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Prevalence of severe neurobehavioral disorders among adults with traumatic brain injury at Mbarara Regional Referral Hospital in southwestern Uganda

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Abstract

Background Traumatic brain injuries (TBI) are frequently accompanied by neuropsychiatric disturbances. Failure to quickly assess and manage these disturbances results in neurobehavioral syndromes, with deleterious effects on recovery and rehabilitation outcomes. This study determined the prevalence and predictors of severe neurobehavioral disorders among patients with TBI at Mbarara Regional Referral Hospital in southwestern Uganda.

Methods In this cross-sectional study, we enrolled participants aged 18 years or older who were able to communicate meaningfully and had been discharged by the neurosurgical team. We obtained information on socio-demographic characteristics, alcohol use, length of stay in the hospital, Glasgow Coma Scale (GCS) score at admission, clinical diagnosis, treatments given, and investigations, including brain computed tomography scans. Neurobehavioral disorders were determined using the Neurobehavioral Rating Scale. Predictors of neurobehavioral disorders were determined using logistic regression.

Results Of the 196 participants, 139 (70.8%) were male. The Median age (interquartile range (IQR)) was 30 (23–40) years, and the median length of hospital stay (IQR) was 7 (5–10) days; median GCS (IQR) was 13/15 (10/15 – 14/15), and the prevalence of neurobehavioral disorders was 55.4%. Factors associated with neurobehavioral disorders were age > 35 years (odds ratio (O.R) = 4.7 (1.6–13.5) and > 7 days of hospital admission (O.*R* = 4.3 (1.4–13.0). Having a GCS score of 13–15 at admission was protective (O.*R* = 0.13 (0.02–0.85) against neurobehavioral disorders compared to a score of < 8.

Conclusion The high prevalence of neurobehavioral disorders among individuals with a history of TBI at the point of discharge from the hospital may affect post-discharge care. Hence, there is a need to meticulously assess and address these challenges early to improve the long-term treatment outcomes of TBI.

Clinical trial number Not applicable.

Keywords Trauma, Brain injury, Neurobehavioral disorders, Recovery, Rural Uganda

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Introduction

Trauma is an invisible but preventable epidemic with profound and lasting effects on individuals, families, and communities, especially in low- and middle-income settings [1, 2]. It encompasses injuries resulting from accidents, violence, or other harmful events. Traumatic brain injury (TBI) is one of the common forms of trauma [3], with over 90% of all TBIs occurring in developing countries, which also have limited resources and infrastructure for neurobehavioral evaluation and treatment [4]. Sub-Saharan Africa has a high rate of TBIs; young males are the most commonly affected persons, accounting for more than 75% of all cases, with widely varying approaches to management [1, 2]. In Uganda, TBI is among the top four common causes of admission in accident and emergency (A&E) departments, with a mortality of about 45.3% in intensive care units [5, 6]. At a national referral hospital, 88.9% and 11.1% of unintentional TBIs were due to road traffic accidents and falls, respectively, and the common victims were pedestrians and motorists [7].

TBI is strongly associated with the risk of developing psychiatric complications, especially with increasing age [8, 9]. Depression and anxiety disorders are the most common psychiatric complications in individuals recovering from TBI [10, 11]. Consequently, reintegration of survivors of TBI in the community and workforce becomes very difficult if they are not meticulously assessed and managed for neurobehavioral disorders.

In Uganda, despite the high number of hospital admissions for traumatic brain injury, there is limited data on neurobehavioral disorders following traumatic brain injury. This study determined the prevalence and predictors of severe neurobehavioral disorders among adults with traumatic brain injury at discharge from Mbarara Regional Referral Hospital (MRRH) in southwestern Uganda.

Methods

Study design

This was a cross-sectional study among adult individuals with traumatic brain injuries being discharged from MRRH in southwestern Uganda.

