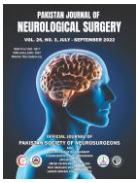

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Original Article

Impact of Intracranial Pressure-Monitored Therapy on Mortality in Patients with Severe Traumatic Brain Injury

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ABSTRACT

Objective: Traumatic brain injury (TBI) is a medical condition causing disability, morbidity, and mortality in the world. The present research aimed to assess the impact of intracranial pressure (ICP) monitored therapy on mortality in patients with severe traumatic brain injury.

Materials and Methods: A randomized controlled trial was conducted at the Department of Neurosurgery, Jinnah Hospital Lahore. Forty patients of both genders, aged between 15 to 60 years were randomly selected and divided into two groups (Control & Experimental). Patients injured within 24 hours with a Glasgow Coma Scale (GCS) of 8 or less and showing radiological evidence of raised intracranial pressure were included. Patients with extradural hematoma, penetrating injury, or those requiring any surgery were excluded from the study. Data were analyzed using SPSS version 20.

Results: No significant difference was found in mean age and gender among the two groups. The GCS of the control group was 6.2 ± 1.6 while that of the experimental group was 6.7 ± 1.6. The mean of the maximum ICP of the experimental group was 25.31 ± 8.48 mm of Hg. There was a significant difference in the mean duration of ventilation between the two groups. In the control group, 10 (50.0%) patients expired whereas in the experimental group, 8 (40.0%) patients expired. The proportion of mortality was higher in the control group but the difference was not statistically significant between the two groups (P value: 0.525).

Conclusion: Intracranial pressure-monitored therapy was effective but statistically showed no significant superiority over unmonitored management. Therefore, it is recommended that ICP monitoring should be used as a part and additional tool of a multimodal approach to severe traumatic brain injury.

Keywords: Intracranial pressure (ICP), Traumatic Brain Injury (TBI), ICP monitoring, Glasgow coma Scale (GCS), Neurovent-P ICP catheter.

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INTRODUCTION

Throughout the world, traumatic brain injury is a major economical and public health issue. The average age of patients who experience TBI is increasing and the history of spontaneous falls is also increasing as compared to road traffic accidents.[1] Approximately 200/100,000 is the incidence of TBI in developed countries and this data only includes patients who reach hospitals in time. This data excludes patients who experience severe and fatal TBIs which results in a false decrease in overall incidence. On the other hand, this data only includes cohort samples of patients from large hospitals and trauma centers which results in over-enumeration of TBI patients and the severity of the injury.[2]

Brain trauma is the leading cause of mortality in all trauma types and is responsible for major disabilities and morbidities.[3,4] Minor injuries like concussions even can lead to cognitive disabilities that affect daily life activities and return to work. Consequently, TBI is one of the most disabling injuries. The percentage (15.7%) of injury-related productivity loss attributed to TBI is 14 times as compared to traumatic spine injury.[6]

The normal intracranial pressure (ICP) in a healthy adult in a recumbent position is within the range of 7–15 mm Hg.[7] Following a head injury, ICP above 20 mm Hg is abnormal, and more aggressive treatment is usually required above 25 mm Hg. Intracranial pressure monitoring used in our study is based on a microchip catheter. Micro transducer chip catheters can be placed in the brain parenchyma (right frontal lobe), making a small burr hole and putting a skull bolt. The Neurovent-P ICP catheter is an electronic chip that increases the capacity of the catheter to maintain drift-free results.[8] The drift of these microchip catheters is as low as 0.6 ± 0.9 mm Hg even after 5 days of insertion.[7] These microchip transducers are very reliable in routine clinical use due to minimal atmospheric drift.[9,10,11]

MATERIAL & METHODS

Study Design & Setting

A Randomized Control Trial (RCT) was conducted at the Department of Neurosurgery, Jinnah Hospital Lahore after approval from the Ethical Review Board of Allama Iqbal Medical College, from January 2019 to January 2022.

