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ORIGINAL ARTICLE

From concussion to control: Evaluating antiepileptic drug use in mild to moderate traumatic brain injury.

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ABSTRACT… Objective: To assess the effectiveness of prophylactic AEDs in preventing early and late post-traumatic seizures in patients with mild to moderate TBI. **Study Design:** Randomized Control Trial study. **Setting:** Department of Accident and Emergency, Farooq Hospital Islamabad. **Period:** March 2024 to September 2024. **Methods:** A total of sixty-two patients were selected from the department of Accident and Emergency with mild to moderate TBI (Glasgow Coma Scale [GCS] 9–15) admitted within 24 hours of head injury. Participants were divided into two groups: Group A (n=31) received prophylactic AEDs (levetiracetam 500 mg twice a day) for 7 days, while Group B (n=31) patients did not receive prophylaxis. Patients were followed for 7 days for early PTS and 3 months for late PTS. Data were analyzed using chi-square and independent sample t tests. **Results:** Post-traumatic seizure was common in both groups, affecting 3 patients (9.7%) in each. In Group A (prophylactic), all patients were improved and neurologically stable at discharge and after three months of follow-up. In group B (non-prophylactic), 28 (90.3%) patients were improved and neurologically stable at discharge and after three months of follow-up, while 3 (9.7%) patients had deteriorated and had mild neurological deficits. **Conclusion:** It was concluded that the overall incidence of post-traumatic seizure was low in mild to moderate traumatic brain injury. The incidence was similar for both prophylactic and non-prophylactic groups, with three patients in each group experiencing seizures.

Key words: Antiepileptic Drug, Prophylactic, Post-traumatic Seizures, Traumatic Brain Injury.

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INTRODUCTION

Physicians in hospital emergency departments are specially trained to recognize and address urgent medical issues using defined clinical guidelines. In emergency departments, traumatic brain injury (TBI), which is characterized as a disruption in normal brain function due to the head injury, continues to be a critical and resource-intensive challenge. The majority of emergency visits globally are caused by TBI, which puts a significant burden on emergency physicians and healthcare systems.[1,2] According to recent estimates from the Global Burden of Disease (GBD) 2021 study, there were roughly 20.8 million new cases of TBI worldwide in 2021, with nearly 37.9 million people living with TBI. This shows an increasing burden of TBI, despite age-standardized incidence decreases in some countries.[3,4] Despite the lack of comprehensive national surveillance data on TBI in Pakistan, several tertiary hospital studies in Pakistan continue to show TBI as a major emergency situation, mostly associated with road traffic accidents and other trauma mechanisms.[5]

A major devastating complication of TBI is the development of post-traumatic seizures (PTS), which are characterised by abnormal electrical discharges triggered by structural and metabolic changes in damaged brain tissue.[6] Clinically PTS is classified according to its onset: early seizures, which occur during the first week of TBI, and late seizures, which occur beyond, with the latter frequently resulting in post-traumatic epilepsy (PTE).[6,7] It is also important that severity of TBI has a substantial impact on the occurrence of PTS. Early seizures have been reported in up to 17.7% of patients with moderate to severe TBI, and that incidence increases with injury severity.[7,8] In the emergency and neurocritical care settings, physician first priority is the termination of seizures using the benzodiazepines or antiepileptic drugs (AEDs). This type of management also includes correcting metabolic abnormalities, maintaining appropriate oxygenation, and

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continuously monitoring electroencephalograms in high-risk TBI patients to identify non-convulsive seizures.[9,10] Prophylactic use of AEDs has been thoroughly investigated, and results from different meta-analyses and randomised trials show that anticonvulsant prophylaxis considerably lowers the incidence of early PTS; however, it does not prevent late PTS.[10,11] Phenytoin is the most widely studied agent for early seizure prevention, whereas levetiracetam has grown in popularity due to its favourable safety profile and fewer medication interactions, albeit current data do not reveal a clear superiority of one agent over another.[10-12]

Post-traumatic seizures are a frequent and highly serious complication of traumatic brain injury, particularly in the early stages, and are linked to prolonged hospitalisation and poor neurological prognosis. Prophylactic antiepileptic medication use may lower the incidence of early PTS, but there is still uncertainty about the most suitable patient selection, drug selection, and practical efficacy across various injury severities. While prophylactic AED therapy is recommended in severe TBI, its role in mild to moderate cases remains controversial. Therefore, this study aims to assess the effectiveness of prophylactic AEDs in preventing early and late post-traumatic seizures in patients with mild to moderate TBI.

