

THE TAMILNADU DR.M.G.R.MEDICAL UNIVERSITY



COMPARISON OF VARIOUS HEAD INJURY PROGNOSTIC SCALES.

**Dissertation submitted in partial fulfillment by the
requirements for the degree of**

**M.Ch. Branch –II
NEUROSURGERY**

Examination in AUGUST 2013

**INSTITUTE OF NEUROLOGY
MADRAS MEDICAL COLLEGE
CHENNAI –600003.**

CERTIFICATE

This is to certify that this dissertation entitled “*COMPARISON OF VARIOUS HEAD INJURY PROGNOSTIC SCALES*” is the bonafide original work of **Dr.Goutham S.P** in partial fulfillment of the requirements for Branch II, M.Ch Neurosurgery, examination of THE TAMILNADU DR.M.G.R MEDICAL UNIVERSITY to be held in August 2013.The period of post graduate study and training was from August 2010 – August 2013.

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DECLARATION

I solemnly declare that this dissertation on “**COMPARISON OF VARIOUS HEAD INJURY PROGNOSTIC SCALES**” was prepared by me in the Institute of Neurology, Madras Medical College and Rajiv Gandhi Government General Hospital-RGGGH Chennai under the able guidance and supervision of Professor of Neurosurgery, Madras Medical College and Rajiv Gandhi Government General Hospital-RGGGH Chennai between 2010 to 2013.

This dissertation is submitted to The Tamilnadu Dr.M.G.R. Medical University, Chennai in partial fulfillment of the university requirements for the award of degree of M.Ch. Neurosurgery.

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ACKNOWLEDGEMENTS

I thank the Dean, Madras Medical College and Rajiv Gandhi Government General Hospital - RGGGH for permitting to carry out this study and also for providing necessary facilities.

I thank my teachers Prof.K.Deiveegan, Prof.Maheshwar.K, Prof.S.D.Subbiah, Prof.Ranganathan Jothi, Prof.Jagan Narayana.G.S, Prof.Syamala.S, and Prof.V.Sundar, Prof.V.G.Ramesh and Prof.S.Sundaram under whom I had great privilege of working as a postgraduate student receiving their constant advice and valuable guidance. I thank my professors towards their immense support and encouragement in preparing this dissertation.

I am profoundly thankful to Prof.K.Deiveegan, professor in Neurosurgery, who initiated this study and under whose supervision this study went on smoothly.

My sincere thanks and gratitude to all the Assistant Professors of Neurosurgery for their guidance and cooperation throughout this study. I thank all my Patients and their relatives for participating in the study.

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INTRODUCTION

Traumatic Brain injury (TBI) is a considerable health care problem¹⁻³ and is one of the most common causes of death. Its incidence is rising at large proportions in regions with rapidly increasing motorization because of industrialized development. The incidence varies from 67 to 317 per 100000 individuals and mortality rates range from around 4-8% for moderate injury to approximately 50% with severe head injury.⁴

The symptoms of TBI can be various depending on the extent of damage to the brain. The outlook for patients with mild TBI is generally a good recovery, while patients with a severe TBI have a substantial risk to die. Predicting outcome for very good or very severe patients is therefore rather easy. However, for severe and moderate TBI patients the outcome is not so easy to predict, while such predictions would be helpful in supporting clinical decision making, providing realistic and evidence based expectations to relatives and care givers, as well as in clinical research.

Any ideal prediction score or model should be easy to apply, with high sensitivity and specificity rates irrespective of the management protocol, its time and place of application. Several

prospective and retrospective studies have been done to derive a baseline predictive model for patients in the intensive care unit in general or specific to traumatic brain injury⁵.

This thesis is aimed at comparing the various head injury prognostic scales so that risk prediction can be applied to patients with moderate and severe traumatic brain injury. This will help us to obtain individual's probability of an outcome from the head injured status.

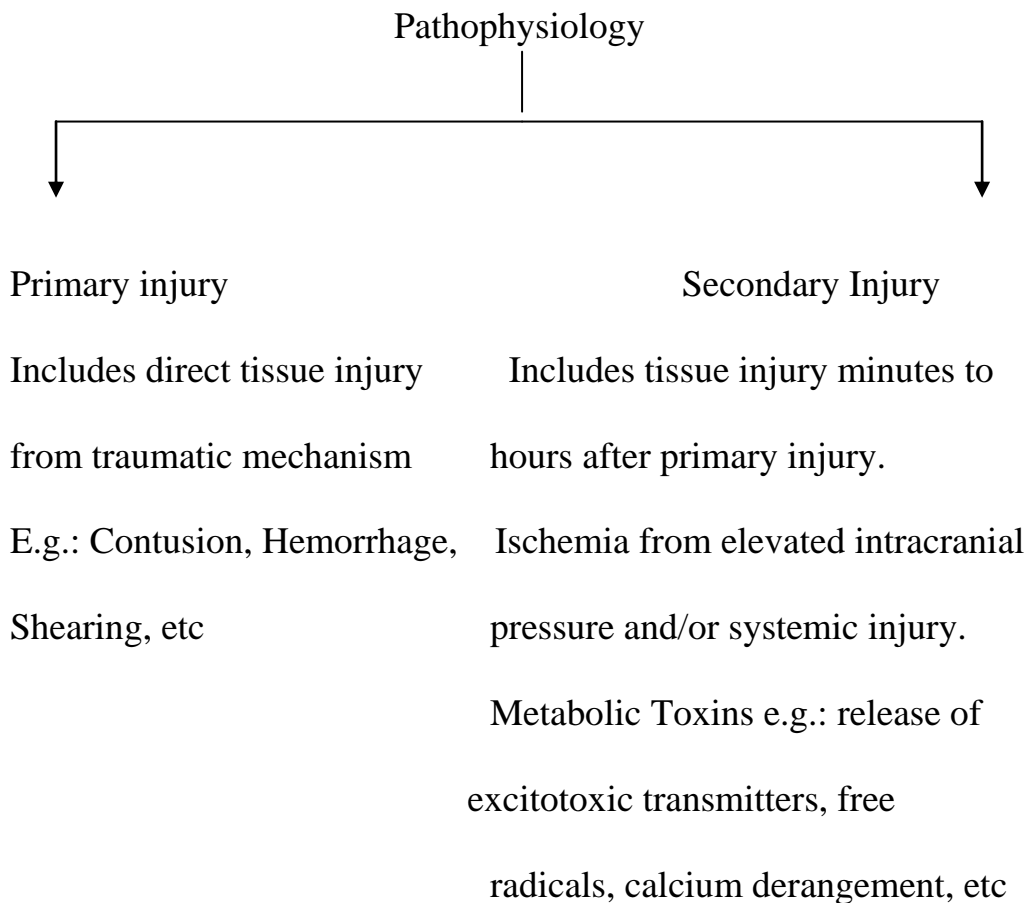
AIM OF THE STUDY

1. The application of various prognostic scales on outcome of moderate and severe traumatic brain injury patients.
2. To compare the sensitivity, specificity and efficacy of the various prognostic scales

REVIEW OF LITERATURE

Traumatic Brain Injury is brain damage resulting from external forces, due to direct impact, rapid acceleration or deceleration⁶.

PATHOPHYSIOLOGY OF TRAUMATIC BRAIN INJURY



Specific Pathophysiology of traumatic brain injury

1. Cerebral blood flow perfusion defects- hypo and hyper perfusion
2. Cerebrovascular dysautoregulation and CO₂-reactivity
3. Cerebral vasospasm
4. Cerebral metabolic dysfunction
5. Excitotoxicity and oxidative stress.
6. Cerebral oxygenation
7. Edema

Traumatic Brain Injury Classification:

Clinical assessment of TBI patients can be done using **GLASGOW COMA SCALE**

The GCS was devised by Teasdale and Jennett in 1974. It is a practical scale to assess the depth of coma objectively. The adult GCS can be used for children >5 years of age.

The parameters assessed in GCS are:

1. Eye Response
2. Verbal Response
3. Motor Response

EYE OPENING:

Spontaneous	4
--------------------	----------

To Verbal Commands	3
---------------------------	----------

To Pain	2
----------------	----------

None	1
-------------	----------

BEST MOTOR RESPONSE:

Obeys Verbal Commands	6
------------------------------	----------

Localizes Pain	5
-----------------------	----------

Flexion /Withdrawal	4
----------------------------	----------

Flexion /Abnormal(decorticate)	3
---------------------------------------	----------

Extension(decerebrate)	2
-------------------------------	----------

None	1
-------------	----------

BEST VERBAL RESPONSE:

Oriented, Conversing	5
-----------------------------	----------

Disoriented , Conversing	4
---------------------------------	----------

Inappropriate Words	3
----------------------------	----------

Incomprehensible Sounds	2
--------------------------------	----------

None	1
-------------	----------

TOTAL :	3-15
----------------	-------------

The minimum score in this scale is 3 and maximum score is 15.

Based on Glasgow Coma Scale , TBI can be classified as follows⁷

GCS 3-8	Severe TBI
GCS 9-13	Moderate TBI
GCS 14-15	Mild TBI

All TBI patients require CT scan imaging of brain.

Marshall CT Classification

Assessment of the extent of structural damage of brain is commonly performed according to the Marshall CT classification given by Marshall et al in 1991 as a descriptive system that focused on the presence or absence of a mass lesion.⁸

Diffuse Injury I	Diffuse injury II	Diffuse Injury III (swelling)	Diffuse Injury IV (shift)
No visible pathology	-Cisterns present -Midline shift (MLS) of 0-5mm. -and/or lesion densities present -no mass lesion >25cc	-Cisterns compressed/absent. -Midline shift of 0-5mm -No mass lesion >25cc	- Midline shift >5mm -no mass lesion >25cc

This classification has a wide inter-observer variability.

Prognostic Classification:

A different approach to classifying patients is by prognostic risk. Recently, due to the large patient groups, well corroborated models have become available to aid this approach.

All these approaches to classification are characterized by some form of scoring of severity.

INCIDENCE

The overall worldwide incidence of TBI is 235 per 100000 population reported by Tagliaferri and colleagues.⁹

National level data in India is not available for TBI as in many developed countries. The only epidemiological study undertaken in Bangalore by Gururaj et al at NIMHANS has revealed an incidence of 150 per 100000 populations.

Patients between 15-24years of age, male gender are at the highest risk with a second peak for both men and women older than 65yrs of age.

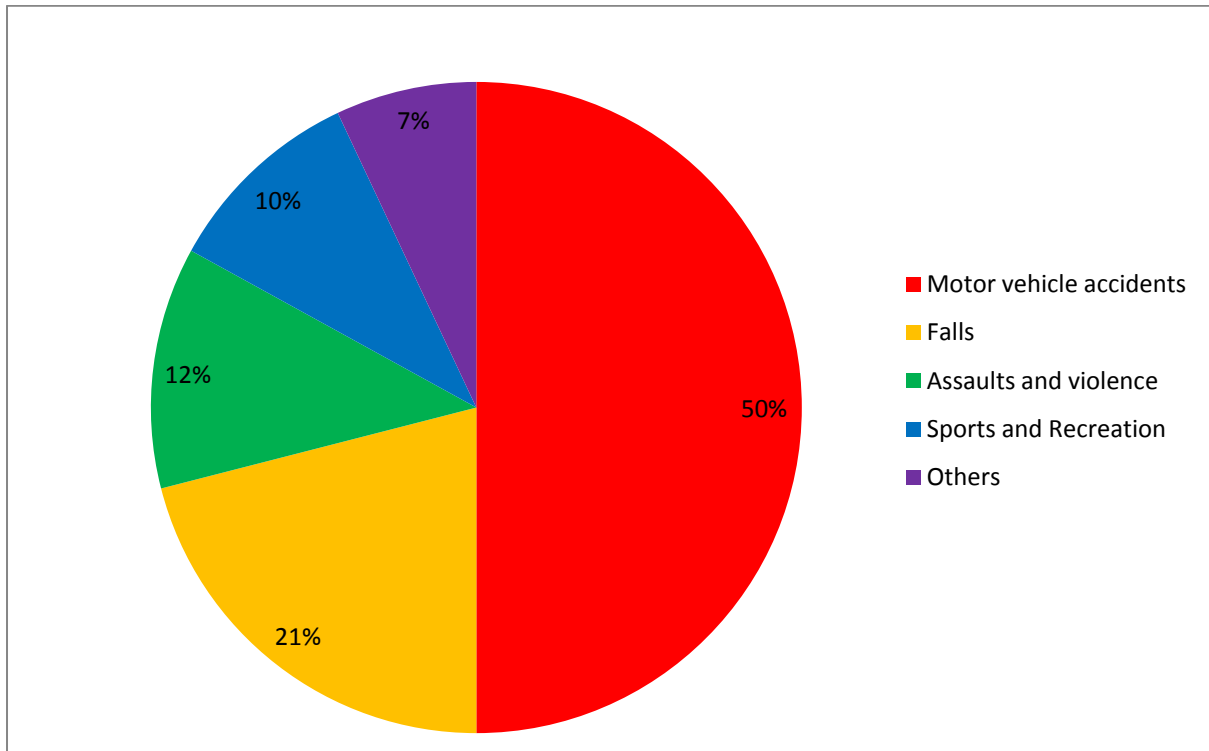
ETIOLOGY OF TRAUMATIC BRAIN INJURY^{10, 11}

The main causes of brain trauma are

- a. Transportation incidents (50%)
- b. Falls (21%)
- c. Gunshot wounds
- d. Assaults or other violent trauma (12%)

e. Sports and recreation related TBI (10%)

ETIOLOGY OF TRAUMATIC BRAIN INJURY



FACTORS AFFECTING THE PROGNOSIS OF Traumatic brain injury:

The factors are:

1. Age
2. Gender
3. Genetics
4. Mechanism of injury
5. Pupillary signs
6. GCS

7. CT Findings
8. Hypotension
9. Hypoxia
10. Hyperglycemia

AGE:

Age plays a crucial part in the prognosis of TBI. Age is a variable which is not altered by observer measurement and hence should be documented on admission. It has a bimodal distribution incidence in traumatic brain injury. The young adult males constitute the larger peak in the incidence followed by the elderly population which constitutes the next smaller peak.

