CLINICAL CHARACTERISTICS AND OUTCOMES OF TRAUMATIC BRAIN INJURY IN PATIENTS ADMITTED TO SURGICAL WARD OF JIMMA MEDICAL CENTER, SOUTHWEST ETHIOPIA

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A THESIS TO BE SUBMITTED TO SCHOOL OF PHARMACY, INSTITUTE OF HEALTH, JIMMA UNIVERSITY FOR THE PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR MASTER OF SCIENCE (MSc.) DEGREE IN CLINICAL PHARMACY

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Abstract

Introduction: Traumatic brain injury (TBI) has become a major public health issue, affecting about 69 million people every year globally. Despite evidence showing the incidence of TBI is high in low-and middle-income countries (LMICs), including Ethiopia, studies assessing the clinical profile and outcomes of TBI are limited.

Objective: The study aimed to assess the clinical profile and outcomes of TBI in patients admitted to the surgical ward of Jimma Medical Center (JMC) from January to July 2022.

Methods: A hospital-based prospective observational study was conducted involving patients admitted with TBI at the surgical ward of JMC from January to July 2022. Structured questionnaires were used to collect data, and a convenient sampling technique was used. For data entry, Epidata version 4.6.0.5 software was used and exported to Stata version 14.0.2 for data analysis. Bivariate Cox regression was conducted to see if there were associations between the dependent and independent variables. A multivariate Cox regression was conducted to evaluate the predictors of mortality. Variables having p-values of < 0.05 were considered statistically significant.

Results: A total of 175 patients were recruited for the study. Of these, 126 (72 %) were males, with a mean (±standard deviation) age of 29.82±10.8 years. Hypoxia (30.86%) and anemia (15.8 %) were the common clinical profiles observed on admission. The incidence of in-hospital complications and in-hospital mortality were 32.0 % and 22 (12.6 %), respectively. The mean length of hospital stay was 5.66±0.34 days. A GCS score of < 8 on admission [Adjusted hazard ratio (AHR) =6.2, 95% CI, 0.75-51, p=0.004)], hyperthermia (AHR: 1.7, 95% CI, 1.02-3.05, p=0.043), and lack of pre-hospital care (AHR: 3.2, 95% CI, 2.2-8.07, p=0.005) were predictors of mortality in TBI patients.

Conclusion and recommendation: Over one-tenth of TBI patients died and more than one-fourth of patients had in-hospital complications during hospitalization. The GCS score of < 8 on admission, hyperthermia, and lack of pre-hospital care were the factors affecting outcome of TBI patients. Screening of patients for antipsychotics should be strengthened.

Key terms: Brain injuries, Clinical outcomes, Traumatic, Ethiopia

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List of abbreviations and acronyms

CDC: Center of Disease Control and prevention

CT: Computed Tomography

EDH: Epidural Hematoma

ENT: Ear, Nose and Throat

GCS: Glasgow Coma Scale

GOSE: Extended-Glasgow Outcome Scale

GOS: Glasgow Outcome Scale

H2RAs: Histamine-2 Receptor Antagonists

HICs: High Income Countries

ICP: Increased Cerebral Pressure

ICU: Intensive Care Unit

ISS: Injury Severity Score

JMC: Jimma Medical Center

LMICs: Low- and Middle-Income Countries

LOC: Loss of Consciousness

LOS: Length of hospital stay

MVA: Motor Vehicle Accident

NICE: National Institute for Health and Care Excellence

PTS: Posttraumatic Seizure

PPIs: Proton Pump Inhibitors

RTA: Road Traffic Accident

RTS: Revised Trauma Score

TBI: Traumatic Brain Injury

SDH: Subdural Hematoma

SSA: Sub-Saharan Africa

SSIs: Surgical site infections

SPSS: Statistical Package for Social Sciences

USA: United States of America

WHO: World Health Organization

1. INTRODUCTION

1.1 Background

Traumatic brain injury (TBI) is an alteration in brain function and other signs of brain disease induced by an external force (1). It is classified as mild, moderate, and severe TBI based on the Glasgow Coma Scale (GCS), which is determined at the moment of injury. Mild TBI is defined by a GCS score of 13–15, moderate as 9–12, and severe as 3–8 (2). Severe TBI has a significant mortality rate, which has been estimated to be between 30 and 40 %, and survivors face significant physical, mental, emotional, and cognitive impairments, which interrupt people's lives and cost society a lot of money. Such limitations are present not only in situations of severe TBI but also in cases of moderate and mild TBI (3).

TBI continues to be a major cause of morbidity and mortality worldwide and is the most frequent reason for a neurosurgical emergency visit. About 69 million people experience a TBI per year (4), and it is becoming one of the top three particular neurological diseases that account for neurological disability globally, both now and in the future (5).

Road traffic accidents (RTAs) are the primary cause of TBI cases, though the damage pattern varies by region. Patients with TBI in low- and middle-income countries (LMICs) are frequently vulnerable road users like pedestrians, cyclists, and motorcyclists. Patients in high-income countries (HICs) are frequently motor vehicle occupants (6). Anybody can suffer a TBI, but those who are at higher risk include young people, low-income individuals, members of ethnic minority groups, people who live in cities, those who have a history of substance misuse, men, and those who have already suffered a TBI (7).

Neurological symptoms like loss of consciousness (LOC), confusion or disorientation, lethargy, obtundation, stuperousness, and signs of higher intracranial pressure (ICP) such dizziness, nausea, and vomiting are among the clinical characteristics of TBI (8). Generalized seizures, posttraumatic amnesia, vertigo, a mild to severe headache, limb weakness, and paresthesia are other neurologic symptoms (9).

The diagnosis of a TBI is typically made by combining a history of external head trauma with the manifestation of impaired neurologic function and/or physical signs of head trauma. Some of

the laboratory tests used to indicate compromised ventilation, and TBI due to intoxication include arterial blood gases (ABGs), blood ethanol levels, and urine drug testing. Cerebrospinal fluid (CSF) otorrhea or rhinorrhea are physical examination findings in TBI patients, along with skull fractures and scalp lacerations. An essential tool for establishing TBI and keeping track of patients over time is a head computed tomography (CT) scan (9,10).

The management of TBI depends on its severity. It must be recognized that almost all forms of treatment for TBI are geared towards the minimization of secondary injury, as it is assumed that primary injury is irreversible. Both non-pharmacologic and pharmacologic management for TBI are initiated based on the patient's scenario. Raising the head of the bed 30° and ventricular drainage if an extra-ventricular drain (EVD) is present are among the non-pharmacologic management of TBI patients with increased intracranial pressure (ICP). Patients with TBI encountering intracranial hypertension may be treated pharmacologically with hyperosmolar therapy, anesthetics, sedatives, and analgesics. Low molecular weight (LMW) or unfractionated heparins (UFH) are used as prophylaxis in patients at risk for deep vein thrombosis in conjunction with mechanical prophylaxis. Seizure prophylaxis is also initiated to decrease the incidence of post-traumatic seizures (PTS) in TBI patients. Other medical management like antihypertensive agents, antibiotics, hypoglycemic agents, and fluid/electrolytes are administered for secondary complications of systemic hypertension, nosocomial infections, hyperglycemia, and electrolyte abnormalities respectively (10–13).

In the case of managing and determining the prognosis of TBI, the commonly identified clinical variables that are predictive of poor outcomes include extremes of age, presence of hypotension, hypoxia and/or coagulopathy, increased ICP, and decreased GCS score (14). Patients with mild TBI recover completely within two weeks in 80–90 % of cases. Ninety (90 %) of people who suffer from moderate TBI recover, though 44% are moderately disabled and 1% progress to severe TBI. The mortality rate for severe TBI is around 35 % (15,16).

1.2 Statement of the problem

TBI has become a serious public health concern across the world; accounting for 30–40 % of all injury-related deaths as well as a significant cause of disability. It can also harm families, communities, and the economy by causing the loss of productive age groups and driving up treatment costs (17,18). The incidence of TBI is estimated to be 369-790/100000, with the great majority of mild TBIs occurring all over the world in a general population (19). According to the WHO report, 69 million individuals worldwide suffer from all-cause of TBI annually (4).

Even though the frequencies of TBI and TBI-related impairments have been reduced in HICs (6), the incidence of TBI in LMICs is high and ranges from 150-316 cases per 100,000 inhabitants per year. This is due to poor implementation of preventive measures, less stringent safety measures and legislative changes, poor public education, unimproved emergency and neuro-trauma services, and poor implementation of evidence-based guidelines in treating TBI survivors (20). TBI rates due to RTA and violence are 156 and 144 per 100,000 respectively, in Sub-Saharan Africa (SSA). It is about 1.5 to 3.3 times higher than the worldwide averages. Similarly, SSA has a considerably greater incidence of long-term intracranial injuries due to conflict, violence, and other accidental injuries than the rest of the world. Conflicts and rapid motorization are considered the main cause of the higher incidence of TBI in the region (20,21).

A TBI has both short- and long-term consequences for patients, and even a mild TBI can result in permanent impairment. It accounts for about 5 % of all cases of epilepsy (6,22) , with a PTS incidence as high as 8.9 % to 20.5 % (23). TBI victims are more likely to contract hospital-acquired infections (HAIs) than other critically sick patients or neurosurgical patients, and the mortality rate associated with infection might be as high as 28 % (24). Different studies reported the incidence of pneumonia ranged from 12.0 % to 29.6 % (25,26).

The yearly fatality rate from TBI is estimated to be over 650,000 people worldwide (27). A systematic review done in 2019 indicated an overall TBI incidence equating of 9.3 million per year (28). TBI is expected to affect 5.980 ±0.3 million people in Africa by 2050, with 0.15 million people in Eastern Africa. It mostly affects men and is most frequent in young people aged 19 to 40 and is a major cause of death and morbidity in SSA (17). It accounted for over 60 % of the fatalities among trauma patients admitted to the surgical department in Ethiopia (29).

In LMICs, TBI patients have worse outcomes than patients in HICs (30). Reports from Africa have found that mortality rates from TBI range from 4.2% to 35 % (21,26). According to the reports of different studies, the possible causes of high mortality could be older age, male gender, low GCS, and cause of injuries are likely non-modifiable risk factors, while hypoxia, hypotension, hyperthermia, hypo or hyperglycemia, and not undergoing surgery or poor adherence to management guidelines are possible modifiable risk factors (31,32).