METHODS

A randomized control trial study on mild-to-moderate traumatic brain injury patients was performed in the Accident and Emergency department of Farooq Hospital, Islamabad, for a duration of six months, from 20th March 2024 to 20th September 2024. The ethical approval for the study was obtained from the Ethical Review Committee of Akhtar Saeed Medical College, Islamabad, which approved the study (No. IRB0604, dated: 20th March 2024). Written consent is also obtained either from the patients or from their relatives after explaining the objectives and benefits of the study.

The study includes the adult patients of either gender, aged 18–65 years, who presented to the emergency department with blunt head trauma within 24 hours of trauma. Patients were diagnosed with traumatic brain injury on the basis of computed tomography (CT), which shows small contusions, subarachnoid haemorrhage, and linear skull fractures. They were further categorised into mild and moderate traumatic brain injury on the basis of the Glassgow Coma Scale (GCS) score on admission. Mild injury was confirmed on a GCS score ranging from 13 to 15, while moderate injury was confirmed on a GCS score ranging from 9 to 12. The study excludes the patients with severe injury confirmed on a GCS score of 8 or less. Patients presenting with penetrating brain injury, a history of seizure disorder, chronic use of antiepileptic drugs (AEDs), or hepatic or renal dysfunction were also excluded.

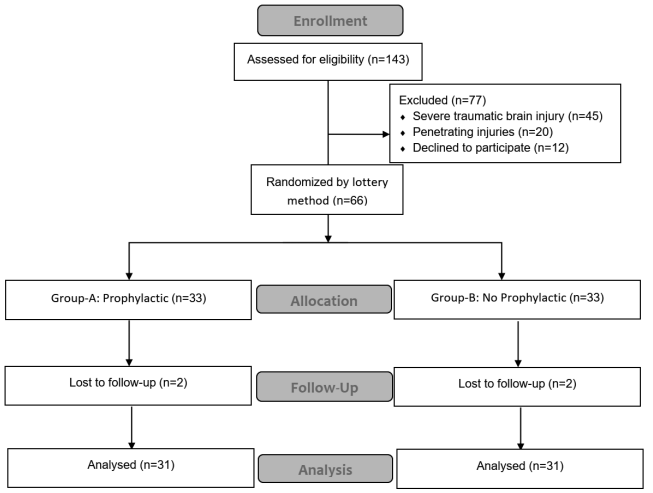
All eligible patients who presented in the emergency department with traumatic brain injury throughout the six-month study period were used to calculate the sample size. A total of 143 patients were evaluated for study inclusion criteria. Of these, 45 were excluded because of severe traumatic brain injury, 20 had penetrating injuries, and 12 patients refused to participate. The remaining 62 patients were enrolled for the final analysis (Figure 1). Participants were divided into two groups by using the lottery method: Group A (n=31) received prophylactic AEDs (levetiracetam 500 mg twice a day) for 7 days, while Group B (n=31) patients did not receive prophylaxis. Patients were followed for 7 days for early PTS and 3 months for late PTS. All data were recorded into a standard case report form and analysed with Statistical Package for Social Sciences (SPSS version 26). Data was analysed using chi-square and independent sample t tests by using a p-value of ≤0.05 as significant.

RESULTS

Of the 62 patients with mild to moderate TBI, male patients were 27 (87.1%) and 22 (71.0%), while female patients were 4 (12.9%) and 9 (29.0%) in group A (prophylactic) and group B (non-prophylactic), respectively. The mean age was 36.03 ± 16.52 years in group A (prophylactic) and 35.36 ± 11.45 years in group B (non-prophylactic). The most common mechanism of traumatic brain injury was road traffic accidents (RTAs) in 25 (80.6%) and 21 (67.7%) patients, followed by falls in 5 (16.1%) and 9 (29.0%) patients in group A (prophylactic) and group B (non-prophylactic), respectively.

