PREVALENCE OF DELIRIUM IN PATIENTS WITH TRAUMATIC BRAIN INJURY AT THE KENYATTA NATIONAL HOSPITAL

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

Declaration by the Principal Investigator:

This dissertation is my original work and has not been presented for degree award, publication, or scientific dissertation in any institution.

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DEDICATION

To my husband and my daughters who have always supported me.

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ABBREVIATIONS

CNS: Central nervous system

CI: Confidence Interval

GCS: Glasgow Coma Scale

ICDSC: Intensive care delirium screening checklist

ICU: Intensive care unit

KNH: Kenyatta National Hospital

PR: Prevalence Ratio

SPSS™: Statistical Product and Service Solutions

TBI: Traumatic Brain Injury

UoN: University of Nairobi

WHO: World Health Organization

DEFINITIONS

Critical care unit: a hospital unit with organized systems for provision of intensive care for patients with life-threatening injuries.

Delirium: refers to an acute, reversible decline in consciousness and cognition due to a direct physiological consequence.

Inattention: refers to inability to focus, shift attention or follow through with a given task.

Traumatic Brain Injury: refers to a disruption in the normal functioning of the brain due to an external force or physical assault.

Agitation: excessive motor or vocal activity that occurs in advanced stages of impaired cognition.

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ABSTRACT

Introduction

Delirium presents with acute cognitive dysfunction and is reversible. It is common and predictable in traumatic brain injury (TBI) patients. It is often underdiagnosed, unrecognized; and occurs in about 20% of hospitalized patients and up to 69% of TBI patients. Delirium in TBI patients increases mechanical ventilation days, hospital stay, and 6-month mortality. Therefore, patients with TBI require regular monitoring with a validated delirium assessment instrument.

Objective

The general study objective was to determine the delirium prevalence among patients with traumatic brain injury at Kenyatta National Hospital (KNH).

Materials and Methods

The study was a cross-sectional, observational, descriptive study. The study site was the surgical wards and the critical care surgical units at the Kenyatta National Hospital. A checklist questionnaire based on the Intensive Care Delirium Screening Checklist (ICDSC) was filled out by the principal investigator on sampled TBI patients. It was used to screen admitted patients for delirium and identify possible risk factors. The checklist questionnaire was coded into the encrypted Google Forms™ application for data entry.

Results

We evaluate 119 patients with TBI sampled consecutively from the admission register at the KNH. The prevalence of delirium was 61.3% in TBI patients at the KNH. The evaluated risk factors of delirium were; female gender (male vs. female; PR, 0.87; 95% CI, 0.75 to1.79), severe TBI with GCS<9 (severe vs. non-severe TBI; PR, 1.5; 95% CI, 0.89 to 1.5), use of restraints (higher in use of restraints vs. no use; PR,1.47; 95% CI 0.90 to 1.50), use of sedatives (higher in use of sedatives vs. no use; PR, 1.45; 95% CI 0.89 to 1.51), absence of neurosurgical intervention (less in patients with neurosurgical intervention than those without (PR, 0.88; 95% CI 0.87 to 1.54), and higher when blood transfusion was done (PR, 1.34; 95% CI 0.82 to 1.64).

Conclusion

The prevalence of delirium was 61.3% in TBI patients at the KNH. Severe TBI with GCS<9, use of restraints, and exposure to sedatives were risk factors for delirium.

CHAPTER 1

1.0 INTRODUCTION

Delirium is an alteration in attention, that is characterized by acute or subacute cognitive fluctuations usually caused by a medical condition.[1] It represents a disturbance in attention (i.e. decreased capacity to focus or shift attention) and awareness that gradually evolves in a short period with a fluctuating course.[1] It is a serious disorder of the central nervous system that often involves impaired perception, psychomotor agitation and sleep disturbances.[1,2] It is a potentially reversible condition that is hardly recognized by healthcare workers. This is partly due to the multiple names attributed to the condition such as acute confusional state, and intensive care unit psychosis.

The syndrome of delirium is typically caused by abnormal brain function due to systemic or cerebral derangements. TBI describes the effects of an external physical force on the brain and is described as one of the causes of delirium.[3] It results in immediate cognitive or neurological disturbances. The prevalence of TBI has been on the rise globally and is a significant public health problem.[4] Persons with TBI have a greater risk of delirium which leads to increased disability and long-term cognitive impairment.[4,5] The development of delirium is a poor prognostic sign that confers a higher duration of hospitalization and death.[5,6] Long-term complications of delirium can lead to unnecessary financial strain on individuals and governments such as the cost of treatment and lost manpower.

Various screening tools used in critical care for delirium have been extensively studied. The ICDSC is an 8-item screening instrument that rates non-cognitive symptoms (disturbances of sleep, mood, psychomotor activity) and cognitive (disorientation, inattention, delusions or hallucinations) [6,7] An individual's behavior over the past 12 hours is then rated. A score of four or greater is positive. It has been validated for use in patients with critical conditions and the Society of Critical Care Medicine (SCCM) recommends its routine application to screen for delirium in these patients.[8]

We seek to establish the prevalence and determinants of delirium in TBI victims admitted to the surgical services at the Kenyatta National Hospital.

CHAPTER 2

2.0 LITERATURE REVIEW

2.1. Background

Delirium has been better understood over time and there is universal agreement of its serious morbidity and poor prognosis. Its association with acute illness was described in the first century.[9] Delirium has multifactorial causes. One of these causes is TBI, an evolving public health epidemic.[4] The most common early cognitive impairment in TBI is delirium. At least 50% of individuals diagnosed with TBI develop delirium within four days.[3]

Various studies have shown an increase in morbidity and mortality among patients who have experienced post-traumatic delirium compared to the general population. These patients also have a higher risk of deliberate self-harm and suicide. [10]

Several studies have shown delirium prevalence in TBI to range from 11 to 70 % [11, 12,13,26]. There remains a scarcity of such studies in Kenya.

2.2 Previous Studies

Maneewong, J. et. al [3] reported on the predictors and pattern of symptoms after TBI in 2017, indicating that the severity of TBI and cognitive impairment predicted the incidence of delirium. Almost half of the evaluated patients developed delirium after an episode of traumatic head injury- suggesting that delirium is common post TBI. In conclusion the total GCS score and verbal replies obtained at admission might predict the presence of delirium. Cognitive symptoms were more severe on the first day of delirium onset and some symptoms resolved rapidly. Only a few cases of TBI were included, limiting the study.

Another study was done by Ganau M et. al [4] on the pathological hypothesis and treatment of delirium and agitation in TBI in 2018. TBI was found to affect both long and short-term cognitive function with a change of emotional and behavioural patterns affecting both the involved patients and relatives. It was reported that 21.3% of patients with a history of TBI may present with at least one psychiatric disorder. It was further postulated that in post-traumatic delirium, inflammation and neurotransmitter imbalance could lead to functional and structural abnormalities. In conclusion, it was found that delirium post TBI is underrecognized due to the lack of a standardized method of diagnosis and management.

Duceppe MA et. al[5] conducted a multicentre prospective study in 2017 on risk factors of delirium that can be modified in trauma patients in the critical care setting. It was found that physical restraints and active infection indicated a higher chance of delirium. However, treatment with opioids, giving more hours of mobilization and frequent exposure to tv or radio reduced the probability of developing delirium. It was concluded that delirium was a common consequence of trauma resulting in longer Intensive Care Unit (ICU) stays and a higher incidence of accidental removal of intravenous access devices. This study was limited by the few number of patients studied and the use of a population in which the detection of delirium couldn't be optimal.

A study done by Cavallazzi et al[6] in 2012 showed that requirement for ventilatory support had an increased incidence of delirium. Delirium led to 32-fold increase in 6 months. It was recommended that physical and occupational therapy were among the non-pharmacologic therapies that decrease the duration of delirium. The recommended pharmacological treatments included the use of haloperidol and 2nd generation anti-psychotics.

Delirium monitoring in neurological injury is important during the primary assessment. A study by Patel, M. B.[13] demonstrated the variety of monitoring tools available for this population. Features of delirium were found to predict poor eventual outcomes. In this systematic review, stroke patients were reported to be predisposed to delirious symptoms secondary to factors such as brain oedema and re-bleeding. This systematic review was limited by its focus on neuro critically ill patients, which would lead to a lack of generalizability of its findings.

Rajlakshmi AK et al,[14] did a study in 2013 on the relationship between cognitive and non-cognitive features of delirium. Cognitive deficits were more prevalent and correlated with severity, but had no correlation with non- cognitive symptoms. Attention deficit was found to be a core symptom. Limitations included the use of a population with several causes leading to delirium.

According to a systematic review study by Neto AS et al[15] on delirium screening instruments accuracy, delirium screening helps in early recognition. The CAM- ICU was found to have a higher specificity for bedside assessment. It however has a low sensitivity in regard to use for routine daily practice. CAM- ICU and ICDSC were also evaluated more frequently. The ICDSC was the screening tool of choice recommended by the SCCM for routine use.

