American Journal of Nursing Research, 2022, Vol. 10, No. 1, 34-40
Available online at http://pubs.sciepub.com/ajnr/10/1/5
Published by Science and Education Publishing
DOI:10.12691/ajnr-10-1-5

Integration of Evidence-Based Care Bundle in Traumatic Brain Injury Patients' Care

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Received January 20, 2022; Revised February 23, 2022; Accepted March 01, 2022

Abstract Traumatic brain injury (TBI) remains an increasingly prevalent cause of death and disability worldwide. Despite the growing evidence that supports the use of an evidence-based care bundle in the emergency department, little is known about this bundle in caring for TBI patients in Egypt. **This study aimed to** investigate the effect of implementing an evidence-based care bundle on the outcome of TBI patients. **Design**: A quasi-experimental research design was used. **Setting**: The study was conducted in the emergency department of the Emergency Hospital, Mansoura University in Egypt. **Subjects:** A convenience sample of 52 patients aged ≥ 18 years of both genders, who were admitted to the previously mentioned setting included in this study. The patients were divided into two groups: control and bundle groups, with 26 patients in each group. **Tools**: Data were collected using one tool: Traumatic Brain Injury Patients' Assessment Sheet. **The results**: There was improvement in the bundle group patients' GCS, pupil size and reactivity, and survival, which was statistically significant except for patients' survival. **Conclusion and Recommendations:** Evidence-based care bundle improves TBI patients' outcomes. Therefore, it is recommended to use this bundle as a fundamental part of the initial nursing care for TBI patients in the emergency department.

Keywords: *emergency nursing, evidence-based care bundle, patient outcome, traumatic brain injury*

Cite This Article: Shimaa Mohamed Awad, Hanaa Hussein Ahmed, and Nahed Kandeel, "Integration of Evidence-Based Care Bundle in Traumatic Brain Injury Patients' Care." *American Journal of Nursing Research*, vol. 10, no. 1 (2022): 34-40. doi: 10.12691/ajnr-10-1-5.

1. Introduction

Trauma is the main cause of death, hospitalization, and long-term impairment [1]. Globally, one in every 10 deaths is due to trauma [2]. Traumatic brain injury (TBI) is a major type of trauma and the leading cause of death and disability universally [3]. TBI affects 69 million people worldwide each year [4]. In Egypt, it affects mainly young males with road traffic accidents, and 20.3% of them usually experience severe injuries [5]. Thus, identifying the characteristics of head injury patients is extremely important [6].

The Centers for Disease Control and Prevention (2021) defined traumatic brain injury as "disruption in the normal function of the brain that can be caused by a bump, blow, or jolt to the head, or a penetrating head injury" (CDC, P.1) [7]. It can impair a person's cognitive, physical, or emotional functioning that may last for years or be lifelong [7]. TBI causes two separate stages of brain damage. At the time of trauma, primary brain injury occurs and its damage is irreversible and unchangeable. After a few hours to days, the process of secondary brain injury begins. This process occurs due to elevated intracranial pressure (ICP) or systemic hypotension, hypoxia, and brain herniation. These factors can have a significant effect on patients' outcomes. Hence, the management of TBI patients focuses on minimizing secondary brain injury [8].

To maintain sufficient brain perfusion, limit neurological cell death, and minimize long-term disability, TBI patients need continuous monitoring and urgent management [9]. Delayed, incorrect, or unsuitable care resulted in higher patient mortality and worse long-term disability. While continuous appropriate TBI care can enhance patients' outcomes and decrease the health care cost [10]. Therefore, immediate assessment and management of patients in the emergency department (ED) is crucial for a better outcome [11].

Some international studies showed that the implementation of care bundles in emergency care improved patients' outcomes [12,13,14]. The Institute for Healthcare Improvement (2022) defined a care bundle as "a structured way of improving the processes of care and patient outcomes: a small, straightforward set of evidence-based practices—generally three to five—that when performed collectively and reliably, have been proven to improve patient outcomes" (P.1) [15]. The TBI care bundle was developed using a primary survey process. It consists of the best available evidence related to airway securement and cervical spine immobilization, oxygenation and ventilation management, circulation and fluid resuscitation, and disability and ICP control [16].