Study setting

The study was conducted at both the accident and emergency and the general surgery wards in the surgery department among adults with traumatic brain injury discharged by the neurosurgical team at MRRH in Mbarara city. The city is approximately 270 km from Kampala, the capital of Uganda, and has a population of 97,500 persons [12, 13]. The majority of the people accessing care in this hospital live in rural areas outside of Mbarara City, and families earn a living through subsistence agriculture, animal husbandry, and local trading, with documented challenges of food and water insecurity [14–16].

The surgery department consists of different specialized units: General surgery, Pediatric surgery, Neurosurgery, Plastic surgery, cardio-thoracic surgery, and orthopedic surgery. The surgery department consists of 2 neurosurgeons, 1 cardio-thoracic surgeon, 1plastic surgeon, 1 orthopedic surgeon, 1 pediatric surgeon, and 5 general surgeons. The neurosurgical team comprises 2 neurosurgeons, neurosurgery fellows, and resident senior medical house officers. The neurosurgical team at the hospital admits about 50 neurosurgical patients (including TBI and spine injuries, and tumors) a month.

Study population

The study included patients admitted to this hospital with a history of TBI who had undergone treatment by the neurosurgical team and were ready for discharge. These were aged above 18 years and were able to comprehend and respond to interviewers. Since the study involved data extraction from patients' medical records, patients with missing medical charts were excluded. Additionally, patients with a history of any psychiatric admission and those with a history of comorbid diagnosis of brain illness, such as stroke and seizures before TBI, were also excluded from this study. This was ascertained through review of medical records and participant reports.

Sample size and sampling

The sample size was 196 participants, calculated using the Kish-Leslie formula at a 95% confidence interval, 5% precision, and a prevalence of neuropsychiatric disorders of 85% [8, 17]. Convenience sampling was used, and participants were recruited consecutively.

Study measures

Exposure variables

The following independent variables were obtained from the patients: age, sex, level of education, district of residence, marital status, occupation, mechanism of injury, employment status, religion, and substance use history.

The following exposure variables were obtained from the patient's chart: mechanism of injury, admission Glasgow Coma Scale (GCS) score [18, 19], post-traumatic amnesia (PTA), history of Loss of Consciousness, Computed Tomography Scan diagnosis and clinical diagnosis, and duration of hospital stay.

Outcome variables

Neurobehavioral disorders were determined using the Neurobehavioral Rating Scale-Revised (NRSR) [20, 21]. The NRSR is a multidimensional improved Neurobehavioral Rating Scale (NRS) that was derived from the Psychiatric Rating Scale and modified to increase its content

validity with respect to the behavioral manifestations of TBI. It was used to assess patients for reduced alertness, hyperactivity and agitation, disorientation, attentional difficulties, difficulties in articulation, difficulties in oral expression, difficulties in oral comprehension, memory difficulties, motor slowing, exaggerated somatic concern, self–appraisal difficulties, hallucination, and unusual thought content. Other areas assessed using the NRSR include anxiety, depressive mood, guilt, lability of mood, blunted affect, irritability, disinhibition, excitement, hostility, suspiciousness, emotional withdrawal, conceptual disorganization, difficulty in mental flexibility, difficulty in planning, decreased initiative or motivation, and mental fatigability. All of the above were scored as absent (0), mild (1), moderate (2), or severe (3).

The 29 dependent variables are categorized into 5 domains as per previous studies done using the same tool: (F1) intentional behavior, (F2) emotional state, (F3) survival-oriented behavior, (F4) arousal state, and (F5) language. The rating for each item as per the domain is defined based on potential impact on the behavior of social and occupational independence [21].

Data extraction tool

We formulated a patient file data extraction tool to collect clinical information about the patient details, including admission GCS, PTA, brain computed tomography (CT) findings, and clinical diagnosis (see supplement 1).

Social demographic questionnaire

We also formulated a questionnaire to capture important information, including patient biodata, relevant psychiatric history, and TBI history (see supplement 2).

Both the data extraction tool and social demographic questionnaire were developed specifically for use during this study by a team of experts including a senior consultant neurosurgeon, neurosurgery fellow, senior consultant psychiatrists and psychiatry residents, emergency physician, and a general practitioner.