An observational study published in 2020 on the long-term cognitive effects that delirium results in.[16] Acute neurologic injury patients with a history of delirium were found to be 58% more likely to develop mild cognitive impairment. An increased incidence of poor cognition (approximately twice) among patients with a history of delirium as compared to non-delirium patients was documented. At least 5.2% of the studied population had a history of in-hospital delirium. Repeated episodes of delirium increase the probability of poor cognitive outcome. The findings of the review indicated that prevention of in-hospital delirium, early identification and management of symptoms leads to improved outcomes in cognition for TBI patients. The study was however limited by underreporting of in-hospital delirium cases in the electronic medical records.

Wortzel HS et al[18] published a study in 2014 on the evaluation of TBI and neuropsychiatric sequelae according to the Diagnostic and Statistical Manual of Mental Disorders (DSM-5). The updated manual helped clearly distinguish TBI severity, thus facilitating recognition and distinction of both behavioural and emotional sequelae. Individuals with such injuries were provided with recovery-promoting information, and clinicians had evidence-based management of neuropsychiatric complications.

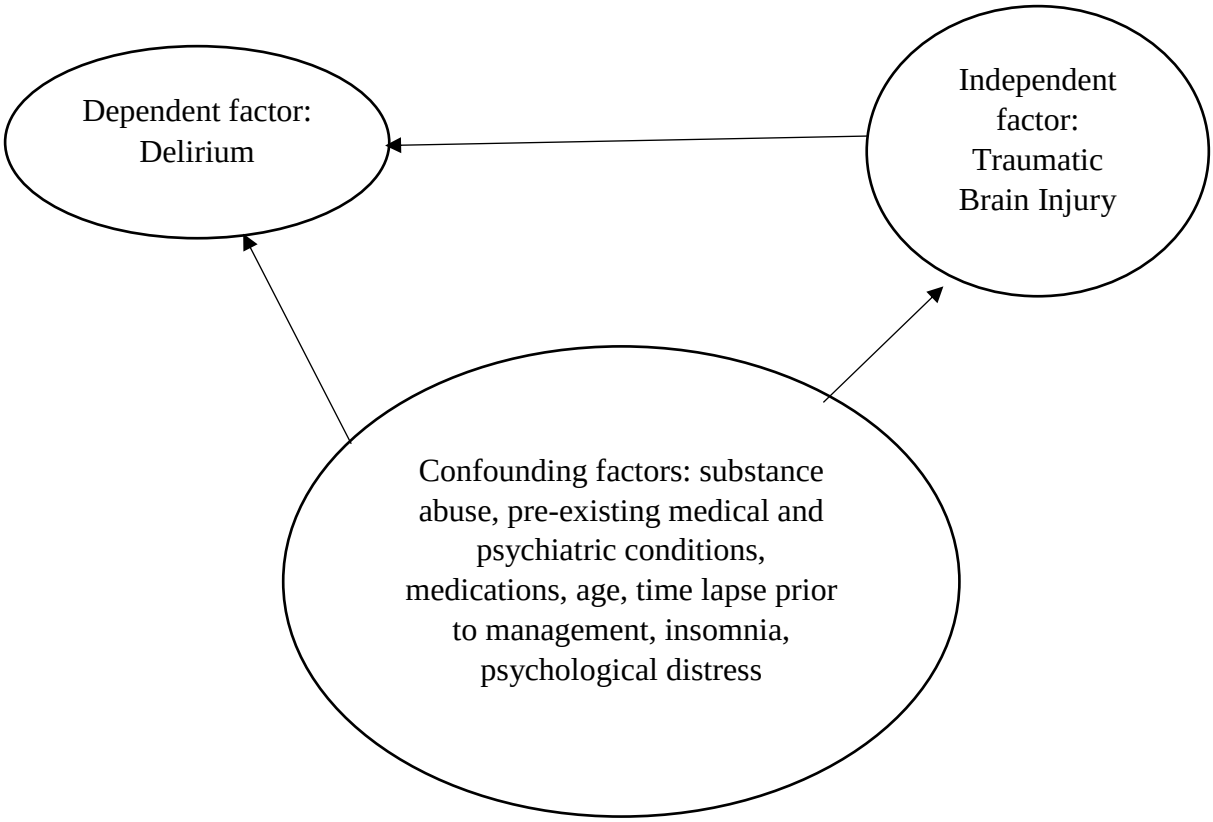
Ryan DJ et al[19] carried out a point prevalence study on predictors, prevalence and detection of delirium in an acute setting of the adult population. It was reported that 1/5 of inpatient adults in the general hospital were diagnosed with delirium. Those with previous cognitive impairment were at a higher risk. This study showed that delirium was prevalent regardless of the specific population or assessment tool used, suggesting that a screening tool should be agreed upon, adopted and used regularly. Encountered limitations included the competency of staff in assessing delirium which might have led to missed diagnoses.

Delirium in the critically ill is a documented universal burden. A systematic review on the association of delirium with short-term clinical outcomes and long-term cognitive deficits by Salluh JI et al[20] demonstrated an increased mortality risk, longer hospital stays and cognitive impairment post-discharge. The study was limited by the exclusion of patients who had undergone organ transplantation or cardiac surgeries.

2.3 Conceptual framework

The independent variable in this study was TBI. The dependent variable was delirium. Confounding factors were co-morbidities, pre-existing psychiatric conditions, substance use, medication effects, insomnia, age, time lapse prior to management and psychological distress.

Figure 1: Diagrammatic Representation of the Conceptual Framework



2.4 Justification of the Study

Almost half of patients with TBI may develop delirium. This predisposes them to increased hospital stays, persistent cognitive impairment, poor quality of life and increased mortality[20]. Delirium is however a potentially reversible disorder. Early recognition of symptoms by clinicians; therefore, helps in identification of underlying diseases and timely treatment.

Delirium develops acutely and has a fluctuating pattern. It is therefore important to continuously monitor the patient to assess risk factors, predisposing and precipitating factors for each patient. A standard algorithm for monitoring delirium is required at Kenyatta National Hospital (KNH) to achieve this, and can only be achieved by the collection of data on risk factors of delirium and prevalence.

There is a scarcity of research on delirium in TBI in Kenya. This study was a basis for upcoming research on the same area and would aid in development of guidelines for its management.

The most common cause of TBI as has been documented in several studies is road traffic accidents. TBI in Kenya accounts for 50% of deaths secondary to road traffic accidents.[21,22] This is a large morbidity burden. KNH admits majority of the trauma cases around the city of Nairobi, leading to a large burden of admissions.[22] Data is required to effect policy changes that could mitigate the epidemic.

Delirium predisposes patients to longer hospital stays and poor functional outcomes post-discharge.[19] Increased mortality has also been reported. This study sought to encourage the use of existing monitoring tools for delirium in TBI to improve the outcomes of patients.

There are known long-term effects on the patients and their families. Patients present with agitation, poor memory, dementia and post-traumatic seizures.[6] These conditions carry a large financial and morbidity burden. This study intended to reveal the need for social support in this population such as specific recovery centres affiliated with referral hospitals such as the KNH, and the basis for guidelines on post-hospital rehabilitation.

2.5 Research Question

What is the prevalence of delirium among traumatic brain injury patients at the Kenyatta National Hospital (KNH)?

2.6 Objectives of the Study

2.6.1 Overall Objective:

To determine the prevalence of delirium among traumatic brain injury patients at KNH.

2.6.2 Specific Objectives:

1. To determine the number and proportion of patients with delirium in traumatic brain injury admitted to surgical wards and critical care units at the KNH.
2. To identify risk factors for delirium in traumatic brain injury patients at the KNH.

CHAPTER 3: METHODOLOGY

3.1 Introduction

The study used primary data collected using an electronically filled questionnaire.

3.2 Study Design

This was a cross-sectional, descriptive, and observational study.

3.3 Study Area

KNH is the apex national teaching and referral hospital that is gazetted by the Government of Kenya. The hospital has a bed capacity of 1455, according to the Kenya Master Health Facility List.[29] It serves as the regional referral hospital for the Republic of Kenya, offering specialized healthcare. This study was carried out in the surgical intensive care unit and general surgical wards at the hospital.

3.4 Study Population

The population to be studied was traumatic brain injury patients who were admitted to the KNH.

3.4.1 Inclusion criteria

1. Patients whose next of kin consent to the study.
2. Patients with a diagnosis of Traumatic Brain Injury.

3.4.2 Exclusion criteria

1. Patients whose next of kin do not consent to be included in the study.
2. Patients who have pre-existing or evolving neurocognitive disorders
3. Patients who are less than 18 years old.
4. Brain-dead patients receiving palliative care.
5. Patients with a severe alteration of consciousness.

3.5 Sample Size Determination

The sample size was estimated from the following formula. [28]

$$n = \frac{z^2 .p.q}{d^2}$$

Assuming that:

n = approximate sample size

z= 1.96 (taking a level of confidence of 95%)

d = 0.05 (the margin of error/estimate is within 5% of the true value)

p = the incidence of delirium in a previous study [12]

q = 1-p

Therefore:

$$n = \frac{(1.96)^2 * (0.69) * (1-0.69)}{(0.05)^2}$$

n =328

The population that was studied was less than 10,000. The average admission of traumatic brain injury patients per month to the surgical service at the Kenyatta National Hospital is approximately 180.