FIGURE-1

Flow diagram of sample size



In Group A (prophylactic), the most frequent clinical presentation was loss of consciousness, observed in 8 patients (25.8%), followed by vomiting in 6 patients (19.4%), headache in 5 patients (16.1%), and post-traumatic amnesia in 4 patients (12.9%). In contrast, headache was the most common presenting symptom in Group B (non-prophylactic), reported in 6 patients (19.4%), followed by loss of consciousness and post-traumatic amnesia, each noted in 4 patients (12.9%). The mean GCS score was 12.97 ± 1.97 in group A (prophylactic) and 13.36 ± 1.58 in group B (non-prophylactic). On the basis of GCS score, TBI severity was mild in 21 (67.7%) and 24 (77.4%) patients and moderate in 10 (32.3%) and 7 (22.6%) patients in group A (prophylactic) and group B (non-prophylactic), respectively. On clinical examination, pupils were normal in most cases in both groups (24 (77.4%) vs. 25 (80.6%)). Similarly, CT scan findings were also normal in most cases in both groups (21 (67.7%) vs. 29 (93.5%)) [Table-I].

The mean pulse rate was 101.13 ± 17.67 in group A (prophylactic) and 102.26 ± 16.18 in group B (non-prophylactic). The mean pulse rate in both groups was >100 beats/min, showing mild tachycardia, which is commonly observed in trauma patients. The mean systolic blood pressure was 139.68 ± 14.72 mmHg in group A (prophylactic) and 136.77 ± 13.51 mmHg in group B (non-prophylactic), while diastolic blood pressure was 86.77 ± 6.53 mmHg in group A (prophylactic) and 136.77 ± 13.51 mmHg in group B (non-prophylactic). The mean systolic and diastolic blood pressure in both groups was mildly elevated at presentation, which is also commonly observed in trauma patients. The mean respiratory rate was 16.39 ± 0.56 breaths/min in group A (prophylactic) and 16.29 ± 0.46 breaths/min in group B (non-prophylactic). The mean respiratory rate in both groups was stable, and there was no immediate respiratory distress at presentation in trauma patients. The mean temperature was 99.73 ± 0.35°F in group A (prophylactic) and 99.78 ± 0.33°F in group B (non-prophylactic). The mean temperature in both groups was normal, and there was no fever at presentation in trauma patients [Table-II].

Post-traumatic seizure was common in both groups, affecting 3 patients (9.7%) in each. In Group A (prophylactic), 2 patients (6.5%) experienced generalised seizures, and 1 patient (3.2%) had a focal seizure. In Group B (non-prophylactic), all 3 patients (9.7%) presented with generalised seizures. On the basis of time, in Group A (prophylactic), 1 patient had an early seizure, and 2 patients (6.5%) had late seizures. In Group B (non-prophylactic), 2 patients (6.5%) experienced late seizures, while 1 patient (3.2%) presented with both early and late seizures. In Group A (prophylactic), all patients were improved and neurologically stable at discharge and after three months of follow-up. In contrast, in group B (non-prophylactic), 28 (90.3%) were improved and neurologically stable at discharge and after three months of follow-up, while 3 (9.7%) patients had deteriorated and had mild neurological deficits at discharge and after three months of follow-up. All three patients presented repeatedly to the emergency department with episodes of status epilepticus [Table-III].

DISCUSSION

In this randomized controlled trial including 62 patients diagnosed with mild to moderate traumatic brain injury, the overall incidence of post-traumatic seizure was low. In fact, the incidence was similar for both groups, with three patients in each group experiencing seizures, making up 9.7% of all cases. Generalised seizures constituted the predominant seizure type in both study groups.

TABLE-I

Baseline Characteristics in TBI Patients (n=62)

A (n=31)		Group		P-Value
		B (n=31)		
Gender	Male	27 (87.1%)	22 (71.0%)	0.119
	Female	4 (12.9%)	9 (29.0%)	
Age	Mean ± SD	36.03 ± 16.52	35.36 ± 11.45	0.852
Mechanism of Injury	RTAs	25 (80.6%)	21 (67.7%)	0.322
	Fall	5 (16.1%)	9 (29.0%)	
	Assault	1 (3.2%)	0 (0.0%)	
	Sports Injury	0 (0.0%)	1 (3.2%)	
Time from Injury to Hospital Presentation	≤1 Hour	13 (41.9%)	16 (51.6%)	0.445
	>1 Hour	18 (58.1%)	15 (48.4%)	
Clinical History	Loss of Consciousness	8 (25.8%)	4 (12.9%)	0.199
	Vomiting	6 (19.4%)	1 (3.2%)	0.279
	Headache	5 (16.1%)	6 (19.4%)	0.740
	PTA	4 (12.9%)	4 (12.9%)	1.000
GCS Score	Mean ± SD	12.97 ± 1.97	13.36 ± 1.58	0.398
TBI Severity	Mild	21 (67.7%)	24 (77.4%)	0.445
	Moderate	10 (32.3%)	7 (22.6%)	
Pupils	Normal	24 (77.4%)	25 (80.6%)	0.922
	Unequal	3 (9.7%)	3 (9.7%)	
	Sluggish	4 (12.9%)	3 (9.7%)	
Focal Neurological Deficit	Present	2 (6.5%)	1 (3.2%)	0.544
	Absent	29 (93.5%)	30 (96.8%)	
CT Findings	Normal	21 (67.7%)	29 (93.5%)	0.098
	Subdural Hematoma	5 (16.1%)	0 (0.0%)	
	Mild Brain Swelling	2 (6.5%)	0 (0.0%)	
	Mild to Moderate Brain Swelling	1 (3.2%)	0 (0.0%)	
	Epidermal Hematoma	1 (3.2%)	1 (3.2%)	
	Skull Fracture	1 (3.2%)	1 (3.2%)	

