

Functional outcomes of patients with moderate / severe traumatic brain injury 1 to 5 years following inpatient rehabilitation.



Dissertation submitted to The Tamil Nadu Dr M.G.R Medical University Chennai, Tamil Nadu in partial fulfilment of the requirements for the M.D Degree Branch XIX (Physical Medicine and Rehabilitation) examination to be held in May 2020

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CERTIFICATE

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DECLARATION

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ABSTRACT

TITLE OF THE ABSTRACT: Functional outcomes of patients with moderate/ severe traumatic brain injury 1 to 5 years following inpatient rehabilitation.

DEPARTMENT : Physical Medicine and Rehabilitation

NAME OF THE CANDIDATE : Dr. PRUDVISH YARLAGADDA

DEGREE AND SUBJECT : M.D. PMR

NAME OF THE GUIDE : Dr. RAJI THOMAS

AIM AND OBJECTIVES: To study the functional outcome of patients with moderate / severe traumatic brain injury 1 to 5 years following inpatient rehabilitation, to compare these with outcomes at discharge and to study association of outcome with severity of injury, age, comorbidities, care pathways and duration of rehabilitation.

METHODS:

Functional outcome of 31 patients with TBI 1-5 years after rehabilitation was studied during review/ home visits using Disability Rating Scale, Glasgow Outcome Scale Extended and Modified Barthel Index after informed consent. Current medical conditions, vocational status and ambulatory status were noted by primary investigator using a questionnaire. Community integration questionnaire was used to measure

integration into home, community and productivity. These were compared with outcome scores at discharge, duration of rehabilitation, severity of initial injury and care pathways and was statistically analysed.

RESULTS:

Significant improvement was seen in the outcome at follow up compared to discharge. (GOSE mean +/- SD change 0.54 +/- 1.17 with P value 0.015, DRS mean change +/- SD 5.55 +/- 4.77 with P value 0.000 and MBI mean change 20.464 with P value 0.000) Total mean CIQ score was 7.59 +/- 8.11 (home integration: 2.31, , social integration: 3.24 and productivity: 2.03) . 40% of the patients returned to either the same or a different job or education. 60% patients were walking independently/ with minimum assistance. 32% were walking with moderate/ maximum assistance. 8% were wheelchair dependent. Correlation of outcome at follow up was seen with severity of injury ,but was not statistically significant.

CONCLUSION:

On long term follow up after rehabilitation, TBI patients continue to have disability. Significant improvement occurred in functional status as well as ADL independence. 37.9 % patients had mild or partial disability on the DRS score while others had greater disability to varying degrees. Almost half of them (51.6%) were independent or needed minimal / moderate assistance while 48.3% continued to be in severely disabled and vegetative state. Community integration was poor indicating need to develop vocational and community rehabilitation services . Outcomes correlated with severity of injury though not statistically significant.

Key words: Traumatic brain injury, long term , outcomes, employment, GOSE, DRS, MBI, CIQ, Rehabilitation, functional

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INTRODUCTION

Traumatic brain injury (TBI) is an acquired brain injury which causes damage to the brain due to a sudden trauma. Injury to the brain occurs when the head suddenly and violently hits an object, or an object pierces the skull and enters brain tissue. Common causes of traumatic brain injury in India are road traffic accidents (RTA), falls and assaults contributing to 60%, 25% and 10% respectively.(1)

Along with economic transformation, personal motorised transport use has increased, especially of motorcycles and two wheelers in developing countries like India. Limited use of safety gear like helmets has further increased risk along with lapses in traffic laws regulations, violations and accidents. In calendar year 2017, road accidents reported by States and Union Territories (UTs) of India are a substantial total of 4,64,910 and grievously injured 1,73,938.(2)

Majority of TBI patients are young males averaging age of 24 years who are in the most productive phase of their life.(3) Some studies done in developed countries show that lost earnings of injured individuals and their caregivers results in a huge economic disruption in the family. The

economic losses in India due to TBI are unmeasured and no statistics are available, though they are expected to be remarkable. With improvement in medical infrastructure and care, mortality rate has been reduced significantly in the last decade. Even though mortality is reduced, morbidity due to brain injury is often not studied in Indian scenarios.

Patients are left with multiple physical, cognitive, emotional and behavioural sequelae, often being dependent for their mobility and activities of daily living to varying degrees. Very few are able to return to school or productive work. Inpatient Rehabilitation services aim to reduce the impairments and achieve the maximum functional outcome. Patients may continue to improve even after discharge from rehabilitation. They are also at risk of various complications including seizures, hydrocephalus and dementia and need continued support during this phase. However there are very few studies that have looked into the long term outcomes of traumatic brain injury patients and the extent of support required in the community. This study aims to analyse the outcome of patients with moderate or severe traumatic brain injury one to five years after inpatient rehabilitation.

JUSTIFICATION

Patients who have had a moderate/severe traumatic brain injury are left behind with multiple sequelae even after rehabilitation. However, there is paucity of literature on the long-term functional outcomes after inpatient rehabilitation among these patients. Most of the long-term studies in patients with TBI have focused on morbidity and mortality(4)or long-term cognitive and psychosocial adjustment.(5,6)Moreover, most of TBI outcome studies in the past 20 years have assessed outcomes 6 months after injury. Studies on degree of dependence for activities of daily living, improvement in global outcomes, return to vocation and community integration after severe TBI are not many in the literature.

Further, few studies have looked at association of long term outcomes with severity of initial injury, outcomes at discharge from rehabilitation, comorbidities, premorbid factors and care pathways . Such studies can be helpful to predict prognosis and plan long term community based rehab services including vocational rehabilitation. Studies have shown that

better functional outcomes occur in patients with less comorbidity, shorter acute care length of stay, and younger age at the time of injury.(7)

In this retrospective cohort study, we aim to study the functional outcomes, extent of independence in ADL and vocational outcome in patients with moderate/severe TBI one to five years after inpatient admission and the association of this outcome with outcomes at the time of discharge from rehabilitation, premorbid factors and components of the care pathway.

AIM

To study the functional outcome of patients with moderate/ severe traumatic brain injury 1 to 5 years after inpatient rehabilitation

OBJECTIVES

Primary objective: To assess the following functional outcomes of patients with moderate/ severe traumatic brain injury (TBI) patients 1 to 5 years after rehabilitation

- a.) Global outcome as measured by Disability Rating Score (DRS) & Glasgow Outcome Scale Extended (GOSE)
- b.) ADL independence as measured by the Modified Barthel Index (MBI)
- c.) Vocational and educational outcomes measured by a questionnaire
- d.) Community integration measured by the Community Integration Questionnaire (CIQ)

Secondary objectives:

- a. To compare the functional outcome of patients with moderate/severe TBI at 1-5 years with outcome at the time of discharge following rehabilitation measured by DRS, GOSE, MBI and ambulatory status.

- b. To evaluate association between functional outcome at 1 to 5 years with duration of inpatient rehabilitation and participation in support groups and follow up clinics after rehabilitation

- c. To evaluate association of functional outcomes at 1 to 5 years with premorbid factors like age, sex, and medical comorbidities as well as with severity of injury.

SUBJECTS AND METHODS

This study aimed to assess the long term outcome of patients with moderate/ severe traumatic brain injury one to five years after their inpatient rehabilitation. The study was conducted in the Department of Physical Medicine and Rehabilitation, Christian Medical College, Vellore. Patients with moderate to severe traumatic brain injury who underwent rehabilitation for a minimum period of 1 month in the Department of PMR and who satisfied the inclusion and exclusion criteria were included in the study from June 2018 to September 2019.

Approval was obtained from the Institutional Review Board.

Patients who satisfied the following inclusion and exclusion criteria were included in the study after obtaining informed consent.

Inclusion criteria:

1. Age 18- 65 years
2. Patients with moderate (Initial GCS 3-8) to severe (Initial GCS 9-12) traumatic brain injury who underwent rehabilitation in the Department of Physical Medicine and Rehabilitation 1-5 years ago

3. Patients who underwent rehabilitation for a minimum period of 1 month
4. Patients who were willing to participate in the study
5. Patient/ caregiver consent obtained

Exclusion criteria:

1. Patients with co-existing spinal cord injury
2. Patients not willing to participate in the study
3. Patients with mild TBI
4. Non traumatic brain injury prior to or following TBI

They were recruited in the study during review / home visits 1- 5 years after rehabilitation, after getting informed consent. Primary investigator collected information through questionnaire for current medical conditions, vocational status and ambulatory status. Reassessment of functional outcome was done with validated outcome scales including Disability Rating Scale, Glasgow Outcome Scale Extended and Modified Barthel Index. Community integration questionnaire was used to

measure the level of integration into home, community and productivity. Information regarding outcome scores at discharge, and other retrospective data required for the study was accessed from the TBI database maintained in the department. Changes in outcome scores from the time of discharge were studied and the association of outcomes at follow up with discharge outcomes was statistically analysed. Association of premorbid factors, severity of initial injury and care pathways with functional outcomes at follow up was also done using suitable statistical tests for qualitative & quantitative data.

Sample Size:

From the literature “*Long-Term Functional and Psychosocial Outcomes after Hypoxic-Ischemic Brain Injury: A Case-Controlled Comparison to Traumatic Brain Injury*” and “*Functional outcome following*

rehabilitation in chronic severe traumatic brain injury patients: A prospective study'' were used as reference articles for statistical input.

The sample size was calculated using nMaster software version 2.0.

The sample size is calculated for each outcome separately with, Absolute precision-2, Standard Deviation 6.9, Absolute Precision 2, Desired confidence level (%) 95 calculated required sample size was 46.

Following formula was used for calculating sample size

Formula

$$n = \frac{z_{1-\alpha/2}^2 \sigma^2}{d^2}$$

Where,

σ : Standard deviation

d : Precision

$1 - \alpha/2$: Desired Confidence level

Primary outcome measures:

- 1.) Global Outcome measured by Disability Rating Score(DRS)
- 2.) Global Outcome measured by Glasgow Outcome Scale Extended (GOSE)
- 3.) Vocational status at follow up
- 4.) Independence in activities of daily living measured by Modified Barthel Index scores (MBI)
- 5.) Community Integration measured by Community Integration Questionnaire

Predictor variables

1. Effect of premorbid conditions and severity of injury on functional status
 - i. Age in years
 - ii. Severity of injury measured by Glasgow Coma Scale

2. Association between care pathways and functional outcome.

- i. Time from injury to rehab admission measured in days
 - ii. Duration of rehabilitation admission measured in days
 - iii. Participation in follow up-Yes/ No
3. Association between functional outcome and discharge scores – DRS, GOSE, MBI and , ambulatory status

Variables

1.) Disability Rating Scale (DRS) provides quantitative information regarding the progress of individuals with severe head injury from “coma to community” (Rappaport et al. 1982). Categories in DRS are eye opening, communication ability, motor response, feeding, toileting, grooming and employability. In DRS, the maximum score of 29 corresponds with a profound vegetative state, and zero score to a condition of no disability. The detailed score is given in the attached appendix 3.

2.) Glasgow Outcome Scale-Extended (GOS-E) classifies global outcomes in traumatic brain injury as 8 categories: Dead corresponding to score 1, Vegetative State to 2, Lower Severe Disability to 3, Upper Severe Disability to 4, Lower Moderate Disability to 5, Upper Moderate Disability to 6, Lower Good Recovery to 7, and Upper Good Recovery to 8. The details of the scoring are given the appendix 2.

3.) Modified Barthel index (MBI) is a tool for assessing self-care, mobility and activities of daily living. Variables addressed in the Barthel index are:

- Presence or absence of bowel incontinence
- Presence or absence of urinary incontinence
- Help needed with grooming
- Help needed with toilet use
- Help needed with feeding
- Help needed with transfers (e.g. from chair to bed)
- Help needed with walking

- Help needed with dressing
- Help needed with climbing stairs
- Help needed with bathing

Scores range from 0 to 100 with higher scores indicating greater independence. The details of the scoring are given the appendix 1.

4. Community Integration Questionnaire (CIQ)

The CIQ consists of a total of 15 questions. The overall score, which represents a summation of the scores from individual questions, can range from 0 to 29. A higher score indicates greater integration, and a lower score reflects less integration. The CIQ can be further divided into three sub scores, corresponding to integration in the home, social integration, and productivity. The details of the scoring are given in appendix 4.

Bias: addressing potential sources of bias

MBI, GOSE and DRS scores were independently measured by the occupational therapist who was unaware of the data regarding premorbid factors, injury characteristics, care pathway and discharge scores which were collected by the primary investigator.

Statistical Analysis:

Data were summarized using mean, SD and minimum maximum for continuous variables and categorical data were expressed as number along with percentages. Scatterplot along with correlation coefficient used for measuring correlation between variables. Wilcoxon Sign Ranks test and Kruskal-Wallis Test used to assess correlations. All analyses done using Statistical Package for Social Services (SPSS) software Version 21.0 (Armonk, NY: IBM Corp)

Source of Data

DATA	SOURCE
<p>Socio-demographic information Age, gender, marital status, religion, socio-economic status, number of years of education, vocation, residence</p> <p>Trauma related information Severity-GCS at presentation Nature of Injury, Location of Injury Treatment given</p> <p>Length of hospital stay -ICU, Ward Time from injury to admission for rehabilitation Duration of Rehabilitation</p> <p>Discharge Scores MBI/DRS/GOSE /ACE Participation in follow up clinics and support groups</p>	<p>Interview/ medical records</p>
<p>Present functional status</p>	<p>Disability Rating Scale Glasgow Outcome Scale-Extended</p>
<p>Level of dependency for ADL</p>	<p>Modified Barthel index</p>
<p>Level of Community Integration</p>	<p>Community Integration Questionnaire</p>
<p>Complications Hemiplegia/hemiparesis Quadriplegia/ quadripareisis Fractures Pre-existing Co morbidities</p>	<p>Physical examination, Investigations and medical records review patient and caregiver interview</p>

REVIEW OF LITERATURE

1. Traumatic brain injury (TBI)

TBI is damage to brain structure or alteration of physiological function caused by an external force.(8) Brain injury is classified as mild, moderate and severe based on Glasgow Coma Scale scores and duration of Post Traumatic Amnesia(PTA).(9)

Following traumatic brain injury, patients present with

- Altered mental status, confusion , disorientation after injury
- Decreased or loss of consciousness of any period,
- Loss of memory for immediate, before or post traumatic events
- Neurological deficits (weakness, paresis/plegia, visual disturbances, aphasia, dyspraxia, sensory loss, etc.)

2. Pathophysiology

Traumatic brain injury can be classified based on severity of injury, pathoanatomic type of injury and by pathophysiology of injury. Severity

of injury is determined at presentation based on the level of consciousness, and the commonly used measuring scale is Glasgow Coma Scale. Motor responsiveness, verbal performance, and eye opening are assessed to give a 15 point score. Scores ranging from 3-8 are classified as severe injury, 9-12 as moderate and 13-15 as mild injury.(10)Traumatic brain injury can result in epidural haemorrhage, subdural haemorrhage, subarachnoid haemorrhage , brain contusion and laceration, intraparenchymal haemorrhage, intraventricular haemorrhage, and focal and diffuse patterns of axonal injury. Brain injury can be caused by either an open head injury (penetrating) or a closed head injury (nonpenetrating). In Penetrating injury, the dura, the outer layer of the meninges, is compromised by bone fragments, knives or bullets. In closed injury, the dura remains intact. Pathophysiologically brain injury results in primary and secondary injuries. Immediate parenchymal damage occurring at the time of trauma is primary injury and includes intracranial hematoma, haemorrhage, brain contusion and diffuse axonal injury. Metabolic and physiologic changes that follow initial brain injury lead to secondary injuries like ischemia, hypoxia, cerebral edema and hydrocephalus.(11) After brain injury,

increase in intracranial pressure may occur because an increase in the volume of any one of the intracranial contents results in compensatory alteration in others, this is called Kellie-Munro principle. The cranium is a closed space, the sum of the intracranial volumes of brain, cerebrospinal fluid, blood and other components (e.g., hematomas, mass lesions) is constant.(12) Raised intra cranial pressure frequently results in pressure changes between compartments and a shift of brain structures. Common herniations seen with raised intra cranial pressure are the subfalcine herniation, uncal herniation(medial temporal lobe), and tonsillar herniation (inferior cerebellum).(13)

Metabolic changes causing secondary injury

Every case of TBI is unique and affected individuals have different regional patterns of injury, different degrees of injury and different recovery patterns. Some of the common underlying neurochemical and metabolic responses to TBI are mentioned here.

Following TBI, an early ionic and neurotransmitter disturbance occurs which initiate a cascade of events that disrupt change in glucose

metabolism, free radical production, mitochondrial dysfunction and affect normal cellular function in brain.(14)

Glucose metabolism in brain after TBI is reflected by decreased brain glucose partly due to greater cellular uptake and utilisation along with elevated end metabolites. Pyruvate and lactate both derived from glucose metabolism reflect glycolytic activity. In relation to mitochondrial oxidative metabolism, greater proportion of glycolytic metabolism is indicated by greater lactate/pyruvate ratio. Timofeev et al in a large study with microdialysis monitoring of extracellular fluid in the brain in patients with acute brain injury found brain lactate and the lactate/pyruvate ratio both of which were lower in patients with favourable outcome as compared with those patients with a poor outcome. Lactate/pyruvate ratio was found to be a significant positive predictor and pyruvate a significant negative predictor of mortality.(15)

Oxidative phosphorylation was significantly reduced in TBI at one hour post injury and the decrease persisted for 14 days. Greater mitochondrial

Ca²⁺ accumulation and lower ATP production were observed in ipsilateral cortex. Activation of both apoptotic and necrotic pathways causing cell death is the result of recurring mitochondrial impairments.(16)

Excessive glutamate signaling also induce cellular damage through activation of destructive calcium dependent proteases such as calpains and caspases, generation of damaging reactive nitrogen and oxygen species.(17)

Traumatic brain injury can trigger changes in excitation and inhibition of electrophysiologic responses of brain involving glutaminergic and GABAergic function. (18)

Unregulated and excessive stimulation of glutamate receptors leads to ionic dysregulation causing accumulation of extracellular potassium and influx of sodium and calcium through glutamate receptor gated ion channels.(19)

A state of metabolic crisis is induced with this ionic influx, ultimately resulting in energy failure as the brain attempts to restore ionic homeostasis through ATP dependent ion pumps.

