



St. Paul Hospital Millennium Medical College postgraduate Study Program

**Functional Outcome of Adult Traumatic Brain Injury patients treated by
Decompressive Craniectomy: A Multi-centered Hospital Based Study.**

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Addis Ababa, Ethiopia

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Saint Paul's Hospital Millennium Medical College (SPHMMC)

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Decompressive Craniectomy: A Multi-centered Hospital Based Study.**

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Research Thesis submission form

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The full title of the research project	Functional Outcome of Adult Traumatic Brain Injury patients treated by Decompressive Craniectomy: A Multi-centered Hospital Based Study.
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Abstract

Background: Surgical removal of a portion of the skull, known as decompressive craniectomy (DC) is performed to relieve elevated intracranial pressure and to improve outcomes in Traumatic Brain Injury (TBI) patients. This study is the first of its kind to assess functional outcome of DC for TBI patients in Ethiopian setup to the principal investigators knowledge.

Objective: This study describes the long-term functional outcome of TBI patients treated by DC and identifies factors that affect functional outcome.

Method: A multi-centered, cross-sectional study design was used to collect data on decompressive craniectomy performed for patients with TBI admitted from May 1, 2018, to May 1, 2021. G.C. Structured extended Glasgow outcome scale (GOSE) questionnaire was used to collect data using in depth phone interview to assess long-term outcome in the survivors. Univariate analysis was done for descriptive statistics using frequency, mean, median, range, and standard deviation. Multivariate regression analyses were used to determine the predictors of functional outcomes. A p-value of less than 0.05 was considered statistically significant.

Result: Seventy-four patients were included in this study. Mean age at time of DC was 33.9 years (range 17–69) with male to female ratio of 11.3:1. Assault was the cause of TBI in 40%. The mean GCS at admission was 8.2 (range, 3–14). Pupillary abnormality was present in 60.8% of patients. Primary DC was done in 93.2%. In Hospital mortality rate was 24.3%. The overall mortality rate was 36.5%. Forty-seven survivors (63.5%) were followed for a median period of 13 months (range, 12–18 months). Favorable functional outcome (GOSE ≥ 4) was seen in forty-three patients (58.1% overall, and in 91.5% of survivors). 85.7% of patients with GCS ≤ 5 had unfavorable functional outcome. Complications occurred in 64.9%. Bone replacement was done for 80.9% of survivors at median duration of 5 month (range, 1 - 9). Age ≥ 40 , [p= 0.045; AOR= 4.380; 95% CI= 1.031 - 18.606], GCS ≤ 5 [P= 0.006; AOR= 18.557; 95% CI= 2.290 - 150.354], presence of chest infections [P= 0.013; AOR= 5.202; 95% CI =1.417 - 19.097], and presence of noninfectious complications [p=0.035; AOR=4.009; 95%CI=1.100-14.607] were an independent predictors of unfavorable functional outcome.

Conclusions: In this study, we demonstrated a good outcome with DC for TBI comparable to other studies. Age, Admission GCS, presence of postoperative chest infection, and presence of noninfectious complications were an independent predictors of unfavorable functional outcomes. Mortality rate and unfavorable outcome were significantly higher in patients with GCS ≤ 5 . The effect of this finding on future decision-making need to be evaluated by a prospective multicenter study with large sample size.

Keywords: Decompressive craniectomy, surgical outcome, factors affecting the surgical outcome

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Acronyms and Abbreviations

Acute Epidural Hematoma (AEDH)

Acute Subdural Hematoma (ASDH)

Addis Ababa Burn, Emergency, Trauma Hospital (AaBET)

Brain Trauma Foundation (BTF)

Central Nervous System (CNS)

Cerebral Perfusion Pressure (CPP)

Cerebrospinal Fluid (CSF)

Computed Tomography (CT)

Cranioplasty (CP)

Decompressive Craniectomy (DC)

Decompressive Craniectomy in Diffuse Traumatic Brain Injury (DECRA)

Deep Surgical Site Infection (DSSI)

Deep Venous Thrombosis (DVT)

Glasgow Coma Scale (GCS)

Glasgow Outcome Scale (GOS)

Glasgow Outcome Scale Extended (GOSE)

High Income Countries (HMIC)

Hospital Acquired Pneumonia (HAP)

Hydrocephalus (HCP)

Institutional Review Board (IRB)

Intensive Care Unit (ICU)

Intracranial Pressure (ICP)

Limited Craniectomy (LC)

Low and Middle-Income Countries (LMIC)

Partial pressure of CO₂ (PaCO₂)

Brain tissue oxygen (PtiO₂)

Penetrating Brain Injury (PBI)

Polymethylmethacrylate (PMMA)

Pulmonary Thromboembolism (PTE)
Randomized Controlled Trial (RCT)
Randomized Evaluation of Surgery with Craniectomy for Uncontrollable Elevation of
Intra-Cranial Pressure (RESCUicp)
Road Traffic Accident (RTA)
Saint Paul's Hospital Millennium Medical College (SPHMMC)
Saint Peter Specialized Hospital (SPSH)
Spinal Cord Injury (SCI)
Standard Trauma Craniectomy (STC)
Statistical Package for Social Science (SPSS)
Superficial Surgical Site Infection (SSSI)
Surgical Site Infection (SSI)
Traumatic Brain Injury (TBI)
Urinary Tract Infection (UTI)
Ventriculoperitoneal Shunt (VPS)
World Health Organization (WHO)

1. Background

According to the Global Burden of Disease study, 27 million new cases of traumatic brain injury (TBI) occur worldwide each year. The proportion of TBI cases in low and middle-income countries (LMICs) is nearly three times that of high-income countries (HICs) ¹.

Falls and road injuries were the leading causes of new cases of TBI and spinal cord injury (SCI) in most regions. According to the World Health Organization (WHO) 93% of the world's fatalities on the roads occur in low- and middle-income countries, even though these countries have approximately 60% of the world's vehicles ².

As the primary damage inflicted by trauma in most patients with TBI cannot be reversed, medical and surgical therapies are primarily directed at reducing secondary neuronal injury. Increased intracranial pressure (ICP) as a consequence of TBI can lead to compression of brain parenchyma, compromised cerebral perfusion, impaired CSF circulation, irreversible neuronal injury, and even brain herniation ³.

To mitigate the detrimental consequences of increased ICP, several first-tier and second-tier measures have been recommended by the Brain Trauma Foundation ⁴. The treatment objectives after TBI include preventing and reversing elevation of ICP and maintaining satisfactory cerebral perfusion pressure (CPP) to prevent further brain injury ⁵. Elevated ICP is treated initially by initiating general measures (head elevation, light sedation, avoiding hypoxia and hypotension, ventilation to achieve normocarbia, and keeping the neck straight in the midline). When general measures fails to control ICP first tier treatments which includes heavy sedation, CSF drain, hyperventilation to PaCO₂ target of 30-35 mmHg, hyperosmolar therapy, will be added to general measures. When all first tier and general measures fails to control ICP second tier treatment will be added, which include barbiturates, augmented hyperventilation (target PaCO₂ 25-30mmHg), hypothermia, and decompressive craniectomy (DC) ^{4,5}.

Decompressive craniectomy (DC) is a neurosurgical procedure that involves the removal of a section of the skull ('bone flap') and opening of the underlying dura ⁶. Decompressive craniectomy (DC) as a measure of controlling ICP is controversial in many centers but some believe it is lifesaving when medical managements fail. Controversies include the associated complications of DC, the need for cranioplasties as well as the disabilities in patients that survived ⁷.

In patients with severe TBI and elevated ICP that is refractory to medical management, DC is sometimes performed to relieve ICP and to provide space for brain tissue to expand as the last option in management protocol or in other instances, it is used in combination with medical options with significant-good outcomes ^{5,8}.

The challenge of knowing the appropriate time to consider DC and selecting appropriate patients is a factor being debated especially in resource-limited regions. This is primarily due to a lack of capacity to monitor ICP. In many instances, the decision to select treatment options for a patient with TBI without an ICP monitor is limited to patient admission status, response to available medical treatments, CT scan findings, and treating physician's decision.