Group A: Prophylactic Group; Group B: Non-Prophylactic Group; RTAs: Road Traffic Accidents; PTA: Post-traumatic amnesia; GCS: Glasgow Coma Scale; CT: Computed Tomography

TABLE-II

Vitals in TBI Patients (n=62)

Vitals	Group		P-Value
	A	B	
Pulse (beats/min)	101.13 ± 17.67	102.26 ± 16.18	0.794
Systolic Blood Pressure (mmHg)	139.68 ± 14.72	136.77 ± 13.51	0.422
Diastolic Blood Pressure (mmHg)	86.77 ± 6.53	86.45 ± 8.77	0.870
Respiratory Rate (breaths/min)	16.39 ± 0.56	16.29 ± 0.46	0.460
Temperature (°F)	99.73 ± 0.35	99.78 ± 0.33	0.525

Group A: Prophylactic Group; Group B: Non-Prophylactic Group.

TABLE-III

Outcome in TBI Patients (n=62)

		Group		P-Value
		A (n=31)	B (n=31)	
Post-Traumatic Seizure	Present	3 (9.7%)	3 (9.7%)	1.000
	Absent	28 (90.3%)	28 (90.3%)	
Type of PTS	Generalized	2 (6.5%)	3 (9.7%)	0.273
	Focal	1 (3.2%)	0 (0.0%)	
Overall PTS	Early	1 (3.2%)	0 (0.0%)	0.572
	Late	2 (6.5%)	2 (6.5%)	
	Both	0 (0.0%)	1 (3.2%)	
Length of Stay (Days)	Mean ± SD	2.23 ± 2.20	1.58 ± 1.48	0.181
Neurological Status	Normal	31 (100.0%)	28 (90.3%)	0.076
	Mild	0 (0.0%)	3 (9.7%)	
Final Outcome	Improved	31 (100.0%)	28 (90.3%)	0.076
	Deteriorated	0 (0.0%)	3 (9.7%)	

Group A: Prophylactic Group; Group B: Non-Prophylactic Group.

In the prophylactic group, two patients experienced generalised seizures, while one patient developed a focal seizure. In comparison, all three patients in the non-prophylactic group who developed post-traumatic seizures presented with generalised seizure activity. Late seizures were the most common type of post-traumatic seizure on the basis of time, observed in two patients in each group, while there was only one patient with an early seizure in the prophylactic group and only one patient with both early and late seizures in the non-prophylactic group. This result indicates there was no statistically significant reduction in the frequency of seizures in our sample of patients with mild to moderate TBI when prophylactic AEDs were regularly used.

Numerous studies from different regions have reported a relatively low incidence of post-traumatic seizures among patients with mild to moderate traumatic brain injury. A recent systematic review by Pease et al. reported post-traumatic seizure rates ranging from 0% to 8% across eight cohort studies. The authors also noted a modest trend toward reduced early post-traumatic seizures with the use of prophylactic antiepileptic drugs; however, none of the individual studies demonstrated a statistically significant difference.[11]

Similarly, Candy et al. reported an early post-traumatic seizure rate of 2.9% in patients who received antiepileptic drugs compared with 3.5% in those who did not.[12] Several other studies have also documented a low prevalence of post-traumatic seizures in mild to moderate traumatic brain injury. Reported seizure rates in prophylactic versus non-prophylactic groups include 0.7% and 3.0% by Pease et al., 0% and 0.6% by Liou et al., 2% and 4% by Pingue et al., 4% and 0% by DJohn et al., 3% and 5% by Faropoulos et al., and 0% and 1% by Hazama et al., respectively.[13-18]