3. Disorders of Consciousness - Coma/Vegetative state/Minimally conscious state

Brain injury can cause a wide range of disturbances of consciousness.

Awareness of the self and the environment is referred to as consciousness.

Mild injuries may cause relatively minor changes in consciousness such as brief confusion or disorientation. Severe injuries cause profound disturbance of consciousness.

Coma is a state where patient does not show intentional response or movement, the eyes remain closed, and they cannot be awakened with no sleep wake cycle is observed. After emerging from coma, patients might evolve into Vegetative state (VS) or Minimally Conscious State (MCS).

Prevalence rates are difficult to estimate in India because of the lack of surveillance and poor database.

Vegetative state is described as a condition of complete unawareness of the self and the environment, accompanied by cycles of eye closure and eye opening giving the appearance of a sleep–wake cycle with either complete or partial preservation of brainstem autonomic and hypothalamic functions. (20)

Royal College of Physicians stated vegetative state to be persistent when it lasts longer than a month and permanent when it lasts longer than one year for traumatic brain injuries and six months for non-traumatic brain injuries.

Minimally Conscious State (MCS) is a condition of altered consciousness in which minimal but definite behavioural evidence of self or environmental awareness is observed. (21) MCS patients show inconsistent responses like following simple commands or gestural or verbal responses or purposeful behaviour. Regardless of accuracy and consistency, purposeful behaviour is observed to relevant environmental stimuli which

are not a reflexive activity. Examples of purposeful behaviours commonly seen are smiling or crying appropriately in response to the linguistic or visual content of emotional topics or stimuli but not to neutral topics, reaching for objects , touching or holding objects in a manner that accommodates the size and shape of the object, focusing (sustained fixation) and tracking(pursuit eye movement) that occurs in response to moving stimuli.(21)

MCS can be distinguished from coma and VS by observing the presence of specific behavioural responses not found in either of these conditions. Patients may evolve to MCS from coma or VS after traumatic brain injury.(22) This condition may also exist as a permanent outcome. Many patients emerge out of the minimally conscious states and recover cognitively to varying extents.

Clinical features of Disorders of Consciousness

Disorder	Coma	Vegetative state/Unresponsive Wakefulness Syndrome	Minimally Conscious State
Arousal and Attention	No sleep wake cycles	Intermittent periods of wakefulness	Intermittent periods of wakefulness
Cognition	None	None	Inconsistent but clear cut behavioural signs of self awareness or environmental awareness
Receptive Language	None	None	Inconsistent one step command following
Expressive language	None	None	A spontaneous and limited to single words or short phrases
Visuoperception	None	Inconsistent visual startle	Visual pursuit Object recognition
Motor function	Primitive reflexes only	Involuntary movement only	Localisation to noxious stimuli Object manipulation Automatic movement sequences

Disorders of consciousness after acquired brain injury(23): Published in Nature Reviews Neurology 2014: Joseph T Giacino, Joseph J. Fins, Steven Laureys, Nicholas D. Schiff

4. Sequelae of TBI

- **Neuromotor impairments**

Several residual neuromotor impairments persist after TBI and may influence functional outcome after severe TBI.(24)Increased need for assistance in locomotion, transfers, and lower-body dressing was found in patients with lower limb strength less than 3/5 on admission to acute rehabilitation. Upper-extremity strength less than 3/5 was associated with the need for assistance in self-care at rehabilitation discharge and at 1 year post injury.(25)Walker et al has noted that more than one-third of patients had at least one neuromotor examination abnormality 2 years after inpatient rehabilitation.(24)Tandem gait was the most frequent abnormality among the tested neuromotor variables in TBI patients after rehabilitation .(24)

- **Cognitive impairments**

Cognitive impairments are commonly associated with moderate and severe TBI patients.(26) Disturbances of attention, memory, and executive functioning are the most common neurocognitive consequences of TBI at all levels of severity. These functions are commonly disrupted following

injury to anterior frontal and temporal areas of the brain which are often affected by TBI.(27)

Inability to execute a function or unable to assess a situation can cause behavioural issues like increased anger, anxiety or depression.

Behavioural issues and cognitive impairments are influenced by each other leading to further limitations in independence and social integration.(27)Interventions need to be person focused rather than discipline focused.(28)

- **Neuropsychiatric issues**

TBI may produce a variety of neuropsychiatric problems including, irritability, anxiety, psychosis, depression, mania and affective lability. Many neuropsychiatric issues are primarily consequences of brain injury rather than symptoms of a premorbid psychiatric disorder. (29)Post-TBI depression has prevalence of 18 to 42% and incidence of 15 to 33%.(30)Post-TBI mania occurs in <10% of patients with TBI.(31) Post-TBI agitation (aggression, disinhibition) occurs in variable frequencies depending on criteria, ranging from 20 to 49%.(32) Although delusions and auditory

hallucinations are common in the acute post-traumatic state, post-TBI psychosis occurs in <10% of the TBI population.(33)

- **Visual disturbances**

Post TBI neuro-ophthalmological abnormalities are due to involvement of the afferent pathway and the efferent pathway. Blurring of vision and field defects like homonymous hemianopia and quadrantanopia are most commonly presented clinically after TBI. Other commonly seen presentations are poor visual acuity, reduced eye movements, and involvement of more complex aspects of vision including visual perception.(34) Neuro-ophthalmic examination should form an important part of the assessment of patients admitted for neurorehabilitation.

5. Complications

- Several medical complications frequently occur after moderate or severe TBI including the following
- **1.Post traumatic epilepsy**

Post traumatic epilepsy frequently occurs after moderate and severe TBI. Post traumatic epilepsy is to be distinguished from repeated seizures in the early stage following TBI. A common set of definitions adopted by many researchers are:

- (1) Immediate seizures, usually defined as those occurring within 24 hours after injury;
- (2) Early seizures, occur less than 1 week after injury; and
- (3) Late onset seizures, which occur more than a week after injury.

Because risk of recurrence after a single late onset post-traumatic seizure is over 70%, it is considered a single late onset post-traumatic seizure as being sufficient for the diagnosis of post traumatic epilepsy. (35)

- **2.Hydrocephalus**

Hydrocephalus can be caused by the blockage of cerebrospinal fluid (CSF) flow, overproduction of cerebrospinal fluid (CSF), or insufficient absorption that results in excessive accumulation of CSF in ventricles and around the brain. The Dandy's report in 1914

recognized syndrome of post-traumatic hydrocephalus (PTH).(36)Variation in reported incidence was contributed by differences in diagnostic criteria and classification. PTH is diagnosed using a combination of clinical, imaging and physiologic data. Post-traumatic ventriculomegaly resulting from atrophy is to be distinguished from symptomatic PTH. Symptomatic PTH patients are likely to improve when treated by shunting. Ventriculomegaly secondary to atrophy is less likely to improve with shunting.(36) PTH influences functional and behavioural outcome and the presentation of posttraumatic epilepsy. The decision of surgery for PTH is made principally on a clinical basis. SPECT may be helpful for differentiating ventricular enlargement due to cortical atrophy and hydrocephalus.(37)

- **3. Deep vein thrombosis**

Deep vein thrombosis (DVT) encountered in brain injury rehabilitation setting is a common, treatable but potentially life threatening complication. Many factors like lower extremity trauma and fractures, hemiparesis, flaccidity, and immobilization

predispose to the development of DVT. Many studies show that some type of prophylaxis is indicated until sufficient mobility has been restored. Subcutaneous heparin and lower extremity external compression devices are most commonly recommended.(38)Clinical examination is less than 50% accurate when screening for DVT and, therefore, often misleading. Venography is the gold standard in screening for and diagnosing DVT; however, it has a 1% to 2% incidence of complications, and it is painful, costly, and invasive. Duplex Doppler ultrasound scanning are safe, non-invasive, and sensitive techniques to screen for and diagnose DVT.(39)

- **4.Heterotopic ossification**

Heterotopic ossification is a pathological phenomenon that causes ectopic bone formation in muscles and connective tissues usually around big joints. This phenomenon is usually seen in prolonged immobilisation and micro trauma following brain injury and spinal cord injury. HO occurs in 11% of TBI patients, with the hip,

shoulder, and elbow being common sites.(40) Heterotopic ossification caused by the induction of pluripotent mesenchymal stem cells by signalling factors that are present in patients with neurologic conditions or trauma. The resulting osteogenic cells lead to aberrant bone formation in extra skeletal tissue.(41) Many humoral factors have been implicated, particularly BMP-4(bone morphogenetic protein-4) and substance P; however, none have been definitively proven to be the primary culprit in heterotopic ossification. (42)Patients present with pain, local swelling, warmth and restriction of movements at involved joints. Serum Alkaline Phosphatase levels, X Rays, Radionuclide bone imaging, Computed Tomography and bone markers are helpful in diagnosis. (43) Treatment includes NSAIDs, Bisphosphonates and surgical resection when indicated.

- **5. Spasticity**

Spasticity is defined as a motor disorder characterized by a velocity dependent increase in muscle tone along with exaggerated tendon jerks, resulting from hyper excitability of the stretch reflexes as one component

of the upper motor neuron syndrome (Lance, 1980). (44) Spasticity may limit bed mobility, and cause difficulty with wheelchair seating and ambulation. Severe spasticity can cause contractures and deformities. Spasticity even mild and moderate also affects patients ADLs and ambulation with significant gait deviations. The modified Ashworth score is the clinical measure most frequently used for assessment of spasticity. Causes of spasticity exacerbation are underlying urinary tract infections, constipation, noxious stimuli, pressure ulcers and other pain causes. Bladder stones may rarely present through worsening of spasticity and hence finding these triggers is an important part of management.(44)

- **6.Autonomic Dysfunction**

Autonomic dysfunction is a complication of brain injury presenting as syndrome of intermittent agitation, hypertension, tachycardia, tachypnea, diaphoresis, hyperthermia, and extensor posturing.(45)This syndrome is explained by dysfunction of autonomic centers in the thalamus or hypothalamus or their connections to cortical, subcortical, and brainstem loci that mediate autonomic function.(46)Cortically provoked release of

adrenomedullary catecholamines during episodes may contribute to the hypertension as well as tachycardia and tachypnea. Before diagnosing as autonomic dysfunction alternative causes of autonomic dysregulation should be considered, especially treatable intracranial abnormalities such as increased intracranial pressure, hydrocephalus, or extra-axial blood or fluid accumulation. Other treatable irritants, such as dehydration, constipation, pain from injuries has to be managed.(45)

- **7. Neuroendocrine disorders**

Neuroendocrine disorders after TBI are recognised more in recent years because of their potential contribution to morbidity, and possibly mortality, after trauma. Hypothalamo-pituitary axis changes have been documented in the acute phase of TBI, with as many as 80% of patients showing evidence of gonadotropin deficiency, 18% growth hormone deficiency, 16% corticotrophin deficiency and 40% of patients demonstrating vasopressin abnormalities leading to diabetes insipidus or the syndrome of inappropriate anti-diuresis.(47) Early abnormalities are transient, whereas new endocrine dysfunctions become apparent in the

post-acute phase as seen in some longitudinal studies.(47)Clinically hypothyroidism leads to lethargy, fatigue and neuropsychiatric manifestations. Untreated diabetes insipidus causes dehydration if water intake is not adequate to compensate due to impaired cognition, physical disability or co-existent hypodipsia. Growth hormone deficiency impairs linear growth and the attainment of normal body composition in children. In adults, it causes decreased exercise capacity, reduced lean body mass and reduced bone mineral density which is of particular significance in immobilised patients.(48,49) Kelly *et al* reported increased neuropsychiatric morbidity in patients with post-TBI growth hormone deficiency or insufficiency.(50) Sex-steroid deficiency results in reduced bone mineral density and osteoporosis. In prolonged periods of immobility that occur after serious TBI along with other anterior pituitary hormone deficiencies, this situation can be exacerbated. Unrecognised and untreated hypopituitarism can have serious adverse consequences for patients with TBI and may impair recovery and rehabilitation.(47)

6. Initial Management

Surgical/ Conservative/VP shunt

Cerebral edema is a complication of traumatic brain injury causing increase in intracranial pressure and in turn reduction of cerebral perfusion pressure leading to harmful effects on cerebral oxygen metabolism.(51)Cerebral contusion following TBI causes edema in 2-3 hours and secondary brain swelling in 2-5 days due to inflammatory cascades.(52,53) These changes and effects are conservatively managed with measures like sedation, analgesia, blood pressure management, and neuromuscular paralysis.(54) On monitoring after conservative management, if signs of raised intracranial pressure persist or a significant mass effect is seen in imaging, immediate surgical management is indicated with decompressive craniectomy.(54)Surgical intervention will rapidly reduce intracranial pressure and mortality. Depending on extent of lesion and size of the hematoma, a large craniotomy or craniectomy is done.(55)Development of post traumatic hydrocephalus (PTH) needs intervention with ventriculoperitoneal shunt if ventriculomegaly is significantly causing pressure effect on the surrounding brain tissue.(56)Even though timing of cranioplasty has minimal effect on post

traumatic hydrocephalus it influences the functional and behavioural outcomes.(37)

7. Rehabilitation

- Post TBI rehabilitation programs focuses on minimising the residual impairments of physical, cognitive, and behavioural domains , on improving functional independence and preventing complications. Multidisciplinary teams include physiatrists, neurologists, clinical psychologists, physio and occupational therapists, speech language pathologists, social workers, rehabilitation nurses and orthotics specialists.(57)
- During the rehabilitation phase, multiple medical problems may be observed which needs to be managed pharmacologically.
 1. Cognitive impairments need to be addressed. For management of attention deficits, dopamine pathway is the key because striatal dopamine transporter expression decreases in TBI.(58) Methylphenidate a dopamine transporter inhibitor, Bromocriptine a D2 receptor agonist

and Amantadine a dopamine enhancer are commonly used pharmacological agents for management.

2. Selective serotonin reuptake inhibitors were found useful in treating behavioural syndromes in TBI patients, particularly in the sub-acute stages of recovery.(59) Serotonin pathways in brain stem ,median raphe regulates attention and cognitive function.(60)
3. Memory dysfunction is a complication of medial temporal lobe injury in TBI, Acetylcholine deficit is likely to contribute to memory dysfunction in this population. Donepezil, an acetylcholine-esterase inhibitor showed memory improvement in post-acute rehabilitation of TBI.(61)
4. Sleep wake cycle is affected and also excessive day time sleepiness is seen after TBI. Modafinil is well tolerated and effective for treatment of post traumatic excessive day time sleepiness.(62)

5. Neuropsychiatric problems like anxiety and agitation are managed commonly with second-generation antipsychotics.

Quetiapine accounted for 48%, followed by Risperidone (19%), Olanzapine (15%) of the second-generation antipsychotics administered.(63)

- Coma stimulation program with sensory, visual, auditory and olfactory stimuli are given to increase responses. Visual sensory stimulation is provided with use of pictures of familiar people, and mirrors to reflect their whole body and face, computer programs and bright objects. Auditory sensory stimulation is given with use of voices, familiar sounds and music. Tactile stimulation is given by positioning, moving patients to be prone, side lying, or seated on mats.(64)
- Physiotherapy aims to reinstate functional motor activity with different approaches. Passive and active strengthening exercises, stretching and range of motion exercises prevent contractures and managing spasticity. Casting is done if required and orthotics are used for improving tone and range of joints. Therapy progresses

from vertical orientation then progressing to standing table and suspension walker to improve pattern and balance.(65,66)

- Swallowing therapy is to manage impaired anatomic and physiologic swallowing mechanism in TBI patients. Nursing care and care giver education is given for preventing complications and aspiration in patients with tracheostomy tube and nasogastric tube feeding. Postural and compensatory swallowing techniques, diet modification are taught in therapy. Swallowing and risk of aspiration is assessed with clinical swallowing examination and instrumental assessment with video fluoroscopic swallow study and fiberoptic endoscopic examination of swallow. Speech therapy aims to establish communication and improving quality of speech.(67)

- **Goal setting in rehabilitation**

After diagnosis and initial assessment, goals are planned for patient centred rehabilitation. Rehabilitation team assess and sets a common functional goal. Setting a goal early helps in monitoring progress and outcome. Another goal is set at discharge for

integration into community, vocational and educational reintegration.(68)

- **Community reintegration**

Post TBI rehabilitation does not end with discharge, patient should be trained for reintegration into community. Three main areas of community integration are living independently at home, social integration and productivity.(69) For successful integration patient needs to be provided with support from family members, allocating resources and removing environmental barriers around them.(70)Severity of injury, marital status, premorbid education and other factors played role in community integration outcome.(71)An Indian study done after neuropsychological rehabilitation has found that TBI patients had difficulty in integrating back to community. Poor integration was observed in all three categories of home integration, social integration and productivity.(72) Very limited and no data is available on community integration of Indian population after rehabilitation.

- **Need for follow up through home visits and support groups**

During transition from rehabilitation to social integration TBI patients are with only family members without clinical support often leading to psychosocial deterioration.(69)Home visits providing residential based services produce greater functional improvement and are more effective at maintaining community integration.(73) Home visits also provide opportunity to assess the patients' living environment and community around them. In a country like India follow up of TBI patients is difficult as they have problems bringing patient with limited ambulation to a hospital. Home visits by multidisciplinary rehabilitation team help in follow up and also management of these patients after discharge.

- **Vocational rehabilitation services for TBI**

Vocational rehabilitation should be started while patient is undergoing neurorehabilitation and at discharge possible options of vocation should be explained based on functional status of patient.