2. Statement of the Problem

The vast majority of studies on DC have been conducted in high-income countries even though 89% of head injuries occur in LMICs. Hence, caution is required in applying evidence to management across the globe ⁶. The decision to select treatment options for the patient with TBI without an ICP monitor is limited to patient admission status, response to available medical treatments, CT scan findings, and operating physician's decision, which is different from practice in HIC. To address this growing public health problem research like this are of significant importance.

The three centers included in this study are tertiary hospitals and they receives a large volume of patients with TBI. Despite having large volume of TBI patients, there was no study done in Ethiopia to assess the effects of DC on functional outcomes of patients treated by DC, which significantly limited our understanding of patient outcomes following the surgical intervention.

3. Significance of the Study

The purpose of this study was to determine the functional outcome of TBI patients treated by decompressive craniectomy at Addis Ababa Burn, Emergency, and Trauma Hospital (AaBET), Saint Peters Specialized Hospital (SPSH), and Menelik II Hospital in a setup that does not have ICP monitoring.

This study provides critical information about patient outcomes, factors influencing surgical outcomes, and post-operative complications. This information will be used to improve future interventions for TBI patients in Ethiopia, and indeed provides additional information to the world regarding the outcome of DC in resource-limited setups compared to other international publications on DC.

Based on the findings of this study, it may be possible to develop a comprehensive decision-making strategy for interventions such as DC based on available resources and expected patient outcomes, allowing us to make efficient use of very limited resources available in our hospitals.

The finding of this study may be used as a baseline data for future prospective studies on DC.

4. Literature review

4.1 Historical Perspectives

The surgical removal of a portion of the skull, either for medical or superstitious reasons is known in the anthropological context as "trepanation." This commonly involved the drilling or scraping of a hole into the skull. Evidence of the most primitive craniectomy has been found in skeletons up to 6,000 years old, with well-documented archaeological findings spread from pre-Columbian Peru to bronze-age Europe and Neolithic Africa ⁹.

In 1901, Emil Theodore Kocher became the first in the modern literature to describe the technique of surgical decompression and its value in relieving intracranial pressure ¹⁰. Harvey Cushing later described a detailed technique of using bilateral subtemporal craniectomy to relieve pressure on the brain from an inaccessible tumor ¹¹. Due to poor clinical outcomes, DC quickly fall into discredit and was almost abandoned when experimental evidence by Cooper *et al.*, suggested that decompression worsens cerebral edema by reducing interstitial fluid pressure and causing edema enhancement ¹².

Similarly, another study done in 1980, by Gerl and Tavan reported their result on extensive bilateral craniectomy with dura opening done for 30 patients with TBI and, they observed rapid reduction of intracranial pressure. This study reported 70% mortality and only 20% of patients achieving full recovery ¹³.

In 1990, Gaab *et al* did a prospective study on 37 patients <40 years old, in this study they performed 19 bifrontal craniotomies and 18 large hemicraniectomies with dura enlargement by use of temporal muscle/fascia. This study reported five deaths, all others patients achieved full social rehabilitation or remained moderately disabled. This study also found an initial posttraumatic Glasgow coma scale (GCS) ≥ 7 as the best predictor of a favorable outcome. After this publication DC has become very popular again, and published papers have had a striking increase ¹⁴.

4.2 Types of DC and surgical techniques.

Primary DC is defined as any bone decompression performed in patients undergoing surgery for the evacuation of any intradural lesion ^{6,15}. The aim of Primary DC is not to control high ICP but to prevent expected postsurgical increases in ICP. In these procedures the decision is taken by the surgeon and is usually based on the CT scan, or intraoperative surgical findings (brain swelling, a tight brain, or difficulties in repositioning the bone flap), or both. Some authors have also proposed the use of primary DC as a therapeutic strategy in the management of some types of brain contusions, as a damage control procedure in patients with acute subdural hematomas, or for severe brain swelling in countries with low resources and limited availability of intensive care facilities ^{16,17}.

Hinge craniotomy is a surgical procedure whereby the bone flap is replaced before closure in such way that it is secured at one bone edge with a titanium plate attachment, and the other edges of the bone flap have a plate attachment secured only on the bone flap (but not connected to the cranial bone edge). This allows the bone flap to expand outward, but prevents it from sinking inward toward the brain ¹⁸.

A secondary DC is defined as a procedure performed on patients with continuous ICP monitoring to control high ICP that is refractory to first tier or second tier medical treatment ¹⁵. This therapeutic option is used as last-tier life-saving therapy for patients with refractory intracranial hypertension (i.e. when all other measures have failed to reduce ICP) or as a second-tier therapy in patients with less pronounced elevation of ICP (i.e. as a neuro-protective measure) ⁶. Guerra *et al.*, included DC done for patients who underwent a first surgical procedure to evacuate a space occupying lesion and who had later developed delayed massive unilateral or bilateral brain swelling in the category of secondary DC, when the purpose of DC was to control delayed high ICP ¹⁹.

The three main approaches to DC are bifrontal craniectomy, unilateral frontotemporoparietal craniectomy (hemicraniectomy) and bilateral hemicraniectomy. Once the bone is removed, the dura is opened to relieve intracranial hypertension.

In study done by Reithmeier and colleagues, five patients with severe brain edema due to subarachnoid hemorrhage, brain injury, or cerebral ischemia have been monitored (ICP, CPP, ptiO₂) before, during, and up to 72 hours after craniectomy. Prior to surgery, mean ICP values were 25.6 mmHg (range, 23–29 mmHg), mean ptiO₂ values were 5.9 mmHg (range, 2.4–9.5 mmHg), and mean CPP values were 66 mmHg (range, 60–70 mmHg). After removing the bone flap, ICP values dropped to physiological values (mean, 7.4 mmHg), whereas ptiO₂ values increased only slightly (mean, 11 mmHg). Opening of the dura resulted in a further decrease of ICP (mean 4.8 mmHg) and an increase of ptiO₂ to normal limits (mean, 18.8 mmHg). After skin closure, mean ICP was 6.8 mmHg and mean ptiO₂ was 21.7 mmHg, respectively. They found a significant decrease of ICP after craniectomy ($p < 0.041$) and after dura enlargement ($p < 0.041$). The results of this study suggest that dura enlargement is the crucial step to restore adequate brain tissue oxygenation ¹⁸.

Skin incision should be larger than the intended craniotomy and pinna should be avoided (12×15 cm for unilateral frontotemporoparietal craniectomy). Bone flap size should be large (12×15 cm for unilateral frontotemporoparietal craniectomy) and have to incorporate removal of bone to the middle cranial fossa floor for both unilateral and bifrontal decompressive craniectomies. The dura should be opened and primary dural closure should not be performed. Expansile dural graft should be used either sutured duraplasty or onlay duraplasty ⁶.

4.3 Outcomes after decompressive craniectomy

Decompressive craniectomy in diffuse traumatic brain injury (DECRA) trial is the first randomized controlled trial done in adults patients with severe diffuse traumatic brain injury and refractory intracranial hypertension, and the study included 155 patients, evenly randomized into a maximal medical therapy group or decompressive craniectomy. In their study, Cooper et al found early bifrontal decompressive craniectomy decreased intracranial pressure and the length of stay in the ICU but it was associated with more unfavorable outcomes. From this study it was shown that

the mortality rate at six month follow-up did not differ between the two groups (19% in decompression group vs. 18% in medical group), and the functional outcome was worse in the decompressive craniectomy group (71% poor), compared to the medically managed group (51% poor outcome) ($p=0.02$)²¹.

The randomized evaluation of surgery with craniectomy for uncontrollable elevation of intra-cranial pressure (RESCUicp) trial, published in 2016, enrolled 408 patients with severe and refractory posttraumatic intracranial hypertension in 20 countries. Patients were randomized to secondary DC (bifrontal DC or hemicraniectomy) or standardized medical therapy (with the option of barbiturates after randomization). The primary endpoint was GOSE score at 6 months. This study at 6 month showed DC resulted in substantially lower mortality (26.9% vs 48.9%) but higher rates of vegetative state (8.5% vs 2.1%), lower severe disability (21.9% vs 14.4%), and upper severe disability (independent at home; 15.4% vs 8%) than medical care. The rates of moderate disability and good recovery were similar in the two groups. This study was extended beyond primary end point of GOSE at 6 month to assess GOSE at 12 month and it was found surgical patients continued improving beyond the 6 months, and at 12 months, 45.4% of surgical patients had a favorable outcome (upper severe disability or better) compared to 32.4% in the medical group ($p = 0.01$). These results suggest that secondary DC can be helpful as a last-tier intervention to reduce mortality in the subset of TBI patients with severe and refractory posttraumatic intracranial hypertension. However, caution is needed because approximately 40% of extra survivors generated by DC will be dependent on others at 12 months³.