Evaluation of outcome is a cornerstone for knowing to what extent the bundle of care improves the patient's condition [17]. For this, the Glasgow Coma Scale (GCS) is commonly used to evaluate TBI patients' outcomes [18]. It is a tool for determining three characteristics of a patient's responsiveness, including eye, verbal, and motor responses [19]. Prognosis information can be found in each of these characteristics. The GCS score declines were linked to higher rates of mortality and negative consequences. The patients' outcomes were also reflected in their pupil reactivity. TBI patients who had no pupil reaction died at a higher rate [18].

An American study revealed that compliance with evidence-based guidelines at the ED was significantly associated with a reduction in the mortality rate of TBI patients [14]. Hence, this study recommended the implementation of this bundle when caring for TBI patients.

From our empirical observations and clinical experience in the ED, we noted that there are no evidence-based care guidelines or bundles used in managing TBI patients in the ED of Mansoura Emergency Hospital. Research which evaluated the effect of these guidelines and bundles on patients’ outcomes is scarce, particularly, in Egypt, despite, the magnitude of the problem and the availability of published guidelines for TBI patient care. This inspired us to integrate the evidence-based care bundle into TBI care in the ED to contribute to the body of knowledge related to the care of TBI patients.

1.1. Aim of the Study

The current study aimed to evaluate the effect of implementing an evidence-based care bundle on the outcomes of TBI patients**.**

1.2. Research Hypothesis

Traumatic brain injury patients who receive the evidence-based care bundle is expected to have improvements in their outcomes compared with patients who receive routine hospital care.

1.3. Operational Definition

Patient’s outcomes: in the context of this study, patient’s outcomes include the following:

- The GCS improves at discharge from the ED more than an admission to it.
- Pupil size and reactivity return to normal following discharge from the ED.
- Survival of the patient: the patient is still alive after receiving the care bundle.

2. Method

2.1. Research Design

A quasi-experimental-two groups pretest/posttest design was used to conduct the current study.

2.2. Setting

The study was conducted at the ED of Emergency Hospital, Mansoura University. There are two rooms in the ED: the accident resuscitation room and the medical resuscitation room. These rooms are well equipped with supplies, equipment, and advanced technology required for emergency services. The accident resuscitation room can receive four patients at admission, while the medical resuscitation room can receive seven patients who need continuous monitoring. The nurse-patient ratio in the resuscitation rooms is nearly 1:2.

2.3. Subjects

The study involved a convenience sample of 52 patients aged ≥ 18 years of both genders who were admitted to the previously mentioned setting. Eligible patients were randomly assigned into two groups: the control group and the bundle group (26 patients in each group). The control group involved the patients who had received the routine hospital nursing management while the bundle group involved the patients who had received the TBI evidence-based care bundle.

2.3.1. Inclusion Criteria

Patients aged ≥18 years with GCS ≤12 were included in this study.

2.3.2. Exclusion Criteria

Patients who experienced cardiovascular disorders, metabolic disorders, and previous history of neurological disorders or had a history of addiction were excluded from this study.

2.3.3. Sample Size Calculation

The sample size was calculated using power analysis and sample size (PASS) software, version 11.0.8. A sample size of 26 patients in each group achieves an 85 % power to detect a difference between the group proportions of 0.3100. The used statistical test was the two-sided Z test with pooled variance with a significance level of 0.0164.

2.4. Tools of Data Collection

Data were collected using one tool that was developed by the primary investigator (PI) based on reviewing relevant literature [16,18,20].

Traumatic Brain Injury Patients’ Assessment Tool:

This tool consisted of three parts as follows:

Part I: Patient's Demographic Data

This part was used to address the patient's profile at admission, including age, gender, marital status, and date of admission.