Data collection

All participants provided written informed consent. A trained research assistant formulated a research identification number for each enrolled patient and interviewed the patient using the pretested comprehensive questionnaire that included a social demographic questionnaire and the Neurobehavioral Rating Scale-Revised (NRSR). An English- and Runyankore/Rukiga (local dialect) speaking clinician assessed adult post-traumatic brain injury patients at discharge from the accident and emergency unit or the surgery ward at MRRH. The patients' files were assessed for more relevant information using a pretested patient file extraction tool with the same patient's research identification number.

Participant recruitment

Data were collected from October 18, 2017 to March 01, 2018. One hundred ninety-six participants were consecutively screened and were able to go through the entire interview at discharge by the neurosurgical team; therefore, they were enrolled for the study. Eighteen other participants were excluded from the study; 17 patients could not participate due to aphasia, and 1 patient was re-operated (see Fig. 1).

Data analysis

To determine the prevalence of severe neurobehavioral disorders, we considered the proportions of patients who had abnormalities in at least one of the five domains of the NRSR. The various types of severe neurobehavioral disorders were expressed as proportions as per the five respective NRSR domains. The factors associated with having severe neurobehavioral abnormality in at least one domain and the corresponding 95% confidence intervals (CIs) were determined using bivariate logistic regression analysis. To adjust for the effects of potential confounders, the forward stepwise selection method was used to construct a multivariate model including all covariates with a p-value ≤ 0.2 at the bivariate analysis stage. First, sociodemographic variables were included in the model beginning with the most significant covariate on bivariate analysis. Upon addition of significant socio-demographic factors in the model, we used the same approach to add age, sex, and brain CT scan findings into the model because of plausibility. Once a covariate was significant (p-value < 0.05) within its tier, it was retained in the final best-fit model. A significance level of < 0.05 was used at every stage of analysis to determine association.

Results

Participant characteristics

Sociodemographic characteristics of 196 study participants enrolled in the study

Of the 196 patients, 70.8% were male, 66.1% were aged ≤ 35 years, median Age (interquartile range (IQR)): 30 (23–40), and 69% were married. 77.0% had closed head injury, and 13.8% of patients were under the influence of alcohol at the time of the accident. The majority (84.7%) of the participants suffered loss of consciousness at the time of admission, and 68.4% of participants had post-traumatic amnesia. Median (IQR) GCS score at admission was 13(10–14), while the median (IQR) duration of hospital stay (IQR) was 7(5–10) days (Table 1).

Prevalence of severe neurobehavioral disorders among adult traumatic brain injured patients

The prevalence of at least one severe neurobehavioral disorder was 55.4% (95% CI: 47.9–62.2) with only 24 (12.3%) participants having deficits in all the five domains