According to reports from Ethiopia, the mortality rate among TBI patients were ranged from 8.2 % to 50.8 % and it was the cause of 21.5 % of all fatalities within 72 hours after presentation (29,33).However, studies assessing in hospital complications related to TBI like PTS and incidence of infections are limited. Even, majority of studies reporting fatality rate of TBI patients are either cross-sectional or retrospective. Therefore, the study planned to assess the clinical profile, in hospital complications, mortality, and the prognostic factors of TBI in patients admitted to surgical ward of Jimma Medical Center (JMC) by prospective study design.

1.3 Significance of the study

The incidence of TBI is raising over time though the baseline clinical profiles, in-hospital complications, survival status, and predictors of mortality are still not known in Ethiopia. Knowing the in-hospital complications, survival status, and prognostic factors TBI patients gives information on patient prognosis and the life expectancy. As the ultimate goal of the health sector is ensuring health service quality, assessing the predictors of TBI patient's survival enables the policy makers to design improvement in the management and care for TBI patients. Also, survival status of TBI patient is a major indicator to monitor the quality of treatment given.

The output of this study will be used by the concerned bodies in the health service delivery sectors including Jimma Medical Center and other organizations as an important input for designing appropriate evidence-based intervention strategies in improving outcomes of the TBI patients among the general population. So, the finding of this study will benefit the patient by addressing the factors affecting the outcomes of TBI patients. The study will also provide an input for the government to allocate resources and making policies in prevention and management of TBI. Finally, the finding of this study may be used an input for future studies on TBI.

2. LITERATURE REVIEW

2.1 Incidences and causes of TBI

The incidence of TBI is increasing across the globe mainly due to the growing use of motor vehicles, urbanization, a lack of safety in high-risk occupations such as construction, and rising conflict and crisis conditions in LMICs and to the aging of the population in developed countries (34). The most common cause of TBI is RTAs (60 %) followed by falls (20 %-25 %) and violence (10 %) globally (35). Due to increased risks for RTA and violence-related injuries, males are more likely to suffer from TBI than females (36).

A prospective observational study done in Dutch on 486 TBI patients showed that nearly all (98.4%) study subjects sustained a closed type of TBI. Patients had a mean age of 56.1 ± 22.4 years and majorities (60.5%) were males. According to the report, TBI was mainly caused by incidental falls (54.3%) or road traffic accidents (36.2%) and occurred on streets (56.2%) or at home (31.5%) (37).

A prospective study done from in Uganda on a total of 387 TBI patients showed that 277 (71.6 %) had moderate TBI, while 113 (29.2 %) patients had severe TBI (38). The highest burden of TBI was recorded among patients assaulted by violence (81.0 %). RTAs accounted for almost half of the mechanisms of injuries, at 188 (48.6 %) (38).

A prospective clinical cohort study conducted in Zambia on 211 TBI patients revealed that RTA was the most common cause of trauma at 56.9 % followed by assault at 34.6 %. The study also showed that clinical TBI using GCS was distributed as 42.7 % for mild, 24.1 % moderate and 33.2 % severe TBI and the case fatality rate was 25.6 % (39).

A retrospective study conducted in Ayder referral Hospital, Mekelle, Ethiopia on 750 TBI patients showed that the leading causes of TBI include falls (41.9 %), interpersonal violence (24.8 %), and RTA (24.9 %). According to the survey, the age range from 6 to 25 years was the most typically afflicted. The patients with TBI came from all across the country, with 422 (56.3 %) being from the city (33).

According to a cross-sectional research conducted at Debra Tabor Teaching and Referral Hospital in South Gondar Zone on 370 trauma patients, the prevalence of TBI is 39.7 %. Two

hundred and sixty-five (72 %) of all trauma patients were men, and 259 (70 %) of all trauma patients were from rural areas. The study also discovered that being younger (20–24 years), being male, drinking alcohol, and living in a rural area were all associated with TBI (40).

A retrospective cross-sectional study done in Nekemte Referral Hospital, Ethiopia on 378 TBI patients showed that most of the patients sustained TBI from RTA which accounted 286 (75.7 %) followed by fall down comprised 50 (13.2 %), and interpersonal violence comprised 42 (11.1%). According to the study, most of the TBI patients were from rural area which account 221 (58.5 %) while 157 (41.5 %) from the urban area (41).

2.2 Clinical Profiles of TBI

A prospective study done in Dutch showed that the mean baseline GCS was 12.7 ± 3.8. Patients sustained mild TBI was (72.8 %), for moderate TBI (8.8 %) and severe TBI (18.4 %) (37). Nearly all (98.4 %) patients sustained closed head injury (37).According to the study, 18.5 % and 15.7 % of patients had underlying medical condition and hyper-thermic on admission.

Prospective, multicenter, longitudinal, observational study conducted on 13138 TBI patients from 52 hospitals in 22 provinces of China revealed that the median GCS score was 13 and 2804 (21%) were classified as having severe TBI, 2930 (22 %) as moderate, and 7404 (56 %) as mild. ICU patients had lower GCS scores, a higher proportion of severe TBI, and more major extra-cranial injuries compared with general ward patients. According to the report, 23.7 % and 12.3 % were hypotensive and were hypoxic, respectively upon arrival (42).

A retrospective study done in surgical ward of India on 1527 TBI patients found that 24.3 % (371) were poly-traumatic on admission. According to the study, 5.93 % had associated spinal cord injury. Episodes of hypotension on admission were present in 25.34% of the study participants (43).

A prospective observational study done in South India showed that among 247 TBI patients 52.23 %, 28.74 % and 19.3 % was admitted with mild, moderate, and severe TBI respectively. According to the study, the common clinical presentations include LOC 65 %, vomiting 61 %, ENT bleed 17 %. CT scan revealed contusions (42 %), fractures (21 %), subdural hematoma (SDH) (21 %) and epidural hematoma (EDH) (16 %) (44).

A retrospective study done in Tanzania on a total of 627 patients showed majority (64 %) sustained mild TBI, 18.2 % moderate and 17.8 % severe TBI. Of the study participants , 82.6 % were admitted by referral (45).A research conducted in Uganda on a total of 194 TBI patients indicated that 30.9 % of patients had severe TBI and an associated skull fracture was observed in 8.8 % (46). A cross-sectional study conducted at Tikur Anbessa hospital, Ethiopia on 91 TBI patients indicated 37.4 % of them cases had mild and 33% had severe TBI. Acute subdural hematoma was seen in 86.8 % of patients (47).

A retrospective follow-up study done in Hawassa, Southern Ethiopia on 1220 patients showed that 66.35% had sustained mild TBI, a moderate TBI was 20.45 %, and a severe TBI was 13.2 %. The study revealed that 5.09 % had hypotensive, 10.4% had hypoxic, and 9.64 % had anemic at admission. Majority (78.43 %) had a head CT-scan done and 73.16 % of them had abnormal CT scan findings. Of these, 27.82 % were skull fractures and followed by 24.06 %, 21.35 % were contusions and epidural hematomas, respectively (48).

2.3 Clinical outcome and predictors of TBI

The mean in-hospital mortality was 12.3 % and ranged from 2.3 % for patients with mild TBI to 62.7 % for patients with severe TBI according to study done in Dutch (37). Length of stay (8 ± 13 days) was substantial and increased with higher TBI severity, presence of intracranial abnormalities, extra-cranial injury and surgical intervention according to the report.

A prospective study done in China revealed 637 (5 %) patients died of 13138 TBI patients. Of 2804 patients with severe TBI, 552 (20 %) died. The leading cause of death was primary injury (64 %), followed by secondary injury (24 %), complications (5 %), and systemic injury (4 %). Survival time to death varied among different causes of death (42).

According to the study done in India, 143 (9.0%) developed posttraumatic seizure. During the study period, 34.58% (n = 528) patients died in hospital, and in-hospital mortality rate was higher in severe TBI (38.56%) as compared to moderate (13.82%). Most of the cases (23.86%) among those who died during hospital stay were stayed for 3–7 days (43).

A retrospective study conducted in Indonesia on 209 TBI patients revealed that the mortality rate was 15.79 %. Among the patients diagnosed with mild TBI, there were no record of death and

15.31% survived. In moderate TBI patients, mortality and survival was 0.96 % and 42.11 % respectively. However, in patients with severe TBI, 26.79 % survived and 14.83 % died. The study showed age, GCS at admission, duration of treatment in hospital, and Marshall CT classification statistically had a significant relationship to the outcome of TBI patients. According to the report, gender and causes of trauma didn't have a significant relationship to the outcome of TBI patients (35).

A report from South India showed among 247 TBI patients, the overall mortality was 17.7 % and the incidence of PTS was 8.9 %. The average duration of stay for the patients presenting with TBI was 5 days. Mean hospital stay was 4.97 ± 5.4 days. Patients with severe TBI had higher mortality (44).A retrospective study conducted in South Africa on 918 patients indicated that in-hospital mortality was 3.4 %. According to the study, transport mode, and hospital arrival time did not substantially affect in-hospital mortality (49).

A prospective study done in a Nigerian tertiary hospital on 150 TBI showed higher proportion of patients with mild/moderate TBI and patients with normal systolic blood pressure (SBP) had good outcome while higher proportion of patients with abnormal SBP had poor outcome. According to the study, the clinical parameters that were significantly predictive of outcomes were GCS on admission and age (50).

A cross-sectional study done in Kenya on 91 TBI patients revealed that factors such as age, injury cause, poly-trauma, time lapse from trauma to hospitalization and the GCS on admission affect the outcome of TBI. According to the study age above 40 years, casual laborers, poly-trauma, patients in surgical ward, and time lapse from trauma to hospitalization were those patient factors that led to poor outcome (51).

A retrospective study conducted on a 2163 TBI patients who visited Addis Ababa burn and emergency treatment hospital reported that in-hospital mortality was 21.7 %. According to the study male gender, patient's clinical conditions like hypotension and hypoxia and GCS at presentation were associated with poor outcome. Timely diagnosis and aggressive resuscitation of patients at earlier golden hours of arrival greatly helps to improve patient's survival (52).

A four-month prospective study done on 52 head injury patients at Jimma University Specialized hospital, Ethiopia revealed that 36.5 % suffered severe TBI, compared to 50% who suffered mild

TBI. Twelve (12.0%) of the study subjects had developed aspiration pneumonia. The mortality rate was 21.2 %. Conservative management was used for 76.9% of the patients. Significant association was found between the outcome and the initial GCS (26).