Part II: Patient's Health Relevant Data

This part focused on the patient's history, the GCS [19], revised trauma score [21], vital signs at admission, pupil size and reactivity, mechanism of injury, and severity of trauma.

Part III: Traumatic Brain Injury Patient's Outcomes Evaluation Sheet:

This part was used to evaluate the effect of implementing the evidence-based care bundle on the TBI patients' outcomes. This part included the patient's survival, the GCS, pupil size, and response to light.

2.5. Validity and Reliability

The content validity of the tool was assessed by three experts from Critical Care and Emergency Nursing and two professors from the Faculty of Medicine, Mansoura University. Their feedback and recommendations were considered. While the reliability of the tool was tested using the Cohen's kappa test to determine inter-observer reliability. The result of Cohen's kappa equals 1 with a *P*-value of 0.025 indicating perfect agreement between both observers (the PI and the emergency health care provider).

2.6. Ethical Considerations

Ethical approval was obtained from the Research Ethics Committee of the Faculty of Nursing, Mansoura University. Informed consent was obtained from the patient's next of kin at admission after explaining the nature, benefits, and risks of the study. The next of kin were informed that participation in the study was voluntary and they had the right to accept or refuse to allow their patients to take part in this investigation. They were also informed that they had the right to withdraw their patients from the study at any stage without responsibility. Moreover, they were assured that patients' personal information would be kept confidential as there was no link between their names and the obtained data.

2.7. Data Collection Procedure

It included three phases as follows:

2.7.1. Preparation Phase

This phase lasted two months from September to October 2019. Official permission to conduct the study was obtained from the administrative authorities of the Emergency Hospital. Informed consent and the data collection tool were prepared, and the content validity and reliability of the tool were checked.

The PI selected some nurses who were providing direct care to TBI patients and accepted to assist the PI in bundle implementation, and involved them in a training program on the evidence-based care bundle. The PI provided clinical training on the implementation of the bundle in three sessions (an orientation session and two training sessions). Every session lasted about 40 minutes. During the orientation session, the PI informed the nurses about the care bundle, its components, and its benefits for the patients. In the other two sessions, the selected nurses received clinical training on how to apply the bundle in an optimum manner and the correct order. The PI emphasized the bundle items that they do not usually perform in TBI patients' care, such as assessing GCS, applying a cervical collar correctly, and assessing pupil size and response to light. Moreover, the importance of using a capnograph and elevating the head of the bed (HOB) was also addressed.

2.7.2. Intervention Phase

Data were collected between November 2019 and May 2020. During this phase; the PI started by screening all patients admitted to the ED to confirm that they were free from the exclusion criteria, then the patients' demographic and health-relevant data were collected using part I and part II of the tool. Also, the allocation of the patients was done by using a lottery randomization technique through choosing one of two cards labeled group A (bundle group) and group B (control group).

The bundle group patients received the evidence-based care bundle once they were admitted to the ED. This bundle was adopted from Damkliang et al. (2014) [22], which includes the following items:

- **Establishing a secure airway along with c-spine protection**: using of the jaw thrust maneuver, nursing management during endotracheal intubation (manual in-line stabilization), confirmation of correct endotracheal tube placement, and applied a cervical collar.
- **Maintaining adequacy of oxygenation and ventilation:** monitoring of oxygen saturation using a pulse oximeter, $ETCO_2$ using capnograph, and RR.
- **Maintaining circulation and fluid balance**: giving intravenous fluids, monitoring of HR and blood pressure using a bedside monitor.
- Assessing the GCS, pupil size, and light reactivity.
- Maintaining cerebral venous outflow through patient positioning: elevating the HOB 30 degrees.
- **Managing the patient's pain, agitation, and irritability**: splinting of fractures, urinary catheterization, using analgesics, and monitoring for signs of agitation.
- **Preparing the patients for an urgent CT scan.**

Implementation of the bundle lasted from 45 to 120 minutes for each patient. The PI applied the bundle with the participation of selected nurses only once at the ED. While, the control group patients received routine hospital care which included: connecting the patient to a bedside monitor, endotracheal intubation if needed, applying a cervical collar, giving patient IV fluid, and performing CT scans.