Finding and maintaining work is difficult due to physical, emotional, cognitive, and interpersonal barriers following TBI.(74)Vocational rehabilitation programme is beneficial in

building up confidence, managing cognitive and behavioural sequelae. Providing co-worker 'twins' in the work place and employers with a personal experience of disability helped individuals to sustain employment.(75)

8. Prognostication and assessing pathways in unresponsive patients

Prognostication and outcome prediction is difficult in patients who are in coma or vegetative state post TBI, With Electroencephalogram (EEG) and Somato Sensory Evoked Potentials (SSEP) the brain activity and cortical responses to stimuli can be studied. Absent somatosensory evoked potential bilaterally is a reliable predictor for poor recovery of brain function and outcome.(76) Visual Evoked Potential (VEP) is an indicator of abnormal conduction in the visual pathway and helps to measure cortical responses in TBI patients with suspected neuroophthalmic problems and optic neuropathies. Sensory brain stem pathway can be assessed with Brain stem Auditory Evoked Potentials (BAEP).

Using Magnetic Spectroscopy imaging and Diffusion Tensor Imaging. Metabolic disruption and structural injury can be detected early within hours of trauma. Diffusion parameters allow identification of severity and

provide evidence of injury progression.(77) Fractional anisotropy reductions in the frontal white matter and splenium of TBI patients may be a useful prognostic factor for long-term cognitive dysfunction.(78)

9. Outcome Measures

To assess disability, progress, and outcomes, various validated scales are proposed for use in TBI patients. To assess physical and cognitive impairments Disability Rating Scale (DRS), Functional Independence Measure (FIM), Modified Barthel Index (MBI) and Glasgow Outcome Scale Extended (GOS-E) are commonly used during initial assessment, midterm assessment and pre discharge. These scores are validated for follow up and outcome measurement also. GOSE-E is a good scale for assessment of outcome after TBI.(79)Modified Barthel Index is based on original Barthel Index but the latter uses 3 point scale and the former a 5 point scale. With the 5 point scale MBI is more sensitive to small improvements in functional independence while still maintaining the qualities of the original.(80)Functional Status Examination (FSE) is a newly developed score, FSE may offer some advantages over GOS-E due its ability to provide a more detailed description of deficits.(81)

Community Integration Questionnaire (CIQ) was developed to assess productivity, social integration and home integration of TBI patients.(82)

10. Long term outcomes in TBI

Studies done in western population have shown that improvement in functional status continued after discharge from hospital. Forslund et al has done a prospective study on 97 moderate to severe TBI survivors following up them at 1,2, 5 and 10 years , measuring their global outcome scores with GOSE Improvement on global outcomes was seen up to 5 years while deterioration was seen in the 5-10 year period.(83)On 5 to 10-year follow-up, approximately 37% worsened one or two categories, 56% showed no change, while 7% of survivors improved one category. They also looked at whether outcomes could be predicted by age, sex, employment and duration of post traumatic amnesia(PTA) which showed male sex, younger age group and shorter period of PTA had better outcomes on follow up.(83) 1-14 year follow up of patients was done by McMillan et al which also showed similar results.(9)Several studies have shown that age of the patient is related to long term outcomes with younger age group showing better improvement and older group having

decreased outcomes over the next 5 years.(84)Marsh konigs et al has done meta-analysis of 11 studies to look at association of functional outcomes with early onset of rehabilitation after TBI. Reported evidence of early onset of rehabilitation at trauma centre and intensive rehabilitation has better functional recovery compared to usual care.(85)A prospective study of 77 severe traumatic brain injury patients done in Indian population has shown that cognitive outcome on one year follow up was poor in many patients post TBI. This study was done in patients who did not get an inpatient rehabilitation.(86) Grauwmeijer et al did prospective follow up of 48 patients at 3, 6, 12, 18, 24, and 36 months and 10 years post-TBI and studied probability of employment and predictors of employment and the association of length of hospital stay and discharge scores with employability. They observed that vocational outcome was better in patients with low severity of injury, higher scores on GOSE, MBI and DRS at hospital discharge.(87)Alexis Ruet et al in their study on 86 patients reported that more than half of students with TBI did not return to education but vocational outcome was better with approximately 45% patients returning to work. Hospital Anxiety and Depression Scale

(HADS) was used for assessing Mood impairment and Dysexecutive Questionnaire (DEX) was used to assess executive dysfunctions in daily life. Alexis Ruet et al also observed a trend for a lower initial GCS score, a longer length of stay in intensive care unit, a lower GOS score upon intensive care unit discharge, a higher HADS depression score, a higher DEX score assessed by a relative, swallowing difficulties, dependence in self-care activities, inability to write a letter to be associated with unemployment.(88) A long term population based follow up study for psychosocial outcome reported that 23-31% of the patients with TBI were unable to return or maintain earlier work/education at pre-injury level.(5)Significantly more no.of patients found emotional control more difficult, as well as increased difficulties with concentration and memory, maintenance of leisure time interests and general life satisfaction. On the long term, an important factor influencing survival among TBI patients seemed to be whether relations with family and friends could be maintained at the pre-injury level.(5)Most of the above mentioned studies were from moderate and severe TBI groups but very few were post rehabilitation.

RESULTS

31 consecutive patients with moderate/ severe traumatic brain injury were included during their review in the outpatient section or at home visit during the study period. All of them satisfied the inclusion and exclusion criteria and had underwent inpatient rehabilitation for a minimum of one month duration 1-5 years ago.

A. Demographic data

1. Distribution of patients based on age

Table 1: Age distribution

Mean age of the participants (years)	36.68
Standard deviation	12.89
Minimum age(years)	19
Maximum age (years)	64

Age distribution

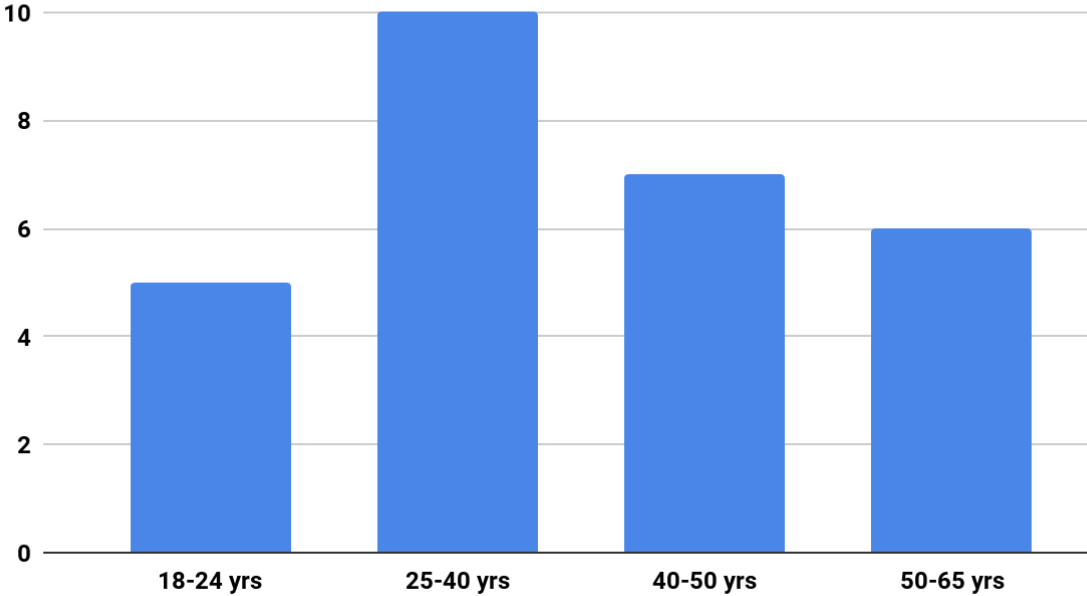


Fig. 1 Age distribution

Among the 31 participants in the study, mean age was 36.68 years with a standard deviation of 12.89 years.

2.Distribution of patients based on gender:

Table 2: Gender distribution

Variable	N=31	Percentage
Males	26	83.9
Females	5	16.1

Gender distribution

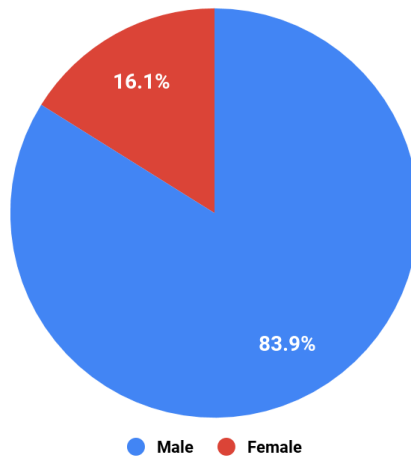


Fig 2. Gender distribution of patients

Demographic characteristics revealed young adult males (18-30) were more vulnerable to head injury.

3. Premorbid education of patients:

Table 3: Premorbid education status

Education	N=31
Illiterate	0
High school	8
Higher secondary	8
Graduate	13
Post Graduate	2

Premorbid Education

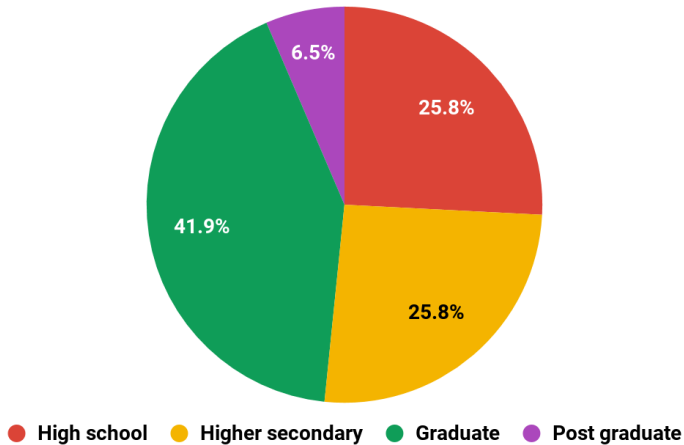


Fig 3: Premorbid education of patients

4. Premorbid Vocation:

Table 4: Vocational status premorbid

Vocation	N=31
Unemployed	0
Student	7
Housewife	2
Self employed	8
Non Professional	5
Professional	8
Retired	1

Premorbid Vocation

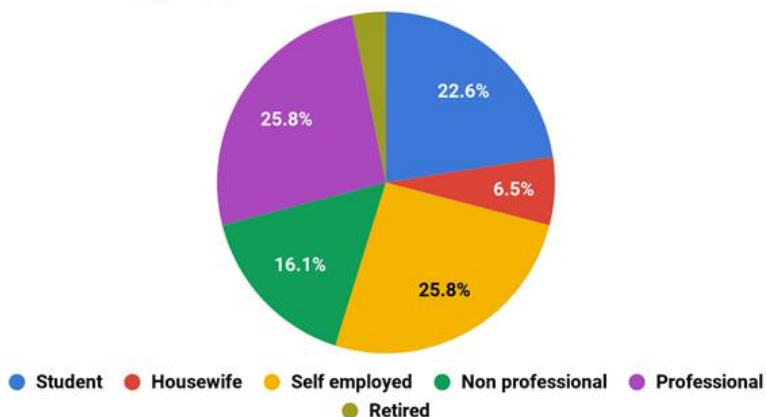


Fig 4: Premorbid vocational status

B. Injury Characteristics

1. Distribution of patients based on duration since injury: The mean duration of injury was 43.19 months. Duration since injury to follow up varied from 13-80 months.

Table 5: Duration since injury

Duration since injury	Months
Mean duration since injury	43.19
Standard deviation	18.47
Minimum duration since injury	13
Maximum duration since injury	80

Duration since injury

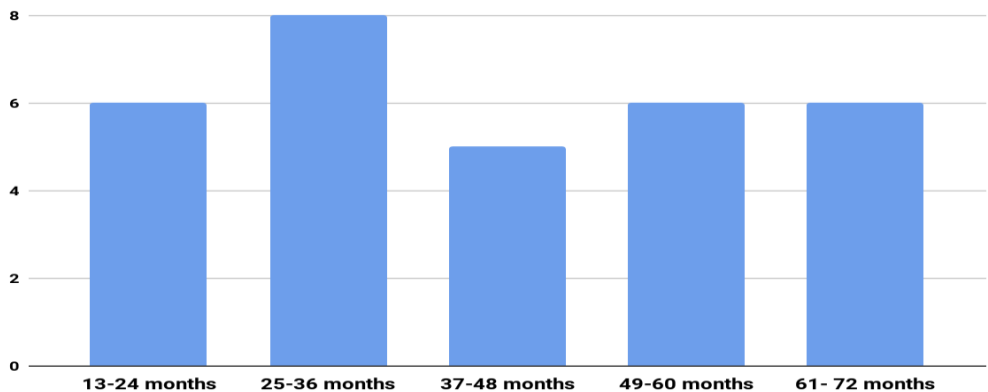


Fig 5. Distribution of patients based on duration since injury

2. Time taken for admission to rehabilitation:

Mean time taken for rehabilitation admission was 4.74 months.

Time taken for admission to rehabilitation varied from within 1 month of injury and up to 18 months later. Majority were admitted within 3 months of injury.

Table 6: Time taken for rehabilitation admission

Time taken for rehabilitation admission	Months
Mean time for rehabilitation admission	4.74
Standard deviation	4.81
Minimum time for rehabilitation admission	1
Maximum time for rehabilitation admission	18

Duration since injury to Rehabilitation admission

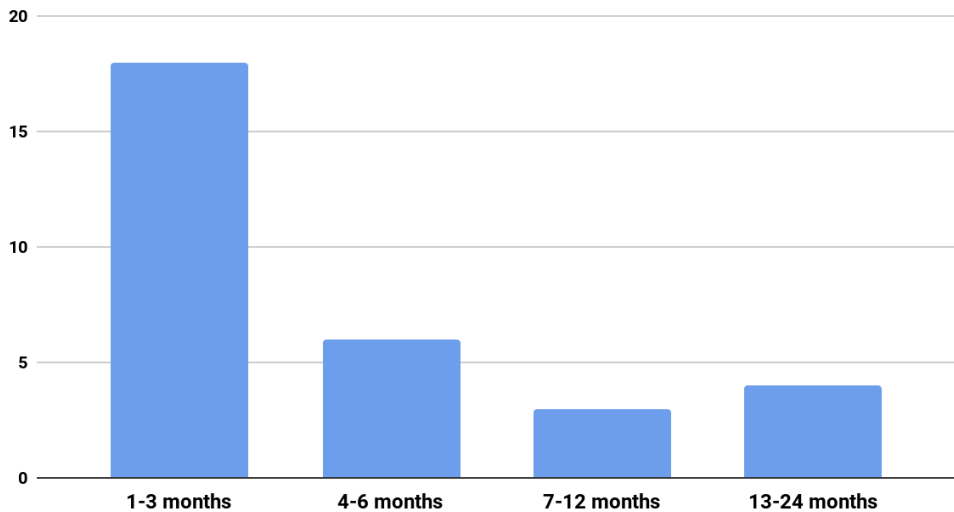


Fig 6. Time taken for admission to rehabilitation

3. Duration since discharge from Rehabilitation:

Mean Duration from discharge to follow up for this study was 35.77 months (11 to 73 months).

Table 7: Duration since discharge

Duration since discharge	Months
Mean duration since discharge	35.77
Standard deviation	18.61
Minimum duration since discharge	11
Maximum duration since discharge	73

Duration since discharge from rehabilitation

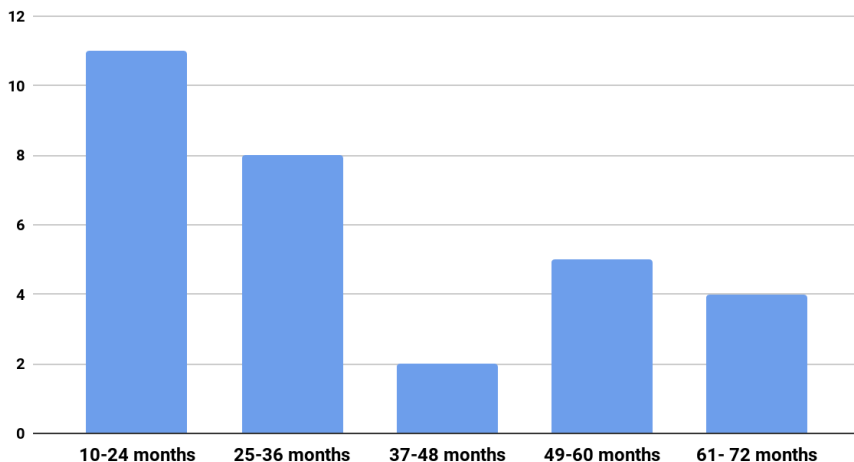


Fig 7. Duration since discharge from rehab

4. Duration of inpatient rehabilitation:

Mean duration of inpatient rehabilitation was 9.84 weeks, minimum period of 4 weeks and maximum of 24 weeks.

Table 8: Duration of rehabilitation in weeks

Rehabilitation duration	Weeks
Mean duration of rehabilitation	9.84
Standard deviation	4.94
Minimum duration of rehabilitation	4
Maximum duration of rehabilitation	24

Duration of inpatient rehabilitation

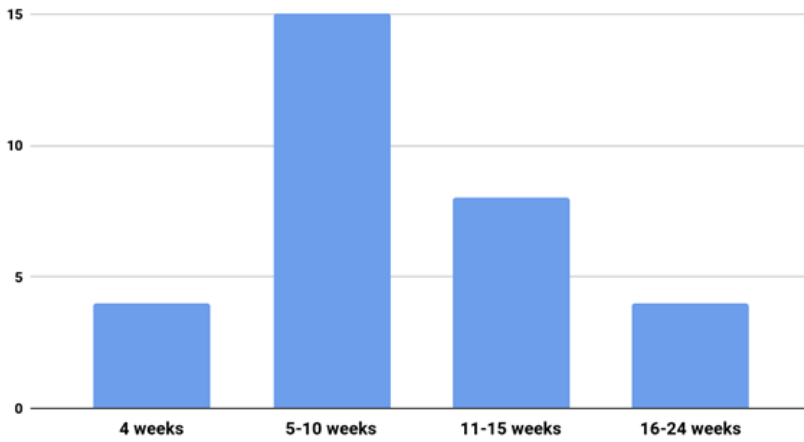


Fig 8. Duration of rehabilitation in weeks

5. Severity of injury:

Table 9: Distribution of patients according to severity of injury

Severity of injury	Frequency
Moderate	2
Severe	21
Missing data	8

Based on Initial GCS was 21 patients had severe head injury with GCS ranging from 3-8, 2 patients had moderate injury with GCS 9-12 . In 8 patients, initial GCS was not recorded.