A retrospective cross-sectional study done in Nekemte referral hospital, Ethiopia showed that overall in hospital mortality was 15.3 %. According to the report, patient age>60years, low GCS, and conservative management were associated with unfavorable outcome. Timely management of TBI before patients develops secondary brain injury and use of surgical intervention based on CT scan diagnosis will reduce the occurrence of unfavorable outcome (41).

2.4 Conceptual Framework

The conceptual framework illustrating the interaction between socio-demographics, clinical characteristics, and type of intervention with the outcome of TBI according to the studies (18,22,26,28,32,34) (figure 1).

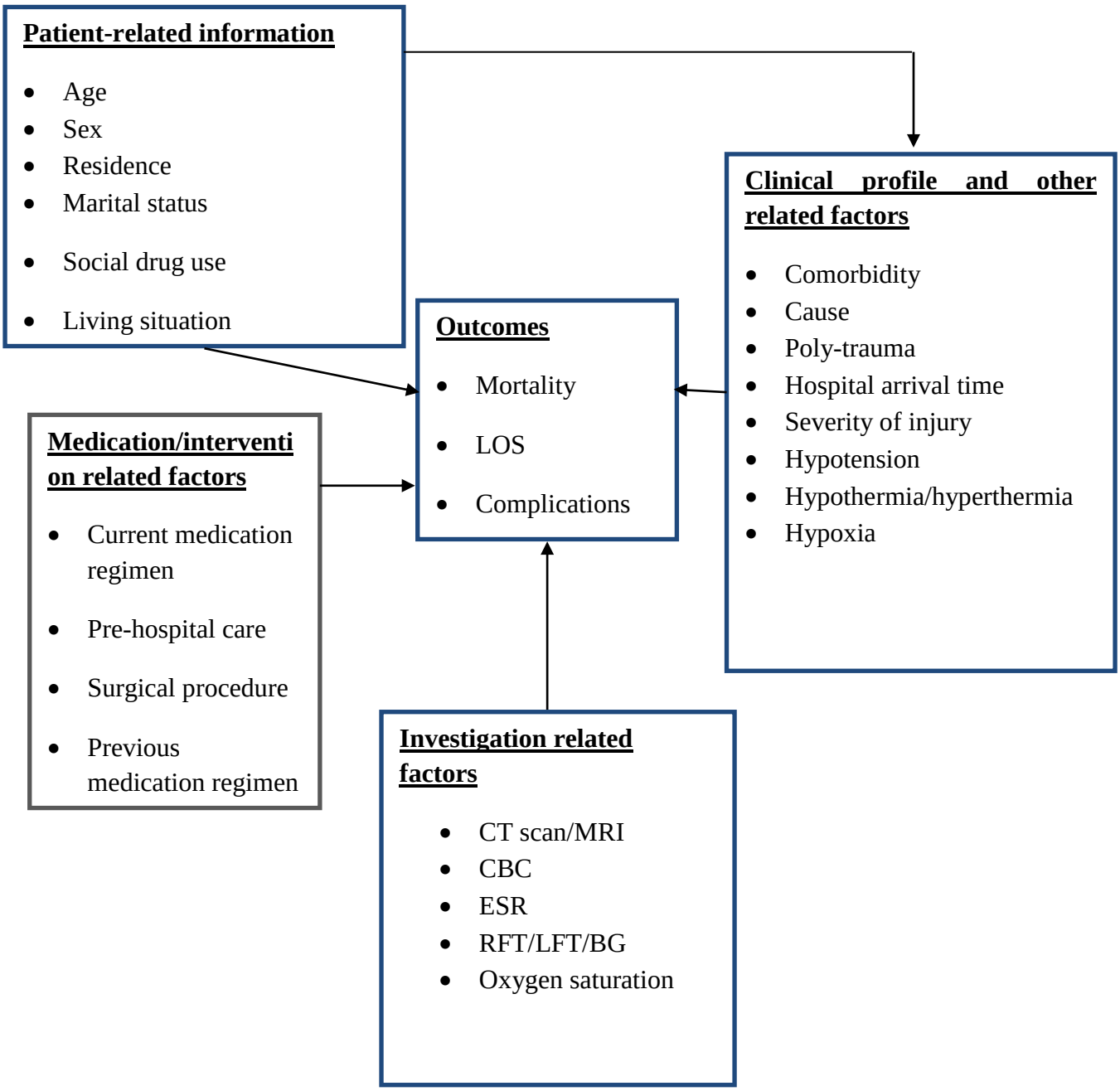

Figure 1: Conceptual framework

3. OBJECTIVES

3.1 General Objectives

- To determine the clinical profile and outcomes of traumatic brain injury patients admitted to surgical ward of JMC from January-July, 2022.

3.2 Specific Objectives

- To identify the clinical profile of traumatic brain injury patients admitted to surgical ward of JMC
- To determine the length of hospital stay of traumatic brain injury patients admitted to surgical ward of JMC
- To determine the incidence of in-hospital complications in TBI patients admitted to surgical ward of JMC
- To determine in-hospital mortality of TBI patients admitted to surgical ward of JMC
- To assess the predictors of TBI mortality in patients admitted to surgical ward of JMC

4. METHODOLOGY

4.1 Study area and period

The study was conducted in the surgical ward of JMC, Oromia regional state, Southwest Ethiopia from January 10, 2022- July 10, 2022. JMC is one of the oldest public hospitals in the country and it was established in 1938 G.C by Italian invaders for the service of their soldiers. Geographically, it is located in Jimma town 352 km southwest of the capital. It is the only teaching and referral hospital in the southwest of Ethiopia providing services approximately for 15,000 inpatients, 160,000 outpatient attendants, 11,000 emergency cases and 4500 deliveries per year from the catchment population of about 15 million people. It has 1600 staff members and 32 care units. Surgical department is one of the units having elective, emergency and outpatient wards.

4.2 Study design

Hospital-based prospective observational study was conducted.

4.3 Population

4.3.1 *Source population*

All TBI patients admitted to surgical ward of JMC.

4.3.2 Study Population

All TBI patients admitted to surgical ward of JMC during data collection period and fulfilling the inclusion criteria.

4.4 Inclusion and Exclusion Criteria

4.4.1 Inclusion criteria

- All TBI patients greater than or equal to 18 years

4.4.2 Exclusion criteria

- Known epileptic patients
- Either patients or care-givers refused to participate in the study

4.5 Sample size determination and sampling techniques

4.5.1 Sample size determination

The sample size was calculated based on single population proportion formula considering the proportion (P) of overall mortality among TBI patients as estimated based on a study done in Jimma University Specialized hospital which was 21.2% (26), an absolute precision of 5% and 95% level of confidence.

P=Mortality of TBI (21.2%) (26)

$Z_{\alpha/2}$ = the corresponding z-score at 95 % CI is 1.96

d= margin of error=0.05

n= required sample size

nf=final sample size

N= the total six month of TBI patients admitted to surgical ward of JMC in the last year

$$n= (Z\alpha_{/2})^2 P (1-P)/d^2$$

$$n = (1.96)^2 \times 0.212(1-0.212)/0.05^2 \quad =257$$

Using correction formula for less than 10,000

nf= N×n/N+n, where N= 417

nf=417*257/417+257= **159**

Considering non-responders as 10 %, the final sample size was **175**

4.5.2 Sampling techniques

A convenient sampling technique was used. All TBI patients admitted at surgical ward of JMC fulfilling the inclusion criteria was selected and followed starting from date of admission to discharge.

4.6 Variables of the study

4.6.1 Dependent Variables

- Mortality (in-hospital)
- Length of hospital stay
- Incidence of in hospital complications (PTS, infectious diseases)

4.6.2 Independent Variables

- ✓ Socio-demographic factors (Age, sex, marital status, residence, occupation, social drug use)
- ✓ Clinical characteristics/related factors (hypotension, hyperglycemia, hypoxia, severity of TBI, poly-trauma, comorbidity)
- ✓ Medication/intervention related factors (previous or current medication, surgical procedure, pre-hospital care)
- ✓ Investigation related factors (CT scan, serum electrolytes, coagulation profile, OFTs)

4.7 Data collection procedures

The data was collected through the structured questionnaire developed by referring different literatures in line with the study's objectives (6,17,22,26). Following two days training, one BSc nurse and one general practitioner collected the data. Data on demographics, clinical characteristics, investigation related, and medication/interventional related were collected from medical chart and interviewing the patients/caregivers/attendants. For incomplete data regarding the socio-demographics, chronic medical illnesses, previous medications and cause of injury, the patient/caregiver/attendants were interviewed. Data related to TBI severity, CT scan finding, and type of hospital management were also collected from the medical chart. Patients were followed until death/discharge from hospital, or transfer to another facility.

4.8 Data quality control

First, the data collection tool with five parts were written in English, then the first **(I)** and second **(II)** parts were translated into two local languages (Amharic and Afan Oromo) and back-translated into English by an independent person to assure its consistency. The tool was pre-tested on nine (9) TBI patients two weeks before starting the actual data collection and then the

necessary adjustment was done. The data was compiled, coded, and checked for consistency before analysis.

4.9 Data processing and analysis

The data was coded and entered into Epidata version 4.6.0.5 and exported to the Stata version 14.2.0 for data analysis. The categorical variables were presented with frequency and percentage. Parametric data was reported with mean ± standard deviation (SD), while non-parametric data was presented with median and interquartile range (IQR). Kaplan-Meier survival analysis of mortality was conducted taking the period from hospital admission to discharge/death time frame and severity of TBI as independent factors. The log-rank test was used to compare the in-hospital survival. Bivariate cox-regression was performed to see the associations between in-hospital mortality patients with TBI and independent variables. Then, multivariate Cox regression [reported with AHR with 95% CI] was performed, including all explanatory variables with a p-value of < 0.25 on bivariate cox-regression to evaluate factors predicting mortality. In all the statistics, a p-value <0.05 was considered statistically significant.

4.10 Outcome measurement

4.10.1 Primary Outcome

The primary outcome variable is in-hospital mortality. All-cause in-hospital mortality was determined during the course of acute care at the hospital which is confirmed by the responsible physician or surgical ward registration database. The time at which the patient admitted until the event of occurrence during the hospital stay was recorded.

