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Original Research Article

Retrospective, Prospective Observational Study of the Impact of Severe Traumatic Brain Injury Management Protocol on Short Term Outcome

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ABSTRACT

Traumatic brain injury (TBI) is one of the leading causes of mortality and morbidity worldwide, especially in low and middle income countries. The outcome of TBI does not only depend on the initial trauma, but is also affected by secondary neurological damage that follows the trauma. These secondary effects can be reduced by implementing an evidence based protocol of management for TBI.
Aim: To evaluate the effect of TBI management protocol on short term outcome.
Methods: retrospective evaluation of medical records of severe TBI patients admitted to ICU during three months prior to implementing the protocol for short term outcome (group 1), then prospective observation of short term outcome of patients with severe TBI admitted to ICU, and managed with the TBI protocol for three months.
Results: there was statistically significant difference between the two groups regarding the GCS after 7 days (p=0.017), the length of ICU stay (p=0.009) and the duration of mechanical ventilation (p=0.013).
Conclusion: There is some evidence that following an evidence based protocol of management for severe TBI improves short term outcome.

Key words: traumatic brain injury, critical care, outcome.

INTRODUCTION

Traumatic brain injury (TBI) is considered to be one of the leading causes of mortality and morbidity worldwide, as about 1.5 million people die annually and several millions receive emergency treatment. [1]

Moreover, victims of TBI suffer loss of productive years and potential outcome making it a major public health problem, in addition to the financial burden imposed on healthcare systems, [2,3] the majority of which (90%) affects low and middle income countries. [4]

Since motor vehicle accidents (MVA) is one of the most important causes of TBI, [5] it is easy to imagine the magnitude of the problem in Saudi Arabia, where the road fatalities per 100,000 inhabitants per year is 24.8, and the road fatalities per 100,000 motor vehicles is 103. [6]

It is of at most importance to understand that most of the neurological damage from TBI does not occur at the time of impact, but develops over the hours and days following the incidence of the trauma, and

consequently better outcomes of severe TBI can be obtained if the secondary (delayed) neurological insults are prevented. [7] This effect of prevention of secondary damage was demonstrated by the reduction of mortality rates of severe TBI from 50% to 25% over the last 30 years. [7]

The reduction in the trend of mortality and better outcomes due to TBI is the result of the use of evidence-based protocols in the management of TBI, with emphasis on maintaining cerebral perfusion pressure (CPP). [8,9]

The impact of implementing evidence-based protocols and guidelines in the management of severe TBI was proven by several studies, that have clearly demonstrated substantially better outcomes such as mortality rate, functional outcome scores, length of hospital stay, and costs. [2,10]

Study design:

This study was carried out in the ICU of King Saud Medical City, Riyadh, KSA. Where we started in October / 2014 to implement an evidence-based protocol of management for severe TBI, based on the third edition of the guidelines of the management of severe traumatic brain injury published by the Brain Trauma Foundation in the Journal of Neurotrauma 2007. [11]

Retrospective part: We reviewed the medical records of all severe TBI patients admitted to our ICU during the months of July, August, and September 2014.

Prospective part: we reviewed medical records of all severe TBI patients admitted to our ICU during October, November, and December 2014.

Inclusion criteria:

- Age: 12 years or more.
- Severe TBI: defined as Glasgow Coma Scale (GCS) = 8 or less on admission.

Exclusion criteria from outcome evaluation:

- Death within 7 days of admission to ICU, due to any cause.

Collected data:

- Demographic Data: Age, gender, nationality, and admission GCS.
- Outcome:
  - Primary: GCS 7 days after admission to ICU.
  - Secondary: Duration of mechanical ventilation, ICU length of stay (LOS), and requirement of tracheostomy.

Groups:

Patients were stratified into two groups:

1- Pre-protocol group: Severe TBI admitted to ICU 7-9/2014

2- Post-protocol group: Severe TBI admitted to ICU 10-12/2014

Statistical analysis:

For age, ICU LOS, and duration of mechanical ventilation, mean ± standard deviation was calculated, and groups were compared by 2 sample t test. For nationality, gender, death before 7 days of admission, and requirement of tracheostomy, percentage was calculated, and groups were compared by Fisher's exact test of two proportions.

For the primary outome: Comparison of GCS on admission and after 7 days within each group, median was calculated, and groups were compared by Mann-Whiteny-U test.