2.7.3. Evaluation Phase

During this phase, patients' GCS, pupil reactivity, and survival until discharge from the ED were monitored for both groups using part III of the tool. These items were monitored immediately after the implementation of the care bundle for the bundle group and after providing the routine care for the control group.

2.8. Statistical Analysis

Data was entered and analyzed using the Statistical Package of Social Sciences (SPSS) version 25. Qualitative data were expressed as frequency (n) and percentage (%). Quantitative data that were normally distributed were expressed as mean and standard deviation (SD), while the interquartile range (IQR) was used for data that were not normally distributed. Additionally, the Z-test was used to compare the means of the two groups. Generalized estimating equations (GEE) were used to analyze dependent variables repeatedly measured (pre-intervention and post-intervention) in the two groups. The results were considered statistically significant if the *p*-value was ≤ 0.050 for any of the used tests.

3. Results

The results of the current study showed that more than half of the bundle and control groups (57.7% & 61.5%, respectively) were in the age group between 30-50 years old, and most of them were males (84.6% & 69.2%, respectively). Besides, the main cause of injury was road traffic accidents (69.2% & 88.5%, respectively). Additionally, 76.9% of the bundle group and 57.7% of the control group had severe TBI.

Table 1. Comparing the GCS on admission and follow-up between the studied groups

Timing	Bundle Group n=26	Control Group n=26	Significance test	
	Median (IQR)	Median (IQR)	*Z* value	*P1*-value
Admission	6 (4 – 8.5)	7 (5 – 12)	-1.432	0.152
Follow-up	7 (5 – 10)	7 (5 – 11)	-0.055	0.956
Progress	1 (0 to 1)	0 (-1 to 0)	-4.981	<0.001
Z value	-3.666	-2.828		
P2 -value	<0.001	0.005		

Data expression: Median, IQR: Interquartile rate, z: Mann-Whitney, p is significant if ≤ 0.05.

Table 1 compares the GCS on admission and follow-up between the studied groups. The results illustrated that the median of the GCS among the bundle group on admission was less than the control group (6 & 7 respectively) with no statistically significant difference between them. However, on follow-up, the median of the GCS was seven for the two groups with no statistically significant difference noted. A significant improvement in the GCS was observed in the bundle group after the implementation of the evidence-based care bundle (*P* <0.001). On the contrary, a significant worsening was noted in the GCS among the control group post receiving the routine care (*P*=0.005). These findings illustrate a highly statistically significant difference in the GCS between both groups (*P* <0.001).

Table 2 compares the pupil equality, size, and reactivity to light between the studied groups. There was a statistically significant difference between both groups on admission and follow-up as regards pupil equality (*P* = 0.019). Unequal pupils were observed in 34.6% of the bundle group and 46.2% of the control group on follow-up as compared with 46.2% and 38.5% respectively on admission.

In addition, 61.5% of patients in the control group had dilated pupils compared with 53.8% in the bundle group on follow-up with no statistically significant difference between the two groups (*p* = 0.095). Moreover, there was a highly statistically significant difference between both groups on admission and follow-up as regards pupil reactivity (*P*<0.001). Most patients in the bundle group (76.9%) had reactive pupils in both eyes on follow-up versus 23.1% in the control group.

Figure 1 portrays the survival of the studied patients on follow-up. All patients in the bundle group were still alive after the implementation of the evidence-based care bundle for TBI patients, while two patients (7.7 %) in the control group died. However, this difference between patients who were still alive in both groups did not achieve statistical significance.