Systematic review of the literature that evaluated 12 articles, of these studies 3 were RCT found DC in specific populations does not offer GOS or mortality advantages compared with medical treatment. Nonrandomized studies included in this systemic review showed decreased mortality and increased GOS when DC performed in patients aged ≤ 50 years, and when DC was performed < 5 hours after TBI in patients with a Glasgow Coma Scale score > 5 ²².

Cochrane Database of Systematic Reviews in 2019 included three trials (590 participants). One single center trial included 27 children; another multicenter trial (three countries) recruited 155 adults, the third trial was conducted in 24 countries,

and recruited 408 adolescents and adults. Each study compared DC with standard care. Except one study, which measured outcomes at 12 and 24 months, all trials measured outcomes up to six months after injury. This study concluded decompressive craniectomy holds the promise of reduced mortality, but the effects of long-term neurological outcomes remain controversial and should consider the priorities of participants and their families ²³.

A systematic review on the efficacy of decompressive craniectomy (DC) in controlling intracranial pressure (ICP) and improving long-term outcomes in children with TBI concluded currently available evidence may support a beneficial role of DC in controlling ICP and improving long-term outcomes ²⁴.

A retrospective review of the medical records of sixteen pediatric patients who underwent DC for TBI showed an average Glasgow Outcome Scale (GOS) at 6-month follow-up of 3.7, whereas 70% of the survivors presented good recovery (GOS 4–5). Follow-up evaluation revealed a cognitive abnormality in 55.6% of the patients. The overall mortality at 6-month follow-up was 37.5%. The study concluded a potential benefit of DC in children with severe TBI, despite the high incidence of neuropsychological impairment in the long-term follow-up ²⁵.

Keeping the conflicting results from the two major RCT DECRA ²¹ and RESCUEicp trials ³ in view, it seems likely that DC may afford a favorable functional outcome in carefully selected patients with TBI.

4.4 Factors affecting outcome in decompressive craniectomy

Different preoperative CT scoring system were used to predict functional outcome after decompressive craniectomy. In the study done by Maas et al, they developed an alternative CT classification, known as the Rotterdam CT scoring system, by determining the relationship between admission CT examination results and mortality at 6 months post injury. They showed better prognostic discrimination for Rotterdam CT scores than for the CT scoring system of Marshall et al., particularly for patients with mass lesions ²⁶.

Another retrospective study done on forty-eight patients treated by DC to assess the relationship between preoperative Rotterdam CT score and functional outcome after DC showed that preoperative Rotterdam CT score was independent predictor of early mortality (operative mortality) and unfavorable outcome at three months ²⁷.

Single-centered interventional study at one hospital in Egypt identified Age and initial posttraumatic GCS remain as the most important factors in determining the postoperative clinical outcome. Decompressive hinge craniotomy provided favorable clinical results in nearly 45% of patients who were otherwise most likely to die ²⁸.

A retrospective and multicenter study were conducted on 526 patients with DC, Age was the most significant predictor factor of survival, together with pupil reactivity, time of decompression, and size of the bone flap ²⁹.

In another retrospective study done by Murray et al., in a cohort of 8686 patients drawn from eight randomized controlled trials and three observational studies. The most powerful independent prognostic variables were age, Glasgow Coma Scale (GCS) motor score, pupil response, and computerized tomography (CT) characteristics, including the Marshall CT classification and traumatic subarachnoid hemorrhage. Prothrombin time was also identified as a powerful independent prognostic factor ³⁰.

Schur et al., in their study, concluded a larger craniectomy flap, representing two-thirds of the Hemi circumference of the skull, is associated with improved ICP control postoperatively. Indeed, a significantly lower ICP in the large flap group, with a tendency toward less mannitol given. They found no association between the bone flap size and the incidence of postoperative complications ³¹.

A randomized trial in 2005 that took place in five centers in China to compare outcomes after a standard-sized trauma DC (12 × 15-cm flap) vs a limited DC (6 × 8-cm flap) in severe TBI patients with refractory intracranial hypertension recruited 486 patients in total. The authors found that the mortality rate was lower (26% vs 35%) and favorable outcome rate higher (39.8% vs 28.6%) after standard trauma DC (STC)

compared to limited DC (LC) ($p < 0.05$). This study concluded STC, rather than LC, be recommended for such patients ³².

4.5 Complications after decompressive craniectomy

A systemic review done by Kurland et al assessed postoperative complications associated with DC from 142 eligible studies and they found hemorrhagic complications (i.e. new ipsilateral, new contralateral, hemorrhagic progression of contusions) in 12% (414/3443) of patients, inflammatory/infectious complications (i.e. SSI, DSI) in 5.5% (150/2720) of patients, and complications related to CSF disturbances (i.e. HCP, CSF hygroma, CSF leak/fistula) in 18.4% (1094/5939) of patients ³³.

This study also assessed post cranioplasty complication rate and pattern and they found post CP hemorrhagic complications in 5.4 % (23/ 426), infectious/inflammatory complications in 7.4 % (172/2318), CSF disturbances in 6.3 % (81/ 1293), and bone Flap resorption/ depression and Cosmetic defects in 12.5 % (144/ 1151) ³³.

4.6 Cranial reconstruction following DC (Cranioplasty)

Multiple studies showed cranial reconstruction (Cranioplasty) following DC restores the original skull contour and improve ICP regulation, CSF dynamics and cerebral blood flow, potentially preventing complications such as hydrocephalus and the syndrome of the trephined ^{34,35}.

The optimal timing for cranioplasty after DC is debatable. Systematic literature review and meta-analysis done on a total of 528 included from eight retrospective observational studies compared neurologic outcome between early cranioplasty (before 90 day), and late cranioplasty (after 90 day), and they concluded better neurologic outcome in early cranioplasty group with statistically significant difference ³⁶.

Another retrospective multi-center study by Yang et al., assessed CT findings of 159 patients between DC and CP, in order to determine the earliest possible CP timing,

and they concluded the earliest possible day for cranioplasty to be 34.60 ± 34.36 days post-DC. This study compared early and late CP and they found no difference in terms of complications between the two groups except for ventriculomegaly, which occurred more frequently in the late CP group ³⁷.

5. Objectives

5.1 General objective

To describe the long-term functional Outcome of adult TBI patients treated by DC using GOSE.

5.3 Specific objectives

To describe the long-term functional outcome of adult TBI patients treated by DC using GOSE.

To assess factors associated with favorable/unfavorable functional outcome following DC.

6. Methods and Materials

6.1 Study area

The study was conducted at AaBET, SPSH, and Menelik II Hospitals, which are government hospitals found in Addis Ababa, Ethiopia. Addis Ababa Burn, Emergency & Trauma Hospital (AaBET Hospital) is an affiliate of St. Paul's Hospital Millennium Medical College and the Hospital has four major departments; Neurosurgery, Plastic Reconstructive, and Hand Surgery, Orthopedics & Traumatology, and Emergency Medicine and Critical Care. AaBET Hospital is an upper-level teaching hospital with 190 beds. It is one of the largest government-based trauma & emergency center in the country, providing a 24-hour service for patients from all over the country. The Neurosurgery department of the SPHMMC provides both emergency and elective Neurosurgical services at AaBET and the other two attachment sites at, SPSH and Menelik II hospitals. The ward service at AaBET hospital is given using 21 beds for adults and 6 beds for pediatrics. The department has one permanent OR table for scheduled surgeries and has a work force of seven consultants and fifteen Neurosurgery residents at different years of study. Saint Peter Specialized Hospital (SPSH) is another hospital where both Elective and Emergency Neurosurgical service is given with the hospital having a capacity of 272 ward beds, 10 ICU beds, and four OR tables. Two Neurosurgeons and four Neurosurgery residents provide Neurosurgical services. Menelik II Hospital is another evolving center where Neurosurgical service is given by two Neurosurgeons and four Neurosurgery residents from SPHMMC.