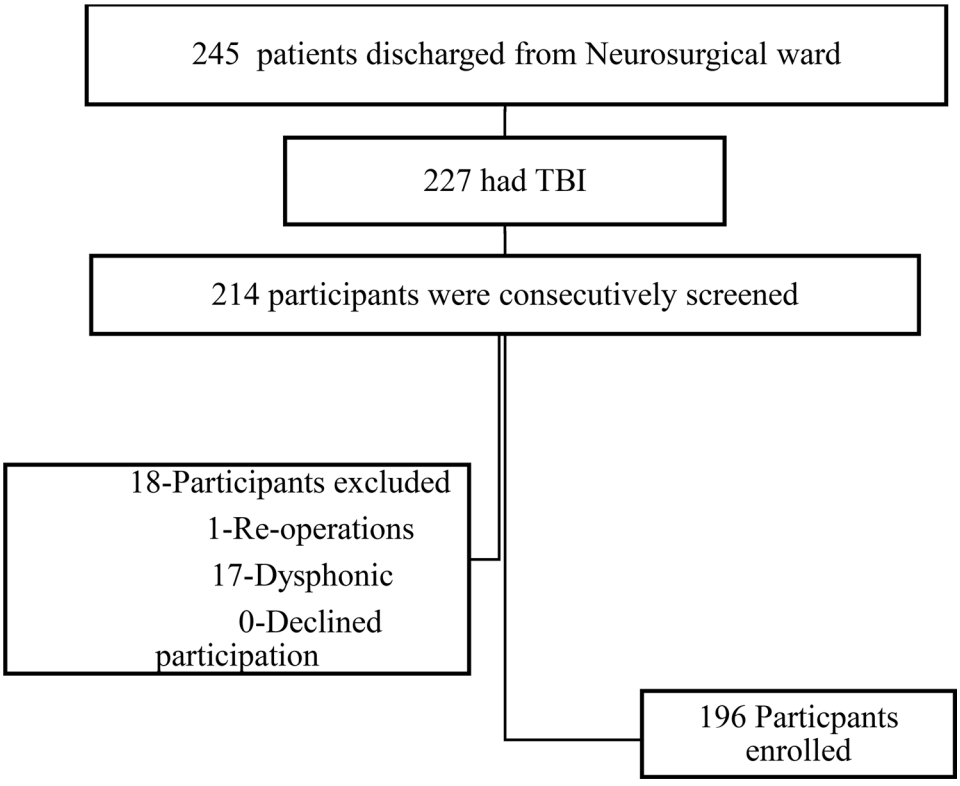


Fig. 1 Recruitment process of the study participants

of the neurobehavioral rating scale. Among the 196 participants, severe domain abnormalities in intentional behavior and arousal state were the commonest at 45.2% each (Table 2).

Considering all the sub-domains, disorientation and memory difficulties (under intentional behavior domain) were the commonest (18.8% each) followed by difficulty in planning (15.8%) and difficulty in oral expression (15.5%) under the language domain. There was no severe irritability, excitement, hostility and suspiciousness for all participants (Table 3).

Factors associated with the risk of neurobehavioral disorders

In the bivariate analysis, the factors that were associated with neurobehavioral change included age ≥ 35 years (OR 3.0; 95% CI 1.4–6.7; p-value 0.005), duration of admission ≥ 7 days (OR 4.3; 95% CI 2.0-6.4; p-value 0.001) and any head injury that resulted into a subdural hematoma (OR 3.7; 95% CI 1.03–13.1; p-value 0.04), epidural hematoma (OR 4.7; 95% CI 1.0–11.0, p-value 0.04) and others (skull fracture, intraventricular bleeds) (OR 3.5; 95% CI 1.0-11.4 p-value 0.04). In the final logistic regression model, even after adjusting for duration of admission, admission GCS score, loss of consciousness, post-traumatic amnesia, and brain CT scan diagnosis, age and duration of admission were significantly associated with cognitive and neuropsychiatric behavioral disorders among adult post-traumatic brain injury. Adults of 35 years of age and above with post-traumatic brain injury were 4.7 times more likely to have cognitive and neuropsychiatric behavioral disorders as compared to those below 35 years of age (adjusted OR (aOR): 4.7, 95% CI: 1.6–13.5, p-value 0.004). Longer duration of admission of at least 7 days for adults with post-traumatic brain injury was associated with 4.34 odds of having cognitive and neuropsychiatric behavioral disorders as compared to shorter duration of admission of less than 7 days. (aOR: 4.3, 95% CI: 1.4–13.0, p-value 0.009). Having a higher GCS score [13–15] was a protective against neurobehavioural disorders compared to GCS score of ≤ 8 (aOR: 0.13, 95% CI: 0.02–0.9, p-value 0.033). Table 4 summarizes the logistic regression of risk factors associated with neuropsychiatric behavioral disorders among 196 enrolled participants.