6. Initial management after TBI:

Table 10: Initial management: Surgical/ conservative

Initial Management	N=31
Surgical management	15
Conservative management	16

Initial management

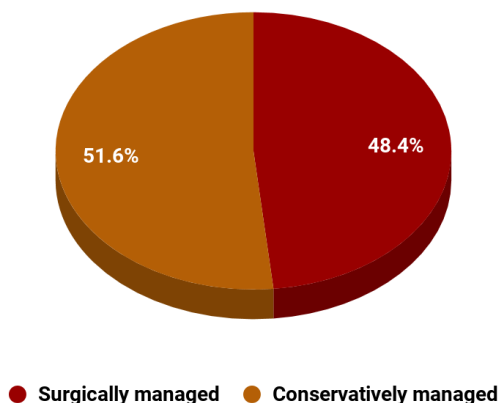


Fig 9: Initial management after TBI

While 48% patients were managed conservatively, 52% patients underwent surgical interventions like craniotomy, decompressive craniectomy and Shunt placement.

7. Comorbidities in patients before injury:

Table 11: Comorbidities in patients

Comorbidity	No of Patients
Diabetes Mellitus	2
Hypertension	2
Psychiatric illness	1
Coronary Artery Disease	1
No known comorbidity	26

8. Regular follow up in Brain Injury support groups

Only 8 of 31 patients attended support groups organised by social workers in the department

C. Outcomes at follow up

I.Global Outcomes at follow up:

I.1. Glasgow Outcome Score Extended (GOS-E)

Table 12: GOSE at follow up

Mean GOSE at follow up	3.94
Standard deviation	1.63
Minimum	1
Maximum	8

GOSE Outcome	N=31
Death	2
Vegetative state	2
Lower severe disability	11
Upper severe disability	6
Lower moderate disability	3
Upper moderate disability	6
Lower good recovery	0
Upper good recovery	1

Table 13:

GOSE at follow up

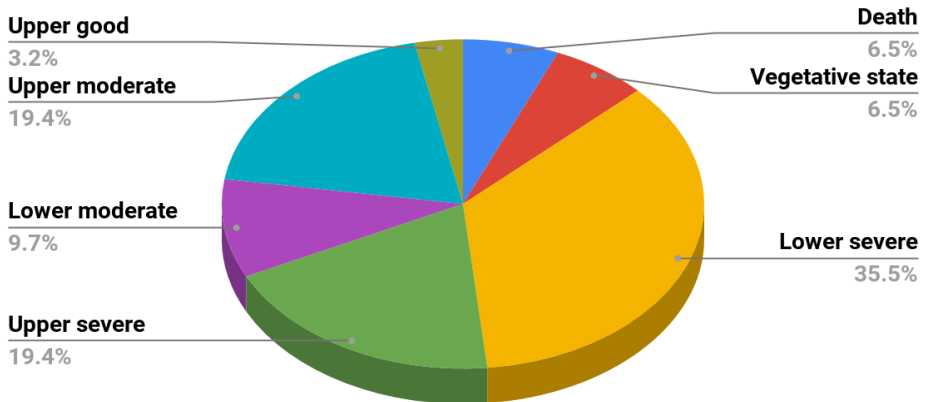


Fig 10: Glasgow outcome score extended at follow up

Based on GOSE scores 3.2% patients were in upper good recovery state, 19.4% in upper moderate disability, 9.7% in lower moderate disability, 19.4% in upper severe disability and 35.5 % of patients in lower severe disability state and 6.5% patients were in vegetative state. 6.5% patients had died at the time of follow up.

I.2. Disability Rating Scale scores at follow up:

Table 14: DRS at follow up

Mean DRS at follow up	7.76
Standard deviation	6.84
Minimum	1
Maximum	24

Table 15:

Level of disability (DRS outcome)	N=29 (2 Dead)
None (0)	0
Mild (1)	3
Partial (2-3)	8
Moderate (4-6)	8
Moderately Severe (7-11)	2
Severe (12-16)	4
Extremely Severe (17-21)	2
Vegetative State (22-24)	2
Extremely Vegetative State (25-29)	0

DRS level of disability

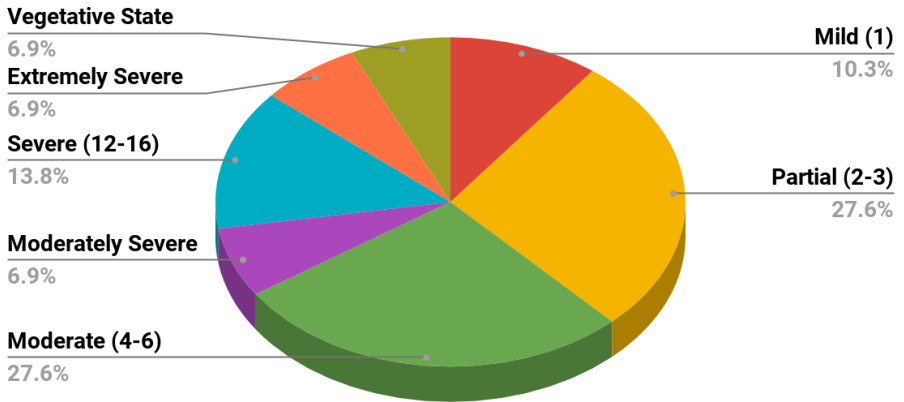


Fig 11: Disability Rating scale outcome at follow up

Based on DRS scores 10.3% patients were found to have mild disability, while 27.6% had partial disability, 27.6% had moderate disability, 6.9% had moderately severe disability, 13.8% had severe disability, 6.9% had extremely severe disability and 6.9% were in vegetative state.

II.ADL independence at follow up

Modified Barthel Index scores at follow up

Table 16: MBI scores at follow up

Mean MBI at follow up	57.28
Standard deviation	38.97
Minimum	0
Maximum	100

Table 17:

Total dependency (0-20)	8
Severe dependency (21-60)	6
Moderate dependency(61-90)	5
Slight dependency (91-99)	9
Independent (100)	1

MBI at follow up

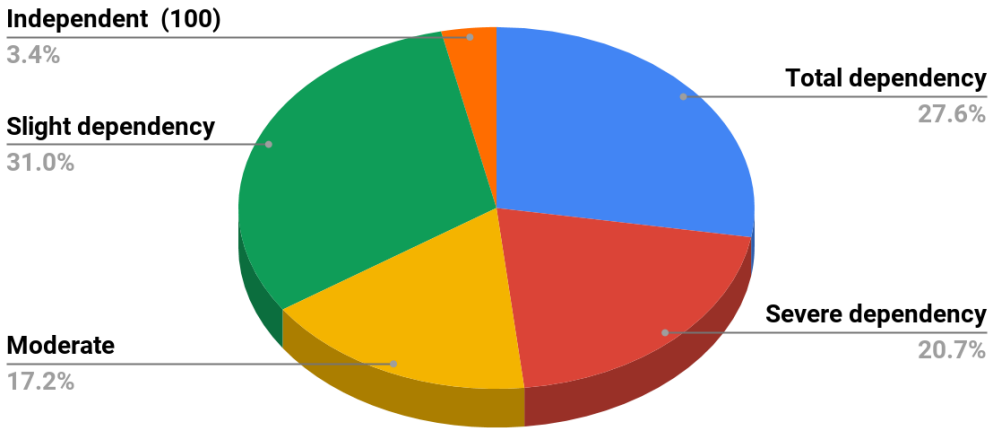


Fig 12: Modified Barthel Index at follow up

MBI showed 27.6% people needed total dependency for all activities of daily living, 20.7% were severely dependent 17.2% were moderately dependent, 31% were slightly dependent and 3.4% were totally independent.

III. Level of community integration at follow up:

Table 18: CIQ scores at follow up

Community Integration Questionnaire (CIQ)	Mean +/- SD	Minimum	Maximum
Home integration score 0-10	2.31 +/- 3.51	0	10
Social integration score 0-12	3.24 +/- 2.94	0	10
Productivity score 0-7	2.03 +/- 2.48	0	6
Total 0-29	7.59 +/- 8.11	0	24

Total CIQ scores at follow up showed poor total scores. All the sub scores showing integration at home and society as well as overall productivity showed poor scores.

IV. Vocational and Educational outcomes at follow up:

Table 19: Return to vocation and education

Outcome at follow up	n=29
Returned to same job or education	4
Joined a different job or course	4
Could not get back to work	21

Vocational and educational outcome

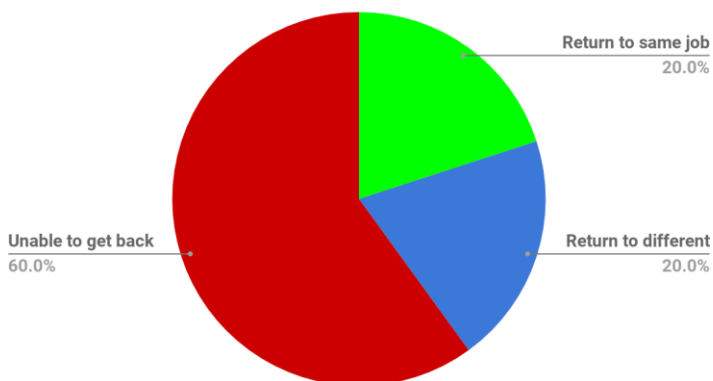


Fig 13: Vocational and educational outcome

While 40% of the patients had returned to either the same job or a different job, 60% were not able to return to any work or education at the time of follow up.

V. Ambulatory status at follow up

Table 20:

Bed bound	4
Wheelchair dependent	2
Walking with maximum support	4
Walking with moderate support	4
Walking with minimum support (quadripod/AFO)	6
Walking with no support	3
Walking on uneven surface - normal gait	6

Ambulatory status

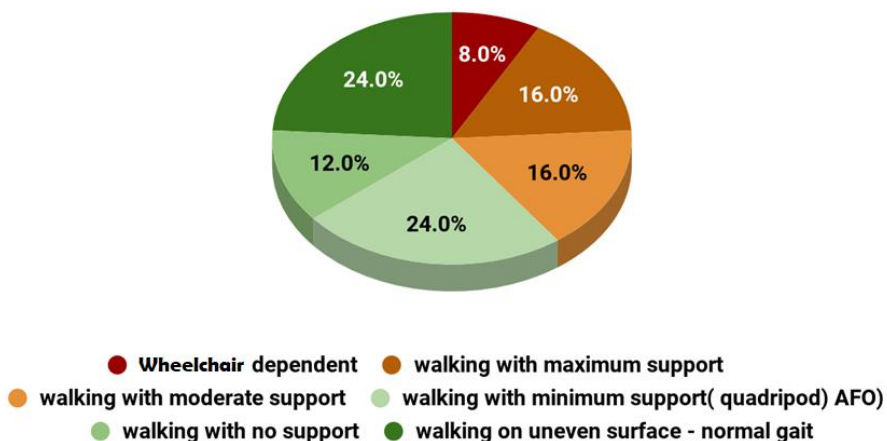


Fig 14: Ambulatory status at follow up

D. Comparison of outcomes at discharge with follow up outcomes

D.1. Comparison of GOSE at discharge and follow up

Table 21: GOSE scores and mean change at follow up

Outcome	Mean +/- SD
GOSE at Discharge	3.39 +/- 1.11
GOSE at Follow up	3.94 +/- 1.63
GOSE change	0.54 +/- 1.17

GOSE Category	No of patients at discharge	No of patients at follow up
Death	0	2
Vegetative state	6	2
Lower severe disability	13	11
Upper severe disability	8	6
Lower moderate disability	3	3
Upper moderate disability	0	6
Lower good recovery	1	0
Upper good recovery	0	1

Table 22: Number of patients in GOSE categories at discharge and follow up

At Discharge and At Follow up

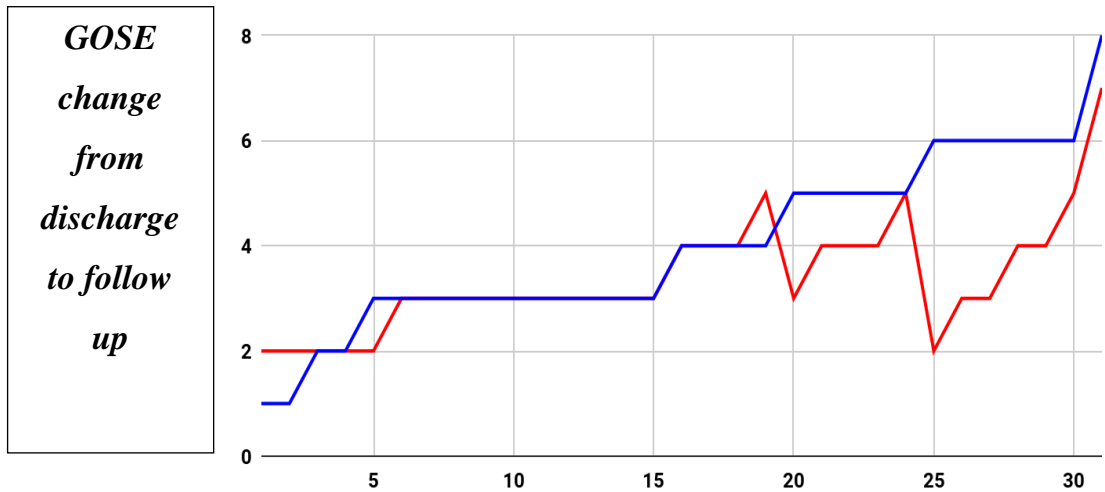


Fig 15: GOSE scores on Y axis and patients on X axis

GOSE category of each patient at discharge and at follow up is plotted on graph with GOSE category on Y axis and patients on X axis.

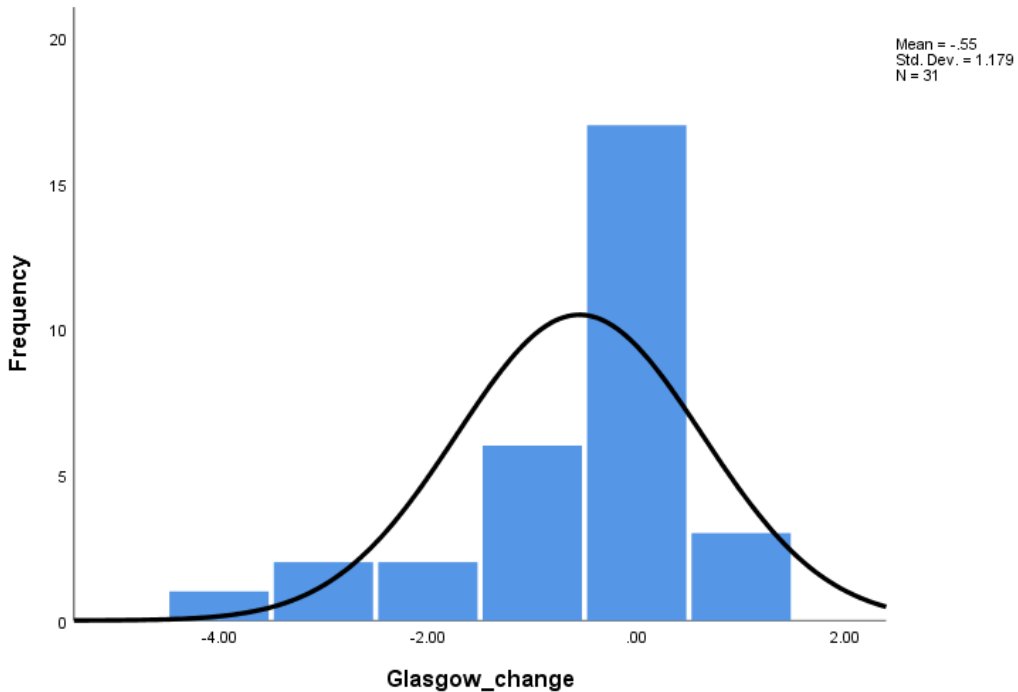


Fig 16: Statistical representation of change in GOSE

P value	.015 (Wilcoxon Signed Ranks Test: Z= 2.428)
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Significant change in GOSE scores from discharge to follow up was observed. Outcome varied from death to upper good recovery with some patients continuing to be in vegetative state. (p=0.015)

D.2. Comparison of DRS scores at discharge and follow up

Table 23: Change in DRS from discharge to follow up

Outcome	Mean +/- SD
DRS at Discharge	14.06 +/- 8.04
DRS at Follow up	7.76 +/- 6.84
Change in DRS	5.55 +/- 4.77