Thus, the following formula is used to estimate the minimum sample size for this study.

$$nf = n/ (1+n/N)$$

In which:

nf = is the desired sample size for a population not exceeding 10,000.

n: is the number of participants that would be used where the population is more than 10,000

We have determined this number to be 328 as shown above.

N = the estimated population size.

At the KNH 180 are admitted to the surgical service per month.[30]

Therefore applying the above:

nf = n/ (1+n/N)

= 328/ (1+328/180)

= 116

The minimum number of patients required for the study was 116.

3.6 Sampling Criteria and Procedure

In this study, the sampling procedure was consecutive sampling from the admission registers until the sample size is achieved.

It included all admitted patients diagnosed with TBI in the study period, and enrolled consecutively until the desired sample size is achieved.

3.7 Recruitment Procedure.

The principal investigator received information about prospective participants from the admitting doctor or receiving nurse at the KNH casualty, surgical intensive care units and general surgical wards.

The primary investigator met the selected patients with their caregivers and screen the patient to determine if they meet the inclusion criteria. Thereafter those who fit the inclusion criteria were informed about the study and any questions were answered.

The primary investigator determined if they are interested in enrolling into the study. Willing participants were recruited. The next of kin of interested participants signed an informed consent form. Patients who presented to the facility unaccompanied were recruited by use of waiver of consent sought from the KNH-UoN Ethics and Research Committee. Next of kin who declined to give consent were thanked and the patients were excluded from the study.

The ICDSC tool was administered to the participating patients on obtaining informed consent after which the patient and next of kin were thanked for participating in the study.

3.8 Study Procedure

After obtaining clearance from the KNH-UoN Ethics and Research Committee, authorization to collect data was sought from the KNH departments to be involved in the study.

The admitting doctors in the Accidents and Emergency department were asked to notify the principal investigator of any TBI patient that is admitted to KNH. In addition to this, the ward nurses were requested to inform the principal investigator once they receive a TBI patient. This was a double-check system for the admission notification to ensure no patient was left out. Once the principal investigator was alerted, she attended to the patient, and check if the inclusion criteria is met. This was done by reviewing the information on the patient's file. If the inclusion criteria are met, informed consent was obtained from the next of kin.

Thereafter the level of consciousness was assessed using the GCS to determine if they were too comatose to be evaluated further. The principal investigator then filled out the ICDSC delirium screening tool. The presence of delirium was evaluated at the time of enrolment to the study, at 12 hours after the first enrolment and whenever the patients developed a mental change. At 12 hours, the principal investigator also reviewed relevant ongoing interventions documented in the patient's file.

3.9 Analysis of Data

Data collected in this study was coded into the Google Forms™application whose access was restricted and password protected. The data forms were continuously checked for completeness and accuracy of the input information.

The core data were exported into a password-secured Microsoft Excel Document designed specifically for the study. The data were then cleaned and then exported to SPSS™version 23.0 where the statistical analysis was performed, with the aid of a statistician. Raw data were presented in tables. Continuous data such as the age of patients were summarized using measures of central tendency such as mean. Categorical data such as sex or type of medical intervention were presented using frequency with the corresponding percentages. Prevalence ratios at 95% confidence intervals were calculated.

The raw data on the password-secured Microsoft Excel document will be kept for 5 years in secure cloud storage and deleted thereafter. No hard copies were used to store data during the study.

3.10 Quality Assurance Procedures

The study adhered to all the quality assurance procedures as per the research guidelines at KNH, the Department of Psychiatry, and the KNH-UoN ethics and research committee. The principal investigator (PI) administered the questionnaire to the next of kin explaining the details and ensuring the completeness of information. The PI also worked closely with a Statistician to ensure that quality checks are done on the tool in use and guarantee proper data handling, entry and analysis to ensure collection of quality data. Data monitoring was done daily, and at analysis to confirm quality.

The statistician ran descriptive statistics on the data, and check for any missing values to ensure updating of the records before completion of the data collection activities. The data collection tools were accessible only to the researcher, statistician and supervisors.

3.11 Ethical Considerations

1. The clearance of the study procedures was sought and obtained from the KNH-UoN Ethics and Research Committee.
2. Authorization for the study was obtained from the KNH departments involved in the study. This was done before commencing data collection.
3. Written consent was sought from the next of kin of patients if they were known. The principal investigator approached the next of kin and explained the study objectives in Kiswahili or English. They were allowed to read the consent and seek clarifications, or ask questions. Voluntary participation was emphasized and they were allowed to opt out of the study at any time. The unknown patients with altered consciousness were included by a waiver of consent sought from the KNH UoN ERC.
4. This was an observational study with no direct interference with patients. The primary caregivers were duly notified about patients found to have delirium, and advised to start a multi-disciplinary treatment approach of their preference.
5. During data collection, the personal identifiers of patients such as their names were not be recorded. During the dissemination of the results of the study, such as publication; there will be patient identifiers in use. The data collected in the study were password protected. Consent forms were kept safely under lock and key to maintain confidentiality.

CHAPTER 4: RESULTS

4.1 Demographic Characteristics

We evaluated 119 patients with traumatic brain injury sampled consecutively at admission to the Kenyatta National Hospital. The calculated minimum sample size for our study was 116 patients, who were recruited accordingly. There were 3 mortalities that occurred before a second assessment could be done at 12 hours, necessitating the recruitment of 3 more patients. However, it was noted during data analysis that the 3 patients who died already had delirium at their first assessment. Therefore, they were included in the data analysis, and the total number of patients analyzed was 119.

There were 109(91.6%) males, and 10(8.4%) females with a diagnosis of Traumatic brain injury (TBI).

Except 7 unknown persons, the age range for the evaluated patients was 14 to 87 years. The average age was 39.2 years old, with a standard deviation of 17.4 years.

The prevalence of delirium in all the patients evaluated in the study was 61.3% (73/119).

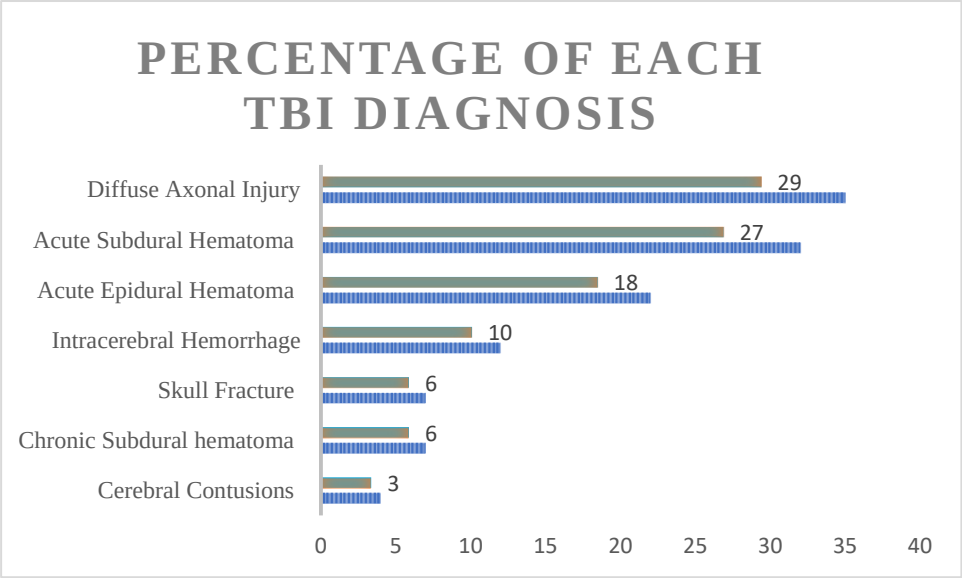
The most common specific diagnosis was Diffuse Axonal Injury, occurring in 29% (34/119) of the patients.

Table 1: Demographic characteristics of TBI patients at KNH.

Demographic characteristics		**n**	**%**
Total number of patients		119	
Age in years	Mean+/- standard deviation	39.2 +/- 17.4	
Sex	Male	109	91.6
	Female	10	8.4
Specific TBI diagnosis	Diffuse axonal injury	35	29
	Acute subdural hematoma	32	27
	Acute epidural hematoma	22	18
	Intracerebral haemorrhage	12	10
	Skull fracture	7	6
	Chronic subdural hematoma	7	6
	Cerebral contusions	4	3
GCS at admission	Severe TBI	35	30
	Non- severe TBI	84	70

The bar chart below shows the percentage of each of the TBI diagnoses.

Bar Chart 1: Percentage of Each TBI Diagnosis.