6.2 Study period

The study was conducted from June 1, 2022 to July 31, 2022 G.C.

6.3 Study design

A multicenter, cross-sectional study design was used

6.4 Population

Source population: all surgically treated TBI patients at AaBET Hospital, Saint Peter Specialized Hospital and Menelik II Hospitals from May 1, 2018, to May 1, 2021, G.C.

Study population: adult TBI patients for whom Decompressive Craniectomy was done from May 1, 2018, to May 1, 2021, G.C.

6.5 Sample size and sampling technique

Sample Size Determination

The sample size was calculated by single population formula. Considering a 95% confidence interval and 5% margin of error.

n = desired sample size for a population

$Z_{\alpha/2}$ = Z-value for a 95% confidence level which is 1.96

P = prevalence of 50% used

d = precision (d) = 5%

The sample size (n) is calculated according to the formula for infinite: **$n = z^2 * p * (1 - p) / e^2$**

$$(1 - p) / e^2$$

Where: z = 1.96 for a confidence level (α) of 95%, p = proportion (expressed as a decimal), e = margin of error.

$$z = 1.96, p = 0.5, e = 0.05$$

$$n = 1.96^2 * 0.5 * (1 - 0.5) / 0.05^2$$

$$n = 384$$

Since the total number of decompressive craniectomy done during the study period is less than the calculated sample size, finite population correction formula was used, and the minimum sample size required will be.

$$n' = [z^2 * p * (1 - p) / e^2] / [1 + (z^2 * p * (1 - p) / (e^2 * N))]$$

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

$$= 384 / (1 + (384-1)/10,000)$$

$$= 252$$

By adding a 10% nonresponse rate, the final sample size calculated for this quantitative study is 278, since the total number of patients for whom Decompressive craniectomy is done during the study period is < 278, all TBI patients for whom decompressive craniectomy was done during the study period meeting the inclusion criteria were enrolled in the study.

Inclusion criteria

- All adult TBI Patients for whom DC was done at AaBET, SPSH, and Menelik II Hospitals from May 1, 2018, to May 1, 2021, G.C.

Exclusion criteria's

- Alive patients with follow-up period of fewer than 1 year
- Patients not available for a phone interview
- Lost chart
- Patients who did not give consent
- Patient age < 16 years

6.6 Data collection and measurement

Variables

Dependent

- Functional outcome measured by GOSE

Independent

- Age
- Sex
- Injury to hospital duration
- Injury to DC duration
- Duration of surgery
- Types of DC
- Mechanism of injury
- GCS at admission
- Pupillary condition at admission
- The severity of CT scan findings based on the Rotterdam CT score
- Duration of hospital stay
- Post-op complication
- Bone replacement

Data Collection Procedure

Instruments and Measurements

A structured questionnaire was used to collect data from the patient's chart and following phone interview. Questionnaire was adapted from works of literature and modifications were made to them with regard to local context. It consists of two parts. Part one of the questionnaire assesses sociodemographic characteristics, clinical presentation, admission CT score, surgery-related conditions, and post-op complications of study participants. Part two utilizes the Standardized GOSE assessment tool to assess the functional outcome of the study participant.

Data collection methods

All patients for whom DC were done identified from operation logbook of the three study hospitals. Patient chart retrieved from chart archives using medical record number. Sociodemographic characteristics, clinical presentation, admission CT score, surgery-related conditions, and post-op complications of study participants were taken from history, physical examination, operation, and post-operative follow-up note by Neurosurgery residents and seniors. Using contact address on the chart in depth telephone interview administered using standardized GOSE questionnaire to assess the long-term functional outcomes of patients on follow-up.

Data collector

The principal investigator collected all the necessary data.

6.7 Data processing and analysis

Data processing and analysis were done using SPSS-26 (a statistical package for the social sciences) software and Univariate analysis was done using frequency, median, and interquartile ranges for categorical and nominal variables. The mean, range, and standard deviation were calculated for continuous variables. Bivariate analysis was done at 25% significance level to identify independent predictor variables for multivariate analysis. Multivariate logistic regression was done to look for the presence of predictor variables for functional outcomes. A p-value of less than 0.05 was considered statistically significant.

6.8 Ethical consideration

A formal letter was written from the SPHMMC Neurosurgery department to the institutional review board of SPHMMC and ethical clearance was given by the IRB

for this study. All the respondents were informed clearly about the purpose of the study and verbal informed consent was taken from the patient or primary caregiver of the patient during the phone interview for the GOSE assessment. Consent was not required for the collection of data from the patient chart.

6.9 Quality control measures

- Questionnaire was Pre-tested on ten subjects from study population.
- The principal investigator verified the data.
- Questionnaires were checked for completeness, accuracy, and missing data.

6.10 Operational definition of terms

Favorable functional outcome: GOSE > 4.

Unfavorable functional outcome: GOSE ≤ 4.

Primary decompressive craniectomy- is defined as any bone decompression performed in patients undergoing surgery for the evacuation of any intradural lesion.

Secondary decompressive craniectomy- is defined as a procedure performed on patients with high ICP (from clinical evaluation and CT findings) that is refractory to available first tier or second tier medical treatment.

Duration of Hospital stay- includes number of day patient stayed in the hospital ward or ICU following DC.

In hospital mortality- includes patient who died while in hospital before discharge after DC.

Duration of surgery- indicate the time from incision to closure obtained from operation note.

Surgical site infection- includes all superficial and deep postoperative wound infection both abdomen and cranial diagnosed by treating physician.

Adult- age sixteen and above years.

7. Results

7.1 Study population characteristics and neurological evaluation findings

Decompressive craniectomy were done for ninety-eight patients during the study period. Eighty-one charts were retrieved, resulting in an 82% chart retrieval rate. Patients who did not meet the inclusion/exclusion criteria were excluded, and seventy-four patients were included in this study. The gender distribution consisted of sixty-eight males (91.9%) and six females (8.1%) with male to female ratio of 11.3:1. The mean age at presentation was 33.99 years (range 17–69, SD = 12.16).

Common mechanisms of traumatic brain injury were assault in thirty patients (40.5%), road traffic accident (RTA) in twenty-one (28.4%), Penetrating brain injury (PBI) in ten cases (13.5%), falling accidents in eight patients (10.8%), and other mechanisms of blunt head trauma in five patients (6.8%). The mean time from trauma to emergency admission was 24.3 hr. (range 1–182, SD = 31.58).

Mean GCS at admission was 8.19 (range 3–14, SD = 2.85). Regarding pupillary reaction to light at admission, bilaterally normal size and reactive pupils were present in twenty-nine patients (39.2%), bilaterally non-reactive dilated pupils in seventeen patients (22.9%), unilaterally abnormal pupils in twenty-eight patients (37.8%).

Rotterdam CT score from preoperative CT scan before surgery showed a mean CT score of 4.7(range 2-6, SD = 0.96). **Table 1**

Table 1: Baseline characteristics and imaging features of study participants in AaBET, SPSH, and Menelik II Hospitals, from March 1, 2018 to March 1, 2021

Characteristics	All patients, N(75)
Age, mean (Range, SD)	33.99 (R 17–69, SD = 12.16)
Sex, N (%)	
Male	68 (91.9%)
Female	6 (8.1%)
Mechanism of injury, N (%)	
RTA	21 (28.4%)
Falling from height	8 (10.8%)
Assault	30 (40.5%)
PBI	10 (13.5%)
Others*	5 (6.8%)
Time from TBI to Hospital, mean (Range, SD)	24.3 hr. (R 1–182, SD = 31.58)
GCS at admission, mean (Range, SD)	8.19 (R 3–14, SD = 2.85)
GCS category of TBI patients, N (%)	
GCS ≥ 10	22 (29.7%)
GCS 6 – 9	38 (51.4%)
GCS ≤ 5	14 (18.9%)
Pupillary status at admission, N (%)	
Normal	29 (39.3%)
Both dilated & fixed	17 (22.9%)
Unilaterally abnormal	28 (37.8%)
Rotterdam CT score, N (%)	
6	14 (18.9%)
5	35 (47.3%)
4	20 (27%)
3	2 (2.7%)
2	3 (4.1%)
1	-

Note- RTA- road traffic accident, PBI- penetrating brain injury, others- Log of tree fall on head, hit by collapsed wall.*

7.2 Surgical procedure and related conditions

Sixty nine patients (93.2%) in this study underwent primary DC. The main indications for DC were ASDH with or without contusions in forty-nine patients (66.2%), Hemorrhagic contusions in twenty patients (27%), and traumatic intracerebral hemorrhage in five (6.8%). The mean time window from injury to surgical DC was 36.3 h (range 2–144 h, SD = 38.7). Decompressive craniectomy was done within four hours of injury for five patients (6.8%), between four to twenty-four hours for thirty-six patients (48.6%), and after twenty-four hours for thirty-three patients (44.6%).