All statistical tests were set to a confidence level of 95%, and p value considered statistically significant if less than 0.05

Normality of distribution for all collected data was evaluated by Shapiro-Wilk test.

All statistical tests were calculated with SPSS 20® for windows.

RESULTS

1- Pre-protocol group (retrospective review): During the months of July, August, and September 2014, 118

patients were admitted to our ICU with severe TBI, nine patients were excluded because of age (less than 12 years), 109 patients were included in the initial assessment, and five patients died within 7 days, so they were excluded from outcome evaluation, which included 104 patients in this group.

2- Post-protocol group (prospective review): During the months of October, November, and December 2014, 129 patients were admitted to our ICU with severe TBI, twelve patients were excluded because of age (less than 12 years), 117 patients were included in the initial assessment, and seven patients died within 7 days, so they were excluded from outcome evaluation, which included 110 patients in this group. (Figure 1)

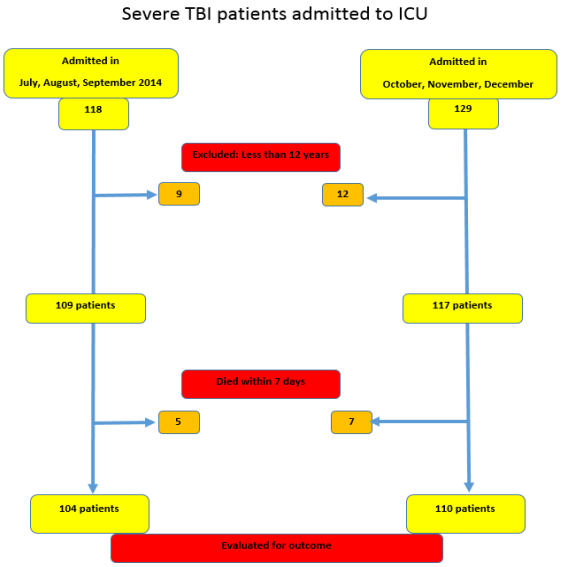

Figure 1: Inclusion and exclusion of patients in both groups.

Mean age of group 1 was 32.31±12.19 years, while mean age of group 2 was 31.9±12.08 years, and there was no difference between both groups (p= 0.798), male gender was more prevalent in both groups, constituting 89 patients (85.6%) of group 1, and 96 patients (87.3%) of group 2, with no statistical difference between the two groups (p= 0.84), similarly, Saudi nationality prevailed in both groups, making up 80 patients (76.9%) of group 1 patients, and 88 patients (80%) of group 2 patients. Again, without statistical difference between the two groups (p= 0.62). All data of both groups were normally distributed.

The median GCS on admission was the same in both groups, with a value of six, and an insignificant p value of 0.562 (table 1).

Table 1: demographic data, and initial GCS of both groups.

	Pre-protocol (n=109)	Post-protocol (n=117)	p value
Age years (mean±SD)	32.31±12.19	31.9±12.08	0.798
Gender Males: (n,%)	89 (81.7%)	96 (82.1%)	0.84
Nationality Saudi (n,%)	80 (73.4%)	88 (75.2%)	0.62
Admission GCS Median	6	6	0.562

The primary outcome (GCS after 7 days) for group 1 had a median of value of eight, whereas, group 2 had a median value of nine, comparison of the two groups showed a significant p value of 0.17. Comparison of the two groups for the secondary outcome showed statistically significant differences concerning the duration of mechanical ventilation, where the mean duration for group 1 was 7.34±1.2 days, while that of group 2 was 6.9±1.45 days with a p value of 0.013, similarly, there was a difference between both groups when compared for the ICU length of stay, as group 1 had a mean duration of 11.84±3.03 days, while group 2 had a mean ICU length of stay of 10.77±2.83 days, with a significant p value of 0.009.

When the two groups were compared for tracheostomy requirement, there was no significant difference, with percentages of 50% and 39.1% for group 1 and 2 respectively (p = 0.13), and the same was

also observed for comparison of death within seven days, as five patients (4.6%) from group 1 died within 7 days, while 7 patients (6%) from group 2 died within 7 days, p value was 0.77

Again, all data of both groups in the outcome comparison were normally distributed. (table 2, figure 2).

Table 2: Outcome comparison of both groups.

