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A CLINICAL COMPARATIVE STUDY ON SURVIVAL AND OUTCOME OF TRAUMATIC BRAIN INJURY PATIENTS REPORTING WITHIN THREE AND SIX HOURS OF SUSTAINING INJURIES- VIS-À-VIS THE “GOLDEN HOUR”

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ABSTRACT: AIM OF THE STUDY: This clinical comparative study is conducted to compare clinical outcomes of hundred traumatic brain injury patients with no other associated injuries reporting to the emergency department within three and six hours after sustaining injury. This study is an effort to compare variance of clinical outcomes of traumatic brain injury patients reporting at two different time intervals beyond the “Golden Hour” after sustaining such injuries. **MATERIALS AND METHODS:** All the patients of this study population sustained traumatic brain injuries and reported to the emergency department beyond the dictum of the Golden Hour, i.e. 3 & 6 hours after sustaining injuries. All the patients were transferred to ICU from the emergency department after initial resuscitation and radiological investigations like X ray, Sonography, CT head & neck etc. All the patient required Neurosurgical interventions during next 24 hours. None of the patients sustained any other associated injuries. **RESULTS:** There is a significant correlation between reduced pre hospital time and reduced mortality. Clinical outcome is proportional to severity of injury and age of the victim. Shortest pre hospital time undeniably influence outcome of the patients with severe head injuries. At the same time there are also significant evidences that all trauma patients need not be rushed to the hospital with such rapidity as it carries chances of some collateral implications. Predominance of age and sex is prevalent as various studies established trauma as disease of the young with male dominance. **CONCLUSIONS:** Management of patients with TBI is a continuous process stretching from the site of the accident to the intensive care unit. Management during the intervening period involves various locations like: during transit, local hospitals, in the emergency department, the radiology department, and the operating room and finally the Intensive Care Unit (ICU). This continuous process of care at various locations cumulatively contribute to the clinical outcome. Shortest pre hospital time undeniably influence outcome of the patients with Traumatic Brain injury. However Traumatic Brain injury victims when managed in dedicated trauma care centers equipped with state of the art facilities, show promising outcomes even if they report beyond the dictum of “Golden Hour”.

KEYWORDS: Golden Hour, Traumatic Brain Injury, Glasgow Coma Score, Intracranial pressure, Intensive Care Unit, Cerebral blood flow.

INTRODUCTION: India is one of the fastest developing nations in the world with huge population density. Urban India has combination of both population and vehicular density, improved road conditions of interstate corridors and highways with fast moving vehicular traffic is contributing to ever increasing incidence of fatal or near fatal road traffic accidents, prompting the government agencies to seriously focus in modernization of trauma care facilities.

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Emphasizing the need for providing definitive trauma care within "GOLDEN HOUR", government agencies have transformed the trauma care mechanism by introducing critical care ambulance services with qualified responders and advanced pre-hospital life support equipments. Air ambulance and helicopter services also contribute to such time limited rescue operations. Such rapid transport facilities with life support equipments are bringing sea changes in clinical outcome of trauma victims. It has dramatically changed survival outcome of Traumatic brain injury (TBI) victims. Rapid transport to appropriate medical facility remains the gold standard for effective management of trauma victims despite conflicting evidences with regard to the concept of golden hour. At the same time there are also significant evidences that all trauma patients need not be rushed to the hospital,^{1,2} with such rapidity as it carries some collateral implications.

Management of patients with TBI is a continuous process stretching from the site of the accident to the intensive care unit. Management during the intervening period involves various locations like: during transit, local hospitals, in the emergency department, the radiology department, and the operating room before they are admitted to the Intensive Care Unit (ICU).

This is a clinical comparative study to analyze outcome and survival of traumatic brain injury patients admitted directly to the ICU from emergency department within 3 and 6 hours of sustaining such injuries. All the patients underwent neurosurgical intervention within 24 hours of admission.