Sixty-seven patients (90.5%) underwent unilateral frontoparietotemporal DC, whereas bifrontal craniectomy was performed in seven patients (9.5%). The mean duration of surgery was 223.6 minutes (range 130-380, SD= 51.52). Duration of surgery was less than three hours in twelve patients (16.2%), between three to four hours in forty-five patients (60.8%), and surgery took more than four hours in seventeen patients (23%). The mean hospitalization time was 21.03 days (range 3–120, SD = 21.74). No patient in this series underwent bilateral frontoparietotemporal DC. ***Table 2 for detail***

Table 2: DC related clinical parameters of study participants in AaBET, SPSH, and Menelik II Hospitals, from March 1, 2018 to March 1, 2021

DC and related parameters	Result, N (%)
Primary DC	69 (93.2%)
Secondary DC	5 (6.8%)
Indications for DC	
ASDH ± HC	49 (66.2%)
HC	20 (27%)
ICH	5 (6.8%)
Injury to surgery, N (%)	
<4 hr.	5 (6.8%)
4-24 hr.	36 (48.6%)
>24 hr.	33 (44.6%)
Type of DC, N (%)	
FPT DC	67 (90.5%)
BF DC	7 (9.5%)
Duration of surgery, mean (R, SD)	223.6 minutes (R 130-380, SD= 51.52).
Length of Hospital stay, mean (R, SD)	21.03 days (R 3–120, SD = 21.74)
<i>Note-ASDH- Acute subdural hematoma, HC- hemorrhagic contusion, ICH- intracerebral hemorrhage, FPT DC- Frontoparietotemporal Decompressive Craniectomy, BF DC- Bifrontal Decompressive Craniectomy</i>	

7.3 Postoperative Complication characteristics in the study population

Forty-eight patients (64.9%) developed complications at some point during inpatient treatment or while on follow-up. Infectious complications were seen in forty-three patients (58.1%). Seventeen patients (23%) developed surgical site infections of which six (8.1%) were cranial SSI, eight (10.8%) abdominal SSI, and four (5.4%) cases of both abdominal and cranial SSI. Ventriculoperitoneal shunt was inserted for three patients (4.1%) with posttraumatic hydrocephalus. Seven patients (9.5%) were diagnosed with syndrome of trephination. **Table 3 for detail**

Table 3: Postoperative complications of study participants in AaBET, SPSH, and Menelik II Hospitals, from March 1, 2018 to March 1, 2021 (N=74)

Post-operative complications	Result, N (%)
Infectious complications, 43 (58.1%)	
Chest infection	36 (48.6%)
Urinary tract infection	12 (6.2%)
SSI	17 (23%)
CNS infection	5 (6.75%)
Others*	6 (8.1%)
Noninfectious complications, 32 (43.2%)	
Post-traumatic HCP	3 (4.1%)
Syndrome of trephination	7 (9.5%)
DVT/ PTE	3 (4.1%)
Others**	31 (41.9%)

Note- SSI- surgical site infection, CNS- central nervous system infection (postoperative meningitis), HCP- hydrocephalus, DVT/PTE- deep venous thrombosis/pulmonary thromboembolism, others- Tracheostomy site infection, complicated malaria, sepsis of gastrointestinal tract focus, infected bedsore , others**- electrolyte disturbance/anemia/autonomic hyperreflexia/.*

Seventeen reoperations (23%) were done for cranial, abdominal, and both cranial and abdominal surgical site infections. Four reoperations (5.4%) done for noninfectious complications (i.e. inadequate decompression, contralateral bleeding, and postoperative hematoma collection). **Figure 1**

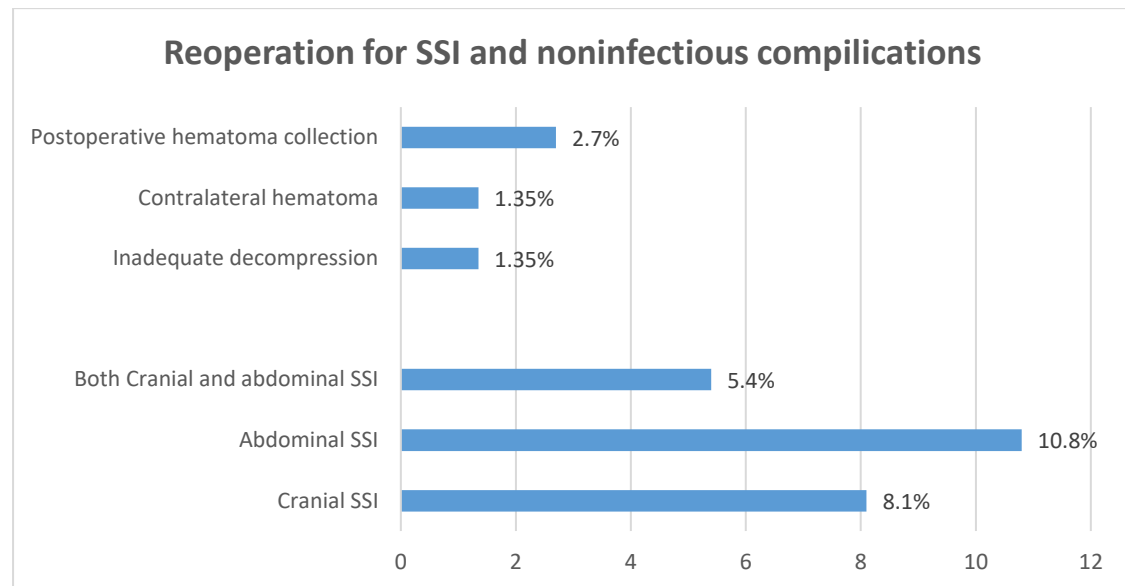


Figure 1: Bar chart showing reoperation for SSI and noninfectious postoperative complications of study participants in AaBET, SPSH, and Menelik II Hospitals, from March 1, 2018 to March 1, 2021.

7.4 Functional Outcome and bone replacement

Discharge conditions for the treated patient were, fifty-six patients (75.7%) discharged, and eighteen patients (24.3%) died while they were in the hospital. Among patients discharged from the hospital, nine patients (16.1%) died while on follow-up, Forty-three patients (76.8%) has favorable functional outcome, and four patients (7.1%) has unfavorable functional outcome. Forty-seven alive patients (63.5%) were followed for a median period of 13 months (range, 12–18 months.

Overall mortality rate was 36.47%. When we see the overall functional outcome of Seventy-four patients included in this study 43 (58.1%) has favorable functional outcome, and 31 (41.9%) has unfavorable functional outcome. Among fourteen patients with $GCS \leq 5$ 85.7% had unfavorable functional outcome. Detail GOSE score finding of the study population is presented in the **Figure 2** below.