These discrepancies are probably caused by changes in the severity of injury, seizure diagnosis criteria, and surveillance intensity between studies. The definition and documentation of seizure episodes may also be a factor in variations in reported seizure rates. Narrative studies showing that individuals with cerebral haemorrhage, cortical contusions, or temporal lobe involvement are more likely to experience both early and late seizures further corroborate the impact of lesion features. On the other hand, seizure rates are typically higher in studies where structural brain lesions or intracranial haemorrhages are more commonly found on imaging.[11-19]

Another significant finding of our study was the overall clinical and neurological outcomes at discharge

and after three months of follow-up. In this study, all patients who were managed in the prophylactic AED group showed clinical improvement during the follow-up period, with no observed neurological deterioration at discharge and after three months of follow-up. In contrast, among patients who did not receive prophylactic AED therapy, clinical deterioration was noted in three cases. These patients were not only clinically deteriorated but also had mild neurological deficits at discharge and after three months of follow-up. All three patients presented repeatedly to the emergency department with episodes of status epilepticus.

Direct comparison with our findings is limited since the majority of prior research on seizure prophylaxis in mild to moderate TBI has focused more on seizure incidence than on clinical or neurological outcomes. Candy et al. found no discernible difference in long-term functional outcomes between both groups, but they did note that patients with additional risk factors, such as intracranial haemorrhage or cortical contusions, were more likely to experience neurological deterioration during the acute phase.[12]

Similarly, Pingue et al. observed that antiepileptic medication use was linked to increased early neurological stability in a selected group of patients, even while seizure prophylaxis did not significantly lower seizure frequency.[15] Pease et al. found no conclusive advantage of preventive AEDs on long-term neurological outcomes in their comprehensive review and meta-analysis.[13] This was mostly because functional endpoints were reported inconsistently and inadequately across the included studies. All of these results point to the possibility that factors other than seizure prevention may have an impact on neurological outcomes following mild to moderate traumatic brain injury.

This distinction raises the possibility that prophylactic AED usage may protect people who have mild to moderate traumatic brain injury from early neurological deterioration. These results support the use of preventive AEDs in certain patients, especially those who are more likely to experience subsequent neurological problems, despite a fact that study was performed on very small sample size. To provide firm suggestions, more research with bigger cohorts is needed.[12,13,19]

During the evaluation of the findings, it is important to take into account the numerous drawbacks of this study. First, patients with mild to moderate TBI were included in the study. Therefore, the overall results cannot be applied to patients with severe TBI, who may have distinct clinical and neurological outcomes and a higher likelihood of seizures. The results' relevance to closed head injuries alone was further limited by the exclusion of patients with penetrating brain injuries. Similarly, patients with penetrating brain injuries were excluded, which further restricts the study application to closed head traumas. Second, this was a single-centre study; thus, it may have been influenced by local patient characteristics, institutional procedures, and management protocols. These variables may vary between centres and have an impact on neurological results as well as seizure incidence, which would reduce external validity. In addition, the small number of participants limits the statistical power to identify modest differences between the prophylactic and non-prophylactic groups, especially for outcomes like post-traumatic seizures that have low event rates. Finally, while follow-up was done for up to three months, longer-term outcomes, such as late post-traumatic seizures and functional recovery after this time, were not evaluated. Further studies involving larger patient populations across multiple centres, with more inclusive eligibility criteria and extended follow-up, are necessary to more clearly define the role of prophylactic antiepileptic therapy in the management of mild to moderate traumatic brain injury.

CONCLUSION

It was concluded that the overall incidence of post-traumatic seizure was low in mild to moderate traumatic brain injury. The incidence was similar for both prophylactic and non-prophylactic groups, with three patients in each group experiencing seizures. In the prophylactic group, all patients demonstrated clinical improvement and remained neurologically stable at discharge as well as at three-month follow-up. In contrast, patients in the non-prophylactic group showed evidence of clinical deterioration, with mild neurological deficits observed during follow-up.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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AUTHORSHIP AND CONTRIBUTION DECLARATION	
1	**Muhammad Nawaz:** Topic selection, manuscript revision.
2	**Inayat Ali Khan:** concept, critically manuscript review.
3	**Bella Virk:** Data collection, writing, data interpretation.
4	**Ihsan Ullah Khan:** Critically review.
5	**Abdul Sami:** Data interpretation.
6	**Binish Gull Arshad:** Critical revisions.