4.10.2 Secondary outcomes

The secondary outcomes such as PTS, LOS, and incidence of infections were determined via following patient following starting from admission to discharge. It was recorded when the patient develops new event associated with TBI after admission and that is either confirmed by clinical assessment made by clinicians or laboratory parameters. The occurrence of seizure (either witnessed or self-reported) and infectious diseases were recorded when it was confirmed by the physician from medical charts. Length of hospital stay was recorded either from patient chart or surgical ward patient discharge registration data base.

4.11 Ethical considerations

The study was conducted after ethical clearance had obtained from research review board of Institute of Health Science, Jimma University (***Ref.no:JUIRB24/22***). The consent was taken from the patient/caregiver/attendants and the names of the patient were not recorded and other information was kept confidential throughout the study process.

4.12 Dissemination of results

This study was aimed to determine the clinical profile and outcomes of TBI patients admitted to JMC. So, the finding of the study will presented to the Jimma University, advisors and examiners. It will be disseminated to School of Pharmacy, Institute of Health, Jimma medical center and other concerned bodies. The results of the study will also be published on reputable journal.

4.13 Operational and terms definitions

Glasgow coma scale (GCS):- scale used for assessing the neurological status of the patient (2).

Glasgow Outcome scale (GOS):- a multi-dimensional scale which assesses various aspects of outcome (4).

Mild TBI:- an injury to the head with GCS score 13-15 (2).

Moderate TBI:- an injury to the head with GCS score 9-12 (2).

Severe TBI:- an injury to the head with GCS score 3-8 (2).

Comorbidity: - refers to any disease co-existing with an index disease.

Primary outcome: -is the death of TBI patients.

Secondary outcomes: - in hospital complications such as PTS, LOS, and incidence of infections associated with TBI determined during hospitalization.

Complication: - newly occurring medical events during hospital stay which are associated with severity of TBI.

Neurological Complication: - the development of posttraumatic seizure secondary to TBI.

Non-neurologic complications: - the development of infectious diseases like pneumonia, HAIs, SSIs, and bone flap infections associated with TBI.

Time variable: - is the time to occurrence of death measured from admission to date of the event.

Immediate PTS:- a seizure occurring in <24 h after TBI (23).

Early PTS:- a seizure occurring in >24 h and < 7 days after TBI (23).

Late PTS:- a seizure occurring in > 7 days after TBI (23).

Hypotension:- SBP <90 mmHg measured at any time point during hospitalization, including the hospital arrival value (6).

Hypoxia:- SaO2 <90% at any time point during hospitalization, including hospital arrival value (48).

Hyperthermia:-a temperature >38˚c during hospitalization (48).

Hypoglycemia:-random blood glucose concentration level <80mg/dL during hospitalization (48).

Anemia: - was considered as anemic when a hemoglobin count is <7mg/dl (54).

Length of hospital stay: - the duration of hospital stay from admission to discharge.

5. RESULTS

5.1 Patient flow chart

Over the six-month study period, 454 TBI patients were admitted to surgical ward of JMC. Of these, 191 were eligible for the study. Six (6) patients were not willing to participate in the study and the rest 10 patients had incomplete medical charts. For final analysis, 175 patients were considered.

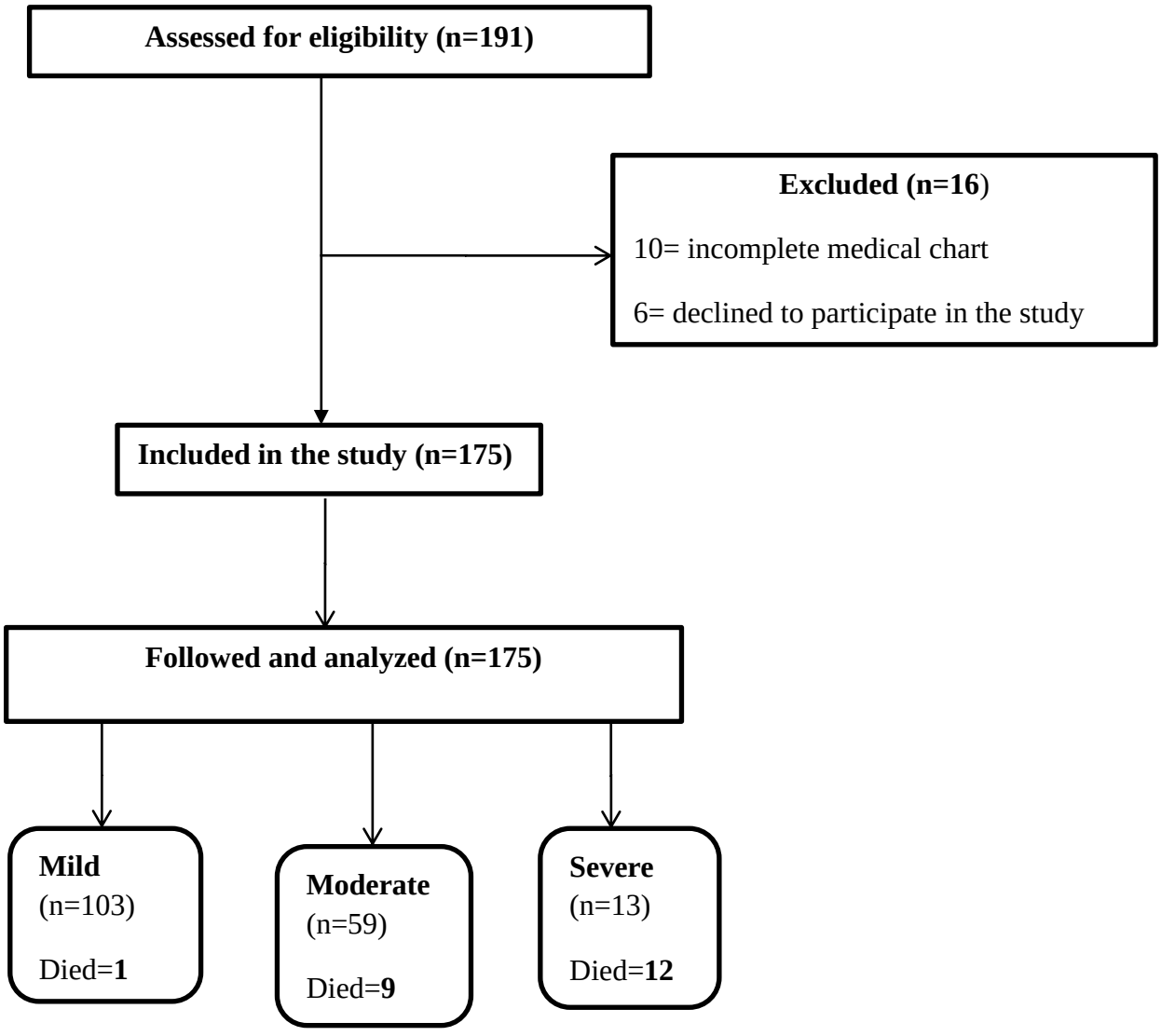

Figure 2: Patient flow chart

5.2 Socio-demographic Characteristics

Among 175 study participants, 126 (72 %) were males. The mean (±standard deviation) age of the participant was 29.82±10.68 years. Eighty-five (48.6%) of patients were married. Of the total study subjects, 104 (59.4 %) of them live in rural area. Sixty-seven (38.29%) of the patients cannot read and write. Seventy-one (40.6 %) drank alcohol. Regarding occupation, 39.4 % and 20 % were farmers and daily laborers, respectively (**Table 1**).

Table 1: Sociodemographics characteristcs of TBI patients admitted to surgical ward of JMC from January to July, 2022.

Variables	Category	Frequency(n)	Percentage(%)
Sex	Male	126	72.0
	Female	49	28.0
Age	18-40	149	85.14
	41-63	21	12.0
	> 64	5	2.86
Residence	Rural	104	59.4
	Urban	71	40.6
Marital status	Single	85	48.6
	Married	85	48.6
	Divorced	5	2.9
Educational status	Cannot read and write	67	38.3
	Primary school	50	28.6
	High school	33	18.86
	Diploma and above	25	14.3
Occupation	Farmer	69	39.43
	Daily laborer	35	20
	Driver/assistant	25	14.29
	Student	17	9.71
	Merchant	15	8.57
	Civil servant	8	4.57

	Military	6	3.43
Living situation	Home	170	97.14
	Homeless/on street	5	2.86
Social drug use	Alcohol	71	40.6
	Khat	34	19.43
	Smokers	18	10.3

5.3 Injury related Characteristics of Patients

RTAs (58.86 %) and violence/assault (26.86 %) were the main causes of TBI. Majority of the study participants (61.71 %) were directly admitted to hospital and hospital arrival time for 54.9 % of them were > 6 hours (**Table 2**).

Table 2: Cause and injury related characteristics of TBI patients admitted to surgical ward of JMC from January to July, 2022.

Variables	Category	Frequency (n)	Percentage (%)
Cause of TBI	RTA	103	58.86
	Violence	51	29.14
	Fall	19	10.86
	Others	2	1.1
	Directly admitted	108	61.71
Admission status	Referral	67	38.29
Mode of arrival	Ambulance	94	53.7
	Public transport	75	42.86
	On foot	6	3.43
Hospital arrival time	≤ 6 hours	79	45.14
	> 6 hours	96	54.86
GCS on admission	13-15	105	60
	9-12	57	32.6
	3-8	13	7.43

RTA, road traffic accident GCS, Glasgow coma scale * Struck by object or animal

5.4 Clinical Characteristics and CT Scan findings

Upon admission, only 12.6 %(n=22) of the study participants have underlying medical condition. Of the clinical findings on admission, hypotension (13.4 %) and anemia (15.8 %) were frequently noted. Regarding the CT scan findings, fractures (33.4 %), and EDH (13.7 %) were the most common findings (**Table 3**).