Sampling Technique

Purposive sampling technique, divided into two groups (A, B, 20 in each group) through the lottery method.

Informed consent was taken from relatives after explaining to them the objectives of the study. It was hypothesized that intracranial pressure monitored therapy reduces mortality in patients with severe traumatic brain injury.

Inclusion Criteria

Patients from both genders aged between 15 to 60 years who sustained severe TBI within 24 hours having GCS ≤ 8, with radiological signs of raised ICP were included in the study.

Exclusion Criteria

Patients having a pre-existing illness that could limit life expectancy to 1 year, an extradural hematoma or any condition requiring cranial or other surgery at the time of selection and with penetrating head injury were excluded. Those patients who had hemodynamic instability and/or respiratory instability and bilaterally fixed dilated pupils were also excluded from this research.

Clinical Management

A total of 40 patients were enrolled under randomization techniques. Group A was treated without ICP monitoring i.e. ventilation and Mannitol 2 gm/kg/day in three divided doses. In Group B, a NEUROVENT-P ICP catheter was placed in the cerebral parenchyma. After

investigating all the baselines including INR, a parenchymal catheter was placed 2 cm deep after making a small burrhole.

An intravenous bolus of Mannitol 50 gm was given at every surge of ICP which was more than 20mmHg and sustained for 5 minutes. A maximum dose of 200 gm Mannitol/day[12,13] was considered. When the ICP remained persistently raised despite administration of 200 gm Mannitol/day, the patient was considered for Decompressive Craniotomy[14,15] and was excluded from the study. A total of 28 cases were excluded from the study due to their consideration for decompressive craniotomy. All surgeries i.e., ICP catheter insertion and decompressive craniectomies were performed by the same emergency department neurosurgical team.

Data Collection

Data was collected using the prescribed proforma. The variables like age, gender, GCS, pupillary reaction, time since injury, intracranial pressure at the time of admission, maximum intracranial pressure recorded during treatment, and duration of hospital stay were properly recorded. Early Outcome was assessed on the 28th-day discharge or death of the patient (whichever was earlier) and was recorded on the proforma.

RESULTS

Age Distribution

The mean age of group A (unmonitored) was 36.0 ± 12.7 years with an age range of 18 to 60 years and the mean age of Group B (monitored) was 38.1 ± 16 years with an age range of 16 to 60 years. An Independent sample t-test was used to compare the mean age between the groups. Results showed that there was no significant difference in mean age between the groups. (Table 1).

Gender Distribution

Out of 40 patients, 35 (87.5%) were male while 5 (12.5%) were female. In group A, 19 (95%) participants were male and only one (5%) was female whereas in group B, 16 (80%) participants were male and 4 (20%) were female.

Pupillary Reaction

Pupils were nonreactive (bilateral) in 5 (12.5%) out of 40 patients. In group A, 2 (10.0%) patients had an absent pupillary reaction whereas in group B, 3 (15.0%) patients had no pupillary reaction.

Time since Injury (h) and GCS at Presentation

The average time since the injury of group A was 2.85 ± 1.31 hours and the time since the injury of group B was 3.75 ± 1.12 hours.

Outcome at the 28th Day

On or within 28 days of admission, 18 (45.0%) out of 40 patients expired. In group A, 10 (50.0%) patients whereas in group B, 8 (40.0%) patients expired. The proportion of mortality was higher in group A as compared to group B but the Chi-square test revealed that there is no statistically significant difference in mortality between both groups (Table 3).

Table 1: Comparison of age between groups.

Group	Age				
	Mean ± SD	Median (Inter-Quartile Range)	Minimum	Maximum	p-value
A	36.0 ± 12.7	34.0 (27.0 – 47.5)	18	60	0.657
B	38.1 ± 16.1	33.5 (22.7 – 57.5)	16	60	

Table 2: Comparison of time since injury (h) and GCS at presentation between groups.