Boto GR et al conducted a study in 2006 and found a step wise threshold for risk after the age of 65years.

Chesnut et al published an article comparing the association between age, outcome after head injury. The study concluded a positive association between advanced age and poor outcome, suggesting a threshold age of 60years.

Age strongly influences the mortality and morbidity. Many studies have proven that children do better than adults with TBI. Age above 60years is a convincing independent factor in predicting the poor outcome.

GENDER:

Many studies have found that there is no correlation between gender and outcome after traumatic brain injury. Gender in traumatic brain injury has been considered as a variable in many clinical and epidemiological studies but the findings have been equivocal, and often gender has not been specifically examined. But a study by Farace and Alves et al has found that women who have survived severe traumatic brain injury have poor outcomes.

Farin et al conducted a study in 2003 and has found that premenopausal females aged 50years and younger are more likely to have brain edema and intracranial hypertension than male patients with similar injury.

A much larger sample size is essential to assess the interaction between gender and prognosis of TBI thoroughly.

GENETICS:

Genetic factors do play a role in predicting outcome after TBI. Waters RJ et al studied the genetic influences on outcome following acute neurological insults and found that the 14 allele of apolipoprotein E predisposes to poor outcome after TBI.

MODE OF INJURY:

Penetrating head injuries have a worse outcome than blunt trauma. Patients with penetrating injuries usually present with a lower

GCS and tend to have a poorer outcome. Pedestrians and cyclists fare worse than occupants inside motor vehicles in an accident.

PUPILLARY REFLEXES:

Various mechanisms associated with head injury can affect pupillary reflexes. It can be due to eye, optic, oculomotor nerve injury at any point in its course. If one excludes direct injury to the eye, then pupillary signs may provide prognostic information.

Haiden et al have found in their study that bilateral fixed pupils occur in about 20-30% of patients with severe head injury and about 70-90% of these patients will have a bad outcome when compared with patients having severe head injury with bilaterally reactive pupils. Braakman R et al found in their study that non reactive pupils are generally associated with the presence of low GCS, hypotension, effaced basal cisterns on CT.

Phonprasert C et al studied that the underlying cause influences the prognostic value of unreactive pupils. Chesnut R et al in their study concluded that anisocoria is associated with an operable mass lesion in 30% of patients.

GLASGOW COMA SCALE:

GCS is the widely used tool for assessment of consciousness, but it is not perfect and other methods do exist. Among the 3 components of GCS eye opening and verbal responses are influenced

by swelling, local trauma and tracheal intubation. Marmarou A et al studied that the motor component of GCS is the most reliable factor in predicting the prognostic outcome in patients with moderate or severe head injury because the eye and verbal response is often absent in this patient.

Many studies have shown a relation between a low score on the GCS and a poor outcome.

CT FINDINGS:

Abnormal finding on Computerized Tomographic study of brain (CT brain) increases with the severity of head injury. Marshall CT classification is the most widely used classification to standardize reporting of CT in TBI.

Haydel et al studied that patients with mild head injury have an abnormal CT rate of 2.5 to 8% whereas patients with moderate and severe head injury have an abnormal CT rate ranging from 50-94%.

In the Brain Trauma Foundation guidelines, the status of basal cisterns, midline shift, presence and type of intracranial lesions and traumatic SAH have been identified to have important prognostic value. Effacement of the basal cisterns and the presence of SAH on CT are the strongest predictors of outcome.

It should be borne in mind that regardless of the CT classification used, other patient factors are important in determining

prognosis. The timing of the scan is important. CT is being performed earlier after traumatic brain injury due to better access to scanning facilities. This may result in missing operable lesions which develop later in the clinical course. Hence serial CT scans should be done in patients with TBI.

HYPOTENSION:

An injured brain is more susceptible to systemic secondary insults like hypotension than normal brain. Secondary insults are common after traumatic injury of brain, and can increase the degree of damage and hence influence the outcome. Many studies have used a cut-off value for early hypotensive event (e.g., episode with a systolic blood pressure <90 mm Hg).

A detailed study of the association between the BP measured on admission and outcome showed that the relation is continuous i.e. low as well as high blood pressure are both associated with poorer outcome (U-shaped relation).

Chesnut RM et al studied the role of secondary brain injury in determining outcome from severe head injury in 1993 and found that even a single episode of hypotension in the period from injury to resuscitation was associated with an approximate doubling of mortality.

HYPOXIA:

Few observational studies in traumatic brain injury have found association between observed early hypoxia and poor outcome. [SpO₂<90% or <7.9 kPa (60 mm Hg)].

But the association is not as strong as for hypotension.

HYPERGLYCEMIA:

Hyperglycemia is quite common after brain injury. Many studies have concluded positive association between hyperglycemia, severity of injury and poor outcome for both early mortality and functional recovery in adults and children.

Peak levels greater than 200mg/dl in the first 24 hours after admission are associated with a significantly worse mortality and functional outcome up to 1 year post-injury.

Prognostic models

Calculating prognosis involves multiple variables and it is a challenge. If we combine the individual variables into a prognostic model it will increase its performance in prognosticating the outcome. All these prognostic models should be externally validated which means that these models should be tested in a different setting that differs in time or place.

Prognostic scores available are as follows

Madras Head Injury Prognostic Score (MHIPS)

This scoring system was devised by V.G.Ramesh et al¹³ in the year 2007. It was a prospective and retrospective study done at Institute of Neurology, Madras Medical College and Government General Hospital involving 459 patients.

The various variables used were:

1. Age
2. Best Motor Response
3. Pupillary Light Reflex
4. Occulocephalic Reflex
5. CT scan findings
6. Systemic Injuries

Each variable is divided into three subgroups and a score is given based on prognosis. Maximum score is 18 and minimum score is 6.

Age was divided into 0-15years, 16-45years and >45 years. Pupillary light reflex and Occulocephalic reflexes were analyzed as impaired, absent or normal responses. CT findings were analyzed as per Marshall's CT classification. Other systemic injuries were also

taken into account. Maximum score in the subgroup was taken as 3 and minimum as 1.

NIMHANS model

This model was devised by S.V.Pillai et al in the year 2003 at NIMHANS Bangalore. It was a retrospective study done on 289 patients⁵. The variables analyzed were

1. Motor Score of GCS
2. Occulocephalic Reflex
3. CT Scan findings

Occulocephalic reflex was scored as 1 and 2 in case of absent and present reflex respectively.

Motor component of GCS was scored from 1 to 5 while midline shift was noted as CT scan finding and given score of 1,2,3 in case of absent, <5mm, >5mm midline shift respectively.

Outcome was predicted using the formula:

$$3 \times \text{Occulocephalic reflex} + 0.5 \times \text{Motor score of GCS} - \text{Midline shift} - 6.6$$

The patients with score of ≥ 0 were considered to have favourable outcome while patients with score < 0 had unfavourable outcome.

Edinburgh Prognostic Model:

This was devised by David F. Signorini et al at the University of Edinburgh, UK in the year 1997. It was a prospective study done on 372 patients¹². The variables analyzed were:

1. Age
2. GCS score
3. Injury Severity Score
4. Pupillary Reflex
5. CT findings

The maximum possible score was 350 while minimum was 0. The probability of survival was calculated using the nomogram chart. The probability of survival was reported as .001 to 0.999.

Narayan's Logistic Model:

This was devised by Raj K Narayan et al in the year 1981 at Department of Neurosurgery, Virginia Medical College. It was a prospective study conducted on 133 patients. The model included variables such as

1. Age
2. GCS score
3. Pupillary reflexes
4. Eye movements
5. Motor response

6. Surgical mass lesions
7. CT scan findings
8. Intracranial pressure measurement
9. Multimodality evoked potentials

Choi's Model:

This model was described by Sung C. Choi et al in the year 1991 at Virginia Medical College. It was a prospective study on 555 patients.

It predicted the outcome after TBI based on age and unilateral or bilateral absent pupillary light reflexes.

Leed's Scoring System:

This scoring system was devised by R.Myles Gibson et al in the year 1983-1987. It was a retrospective study done on 187 patients. The variables used in this model were:

1. Unreactive pupils
2. ICP
3. Systolic BP
4. GCS Score
5. High density lesion on CT scan
6. Other extra cranial injuries.

Klauber's Logistic Model:

This was described by Klauber M.R et al in the year 1980-81 at California University Medical Centre. It was a prospective study done on 7912 patients. It included variables like:

1. Motor component of GCS
2. Pupillary light reflex
3. Systolic BP
4. Age
5. Chest Injury
6. Abdominal Injury

The three scores MHIPS, NIMHANS Model, Edinburgh Prognostic score are simple, easy to apply on bedside to prognosticate outcome after moderate or severe traumatic brain Injury.

MATERIALS AND METHODS

This study was conducted at **Madras Medical College and Rajiv Gandhi Government. General Hospital, Institute of Neurology** which included **300 patients** with moderate and severe traumatic brain injury. It was a prospective study from 2010 to 2013.

A thorough Clinical and detailed neurological examination was done and the patient details were recorded in a Proforma and the following Prognostic Scores were calculated for every patient:

- Madras Head Injury Prognostic Scale (MHIPS).
- NIMHANS Model (NM).
- Edinburgh Prognostic Scale

The efficacy, sensitivity and specificity was noted for every score and compared for the outcome of these patients.

All Patients presenting to the trauma ward of our hospital with moderate and severe head injury along with other systemic injuries were **included** in our study population.

All patients presenting with mild head injury were **excluded** from our study population.

The primary reason for choosing to compare these three scores in this study is:

1. All the three scores have taken into account almost similar variables.
2. All these scores are objective and measurable on a numerical scale.
3. All the three scores are simple enough to be used during a routine bed side clinical assessment.
4. Also these scores are easy to apply even for a junior member of the team.

The scoring system was calculated as per the following charts:

MHIPS:

1. Age :
 - a. 0-15 yrs (3 points)
 - b. 16-45yrs (2points)
 - c. > 45yrs (1 point)

2. Best Motor Response :
 - a. 1-2 (1 point)
 - b. 3-4 (2 points)
 - c. 5-6 (3 points)

3. Pupillary Light Reflex:
 - a. Absent (1 point)
 - b. Impaired (2 points)
 - c. Normal (3 points)

3. Oculocephalic reflex :

- a. Absent (1 point)
- b. Impaired (2 points)
- c. Normal (3 points)

5. CT Findings:

- a. Absent basal
cistern/midline
shift > 5mm/lesion
density > 3cm diameter
(1 point)
- b. Partly seen basal
cistern/midline shift
< 5mm/lesion
density < 3cm diameter
(2 points)
- c. Normal basal cistern/no
midline shift/no lesion
(3 points)

6. Systemic Injuries :

- a. Thoracic/abdominal/visceral injuries/>2 long bone # (1 point)
- b. One or two long bone # (2 points)
- c. No other systemic or long bone injuries (3 points)

NIMHANS Score:

1. Oculocephalic Reflex :

- a. Absent (1 point)
- b. Present (2 points)

2. Motor Score of GCS :

- a. 1 (1 point)
- b. 2 (2 points)
- c. 3 (3 points)
- d. 4 (4 points)
- e. 5 (5 points)

3. Midline Shift Score :

- a. Absent (1 point)
- b. <5mm (2 points)
- c. >5mm (3 points)

Prediction Score = (3 x Oculocephalic reflex) + (0.5 x Best motor response) – (Midline shift)-6.6.