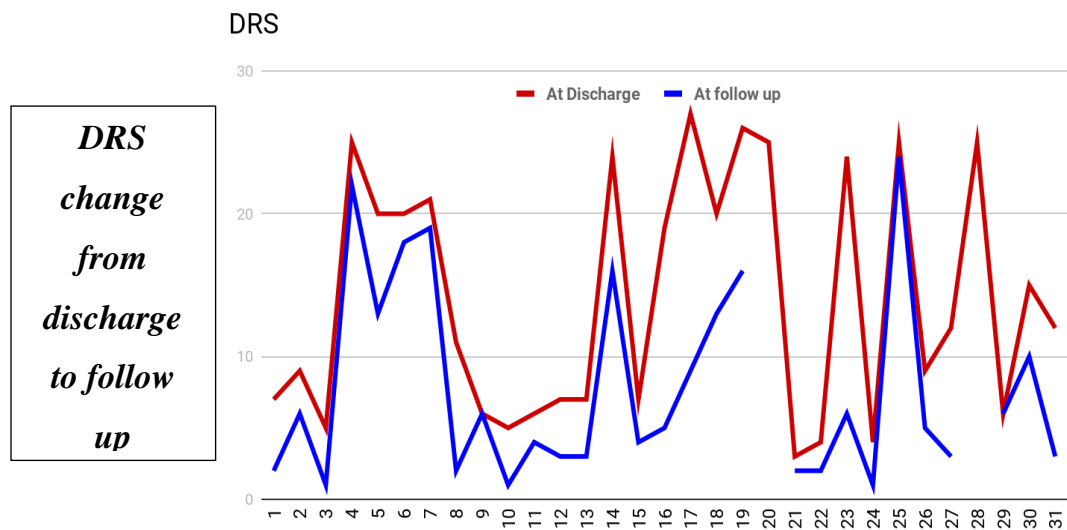


Fig 17: DRS scores on Y axis and patients on X axis

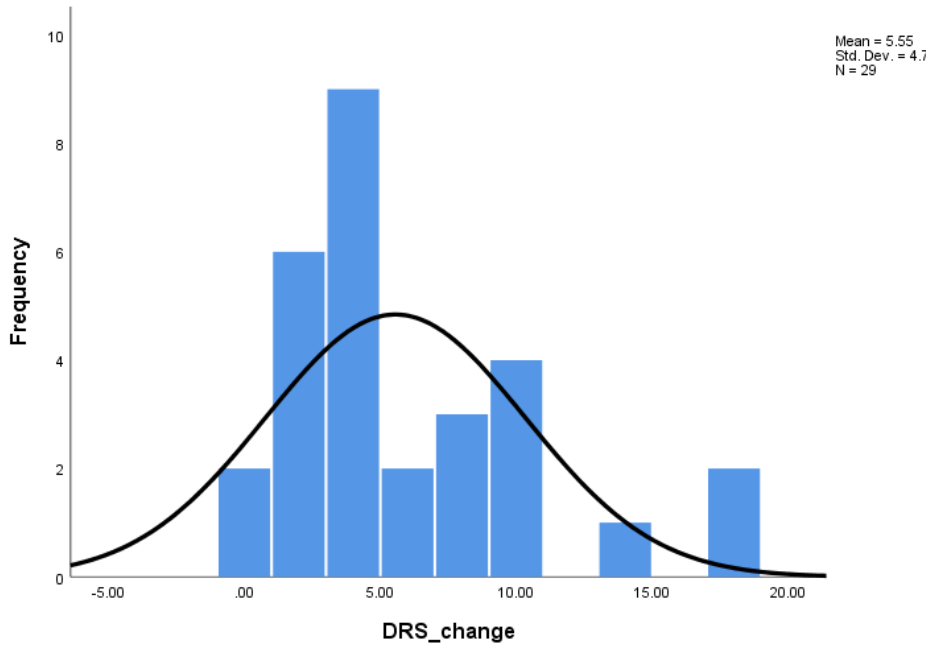


Fig 18: Statistical data of change in DRS scores from discharge to follow up

P value	.000 (Wilcoxon Signed Ranks Test: Z= 4.549)
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Significant improvement ($p=0.000$) was seen in DRS from discharge to follow up.

D.3.Comparison of MBI scores at discharge and follow up

Table 24: Change in MBI scores from discharge to follow up

Outcome	Mean +/- SD
MBI at Discharge	35.67 +/- 35.02
MBI at Follow up	57.28 +/- 38.97
MBI change	20.464

At Discharge and At Follow up

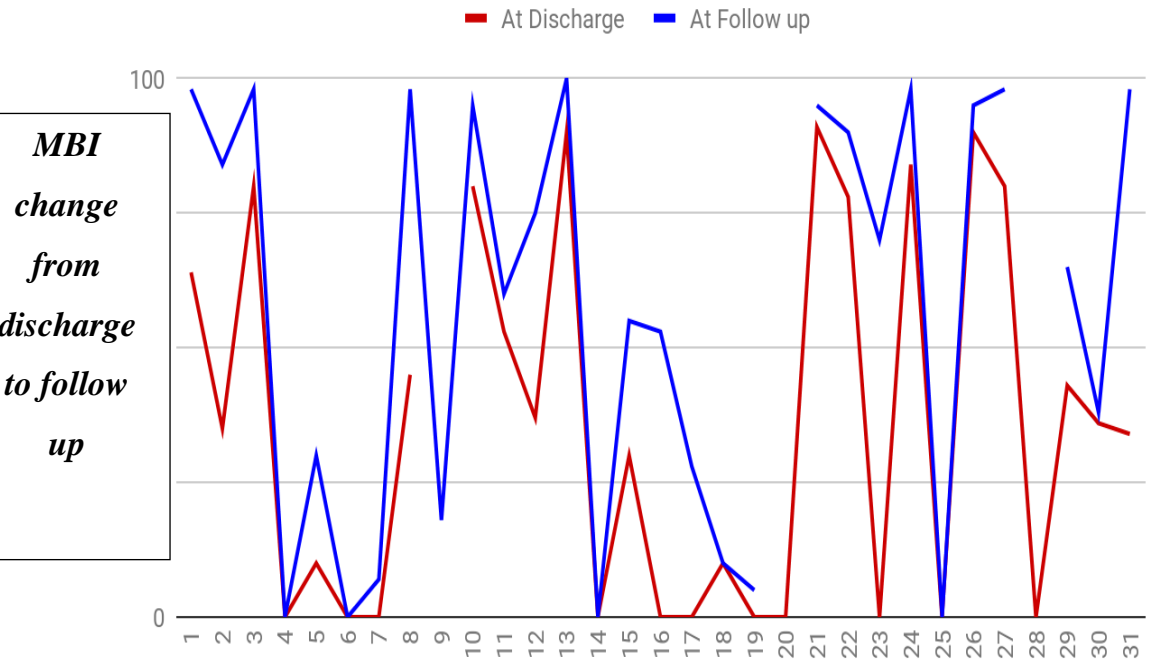


Fig 19: MBI scores on Y axis and patients on X axis

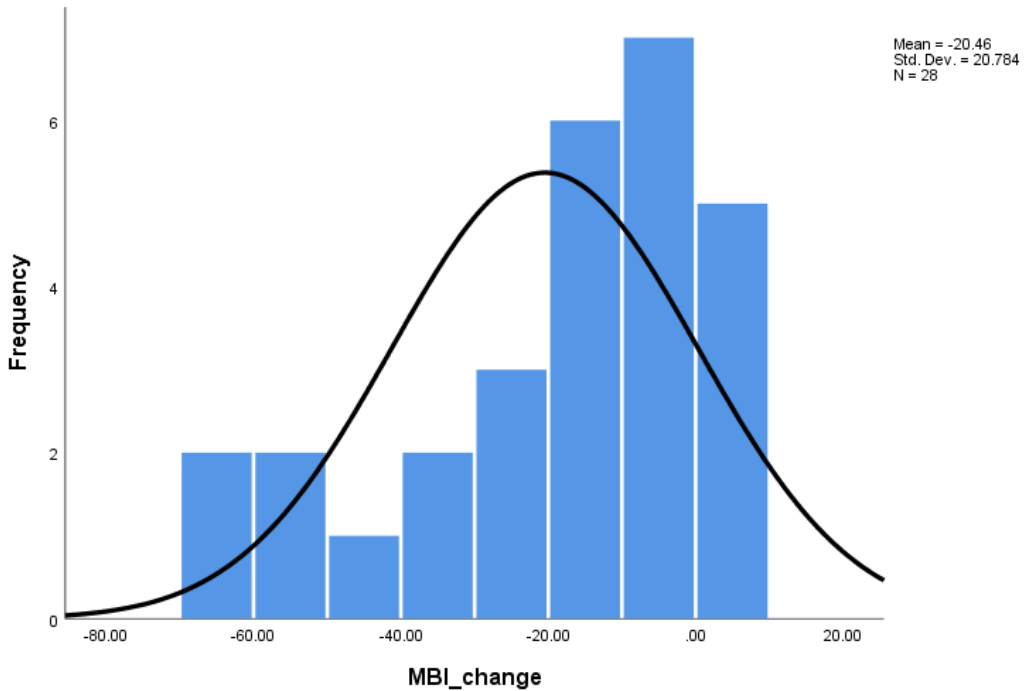


Fig 20: Statistical data of change in MBI scores from discharge to follow up

P value	.000 (Wilcoxon Signed Ranks Test: $z = -4.198$)
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Significant improvement ($p=0.000$) was seen in MBI scores from discharge to follow up

D.4. Comparison of ambulatory status at discharge and follow up

Table 25: Change in ambulatory status from discharge to follow up

Ambulatory status	No of patients at discharge	No of patients at follow up
Bed bound	4	4
Wheelchair dependent	8	2
Walking with maximum support	5	4
Walking with moderate support	4	4
Walking with minimum support (quadripod/ AFO)	7	6
Walking with no support	3	3
Walking on uneven surface - normal gait	0	6

Ambulatory status of patients improved from majority being bed bound, wheel chair dependent and needing maximum to moderate support at discharge to most of the patients walking with minimum support and walking with no support on uneven terrain and outdoor at follow up.

Table 26: Wilcoxon Signed Ranks Test

	Z score	Asymp. Sig. (2-tailed)
GOSE at follow up - GOSE at Discharge	-2.428 ^b	.015
DRS at follow up - DRS at discharge	-4.549 ^c	.000
MBI at follow up - MBI at discharge	-4.198 ^b	.000

a. Wilcoxon Signed Ranks Test

b. Based on negative ranks.

c. Based on positive ranks.

Non parametric Wilcoxon signed rank test were performed to test the hypothesis on change at different time points. Since the p value is lesser than 0.05 we can conclude that there is statistically significant difference in the ranks on the parameter GOSE MBI and DRS from discharge to follow up.

E. Correlations of outcomes with severity of injury

E.1. Correlation of Initial GCS with DRS at follow up

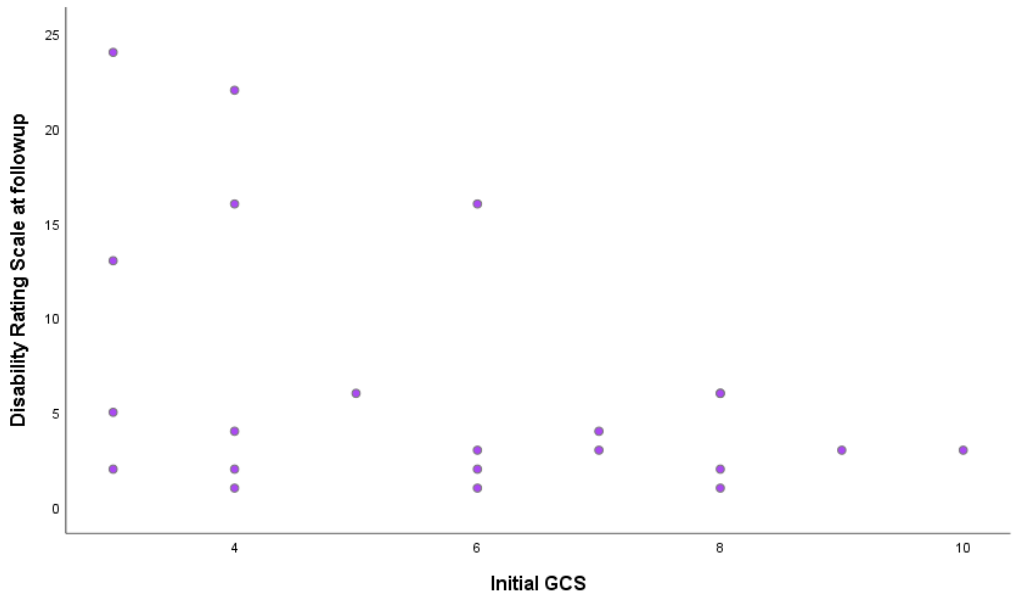


Fig 21: Correlation of Severity of injury with DRS at follow up

Pearson Correlation -0.415*

It was seen that there was a correlation between the severity of initial injury and the DRS scores at follow up; the more severe the initial injury, the higher was the DRS scores indicating more severe disability. However this correlation was not statistically significant at the 0.055P value.

E, 2. Correlation of Initial GCS with GOSE at follow up

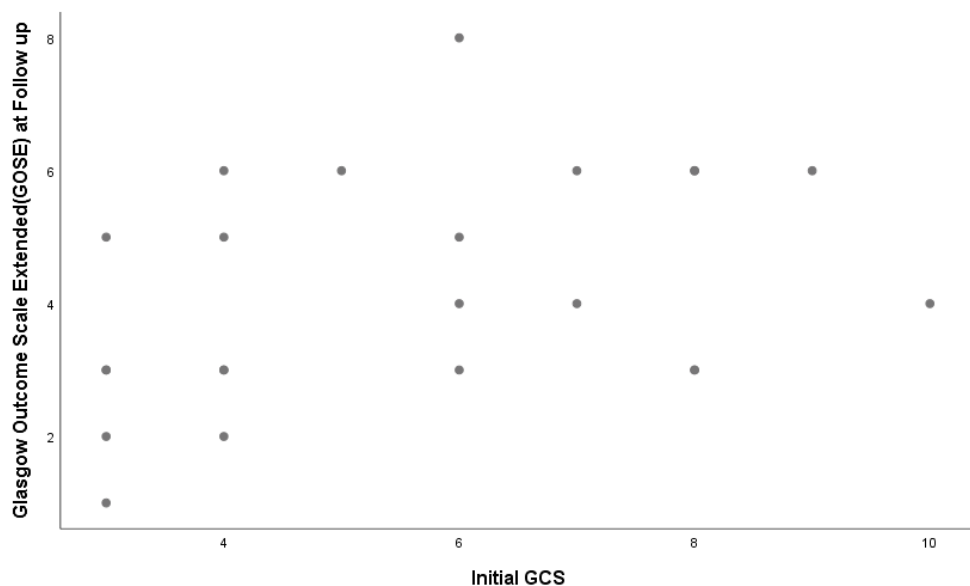


Fig 22: Correlation of Severity of injury with GOSE at follow up

Pearson Correlation 0.383 *

These results showed correlation between the initial severity of injury and the GOSE scores at follow up. This was however not statistically significant with 0.071P value.

E.3. Correlation of Initial GCS with MBI at follow up

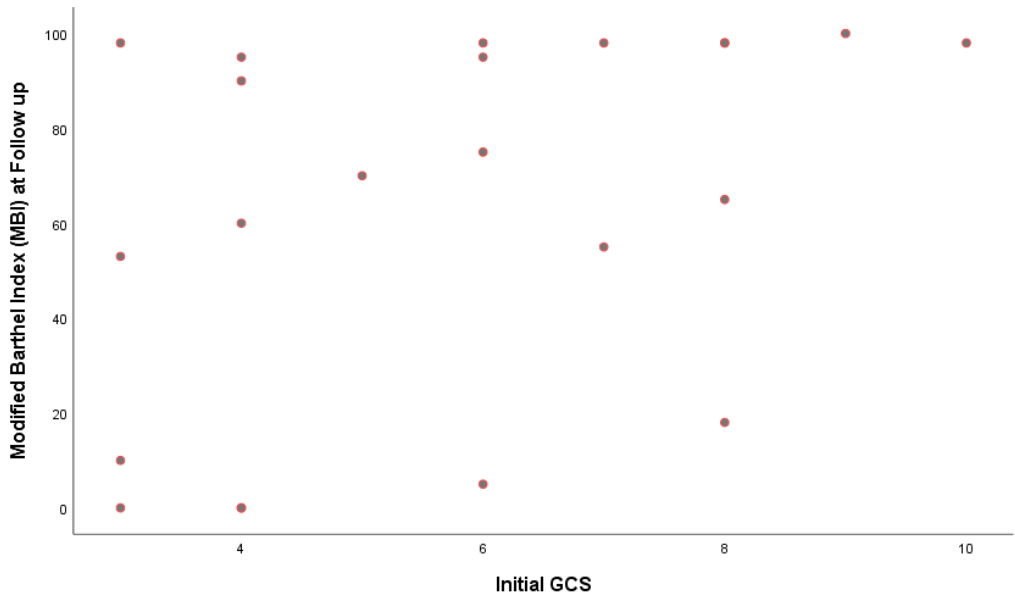


Fig 23: Correlation of Severity of injury with MBI at follow up

Pearson Correlation 0.415*

The more severe the initial injury, the lower was the Modified Barthel Index at follow up indicating more dependence for ADL, However this was not statistically significant with P value 0.055

E.4 Correlation of Initial GCS with CIQ at follow up

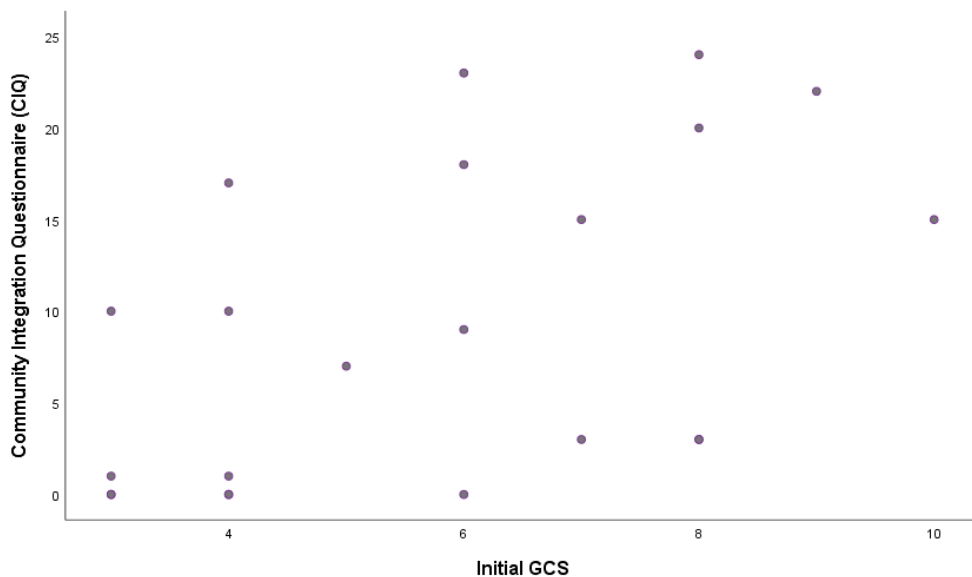


Fig 24: Correlation of Severity of injury with CIQ

Pearson Correlation 0.515*

Positive correlation noted between severity of injury and CIQ outcome which is statistically **significant** with **P value 0.014**.