Discussion

In this study, we aimed at determining the prevalence of neurobehavioral disorders among adult traumatic brain-injured patients at discharge from MRRH. We found a high prevalence of 55% neurobehavioral disturbances among these patients which were associated with GCS score at admission, age, and duration of admission. These findings further emphasize those of existing studies which have indicated that patients with traumatic brain

Table 1 Sociodemographic and clinical characteristics of study participants ($n=196$)

Factor	Frequency (%)
Gender	
Male	139 (70.8)
Female	57 (29.2)
Age- Median (IQR)	30 (23 – 4)
≤ 35 years	130(66.2)
> 35 years	66(33.9)
Marital status	
Married	136(69.2)
Single	56(28.5)
Others	5(2.3)
District of origin	
Mbarara	59 (30.0)
Isingiro	21 (10.8)
Others	116 (59.2)
Tribe	
Nkole	134 (68.5)
Kiga	44 (22.3)
Others	18 (9.3)
Religion	
Catholic	98 (50.0)
Anglican	83 (42.3)
Others	15 (7.7)
Occupation	
Peasant	81 (41.5)
Motor cyclist	33 (16.9)
Student	23 (11.5)
Others	59 (30.0)
Education level	
None	20 (10.2)
Primary	112 (57.1)
Secondary/Tertiary	64 (32.7)
Cause of your traumatic head injury	
Road traffic accident	152 (77.7)
Falls	11 (5.4)
Assault	32 (16.2)
Other	2 (0.8)
Have a family history of mental illness.	
Yes	21 (10.8)
No	175 (89.2)
Episodes of head injury	
Once	184(93.9)
Twice	9(4.6)
Thrice	3(1.5)
GCS-Median (IQR) 13(10–14)	
≤8	23(11.7)
9–12	64(32.8)
13–15	109(55.5)
Did patient suffer any loss of consciousness	
Yes	166(84.7)
No	30(15.3)
Post traumatic amnesia after injury	
Yes	134(68.9)
No	62(31.1)
Clinical diagnosis of the patient	
Closed Head Injury	151(77.0)
Open Head Injury	45(23.0)
Other physical injuries	
Yes	30(15.3)
No	166(84.7)
Duration of admission; median (IQR) 7(5–10) days	
> 7days	116(59.2)
≤ 7days	80(40.8)

injury suffer various neurological and behavioural disturbances beyond their hospital admission periods [22, 23]. However, the heterogeneity of the measures used in the various studies limits comparability. Unlike most existing studies which have focused on long term impact of TBI [24, 25], this study provides preliminary results on the acute neurobehavioral disorders before their reintegration back into the community.

The most prevalent severe neurobehavioral disturbances were under intentional behaviour (cognition) domain including disorientation, memory and planning difficulties, with additional disturbances in language domain. These are partially in line with that reported by McCauley et al. whereby majority of the participants had sever deficits in cognition specifically experiencing disorientation, planning, memory and mental flexibility difficulties 6 months after severe closed head injury [25]. Another study by deGuise et al. which assessed neurobehavioral disturbances at discharge and at 2–5 year follow up found that the commonest neurobehavioral disturbances at discharge included intentional behaviour, arousal state and language [24]. These findings also align with our study showing that TBI patients are more likely to experience intentional behaviour and language difficulties in the short-term as they recover. However, the same study by deGuise et al. also showed that these difficulties significantly improved at the 2-5year follow up. Hence in light of the above studies, we can deduce that TBI patients experience neurobehavioral difficulties which may vary and evolve over time with possibility of improvement.

A study that was conducted among 25 severe brain-injured patients, comparing them with 25 multiple trauma patients with no brain injuries, using the Neurobehavioral rating scale, further highlighted that TBI patients were at a higher risk of developing all forms of neurobehavioral difficulties compared to their non-TBI counterparts [26]. Whereas all trauma patients may have a risk of developing neurobehavioral difficulties, the risk is higher among TBI patients pointing to a heightened

Table 2 Prevalence of the common cognitive and neuropsychiatric behavioral disorders among adult post traumatic brain injured patients

Domain	Frequency (*n*)	Percentage (%)
Intentional behavior	88	45.2
Emotional state	84	43.3
Survival oriented behaviour	53	27.6
Arousal state	88	45.2
Language	51	26.6

need to evaluate them for these behavioural problems at discharge to prevent undesirable outcomes in the long term.