Edinburgh Prognostic Score:

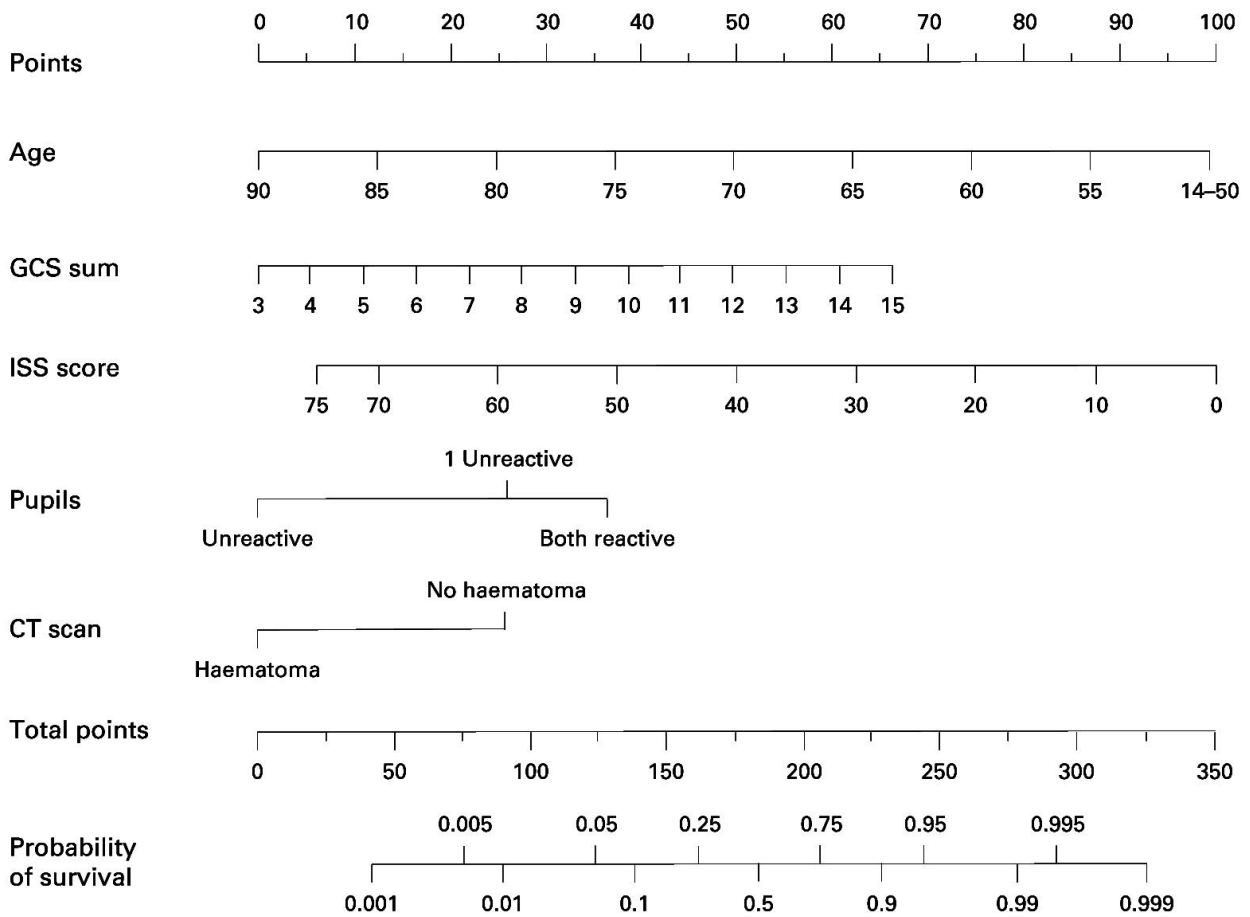
- 1. Age :
- 2. GCS Sum:
- 3. Injury Severity Score :

Region	Injury description	Abbreviated Injury Score	Square top three
Head and Neck			
Face			
Chest			
Abdomen			
Extremity			
External			

- 4. Pupils :
 - a. One Unreactive
 - b. Both Unreactive
 - c. Both Reactive

- 5. CT Scan
 - a. No Hematoma
 - b. Hematoma

Edinburgh Normogram



Total Points =
 Probability of Survival =

The 5 variables common to all the three studies were:

1. Age
2. Best Motor Response
3. Pupillary Reflex
4. Oculocephalic Reflex
5. CT findings

As per the enclosed Proforma, the data from all 300 patients are collected.

Outcome is assessed for the same patients at 1 month interval.

The collected data are arranged as per the enclosed master chart.

From the master chart data statistical analysis is done.

RESULTS AND DISCUSSION

1. Gender Distribution

Out of 300 patients studied, 269(89.7%) patients were male while 31(10.3%) patients were female.

Gender Distribution

Total number of patients	300	100%
Male	269	89.7%
Female	31	10.3%

Table 1

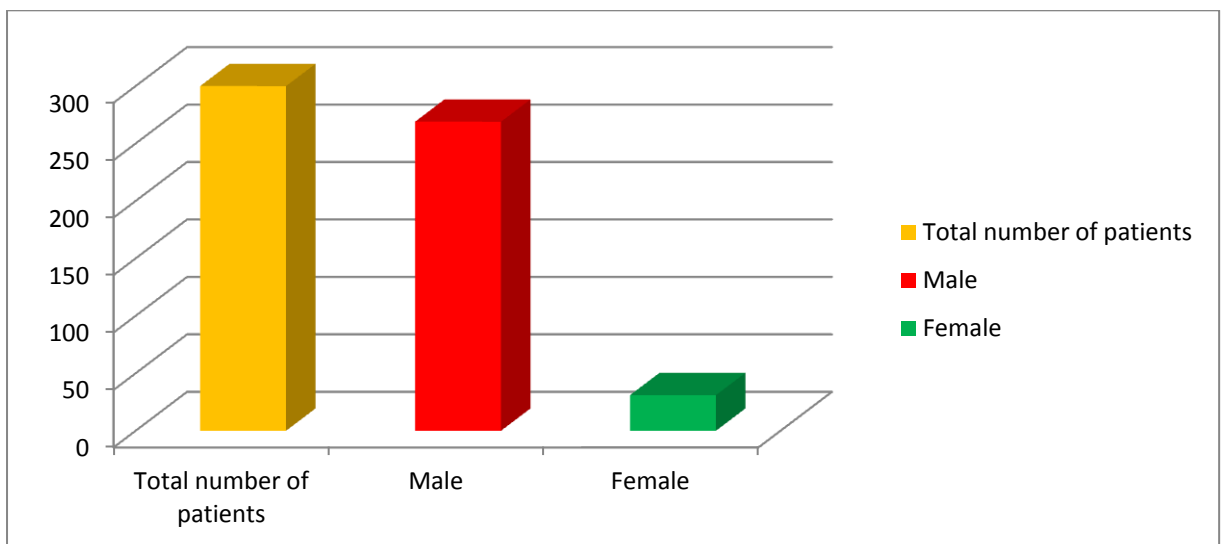


Chart 1: Gender Distribution

In this study, out of the total number of patients studied i.e. 300, there was a predominance of the male population i.e. 269 (89.7%) with traumatic brain injury than female population (10.3%).

A much larger sample size is essential to assess the interaction between gender and prognosis of TBI thoroughly.

2. (A) Analysis of Age Distribution

Age Group	No. Of Patients	Percentage
0-15 years	12	4%
16-45 years	198	66%
>45 years	90	30%

Table 2

Age Distribution

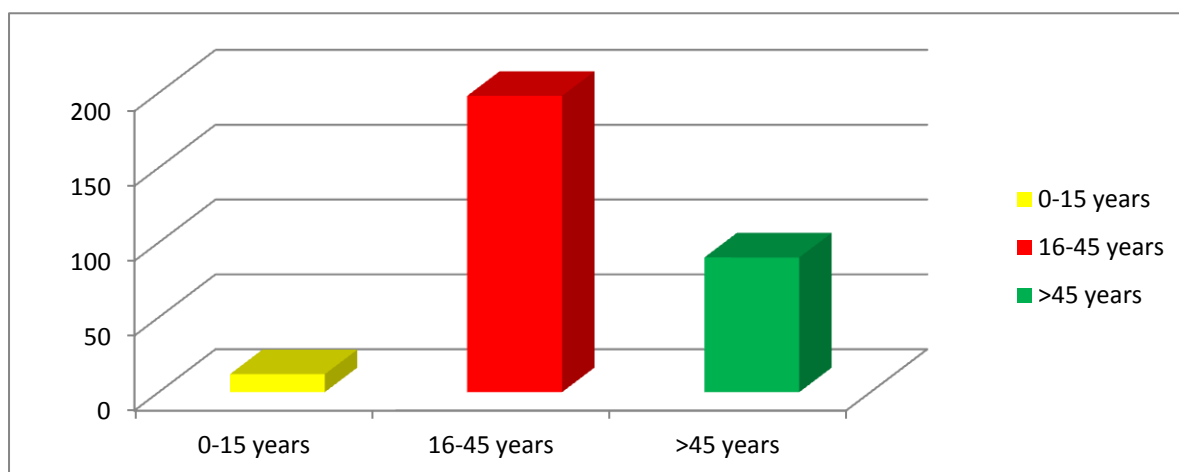


Chart 2

Out of the 300 patients studied, the maximum numbers of patients were in the age group of 16-45 years i.e. 198 patients, 66% of study population.

(B) Age versus Outcome

Age	Unfavourable (Dead + Poor)	Favourable (Good)	Total
0 -15 years	4 (33.3%)	8 (66.7%)	12
16-45 years	96 (48.5%)	102 (51.5%)	198
>45years	57 (63.3%)	33 (36.7)	90

(p value =.031)

Table 3

Age versus outcome

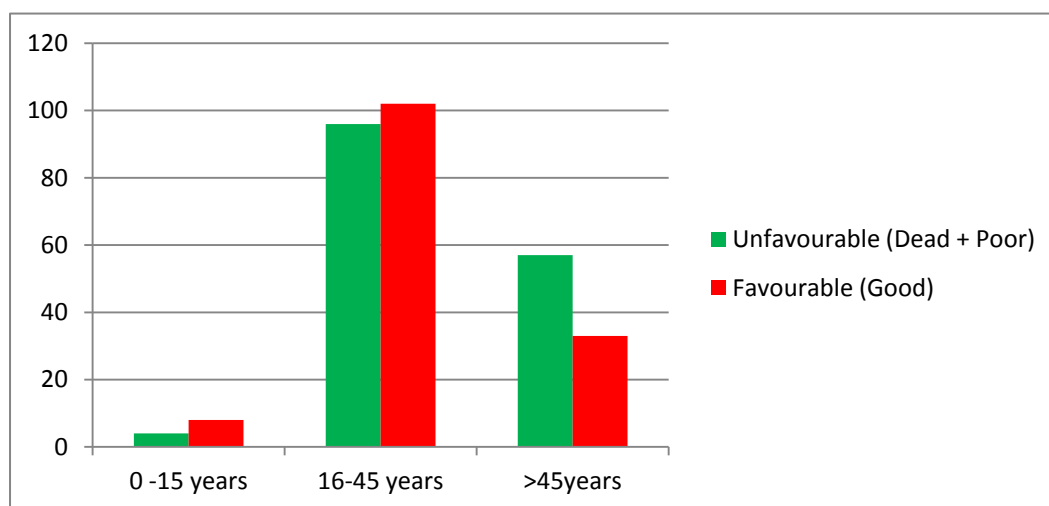


Chart 3

On applying statistical analysis on age versus outcome in this study, 2/3rd patients in age group 0-15years showed good outcome while 1/3rd had unfavorable outcome. 2/3rd patients in the age group >45years had unfavourable outcome and only 1/3rd had favourable outcome.

The patients admitted with TBI were mainly in the age group between 16 -45 years i.e.198 patients constituting 66% of the study population. The main cause of TBI was road traffic injury.

The outcome of TBI was seen to be worse with advancing age. Out of the 12 patients admitted in the age group of 0-15years, majority i.e.8 (66.7%) patients were seen to have good a good outcome at discharge.

While patients aged >45years were 90, out of which majority i.e. 57(66.3%) had an unfavorable outcome i.e. were either dead or had a poor outcome which included severe disability and persistent vegetative state based on Glasgow Outcome Scale.

Chantal W.P.M Hukkelhoven et al on a prospective study on 5600 patients did an analysis about patient age and outcome following severe traumatic brain injury. The analysis revealed a mortality of 21% and unfavourable outcome of 39% in patients less than 35years of age. The mortality was 52% and unfavourable outcome was 74% in patients older than 55 years. The study concluded that older age is constantly associated with a worsening outcome after TBI.

S.V Pillai et al in their retrospective study on 289 patients with severe traumatic brain injury found that 91% of patients with age >45years had unfavourable outcome while 71% of patients with age <45years had unfavourable outcome.