F. Correlation of outcomes with duration of rehabilitation

1. Correlation of rehabilitation duration with GOSE at follow up

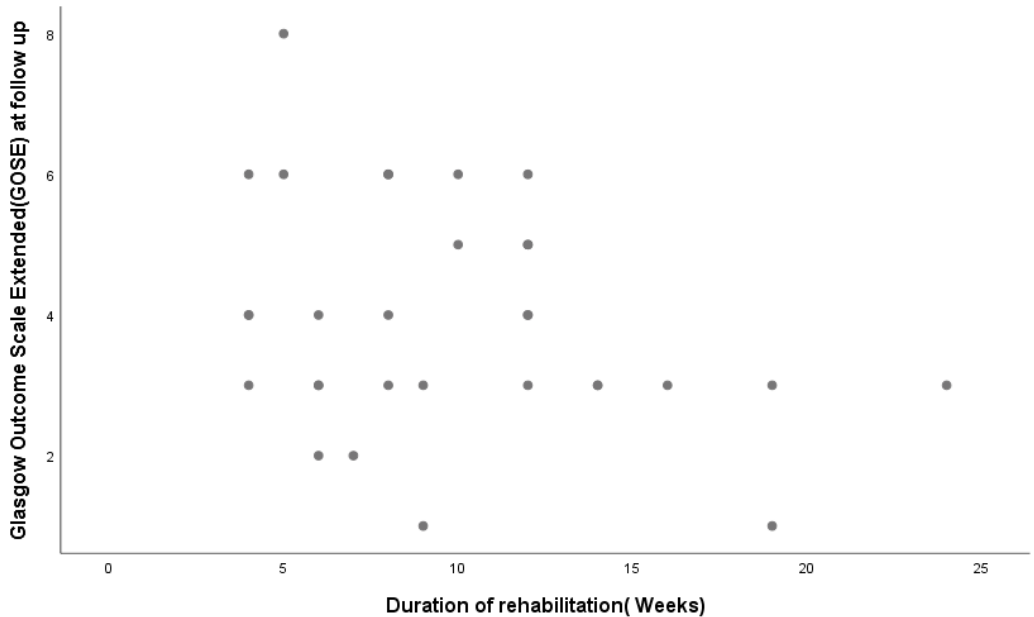


Fig 25: Correlation of Duration of rehabilitation with GOSE at follow up

Pearson Correlation -0.307*

*. Correlation is not significant at the 0.093 level

F.2 Correlation of rehabilitation duration with DRS at follow up

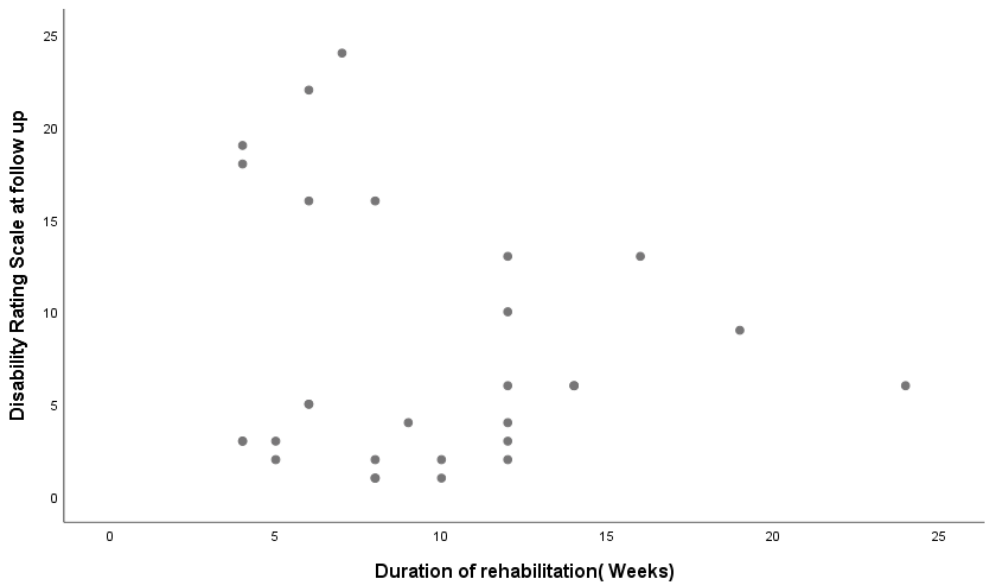


Fig 26: Correlation of Duration of rehabilitation with DRS at follow up

Pearson Correlation -0.134*

*. Correlation is not significant at the 0.489 level

F.3. Correlation of rehabilitation duration with MBI at follow up

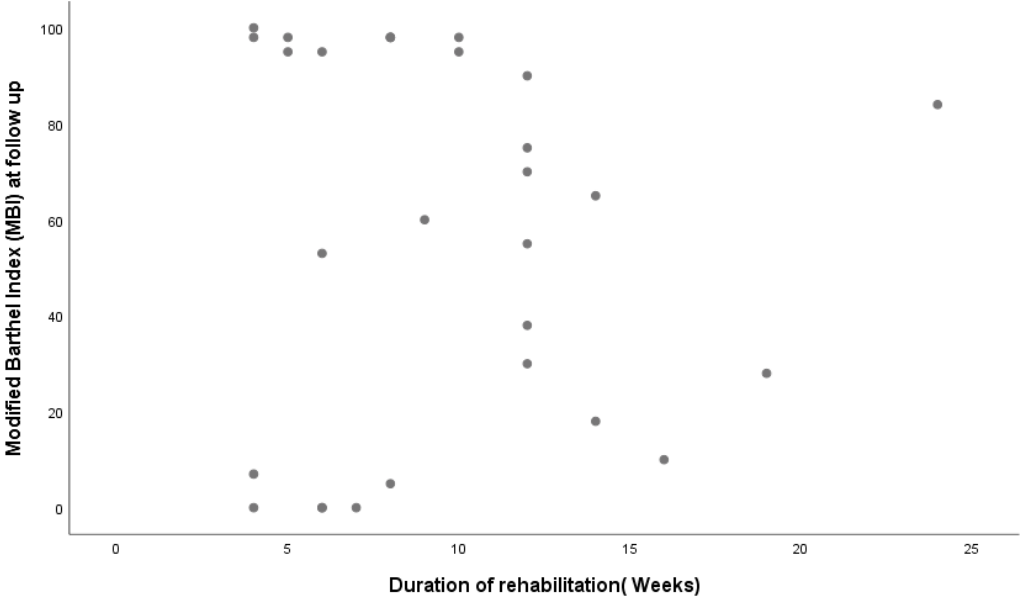


Fig 27: Correlation of Duration of rehabilitation with MBI at follow up

Pearson Correlation -0.031*

*. Correlation is not significant at the 0.872 level

Kruskal-Wallis Test

Table 27:

	Initial GCS	Glasgow Outcome Scale Extended(GOSE) at Discharge	Glasgow Outcome Scale Extended(GOSE) at follow up	Disability Rating Scale at discharge	Disability Rating Scale at follow up
Kruskal-Wallis H	1.296	.650	4.307	.434	2.048
Df	2	2	2	2	2
Asymp. Sig.	.523	.723	.116	.805	.359

Test Statistics^{a,b}

	Modified Barthel Index (MBI) at discharge	Modified Barthel Index (MBI) at follow up	Community Integration Questionnaire (CIQ)
Kruskal-Wallis H	.446	1.418	1.571
Df	2	2	2
Asymp. Sig.	.800	.492	.456

a. Kruskal Wallis Test

b. Grouping Variable: Duration of injury to admission for rehabilitation

Non parametric Kruskal Wallis test were performed to test the hypothesis for different groups on various parameters. Statistical significant difference was not seen in any of these parameters with the p value >0.05

G. Complications post discharge

Table 28:

Complication	No of patients
Seizures	9
Hydrocephalus	3
Pneumonia	4
Heterotopic ossification	2
Bradykinesia	9
Ataxia	5
Tracheostomy related issues	6
Recurrent falls	4
Contractures	15

Complications post discharge

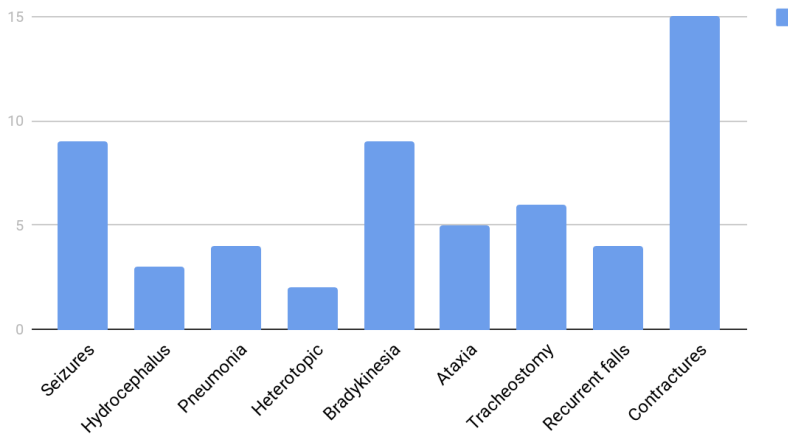


Fig 28: Complications in patients at follow up

Common complications noticed in patients post discharge were seizures, bradykinesia and contractures in 9,9,15 patients respectively.

DISCUSSION

Dependence for activities of daily living and difficulties related to injury are present for a long term in patients who had traumatic brain injury.

With improved infrastructure and better care, mortality rate in TBI has decreased but morbidity is persisting in these patients. Rehabilitation is focused on improving their independence and preventing complications. Post rehabilitation, along with independence in ADLs, integration into community and return work or education also has to be achieved. Studies on long term outcomes after rehabilitation in moderate and severe TBI patients are sparse in Indian population and literature.

Our study was designed to assess long term functional outcomes of patients with severe TBI who had undergone inpatient rehabilitation and their integration into community. A total of 31 patients were recruited in the study from June 2018 till September 2019. Those who satisfied the inclusion criteria and were willing to give their informed consent towards participation in the study were included.

Our study included 31 patients. 26 patients (83.9%) were males and 5 (16.1%) patients were females. The patients were in the age group 19-64 years with mean age of 36.68 years. Most common cause of Traumatic Brain Injury in this population was Road Traffic Accidents followed by assault. This correlates with other studies. Young male adults in prime of their working age were the major group who sustained head injury in this study. This can be due to increased association with outdoor activities and driving.

Severity of injury was moderate in 2 patients and severe in other 29. Mean duration after brain injury to admission for rehabilitation was 4.74 months ranging from as early as 1 week to 18 months. Mean period they underwent inpatient rehabilitation was 9.84 weeks. Duration since injury to follow up varied from 13 to 80 months with mean duration of 43.19 months.

31 patients were recruited from home visits, support groups, review appointments and readmission for rehab. Patients were assessed for their

outcomes using validated scales, and physical examination done to look for any complications developed after discharge. 2 patients died after discharge, one with pneumonia and other with dyselectrolytemia. Global outcomes showed mean GOSE score of 3.94 with 35.5 % of patients in lower severe disability state and 19.4% in upper severe disability, 9.7% in lower moderate disability, 19.4% in upper moderate disability, 3.2% in upper good recovery state, 6.5% in vegetative state and 6.5% death. In our patients 68% were in GOSE category of 1-4 and 32% were in category 5-8. Comparing to another study done by Stalnake et al using GOSE as outcome measure in severe TBI, patients who were treated at a rehabilitation institute has shown mean GOSE of 4.7 at 7 years follow up and in their patients they found 42% were in GOSE category of 1-4 and 58% in 5-8.(89)

Level of disability based on DRS was mild disability in 10.3% patients, 27.6% with partial disability, 27.6% with moderate disability, 6.9% with moderately severe disability, 13.8% with severe disability, 6.9% with extremely severe disability and 6.9 % in vegetative state. Mean +/- change of DRS in our patients at follow up was 5.55 +/- 4.77Plata et al reported

DRS change at 5 years follow up as 2.7+/- 3.34 in 16-26 year age group, 2.39+/- 2.39 in 27-39 age group and 3.08+/- 2.1 in 40-85 year age group. They also included patients with mild, moderate and severe TBI who underwent rehabilitation. They further classified age groups comparing DRS outcomes.(84)

Functional status of patients on follow up was assessed with MBI which showed 27.6% people in total dependency for all activities of daily living, 20.7% in severe dependency, 17.2% in moderate dependency, 31% in slight dependency and 3.4 % were totally independent.

Community integration was assessed with CIQ which showed mean total CIQ scores of 7.59 which was a poor outcome. Among sub categories mean score were 2.31 for home integration, 3.24 for social integration and 2.03 for productivity. These scores were consistent with other studies but social integration was less in our patients in South India.(90)Community Integration Questionnaire has few questions designed for western population which were not suitable for Indian subjects which reflected as low integration scores.

Vocational and educational status data collected at follow up showed 20% returned same job or education, 20% patients joined new job or new course. Majority that is 60% of patients followed up could not get back to any work. Results and feedback from patients were indicating need to develop vocational and community rehabilitation services. A 10 year follow up study by Grauwmeijer et al assessed employment status of 48 patients post TBI. In their prospective study ,they found that 45% patients returned to work and more than half of patients did not return to education. These results were similar to the outcome of patients in our study.(87)

Before rehabilitation while majority of patients were bed bound or wheelchair dependent, on follow up, 60% of these patients were walking independently and with minimum assistance and 32% were walking with moderate and maximum assistance. 8% were wheelchair dependent.

Correlations with severity of injury with outcomes was looked at.

Correlation with initial GCS and DRS had moderate negative correlation of -0.415 as lower the DRS scores better outcome it is. Correlation with

initial GCS and GOSE, MBI, CIQ had moderate correlation with positive Pearson's coefficient of 0.383, 0.415 and 0.515 respectively. Correlation was established but the results for these were not statistically significant. This showed that higher the GCS or lower the severity of injury, the better were the outcomes .

Correlation with duration of rehabilitation and outcomes was also looked at which showed no correlation with each other. Duration of rehabilitation varies from patient to patient depending on complications and time they take to respond for management, so duration of rehabilitation alone might not affect outcome.

Correlation with age, premorbid comorbidities and attendance in follow up support groups could not be assessed due to less no of patients in those groups. Age wise patients were clustered in young age group, only 5 patients had comorbidities and only 8 patients were coming for support groups.

Studies done previously were focused mostly on functional outcome, global outcomes, employability and psychosocial problems as separate outcomes. Few studies have looked at all these outcomes and even assessed correlation with each other. Such studies give an overall picture of patients' status and probable factors associated. In our study we tried to do the same and showed that majority of patients continued to have disability of varying degrees, though there was continued improvement post discharge. However, smaller sample size had limitations due to which correlations with several factors like age, premorbid vocation and education could not be analysed. Many studies assessed outcomes after TBI but inpatient rehabilitation was not a criteria in their inclusion which has an effect on outcome. Countries with national database for TBI patients has done studies with larger sample size, which suggests that maintaining national database of TBI patients gives a better chance to study and assess outcomes in countries like India which has high incidence of road traffic accidents and TBI.

SCOPE FOR FUTURE RESEARCH

1. The study can be continued with a larger sample size
2. Follow up of these patients over a longer period of time will help to understand how the outcomes change over time.
3. Follow up of patients with mild, moderate and severe injuries can be done . In our study population we observed mostly patients with severe TBI admitted for rehabilitation in our centre.
4. Community integration questionnaire to be modified or other scales may be used for Indian population.

CONCLUSION

1. On long term follow up after rehabilitation, it was noted that TBI patients continue to have disability, though there was a significant improvement in functional status as well as ADL independence following discharge. About 37.9 % patients had mild or partial disability on the DRS score while the others had greater disability to varying degrees. Almost half of them(51.6%) were independent or needed minimal/moderate assistance while 48.3% continued to be in severely disabled and vegetative state.
2. Community integration continued to be poor with mean total CIQ scores of 7.59
3. 60 % of patients could not get back to work or education while 40 % could go to pre-morbid or new job and education. These indicate need to develop vocational and community rehabilitation services to enable TBI patients to return to work in a supervised manner

4. There was correlation of outcomes with severity of injury but this was not statistically significant.

5. Correlation of outcomes with duration of rehabilitation was low and was not statistically significant.

LIMITATIONS

1. Smaller sample size due to difficulties in follow up.
2. Discharge scores collected retrospectively had been assessed by different occupational therapists causing inter rater variability.
3. Missing data due to retrospective nature of collecting demographic data
4. The sample population studied may not be representative of all the severe TBI patients as patients admitted for inpatient rehabilitation are often those who have not recovered in the initial few months.
5. Structured interview for community integration designed for western population.
6. No validated scales used for vocational and educational outcomes.