Table 3: Baseline clinical profiles of TBI patients admitted to surgical ward of JMC from January to July, 2022

Variables	Category	Frequency(n)	Percentages (%)
Comorbidities	HTN	9	40.9
	DM	6	27.27
	CHF	4	18.18
	Asthma	3	13.64
V/S on admission	Hypoxia	54	30.86
	Hyperthermia	28	16.0
	Hypotensive	23	13.14
	Hypothermia	23	13.14
	Tachycardia	15	8.6
	Bradycardia	3	3.43
RBS on admission	<80 mg/dl	9	5.14
	>160mg/dl	11	6.3
Electrolytes	Hyponatremia	28	16.0
	Hypokalemia	30	17.14
Platelets	Low	16	9.14
	High	12	6.86
Hgb	< 7 mg/dl	18	15.8
RFTs	Normal	40	22.86
	Abnormal	38	21.71
LFTs	Normal	60	34.3

	Abnormal	18	10.3
CT Scan findings	Fractures	58	33.14
	EDH	24	13.7
	Contusion	18	10.3
	SDH	13	7.43
	Pneumocephalus	9	5.14
	SAH	4	2.3

ESR, erythrocyte sedimentation rate Hgb, Hemoglobin RFTs, renal function tests LFTs, liver function tests EDH, epidural hematoma SDH. Subdural hematoma SAH, subarachnoid hematoma

5.5 Intervention/management at surgical ward

In this study, majority of patients 119 (68.0%) managed surgically. Of the total study participants, 42 (24.0 %) patients were resuscitated before admission to the hospital. Among the participants, 14.29% of the patients developed ICP. Fracture elevation 52 (43.7%) and burr hole 26 (21.85%) were the common neurosurgical procedures done for the candidate patients. Seizure prophylaxis was initiated for 123 (70.3 %) of study subjects included in the study. Antibiotics were initiated for 135 (79.1 %) of TBI patients (**Table 4**).

Table 4: Overall management status of TBI patients admitted to surgical ward of JMC from January to July, 2022

Variables	**Care**	**Frequency (n)**	**Percentages (%)**
Pre-hospital care	Resuscitation	42	24.0
	Analgesics	12	6.86
	Both	10	5.71
Intervention done	Neurosurgery	119	68.0
	Conservative	56	32.0
Neurosurgery	Fracture elevation	52	29.7
	Burr hole	26	14.86
	Cranioctomy	14	8.0

	Evacuation	12	6.86
	Craniotomy	9	5.14
	Others	6	3.43
Seizure prophylaxis	Phenytoin	108	61.71
	Phenytoin + Diazepam	15	8.6
DVT prophylaxis	UFH	21	12.0
Antibiotics	Ceftriaxone + Metronidazole	56	32.0
	Ceftriaxone	14	8.0
	Cephalexin	15	8.6
	Vancomycin	4	2.3
SUP	Cimetidine	56	32.0
Antiemetic	Hyoscine	18	10.3
	Metoclopramide	11	6.3
Antipsychotics	Haloperidol	28	16.0
	Risperidone	14	8.0
Analgesics/Opioids	Diclofenac + Tramadol	117	66.86
	Paracetamol	22	12.6
	+Tramadol	16	9.14
	Tramadol		

DVT, deep vein thrombosis UFH, unfractionated heparin SUP, stress ulcer prophylaxis others: Thoracotomy, Incision and debridement, Soft tissue repair

5.6 Treatment Outcomes

In this study, a total of 175 patients were followed for a minimum of 1 day and maximum of 45 days, with a mean follow up/length of hospital stay was of 5.66± 0.34 days. The incidence rate of death was 2.22 per 100 persons- days of follow-up. During the study period, 22 (12.6 %) patients were died. In-hospital complications was recorded in 32.0 %(n=56). Of the study participants,

16.0 % and 4.6 % developed early and late PTS, respectively. Among study subjects who developed early PTS, 72.2 % experienced the event on their 3rd day of injury. However, 11.1 % and 16.67 % of them experienced the seizure on the 2nd and 5th day of injury respectively. Of the total participants, 11.43 % (n=20) of them developed non-neurological complications (**Table 6**).

Table 5: Clinical outcomes of TBI patients admitted to Surgical Ward of JMC from January to July, 2022

Variables	Category	Frequency (%)
Mortality	In-hospital	22 (12.6)
In hospital complications	**Neurological**	36 (20.6)
	Early PTS	28 (16.0)
	Late PTS	8(4.6)
	Non-neurological	20 (11.43)
	Aspiration pneumonia	14 (8.0)
	HAIs	5 (2.86)
	Bone flap infection	1(0.6)

5.6.1 Survival status of TBI patients

In this study, a total of 175 TBI patients prospectively followed up for a total of 990 days and the median survival time was 34 days. Survival estimation based on the Kaplan-Meier curve showed that the overall estimated survival rate after diagnosis of TBI was 34 %. Among 13 (7.43%) TBI patients diagnosed with severe TBI (GCS $\leq$ 8) based on their GCS score at admission, the incidence of death was 17.6% and the median survival rate was 3% (95% CI; 2-4%). For the patients diagnosed with moderate TBI the incidence of death was 3.04 % and the median survival time was 37 days (95% CI: 35–38%) and those for the remaining mild TBI patients, the incidence of death and the median survival time was 3.1 % and 34 days ,respectively.

The survival time differed among the TBI patients based on their GCS on admission. Ten-percent (10%) of patients with mild TBI had died after 32 days (95 % CI 2-32) as opposed to 3 and 1 days for moderate and severe TBI patients, respectively (Figure 3).

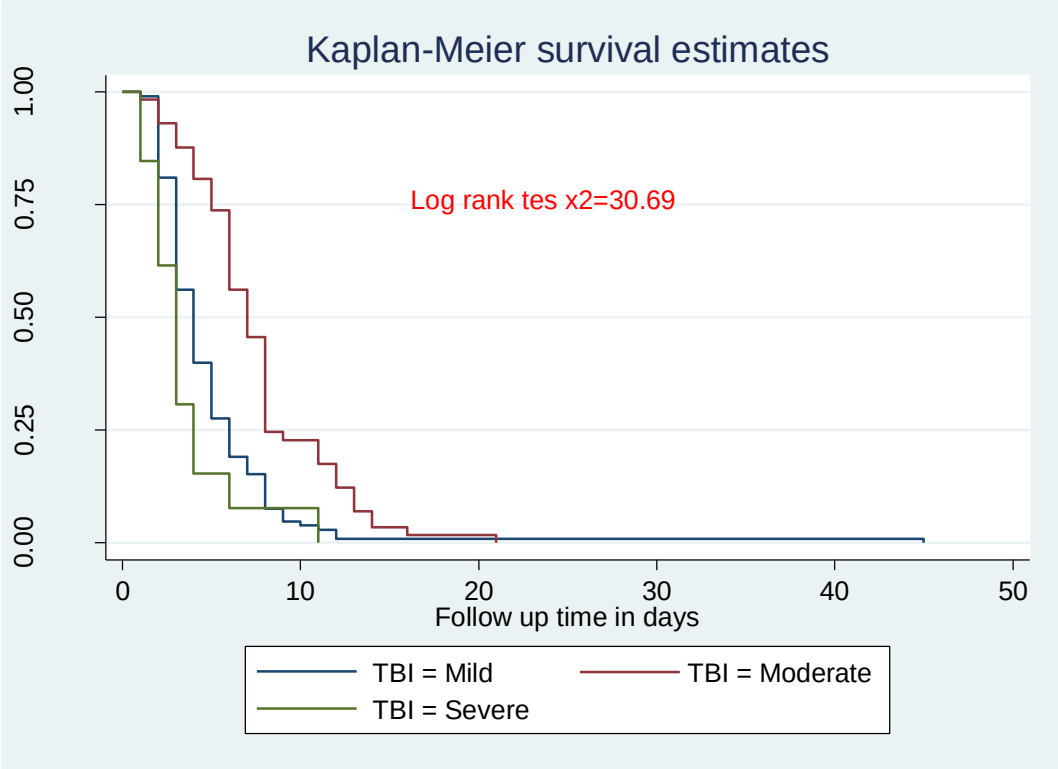

Figure 3: Kaplan–Meier curve for estimating survival status of patients with TBI patients based on severity at surgical ward of JMC, Jimma, Ethiopia, from January 10, 2022 to June 10, 2022.

5.7 Factors affecting Outcome

According to the bivariate Cox regression model smoking (AHR: 1.8, 95 % CI, 1.03-3.1, p=0.038), arrival by public transport (AHR: 0.5, 95 CI, 1.13-2.12, p=0.007), poly-trauma (AHR: 0.58, 95% CI, 0.43-0.8, p=0.001) were associated with TBI related mortality. Among clinical factors, GCS score 3-8 on admission (AHR: 1.8, 95 % CI, 1.03-3.1, p=0.038), hypoxia (AHR: 0.67, 95 % CI, 0.49-0.9, p=0.018) were predictors of mortality on bivariate cox regression analysis. However, of intervention related factors seizure prophylaxis (AHR: 0.53, 95 % CI 1. 0.7-0.74, p=0.00), neurosurgery (AHR: 2.1, 95 % CI, 1.5-2.91, p=0.00), lack of pre-hospital care (AHR: 1.4, 95% CI, 1. 1.05-1.98, p=0.023,), antibiotic not initiated (AHR: 3.7, 95 % CI, 2.4-5.9, p=0.00), and initiating antipsychotics (AHR: 0.68, 95 % CI, 0.47-1.0, p=0.039) were all associated with TBI related mortality.

On multivariate regression, living on street (AHR: 1.3, 95 % CI 1.01-7.72, p=0.031), GCS score 9-12 on admission (AHR: 0.18, 95 % CI 0.13-0.76 p=0.019), and initiating antipsychotics (AHR: 0.57, 95 % CI 0.34-9.7 p=0.038) were protective predictors of mortality in TBI patients. GCS score 3-8 on admission (AHR: 6.2, 95 % CI, 0.75-51.1, p=0.004), hyperthermia (AHR: 1.7, 95 % CI, 1.02-3.05, p=0.043), and lack of pre-hospital care (AHR: 3.2, 95 % CI, 2.2-8.07, p=0.005) were all associated with TBI related mortality ($p < 0.05$).