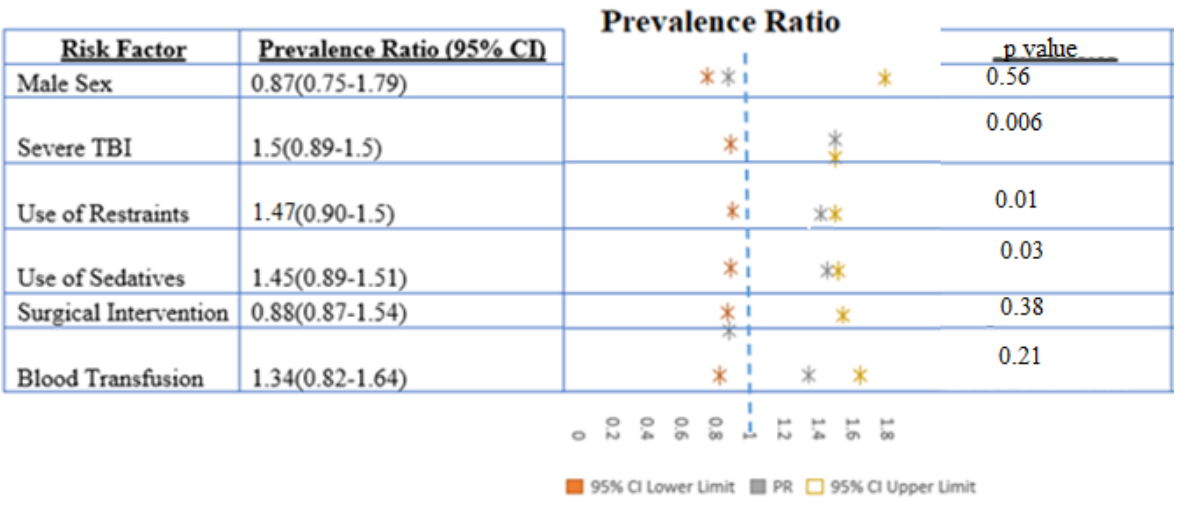


4.2 Presence of Risk Factors for Delirium:

Several risk factors for development of delirium were evaluated in the study.

We sought to determine the prevalence ratios of various risk factors of delirium and the figure below summarizes the predictors of delirium inferred from measures of association, and variation at 95% confidence intervals. Statistical significance was taken at p-values less than 0.05.

Figure 2: Multivariate Analysis of Specific Risk Factors for Delirium



4.2.1 Sex

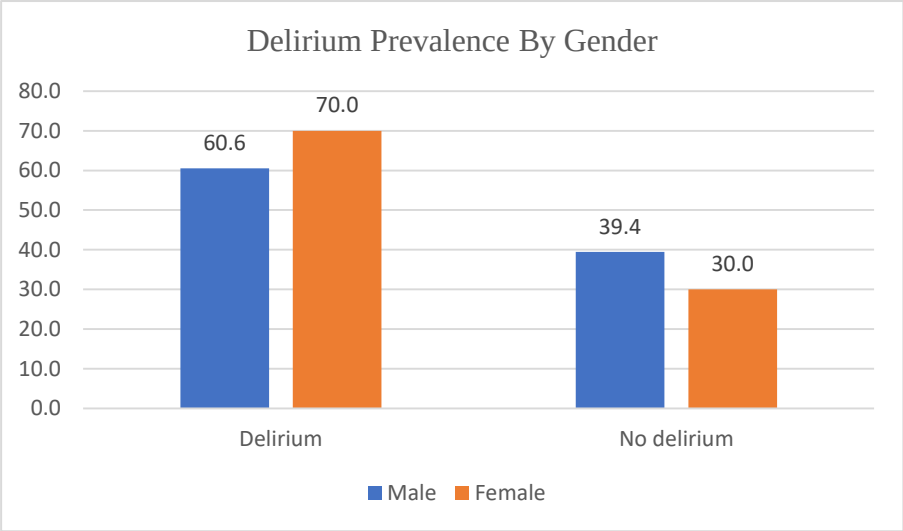
109 males were evaluated in the study, where 60.5% (66/109) developed delirium.

There were 10 females with TBI, and 70% (7/10) had delirium. Females were more likely to develop delirium; prevalence ratio, 0.87; 95% CI, 0.75 to 1.79

P value (0.56) indicated that this risk factor was statistically insignificant.

Bar Chart 2 shows the prevalence of delirium by gender.

Bar Chart 2: Delirium Prevalence by Gender



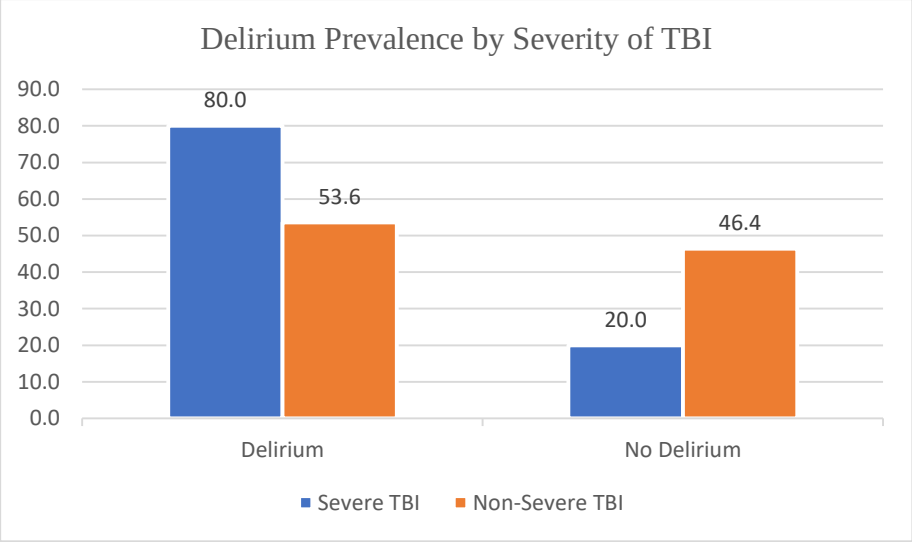
4.2.2 Severity of TBI

The prevalence of delirium was higher in patients with severe TBI, defined as GCS<9, at 80% (28/35), compared to non-severe TBI at 54% (45/84).The prevalence ratio was 1.5; 95% CI, 0.89 to 1.5.

Severity of TBI was significantly associated with delirium as shown by the P value (0.006).

The percentage of patients with delirium, with severe or non-severe TBI is shown in the bar chart 3 below.

Bar Chart 3: Delirium Prevalence by Severity of TBI



4.2.3 Use of Sedatives.

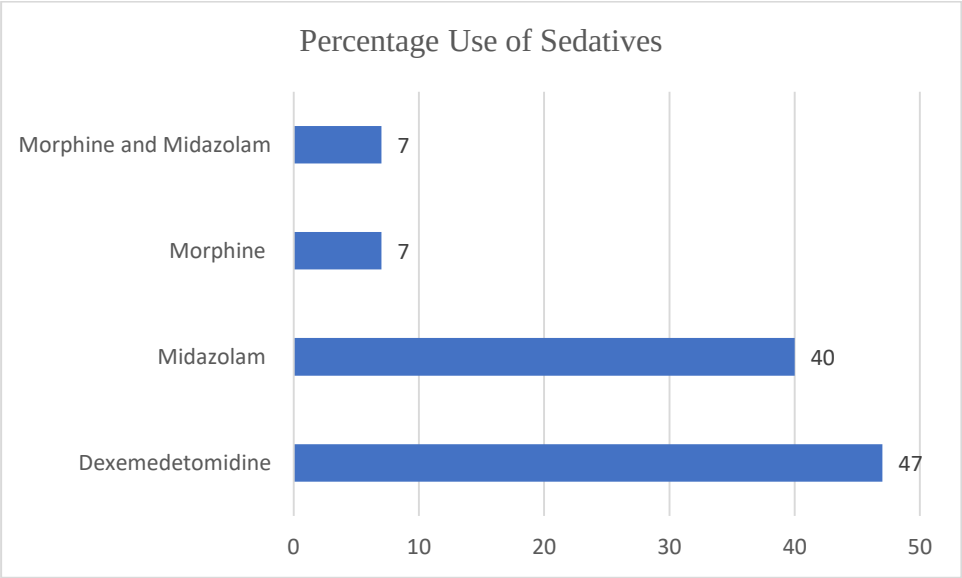
There was a higher prevalence of delirium in sedated patients, 83% (15/18), versus non-sedated patients 57.4% (58/101). The prevalence ratio was1.45; 95% CI, 0.89 to 1.51

The proportion of patients receiving sedation was smaller (18/119), compared to those who did not receive sedation (101/119).

The P value (0.003) shows sedatives as a statistically significant value.

The types of sedatives used are represented with increasing frequency in bar chart 4 below.