3. (A) Motor Response of GCS

Analysis of Motor Response

Best motor response	Number of patients	Percentage
1-2	69	23%
3-4	105	35%
5-6	126	42%

Table 4

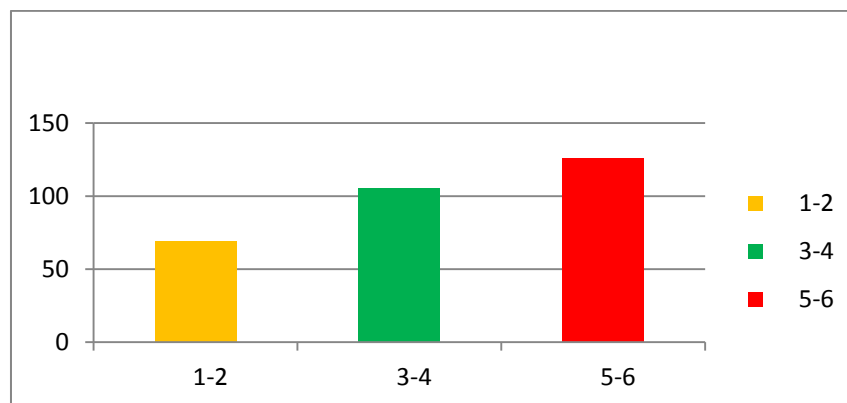


Chart 4: Motor Response

Motor response of study patients according to GCS scoring was analyzed.

Out of the 300 patients studied, the maximum numbers of patients had best motor response of 5-6 i.e. 127(42.3%) patients, followed by 104(34.7%) with best response between 3-4 and 69 (23%) patients with best motor response between 1-2.

(B) Motor Response of GCS versus Outcome

Best Motor Response	Unfavourable (Dead + Poor)	Favourable (Good)	Total
1-2	67 (97.1%)	2 (2.9%)	69
3-4	60 (57.1%)	45 (42.9%)	105
5-6	30 (23.8%)	96 (76.2%)	126
Total	157	143	300

(p value =.000)

Table 5

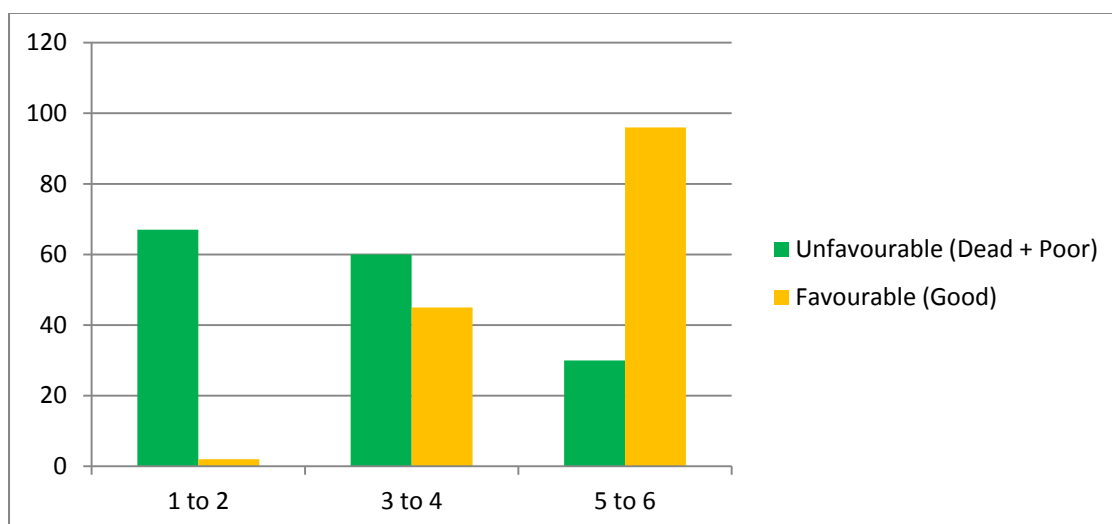


Chart 5: Motor Response versus outcome

Our study included 126 patients with best motor response of GCS between 5-6.

96 (76.2%) patients had a favourable outcome at discharge (p value=.000). The number of patients with best motor response between 3-4 were 105 out of which 57.1% patients had unfavourable

outcome and score between 1-2 were 69 with 97.1% patients showed unfavourable outcome This showed that motor component of GCS is a reliable factor in predicting the prognostic outcome in patients with moderate and severe TBI.

The better the motor component of GCS on admission, the better the outcome.

(p value =.000)

Raj K Narayan et al conducted a prospective study on 133 patients on improved confidence of outcome prediction in severe head injury and found that patients with best motor response 1-2, 68% had unfavourable outcome and 32% had favourable outcome. Best motor response 3-4 59% patients had unfavourable outcome. Patients with best motor response 5-6, 96% of them had favourable outcome.

S.V.Pillai et al on their retrospective analysis of 289 patients on outcome model for severe traumatic brain injury had found that patients with best motor response on 1-2 had 96% unfavourable outcome and patients with best motor response 2-4 had 73% unfavourable outcome. Patients with best motor response 5-6 had 47% unfavourable outcome.

4. Pupillary Light Reflex:

(A) Analysis of Pupillary Light reflex

Pupillary Light Reflex	Number of patients	Percentage
Absent	36	12%
Impaired	72	24%
Normal	192	64%

Table 6

Among the 300 patients, pupillary light reflex was normal in 192(64%) patients whereas it was impaired in 72 patients (24%) and absent in 36 patients (12%).

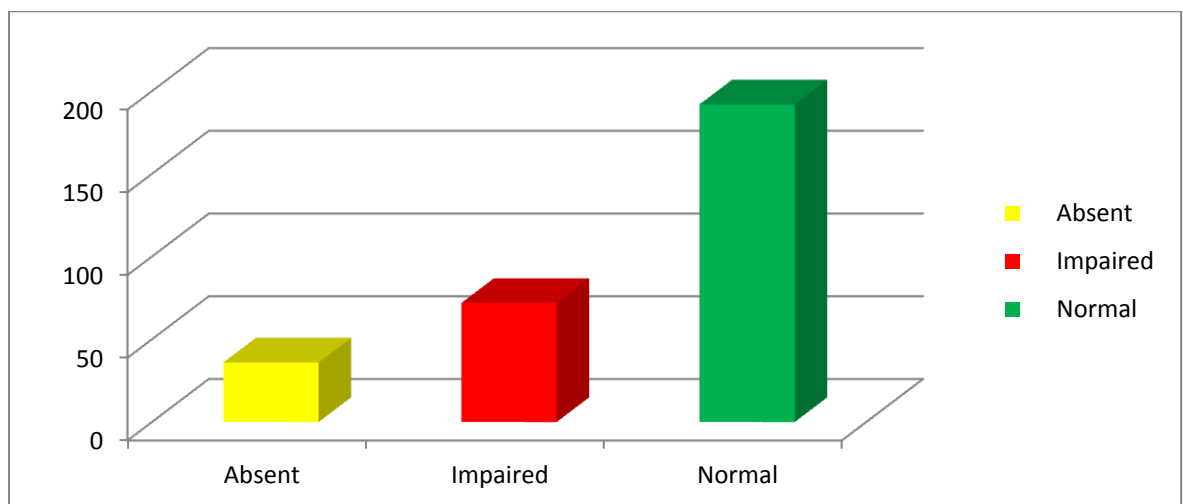


Chart 6: Analysis of pupillary Light Reflex

(B) Pupillary Light Reflex versus Outcome

Pupillary Light Reflex	Unfavourable (Dead + Poor)	Favourable (Good)	Total
Absent	29 (80.6%)	7 (19.4%)	36
Impaired	67 (93.1%)	5 (6.9%)	72
Normal	61 (31.8%)	131 (68.2%)	192
Total	157	143	300

(p value = .000)

Table 7

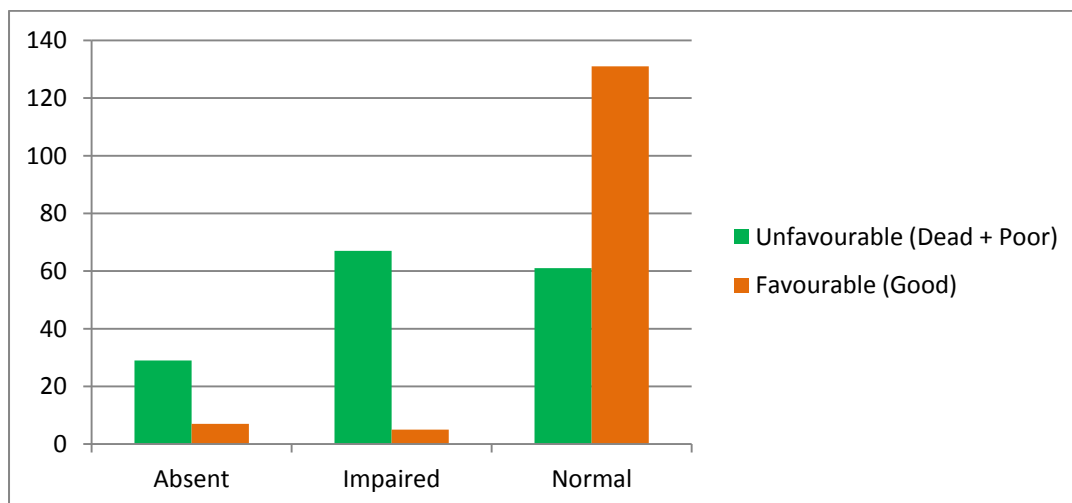


Chart 7

The pupillary reflex was categorized as normal, impaired and absent. The majority of the patients with absent pupillary reflex i.e. 29 out of 36 had an unfavourable outcome at discharge(80.6%).The patients with normal pupillary reflex on admission in this study fared

to a good prognosis on discharge. 131 (68.2%) out of 192 patients with normal pupillary reflex had favourable outcome.

If one excludes direct injury to the eye, then pupillary signs provide prognostic information in moderate to severe TBI patients.

S.V.Pillai et al on their retrospective analysis of 289 patients found that among patients with absent pupillary light reflex, 96% had unfavourable outcome whereas patients in whom pupillary light reflex was present had only 60% unfavourable outcome.

Raj K Narayan et al on his prospective study on 133 patients showed that in patients with normal pupillary light reflex had 76% favourable outcome and 24% unfavorable outcome. In patients with absent pupillary light reflex ,70% had unfavourable outcome.

5. Oculocephalic Reflex

(A) Analysis of Oculocephalic Reflex

Oculocephalic Reflex	Number of patients	Percentage
Absent	18	6%
Impaired	79	26.3%
Normal	203	67.6%

Table 8

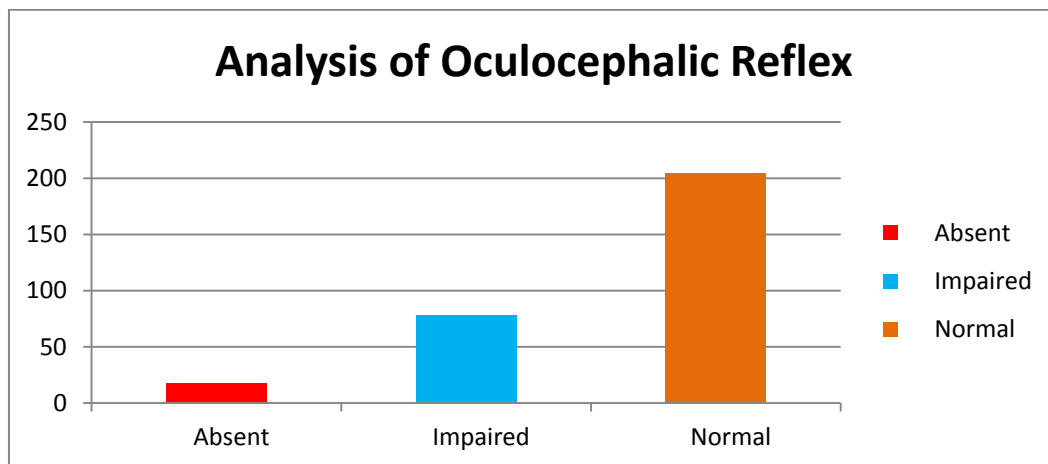


Chart 8

Evaluating Oculocephalic reflex, 203 patients showed normal reflex constituting 67.6% whereas it was impaired in 79 patients i.e. 26.3% and absent in 18 patients (6%).