Table 6: Bivariate and multivariate cox regression analysis of to identify predictors of in-hospital mortality among patients with TBI at JMC, Ethiopia

Variables	**Category**	**Discharge status**		**CHR (95%CI)**	**p-value**	**AHR (95% CI)**	**p-value**
		Died n=22	**Alive n=153**				
Living	Home	20	150	1			
	Street	2	3	0.3(0.1-1.3)	0.108	1.3(1.01-7.72)	**0.031**
Smoking	No	18	139	1			
	Yes	4	14	1.8(1.03-3.1)	**0.038**	1.6(.34-7.01)	0.58
GCS	13-15	1	104	1			
	9-12	9	48	0.5(0.36-0.71)	0.13	0.2(.13-0.76)	**0.019**
	3-8	12	1	1.1(1.00-1.19)	**0.04**	6.2 (0.75-51.1)	**0.001**
Transport	Ambulance	12	82	1			
	Public	9	66	1.5(1.13-2.12)	**0.007**	3.5(.85-13.9)	0.08
	Walking	1	5	1.9 (0.83-4.4)	0.129	1.2(0.33-4.02)	0.83
Poly-trauma	No	5	99	1			
	Yes	17	54	0.58(0.43-0.8)	**0.001**	0.7(0.44-1.05)	0.08
Temperature	Normal	5	129	1			

	Hypothermia	5	8	1.12(.63-1.98)	0.705	1.3(0.62-2.77)	0.49
	Hyperthermia	12	16	1.4(0.76-2.4)	0.144	1.7(1.02-3.05)	**0.043**
SBP	Normal	6	136	1			
	Hypotension	15	8	1.3 (0.98-2.4)	0.205	1.4(0.74-2.7)	0.93
	Hypertension	1	9	1.2 (0.6-2.13)	0.710	1.4(0.67-3.1)	0.36
SaO2	Normal	5	116	1			
	Hypoxia	17	37	0.7(0.49-0.9)	**0.018**	0.95(0.63-1.44)	0.82
Seizure	No	2	50	1			
prophylaxis	Yes	20	103	0.53(0.7-0.74)	**0.00**	0.73(3.8-1.4)	0.348
Comorbidity	No	20	133	1			
	Yes	2	20	1.4 (0.87-2.1)	0.176	0.58(0.33-1.02)	0.061
Neurosurgery	Yes	20	99	1			
	No	2	54	2.1(1.5-2.91)	**0.000**	1.2 (.043-30.9)	0.954
Pre-hospital	Yes	3	61	1			
care	No	19	92	1.4(1.05-1.98)	**0.023**	3.2(2.2-8.07)	**0.005**
Antibiotics	Yes	8	81	1			
	No	14	72	3.7(2.4-5.9)	**0.000**	0.75(0.26-2.2)	0.591
Fluid	Yes	10	129	1			
	No	12	34	2.14 (1.5-3.1)	**0.000**	0.54(0.14-2.8)	0.157
Antipsychotic	No	15	118	1			
	Yes	7	35	0.68(0.47-1.0)	**0.039**	0.57(0.34-9.7)	**0.038**

6. DISCUSSION

This study assessed the clinical profiles and outcomes of 175 TBI patients admitted to the surgical ward of JMC. During their hospitalization, 22 (12.6%) deaths were recorded. The higher deaths were recorded in patients with severe TBI (54.55%) as compared to moderate (40.9%) and mild TBI (4.55%).The overall incidence of in-hospital complications was 32.0 %. The GCS score on the admission of <8, hyperthermia, and lack of pre-hospital care were independent predictors of in-hospital mortality.

In the current study, 30.86% of TBI patients had hypoxia at the time of admission. The study conducted in Addis Ababa, Ethiopia, yielded outcomes that were similar (55). However, compared to Hawassa and Bahir Dar, the finding is higher (48,56). The difference could result from a delay in timely diagnosis and resuscitation in comparison to the study participants' arrival times, which were included in our study.

This study found that 15.8 % (n=18) of study subjects were anemic on admission. This finding is in line with different studies but it is higher compared to the study done in Hawassa, Ethiopia 9.64 % (48). The discrepancy may be caused by the delay in hospital arrival time for more than half of our study subjects achieved care > 6 hours post-injury.

In this study, 13.4 % (n=23) of TBI patients were hypotensive during surgical ward admission. This result is lower compared to studies done in Pittsburgh 17 %(57) and India 25.34% (43,58). The variation could be due that majority of the study participants were resuscitated before being admitted to the surgical ward. This suggested that in order to increase the likelihood of the patient surviving, prompt diagnosis and intensive resuscitation during the first crucial hours of hospital arrival must be considered in order to prevent further brain injury caused by hypotension.

In the current study, the overall in-hospital complications was found to be 32.0 % (n=56). This is in line with the study done in Taiwan which revealed the incidence of in-hospital infections around 29.66 % (25). However, it is higher than the study done in china 5 % (42). This could be due to variation in advanced care and availability of higher quality neuro-trauma center and well-established pre-hospital care for traumatic patients in China. The other potential reasons could be the lower infection prevention techniques and lack of on time diagnosis of infectious diseases in

our setting. This implied that there is a lack of special emphasis to be given to trauma patients in our country.

This study found that 36 (20.6%) developed a posttraumatic seizure among the recorded in-hospital complications. This finding is almost similar to the study conducted in the USA which revealed the incidence of PTS as 20.5 % (59). However, it is higher compared to the study done in India, 9.0 % (44). The possible reasons for this discrepancy could be due to the variation in reporting of posttraumatic seizures and length of hospital stay since our study considered all incidences of PTS and the higher chance of seizure occurrence as the length of hospital stay increased.

In the current study, the incidence of infections was recorded in 11.43 percent (n = 20) of study subjects. Of these, 2.9 % of them developed aspiration pneumonia, and another 8.0 % developed HAIs. This finding is lower compared to the study done in Greece (24). which showed 47 % for the lower respiratory tract and 17 % for HAIs. This could be due to advancements in treatment because study done in Greece was before a decade ago.

The incidence of in-hospital mortality was 12.6 % (22/175) in the current study. A similar finding was reported from the Dutch at 12.3 %, Rwanda at 12.8% and Hawassa, Ethiopia at 12.7 % (32, 37,48). The current finding is lower than the studies conducted in South India (17.7%), Uganda (33.3%), and Jimma, Ethiopia (21.2%). This could be due to progression and advancement in patient care across the years.

This study showed that the mean length of hospital stay was 5.65± 0.36 days. This is almost in line with a study done in South India at 4.97 ±5.4 days (44) and it is lower than the study conducted in the Netherlands at 8 ±13 days (37). This difference could be due to the difference in the severity of TBI patients included in the study, since 26.5 % of severe TBI patients were included in the study compared to 13 (7.43 %) in our study.

This study found that there was a statistical association among patients who lived on the street and in-hospital mortality compared to those who lived at home. The risk of death among participants who live on the street was 1.2 times higher than those who live at home. The higher risk of death could be due to lack of supporting families to get appropriate care.

The risk of death among patients with severe TBI was 6.2 times higher than that of mild TBI. This was in agreement with different studies (35, 37, 48). The possible reasons might be increased risk of infections, not being assisted with ventilator, and poor adherence to evidence-based treatment guidelines. Patients with GCS score of 9-12 had lower risk of death compared to mild TBI. The possible reason for this contradictory finding may be due to less emphasis were not given for mild head injured patients or the victims ignorance not to get appropriate management.

When compared to individuals who were normothermic, the risk of death among TBI patients who were subjected to hyperthermia was 2.1 times higher. This result is in line with one from a Chinese study. This might be caused by a rise in the metabolic needs of the brain, an increase in ICP, and cell damage brought on by an increase in body temperature (6).

Patients who received pre-hospital care had a 3.2 times lower mortality risk than those who did not. Different studies (32,36,48) were in line with this finding. This implied the need for prompt resuscitation in order to stop secondary brain damage. Therefore, pre-hospital care for TBI patients should be a priority for clinicians.

Antipsychotic use and in-hospital mortality were significantly linked in the current investigation among the study patients. When TBI patients took either antipsychotic medication, their risk of dying was 43% lower than it was for those who did not. This alerted medical professionals that TBI patients require a comprehensive approach to care and antipsychotic medication selection.

Strengths and Limitations

The present study was able to determine and assess the clinical profile and outcomes in patients with TBIs and mortality predicting factors. Nevertheless, the authors would like to acknowledge the following limitations.

- ✓ Shorter follow up period
- ✓ The survival status of the study subjects was followed only for duration of hospital stay.

Furthermore, the consideration of a single-center and small sample size may have affected the power of the present study

7. CONCLUSION AND RECOMMENDATION

7.1 Conclusion

In-hospital mortality was recorded in over one-tenth of TBI patients. More than one-fourth of patients had in-hospital complication. The GCS score of < 8 on admission, hyperthermia, and lack of pre-hospital care were the predictors of in-hospital mortality in TBI patients.

7.2 Recommendation

The following recommendations were forwarded based on the findings of the study.

For Jimma Medical Center

- ✓ Health care providers should give special attention to TBI patients with low GCS, and high body temperature
- ✓ Should consult clinical pharmacists on the use in TBI patient's candidate for antipsychotics selection.

For Federal Ministry of Health

- ✓ Should allocate budget and resources and work with the woredas, zone and regional health offices and respective administrators in order to establish a standard on scene management for traumatic patients

For Government and Policymakers

- ✓ Majority of TBI were caused by road traffic accidents and violence/ assault. So, concerned government (i.e. Ethiopian road and transport agency) should work on improving the road safety and traffic rules and regulations.

For Researchers

- ✓ Researchers should conduct further study in order to overcome the limitations of this study.

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ANNEXES

ANNEX I: PARTICIPANT INFORMATION SHEET (English Version)

Principal Investigator:-Gemechis Belay Dibera

Dear participant! Here, I undersigned, at Jimma University, Institution of Health, School of Pharmacy, Department of Clinical Pharmacy Graduate Study Program, currently undertaking a research on a title: Clinical Characteristics and Outcomes of Traumatic Brain Injury in patients admitted to surgical ward of Jimma Medical Centre, Jimma, South-west Ethiopia. For this study, you were selected as a participant and before getting your consent, you need to know all necessary information related to the study whose detail is explained as follows.

Objective:- The objective of this study is to determine the clinical profile, outcomes and the prognostic factors of Traumatic Brain Injury (TBI) patients admitted to surgical ward of JMC. **Risks:**-The study will not impose any risk to participants. **Benefits:-**There is no immediate benefit from participating in this study. However, your participation helps to improve the care and identify the prognostic factors of TBI patients. **Confidentiality:-** The information which is collected from you was kept confidential and used only for research purpose. We assign a code to questionnaires to assure confidentiality instead of using your name and we don't disclose the information to third body. **Participant's right:-** Your participation is voluntary and you are not obliged to answer any question you do not want to answer. If you are not comfortable with interview you can leave at any time you need as there is no harm if you don't answer the questions. **Contact:-** For more information and question here is the contact address of the investigator; Gemechis Belay: Tel: +251934176718 Email: romebeck2012@gmail.com.