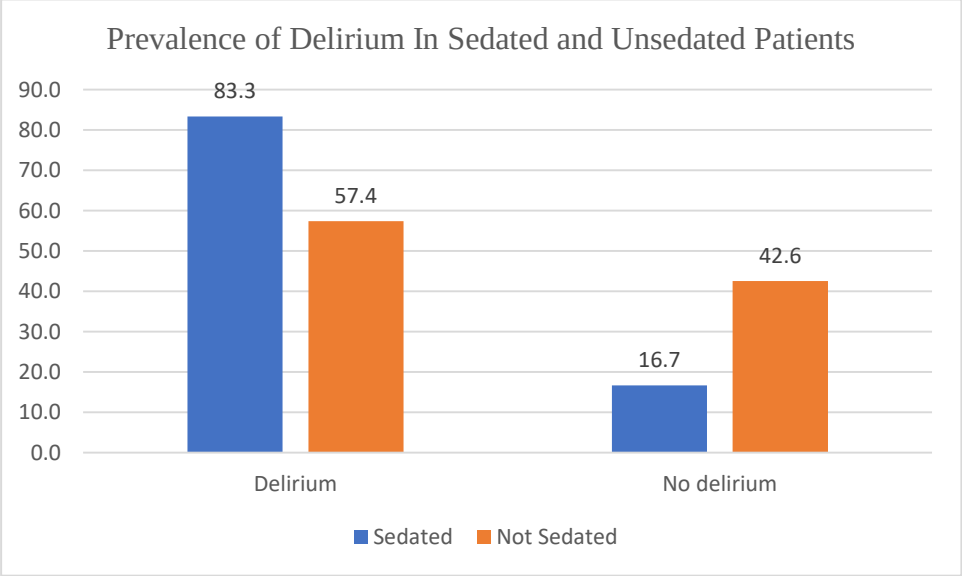
Bar Chart 4: Type of Sedatives in Use



The number of evaluated patients who were sedated was too small to permit a subgroup analysis of the relationship between sedative type and prevalence of delirium.

The prevalence of delirium in sedated and unsedated patients is shown in the bar chart below.

Bar Chart 5: Prevalence of Delirium by Sedation

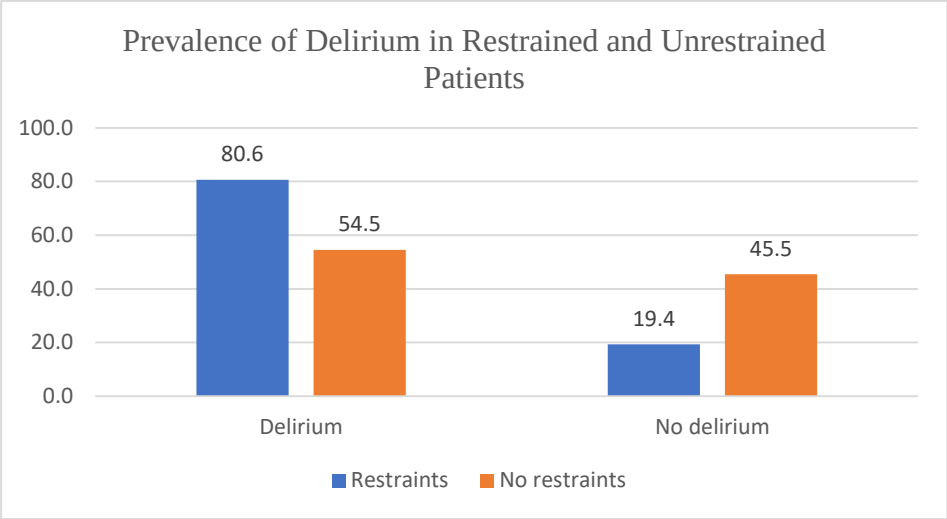


4.2.4 Use of Restraints

There was use of restraints 31/119(26%), and delirium was more common in restrained patients, 80.6%(25/31), unlike unrestrained ones 54.5%(48/88). The prevalence ratio was 1.47; 95%CI 0.90 to 1.5. P value (0.01) showed this value to be statistically significant

We represent the prevalence of delirium in restrained and unrestrained patients in the bar chart below.

Bar Chart 6: Prevalence of Delirium in Unrestrained and Restrained Patients

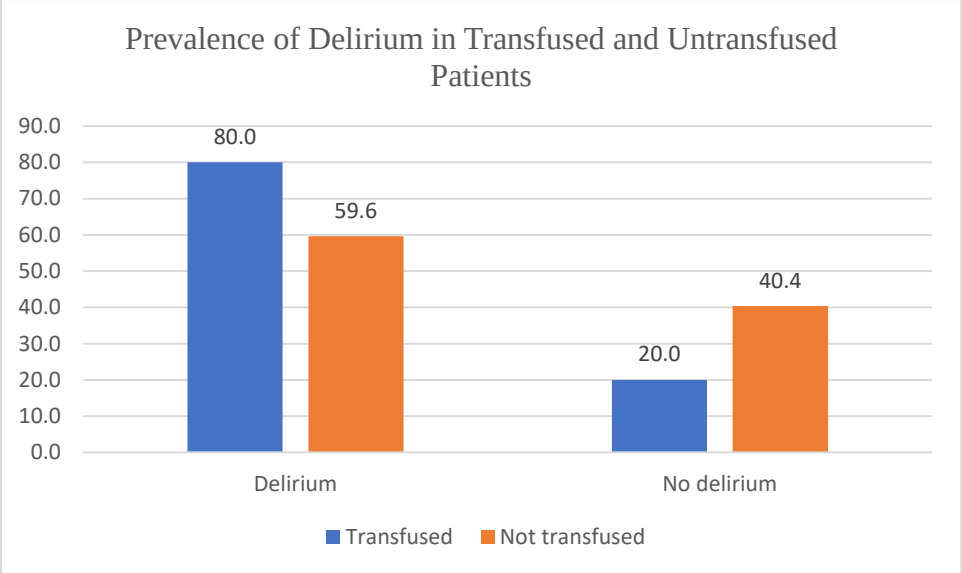


4.2.5 Blood Transfusion

Blood transfusion was done in 10/119(8.4%) of patients. Delirium was more common in transfused patients, 80% (8/10), unlike untransfused ones 59.6% (65/109). The prevalence ratio was 1.34; 95% CI , 0.82 to 1.64. This was statistically insignificant as shown by P value (0.21)

Bar chart 7 compares the prevalence of delirium in patients who got blood transfusion with those who did not.

Bar Chart 7: Prevalence of Delirium in Transfused and Untransfused Patients



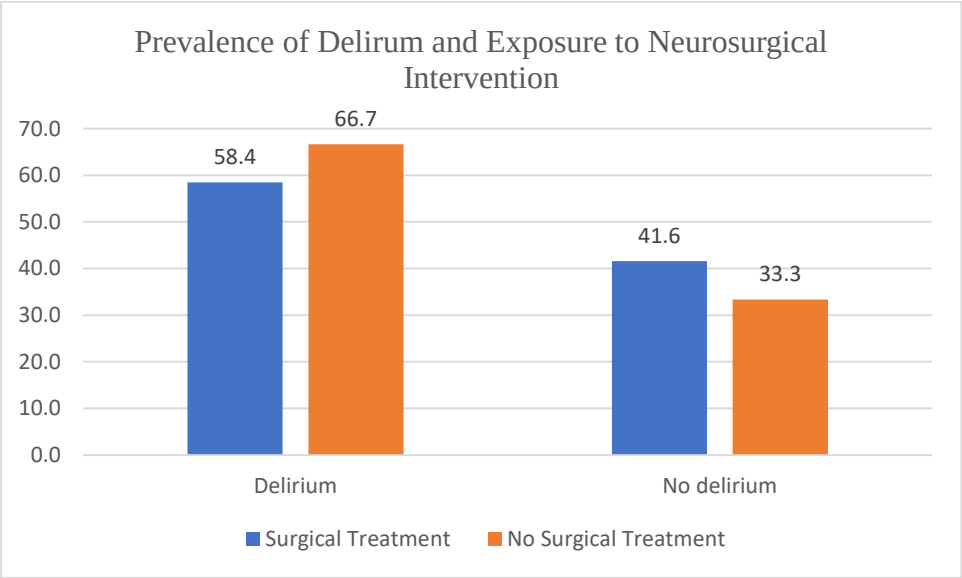
4.2.6 Surgical Intervention

There was surgical intervention for 10/119(8.4%) of patients. Delirium was less common in patients who underwent neurosurgical procedures, 58.4%(45/77), unlike those managed by non-surgical means 66.7%(28/42). The prevalence ratio was 0.88; 95% CI, 0.87 to 1.54.

P value (0.38) showed this value to be statistically insignificant.

The bar chart below illustrates the differences in prevalence of delirium between patients who underwent neurosurgical procedures and those who did not.

Bar Chart 8: Prevalence of Delirium and Exposure to Neurosurgical Intervention



CHAPTER 5: DISCUSSION

Delirium in traumatic brain injury is a universal burden that is under-recognized and hence not managed appropriately.[4] Delirium is documented to cause increased morbidity and mortality in patients with traumatic brain injury.[4-6] Early recognition and management have been demonstrated to lead to better outcomes. Studies of delirium in this population have led to evolution of the management strategies and continued research efforts are ongoing.