AIM OF THE STUDY: This clinical comparative study is conducted to compare clinical outcomes of hundred traumatic brain injury patients with no other associated injuries, divided into two groups, Group A comprising fifty traumatic brain injury patients reporting to the emergency department within three hours of sustaining injury and Group B comprising fifty traumatic brain injury patients reporting to the emergency department within six hours of sustaining injury, all the victims reported. To emergency department beyond the Golden Hour dictum of trauma management.

All the patients were treated in a state of the art trauma care facility and an effort was made to study variance of clinical outcomes of traumatic brain injury patients reporting at two different time intervals beyond the "Golden Hour" after sustaining such injuries.

MATERIAL AND METHODS: The present study is carried out in the Department of Emergency Medicine Gauhati Medical College & Hospital Guwahati, Assam; the retrospective study is aimed at analyzing influence of rapid transport, early surgical intervention and role of comprehensive ICU care on survival of patients with traumatic brain injury, admitted beyond the dictum of Golden Hour, i.e. 3 & 6 hours after sustaining injuries.

All the patients were transferred to the ICU from the emergency department after initial resuscitation, radiological investigation and undergone de-compressive neurosurgical procedures within 24 hours of admission.

All the patients of this study population sustained traumatic brain injuries and reported to the emergency department with GCS 9, beyond the dictum of the Golden Hour, i.e. 3 & 6 hours after sustaining injuries. All the patients were transferred to the ICU from the emergency department after initial resuscitation and radiological investigations (x ray, USG FAST, CT head & neck). None of the patients sustained any other associated injuries

Inclusion Criteria:

- Patients with GCS 9 (Glasgow Coma Scale), irrespective of ASA physical status.

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- Both male and female.
- Traumatic brain injury patients reporting to the emergency department beyond the dictum of “Golden Hour”, i.e. within three & six hours after sustaining injuries.
- Patients in the age group of 20-50 years.

Exclusion Criteria:

- Patient below 20 and above 50 years.
- Patients with other associated injuries.

Grouping of the Patients: Group A includes 50 traumatic brain injury patients reporting to the emergency department within 3 hours of sustaining injury and directly transferred to the ICU.

Group B includes 50 traumatic brain injury patients reporting to the emergency department within 6 hours of sustaining injury and directly transferred to the ICU

RESULTS & OBSERVATIONS: The Descriptive Analysis of Age Distribution in both the Groups:

The age distribution of the patients in both the groups exhibit fair amount of homogeneity. (Table: 1 & Figure 1). There was no significant difference between the groups with regard to the age of the population at $p < 0.05$.

The Descriptive Analysis of Sex Distribution across the Groups: The sex distribution of patients in both the groups exhibit fair amount of homogeneity. (Table: 2 & Figure 2). There was no significant difference between the groups with regard to the sex distribution of the population at $p < 0.05$.

Mode of Injury:

The observed mode of traumatic brain injuries in the population of our study comprised, Road traffic accident 78% & 82%, Assault 8% & 12% and fall from height 14% & 6%, in Group A and Group B respectively. (Table: 3 & Figure 3). The distribution of patients with different mode of injury in both the groups exhibit fair amount of homogeneity. There is no significant difference between the groups with regard to the mode of injury to the population at $p < 0.05$.

Types of Traumatic Brain Injuries: The types of traumatic brain injuries observed in both the groups of population under study exhibit fair amount of homogeneity. (Table 4 & Figure 4).

The distribution of population with different types of injury in both the groups exhibit fair amount of homogeneity. There is no significant difference between the groups with regard to the types of injury to the population at $p < 0.05$.

Survival and Mortality: Descriptive statistics of survival and mortality as observed in the study population of both the groups exhibited fair amount of homogeneity and no significant differences could be established. (Table: 5 & Figure 5). There is no significant difference between the groups with regard to survival and mortality of the population at $p < 0.05$.