Participant's consent form (English Version)

I have been informed the importance and objective of the study going to be conducted by Mr. Gemechis Belay on the Clinical Characteristics and Outcomes of Traumatic Brain Injury in patients admitted to surgical ward of Jimma Medical Center, Jimma, South West Ethiopia. I had the chance to ask questions about the study and all questions have been answered to my understanding. I have been informed and understood that participation is entirely voluntary and that I can withdraw my consent at any time if I wish so. I consent voluntarily to participate in this study as a respondent.

Participant's Signature: _____

Name and signature Data collector: _____

Date: _____

Participants Information Sheet (Amharic Version)

የተሳታፊዎች መረጃ ቅፅ

ዋና መርማሪ፡ገመቺስ በላይ ዲበራ

ውድ ተሳታፊ! እዚህ፣ በጅማ ዩኒቨርሲቲ፣ በጤና ተቋም፣ በፋርማሲ ትምህርት ቤት፣ በክሊኒካል ፋርማሲ ምሩቃን ትምህርት ክፍል በአሁኑ ወቅት ደቡብ ምዕራብ ኢትዮጵያ በጅማ ሕክምና ማዕከል የቀዶ ጥገና ክፍል በገቡ ሕሙማን ላይ ክሊኒካ ዊባህሪያት እና የአሰቃቂ የአንጎል ጉዳት ውጤቶች ላይ ጥናት በማድረግ ፈርሜያለሁ። ለዚህ ጥናት እንደ ተሳታፊ ሆነው ይመረጣሉ እና ስምምነትዎን ከማግኘትዎ በፊት ዝርዝሩ በሚከተለው መልኩ ከተገለፀው ጥናት ጋር የተያያዙ ሁሉንም አስፈላጊ መረጃዎች ማወቅ ያስፈልግዎታል.

ዓላማው፡የዚህ ጥናት ዓላማ በJMC የቀዶ ጥገና ክፍል ውስጥ የገቡትን የአሰቃቂ የአንጎል ጉዳት (**TBI**) ክሊኒካዊ መገለጫ፣ ውጤቶች እናት ንበያ ሁኔታዎችን መወሰን ነው።

ስጋቶች: - ጥናቱ ለተሳታፊዎች ምንም ዓይነት አደጋ አይፈጥርም.

ጥቅማጥቅሞች፡-በዚህ ጥናት ውስጥ መሳተፍ ፈጣን ጥቅም የለም። ነገር ግን፣ የእርስዎ ተሳትፎ እንክብካቤውን ለማሻሻል እና የ**TBI** ሕመምተኞች ትንበያ ምክንያቶችን ለመለየት ይረዳል።

ሚስጥራዊነት፡ከእርስዎ የሚሰበሰበው መረጃ በሚስጥር ይጠበቃል እና ለምርምር ዓላማ ብቻ ጥቅም ላይ ይውላል።የእርስዎን ስም ከመጠቀም ይልቅ ምስጢራዊነትን ለማረጋገጥ ለጥያቄዎች ኮድ ሰጥተናል እና መረጃውን ለሶስተኛ አካል አንገልጽም።

የተሣታፊመብት፡የእርስዎ ተሳትፎ በፈቃደኝነት ነው እና እርስዎ መመለስ የማይፈልጉትን ማንኛውን ምጥያቄ ለመመለስ አይገደዱም። በቃለመጠይቅ ካልተመቸዎት ለጥያቄዎቹ መልስ ካልሰጡ ምንም ጉዳት ስለሌለ በሚፈልጉበት ጊዜ መሄድ ይችላሉ።

እውቂያ: - ለበለጠ መረጃ እና ጥያቄ እዚህ የመርማሪው አድራሻ ነው; ገመቺስ በላይ፡ ስልክ፡ +251934176718

ኢሜል፡ romebeck2012@gmail.com

የ ተሳታፊውፈቃድ ቅጽ(Amharic version)

በደቡብምዕራብኢትዮጵያ ጅማ ህክምና ጣቢያ በቀዶ ህክምና ክፍል በገቡ ህሙማን ላይ በአቶ ገመቺስ በላይ የሚካሄደው የጥናት አስፈላጊነት እና አላማ ተነግሮኛል። ስለጥናቱ ጥያቄዎችን የመጠየቅ እድል ነበረኝ እና ሁሉም ጥያቄዎች ለኔ ግንዛቤ ምላሽ አግኝተዋል። ተሳትፎው ሙሉ በሙሉ በፈቃደኝነት እንደሆነ እና ከፈለግኩ በማንኛውም ጊዜ ፈቃዴን ማንሳት እንደምችል ተነግሮኛል እናተረድቻለሁ። በዚህ ጥናት ላይ እንደምላሽ ሰጪ ለመሳተፍ በፈቃደኝነት ተስማምቻለሁ።

የተሳታፊ ፊርማ:_____

የሰብሳቢ ስም እና ፊርማ:_____

ቀን፡_____

Participant's Information Sheet (Afan Oromo version)

Waraqaa Ibsa Hirmaattotaa

Maqaa Qorataa: Gammachiis Balaay

Kabajamaa hirmaataa! Kibba-lixaItophiyaa, Giddu-gala fayyaatti mata-duree qorannoo amaloota kilinikaalaa fi bu'aa yaalii dhukkubsattoota balaa-alaatiin sammuun isaanii miidhame gara kutaa baqaqsanii yaaluu ciisan qorachuuf gaditti mallatteesseera. Isin qorannoo kana keessatti hirmaataataataniittu. Waliigaluu keessan dura garuu odeeffannoowwan adeemsa qorannoo kana keessa jiran armaan gaditti heerame hubachuu keessan mirkaneeffadha.

Ijoo qorannichaa: Yuunivarsitii Jimmaatti Giddu Gala Fayyaa (JMC) kutaa baqaqsanii yaaluutti sabababa laatiin namoota sammuun miidhame wantoota bu'aa yaalii isaanii irratti dhiibbaa qabuufi amaloota kilinikaalaa isaanii beekuu.

Rakkina jiru: Qorannoon kun hirmaattota irratti rakkoo tokko hin fidu.

Mirga Hirmaattotaa: Dhukkubsattoonni gaaffiifi deebii addaan kutuun dhiisuu akkasumas kaardii isaanii qorannoof akka hin oolle yoo barbaadan dhiisuus mirga guutuu qabu.

Fayyadamummaa: Qorannoon kun faayidaa battalaa hin qabu. Garuu, dhukkubsattoota miidhama walfakkaataan dhufaniif wantoota bu'aa yaalii isaanii dhiibbaa uumu danda'u beekuun yaalii fooyya'aa kennuuf oola.

Kennaa: Kennaa addaa dhukkubsataan ykn hirmaattotni argatan hinjiru. Sababa hirmaataniif garuu galata guddaa qabu.

Dhoksaa Eenyummaa: Odeeffannoo dhukkubsataa utuu hin saaxilin akkasumas maqaan dhukkubsattootaa akka hin beekamneef koodiiitti gochuudhaan kan odeeffannoo fudhanne dhimmaqorannoo qofaaf oolchina.

Dabalataan Ragaa Argachuuf: Ragaa dabalataa argachuuf ta'ee rakkinni yoo isin qunname eddo armaan gadii kanaan naa rgachuu ni dandeessu.

Gammachiis Balaay: Bilbila: 0934176718, Email: romebeck2012@gmail.com

Unka fedhii waliigaltee Afaan Oromootiin

Giddu-gala fayyaa Jimmaatti dhukkabsattoota sababa balaa alaatiin sammuun miidhame bu'aa yaalii fi amaloota kilinikaalaa isaanii qorachuu kan jedhu irratti qorannoon adeemsifamu kaayyoo fi barbaachisummaan isaa naaf ibsamee jira.Anis wanta naaf ibsame hubadheen jira. Akkasumas sa'aatiin barbaadetti hirmaannaakoo dhaabuu akkan danda'u natti himamee jira. Qorannoo kana irratti hirmaachuu kootiin faayidaa addaa (birrii) kanan hin arganne ta'uu, miidhaa fayyaa narraan ga'u akkan qabne akkasumas odeeffannoon narraa fuudhamu iccitiin isaa kan eegamuu fi qaama biraaf dabarfamee kan hin kennamne ta'uu hubadheen jira.

Kanaafuu, qorannoo kana irratti hirmaachuuf fedha qabaachuukoo mallattoo kootiin nan mirkaneessa.

Mallattoo hirmataa/ttuu_____

Maqaa fi mallattoo sassaabaa odeeffannoo_____

Guyyaa_____

ANNEX II: QUESTIONNAIRIES

Checklist designed to collect data on prospective analysis of clinical characteristics and outcome of TBI patients admitted to surgical ward of Jimma Medical Center (JMC).

Principal investigator: Gemechis Belay (B.Pharm, MSc candidate) Phone: +251934176718

Data collector: _____ Date: _____ Signature: _____

I: SOCIO-DEMOGRAPHICS INFORMATION

1. Card No:_____
2. Date of admission_____
3. Phone number of the patient:_____ Caregiver's Phone number:_____
4. Age (in years) _____
5. Sex: ☐ Male ☐Female
6. Residence: ☐ Urban ☐ Rural ☐ Missed
7. Educational status: ☐ Unable to read and write ☐ Primary ☐ Preparatory ☐ Diploma and above
8. Marital status ☐Single ☐ Married ☐ Divorced ☐ Widow
9. Occupation ☐Student ☐Civil servant ☐Driver/Assistant ☐Daily laborer ☐ Merchant ☐ Unemployed ☐ Farmer ☐ House wife ☐ Others
10. Living situation: ☐ Home ☐ Street ☐ Missed
11. Social drug use: ☐ Smoker ☐ Chew chat ☐ Alcohol drinker ☐ Others

II: INJURY RELATED INFORMATION

12. Cause of Injury
    a. Road traffic accident b. Fall c. Violence e. Others(Specify):_____

13. Mode of arrival to the hospital
    a. Ambulance b. Taxi c. Police car d. Carried by attendants e. Walking f. Private car
14. Post-injury arrival time
    a. ≤6 hours b. >6 hours c. unknown

III. CLINICAL PROFILE INFORMATION

15. **Vital signs on admission**

Vitals signs on admission	Value
BP (in mmHg)	
Temperature (in Celsius)	
Pulse rate (in bpm)	
Respiratory rate (in bpm)	
O2 saturation (in mmHg)	