We evaluated patients with a diagnosis of TBI by consecutive sampling during admission at the Kenyatta National Hospital for delirium in a sample of 119 patients. The prevalence of delirium in TBI was 61.3% among these patients. These findings were similar to a study by Nakase-Thompson et al.[12] on acute confusion following traumatic brain injury where the prevalence of delirium was 69%.

Our study showed that more males than females had a diagnosis of TBI. A study by Shisoka JM et al. found that more males presented with a diagnosis of TBI (89%) at the KNH[30]. Different sampling methods were adopted in these studies i.e., consecutive sampling in our study and purposive sampling in the study by Shisoka with both giving a similar conclusion. Similar findings in these two studies suggest that males were more likely to present with a diagnosis of TBI in the population of patients admitted to the KNH. Whereas Shisoka JM et al did not describe the specific types of head injury in their study, we found in our study that diffuse axonal injury was the commonest specific diagnosis of TBI (29%).

We determined that females were at a higher risk of developing delirium, similar to a study by Hansen PM et al.[34] There were more males than females sampled in their study and this is also similar to our study. An equal number of male and female TBI patients would need to be sampled for prevalence ratio as a measure of association to be accurately applied. The significantly lower number of females in our study compared to Martin et al., may have led to sampling bias. This is because we used consecutive sampling in an environment where TBI is known to be more common in males[30], making the lower number of females affect the prevalence ratio.

The severity of TBI was classified using the Glasgow Coma Scale (GCS) as mild (13-15), moderate (9-12) and severe (< 9). This study showed a higher prevalence of delirium in patients with a diagnosis of severe TBI (GCS<9). There is paucity of data comparing the prevalence of delirium among severe and non-severe TBI cases, and this is why the reported prevalence varies among studies. A study by Maneewong et al found that patients with lower GCS scores were more likely to develop delirium with prominent cognitive symptoms on the first day of admission.[3] This is similar to what was found in our study. Most studies do not differentiate delirium according to the severity of TBI, thus determination of prevalence by severity is difficult. This is unfortunate because severe TBI patients usually have a lower GCS and are more likely to develop delirium which is then missed.

Sedation was associated with delirium as was found in this study. This is similar to findings by Yang J et al.[35] that was done in 2017. Dexmedetomidine sedation has been shown to reduce the incidence of delirium.[35] We found in our study that dexmedetomidine was the most commonly used sedative (47%). However, the number of sedated patients in our study was too small to permit a sub-group analysis of the differences in prevalence among various sedative agents.

Restrained patients were found to be more likely to develop delirium or have worsening of symptoms according to this study. Pan Y et al, conducted a study with similar findings that found an increased risk of developing delirium in restrained patients (39.8%)[36]. Those who were restrained more than once according to Pan Y, had an even higher risk of developing delirium. However, factors such as the site, appliance used and duration of application had no effect on the incidence of delirium. The practice in KNH is that the use of restraints is not properly documented and we were unable to assess if they were placed prophylactically or started due to delirium itself. Despite this, we still conclude that the presence of restraints regardless of the indication or timing did not yield a positive outcome in terms of prevalence of delirium.

Transfusion with blood was found to increase the risk of developing delirium in this study. The SCCM[8] has identified transfusion exposure as a modifiable risk factor giving similar conclusions. The number of transfused patients in our study was small, and we did not determine if this was due to practices of restrictive rather than liberal transfusions. The number of anaemic patients could have been small, or the practice at the time of the study could have been restrictive transfusion. This assessment was beyond the scope of our study.

Patients who had undergone surgical procedures in this study had a lower risk of delirium. However, studies have indicated that surgery generally increases delirium, due to factors such as pain, exposure to anaesthetic agents, prolonged fasting, and unfamiliar environments.[37] The lower prevalence of delirium in patients managed by neurosurgical procedures in our study may be due to the removal of offending agents, such as the evacuation of an intracerebral bleed, leading to faster recovery; compared to diffuse axonal injury where no surgical management options exist for reversal. There is paucity of data comparing non-surgical vs neurosurgical treatment and delirium in TBI patients. It would also be difficult to make inferences unless comparisons were to be done among patients of similar ages, diagnoses and sex. This would be ethically impossible because surgery must be done either way if it were indicated. Therefore, we cannot recommend for or against neurosurgical interventions if indicated.

CHAPTER 6

6.1 Conclusions

The prevalence of delirium was 61.3% in TBI patients at the KNH.

The identified risk factors of delirium were; severe TBI with GCS<9 (severe vs. non-severe TBI; PR, 1.5; 95% CI, 0.89 to 1.5), use of restraints (higher in use of restraints vs. no use; PR,1.47; 95% CI 0.90 to 1.50), and use of sedatives (higher in use of sedatives vs. no use; PR, 1.45; 95% CI 0.89 to 1.51).

6.2 Recommendations

1. TBI patients at the KNH should be screened for delirium since its prevalence is high.
2. More studies need to be done on delirium at the KNH, with a focus on being controlled for the specific risk factors above.
3. There should be a protocol for screening delirium in TBI patients at the KNH and staff involved in the management of TBI patients be trained to use it.
4. The use of restraints should be avoided in TBI patients at the KNH
5. Dexmedetomidine should continue being used in preference to the other medications.

6.3 Limitations of the Study

Some limitations arose in the study:

1. Patients with multiple organ injuries that may contribute to delirium were only assessed based on the TBI diagnosis and not the contribution of the other organs.
2. The study may not be generalized to the whole population as it was carried out in a single institution, the Kenyatta National Hospital.
3. Recent unknown substance use could taint the results of the patients being assessed.

6.4 Dissemination and Application of the Study Results

The data collected and analyzed were shared with the involved departments at the KNH and the University of Nairobi.

The study results will be availed to KNH-UoN Ethics and Research Committee, the University of Nairobi Library, and the University of Nairobi Online Repository.

A publication of the results will be done in a peer-reviewed scientific journal.

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APPENDICES

APPENDIX 1: DATA COLLECTION TOOL

A: Demographic characteristics:

Age:

Sex:

Date of admission:

Diagnosis:

GCS at admission:

Surgical Intervention: Yes/No

Name of sedative agent used if any:

Pre-existing substance use: Yes/No

Blood transfusion: Yes/No

Use of restraints: Yes/No

B. ICDSC TOOL

Intensive Care Delirium Screening Checklist (ICDSC)

1. Altered level of consciousness. Choose one from A to E		
A. Exaggerated response to normal stimulation	SAS = 5, 6, 7 or RASS = +1 to +4	(1 point)
B. Normal wakefulness	SAS = 4 or RASS = 0	(0 points)
C. Response to mild or moderate stimulation (follows commands)	SAS = 3 or RASS = −1 to −3	(1 point)
D. Response only to intense and repeated stimulation (e.g., loud voice and pain)	SAS = 2 or RASS = −4	Stop assessment
E. No response	SAS = 1 or RASS = −5	Stop assessment
2. Inattention (1 point if any present)		
A. Difficulty in following commands or		
B. Easily distracted by external stimuli or		
C. Difficulty in shifting focus		
Does the patient follow you with their eyes?		
3. Disorientation (1 point for any abnormality)		
A. Mistake in either time, place, or person		
Does the patient recognize ICU caregivers who have cared for him/her and not recognize those who have not? What kind of place are you in? (list examples)		
4. Hallucinations or delusions (1 point for either)		
A. Equivocal evidence of hallucinations or a behavior due to hallucinations (hallucination = perception of something that is not there with no stimulus) or		
B. Delusions or gross impairment of reality testing (delusion = false belief that is fixed/unchanging)		
Any hallucinations now or over past 24 hr? Are you afraid of the people or things around you? (fear that is inappropriate to the clinical situation)		
5. Psychomotor agitation or retardation (1 point for either)		
A. Hyperactivity requiring the use of additional sedative drugs or restraints in order to control potential danger (e.g., pulling IV catheters out or hitting staff) or		
B. Hypoactive or clinically noticeable psychomotor slowing or retardation		
Based on documentation and observation over shift by primary caregiver		
6. Inappropriate speech or mood (1 point for either)		
A. Inappropriate, disorganized, or incoherent speech or		
B. Inappropriate mood related to events or situation		
Is the patient apathetic to current clinical situation (i.e., lack of emotion)?		
Any gross abnormalities in speech or mood? Is patient inappropriately demanding?		
7. Sleep/wake cycle disturbance (1 point for any abnormality)		
A. Sleeping < 4 hr at night or		
B. Waking frequently at night (do not include wakefulness initiated by medical staff or loud environment) or		
C. Sleep ≥ 4 hr during day		
Based on primary caregiver assessment		
8. Symptom fluctuation (1 point for any)		
Fluctuation of any of the above items (i.e., 1–7) over 24 hr (e.g., from one shift to another)		
Based on primary caregiver assessment		
Total Intensive Care Delirium Screening Checklist score (add 1–8) _____		

*Delirium assessment can not be completed in patients who are stuporous or comatose.
SAS = Riker Sedation-Agitation Scale, RASS = Richmond Agitation-Sedation Scale.
Modified from Devlin JW, Marquis F, Riker RR, et al: Combined didactic and scenario-based education improves the ability of intensive care unit staff to recognize delirium at the bedside. *Crit Care* 2008; 12:R19.