Average Length of ICU Stay: On analysis of length of ICU stay of patients of both the groups, it has been observed that in Group A average duration of ICU stay of discharged patients was 9.69 ± 3.52 days and in Group B 11.03 ± 5.06 days. Average duration of ICU stay of patients who died during treatment was, in Group A 7.23 ± 3.46 days and in Group B 5.52 ± 4.98 days. (Figure: 6). Length of ICU stays of population of both Group A and Group B bear not significant difference at $p < 0.05$ irrespective of its outcome.

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Management protocol of Traumatic brain injury patients in Intensive Care Unit;

Critical Care Management: The acute care provided during the "GOLDEN HOUR", from the time of injury till initiation of the comprehensive care, modulates the survival outcome during the ensuing period of the definitive treatment.

The critical care management of severe TBI is followed as per the "Guidelines for the Management of Severe Traumatic Brain Injury" published by the Brain Trauma Foundation with laid down objectives of optimization of cerebral Oxygenation, prevention and management of intracranial hypertension and secondary brain injuries with preservation of cerebral perfusion pressure (CPP). Several researchers observed encouraging impact of implementation of guidelines-based management protocols in treatment and outcome of Traumatic brain Injury patients.^{3,4}

Although every ICU has its own local protocols of management, however treatment modalities formulated as per guidelines are associated with improved outcomes like mortality rate, length of hospital stay, functional outcomes and lower economic involvement.^{5,6}

Traumatic Brain injury basically encompasses two distinct events like primary and secondary brain injuries. The primary brain injury occurs due to the traumatic event itself causing physical damage to the brain parenchyma (tissue & vessels) resulting in shearing and compression of the surrounding brain tissue. During the ensuing hours and days the most complicated intracranial, extracranial and systemic chain of events set in causing the secondary brain injury.

The primary brain injury is caused by damage to the brain due to impact of the head injury itself, but Critical care physicians need to address with proficiency the secondary intracranial insults like cerebral edema, haematomas, intracranial hypertension, seizures, metabolic derangement, vasospasm, infection and calcium ion toxicity etc.^{7,8}

Critical Care Management guidelines are basically formulated to modulate secondary brain insults that are both preventable and reversible. Clinical manifestations of secondary brain injury are Hypoxemia ($\text{PaO}_2 < 60\text{mm Hg}$; O_2 Saturation $< 90\%$), Acid-base disorders (Acidemia: $\text{pH} < 7.35$; alkalemia: $\text{pH} > 7.45$), Hypercapnia ($\text{PaCO}_2 > 45\text{mm Hg}$), Hypocapnia ($\text{PaCO}_2 < 35\text{mm Hg}$), Hypotension ($\text{SBP} < 90\text{mm Hg}$), Hypertension ($\text{SBP} > 160\text{mm Hg}$, or mean arterial pressure $> 110\text{mm Hg}$), Hyponatremia (serum sodium $< 142\text{mEq/L}$), Hyperglycemia, Hypoglycemia, Fever, Hypothermia, Anemia (Hemoglobin ($\text{Hb} < 10\text{g/dl}$) and Infections.

Serial ABG, regular estimation of electrolytes, coagulation profiles, renal function tests and liver function tests are basic investigations carried out on routine basis to monitor and arrest progression of secondary brain injuries. Routine blood examinations and isolation of responsible organisms by culture and sensitivity of blood, urine and tracheal aspirates play pivotal role in management and sepsis prevention.

General Monitoring: Components of neurointensive care of severe TBI encompasses monitoring of general parameters like electrocardiography (ECG monitoring), arterial oxygen saturation (SpO_2), arterial blood gases capnography (end-tidal CO_2), arterial blood gases, arterial blood pressure (Arterial catheter), central venous pressure (CVP), systemic temperature, urine output, and serum electrolytes and osmolality etc. Hemodynamically unstable patients unresponsive to fluid resuscitation need vasopressors and inotropes. These patients need continued attention of critical care physicians.

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Neuro Monitoring: Electroencephalogram (EEG) is useful tool for detecting non-convulsive or sub-clinical seizures or seizures activity in pharmacologically paralyzed patients. EEG can also monitor depth of coma and diagnose of brain death.^{9,10} Although Continuous EEG has been suggested for the diagnosis of post-traumatic seizures (PTS) in patients of TBI receiving neuromuscular blockades, it is not currently practiced in our ICU.