(B) Oculocephalic Reflex versus Outcome

Occulocephalic Reflex	Unfavourable (Dead + Poor)	Favourable (Good)	Total
Absent	17 (94.4%)	1 (5.6%)	18
Impaired	74 (93.7%)	5 (6.3%)	79
Normal	66 (32.5%)	137(67.5%)	203
Total	157	143	300

(p value = .000)

Table 9

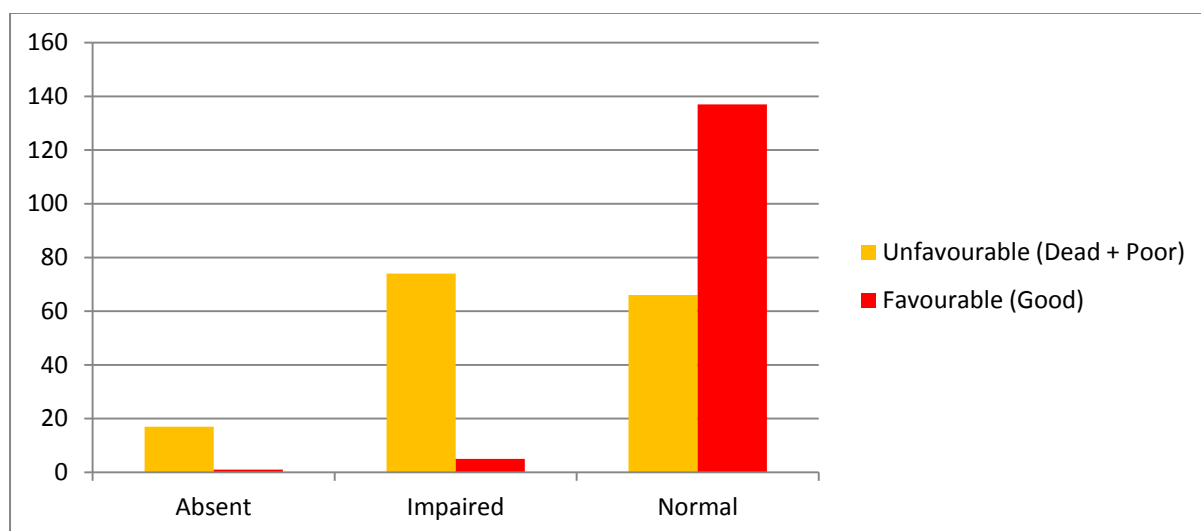


Chart 9

Out of the 203 patients with normal pupillary response, 137 patients i.e. 67.5% patients had favorable outcome on discharge, while out of the 18 patients admitted with absent pupillary response on admission 17 (94.4%) patients had unfavourable outcome on discharge.

This showed a significant correlation between Oculocephalic reflex and outcome at discharge. (p value=.000).

S.V Pillai et al on their retrospective analysis of 289 patients found that in patients with absent Occulocephalic reflex, 98.4% had unfavourable outcome while patients with normal occucephalic reflexes 55% had unfavourable outcome. In our study 74 patients with impaired Oculocephalic reflex had unfavourable outcome.

50% of the study population had an unfavourable outcome with 2/3rd of patients showing absent or impaired Oculocephalic reflex.

6. CT Scan Findings

(A) Analysis of CT Findings

CT Findings	Number of patients	Percentage
Group 1	65	21.7%
Group 2:	182	60.7%
Group 3:	53	17.6%

Table 10

The study patients were grouped as follows based on CT findings:

Group 1: Absent basal cisterns/midline shift $>5\text{mm}$ /lesion density $>3\text{cm}$.

Group 2: Partly effaced basal cisterns/midline shift $<5\text{mm}$ /lesion density $<3\text{cm}$.

Group 3: Normal basal cisterns/ no midline shift/ no lesions.

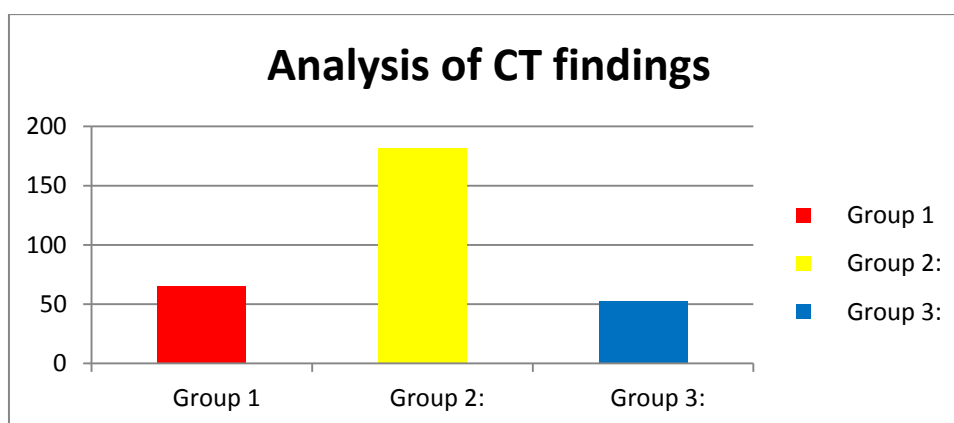


Chart 10

Out of 300 patients, normal CT findings were found in 53 i.e. (17.6%) patients. Group 1 constituted 65(21.7%) patients while group 2 constituted the maximum i.e.182 patients (60.7%).

(B) CT Scan findings versus Outcome

CT findings	Unfavourable (Dead + Poor)	Favourable (Good)	Total
Group 1	53 (81.5%)	12 (18.5%)	65
Group 2	75 (41.2%)	107 (58.8%)	182
Group 3	29 (54.7%)	24 (45.3%)	53
Total	157	143	300

(p value = .000) **Table 11**

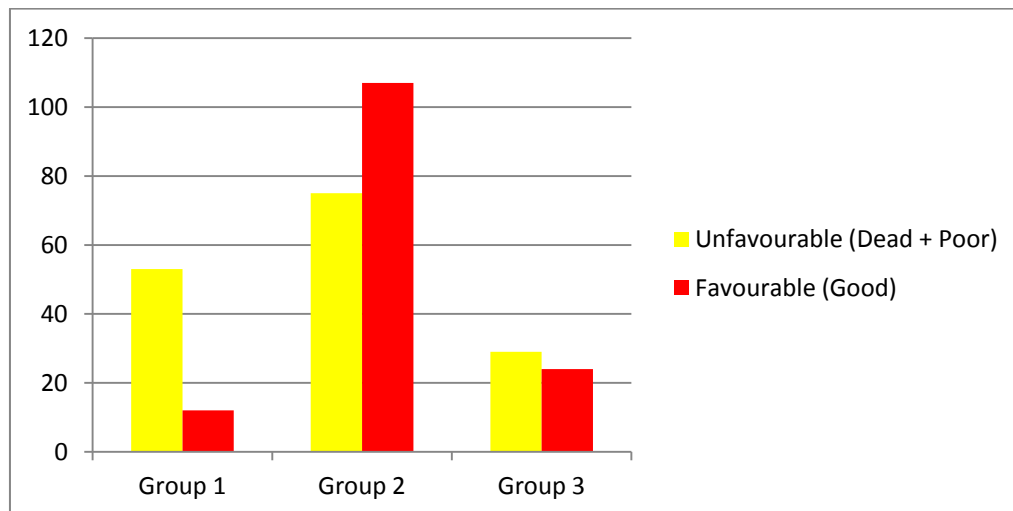


Chart 11

65 patients had group 1 CT findings on admission. Out of them 53 (81.5%) patients were either dead or were having a poor outcome on discharge or at the end of 1 month.

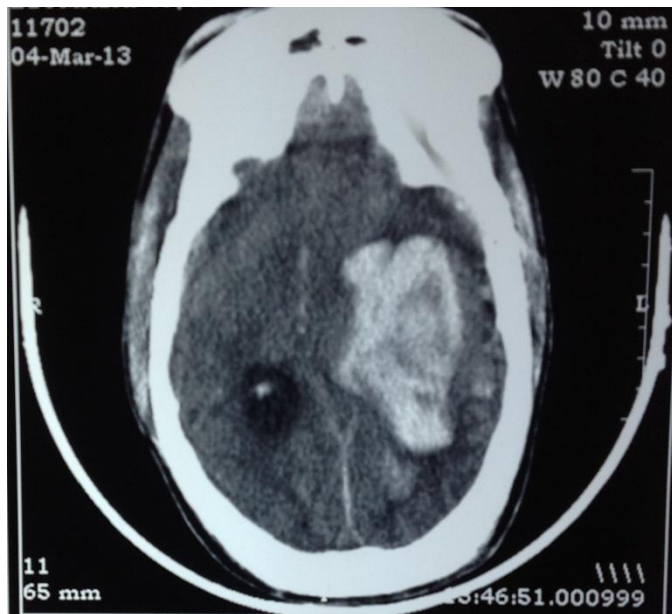
The 182 patients showed group 2CT findings on admission. Out of them 107 (58.8%) patients had a good outcome on discharge or at the end of 1month.

53 patients CT scan findings were in group 3, out of which 29 patients showed unfavourable outcome, while 24 patients showed favourable outcome.

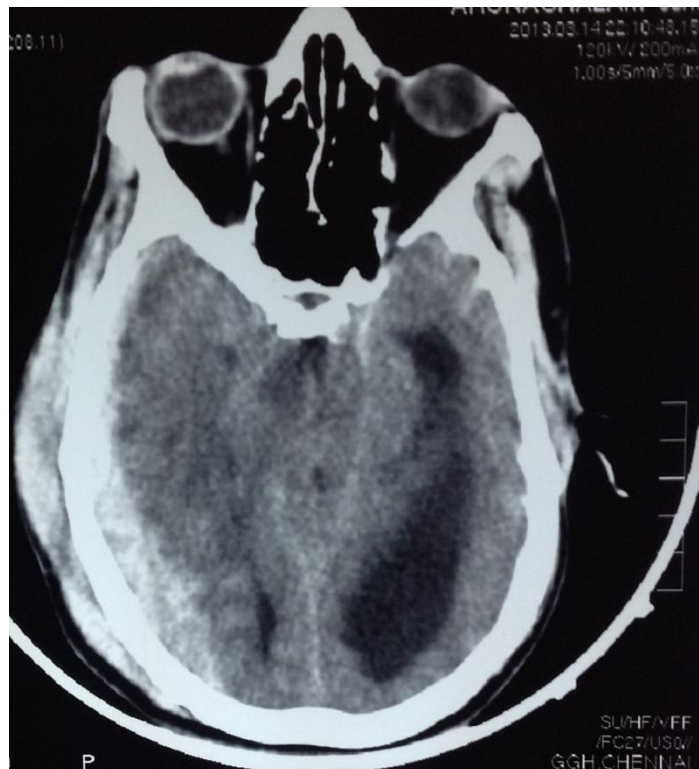
CT scan analysis shows that even though normal CT scan is there, still unfavourable outcome happened in group 3.

The study showed that effacement of the basal cisterns and the presence of SAH on CT are good predictors of outcome in TBI patients.

As per Steven M. Toutant et al on a prospective study about absent or compressed basal cisterns on first CT scan: ominous predictors of outcome in severe head injury. The mortality rates were 77% in patients with absent basal cistern, 39% with compressed basal cistern, and 22% among normal basal cisterns.



CT scan showing traumatic intra cerebral hemorrhage with lesion density >3cm



CT scan showing an acute right subdural hematoma with mass effect, midline shift and effaced basal cisterns

7. Analysis of MHIPS Score

(A) Analysis of MHIPS SCORE

Score	Number of patients	Percentage
≤ 12	62	20.7 %
13-14	80	26.7%
≥ 15	158	52.6%

Table 12

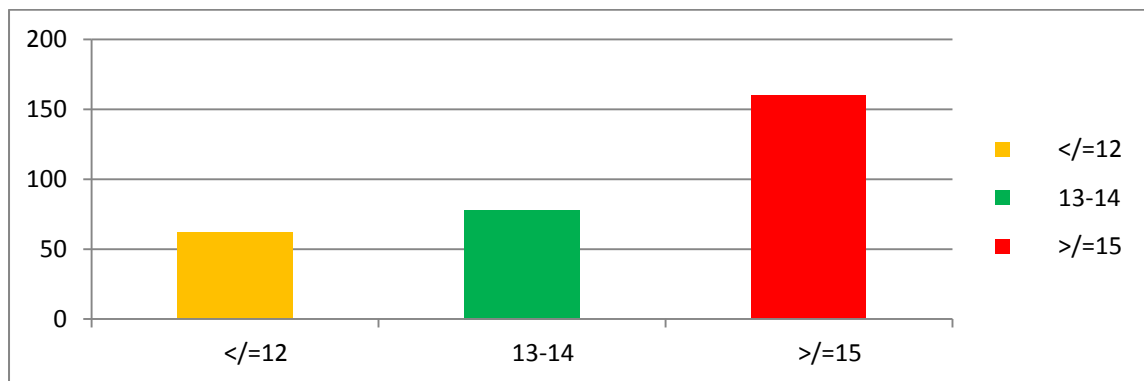


Chart 12

Applying MHIPS score, 158 patients scored ≥ 15 while 80 patients were within the range of 13-14 score and 62 patients scored ≤ 12 .