Several studies agree that low age and high GCS score are protective against neuropsychiatric behavioural disorders in TBI. A study done to predict long-term global outcomes after traumatic brain injury to develop a practical prognostic tool used the TBI model systems national database, reported that patients' outcomes improved with younger age, greater premorbid productivity, and higher premorbid vocational and educational achievement [27]. Also, the results of this study agree with a study conducted among patients at Level 1 Trauma Center in California which reported that unfavourable outcomes of TBI including neurobehavioral disturbances were associated with increasing patient age [28]. Although the results of the two studies are comparable to this study, most of the patients (66.15%) were less than 35 years of age, which is biologically protective from neurobehavioral disorders. Hence, with the increasing life span among developing countries like Uganda, it is important to consider

Table 3 Frequency distribution of the neurobehavioral rating disorders among adult post traumatic brain injury patients (*N* = 196)

Neurobehavioral domain	Proportion, %			
	Not present	Present/severity		
		Mild	Moderate	Severe
Intentional behavior				
Disorientation	51.6	10.9	19.5	18.0
Memory difficulties	39.1	28.1	14.8	18.0
Self-Appraisal Difficulties	66.9	11.8	13.2	7.9
Blunted Affect	51.2	26.8	19.7	2.4
Conceptual Disorganization	61.4	18.1	18.9	1.6
Difficulty in Mental Flexibility	60.6	24.4	10.2	4.7
Difficulty in Planning	54.3	22.1	7.9	15.8
Decreased Initiative or motivation	46.5	29.1	17.3	7.1
Emotional state				
Anxiety	27.6	57.5	14.2	0.8
Depressive Mood	19.5	48.4	26.6	5.5
Emotional Withdrawal	25.0	39.8	32.8	2.3
Survival oriented behaviour				
Hyperactivity and Agitation	54.7	30.5	12.5	2.3
Unusual Thought Content	79.2	16.8	3.2	0.8
Lability of Mood	75.2	12.8	9.6	2.4
Irritability	69.3	23.6	9.0	0.0
Disinhibition	82.7	7.09	4.7	5.51
Excitement	94.5	3.9	1.6	0.0
Hostility	86.6	10.2	3.2	0.0
Suspiciousness	81.9	13.4	4.7	0.0
Arousal state				
Reduced alertness	28.9	41.4	25.8	3.9
Attentional difficulties	53.5	14.2	23.6	8.7
Motor Slowing	52.3	25.8	15.6	6.3
Mental Fatigability	44.1	35.4	17.3	3.2
Language				
Difficulties in Articulation	57.8	19.5	10.9	11.7
Difficulties in Oral Expression	57.8	18.0	11.7	15.5
Difficulties in Oral Comprehension	53.9	20.3	12.5	13.3
Exaggerated somatic concern	90.6	10.0	1.0	1.0
Hallucinations	72.4	9.5	11.8	6.3
Guilt	73.2	19.7	6.3	0.8

Table 4 Logistic regression of risk factors associated with neuropsychiatric behavioral disorders among the study participants

Variable	Bivariate		Multivariate	
	OR(95%CI)	*p*-value	aOR(95%CI)	*p*-value
Age				
≤ 35 years	1		1	
> 35 years	**3.0(1.4–6.7)**	**0.005**	4.7(1.6–13.5)	**0.004***
Duration of admission				
≤7 days	1		1	
> 7 days	**4.3(2.0-6.4)**	**0.001**	4.3(1.4–13.0)	**0.009***
Glasgow coma scale (GCS)				
≤ 8	**1**			
9–12	0.50(0.1–2.1)	0.338	0.3(0.04–1.7)	0.165
13–15	0.2(0.1–0.7)	0.014	**0.13(0.02–0.9)**	**0.033**
Loss of consciousness				
No	1		1	
Yes	2.1(0.8–5.4)	0.147	1.7(0.2–8.7)	0.602
Post traumatic amnesia (PTA)				
No	1		1	
Yes	2.0(0.9–4.2)	0.076	1.6(0.4–6.6)	0.526
Brain CT scan diagnosis				
Normal	1		1	
Subdural hematoma	3.7(1.0-13.1)	**0.044**	0.9(0.2-4.0)	0.877
Epidural hematoma	4.7(1.0–11.0)	**0.045**	1.2(0.2–9.1)	0.849
Others	3.5(1.0-11.4)	**0.042**	0.9(0.2–3.9)	0.923

*statistically significant at multivariate analysis at 5% level of significance

preventive measures for neurobehavioral disturbances among older persons in the face of increasing trauma.