Fluid Management: After successful fluid resuscitation and determination of normal volume status intravenous fluids are administered only for maintenance of a state of euvolemia or mild hypervolemia.

Mechanical Ventilation: Rapid sequence intubation is performed to secure the airway; intravenous lidocaine is administered to obtund significant haemodynamic response of endotracheal intubation in traumatic brain injury patients.¹¹

In ICU severe head injury patients require mechanical Ventilation⁷⁰ to maintain adequate arterial PO₂ and PCO₂. Positive end expiratory pressure (PEEP) in hypoxaemic patients is not contraindicated unless the increase in thoracic venous pressure causes an unacceptable rise of ICP. Permissive hypercapnea should be avoided because it causes cerebral vasodilatation and increases in ICP.

Neuromuscular blockade with boluses or infusion of non-depolarizing muscle relaxants contains coughing and straining which can increase ICP,¹²

Sedation: Sedation is used to contain agitation of intubated patients. Short acting analgesics and sedatives are routinely used in carefully titrated doses with periodic withholding for neurological monitoring. Sedation reduces the cerebral metabolic rate of oxygen consumption, and facilitates mechanical ventilation.

ICP Management: ICP is reduced due to improved venous outflow from the brain when head end of the bed is elevated 20-30°. In hypovolaemic patients elevation of the head should be avoided as it may lower cardiac output and CBF; Elevation of the head should be avoided in patients with suspected spinal injury or till stabilization of unstable spine. Appropriate Effective ICP management in severe head injury patients is associated with lower mortality,¹³ and morbidity.

Management of Cerebral Perfusion Pressure: CPP management involves artificially elevating the blood pressure to increase the MAP and the CPP. Metabolic therapies are intended to reduce the cerebral metabolic rate, which decreases ICP. Metabolic suppression may be achieved through drug therapies or induced hypothermia. Barbiturates are the most common class of drugs used to suppress cerebral metabolism. Barbiturate coma is typically induced with pentobarbital. Hypothermia may also be used to suppress cerebral metabolism.

Management of Seizure Activity: Post traumatic seizures activities are common in patients with penetrating cerebral injury, which eventually present with late seizures. In TBI post traumatic seizures are common manifestations. Early seizures occur within 24 hours of the initial injury, intermediate seizures occur 1-7 days following injury, and late seizures occur more than 7 days after the initial injury.

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Role of anticonvulsants in patients with TBI is controversial. Prevention of early posttraumatic seizures does not influence the clinical outcome of TBI. The Prophylactic use of anticonvulsants is not recommended for more than 7 days following the injury. Temkin et al demonstrated that the routine use of Dilantin in the first week following TBI decreases the incidence of early-onset seizures but does not change the incidence of late-onset seizures.¹⁴

Diuretics: Diuretics effectively decrease ICP by decreasing the brain volume. Mannitol is the most commonly used diuretic to manage cerebral edema; it is an osmotic diuretic with rapid onset of action. As mannitol causes significant diuresis, electrolytes and serum osmolality must be monitored carefully during its use and adequate hydration should be provided to maintain a state of euvolemia. Other diuretic that commonly used in patients with TBI is furosemide. Mannitol is preferred over furosemide because it tends to cause less severe electrolyte imbalances than a loop diuretic. Mannitol and furosemide have synergistic effect when used in combination.

Hypertonic saline is gaining interest in the management of intracranial hypertension secondary to brain edema because it is considered to be less disturbing to fluid and electrolyte balance than other diuretic agents.

Standard Protocol of ICU Care: Maintenance of neutral position of the head and neck to facilitates cerebral venous drainage and reduces ICP.

Raising head end of bed to 30°-45°: to reduce ICP and improves CPP, this position reduces risk of ventilator-associated pneumonia (VAP).

Proper care is needed to avoid compression of the neck veins.

