advocated. The society needs to be aware of the impact of head trauma in the country as most of these patients are young productive people.
5. Intensive care units need to be expanded in more centres in the country to avoid delays in management of TBI patients. More neurosurgical centres need to be opened with qualified staff to care for these patients.
6. Future studies showing impact of longer term outcome of severe TBI patients at 6 months and one year would be useful.

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APPENDICES

APPENDIX 1: DATA COLLECTION SHEET

1. BIODATA
    a. STUDY SUBJECT NO……..
    b. IP NO……..
    c. SEX…….
    d. AGE (yrs)……
    e. DATE AND TIME OF ADMISSION……..
    f. 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)……

    b. GLASGOW COMA SCALE ON ADMISSION(after resuscitation)
    M…….E……..V……..TOTAL…….

    c. PUPIL REACTIVITY
        i. ANISOCORIA(Y/N)……SIZE(MM)……
        ii. BRISK/SLOW/NON-REACTIVE…….

    d. 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
    (Circle 'a' or 'b')

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

6. PREMEDICATION GIVEN(Y/N)…….
    Specify……
    …….

7. CT SCAN CHARACTERISTICS(ON ADMISSION)

    a. Report done by consultant radiologist……resident……..(tick)
    b. Time interval of 1st CT scan from time of injury(hrs. minutes)……..

    c. MARSHALL CT SCAN SCORE:

Table 1: Marshall CT classification

Diffuse Injury I	No visible intracranial pathological changes seen on CT scan
Diffuse Injury II	Cisterns are present with midline shift 0-5mm and/or lesions densities present; no high or mixed density lesion >25cm^3 may include bone fragments and foreign bodies
Diffuse Injury III	cisterns compressed or absent with midline shift 0-5mm; no high or mixed density lesion >25 cm^3
Diffuse Injury IV	midline shift >5mm; no high or mixed density lesion > 25cm^3
Evacuated Mass lesion (V)	any lesion surgically evacuated
Nonevacuated mass lesion (VI)	high or mixed lesion >25cm^3; not surgically evacuated

d. INDIVIDUAL CHARACTERISTICS:
    i. PRESENCE OF HEMATOMA (tick if present)
        1. Epidural…….
        2. Acute subdural hematoma……..
        3. Intracerebral hematoma…….
        4. Traumatic subarachnoid hemorrhage……
    ii. VOLUME OF HEMATOMA(S) –total vol in cm3
    ……

MARSHALL SCORE……

8. TIMING OF SURGERY (from admission time)…….

9. REPEAT CT DONE DURING 3-MONTH PERIOD
    a. Reason for repeat Scan……..
    b. Interval of CT scan from time of injury (days/ hrs)……
    c. GCS at time of scan……..
    d. Pupillary changes (see above)……..
    e. Marshall CT SCORE of repeat scan……
    f. Surgical intervention done based on repeat scan
    ……
    g. Subsequent CT scans done (use 9a.-f. to define further)……
    ……
    …….

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

    b. GLASGOW OUTCOME SCORE
        i. AT TWO WEEKS…….
        ii. AT THREE MONTH…….

11. GLASGOW OUTCOME SCALE

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)

APPENDIX 2: CONSENT FORM

Study No……. Hospital No……

The study is being carried out by Dr. Nilesh Mohan who is a post-graduate student in the Department of surgery at the University of Nairobi.

Purpose of study

The purpose of the study is to compare Computed tomography (CT) scanning of the head and clinical measurements e.g. blood pressure, effects of other injuries on outcome of severe head injury patients. The CT scans and clinical measurements are normally used to show the severity of injury to the head. We will compare these and check their value in the eventual outcome at 3 months of the patient. The information from the study will also assist to show the effect of head injury to our society.It will also give new information to the clinicians of what to emphasize on when reviewing a patient with severe brain injury

Procedure

After you have accepted to participate in the study and signed this consent form, I will ask you questions to confirm, or clarify where necessary information in the patient's file regarding 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 3 months. This follow-up will be done at our hospital or when discharged, at follow-up at our outpatient clinic at KNH.

Risks and benefits

This is to assure you that there is no harm or risk to the patient or to 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.

Voluntary participation

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.

Confidentiality

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

I, the undersigned have been explained to, understand the above, and voluntarily provide consent on behalf of the patient to participate in the study. This is due to the patient being unconscious and not of sound mind.

Signature/Thumb print: ……Telephone No. ……..

Guardian/Next of Kin (full names) ……

At 3 month period, if patient is well recovered and good neurologic function, additional consent may be obtained from patient (optional)

Signature/thumb print…….

Dr. Nilesh Mohan 0736912517 UON / KNH research committee Tel: 020-2726300 ext 4435

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Ref: KNH-ERC/A/131 Link:www.uonbi.ac.ke/activities/KNHUoN 8th May 2014

Dr. Nilesh K. Mohan
Dept.of Neurosurgery
School of Medicine
University of Nairobi

Dear Dr. Mohan

Research proposal: Comparison of Computed Tomography (CT) Model and clinical Parameters as Predictors of outcome in severe Traumatic Brain injury patients at the Kenyatta National Hospital (P605/12/2013)

This is to inform you that the KNH/UoN-Ethics & Research Committee (KNH/UoN-ERC) has reviewed and **approved** your above proposal. The approval periods are 8th May 2014 to 7th May 2015.

This approval is subject to compliance with the following requirements:

a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b) All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH/UoN ERC before implementation.
c) Death and life threatening problems and severe adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH/UoN ERC within 72 hours of notification.
d) Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH/UoN ERC within 72 hours.
e) Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
f) Clearance for export of biological specimens must be obtained from KNH/UoN-Ethics & Research Committee for each batch of shipment.
g) Submission of an *executive summary* report within 90 days upon completion of the study
This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/or plagiarism.

For more details consult the KNH/UoN ERC website **www.uonbi.ac.ke/activities/KNHUoN.**

Yours sincerely

PROF. M. L. CHINDIA
SECRETARY, KNH/UON-ERC

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