Our findings agree with the risk of neurobehavioral disorders at 7 days post-TBI in an Australian cohort study of adults with mild traumatic brain injury compared to those with other minor injuries [29]. Although the results of our study are comparable to the study by Ponsford et al., we retrospectively averaged the duration of participants from the day of admission to the day of neurobehavioral assessment and discharge among adult TBI patients, and 88.12% participants had mild to moderate TBI. In both studies, TBI was associated with increased risk of neurobehavioral disorders including memory problems though majority of these dissipate over time. Unlike the study by Ponsford et al., our findings indicate that the longer the hospital stay, the higher the odds of developing neurobehavioral disturbances. Longer duration of hospital stay may be a marker of severe TBI which increases risk of neurobehavioral difficulties. On bivariate analysis, the presence of hematoma (subdural, epidural, and skull fractures) was associated with neurobehavioral change. However, this association was not significant, probably because patients with hematomas are normally admitted and spend longer days on the ward.

The clinical and public health significance of such high levels of associations of GCS, age, and duration of admission with cognitive and neurobehavioral change in a relatively young patient population is seriously worrying and warrants medical interventions.

Study limitations

This study had some limitations. First, the tool has not been validated in African settings; however, it has been heavily used in Europe, Asia, and North American settings with consistent results. Secondly, this was a one-center study, which may not exactly reflect the risk of developing neurobehavioral disorders after TBI in other parts of Uganda, hence affecting the generalization of findings. Finally, the center had technical challenges with its free brain CT scan services, which limited our sample size as some potential participants could not have CT scan done.

Conclusion and recommendations

The findings of this study demonstrate the importance of neuropsychiatric behavioral disorders/difficulties assessment among all patients who present with TBI before being discharged from the hospital. The study highlights the need to design comprehensive biopsychosocial approaches in the management of all TBI patients. This is because neurobehavioral disorders are due to a complex and dynamic interaction between neurobiological, personal, and environmental factors (e.g., problematic and anxiety-inducing situations related to brain injury). Therefore, integrated multidisciplinary approaches should be prioritized for the management of TBI patients, such as Speech therapists, physiotherapists, neuropsychiatric care, occupational therapists, and social workers, to optimize health outcomes. Further longitudinal studies

are required to provide a better understanding of the long-term neurobehavioral sequelae of TBI.

Abbreviations

A&E	Accident and emergency
aOR	Adjusted odds ratio
CI	Confidence intervals
CT	Computed tomography
GCS	Glasgow coma scale
IQR	Interquartile range
MRRRH	Mbarara Regional Referral Hospital
NRS	Neurobehavioral Rating Scale
NRSR	Neurobehavioral Rating Scale-Revised
O.R	Odds ratio
PTA	Post-traumatic amnesia
TBI	Traumatic brain injuries

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12888-026-08427-w.

Supplementary Material 1

Supplementary Material 2

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Author contributions

BS conceived the idea, secured funding, wrote proposal, and participated in data collection, analysis and interpretation. JK contributed to conception of idea, proposal writing, data analysis, and interpretation and drafted the first manuscript draft. GZR, SA, DK and SM contributed to proposal development, study implementation, data analysis and interpretation. CEA contributed to study implementation, data collection, management, analysis and interpretation. All authors reviewed all versions of manuscripts and approved the final version.

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Data availability

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethical approval and consent to participate

Ethical approval to conduct the study was obtained from Mbarara University of Science and Technology Research Ethics Committee (number: 29/05–17). In addition, permission to collect data was sought from the administrators of both MRRH. Written informed consent was obtained from all participants prior to participation in the study. The study protocol writing and implementation was in adherence to the Declaration of Helsinki.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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