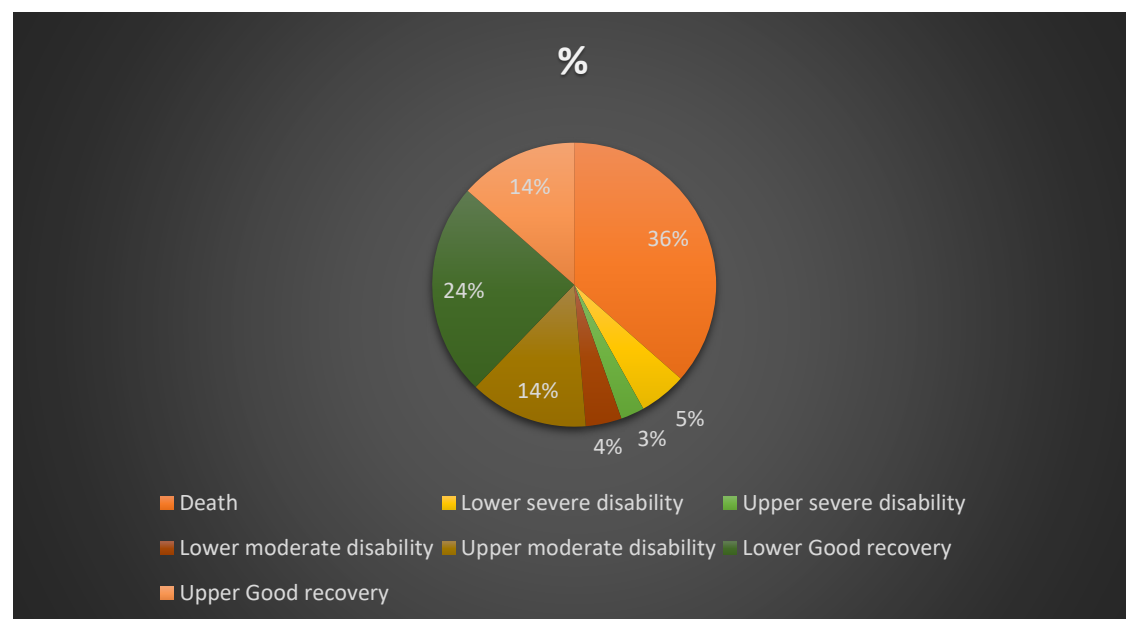


Figure 2: Pie chart showing GOSE of study participants in AaBET, SPSH, and Menelik II Hospitals, from March 1, 2018 to March 1, 2021

A bone replacement was done in 80.9% of the survivors (38/47). Thirty-six (94.7%) bone replacements were done using the patient's bone that was buried in the abdomen and two (5.3%) Cranioplasty were done using polymethyl methacrylate. One case of surgical site infection after bone replacement was reported. The median duration to bone replacement was five month (range, 1 - 9 months). During the study period, nine patients did not have bone replacement because they were from remote part of the

country, with unfavorable functional outcomes in three patients, and discarded bone due to infection, and problems with affordability and availability of cranioplastic material in six patients. (Table 4).

Table 4: Functional outcome and bone replacement characteristics of study participants in AaBET, SPSH, and Menelik II Hospitals, from March 1, 2018 to March 1, 2021

Functional outcome	Result, N (%)
Hospital mortality rate, N (%)	18 (24.3%)
Overall mortality rate, N (%)	27 (36.47%)
Functional outcome among discharged, N= 56 (75.7%)	
Favorable functional outcome (GOSE $\geq$ 4)	43 (76.78%)
Unfavorable functional outcome (GOSE < 4 without death)	4 (7.1%)
Death on follow-up	9 (16.1%)
Overall functional outcome, N (%)	
Favorable functional outcome (GOSE $\geq$ 4)	43 (58.1%)
Unfavorable functional outcome (GOSE < 4)	31 (41.89%)
Cranioplasty, N (%)	38 (80.9%)
Cranioplasty type, (N=38)	
Patient own bone	36 (94.7%)
Cranioplasty material	2 (5.3%)
DC to Cranioplasty time, median (R)	5 month (R, 1 - 9)
Follow-up duration, median (R)	13 month (R, 12-18)

7.5 Factors affecting functional outcome

Multivariate analysis was done using forward stepwise selection method using independent variables identified by bivariate analysis at 25% level of significance.

The assumption of multicollinearity was met and there were no outliers. The model was statistically significant, $X^2(5, N=74) = 36.48$, $P < 0.01$, suggesting that it could distinguish between those with favorable and unfavorable functional outcomes. The model explained between 38.9% (Cox & Snell square) and 52.2% (Nagelkerke R

square) of the variance in the dependent variable and correctly classified 79.7% of the cases.

Accordingly, patients with admission GCS $\leq$ 5 were 18.5 times more likely to have unfavorable functional outcome [P= 0.006; AOR= 18.557; 95% CI= 2.290 - 150.354].

Patients in the age group $\geq$ 40 were 4.4 times more likely to have unfavorable functional outcome [p= 0.045; AOR= 4.380; 95% CI= 1.031 - 18.606]. Presence of postoperative chest infections was associated with 5.2 times increased risk of unfavorable functional outcome [P= 0.013; AOR= 5.202; 95% CI=1.417 - 19.097].

Presence of noninfectious complications increased the likelihood of unfavorable functional outcome by 4 times [p=0.035; AOR=4.009; 95%CI=1.100-14.607]. **Table 6**

Table 5: Bivariate and multivariate analysis of factors associated with functional outcome of study participants in AaBET, SPSH, and Menellik II Hospitals, from March 1, 2018 to March 1, 2021.

	Functional outcome		COR(95% CI)	P-value	AOR(95 % CI)	P-value
Predictor variable	FFO	UFO				
Age in years						
<40	36 (66.7%)	18 (33.3%)			1.00	
≥40	7 (35%)	13 (65%)			4.380 (1.031 - 18.606)	0.045*
Admission GCS						
3-5	2 (14.3)	12 (85.7%)	16.000 (2.734-93.623)	0.002	18.557(2.290 150.354)	0.006*
6-8	25 (65.8%)	13 (34.2%)	1.387 (0.438-4.393)	0.578	1.674 (0.420 - 6.677)	0.465
9-15	16 (72.7%)	6 (27.3%)			1.00	
Postoperative complications						
Chest infection	13 (36.1)	23 (63.9%)	6.635 (2.357-18.673)	<0.001	5.202 (1.417 - 19.097)	0.013*
Noninfectious complications	12 (37.5%)	20 (64.5%)	4.697 (1.741-12.674)	0.002	4.009 (1.100 - 14.607)	0.035*

*Note- *Indicates statistical significance (P<0.05). FFO- Favorable functional outcome, UFO- Unfavorable functional outcome, GCS- Glasgow coma scale, COR- Crude odds ratio, AOR- Adjusted odds ratio, CI- confidence interval, UTI- Urinary tract infection, Noninfectious complications (i.e. Posttraumatic hydrocephalus, syndrome of trephination, DVT/PTE, anemia, and electrolyte disturbances).*

8. Discussion

Several studies have recently indicated that DC might significantly improve the outcome of patients with severe traumatic brain injury (TBI) and medically refractory intracranial hypertension when used for appropriate group of patients ^{4,8}.

8.1 Baseline characteristic of the study population

In this multicenter study, seventy-four patients meeting inclusion criteria were included. Majority of our study subjects were males (91.9 %) similar to finding of other publications on DC^{38,39}. Assault was the leading cause of TBI in 40.5% patients this study. This finding is in contrary to reports in different studies, which state RTA as a leading cause of TBI in LMICs ². The mean age of the study individuals was 33.99 years. These observations underscore the fact that TBI affects the young and economically productive proportion of the society and the finding is comparable to other studies^{40,41}.

The mean time from injury to hospital admission in this series was very long 24.5 hours compared to other studies ^{38,42}. A possible explanation for this observation maybe is the fact that the study centers were tertiary care centers and in the absence of a structured prehospital triage system, referrals from different parts of the country far from the study setup significantly delay time to admission and time to surgery.

This study did not find a statistically significant association between duration from TBI to DC, and functional outcomes. This finding was different from retrospective study Lan *et al* on of 143 patients treated by DC which found duration to surgery ≥ 1 hour was an independent predictor of unfavorable functional outcome (GOS ≤ 3) ⁴².

8.2 Surgical procedure and postoperative complications in study population

Primary DC was done for 93.2% of patients in this study, which is similar to type of DC done in most resource limited setups ⁴³. The finding of this study is difficult to compare to other RCTs, which primarily evaluate secondary DC ^{3,15}.