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APPENDIX 1: MODIFIED BARTHEL INDEX

INDEX ITEM	SCORE	DESCRIPTION
CHAIR/BED TRANSFERS	0	Unable to participate in a transfer. Two attendants are required to transfer the patient with or without a mechanical device.
	3	Able to participate but maximum assistance of one other person is require in <u>all aspects</u> of the transfer.
	8	The transfer requires the assistance of one other person. Assistance may be required <u>in any</u> aspect of the transfer.
	12	The presence of another person is required either as a confidence measure, or to provide supervision for safety.
	15	The patient can safely approach the bed walking or in a wheelchair, lock brakes, lift footrests, or position walking aid, move safely to bed, lie down, come to a sitting position on the side of the bed, change the position of the wheelchair, transfer back into it safely and/or grasp aid and stand. The patient must be independent in all phases of this activity.
	0	Dependent in ambulation.
	3	Constant presence of one or more assistant is required

AMBULATION		during ambulation.
	8	Assistance is required with reaching aids and/or their manipulation. One person is required to offer assistance.
	12	The patient is independent in ambulation but unable to walk 50 metres without help, or supervision is needed for confidence or safety in hazardous situations.
	15	The patient must be able to wear braces if required, lock and unlock these braces assume standing position, sit down, and place the necessary aids into position for use. The patient must be able to crutches, canes, or a walkalette, and walk 50 metres without help or supervision.
AMBULATION/WHEELCHAIR		
* (If unable to walk) Only use this item if the patient is rated “0” for Ambulation, and then only if the patient has been trained in	0	Dependent in wheelchair ambulation.
	1	Patient can propel self short distances on flat surface, but assistance is required for all other steps of wheelchair management.
	3	Presence of one person is necessary and constant assistance is required to manipulate chair to table, bed, etc.
	4	The patient can propel self for a reasonable duration over regularly encountered terrain. Minimal assistance may still be required in “tight corners” or to negotiate a kerb 100mm high.
	5	To propel wheelchair independently, the patient must be able to go around corners, turn around, manoeuvre the chair to a table, bed, toilet, etc. The patient must be

wheelchair management.		able to push a chair at least 50 metres and negotiate a kerb.
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IND EX ITE M	SCO RE	D E S C R I P T I O N
STAIR CLIMBING	0	The patient is unable to climb stairs.
	2	Assistance is required in all aspects of chair climbing, including assistance with walking aids.
	5	The patient is able to ascend/descend but is unable to carry walking aids and needs supervision and assistance.
	8	Generally no assistance is required. At times supervision is required for safety due to morning stiffness, shortness of breath, etc.
	10	The patient is able to go up and down a flight of stairs safely without help or supervision. The patient is able to use hand rails, cane or crutches when needed and is able to carry these devices as he/she ascends or descends.
TOILET TRANSFERS	0	Fully dependent in toileting.
	2	Assistance required in all aspects of toileting.
	5	Assistance may be required with management of clothing, transferring, or washing hands.
	8	Supervision may be required for safety with normal toilet. A commode may be used at night but assistance is required for emptying and cleaning.
	10	The patient is able to get on/off the toilet, fasten clothing and use toilet paper

		without help. If necessary, the patient may use a bed pan or commode or urinal at night, but must be able to empty it and clean it.
BOWEL CONTROL	0	The patient is bowel incontinent.
	2	The patient needs help to assume appropriate position, and with bowel movement facilitatory techniques.
	5	The patient can assume appropriate position, but cannot use facilitatory techniques or clean self without assistance and has frequent accidents. Assistance is required with incontinence aids such as pad, etc.
	8	The patient may require supervision with the use of suppository or enema and has occasional accidents.
	10	The patient can control bowels and has no accidents, can use suppository, or take an enema when necessary.
BLADDER CONTROL	0	The patient is dependent in bladder management, is incontinent, or has indwelling catheter.
	2	The patient is incontinent but is able to assist with the application of an internal or external device.
	5	The patient is generally dry by day, but not at night and needs some assistance with the devices.
	8	The patient is generally dry by day and night, but may have an occasional accident or need minimal assistance with internal or external devices.
	10	The patient is able to control bladder day and night, and/or is independent with internal or external devices.

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INDEX ITEM	SCORE	DESCRIPTION
BATHING	0	Total dependence in bathing self.
	1	Assistance is required in all aspects of bathing, but patient is able to make some contribution.
	3	Assistance is required with either transfer to shower/bath or with washing or drying; including inability to complete a task because of condition or disease, etc.
	4	Supervision is required for safety in adjusting the water temperature, or in the transfer.
	5	The patient may use a bathtub, a shower, or take a complete sponge bath. The patient must be able to do all the steps of whichever method is employed without another person being present.
DRESSING	0	The patient is dependent in all aspects of dressing and is unable to participate in the activity.
	2	The patient is able to participate to some degree, but is dependent in all aspects of dressing.
	5	Assistance is needed in putting on, and/or removing any clothing.

	8	Only minimal assistance is required with fastening clothing such as buttons, zips, bra, shoes, etc.
	10	The patient is able to put on, remove, corset, braces, as prescribed.
PERSONAL HYGIENE (Grooming)	0	The patient is unable to attend to personal hygiene and is dependent in all aspects. Assistance is required in all steps of personal hygiene, but patient able to make some contribution.
	1	Some assistance is required in one or more steps of personal hygiene.
	3	Patient is able to conduct his/her own personal hygiene but requires minimal assistance before and/or after the operation.
	4	The patient can wash his/her hands and face, comb hair, clean teeth and shave. A male patient may use any kind of razor but must insert the blade, or plug in the razor without help, as well as retrieve it from the drawer or cabinet. A female patient must apply her own make-up, if used, but need not braid or style her hair.
	5	
FEEDING	0	Dependent in all aspects and needs to be fed, nasogastric needs to be administered. Can manipulate an eating device, usually a spoon, but someone must provide active assistance during the meal.
	2	Able to feed self with supervision. Assistance is required with associated tasks such as putting milk/sugar into tea, salt, pepper, spreading butter, turning a plate or other "set up" activities.
	5	Independence in feeding with prepared tray, except may need meat cut, milk carton opened or jar lid etc. The presence of another person is not required. The patient can feed self from a tray or table when
	8	

	10	someone puts the food within reach. The patient must put on an assistive device if needed, cut food, and if desired use salt and pepper, spread butter, etc.
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SCORE	INTERPRETATION
00 - 20	Total Dependence
21 - 60	Severe Dependence
61 - 90	Moderate Dependence
91 - 99	Slight Dependence
- 100	Independence

The MBI has been shown to have high content reliability with a Cronbach’s coefficient alpha of internal consistency of $\alpha = 0.90$ recorded at the commencement of rehabilitation (Shah, et al. 1989). It has good interrater variability.

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APPENDIX 2: GLASGOW OUTCOME SCALE EXTENDED

Glasgow Outcome Scale

The Glasgow Outcome Scale (GOS) is a global scale for functional outcome that rates patient status into one of five categories: Dead, Vegetative State, Severe Disability, Moderate Disability or Good Recovery. The Extended GOS (GOSE) provides more detailed categorization into eight categories by subdividing the categories of severe disability, moderate disability and good recovery into a lower and upper category:

Table 1: Extended Glasgow Outcome Scale (GOSE)

POST DISCHARGE STRUCTURED INTERVIEW FOR GOSE

Respondent: 0 =Patient alone	1
=Relative/friend/caretakeralone	2 = Patient
plusrelative/friend/caretaker	

Conciousness:

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 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)

If no: go to3

Note: for a NO answer they should be able to look after themselves at home for 24 hours if necessary, though they need not actually 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.

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

Yes(lowerSD)

No (upperSD)

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 actually look after themselves

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

Yes

No

Independence outside home:

3a. Are they able to shop without assistance?

Yes

No (upperSD)

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 (upperSD)

Note: they may drive or use public transport to get around. 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?

a. (Upper MD)

b. Able to work only in a sheltered workshop or non-competitive job or currently unable to work?

b. (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 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 loss of interest or motivation, then this is also considered a disability.

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

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

- b. Frequent - once a week or more, but not tolerable
- c. Constant - daily and intolerable

- b. (Upper MD)
- c. (Lower MD)

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

Yes

No

Note: if there were some problems before 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(LowerGR)

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 outcome?

a. Effects of head injury

b. Effects of illness or injury to another part of the body

c. A mixture of these

Note: extended GOS grades are shown beside responses on the CRF. The overall rating is based on the lowest outcome category indicated.

Areas in which there has been no change with respect to the pre-trauma situation are ignored when the overall rating is made

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

Use of the structured interview is recommended to facilitate consistency in ratings.

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APPENDIX 3: DISABILITY RATING SCALE

DRS FORM

Patient Name: _____ Date of Rating: _____

Name of Person Completing Form: _____

DISABILITY RATING SCALE:

A. EYE OPENING:

- (0) Spontaneous
- (1) To Speech
- (2) To Pain
- (3) None

0- SPONTANEOUS: eyes open with sleep/wake rhythms indicating active arousal mechanisms, does not assume awareness.
1- TO SPEECH AND/OR SENSORIAL STIMULATION: a response to any verbal approach, whether spoken or shouted, not necessarily the command to open the eyes. Also, response to touch, mild pressure.
2- TO PAIN: tested by a painful stimulus.
3- NONE: no eye opening even to painful stimulation.

B. COMMUNICATION ABILITY:

- (0) Oriented
- (1) Confused
- (2) Inappropriate
- (3) Incomprehensible
- (4) None

0- ORIENTED: implies awareness of self and the environment. Patient able to tell you a) who he is; b) where he is; c) why he is there; d) year; e) season; f) month; g) day; h) time of day.
1- CONFUSED: attention can be held and patient responds to questions but responses are delayed and/or indicate varying degrees of disorientation and confusion.
2- INAPPROPRIATE: intelligible articulation but speech is only in an exclamatory or random way (such as shouting and swearing); no sustained communication exchange is possible.
3- INCOMPREHENSIBLE: moaning, groaning or sounds without recognizable words, no consistent communication signs.
4- NONE: no sounds or communication signs from patient.

C. MOTOR RESPONSE:

- (0) Obeying
- (1) Localizing
- (2) Withdrawing
- (3) Flexing
- (4) Extending
- (5) None

0- OBEYING: obeying command to move finger on best side. If no response or not suitable try another command such as “move lips,” “blink eyes,” etc. Do not include grasp or other reflex responses.

1- LOCALIZING: a painful stimulus at more than one site causes limb to move (even slightly) in an attempt to remove it. It is a deliberate motor act to move away from or remove the source of noxious stimulation. If there is doubt as to whether withdrawal or localization has occurred after 3 or 4 painful stimulations, rate as localization.

2- WITHDRAWING: any generalized movement away from a noxious stimulus that is more than a simple reflex response

3- FLEXING: painful stimulation results in either flexion at the elbow, rapid withdrawal with abduction of the shoulder or a slow withdrawal with adduction of the shoulder. If there is confusion between flexing and withdrawing, then use pinprick on hands.

4- EXTENDING: painful stimulation results in extension of the limb.

5- NONE: no response can be elicited. Usually associated with hypotonia. Exclude spinal transection as an explanation of lack of response; be satisfied that an adequate stimulus has been applied.

D. FEEDING (COGNITIVE ABILITY ONLY)

- (0.0) Complete
- (1.0) Partial
- (2.0) Minimal
- (3.0) None

Does the patient show awareness of how and when to perform this activity? Ignore motor disabilities that interfere with carrying out this function. (This is rated under Level of Functioning described below.)

0- COMPLETE: continuously shows awareness that he knows how to feed and can convey unambiguous information that he knows when this activity should occur.

1- PARTIAL: intermittently shows awareness that he knows how to feed and/or can intermittently convey reasonably clearly information that he knows when the activity should occur.

2- MINIMAL: shows questionable or infrequent awareness that he knows in a primitive way how to feed and/or shows infrequently by certain signs, sounds, or activities that he is vaguely aware when the activity should occur.

3- NONE: shows virtually no awareness at any time that he knows how to feed and cannot convey information by signs, sounds, or activity that he knows when the activity should occur.

E. TOILETING (COGNITIVE ABILITY ONLY)

- (0.0) Complete
- (1.0) Partial
- (2.0) Minimal
- (3.0) None

Does the patient show awareness of how and when to perform this activity? Ignore motor disabilities that interfere with carrying out this function. (This is rated under Level of Functioning described below.) Rate best response for toileting based on bowel and bladder behavior

0-COMplete: continuously shows awareness that he knows how to toilet and can convey unambiguous information that he knows when this activity should occur.

1-PARTIAL: intermittently shows awareness that he knows how to toilet and/or can intermittently convey reasonably clearly information that he knows when the activity should occur.

2-MINIMAL: shows questionable or infrequent awareness that he knows in a primitive way how to toilet and/or shows infrequently by certain signs, sounds, or activities that he is vaguely aware when the activity should occur. **3-NONE**: shows virtually no awareness at any time that he knows how to toilet and cannot convey information by signs, sounds, or activity that he knows when the activity should occur.

F. GROOMING (COGNITIVE ABILITY ONLY)

- (0.0) Complete
- (1.0) Partial
- (2.0) Minimal
- (3.0) None

Does the patient show awareness of how and when to perform this activity? Ignore motor disabilities that interfere with carrying out this function. (This is rated under Level of Functioning described below.) Grooming refers to bathing, washing, brushing of teeth, shaving, combing or brushing of hair and dressing.

0-COMplete: continuously shows awareness that he knows how to groom self and can convey unambiguous information that he knows when this activity should occur.

1-PARTIAL: intermittently shows awareness that he knows how to groom self and/or can intermittently convey reasonably clearly information that he knows when the activity should occur.

2-MINIMAL: shows questionable or infrequent awareness that he knows in a primitive way how to groom self and/or shows infrequently by certain signs, sounds, or activities that he is vaguely aware when the activity should occur.

3-NONE: shows virtually no awareness at any time that he knows how to groom self and cannot convey information by signs, sounds, or activity that he knows when the activity should occur.

G.LEVEL OF FUNCTIONING (PHYSICAL, MENTAL, EMOTIONAL OR SOCIAL FUNCTION))

- (0.0) Completely Independent
- (1.0) Independent in special environment
- (2.0) Mildly Dependent-
Limited assistance (non-resid -
helper)
- (3.0) Moderately Dependent-
moderate assist (person in
home)
- (4.0) markedly Dependent-
assist all major activities, all
times
- (5.0) Totally Dependent-24
hour nursing care.

0-COMPLETELY INDEPENDENT: able to live as he wishes, requiring no restriction due to physical, mental, emotional or social problems.
1-INDEPENDENT IN SPECIAL ENVIRONMENT: capable of functioning independently when needed requirements are met (mechanical aids)
2-MILDLY DEPENDENT: able to care for most of own needs but requires limited assistance due to physical, cognitive and/or emotional problems (e.g., needs non-resident helper).
3-MODERATELY DEPENDENT: able to care for self partially but needs another person at all times. (person in home)
4-MARKEDLY DEPENDENT: needs help with all major activities and the assistance of another person at all times.
5-TOTALLY DEPENDENT: not able to assist in own care and requires 24-hour nursing care.

H."EMPLOYABILITY"(AS A FULL TIME WORKER, HOMEMAKER, OR STUDENT)

- (0.0) Not Restricted
- (1.0) Selected job
competitive
- (2.0) Sheltered workshop,
Non-competitive
- (3.0) Not Employable

0-NOT RESTRICTED: can compete in the open market for a relatively wide range of jobs commensurate with existing skills; or can initiate, plan execute and assume responsibilities associated with homemaking; or can understand and carry out most age relevant school assignments.
1-SELECTED JOBS, COMPETITIVE: can compete in a limited job market for a relatively narrow range of jobs because of limitations of the type described above and/or because of some physical limitations; or can initiate, plan, execute and assume many but not all responsibilities associated with homemaking; or can understand and carry out many but not all school assignments.
2-SHELTERED WORKSHOP, NON-COMPETITIVE: cannot compete successfully in a job market because of limitations described above and/or because of moderate or severe physical limitations; or cannot without major assistance initiate, plan, execute and assume responsibilities for homemaking; or cannot understand and carry out even relatively simple school assignments without assistance.
3-NOT EMPLOYABLE: completely unemployable because of extreme psychosocial limitations of the type described above, or completely unable to initiate, plan, execute and assume any responsibilities associated with homemaking; or cannot understand or carry out any school assignments.

The psychosocial adaptability or “employability” item takes into account overall cognitive and physical ability to be an employee, homemaker or student.

This determination should take into account considerations such as the following:

1. Able to understand, remember and follow instructions.
2. Can plan and carry out tasks at least at the level of an office clerk or in simple routine, repetitive industrial situation or can do school assignments.
3. Ability to remain oriented, relevant and appropriate in work and other psychosocial situations.
4. Ability to get to and from work or shopping centers using private or public transportation effectively.
5. Ability to deal with number concepts.
6. Ability to make purchases and handle simple money exchange problems
7. Ability to keep track of time and appointments

- Evaluates 8 areas of functioning in 4 categories:
 - 1) consciousness (eye opening, verbal response, motor response)
 - 2) cognitive ability (feeding, toileting, grooming)
 - 3) dependence on others
 - 4) employability
- Each area of functioning is rated on a scale of 0 to either 3 or 5 (maximum score = 29-extreme vegetative state, minimum score = 0-person without disability) with the highest scores representing the higher level of disability.

Disability Categories

Total DRS score	Level of Disability
0	None
1	Mild
2-3	Partial
4-6	Moderate
7-11	Moderately Severe
12-16	Severe
17-21	Extremely Severe
22-24	Vegetative State
25-29	Extreme Vegetative State

Scoring Instructions Reference:

Rappaport et al., (1982). Disability rating scale for severe head trauma patients: coma to community. *Archives of Physical Medicine and Rehabilitation*, 63: 118-123

Appendix 4: COMMUNITY INTEGRATION QUESTIONNAIRE

Community Integration Questionnaire (CIQ)

The Community Integration Questionnaire (CIQ) is intended as a brief, reliable measure of an individual's level of integration into the home and community following traumatic brain injury.

1. Who usually does shopping for groceries or other necessities in your household?
 - yourself alone
 - yourself and someone else
 - someone else

2. Who usually prepares meals in your household?
 - yourself alone
 - yourself and someone else
 - someone else

3. In your home, who usually does normal everyday housework?
 - yourself alone
 - yourself and someone else
 - someone else

4. Who usually cares for the children in your home?
 - yourself alone
 - yourself and someone else
 - someone else

___ not applicable/ no children under 17 in the home.

5. Who usually plans social arrangements such as get-together's with family and friends?

___ yourself alone

___ yourself and someone else

___ someone else

6. Who usually looks after your personal finances, such as banking or paying bills?

yourself alone

___ yourself and someone else

___ someone else

Can you tell me approximately how many times a month you now usually participate in the following activities outside your home?