(B) MHIPS Score versus Outcome

Outcome	MHIPS Score			Total
	≤ 12	13-14	≥ 15	
Dead	57 (92%)	33 (41.3%)	25 (15.8%)	115
Poor	3 (4.8%)	31 (38.7%)	08 (5.1%)	42
Good	2 (3.2%)	16 (20%)	125 (79.1%)	143
Total	62	80	158	300

Table 13

Sensitivity = 0.87

Specificity = 0.79

Positive Predictive Value = 0.79

Negative Predictive Value = 0.87

P value = .000

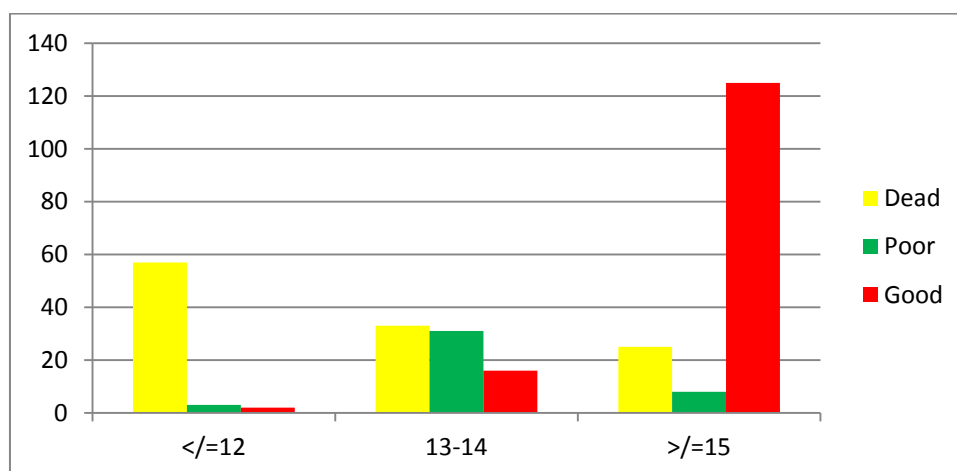


Chart 13

Out of the 62 patients with MHIPS score ≤ 12 , 57 patients i.e. 92% patients were dead and 3 patients i.e. 4.8% patients had poor outcome on discharge or at 1 month after TBI.

Out of 80 patients with score of 13-14, 64 patients i.e. 80% of the patients had unfavourable outcome and only 20% patients had favourable outcome.

Out of the 158 patients admitted with MHIPS score of ≥ 15 , 125 patients i.e. 79.1% had good outcome and 11.9% had unfavourable outcome.

Therefore, a low MHIPS score was associated with unfavourable outcome and high MHIPS score was associated with favourable outcome in this study. This was consistent with the study conducted by V.G.Ramesh et al in 2007.

This scoring method has a good sensitivity of 87% and specificity of 79% for predicting the outcome in moderate and severe TBI.

The p value is .000 which makes this scoring system statistically significant.

8.Edinburgh Model

(A) Analysis of Edinburgh Model

Score	Number of patients	Percentage
<0.5	25	8.3%
>0.5	275	91.7%

Table 14

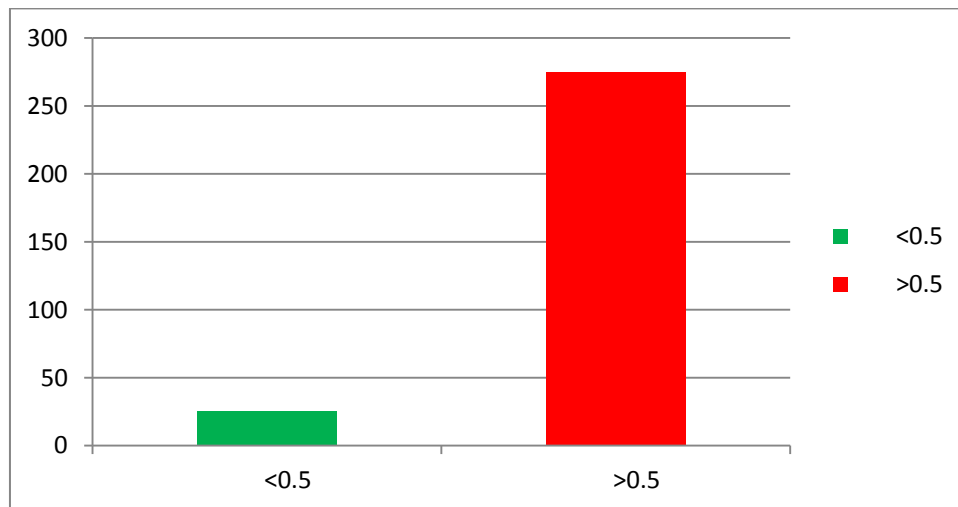


Chart 14

The second score applied in this study was Edinburgh model where the scores were <0.5 and >0.5.

275(91.7%) patients scored >0.5 in this model while 25(8.3%) scored <0.5.

(B)Edinburgh Model versus Outcome

Outcome	Edinburgh Model		Total
	<0.5	>0.5	
Unfavourable (Poor+ Dead)	20(80%)	137(49.8%)	157
Favourable (Good)	5(20%)	138(50.2%)	143
Total	25	275	300

Table 15

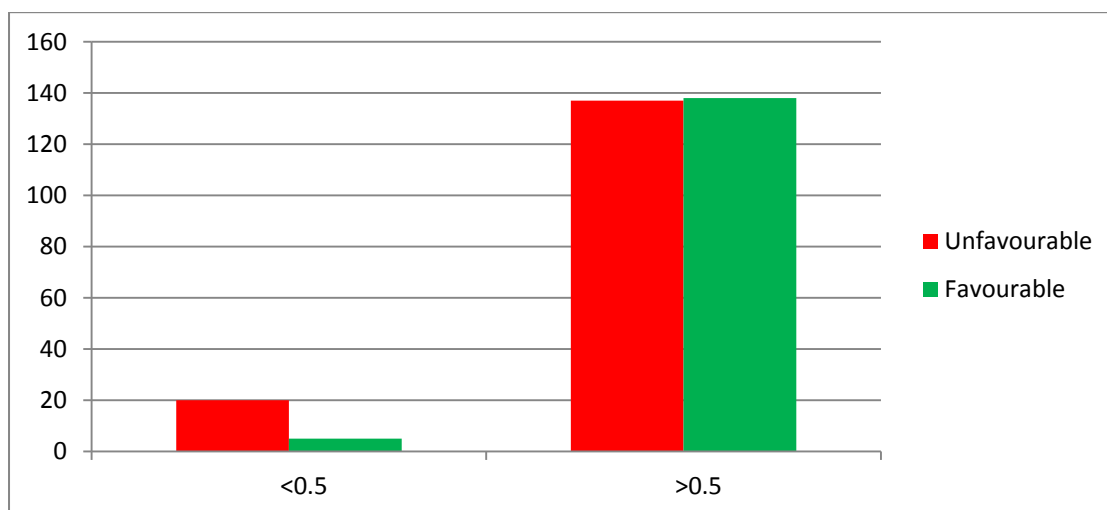


Chart 15

Sensitivity =0.97

Specificity = 0.13

Positive Predictive Value=0.50

Negative predictive Value=0.80

P value =.003

In this study, the number of patients admitted with a score of < 0.5 (probability of survival) were 25. Out of them 80% had unfavourable outcome and 20% had favourable outcome.

Out of the 275 patients admitted with score of >0.5 , 137 (49.8%) patients had unfavourable outcome and 138 (50.2%) patients had favourable outcome.

This scoring method predicted the poor outcome in patients with low scores; hence the sensitivity was high i.e. 97%.

But in patients with score >0.5 , the prediction was not as accurate hence the specificity was only 13%.

This study was conducted to see the outcome on discharge or at a period of 1 month. In the original study the outcome was seen at the end of 1 year. Hence this scoring method needs to be evaluated for a longer period of time and on a larger population study.

The p value is .003 which makes this scoring system statistically significant.

9. NIMHANS Score

(A) Analysis of NIMHANS Score

Score	Number of patients	Percentage
<0	242	81.4%
>0	58	18.6 %

Table 16

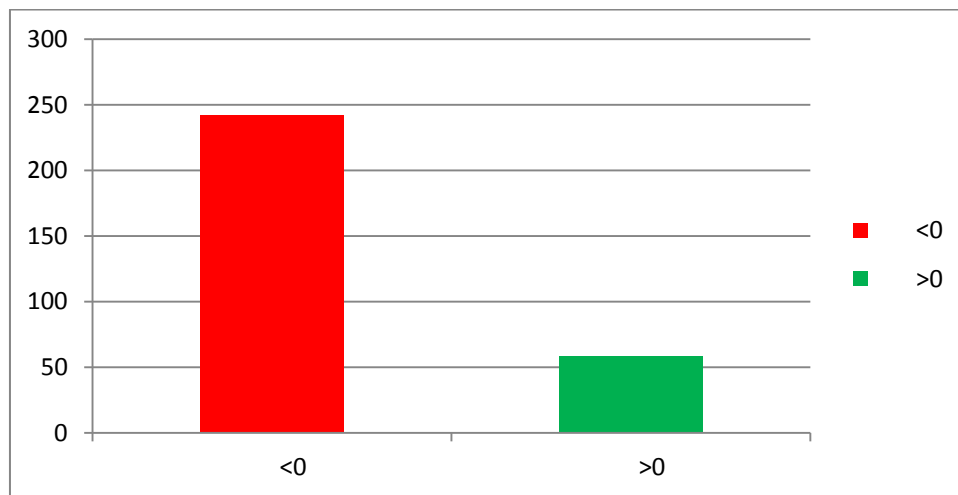


Chart 16

Applying NIMHANS score to the study population which has two variables <0 and >0. 242 patients scored <0 while 58 patients scored >0.

(B) NIMHANS Score versus Outcome

Outcome	NIMHANS Score		Total
	<0	>0	
Unfavourable (Poor+ Dead)	127 (52.5%)	30(51.7%)	157
Favourable (Good)	115(47.5%)	28(48.3%)	143
Total	242	58	300

Table 17

NIMHANS Score versus Outcome

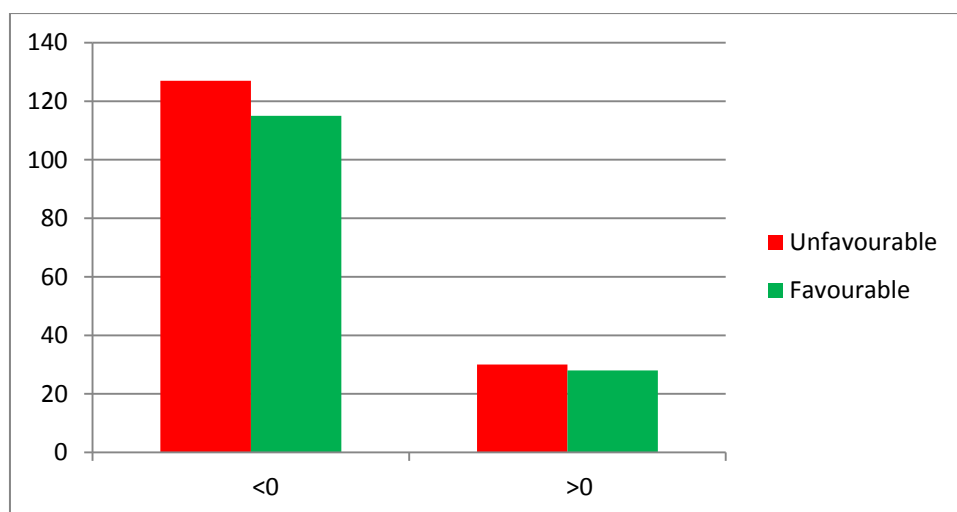


Chart 17

Sensitivity = 0.20

Specificity = 0.81

Positive Predictive value=0.48

Negative predictive value=0.52

P value = 0.517

Out of the 242 patients with score $<0,127$ i.e. 52.5% patients had unfavourable outcome while 115 patients i.e. 47.5% patients had favourable outcome.

Out of 58 patients admitted with score >0 , 30 patients i.e. 51.7% had unfavourable outcome while 28 patients i.e. 48.3% had poor outcome.

This scoring system in this study did not predict satisfactorily the prognostic outcome in comparison to the actual outcome. The sensitivity of the scoring system was only 20% while specificity was 81%.The p value is 0.517 which was not statistically significant.

Hence this scoring method needs to be evaluated with a larger population study group.

10.Receiver Operating Characteristic curve (or ROC curve.)