Khan et al reported finding of primary DC done on 98 patients and they found infectious and noninfectious complications in 28 (28.6%) and 13 (13.3%) patients respectively. SSI rate in this study was 6.1%. Another systemic review by Kurland et al reported overall complication rate of 11.9% after DC. In this review infectious, Hemorrhagic, and complications related to CSF disturbances (HCP, Syndrome of trephination, CSF hygeroma) were reported in 5.5 %, 11.9 %, and 18.4 % of patients respectively, which is lower than finding of our study which showed 64% overall complication rate and SSI in 22% of patients ^{33,38}.

Kesinger et al. studied 141 individuals with TBI up to 5 years after discharge and reported a 30% incidence of HAP. In the study HAP was an independent predictor of low GOSE score ($GOSE \leq 6$) (OR, 4.59; 95% CI, 1.82-11.60; $p = 0.001$). Similarly in our study pneumonia occurred in 48.6% of patients treated with DC and in 63.9% of patients with unfavorable functional outcome. On multivariate analysis it is an independent predictor of unfavorable functional outcomes [$P = 0.013$; AOR= 5.202; 95% CI =1.417 - 19.097] ⁴⁴.

In this study, noninfectious complications (i.e. posttraumatic hydrocephalus, syndrome of trephination, DVT/PTE, anemia, and electrolyte disturbances) were seen in 64.5% of patients with unfavorable functional outcome and 37.5% of patients with favorable functional outcome. On multivariate analysis, noninfectious compilations were independent predictors of unfavorable functional outcome [$p=0.035$; AOR=4.009; 95%CI=1.100-14.607]. No statistically significant predictors were found on subgroup analysis.

8.3 Functional outcome and factors affecting functional outcome of the study population

Numerous studies have reported a wide range of functional outcomes, with a significant percentage of patients experiencing a favorable outcome, ranging from 16% to 69%. The wide range of outcomes after DC is most likely to be secondary to the wide clinical variation in patients who undergo DC.

Aarabi et al reported study on 50 patients undergone DC and found overall mortality rate of 28%, and among 39 patients who survived the first 30 days after decompression good outcome (GOS $\geq$ 4) was seen in 20 (51.3%)⁴³. Another study by Khan *et al* on 98 patients treated with DC reported 25.5% overall all mortality and 45.9% favorable functional outcome. Finding of this study also showed comparable result with overall mortality rate of 36.47%, and favorable functional outcome in (56%)³⁸.

The finding of this study is found to be better when compared to similar studies done in a resource-limited setup^{45 38}. A study done in South Africa on 76 cases of DC showed 44% mortality and 33.4% favorable functional outcome⁴⁶. This difference in outcome may be due to relatively high number of secondary DC with poor outcome in their study (25%) compared to ours (6.8%). Another study done in Senegal showed a 62.5% mortality rate, and 44% favorable functional outcome in twenty-four cases treated by DC⁴³. The difference in outcome between this study and our study may be due to small sample size and higher number of secondary DC done for indications other than TBI in their study.

A major argument that is often used against decompressive craniectomy is that this procedure will decrease mortality at a cost of increased morbidity (patients that are functionally incapacitated for life)⁷. This study showed that 73.7% of patients discharged after DC achieved a favorable functional outcome. This is an encouraging treatment outcome considering the expected poor outcome of TBI with medical treatment alone in resource constraint setups. Data from other series also support findings^{39,47}.

Williams et al did a retrospective analysis of one hundred and seventy-one patients treated by DC and reported overall mortality of 32%. Of the 117 survivors in this study, functional outcome was measured using GOSE at 1 to 6 years post injury. Good outcome was achieved in 96 patients (56% overall, and in 82% of survivors). Younger age was associated with improved survival (median age of favorable functional outcome group was 26 years versus median age of unfavorable functional outcome group of 41 years, with statistically significant difference of $p = 0.0223$)⁴⁸. Similarly, age ≥ 40 was an independent predictor of unfavorable functional outcomes in our study [$p = 0.045$; AOR= 4.380; 95% CI= 1.031 - 18.606]. Most previously published studies have also shown increasing age as a predictor of mortality and unfavorable functional outcome after TBI^{30,49,50}.

More than half of patients in this study have abnormal pupillary light reflex at admission (60.8%). Pupillary abnormality to light reflex was not found to be associated with functional outcome and mortality in this study. In study by Aarabi et al on 50 patients functional outcome was not affected by abnormal pupillary response to light^{51 39}. Most other studies showed presence of pupillary abnormality as an independent predictor of unfavorable functional outcome³⁰.

In this series, admission GCS was strongly associated with functional outcomes and $GCS \leq 5$ was statistically significant predictor of the unfavorable functional outcome [$P = 0.006$; AOR= 18.557; 95% CI= 2.290 - 150.354]. Fourteen patients in this series had $GCS \leq 5$ and mortality in this group was 71%, among survivors 14% had favorable outcome. This finding was similar to the finding of review done by Murray *et al.*, on a cohort of 8686 patients drawn from eight randomized controlled trials and three observational studies, which showed age and GCS as powerful independent prognostic variables for³⁰.

The majority of patients in this series had an admission Rotterdam CT score of five (47.3%) which correlate with the severity of traumatic brain injury. There was no statistically significant association between Rotterdam CT score and functional outcome in this study. Other studies reported Rotterdam CT score as an independent predictor of early mortality and unfavorable functional outcome at 3 months^{26,27}

8.4 Bone replacement characteristics of study population

Finding of bone replacement in our study was different when compared to reports of other publications. In this series bone replacement was done for 80.9% (38/47) of discharged patients with a median duration to bone replacement of five months (range, 1-9) which was long compared to other studies^{36,52,53}. Patients own bone buried in the abdomen was used for bone replacement in 36 (94.7%) of patients and cranioplasty with PMMA done in two patients (5.3%).

There was no statistically significant difference in outcome between early and late bone replacements (early ≤ 3 month and late > 3 month) in our study. This finding was different from the finding of meta-analysis by Malcolm et al on 528 patients included from eight retrospective observational studies compared neurologic outcome between early cranioplasty (before 90 day), and late cranioplasty (after 90 day), and they concluded better neurologic outcome in early cranioplasty group with statistically significant difference³⁶. Absence of difference in outcome in this study may be due to few early bone replacements done in this study (early ≤ 3 month in 18.4% and late > 3 month in 81.6%).

This study also showed relatively high rate of complication related to disturbance of CSF dynamics (posttraumatic HCP that required VPS in 4.1%, syndrome of trephination in 9.5%), which may be is related to delayed bone replacement done in this study. In prospective multicenter study by Chibbaro et al on a series of 147 consecutive patient's cranioplasty was performed in all patients within 12 weeks (median 6 weeks, range 4–12weeks). This study does not record any complications related to CSF disturbances (hydrocephalus, CSF hygroma, and syndrome of trephination) and they attributed this findings to early cranioplasty they performed⁵³.

During the study period, nine patients did not have bone replacement because they were from remote part of the country, with unfavorable functional outcomes in three patients, and discarded bone due to infection, and problems with affordability and availability of cranioplastic material in six patients.

9. Limitations

The retrospective nature of this study may affected the quality of data collected and chart retrieval rate.

Definition used for secondary DC in this study was not in accordance with standard definition because of unavailability of ICP monitoring.

Finally, most patients in our study underwent primary DC with mass evacuation, and thus, the results of this study may not be generalizable for secondary DC (where DC is used as a last-tier intervention).

10. Conclusions

In this study, we demonstrated a good outcome with DC for TBI comparable to other studies. Age ≥ 40 years, Admission GCS ≤ 5 , presence of postoperative chest infection, and presence of noninfectious complications were independent predictors of unfavorable functional outcomes. The mortality rate and unfavorable functional outcome were significantly higher in patients with GCS ≤ 5 , and the impact of this finding on future decision-making needs to be evaluated in a large-scale prospective multicenter study.

11. Recommendations

In order to reduce the high rate of SSI, infection prevention strategies at study centers must be assessed and improved in accordance with standards.

To reduce the significant delay in arrival at the hospital, the neurosurgical service should be expanded to a remote part of the country, and the referral system should be improved.

Measures to reduce the significant delay from DC to bone replacements and increase the utilization of other cranioplastic materials for bone replacement for patients with discarded bones needs to be implemented at study setups.