7. Shopping

___ Never

___ 1-4 times

___ 5 or more

8. Leisure activities such as movies, sports, restaurants, etc.

___ Never

___ 1-4 times

___ 5 or more

9. Visiting friends or relatives

Never

1-4 times

5 or more

10. When you participate in leisure activities, do you usually do this alone or with others?

mostly alone

mostly with friends who have head injuries

mostly with family members

mostly with friends who do not have head injuries

with a combination of family and friends

11. Do you have a best friend with whom you confide?

yes

no

12. How often do you travel outside the home?

almost everyday

almost every week

seldom/never (less than once per week)

13. Please choose the answer below that best corresponds to your current (during the past month) work situation:

full-time (more than 20 hours per week)

part-time (less than or equal to 20 hours per week)

- not working, but actively looking forwork
- not working, not looking forwork
- not applicable, retired due toage

14. Please choose the answer below that best corresponds to your current (during the past month) school or training programsituation:

- full-time
- part-time
- not attending school or trainingprogram

15. In the past month, how often did you engage in volunteeractivities?

- Never
- 1-4times
- 5 ormore

Scoring Guidelines

The CIQ consists of a total of 15 questions. The overall score, which represents a summation of the scores from individual questions, can range from 0 to 29. A higher score indicates greater integration, and a lower score reflects less integration. The CIQ can be further divided into three subscores, corresponding to integration in the home, social integration, and productivity. Procedures for deriving the subscores are outlined on the scoring sheet.

The following guidelines provide scoring information for specific items or groups of items.

Items 1 to 6:

Score:

- 2 = The activity is performed alone
- 1 = The activity is performed with someone else
- 0 = The activity is performed by someone else

Note: For item 4, if there are no children under 17 in the home, the average (mean) score for items 1 through 3 and item 5 should be substituted.

Items 7 to 9:

Score:

- 2 = The activity was performed 5 or more times in the pastmonth
- 1 = The activity was performed 1 - 4 times in the pastmonth
- 0 = The activity was not performed in the pastmonth

Item 10

Score:

2 = Mostly with friends without head injury or combination of family and friends

1 = Mostly with friends who have head injuries or with family

0 = Mostly alone

Item 11

Score:

2 = Yes response

0 = No response

Item 12

Score:

2 = Almost everyday

1 = Almost every week

0 = Seldom/never (less than once per week)

Items 13 to 15

Although these items are collected individually, they will be combined to form one variable, Productivity. The scoring of this variable is dependent on the combination of answers to questions 13, 14 and 15. On page 4, is a listing of answer sets to these questions and their associated score.

Scoring of the Productivity Variable

Question#	Question	Question#1	Score
13	#14	5	
Work	School	Volunteer Work	
Not working/not looking	+ No school	+ No Volunteering	= 0
Not working/not looking	+ No school	+ 1-4 times/month	= 1
Not working/not looking	+ No school	+ 5 or more times/month	= 1
Not working/looking	+ No school	+ No Volunteering	= 0
Not working/looking	+ No school	+ 1-4 times/month	= 2
Not working/looking	+ No school	+ 5 or more times/month	= 2
Retired due to age	+ No school	+ No Volunteering	= 0
Retired due to age	+ No school	+ 1-4 times/month	= 2
Retired due to age	+ No school	+ 5 or more times/month	= 3
Retired due to age	+ Part-time	+ No Volunteering	= 4
Retired due to age	+ Part-time	+ 1-4 times/month	= 5
Retired due to age	+ Part-time	+ 5 or more times/month	= 5
Retired due to age	+ Full-time	+ Any answer	= 5
Not working	+ Full-time	+ Any answer	= 3

Not working	+	Part-time	+	Any answer	= 4
Part-time	+	No school	+	Any answer	= 3
Part-time	+	Part-time	+	Any answer	= 4
Part-time	+	Full-time	+	Any answer	= 5
Full time	+	No school	+	Any answer	= 4
Full time	+	Part-time	+	Any answer	= 5

Subscales

Subscales have been developed to allow an analysis of integration within specific domains of everyday life. Items have been grouped with respect to their association with: 1) activities primarily related to the home; 2) activities associated with socialization; and 3) educational or vocational activities. These groupings have been made both logically and on the basis of principal components analysis of items which cluster together. Separate home integration, social integration and productivity subscale scores are derived as follows:

HomeIntegration: Summation of items 1 through 5

SocialIntegration: Summation of items 6 through 11

Productivity: Summation of item 12 and the Productivity variable

The overall CIQ score is the additive sum of items 1 through 12 and the Productivity variable.

CIQ Scoring Sheet

Item Number	Description	Sub-Score	Score
-------------	-------------	-----------	-------

Home Integration Scores

1	Shopping	_____
2	Prepare Meals	_____
3	Housework	_____
4	Caring for Children	_____
5	Social Arrangements	_____

HOME INTEGRATION SUBSCALE _____

Social Integration Scores

6	Personal Finances	_____
7	Shopping (times/month)	_____
8	Leisure Activities (times/month)	_____
9	Visiting friends or relatives	_____
10	Having a best friend	_____

SOCIAL INTEGRATIONSUBSCALE

Productivity Scores

12 Travel outside of home _____

13, Productivity _____

14, _____

15 **PRODUCTIVITYSUBSCALE**

CIQ TOTALSCORE

The Community Integration Questionnaire (CIQ) was intended to be a brief, reliable measure of an individual's level of integration into the home and community.

References:

Willer, B., Rosenthal, M., Kreutzer, J. S., Gordon, W. A., & Rempel, R.

(1993). Assessment of community integration following rehabilitation for traumatic brain injury. *Journal of Head Trauma Rehabilitation, 8*, 75–87.

Dijkers M. (2011) Community Integration Questionnaire. In: Kreutzer J.S., DeLuca J., Caplan B. (eds) *Encyclopedia of Clinical Neuropsychology*. Springer, New York, NY

ANNEXURES

ANNEXURE 1: Patient Information sheet

Title of the study : Functional outcomes of patients with moderate / severe traumatic brain injury 1 to 5 years following inpatient rehabilitation.

Aim: To study the functional outcome of patients with severe traumatic brain injury 1 to 5 years after rehabilitation and the factors associated with the outcome.

Methods:

Patients or care takers of those patients who will be included in the study will be asked questions from a questionnaire which would be helpful in assessing the physical, behavioural and vocational problems the patient has. This questionnaire will be administered once during their visit to PMR department 1 to 5 years after rehabilitation. We will then observe what the changes are during these assessments and calculate the severity and frequency of the problems using some scoring systems.

Description of risks, discomforts or inconveniences:

There is no direct or indirect risks for patient to participate in the study that will increase the present disability or cause death.

Unforeseeable risks: None

Anticipated benefits from the study:

- a. Physical, behavioural and vocational problems will be identified and treated
- b. Improve future patient care

Compensation for participation:

Since there is no direct or indirect chance of risk causing increase in disability or death, there is no such provision for compensation.

What happens if you choose to withdraw from study participation?

The participation in the study will be voluntary. There will be no change in treatment or future management even if the person

involved withdraws from the study. Information gained will not be used for any publication or study purpose.

Confidentiality:

All the data collected will be stored in the computer in a separate folder which will be password protected. This computer will only be accessed by the primary investigator. Each participant will be assigned a unique ID while filling the proforma and data entry and further reference will be in relation to this number. Proforma containing the patients' identification details will be kept safe in a locker accessed only by the principal investigator.

Privacy:

Your identity will not be revealed to anyone else as study identity number will be the one which will be shared with co investigators. Personal identifiers will be removed before the data is sent for publication. However, data of the study may be shared with Institutional Review Board of Christian Medical College.

Contact information:

If you have any questions about this research study or possibly, please contact:

Dr.PrudvishYarlagadda, PG Registrar, Department of PMR, CMC, Vellore- 632004

+919441233262, prudvishy@gmail.com

ANNEXURE 2: INFORMED CONSENT

Study Title: Functional outcomes of patients with severe traumatic brain injury 1 to 5 years following rehabilitation.

Study Number: _____

Subject's Initials: _____

Subject's Name: _____

Date of Birth / Age: _____

(Subject)

(i) I confirm that I have read and understood the information sheet dated

_____ for the above study and have had the opportunity to ask

questions. []

(ii) I understand that my participation in the study is voluntary and that I am

free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. []

(iii) I understand that the Ethics Committee and the regulatory authorities will

not need my permission to look at my health records both in respect of the

current study and any further research that may be conducted in relation to

it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information

released to third parties or published. []

(iv) I agree not to restrict the use of any data or results that arise from this study

provided such a use is only for scientific purpose(s).[]

(v) I agree to take part in the above study.[]

Signature (or Thumb impression) of the Subject/Legally Acceptable

Date: ____/____/____

Signatory's Name:

_____Signature:

Signature of the Investigator: _____

Date: ____/____/____

Study Investigator's Name: _____

Signature or thumb impression of the Witness:

Date: ____/____/____

Name & Address of the Witness:

**ANNEXURE 3:PROFORMA FOR DATA
COLLECTION**

**PROFORMA FOR DEMOGRAPHIC, CLINICAL AND
FUNCTIONAL OUTCOMES ASSESSMENT OF PATIENTS
WITH MODERATE/SEVERE TRAUMATIC BRAIN INJURY
1 TO 5 YEARS FOLLOWING INPATIENT
REHABILITATION.**

ID:

Mobile No:

Name:

DOB:

Gender:

Hospital No:

Date of Injury:

Date of initial hospital admission:

Date of discharge from initial hospital:

Date of Admission for rehabilitation:

Date

of Discharge following rehabilitation:

Duration of Rehabilitation:

Review in follow up clinics: Yes/No

If Yes, No of clinics attended:

Pre morbid Education - Illiterate/ High School/ Higher Secondary/
Graduate/ Post graduate

Vocation – Student/Housewife/ Self Employed/ Govt-professional/ Private-professional/ Govt-nonprofessional/Private nonprofessional/Unemployed/ Retired

Marital status - married/ unmarried

ETIOLOGY

Mode of trauma - Fall/ Assault/ RTA/

Penetrating/ Bullet shot

Initial GCS (3-15):/Missing

MANAGEMENT

Initial management- Conservative/ Surgical/ Missing

Repeat Surgery No/ yes/ Not Applicable/ Missing

VP Shunt / Cranioplasty

Hospital where initial management done - CMC/Elsewhere/ Missing

OTHER INJURIES

No/Yes/ Not Applicable/ Missing

[Type text]

[Ty

SCI/ Orbital Injury/ Hemothorax/ Vertebral fracture/ Soft tissue injury/ Visceral Injury

Brachial plexus injury/ Peripheral nerve injury/Facial fracture/ Long bone fracture / Fracture site:.....

Management of long bone fracture- Conservative/ Surgical

Any other injuries-

.....
....

COMORBIDITIES—No/ Yes/ Missing

Diabetes / Cardiac disease/ Hypertension/ Tuberculosis/ Asthma/ / Psychiatric illness

Hepatitis B/ Hepatitis C/ HIV /Alcoholic liver disease/Hypothyroidism/Renal disease/ /Any other comorbidity.....

CLINICAL EXAMINATION

Hemineglect	Absent/ Present
Involuntary movements	Absent/ Mild / Moderate/ Severe
Bradykinesia	No/ Yes
Ataxia	No/Mild/ Moderate/ Severe
Pain	No/Musculoskeletal/ Neuropathic/ NT
Feeding	NG/OG/PEG/PEJ/Oral
Bladder	self/diaper/condom/uret hral/suprapubic
Bowel	self/incontinent/DE/sup pository
Tracheostomy	Absent/ Present

EDUCATIONAL OUTCOME

Returned to school: Yes/No

VOCATIONAL OUTCOME:

Return to work : Yes/No

If Yes : Full time/ Part time

Premorbid job/ New job

Skilled/unskilled

Unsupervised/supervised

AMBULATORY STATUS:

Outcome Scores:

	AT DISCHARGE	REVIEW AT 1-5 YEARS
DRS		
GOS-E		
MBI		
CIQ	-	
Vocational outcome	-	
Educational Outcome	-	
Ambulatory status		

Annexure 4 : Institutional Review Board Acceptance



**OFFICE OF RESEARCH
INSTITUTIONAL REVIEW BOARD (IRB)
CHRISTIAN MEDICAL COLLEGE, VELLORE, INDIA**

Dr. B.J. Prashantham, M.A., M.A., Dr. Min (Clinical)
Director, Christian Counseling Center,
Chairperson, Ethics Committee.

Dr. Anna Benjamin Pulimood, M.B.B.S., MD., Ph.D.,
Chairperson, Research Committee & Principal

Dr. Biju George, M.B.B.S., MD., DM.,
Deputy Chairperson,
Secretary, Ethics Committee, IRB
Additional Vice-Principal (Research)

September 27, 2018

Dr. Prudvish Yarlagadda,
PG Registrar,
Department of PMR,
Christian Medical College,
Vellore – 632 002.

Sub: Fluid Research Grant: New Proposal:

Functional outcomes of patients with moderate / severe traumatic brain injury 1 to 5 years following inpatient rehabilitation.
Dr. Prudvish Yarlagadda, Employment Number: 21469, PG Registrar/ Physical Medicine and Rehabilitation, Dr. Raji Thomas, Employment Number: 30883, Physical Medicine and Rehabilitation, Dr. Prashanth Chalageri Employment Number: 20777, Physical Medicine and Rehabilitation, Dr. Jane Elizabeth Sajan Employment Number: 32581, Physical Medicine and Rehabilitation, DR. ELANGO A, Employment Number: 13546, Reetha Janet Sureka S , Employment Number: 80021, Suhany BT , Employment Number: 31780, Physical Medicine and Rehabilitation.

Ref: IRB Min. No. 11296 [OBSERVE] dated 04.04.2018

Dear Dr. Prudvish Yarlagadda,

I enclose the following documents:-

1. Institutional Review Board approval
2. Agreement

Could you please sign the agreement and send it to Dr. Biju George, Addl. Vice Principal (Research), so that the grant money can be released.

With best wishes,

Dr. Biju George
Secretary (Ethics Committee)
Institutional Review Board

Dr. BIJU GEORGE
MBBS, MD, DM.
SECRETARY - (ETHICS COMMITTEE)
Institutional Review Board,
Christian Medical College, Vellore - 632 002.

Cc: Dr. Raji Thomas, Dept. of PMR, CMC, Vellore

1 of 4



**OFFICE OF RESEARCH
INSTITUTIONAL REVIEW BOARD (IRB)
CHRISTIAN MEDICAL COLLEGE, VELLORE, INDIA**

Dr. B.J. Prashantham, M.A., M.A., Dr. Min (Clinical)
Director, Christian Counseling Center,
Chairperson, Ethics Committee.

Dr. Anna Benjamin Pulimood, M.B.B.S., MD., Ph.D.,
Chairperson, Research Committee & Principal

Dr. Biju George, M.B.B.S., MD., DM.,
Deputy Chairperson,
Secretary, Ethics Committee, IRB
Additional Vice-Principal (Research)

Dr. Vivek Mathew	MD (Gen. Med.) DM (Neuro) Dip. NB (Neuro)	Professor, Neurology, CMC, Vellore	Internal, Clinician
Dr. Santhanam Sridhar	MBBS, DCH, DNB	Professor, Neonatology, CMC, Vellore	Internal, Clinician
Dr. Barney Isaac	M.B.,B.S. D.N.B (Respiratory Diseases)	Associate Professor, Pulmonary Medicine, CMC, Vellore	Internal, Clinician
Dr. John Antony Jude Prakash	MBBS, MD	Professor, Clinical Microbiology, CMC, Vellore.	Internal, Clinician.
Dr. Ajith Sivadasan	MD, DM	Professor, Neurological Sciences, CMC, Vellore	Internal, Clinician
Mrs. Sophia Vijayanathan	MSc Nursing	Addl. Deputy Dean CMC, Vellore	Internal, Nurse
Dr. Asha Solomon	MSc Nursing	Associate Professor, Medical Surgical Nursing, CMC, Vellore	Internal, Nurse

We approve the project to be conducted as presented.

Kindly provide the total number of patients enrolled in your study and the total number of Withdrawals for the study entitled: "Functional outcomes of patients with moderate / severe traumatic brain injury 1 to 5 years following inpatient rehabilitation" on a monthly basis. Please send copies of this to the Research Office (research@cmcvellore.ac.in).

Fluid Grant Allocation:

A sum of 20,100/- INR (Rupees Twenty Thousand One hundred Only) will be granted for 18 Months.

Yours sincerely,


Dr. Biju George
Secretary (Ethics Committee)
Institutional Review Board

Dr. BIJU GEORGE
MBBS, MD, DM
SECRETARY - (ETHICS COMMITTEE)
Institutional Review Board,
Christian Medical College, Vellore - 632 002.

IRB Min. No. 11296 [OBSERVE] dated 04.04.2018

4 of 4

Annexure 5: LIST OF ABBREVIATIONS

ADL: Activities of Daily Living

AFO: Ankle Foot Orthosis

ATP: Adenosine Triphosphate

BAEP: Brainstem Auditory Evoked Potential

BMP-4: Bone Morphogenetic Protein 4

CIQ: Community Integration Questionnaire

CSF: Cerebrospinal Fluid

DEX: Dysexecutive Questionnaire

DRS: Disability Rating Score

DVT: Deep Vein Thrombosis

EEG: Electroencephalogram

FIM: Functional Independence Measure

FSE: Functional Status Examination

GABA: Gamma Amino Butyric Acid

GCS: Glasgow Coma Scale

GOSE: Glasgow Outcome Scale Extended

HADS: Hospital Anxiety & Depression Scale

MBI: Modified Barthel Index

MCS: Minimally Conscious State

NSAID: Non-Steroidal Anti-Inflammatory Drug

PTA: Post-Traumatic Amnesia

PTH: Post-Traumatic Hydrocephalus

RTA: Road Traffic Accident

SD: Standard Deviation

SPECT: Single Photon Emission Computed Tomography

SPSS: Statistical Package for Social Services

TBI: Traumatic Brain Injury

UT: Union Territory

VS: Vegetative State

164 Visual Evoked Potential