Strict maintenance of skin hygiene, oral and eye care regularly.

For prevention of pressure sores frequent changing of position is done and air or water mattress is used.

Enforcement of evidence-based bundles for prevention of infection including VAP and central line related infections.

Proper bowel management is necessary to avoid constipation and prevent rise of intra-abdominal pressure and ICP.

Graduated compression devices are used for Thromboprophylaxis.

Adequate nutrition and regular physiotherapy is essential for early recovery.

Neurosurgical Interventions: Decompressive craniectomy is a commonly practiced therapeutic approach for patients with severe TBI who are at risk of developing severe cerebral edema. Decompressive surgery is undertaken as a life-saving procedure when death is imminent from intracranial hypertension. In patients of severe Traumatic Brain Injuries commonly considered indications for neurosurgical interventions are: extra-axial haematomas with midline shift greater than 5mm, intra-axial haematomas with volume greater than 30ml, depressed skull fracture with more than 1cm of inward displacement or open skull fracture.

All frontal, parietal, occipital, temporal or cerebellar haematomas larger than 3 cm in diameter are considered high-risk haematomas as these areas of the brain have little space to accommodate additional mass. These high-risk haematomas are normally evacuated immediately

DISCUSSIONS: There is a significant correlation between reduced pre hospital time and reduced mortality and clinical outcome is proportional to severity of injury and age of the victim.^{15,16} Shortest pre hospital time undeniably influence outcome of the patients with severe head injuries.^{17,18}

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The first 1 hour after traumatic injury is termed as the “golden hour.”¹⁹ This concept has been taught, and practiced for decades. The concept of “Golden Hour” was first described by R Adams Cowley, at the University of Maryland Medical Center in Baltimore from his experiences and observations in post-World War II Europe, and then in Baltimore in the 1960s, Dr. Cowley recognized that the sooner the definitive care can be provided, particularly if the arrival is within 60 minutes of sustaining injuries the better is their chances of survival.

However, researchers are now observing that definitive references are not provided while discussing this concept and they are still looking for available objective data in support of the concept.

Rapid transport to appropriate medical facility remains the gold standard for effective management of trauma victim despite conflicting evidences with regard to the concept of golden hour. At the same time there are also significant evidences that all trauma patients need not be rushed to the hospital,^{20, 21} with such rapidity as it carries some collateral implications.

As fast moving ambulances carry trauma victims through narrow and crowded streets of our cities they do subject the general population to significant risks. It is seen that fast moving ambulances carrying victims of any nature, causing road traffic accidents and rather generating more numbers of victims and fatalities. At times even air ambulances are seen to be operating in adverse weather conditions with considerable risks.

Researchers also established that quality of chest compression being compromised during transportation owing to the speed of ambulances.²² Some researcher even recognized high incidence of transportation related injuries to emergency service workers and their patients.²³ Transit injuries and deaths due to helicopter and ambulance crashes are attributable to over emphasis on constraints of pre hospital time limitations.^{24, 25}

Globally Road traffic accident claims more lives of individuals above the age of four years than cardio vascular diseases.²⁶ Road traffic injuries are the leading cause of death among young people aged 15-29 years.^{27, 28} Nearly 1.3 million people die every year on the world's roads and about 20 to 50 million people suffer non-fatal injuries. ²⁷ Head injuries contribute to significant portion of such fatalities.

The extent and degree of injury to the skull and its content is not necessarily proportional to the quantum of force applied to the head. According to Munro, any type of cranio-cerebral injury is possible with any kind of blow on any sort of head.²⁹

While emphasizing the need for rapid transport of trauma victims to appropriate medical facility from the scene of injury with continued care of qualified responders and advanced pre-hospital life support equipments, there is also scope to discuss that all trauma victims need not be transported with such rapidity only to fulfill the limitations of “Golden Hour” dictum.

This study is about comparing clinical outcomes of patients of Traumatic brain injury, admitted directly to the ICU from the emergency department after 3 hours and 6 hours of sustaining such injuries. All the patients of both the groups underwent neurosurgical interventions within 24 hours of admission.