APPENDIX 2

PARTICIPANT INFORMATION AND CONSENT FORM SAMPLE ADULT CONSENT FOR ENROLLMENT IN THE STUDY

Title of Study: **PREVALENCE OF DELIRIUM IN TRAUMATIC BRAIN INJURY PATIENTS AT THE KENYATTA NATIONAL HOSPITAL**

Principal Investigator and institutional affiliation: **Dr. Angela Amondi Otedo, MB ChB.**

Postgraduate student in Psychiatry, University of Nairobi.

Co-Investigators and institutional affiliation: None

Introduction: I would like to tell you about a study being conducted by the above listed researchers. 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. This process is called 'informed consent'. Once you understand and agree to be in the study, I will request you to sign your name on this form. You should understand the general principles which apply to all participants in a medical research:

i) Your decision to participate is entirely voluntary
ii) You may withdraw from the study at any time without necessarily giving a reason for your withdrawal
iii) Refusal to participate in the research will not affect the services you are entitled to in this health facility or other facilities. We will give you a copy of this form for your records. May I continue? YES / NO

This study has approval by The Kenyatta National Hospital-University of Nairobi Ethics and Research Committee protocol No. _____

WHAT IS THIS STUDY ABOUT

The researchers listed above are interviewing individuals with a history of traumatic brain injury in the critical care units. The purpose of the interview is to find out how many patients

present with delirium after traumatic brain injury. Participants in this research study will be asked questions to evaluate their level of consciousness, attention, sleep cycle disturbances, appropriateness of speech and presence of disorientation or hallucinations. Participants will also have the choice to undergo lab tests to assess other factors that may contribute to worsening of delirium symptoms. There will be approximately 119 participants in this study randomly chosen. We are asking for your consent to consider participating in this study.

WHAT WILL HAPPEN IF YOU DECIDE TO BE IN THIS RESEARCH STUDY?

If you agree to participate in this study, the following things will happen: You will be interviewed by a trained interviewer in a private area where you feel comfortable answering questions. The interview will last approximately thirty minutes. After the interview has finished, (explain in details any procedures that are necessary e.g blood draws, counseling etc.) We will ask for a telephone number where we can contact you if necessary. If you agree to provide your contact information, it will be used only by people working for this study and will never be shared with others. The reasons why we may need to contact you include: to update you on study results or get clarification of information previously shared.

ARE THERE ANY RISKS, HARMS DISCOMFORTS ASSOCIATED WITH THIS STUDY?
Medical research has the potential to introduce psychological, social, emotional and physical risks. Effort should always be put in place to minimize the risks. One potential risk of being in the study is loss of privacy. We will keep everything you tell us as confidential as possible. We will use a code number to identify you in a password-protected computer database and will keep all of our paper records in a locked file cabinet. However, no system of protecting your confidentiality can be absolutely secure, so it is still possible that someone could find out you were in this study and could find out information about you. Also, answering questions in the interview may be uncomfortable for you. 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. It may be embarrassing for you to have to answer personal questions e.g history of substance abuse or chronic illnesses. We will do everything we can to ensure that this is done in private. Furthermore, all study staff and interviewers are professionals with special training in these examinations/interviews. You will be evaluated multiple times in a day which may be

stressful. In case of an injury, illness or complications related to this study, contact the study staff right away at the number provided at the end of this document. The study staff will treat you for minor conditions or refer you when necessary.

ARE THERE ANY BENEFITS BEING IN THIS STUDY? You may benefit by receiving free Counselling on how to cope in patients who have had a diagnosis of delirium and health information .We will refer you to a hospital for care and support where necessary. Also, the information you provide will help us better understand how to identify patients with delirium in traumatic brain and intervene early to reduce the mortality and morbidity it causes. This information is a contribution to science and planning for better care in relation to mental health.

WILL BEING IN THIS STUDY COST YOU ANYTHING?

You will not be required to pay for any services or participation in this study.

WILL YOU GET REFUND FOR ANY MONEY SPENT AS PART OF THIS STUDY?

You will not get any payment for participating in this study.

WHAT IF YOU HAVE QUESTIONS IN FUTURE?

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 at the bottom of this page.

For more information about your rights as a research participant you may contact the Secretary/Chairperson, Kenyatta National Hospital-University of Nairobi Ethics and Research Committee Telephone No. 2726300 Ext. 44102 email uonknh_erc@uonbi.ac.ke.

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

WHAT ARE YOUR OTHER CHOICES? Your decision to participate in research is voluntary. You are free to decline participation in the study and you can withdraw from the study at any time without injustice or loss of any benefits.

CONSENT FORM (STATEMENT OF CONSENT) Participant's statement I have read this consent form or had the information read to me. I have had the chance to discuss this research study with a study counselor. I have had my questions answered in a language that I understand. The risks and benefits have been explained to me. I understand that my participation in this

study is voluntary and that I may choose to withdraw any time. I freely agree to participate in this research study. I understand that all efforts will be made to keep information regarding my personal identity confidential.

By signing this consent form, I have not given up any of the legal rights that I have as a participant in a research study. I agree to participate in this research study: Yes No

I agree to have (define specimen) preserved for later study: Yes No

I agree to provide contact information for follow-up: Yes No

Participant printed name: _____

Participant signature / Thumb stamp _____ Date _____

Researcher's statement

I, the undersigned, have fully explained the relevant details of this research study to the participant named above and believe that the participant has understood and has willingly and freely given his/her consent.

Researcher's Name: _____ Date: _____

Signature _____

Role in the study: _____ [i.e. study staff who explained informed consent form.]

For more information contact _____ at _____ from _____ to _____

Witness Printed Name (If witness is necessary, A witness is a person mutually acceptable to both the researcher and participant)

Name _____ Contact information _____

Signature /Thumb stamp: _____ Date; _____

APPENDIX 3

TAARIFA NA FOMU YA MSHIRIKI MFANO WA RIDHAA YA KUJIANDIKISHA KATIKA MASOMO

Kichwa cha Utafiti: KUENEA KWA DELIRIUM KATIKA WAGONJWA WA KUJERUHIA UBONGO KATIKA HOSPITALI YA TAIFA YA KENYATTA.

Mpelelezi Mkuu na uhusiano wa kitaasisi: Dr. Angela Amondi Otedo, MB ChB.

Postgraduate student in Psychiatry, University of Nairobi.

Wachunguzi-wenza na uhusiano wa kitaasisi: Hakuna

Utangulizi: Ningependa kukuambia kuhusu utafiti unaofanywa na watafiti walioorodheshwa hapo juu. Madhumuni ya fomu hii ya idhini ni kukupa taarifa utakayohitaji ili kukusaidia kuamua kama kuwa mshiriki au la katika utafiti. Jisikie huru kuuliza maswali yoyote kuhusu madhumuni ya utafiti, nini kitatokea ikiwa utashiriki katika utafiti, hatari na manufaa yanayoweza kutokea, haki zako kama mtu wa kujitolea, na kitu kingine chochote kuhusu utafiti au fomu hii ambacho hakiko wazi. Wakati tumejibu maswali yako yote kwa kuridhika kwako, unaweza kuamua kuwa katika utafiti au la. Utaratibu huu unaitwa 'ridhaa iliyoarifiwa'. Ukishaelewa na kukubali kuwa katika utafiti, nitakuomba utie sahihi jina lako kwenye fomu hii. Unapaswa kuelewa kanuni za jumla zinazotumika kwa washiriki wote katika utafiti wa matibabu:

i) Uamuzi wako wa kushiriki ni wa hiari kabisa

ii) Unaweza kujiondoa kwenye utafiti wakati wowote bila ya kutoa sababu ya kujiondoa kwako

iii) Kukataa kushiriki katika utafiti hakutaathiri huduma unazostahili kupata katika kituo hiki cha afya au vituo vingine. Tutakupa nakala ya fomu hii kwa rekodi zako. Naweza kuendelea? NDIO LA

Utafiti huu umeidhinishwa na Itifaki ya Kamati ya Maadili na Utafiti ya Hospitali ya Kitaifa ya Kenyatta-Chuo Kikuu cha Nairobi Namba.

SOMO HILI LINAHUSU NINI

Watafiti walioorodheshwa hapo juu wanawahoji watu walio na historia ya jeraha la kiwewe la ubongo katika vitengo vya utunzaji muhimu. Madhumuni ya mahojiano ni kujua wagonjwa wangapi

uwepo wa delirium baada ya jeraha la kiwewe la ubongo. Washiriki katika utafiti huu wataulizwa maswali ili kutathmini kiwango chao cha fahamu, usikivu, usumbufu wa mzunguko wa kulala, ufaafu wa usemi na uwepo wa kuchanganyikiwa au kuona. Washiriki pia watakuwa na chaguo la kufanyiwa vipimo vya maabara ili kutathmini mambo mengine ambayo yanaweza kuchangia kuzorota kwa dalili za delirium. Kutakuwa na takriban washiriki 119 katika utafiti huu waliochaguliwa bila mpangilio. Tunaomba idhini yako ya kuzingatia kushiriki katika utafiti huu.