	Mean ± SD	Median (Inter-Quartile Range)	Minimum	Maximum	p-value
Time Since Injury (h)					
Group A	2.85 ± 1.31	3.0 (2.0 – 4.0)	1	5	0.025 (significant result)
Group B	3.75 ± 1.12	4.0 (3.0 – 4.75)	2	6	
GCS at Presentation					
Group A	6.2 ± 1.6	6.5 (5.0 – 8.0)	-		-
Group B	6.7 ± 1.6	6.6 (5.25 – 8.0)	-		

Intracranial Pressure

At the time of admission, the mean intracranial pressure of patients of group A was 18.19 ± 7.05 mm of Hg while it was 25.31 ± 8.48 mm of Hg (Table 4).

Duration of Ventilation

The mean duration of ventilation in group A was 10.25 ± 1.64 days while in group B, it was 5.80 ± 4.49 days. Group A had a higher mean duration of ventilation as compared to group B.

Table 3: Comparison of the outcome on the 28th day between groups.

	Expired n (%)	Survived/Discharged n (%)	p-value
Group A	10 (50.0%)	10 (50.0%)	
Group B	8 (40.0%)	12 (60.0%)	0.525
Total	18 (45.0%)	22 (55.0%)	

Table 4: Intracranial Pressure of patients in group B.

	Intracranial Pressure (mmHg)			
	Mean ± SD	Median (Inter-Quartile Range)	Minimum	Maximum
Intracranial Pressure at Admission	18.19 ± 7.05	18.4 (13.4 – 23.7)	3	30
Maximum Intracranial Pressure	25.31 ± 8.48	24.0 (23.0 – 27.7)	9	51

Table 5: Comparison of duration of ventilation between both groups.

	Duration of Ventilation (days)				
	Mean ± SD	Median (Inter-Quartile Range)	Minimum	Maximum	p-value
Group A	10.25 ± 1.64	7.0 (4.0 – 17.0)	2	31	0.038
Group B	5.80 ± 4.49	5.0 (1.75 – 8.75)		16	

Table 6: Comparison of improvement in GCS between both groups.

	Glasgow Coma Scale			
	At presentation	At 28th Day	Improvement in GCS	p-value
Group A	6.2 ± 1.6	11.9 ± 1.66	5.3 ± 1.25	0.627
Group B	6.7 ± 1.6	12.67 ± 0.99	5.1 ± 0.79	

Improvement in GCS

The mean improvement in GCS in group A was 5.3 ± 1.25 and the mean improvement in GCS of group B was 5.1 ± 0.79. The result revealed that there is no significant difference in mean improvement in GCS between the groups (Table 6).

DISCUSSION

This research aimed to assess the effects of ICP monitoring in patients with severe TBI based on mortality. Results from the present study have shown a reduction in the mortality rate in ICP monitored group but the results are not significant. A study was done in Holland by Cremer et al and, van Dijk, et al,[16,17] in two selected centers. In one center, intensive care management was done based on mean arterial pressure (MAP) with MAP 90 mm Hg, while in the other center; treatment was done on a clinical observation basis and radiological findings only. Their study also could not prove a significant improvement in mortality or morbidity in the monitored group but similar to the present study. The study rather increased the controversy over the ICP-monitored management of STBI.[18]

It was seen in a meta-analysis, which included 6 randomized controlled trials and 12 cohort studies, and a total of approximately 13,486 patients, that ICP monitoring for severe TBI patients did not decrease hospital mortality, mechanical ventilator use, pulmonary infection rate, and duration of hospital stay but it improved the prognosis of patients by reducing the rate of renal failure and electrolyte imbalance.[19]

It was also found in another meta-analysis that ICP monitoring did not reduce mortality but our results are different. They concluded from the meta-analysis that the rate of complications is decreased by ICP monitoring, leading to an increase in favorable functional outcomes. However, there was no significant reduction in mortality, the use of mechanical ventilation, and the duration of hospital stay also remained the same as in the unmonitored group. Although the results have shown no significance but present study has found that TBI patients can benefit from ICP monitoring. RCT is a reasonable design to evaluate the impact of the intervention and we believe that the present results are very reliable.