Prospective studies with a large sample size are needed in the future to determine the effect size of the predictor variable identified in this study and to improve surgical decision-making.

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Annex I: Questionnaire

Questionnaire informed consent for an in-person interview

SPHMMC, AaBET Hospital, Neurosurgery Department, Questionnaire to assess the effect of decompressive craniectomy on functional outcome and factors that affect functional outcome. This research is being conducted by Dr.Sisay Abush Neurosurgery resident at SPHMMC Department of neurosurgery. The reliability and accuracy of information filled in the questionnaire below are very important to achieve the objectives of this study so the data collector has to be accurate in filling out the questionnaires. Participation in this study is voluntary. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. You are free to withdraw from the study, and withdrawal from the study will in no way prejudice future service to which the participant is entitled. All information obtained from this study will be kept strictly confidential.

Consent: I have understood the above information, have had any questions answered satisfactorily, and I willingly consent to participate in this study-----
(signature)

I. Socio-Demographic characteristics of the patient.

Ser.No	Question	Finding
1	Age of patient in years	-----
2	Sex	a) Male b) Female

II. Surgery and surgery-related conditions

1	Duration of time from injury to arrival in hours	-----
2	Duration of time from injury to surgery in hours	-----
3	Duration of surgery in minutes	a) The total duration of surgery in minutes ----- b) The total duration of anesthesia in minutes -----
3	Indication for DC	a) ASDH b) AEDH c) Hemorrhagic contusions d) Diffuse brain injury e) Others (specify)
4	Type of surgery	a) Bifrontal craniectomy b) Frontoparietotemporal craniectomy(specify right or left) c) others(specify)
5	Type of DC	a) Primary DC b) Secondary DC
6	Duration of hospital stay in days	-----
7	Duration of ICU stay in days	-----

III. Issues related to post-operative complications

Ser.No	Questions	Finding
1	Infectious complication	a) Pneumonia b) Urinary tract infection c) CNS infection(specify) d) Wound site infection (specify DSSI vs SSI) e) Others(specify)

2	Noninfectious complication	a) Hydrocephalus b) DVT c) Subdural hematoma d) Syndrome of trephination e) Others(specify)
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IV. Issues related to clinical presentation

Ser.No	Questions	Finding
1	Mechanism of injury	a) Road traffic accident b) Falling accident c) Fighting accident d) Penetrating brain injury (specify the type of PBI) e) Others (specify)
4	Post resuscitation GCS at presentation	E = -----
		V = -----
		M = -----
5	Pupillary status	Right = -----
		Left = -----

V. Issues related to condition at discharge and at time of phone interview

Ser. №	Questions	Finding
1	Condition at discharge	a) Death (If death specify the day of death from trauma and cause of death) b) Discharged
2	GOSE at time of phone interview	a) Death b) Vegetative state c) SD- d) SD+ e) MD- f) MD+ g) GR- h) GR+

VI. Issues related to Rotterdam CT score ²⁶

Ser. №	CT scan finding	Score
1	Basal cistern	0-Normal 1-Compressed 2-Absent
2	Midline shift	0-absent, 1- ≤ 5 mm 2- > 5 mm
3	Epidural hematoma	0-absent 1-present
4	Intraventricular hemorrhage/Subarachnoid hemorrhage	0-absent 1-present
5	Adjustment	+1
6	Total score	

Annex II: Post Discharge Structured Interview and table for categorization of GOSE

Table 6: Extended Glasgow Outcome Scale (GOSE) ⁵⁴.

1	Death	D
2	Vegetative state	VS
3	Lower severe disability	SD-
4	Upper severe disability	SD+
5	Lower moderate disability	MD-
6	Upper moderate disability	MD+
7	Lower good recovery	GR-
8	Upper good recovery	GR+

Post Discharge Structured Interview for GOSE assessment ⁵⁴.

Patient's name: _____ Date of interview: _____
_____ Date of Birth: _____ Age at injury: _____
Date of injury _____ Gender: M / F Interval post-injury: _____
Respondent: Patient alone ____ Relative/ friend/ carer alone ____ Patient + relative/
friend/ carer ____
Interviewer: _____

Consciousness:

1. Is the head-injured person able to obey simple commands or say any words?

- ☐ Yes ☐ No (VS)

Note: anyone who shows the ability to obey even simple commands or utter any word or communicate specifically in any other way is no longer considered to be in a vegetative state. Eye movements are not reliable evidence of meaningful responsiveness. Corroborate with nursing staff and/or other caretakers. Confirmation of VS requires full assessment.

Independence at home:

2a. Is the assistance of another person at home essential every day for some activities of daily living?

- ☐ Yes ☐ No (VS)

Note: for a NO answer they should be able to look after themselves at home for 24 hours if necessary, though they need not look after themselves. Independence includes the ability to plan for and carry out the following activities: getting washed, putting on clean clothes without prompting, preparing food for themselves, dealing with callers, and handling minor domestic crises. The person should be able to carry out activities without needing prompting or reminding and should be capable of being left alone overnight.

If no: go to 3

2b. Do they need frequent help from someone to be around at home most of the time?

- ☐ Yes (lower SD) ☐ No (upper SD)

Note: for a NO answer they should be able to look after themselves at home up to eight hours during the day if necessary, though they need not look after themselves

2c. Was the patient independent at home before the injury?

- ☐ Yes ☐ No

Independence outside the home:

3a. Are they able to shop without assistance?

- ☐ Yes ☐ No (upper SD)

Note: this includes being able to plan what to buy, take care of money themselves, and behave appropriately in public. They need not normally shop but must be able to do so.

3b. Were they able to shop without assistance before?

- ☐ Yes ☐ No

4a. Are they able to travel locally without assistance?

- ☐ Yes ☐ No (upper SD)

Note: they may drive or use public transport to get around. The ability to use a taxi is sufficient, provided the person can phone for it themselves and instruct the driver.

4b. Were they able to travel locally without assistance before the injury?

- Yes
- No

Work:

5a. Are they currently able to work (or look after others at home) to their previous capacity?

- Yes
- If yes, go to 6
- No

5b. How restricted are they?

- a. Reduced work capacity? (Upper MD)
- b. Able to work only in a sheltered workshop or non-competitive job or currently unable to work? (Lower MD)

5c. Does the level of restriction represent a change in respect to the pre-trauma situation?

- Yes
- No

Social and Leisure activities:

6a. Are they able to resume regular social and leisure activities outside the home?

- Yes
- If yes, go to 7
- No

Note: they need not have resumed all their previous leisure activities, but should not be prevented by physical or mental impairment. If they have stopped the majority of activities because of a loss of interest or motivation, then this is also considered a disability.

6b. What is the extent of the restriction on their social and leisure activities?

- a. Participate a bit less: at least half as often as before injury (Lower GR)
- b. Participate much less: less than half as often (Upper MD)
- c. Unable to participate: rarely, if ever, take part (Lower MD)

6c. Does the extent of restriction in regular social and leisure activities outside the home represent a change in respect to pre-trauma

- Yes
- No

Family and friendships:

7a. Has there been family or friendship disruption due to psychological problems?

- Yes
- No If no, go to 8

Note: typical post-traumatic personality changes are: quick temper, irritability, anxiety, insensitivity to others, mood swings, depression, and unreasonable or childish behavior.

7b. What has been the extent of disruption or strain?

- a. Occasional - less than weekly o (Lower GR)
- b. Frequent - once a week or more, but not tolerable o (Upper MD)
- c. Constant - daily and intolerable o (Lower MD)

7c. Does the level of disruption or strain represent a change in respect to the pre-trauma situation?

- Yes
- No

Note: if there were some problems before the injury, but these have become markedly worse since the injury then answer yes to question

Return to normal life:

8a. Are there any other current problems relating to the injury which affect daily life?

- Yes (Lower GR)
- No (Upper GR)

Note: other typical problems reported after head injury: headaches, dizziness, sensitivity to noise or light, slowness, memory failures, and concentration problems.

8b. If similar problems were present before the injury, have these become markedly worse?

- Yes
- No

9. What is the most important factor in the outcome?

- a. Effects of head injury
- b. Effects of illness or injury to another part of the body
- c. A mixture of these