NINI KITAENDELEA UKIAMUA KUWA KATIKA UTAFITI HUU?

Ukikubali kushiriki katika utafiti huu, mambo yafuatayo yatafanyika: Utahojiwa na mhoji aliyefunzwa katika eneo la faragha ambapo unahisi kujibu maswali. Mahojiano yatadumu takriban dakika thelathini. Baada ya mahojiano kukamilika, (eleza kwa undani taratibu zozote ambazo ni muhimu k.m kuchota damu, ushauri nasaha n.k.) Tutaomba nambari ya simu ambapo tunaweza kuwasiliana nawe ikibidi. Ukikubali kutoa maelezo yako ya mawasiliano, yatatumiwa na watu wanaofanya kazi katika utafiti huu pekee na kamwe hayatashirikiwa na wengine. Sababu ambazo tunaweza kuhitaji kuwasiliana nawe ni pamoja na: kukuarifu kuhusu matokeo ya utafiti au kupata ufafanuzi wa maelezo yaliyoshirikiwa hapo awali.

JE, KUNA HATARI, MADHARA YOYOTE YANAYOHUSISHWA NA UTAFITI HUU?

Utafiti wa kimatibabu una uwezo wa kuanzisha hatari za kisaikolojia, kijamii, kihisia na kimwili. Jitihada zinapaswa kuwekwa kila wakati ili kupunguza hatari. Hatari moja inayoweza kutokea ya kuwa katika utafiti ni kupoteza faragha. Tutaweka kila kitu unachotuambia kama siri iwezekanavyo. Tutatumia nambari ya msimbo kukutambua katika hifadhidata ya kompyuta iliyolindwa na nenosiri na tutaweka rekodi zetu zote za karatasi kwenye kabati ya faili iliyofungwa. Hata hivyo, hakuna mfumo wa kulinda usiri

wako unaoweza kuwa salama kabisa, kwa hivyo bado kuna uwezekano kwamba mtu anaweza kujua ulikuwa kwenye utafiti huu na kupata taarifa kukuhusu. Pia, kujibu maswali katika mahojiano kunaweza kuwa na wasiwasi kwako. Ikiwa kuna maswali yoyote ambayo hutaki kujibu, unaweza kuyaruka. Una haki ya kukataa mahojiano au maswali yoyote yaliyoulizwa wakati wa mahojiano. Inaweza kuwa aibu kwako kujibu maswali ya kibinafsi k.m historia ya matumizi mabaya ya dawa za kulevya au magonjwa sugu. Tutafanya kila tuwezalo kuhakikisha kuwa hili linafanyika kwa faragha. Zaidi ya hayo, wafanyakazi wote wa utafiti na wahojaji ni wataalamu walio na mafunzo maalum katika mitihani/mahojiano haya. Utatathminiwa mara kadhaa kwa siku ambayo inaweza kuwa ya kufadhaisha. Iwapo kuna jeraha, ugonjwa au matatizo yanayohusiana na utafiti huu, wasiliana na wafanyakazi wa utafiti mara moja kwa nambari iliyotolewa mwishoni mwa waraka huu. Wafanyikazi wa utafiti watakushughulikia kwa masharti madogo au watakuelekeza inapohitajika.

JE, KUNA FAIDA YOYOTE KUWA KATIKA UTAFITI HUU? Unaweza kufaidika kwa kupokea Ushauri Nasaha bila malipo juu ya jinsi ya kukabiliana na wagonjwa ambao wamegunduliwa kuwa na ugonjwa wa delirium na habari za afya .Tutakuelekeza kwa hospitali kwa huduma na usaidizi inapohitajika. Pia, maelezo utakayotoa yatatusaidia kuelewa vyema jinsi ya kutambua wagonjwa walio na kizunguzungu kwenye ubongo wenye kiwewe na kuingilia kati mapema ili kupunguza vifo na maradhi yanayosababishwa. Habari hii ni mchango kwa sayansi na mipango ya utunzaji bora kuhusiana na afya ya akili.

JE, KUWA KWENYE SOMO HILI LITAKUGHARIMU LOLOTE?

Hutahitajika kulipia huduma au ushiriki wowote katika utafiti huu.

JE, UTAREJESHWA KWA FEDHA ZOZOTE ULIZOTUMIA SEHEMU YA UTAFITI HUU?

Hutapata malipo yoyote kwa kushiriki katika utafiti huu.

VIPI IKIWA UNA MASWALI BAADAYE?

Ikiwa una maswali zaidi au wasiwasi kuhusu kushiriki katika utafiti huu, tafadhali piga simu au tuma ujumbe mfupi wa maandishi kwa wafanyikazi wa utafiti kupitia nambari iliyotolewa chini ya ukurasa huu.

Kwa maelezo zaidi kuhusu haki zako kama mshiriki wa utafiti unaweza kuwasiliana na Katibu/Mwenyekiti, Hospitali ya Kitaifa ya Kenyatta-Kamati ya Maadili na Utafiti ya Chuo Kikuu cha Nairobi Nambari 2726300 Ext. 44102 barua pepe uonknh_erc@uonbi.ac.ke.

Wafanyikazi wa utafiti watakulipa malipo yako kwa nambari hizi ikiwa simu ni ya mawasiliano yanayohusiana na masomo.

UCHAGUZI WAKO MENGINE NI GANI? Uamuzi wako wa kushiriki katika utafiti ni wa hiari. Uko huru kukataa kushiriki katika utafiti na unaweza kujiondoa kwenye utafiti wakati wowote bila dhuluma au hasara ya manufaa yoyote.

FOMU YA RIDHAA (TAARIFA YA RIDHAA) Taarifa ya Mshiriki Nimesoma fomu hii ya idhini au nimesomewa maelezo. Nimepata nafasi ya kujadili utafiti huu na mshauri wa utafiti. Nimejibiwa maswali yangu kwa lugha ninayoielewa. Hatari na faida zimeelezewa kwangu. Ninaelewa kuwa ushiriki wangu katika utafiti huu ni wa hiari na kwamba ninaweza kuchagua kujiondoa wakati wowote. Ninakubali kwa uhuru kushiriki utafiti huu. Ninaelewa kuwa juhudi zote zitafanywa ili kuweka maelezo kuhusu utambulisho wangu wa kibinafsi kuwa siri.

Kwa kutia saini fomu hii ya idhini, sijaacha haki zozote za kisheria nilizo nazo kama mshiriki katika utafiti wa utafiti. Ninakubali kushiriki katika utafiti huu: Ndiyo Hapana

Ninakubali (kufafanua sampuli) kuhifadhiwa kwa ajili ya utafiti wa baadaye: Ndiyo Hapana

Ninakubali kutoa maelezo ya mawasiliano kwa ufuatiliaji: Ndiyo Hapana

Jina lililochapishwa la mshiriki: _____ Sahihi ya mshiriki / Muhuri wa kidole gumba _____ Tarehe _____

Kauli ya mtafiti

Mimi, aliyetia sahihi hapa chini, nimeeleza kikamilifu maelezo muhimu ya utafiti huu kwa mshiriki aliyetajwa hapo juu na ninaamini kuwa mshiriki ameelewa na ametoa ridhaa yake kwa hiari na kwa uhuru.

Jina la Mtafiti: _____ Tarehe: _____
Sahihi

_____

Nafasi katika utafiti: _____ [i.e. wafanyikazi wa utafiti ambao walielezea fomu ya idhini iliyo na taarifa.]

Kwa habari zaidi wasiliana na _____ kwa _____ kutoka _____ hadi _____

Jina Lililochapishwa na Shahidi (Ikiwa shahidi ni muhimu, Shahidi ni mtu anayekubalika kwa pande zote mbili kwa mtafiti na mshiriki)

Jina _____ Maelezo ya mawasiliano _____ Sahihi /muhuri wa kidole gumba: _____ Tarehe; _____

APPENDIX 4

Study Timeline/Workplan

Date **Activity**	Oct 2021 to Dec 2022	Dec 2022	Dec 2022 to April 2023	April 2023 to June 2023	June 2023 to July 2023
Proposal Development					
Departmental Approval					
Institutional Ethics Clear-ance					
Data Collection					
Data cleaning and Analysis					
Thesis Compilation					
Thesis Presenta-tion and Correc-tions					
Journal Publication					August 2023

APPENDIX 5

Study Budget.

The study was sponsored by the principal investigator's savings, with the following budget in Kenya Shillings.

Item	Cost per Unit	Quantity	Total
Statistician	50000	1	40000
Stationary	3000	5	15000
Pen Drive	2500	1	2000
Portable tablet	40000	1	40000
Total			97000

Justification of the Budget.

The budget is an estimate of costs. A portable tablet was needed for data collection electronically. An extra Kshs.20000 was kept aside for incidental costs.