Previous studies have also proved our results by favoring the use of ICP monitoring therapy. Analysis done by Shen, et al,[19] showing the effects of Intracranial Pressure monitoring on mortality in patients with severe Traumatic Brain Injury, it was observed that ICP-monitored patients had better survival. In this meta-analysis, there were 18 studies. It concluded that ICP monitoring reduces the mortality of patients with severe TBI.

Our study has not proved the hypothesis (Intracranial pressure monitored therapy reduces mortality in patients with severe traumatic brain injury) so, the superiority of ICP-guided treatment over management guided by examination and radiology in patients with STBI could not be supported. Data from randomized, controlled trials supports the monitored management of intracranial pressure, leading the Brain Trauma Foundation (BTF) to issue the guidelines in subsequent editions regarding the importance of ICP-monitored therapies, i.e., ICP cannot be reliably predicted by radiological evidence. So, ICP monitoring data help predict the outcome and guide the management protocols. BTF guidelines further add that if ICP is not monitored while treating an STBI patient, it can lead to a deleterious and poor outcome.[23] Although there has been a regular need and calls for a randomized, controlled trial, in a few retrospective studies, there was no improvement in outcome in monitored patients[18,] or even a worse outcome was seen in the ICP-monitored patients as compared to the control group.[21]

LIMITATIONS OF STUDY

It was a single-center study conducted at the

Department of Neurosurgery, Jinnah Hospital, Lahore; the extent to generalize the findings to other patient populations is debatable and needs discussion. Although the care provided in the study hospital adhered to the basics of Neuro ICU care and remained consistent with the research, prehospital care, and resuscitation are not much developed in Pakistan as compared to the developed countries. Similarly, the availability of limited resources after discharge from the NICU is another important factor that can affect the study compared to the advanced countries.

RECOMMENDATIONS

Further studies need to be done with a larger sample size and fewer limitations of the study, at a larger scale. Further studies are suggested to come up with the impact of ICP monitoring on the Glasgow outcome scale, and cognitive and motor impairment. Our study tested the mortality on the 28th day, it is suggested to add up further studies to reassess the patients on the 3rd and 6th month and collect the functional outcome data of the patients.

So, it is recommended that ICP monitoring should be used as part of a multimodal approach to STBI patients and may be considered as an additional tool for the treatment of Traumatic Brain Injury.

CONCLUSION

Our study revealed that ICP-monitored therapy has no significant statistical superiority over the unmonitored group. It is suggested that ICP monitoring may be used as an indicator of disease severity rather than a treatment variable along with the other factors of multimodal management to treat severe traumatic brain injury.

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Additional Information

Disclosures: Authors report no conflict of interest.
Ethical Review Board Approval: The study was conformed to the ethical review board requirements.
Human Subjects: Consent was obtained by all patients/participants in this study.
Conflicts of Interest:
In compliance with the ICMJE uniform disclosure form, all authors declare the following:
Financial Relationships: All authors have declared that they have no financial relationships at present or within the previous three years with any organizations that might have an interest in the submitted work.
Other Relationships: All authors have declared that there are no other relationships or activities that could appear to have influenced the submitted work.

AUTHORS CONTRIBUTIONS:

Sr.#	Author's Full Name	Intellectual Contribution to Paper in Terms of:
1.	Usman Ahmad Kamboh	1. Study design and methodology.
2.	Adeel Rauf, & Sana Jamal	2. Paper writing.
3.	Sana and Mehreen	3. Data collection and calculations.
4.	Mahwish Manzoor, & Naseer ud Din	4. Analysis of data and interpretation of results.
5.	Nazir Ahmed, & Kashif Sultan	5. Literature review and referencing.
6.	Manzoor Ahmad	6. Editing and quality insurer.