Challenges for Critical care physicians always remained focused on successful management of Severe traumatic brain injury (TBI) which present as Head injuries with a Glasgow Coma Scale (GCS) score of 3 to 8.³⁰ In this study all the patients were of Glasgow Coma Scale (GCS) score of 9.

The critical care management of severe TBI are followed as per the “Guidelines for the Management of Severe Traumatic Brain Injury” published by the Brain Trauma Foundation. The

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objectives of the guidelines are designed for optimization of cerebral Oxygenation, prevention and management of intracranial hypertension, secondary brain insults and preservation of cerebral perfusion pressure (CPP).

Although every ICU has its own local protocols of management, however treatment delivered as per guidelines is associated with improved outcomes like mortality, length of hospital stay, functional outcomes and less financial involvement.^{31, 32}

No significant variation in survival outcome could be established between the groups as mortality in Group A is found to be 34 percent and that in Group B is 38 percent. The means of Group A and Group B are not significantly different at $p < 0.05$. The means of both data sets are equal so we can conclude that there is no significant difference between them.

On analysis of length of ICU stay of both the groups, it has been observed that in Group A duration of ICU stay of discharged patient was 9.69 ± 3.52 days and Group B 11.03 ± 5.06 days. Length of ICU stay of patients who died during treatment was in Group A 7.23 ± 3.46 days and in Group B 5.52 ± 4.98 days. (Figure: 6). Length of ICU stays of population both Group A and Group B bear not significant difference at $p < 0.05$ irrespective of outcomes.

CONCLUSION: Rapid transport of trauma victims to best available medical facility from the scene of injury with continued care of qualified responders and advanced pre-hospital life support in shortest possible time is the gold standard for effective management of trauma victims, despite conflicting evidences with regard to the concept of golden hour. At the same time there are significant evidences that all trauma patients need not be rushed to the hospital with such rapidity as it carries chances of collateral injuries.

Management of patients with TBI is a continuous process stretching from the site of the accident to the intensive care unit. Management during the intervening period involves various locations like: during transit, local hospitals, in the emergency department, the radiology department, the operating room and finally the Intensive Care Unit (ICU). This continuous process of care at various locations cumulatively contribute to the final clinical outcome.

Shortest pre hospital time undeniably influence outcome of the patient with Traumatic Brain injury. However Traumatic Brain injury victims when managed in dedicated trauma care centers equipped with the state of the art facilities, show promising outcomes even if they report beyond the dictum of "Golden Hour".

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Age	Group A	Group B
20-30	16	21
31-40	23	19
41-50	11	10

Table 1: Age distribution

Sex	Group A	Group B
Male	40	41
Female	10	9
Total	50	50

Table 2: Sex distribution

Mode of Injury	Group A	Group B
RTA	39 (78%)	41 (82%)
Assault	4 (8%)	6 (12%)
Fall From Height	7 (14%)	3 (6%)

Table 3: Mode of Injury

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Types of Injury	Group A	Group B
Fracture Skull + EDH	12	15
Fracture + EDH and Contusion	2	2
EDH	19	14
Contusion	1	4
SDH	9	11
Fracture Skull + SDH	2	1
Fracture Skull + SAH	1	1
ICH	1	2

Table 4: Types of Traumatic Brain Injury

Outcome	Group A	Group B
Discharged	33(66%)	31(62%)
Death	17(34%)	19(38%)

Table 5: Survival & Mortality

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Abbreviations:

ASA American Society of Anesthesiologists
 ABG Arterial Blood Gas
 CBF Cerebral blood flow.
 CVP Central venous pressure
 ETCO₂ End tidal Carbon dioxide
 EEG Electroencephalogram
 GCS Glasgow Coma Scale
 ICP Intracranial pressure.
 ICU Intensive Care Unit
 PTS Post-traumatic seizures
 SpO₂ Oxygen saturation of arterial blood.
 TBI Traumatic Brain Injury

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