	Pre-protocol	Post-protocol	ρ value
GCS at 7 days median	8	9	0.017
Ventilator days (mean±SD)	7.34±1.2	6.9±1.45	0.013
ICU days (mean±SD)	11.84±3.03	10.77±2.83	0.009
Required tracheostomy (n,%)	52 (50%)	43 (39.1%)	0.13
Died before 7 days (n, %)	5 (4.6%)	7 (6%)	0.77

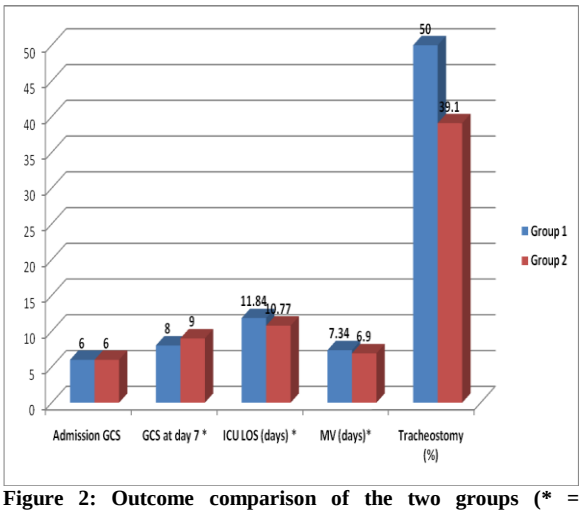

Figure 2: Outcome comparison of the two groups (* = significant p value)

DISCUSSION

The results of our study showed a predominance of male gender in both groups (81.7% and 82.1% in group 1 and 2 respectively), which is consistent with most of the published studies on TBI. [2,12] As well as a predominance of Saudi citizens, as expected in a study conducted in the largest Ministry Of Health in Saudi Arabia. There was no difference, however, between the two groups of the study neither in regard to demographic data, nor to admission GCS.

The primary outcome of the study, which is the GCS after seven days, was significantly different between both groups (p = 0.017), and can be attributed to the implementation of an evidence-based protocol of management for severe TBI cases. Despite being statistically significant at a p value less than 0.05, the difference cannot be said to be huge or great, and this may be attributed to the fact that we in the ICU have been actually implementing most if not all elements of the guidelines, but not in a systematic organized way, and what the protocol added to us was an organized way of implementation, that does not allow for any point or element to be missed.

Secondary outcome measures also showed significant difference between both groups, as the ICU length of stay in group 2 was lower than that of group 1 (p=0.009), with a mean duration of 10.77±2.83 days in group 2, which is higher than that reported in some studies, [2] but lower than others. [13] Similarly, the duration of mechanical ventilation in group 2 patients was significantly lower than that of group 1 (p=0.013), group 2 patients had a mean duration of mechanical ventilation of 6.9 ±1.45 days, which is better than that reported in a study conducted in 2014, [14] where the mean duration of mechanical ventilation was 14.1± 5.7 days.

Yet again, despite a statistically significant difference between the study groups in regard to ICU length of stay and duration of mechanical ventilation, the difference was not huge or tremendous, and this is also attributed to the fact that we were previously practicing almost all components of severe TBI protocol, but in a disorganized way, and development of the protocol helped to organize our practices.

The results of our study showed no significant difference between the two groups in the requirement of tracheostomy (p=0.13), despite an improvement in GCS,

which indicates that early tracheostomy does not improve the duration of mechanical ventilation, the same was concluded in a study on early tracheostomy in TBI patients, [14] where the p value of the difference of the duration of mechanical ventilation was 0.23 between early tracheostomy and no early tracheostomy groups.

Finally, death rates at 7 days were similar in both groups of our study, which could not be compared to other studies that report mortality rates at much longer periods, and even the significant decrease in mortality rates at 14 days reported by Fakhry SM et.al [2] was close to the level of insignificance with a p value of 0.047

CONCLUSION

There are some evidence indicating that implementing an evidence-based protocol for the management of severe TBI, improves GCS, ICU length of stay, and duration of mechanical ventilation. But it does not affect short term mortality, nor decreases the need of tracheostomy.

Limitation:

This study was prospectively conducted over the period of 3 months, with retrospective evaluation of patients' records 3 months earlier. We believe that more conclusive result may be achieved with longer periods of study. In addition, the long term outcome of the patients treated with the management protocol also needs to be studied.

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