16. **Laboratory findings on admission**

CBC	Result	Serum electrolytes	Result	RFTs	Result
WBC		Na		BUN	
RBC		K		Urea	
Hgb		Ca		Cr.	
Hct		**Coagulation Profile**	**Result**	**LFTs**	
PLT		INR		AST	
Neu		aPT		ALP	
Lymp		PT		ALT	

17. GCS on admission:

18. RBS

19. ESR

20. CT findings

a. Normal
b. Depressed skull fractures
c. Basal skull fractures
d. Acute epidural hematoma
e. Contusions
f. Linear skull vault fractures
g. Sub-acute/chronic subdural hematoma
h. Others (specify) :_____

21. MRI result:_____

22. Is there any associated injuries? Yes ☐ No ☐

23. If the answer for Question no 22 is yes, which part of body is injured?

a.Neck b. Abdomen c. Leg d. maxillofacial e. Others (specify)

24. Are there any medical conditions prior to trauma? Yes ☐ No ☐

25. If yes for question no 24, which of the following?

a. CHF d. Epilepsy g. Others (specify)_____

b. HTN e. Stroke

c. DM f. Prior TBI

26. Is there any medications used prior to admission? Yes ☐ No ☐

27. If the answer for question no 26 is yes, which medications are used?

a. ACEIs/ARBs e. Antipsychotics i. Others(Specify)_____

b. BBs f. Diuretics

c. Metformin g. Statins

d. AEDs h. Anticoagulants/antiplatelet

IV. INTERVENTION-RELATED INFORMATION

28. Which intervention is used for management of TBI?

a. Pharmacological therapy b. Surgical C. Both

29. If surgical therapy, which type of surgery?

a. Craniotomy b. Burr hole c. EVD d. Skull elevation e. Others (Specify)_____

30. If pharmacological therapy, which pharmacological treatment options are initiated?

I. Is DVT prophylaxis initiated? If yes, which agent is indicated?

a. UFH b. Enoxaparin c. Warfarin d. Others (Specify)_____

II. Is seizure prophylaxis initiated? Yes ☐ No ☐

III. If yes for the above question, which medication is initiated?

a. Phenytoin b. Phenobarbital c. Diazepam d. Others(specify)

IV. Is ICP management indicated? If so, which agent is used?

a. Mannitol b. Furosemide c. Others (specify)_____

V. Is surgical prophylaxis initiated? If yes, which antibiotic is used?

a. Ceftriaxone b. Vancomycin d. Metronidazole e. Others (specify)___

VI. Is the patient resuscitated? If yes, which fluid is used?

a. NS b. RL c. DNS d. Others (specify) _____

VII. Is stress-ulcer prophylaxis initiated? If so which agents are used?

a. PPIs b. H2RAs

VIII. Is any anti-emetic medications initiated? If so, which agent is used?

a. Metoclopramide b. Hyoscine c. Others (specify)_____

IX. Is any antipsychotics initiated? If so, which agent(s) is used?

a. Risperidone b. Haloperidol c. Others(specify)_____

X. Is any antidepressants initiated? If so, which agent(s) is used? :_____

XI. Is any mood stabilizers initiated? If so, which agent(s) is used? :_____

XII. Are any Hypnotics /Sedatives /Analgesics/Antipyretics initiated? If so, which agent(s)?

a. NSAIDs b. Opioids c. Barbiturates d. Others (specify)

V: OUTCOMES

A. Outcomes to be recorded during hospitalization

1. Is there is an incidence of early seizure? Yes ☐ No ☐
   a. If yes, time of event (mins/hrs./days) :_____
2. Is there an episode of late seizure? Yes ☐ No ☐
   a. If yes, time of event (mins/hrs./days) :_____
3. Is there is a record of 'in-hospital mortality'? Yes ☐ No ☐
   a. If Yes, time of death(in mins/hrs./days) after admission:_____
4. Is there an occurrence of infections? If Yes, which of the following?

a. Aspiration pneumonia
b. Surgical site infection
c. Sepsis
d. Meningitis
e. Others(specify)_____

5. Length of hospital stay:_____(Discharge date:_____)

ANNEX II: UNKA SASSAABBII ODEEFFANNOO (Afan oromootiin)

Yuunivarsiitii Jimmaa, giddu-gala yaala fayyaatti unka sassaabbii odeeffannoo qorannoo amaloota kilinikaalaa fi bu'aa yaalii dhukkuba sammuu balaa alaatiin dhufu kan kutaa baqaqsanii yaaluu ciisanii

***Maqaa qorataa**: Gammachiis Balaay (B.Pharm, MSc kaadhimamaa) Bilbila: +251934176718*

***Sassaabaa**: _____ Guyyaa: _____ Mallattoo: _____*

I: Odeeffannoo Dugduubee

1. Lakk. Kaardii:_____
2. Guyyaa galmee: _____
3. Lakk.bilbilaa dhukkubsataa:_____ Lakk. bilbilaa dhukkubsachiisaa:_____
4. Umrii (baraan) _____
5. Saala: ☐ Dhiira ☐Dhalaa
6. Bakka jireenyaa: ☐ Magaala ☐ Baadiyyaa ☐ Hin beekamne
7. Sadarkaa barumsaa: ☐ Barreessuus dubbisuus hin danda'u ☐ sadarkaa 1ffaa☐ Sadarkaa 2ffaa ☐ Diploomaafi isaa ol
8. Haala gaa'elaa ☐ Qeenxee ☐ Fuudhe/heerume ☐ Hiike/te ☐ Kan irraa/jalaa du'e/duute
9. Hojii☐Barataa☐ Hojjetaa mootummaa☐ Konkolaachisaa/gargaaraa☐ Dafqee bulaa ☐ Daldalaa ☐ Hoji-dhabaa ☐ Qonnaan bulaa ☐ Haadha manaa ☐ Kan biraa
10. Haala jiraatu: ☐ Maatii waliin ☐ Karaarra ☐ hin baramne
11. Fayydama-qoricha hawaasaa: ☐ Ni xuuxa ☐ Qaamuu ☐ Alkoolii ☐ Kan biraa

II: ODEEFFANNOO BALAAN WAL QABATU

12. Sababa balaa
    b. Konkolaataa c. Wal-dhabdee d. Kan biraa (Ibsi):_____
    c. Kufaatii
13. Akka itti hospitaala dhufe
    b. Ambulaansii b. Taaksii c. Konkolaataa poolisii d. Baatamee e. Deemee
14. Balaa booda sa'aatti hospitaala ga'e
    b. Sa'aa 6 fi isaa gad b. Sa'aa 6 ol c. hin beekamu

ANNEX II: QUESTIONNAIRES (Amharic version)

ወደ ጅማ ሜዲካል ሴንተር (JMC) የቀዶ ጥገና ክፍል የገቡትን የ**TBI** ሕሙማንን ክሊኒካዊ ባህሪያት እና ውጤቱን በተመለከተ መረጃ ለመሰብሰብ የተነደፈ ማረጋገጫ ዝርዝር።

ዋና መርማሪ፡ *ገመቺስ በላይ (B.Pharm፣ MSc ኦጩ) ስልክ፡ +251934176718*

መረጃ ሰብሳቢ _____ *ቀን:* _____ *ፊርማ:*_____

I: የሶሺዮ-ዲሞክራሲያዊ መረጃ

1. የካርድ ቁጥር:_____
2. የመግቢያ ቀን: _____
3. የታካሚው ስልክ ቁጥር:_____ የተንከባካቢ ስልክ ቁጥር:_____
4. ዕድሜ (በአመታት)_____
5. ወሲብ፡ ☐ ወንድ ☐ሴት
6. መኖሪያ: ☐ ከተማ ☐ ገጠር ☐ ጠፋ
7. የትምህርት ደረጃ፡ ☐ ማንበብ እና መፃፍ አልተቻለም: ☐ የመጀመሪያ ደረጃ ☐ መሰናዶ☐ ዲፕሎማ እና ከዚያ በላይ
8. የጋብቻ ሁኔታ ☐ ነጠላ ☐ ያገባ☐ የተፋታ☐ መበለት
9. የስራ መደብ ☐ተማሪ☐ የመንግስት ሰራተኛ ☐ ሹፌር/ረዳት☐ የቀን ሰራተኛ ☐ ነጋዴ ☐ ስራ አጥ ☐ የገበሬ ☐ የቤት እመቤት☐ ሌሎች
10. የኑሮ ሁኔታ: ☐ የቤት☐ ጎዳና ☐ ጠፋ
11. ማህበራዊ እፅ መጠቀም: ☐ አጫሽ☐ ቻት ☐ አልኮል ጠጪ ☐ ሌሎች

II: ከጉዳት ጋር የተያያዘ መረጃ

12. የጉዳት መንስኤ
    a. የመንገድ ትራፊክ አደጋ b. ውድቀት c. ሁከት d. ሌሎች (ይግለጹ):_____
13. ወደ ሆስፒታል የመድረስ ሁኔታ
    c. አምቡላንስ b. ታክሲ c. የፖሊስ መኪና d. በአስተናጋጆች የተሸከመው e. መራመድ
14. ከጉዳት በኋላ የመድረሻ ጊዜ
    a. ≤6 ሰአት b. > 6 ሰዓታት c. የማይታወቅ

JIMMA UNIVERSITY

INSTITUTE OF HEALTH SCIENCE

SCHOOL OF PHARMACY

Declaration

This is to certify that this thesis is prepared by Gemechis Belay which is entitled by: Clinical Characteristics and Outcomes of Traumatic Brain Injury in patients admitted to Surgical Ward of Jimma Medical Center, Jimma Southwest Ethiopia: Prospective study for the partial fulfillment of Master's Degree in Clinical Pharmacy .

I declare that this research paper is my own original work and that has not been presented to any other university for similar or any other degree award.

Name of principal investigator: Gemechis Belay (BPharm.)

Date: _____ Signature_____

Approval

Advisor: Mr. Mengist Assistant Professor of Clinical Pharmacy)

Date: _____ Signature_____

External examiner: Mr. Assefa Mulu (Assistant Professor of Clinical Pharmacy)

Date: _____ Signature_____

Internal examiner: Mr. Fekede Bekele (Assistant Professor of Clinical Pharmacy)

Date: _____ Signature_____

School Head: Mr. Girma Mamo (Assistant Professor of Clinical Pharmacy)

Date: _____ Signature_____