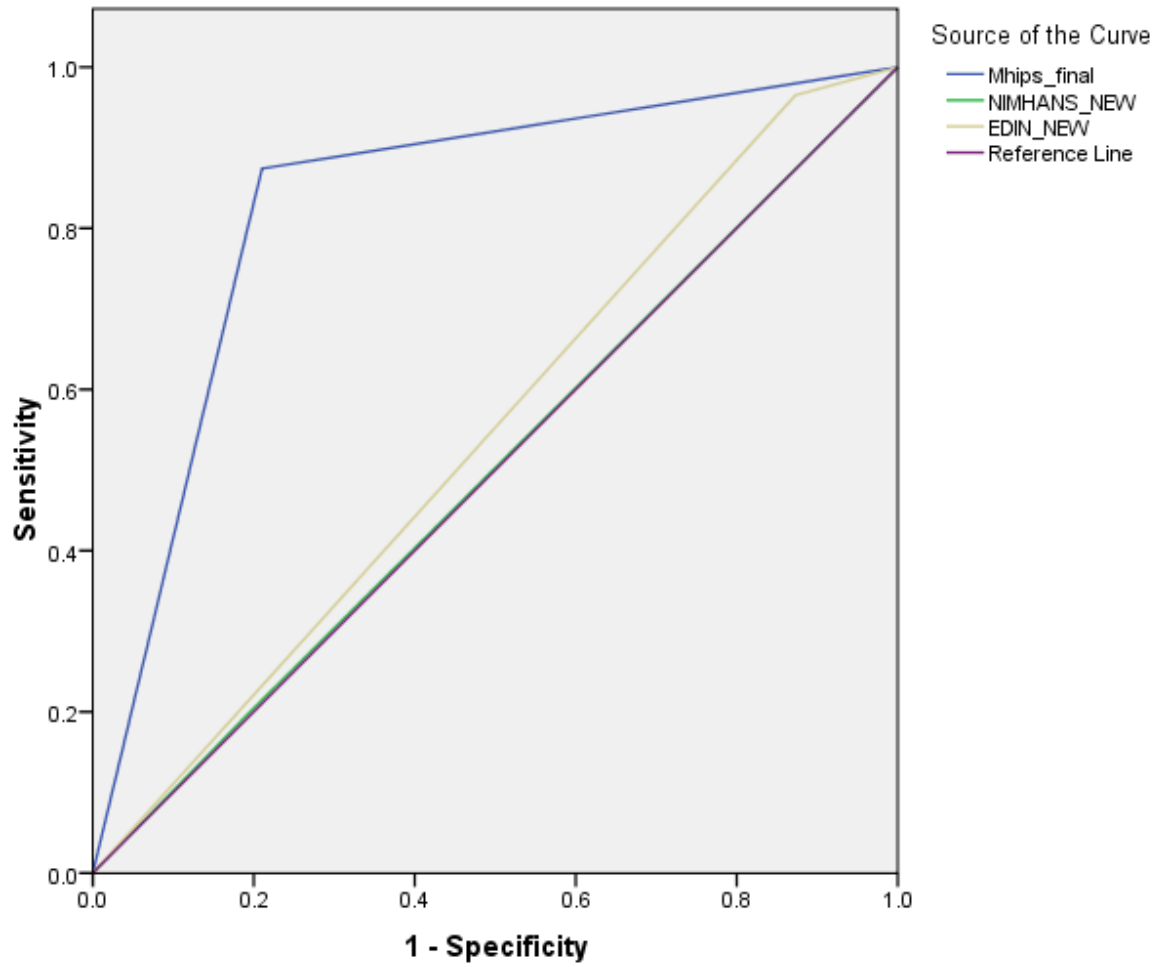
Test Result Variable(s)				95% Confidence Interval	
	Area	Standard Error	Asymptotic Significance	Lower Bound	Upper Bound
MHIPS	.832	.025	.000	.783	.881
NIMHANS	.502	.033	.944	.437	.568
Edinburgh	.546	.033	.167	.481	.611

Table 18

This shows that the maximum area under the curve is for MHIPS score i.e.0.832 followed by Edinburgh model i.e. 0.546 and least by NIMHANS score (0.502).

This proves MHIPS score to the best amongst all the three scores followed by Edinburgh Model. NIMHANS model as mentioned earlier was not statistically significant in this study population.

ROC Curve



Diagonal segments are produced by ties.

CONCLUSION

- In patients with moderate and severe head injury age of the patient plays a significant role in deciding the outcome. Older the patient poorer the prognosis.
- In Glasgow Coma Scale, the best motor response is the most accurate predictor of outcome in moderate and severe head injury patients.
- Both Occulocephalic and pupillary reflexes should be noted on admission in patients with moderate and severe TBI. Their response holds a significant correlation to the final outcome.
- Single variable is not enough to prognosticate the outcome in traumatic brain injury patients. The scoring should always be a multivariate analysis
- In this study Madras Head Injury prognostic Scale (MHIPS) was the most significant scoring system in accurate prediction of outcome in moderate and severe head injury patients as compared to Edinburgh and NIMHANS models.

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ABBREVIATIONS

TBI	– Traumatic Brain Injury
MLS	– Midline shift
EDH	– Extra dural hematoma
SDH	– Sub dural hematoma
BP	- Blood pressure
SAH	– Sub arachnoid hemorrhage
AIS	– Abbreviated injury Score
ISS	– Injury Severity Score
GCS	– Glasgow Coma Scale
ICP	– Intracranial Pressure
ER	– Emergency room
GOS	– Glasgow Outcome Scale
MHIPS	- Madras Head Injury Prognostic Scale
NIMHANS	- National Institute of Mental Health and Neurosciences
#	- Fracture

PROFORMA

MHIPS

Name:

IP No.

DOA:

Age

Sex

DOD:

1. Age :

- a. 0-15 yrs
- b. 16-45 yrs
- c. > 45yrs

2. Best Motor Response:

- a. 1-2
- b. 3-4
- c. 5-6

3 .Pupillary Light Response:

- a. Absent
- b. Impaired
- c. Normal

4. Oculocephalic response:

- a. Absent
- b. Impaired
- c. Normal

5.CT Scan Findings :

- a. Absent basal cistern/midline shift>5mm/lesion density>3cm diameter
- b. Partly effaced basal cistern/midline shift <5mm/lesion density<3cm diameter
- c. Normal basal cistern/no midline shift/no lesion

6. Systemic Injuries:

- a. Thoracic/abdominal visceral injuries/>2long bone #
- b. One or two long bone #
- c. No other systemic or long bone injuries

MHIPS SCORE=

NIMHANS Score:

1. Oculocephalic Reflex :

- a. Absent
- b. Present

2. Motor Score of GCS:

- a. 1
- b. 2
- c. 3
- d. 4
- e. 5

3. Midline Shift Score:

- a. Absent
- b. <5mm
- c. >5mm

Prediction Score = (3 x OCR) + (0.5 x MGCS) – (MS) - 6.6
SCORE =

Edinburgh Score:

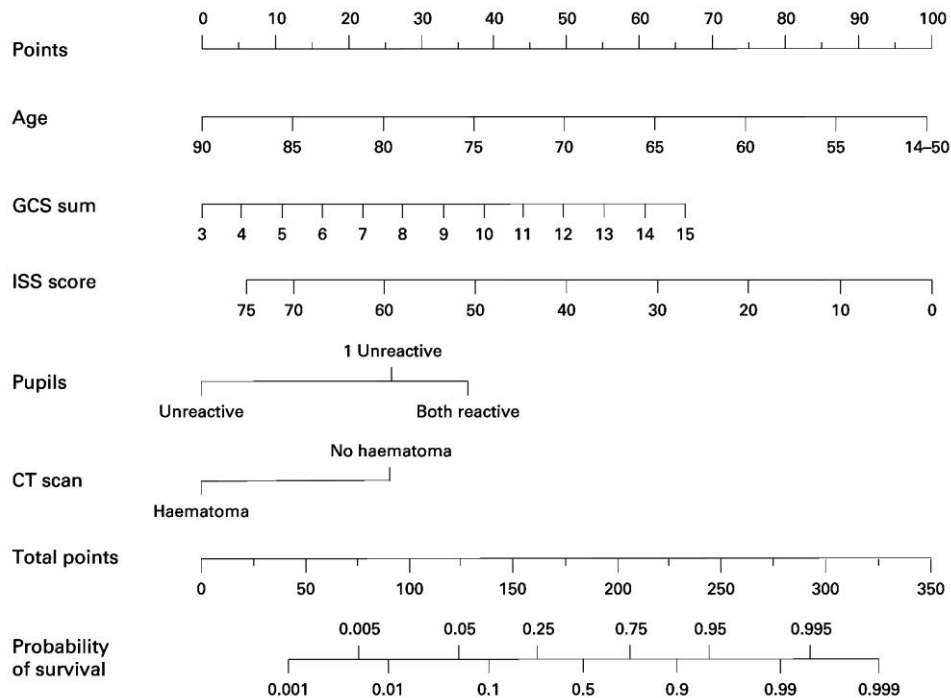
1. Age:
2. GCS Sum:
3. ISS Score:

Region	Injury description	AIS	Square top three
Head and Neck			
Face			
Chest			
Abdomen			
Extremity			
External			

1. Pupils :
- a. One Unreactive
 - b. Both Unreactive
 - c. Both Reactive

5. CT Scan
- a. No Hematoma
 - b. Hematoma

Edinburgh Normogram



TOTAL POINTS =
 Probability of Survival =

275	Patient 275	M	124037	31/12/12	01-08-2013	NO	NO	YES	NO	NO	YES	NO	NO	YES	NO	NO	YES	NO	YES	NO	NO	NO	YES	16	-0.1	0.98	NO	YES	NO
276	Patient 276	M	123922	31/12/12	01-08-2013	NO	YES	NO	NO	NO	YES	NO	NO	YES	NO	NO	YES	NO	YES	NO	NO	NO	YES	16	-0.1	0.99	NO	YES	NO
277	Patient 277	M	121940	24/12/12	01-05-2013	NO	YES	NO	NO	NO	YES	NO	NO	YES	NO	NO	YES	NO	YES	NO	NO	NO	YES	15	-0.6	0.9	NO	YES	NO
278	Patient 278	M	4	01-01-2013	01-10-2013	NO	YES	NO	NO	NO	YES	NO	NO	YES	NO	NO	YES	NO	NO	YES	NO	NO	YES	16	-0.1	0.5	NO	YES	NO
279	Patient 279	M	2211	07-01-2013	01-09-2013	NO	YES	NO	YES	NO	NO	YES	NO	NO	YES	NO	NO	YES	NO	NO	NO	NO	YES	9	-4.1	0.8	YES	NO	NO
280	Patient 280	M	2030	07-01-2013	01-08-2013	NO	YES	NO	YES	NO	NO	NO	YES	NO	NO	YES	NO	NO	YES	NO	NO	NO	YES	11	-2.1	0.76	YES	NO	NO
281	Patient 281	M	1667	06-01-2013	01-08-2013	NO	YES	NO	NO	YES	NO	NO	YES	NO	NO	YES	NO	YES	NO	NO	NO	NO	YES	11	-1.6	0.91	YES	NO	NO
282	Patient 282	M	185	01-01-2013	01-11-2013	YES	NO	NO	NO	NO	YES	NO	NO	YES	NO	NO	YES	NO	NO	YES	NO	NO	YES	16	-0.1	0.5	NO	YES	NO
283	Patient 283	M	3919	13/1/13	14/1/13	NO	YES	NO	YES	NO	NO	YES	NO	NO	YES	NO	NO	NO	YES	NO	NO	YES	12	0.6	0.74	YES	NO	NO	
284	Patient 284	M	2590	09-01-2013	01-11-2013	NO	YES	NO	YES	NO	NO	NO	NO	YES	NO	NO	YES	NO	YES	NO	NO	NO	YES	14	-0.6	0.94	YES	NO	NO
285	Patient 285	M	309	01-08-2013	01-12-2013	NO	NO	YES	YES	NO	NO	NO	NO	YES	NO	NO	YES	NO	YES	NO	NO	NO	YES	14	-1.6	0.94	YES	NO	NO
286	Patient 286	M	122582	26/12/12	01-08-2013	NO	YES	NO	NO	NO	YES	NO	NO	YES	NO	NO	YES	NO	NO	YES	NO	NO	YES	17	-0.1	0.99	NO	YES	NO
287	Patient 287	M	610	01-02-2013	01-08-2013	NO	YES	NO	NO	NO	YES	NO	NO	YES	NO	NO	YES	NO	YES	NO	NO	NO	YES	16	-0.1	0.98	NO	YES	NO
288	Patient 288	M	3020	01-10-2013	01-10-2013	YES	NO	NO	YES	NO	NO	YES	NO	NO	YES	NO	NO	YES	NO	NO	NO	NO	YES	9	-4.1	0.8	YES	NO	NO
289	Patient 289	M	2925	01-09-2013	01-11-2013	NO	YES	NO	YES	NO	NO	NO	YES	NO	NO	YES	NO	NO	YES	NO	NO	NO	YES	11	-2.1	0.76	YES	NO	NO
290	Patient 290	M	2918	01-09-2013	01-09-2013	NO	NO	YES	NO	YES	NO	NO	YES	NO	NO	YES	NO	YES	NO	NO	NO	NO	YES	11	-1.6	0.91	YES	NO	NO
291	Patient 291	F	1013	01-03-2013	01-07-2013	NO	YES	NO	NO	NO	YES	NO	NO	YES	NO	NO	YES	NO	NO	YES	NO	NO	YES	16	-0.1	0.5	NO	YES	NO
292	Patient 292	M	677	01-03-2013	01-07-2013	YES	NO	NO	NO	NO	YES	NO	NO	YES	NO	NO	YES	NO	NO	YES	NO	NO	YES	17	-0.1	0.99	NO	YES	NO
293	Patient 293	M	978	01-03-2013	01-09-2013	NO	YES	NO	NO	NO	YES	NO	NO	YES	NO	NO	YES	NO	YES	NO	NO	NO	YES	16	-0.1	0.98	NO	YES	NO
294	Patient 294	M	970	01-03-2013	01-09-2013	NO	YES	NO	NO	NO	YES	NO	NO	YES	NO	NO	YES	NO	YES	NO	NO	NO	YES	16	-0.1	0.99	NO	YES	NO
295	Patient 295	M	1063	01-04-2013	01-09-2013	NO	YES	NO	NO	NO	YES	NO	NO	YES	NO	NO	YES	NO	YES	NO	NO	NO	YES	15	-0.6	0.9	NO	YES	NO
296	Patient 296	M	123537	30/12/12	01-09-2013	NO	YES	NO	NO	NO	YES	NO	NO	YES	NO	NO	YES	NO	NO	YES	NO	NO	YES	16	-0.1	0.5	NO	YES	NO
297	Patient 297	M	123608	30/12/12	01-09-2013	NO	YES	NO	NO	NO	YES	NO	NO	YES	NO	NO	YES	NO	NO	YES	NO	NO	YES	17	-0.1	0.99	NO	YES	NO
298	Patient 298	M	123637	30/12/12	01-10-2013	NO	YES	NO	NO	NO	YES	NO	NO	YES	NO	NO	YES	NO	YES	NO	NO	NO	YES	16	-0.1	0.98	NO	YES	NO
299	Patient 299	M	1074	01-04-2013	01-07-2013	NO	YES	NO	YES	NO	NO	YES	NO	NO	YES	NO	NO	YES	NO	NO	NO	NO	YES	9	-4.1	0.8	YES	NO	NO
300	Patient 300	M	3061	01.12.12	02-01-2013	NO	YES	NO	NO	NO	YES	NO	NO	YES	NO	NO	YES	NO	NO	YES	NO	NO	YES	16	-0.1	0.5	NO	YES	NO

Note :- G1 = Group 1, G2 = Group 2, G3 = Group 3

INFORMATION SHEET

We are conducting “**Comparison of various head injury prognostic scales**” among patients attending Rajiv Gandhi Government General Hospital, Chennai and for that your specimen may be valuable to us.

The purpose of this study is to

- a. Apply various prognostic scales on the outcome of moderate and severe head injury patients.
- b. Assessment of the efficacy of the prognostic score
- c. To recognize the sensitivity and specificity of the various prognostic scales

We are selecting certain cases and if your radiological image is found eligible, we may be using your specimen to perform extra tests and special studies which in any way do not affect your final report or management.

- The privacy of the patients in the research will be maintained throughout the study. In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.
- Taking part in this study is voluntary. You are free to decide whether to participate in this study or to withdraw at any time; your decision will not result in any loss of benefits to which you are otherwise entitled.
- The results of the special study may be intimated to you at the end of the study period or during the study if anything is found abnormal which may aid in the management or treatment.

Signature of investigator Signature of participant

Date:

ஆராய்ச்சி தகவல் தாள்

- தங்களின் சிடி ஸ்கேன் / எம்.ஆர்.ஐ ஸ்கேன் படம் அல்லது படத்தின் நகல் அல்லது படத்தின் நிழல்படம் இங்கு பெறப்பட்டுள்ளது
- ராஜீவ் காந்தி அரசு மருத்துவக்கல்லூரி மற்றும் அரசு பொது மருத்துவமனையின் நரம்பியல் அறுவை சிகிச்சைத் துறையில் "தலையில் காயம் பல்வேறு முன்கணிப்பு செதில்கள் ஒப்பீடு" பற்றிய ஆய்வு நடைபெறுகிறது
- சிடி ஸ்கேன், மற்றும் எம்.ஆர்.ஐ ஸ்கேன் ஆகியவற்றின் அடிப்படையில் இந்த ஆய்வு நடைபெறுகிறது
- இவ்வாய்வில் கலந்து கொள்பவர்களின் சொந்த தகவல்கள் ரகசியமாக பாதுக்காகப்படும்
- இந்த ஆய்வின் முடிவுகளை பிரசுரிக்குபோது அல்லது வெளியிடும்போதோ தங்களின் சொந்த தகவல்கள் ஏதும் வெளியிடப்படாது
- இந்த ஆய்வில் பங்குபெற அல்லது விலகிக்கொள்ள உங்களுக்கு முழு சுதந்திரம் உண்டு
- இந்த ஆய்வில் இருந்து நீங்கள் விலகிக்கொண்டாலும் உங்களுக்கு கிடைக்கவேண்டிய சிகிச்சை தொடர்ந்து கிடைக்கும்

ஆராய்ச்சியாளர் கையொப்பம்பங்கேற்பாளர் கையொப்பம்

நாள்

ஆராய்ச்சி ஒப்புதல் கடிதம்

ஆராய்ச்சி தலைப்பு :

பெயர் : வயது/பால் :

தேதி :

ஆராய்ச்சி சேர்க்கை எண் :

- ராஜீவ் காந்தி அரசு மருத்துவக்கல்லூரி மற்றும் அரசு பொது மருத்துவமனையின் நரம்பியல் அறுவை சிகிச்சைத் துறையில் "தலையில் காயம் பல்வேறு முன்கணிப்பு செதில்கள் ஒப்பீடு" பற்றிய ஆய்வு நடைபெறுகிறது என்பதை அறிந்து கொண்டேன்
- சிடி ஸ்கேன், மற்றும் எம்.ஆர்.ஐ ஸ்கேன் ஆகியவற்றின் அடிப்படையில் இந்த ஆய்வு நடைபெறுகிறது என்பதையும் மேலும் அறுவை சிகிச்சையின் போது நேரடியாக பார்க்கப்படுவதை வைத்தும் ஆய்வு நடைபெறுகிறது என்பதையும் அறிந்து கொண்டேன்
- இவ்வாய்வில் கலந்து கொள்பவர்களின் சொந்த தகவல்கள் ரகசியமாக பாதுக்காகப்படும் என்பதையும் இந்த ஆய்வின் முடிவுகளை பிரசுரிக்குபோது அல்லது வெளியிடும்போதோ தங்களின் எனது தகவல்கள் ஏதும் வெளியிடபடாது என்பதையும் அறிந்து கொண்டேன்
- இந்த ஆராய்ச்சியிலிருந்து எந்த நேரமும் பின் வாங்கலாம் என்றும், அதனால் எந்த பாதிப்பும் ஏற்படாது என்பதையும் அறிந்து கொண்டேன்
- இந்த ஆய்வில் பங்குபெற அல்லது விலகிக்கொள்ள எனக்கு முழு சுதந்திரம் உண்டு என்பதையும், இந்த ஆய்வில் இருந்து நான் விலகிகொண்டாலும் எனக்கு கிடைக்கவேண்டிய சிகிச்சை தொடர்ந்து கிடைக்கும் என்பதையும் அறிந்து கொண்டேன்
- இந்த ஆராய்ச்சியின் விவரங்களும், அதன் நோக்கங்களும் எனக்கு தெளிவாக விளக்கப்பட்டது. எனக்கு விளக்கப்பட்ட விவரங்களை புரிந்து கொண்டு, இந்த ஆய்வில் கலந்து கொள்ள சம்மதிக்கிறேன்
- இந்த ஆராய்ச்சியில் பிறரின் நிர்பந்தமின்றி என் சொந்த விருப்பத்தின் பேரில் தான் பங்கு பெறுகிறேன்

கையொப்பம்

INFORMED CONSENT FORM

Title of the study :““ **Comparison of various head injury prognostic scales**””

Name of the Participant: Dr. Goutham S P

Name of the Principal (Co-Investigator): Prof. K. Deiveegan, M.S., M.Ch.,

Name of the Institution: Institute of Neurology, Madras Medical College and Rajiv Gandhi Government General Hospital, Chennai

Name and address of the sponsor / agency (ies) (if any): None.

Documentation of the informed consent

I _____ have read the information in this form (or it has been read to me). I was free to ask any questions and they have been answered. I am over 18 years of age and, exercising my free power of choice, hereby give my consent to be included as a participant in “**Comparison of various head injury prognostic scales**”

1. I have read and understood this consent form and the information provided to me.
2. I have had the consent document explained to me.
3. I have been explained about the nature of the study.
4. I have been explained about my rights and responsibilities by the investigator.
5. I have been informed the investigator of all the treatments I am taking or have taken in the past _____ months including any native (alternative) treatment.
6. I have been advised about the risks associated with my participation in this study.*
7. I agree to cooperate with the investigator and I will inform him/her immediately if I suffer unusual symptoms. *
8. I have not participated in any research study within the past _____ month(s). *

9. I have not donated blood within the past _____ months—Add if the study involves extensive blood sampling. *

10. I am aware of the fact that I can opt out of the study at any time without having to give any reason and this will not affect my future treatment in this hospital. *

11. I am also aware that the investigator may terminate my participation in the study at any time, for any reason, without my consent. *

12. I hereby give permission to the investigators to release the information obtained from me as result of participation in this study to the sponsors, regulatory authorities, Govt. agencies, and IEC. I

understand that they are publicly presented.

13. I have understand that my identity will be kept confidential if my data are publicly presented

14. I have had my questions answered to my satisfaction.

15. I have decided to be in the research study.

I am aware that if I have any question during this study, I should contact the investigator. By signing this consent form I attest that the information given in this document has been clearly explained to me and understood by me, I will be given a copy of this consent document.

For adult participants:

Name and signature / thumb impression of the participant (or legal representative if participant incompetent)

Name _____ Signature_____

Date_____

Name and Signature of impartial witness (required for illiterate patients):

Name _____ Signature_____

Date_____

Children being enrolled in research:

Whether child's assent was asked: Yes / No (Tick one)

[If the answer to be above question is yes, write the following phrase:

You agree with the manner in which assent was asked for /from your child and given by your child. You agree to have your child take part in this study].

[If answer to be above question No, give reason (s) :_____.

Although your child did not or could not give his or her assent, you agree to your child's participation in this study.

Name and Signature of / thumb impression of the participant's parent(s) (or legal representative)

Name _____ Signature_____

Date_____

Name _____ Signature_____

Date_____

Name and Signature of impartial witness (required for parents of participant child illiterate):

Name _____ Signature_____

Date_____

Address and contact number of the impartial witness:

Name and Signature of the investigator or his representative obtaining consent

:Name _____ Signature_____

Date_____

INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE, CHENNAI -3

Telephone No : 044 25305301
Fax : 044 25363970

CERTIFICATE OF APPROVAL

To
Dr.S.P. Goutham
PG in Neurosurgery
Madras Medical College, Chennai -3

Dear Dr.S.P.Goutham,

The Institutional Ethics committee of Madras Medical College, reviewed and discussed your application for approval of the proposal entitled " Comparison of various head injury prognostic scales" No.26112012.

The following members of Ethics Committee were present in the meeting held on 01.11.2012 conducted at Madras Medical College, Chennai -3.

- | | |
|---|---------------------|
| 1. Prof. R. Nandhini MD
Director, Instt. of Pharmacology ,MMC, Ch-3 | -- Member Secretary |
| 2. Prof. Reghu MD
Director , Inst. Of Internal Medicine, MMC, Ch-3 | -- Member |
| 3. Prof. Shyamraj MD
Director i/c , Instt. of Biochemistry , MMC, Ch-3 | -- Member |
| 4. Prof. P. Karkuzhali. MD
Prof., Instt. of Pathology, MMC, Ch-3 | -- Member |
| 5. Prof. G.Muralidharan MS
Prof of Surgery, MMC, Ch-3 | -- Member |
| 6. Thiru. S. Govindsamy. BA, BL | -- Lawyer |

We approve the proposal to be conducted in its presented form.

Sd/ Chairman & Other Members

The Institutional Ethics Committee expects to be informed about the progress of the study, and SAE occurring in the course of the study, any changes in the protocol and patients information / informed consent and asks to be provided a copy of the final report.

R Nandini 19/11/12
Member Secretary, Ethics Committee

THE TAMILNADU DR.M.G.R.MEDICAL UNIVERSITY

Refresh



COMPARISON OF VARIOUS HEAD INJURY PROGNOSTIC SCALES.

Dissertation submitted in partial fulfillment by the requirements for the degree of

M.Ch. Branch -II
NEUROSURGERY

Match Overview

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