Table 2. Comparing the pupil equality and reactivity to light between the studied groups

Variables	(n=52)		Significance test	
	Bundle Group n=26 N. (%)	Control Group n=26 N. (%)	Test	P value
Pupil equality:			GEE	0.019
Equal pupils				
On admission	14 (53.8%)	16 (61.5%)		
On follow-up	17 (65.4%)	14 (53.8%)		
Unequal Pupils				
On admission	12 (46.2%)	10 (38.5%)		
On follow-up	9 (34.6%)	12 (46.2%)		
Pupil size:			GEE	0.095
Normal pupils				
On admission	10 (38.5%)	12 (46.2%)		
On follow-up	12 (46.2%)	10 (38.5%)		
Dilated pupils				
On admission	16 (61.5%)	14 (53.8%)		
On follow-up	14 (53.8%)	16 (61.5%)		
Pupil reactivity:			GEE	<0.001
On admission				
Both	12 (46.2%)	15 (57.7%)		
One	10 (38.5%)	7 (26.9%)		
None	4 (15.4%)	4 (15.4%)		
On follow-up				
Both	20 (76.9%)	6 (23.1%)		
One	5 (19.2%)	11 (42.3%)		
None	1 (3.8%)	9 (34.6%)		

Data are expressed as numbers (N) and frequency (%). GEE: Generalized estimating equation; group-by-timing interaction, p is significant if ≤ 0.05.

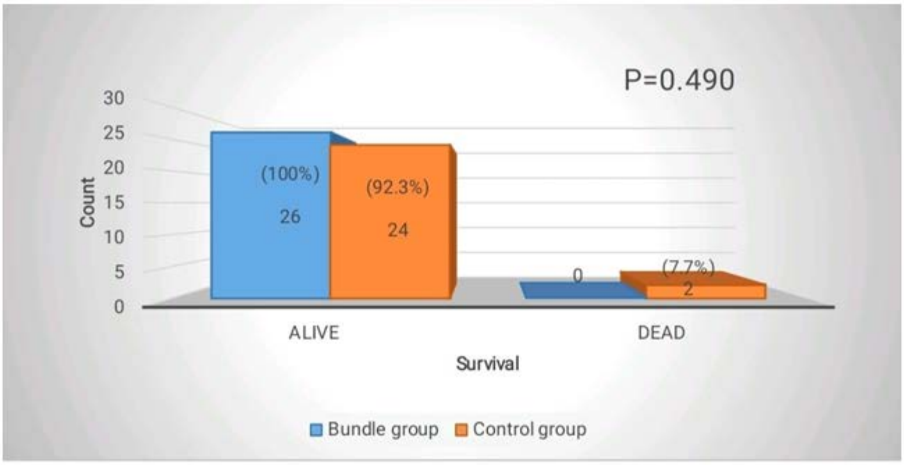

Figure 1. Patients' survival on follow-up

4. Discussion

Traumatic brain injury is a complex disorder with many consequences that extend to death and long-term complications [23]. In Egypt, around 262 264 people experienced TBI in 2016, which means it is a public health problem [24]. However, there is limited research to support the effectiveness of TBI management guidelines on patients' outcomes [23]. Thus, the discussion of the current study focuses upon the interpretation of the findings related to this issue. It addresses the GCS, pupil size changes and reactivity, and the patients' survival in the studied groups.

4.1. Comparing Glasgow Coma Scores between the Studied Groups

The initial GCS is an important predictor of neurological prognosis and survival in TBI patients [25]. A greater fatality rate was observed in TBI patients with a lower baseline GCS at admission [26,27]. The current study's findings revealed a highly statistically significant difference in GCS between the two groups. After implementing the care bundle, the GCS of the bundle group improved significantly, compared to a worsening in the GCS of the control group who received the routine care.

The improvement of patients' GCS in the bundle group could be owing to the integration of the care bundle into patients' care**.** This finding is supported by several studies which reported improvements in patients' clinical outcomes and a decrease in the mortality rate and length of stay in hospitals following the implementation of different care bundles and guidelines [12,13,14,16,28,29].

One of the core elements of the care bundle in the current study is elevating the HOB 30 degrees, which may have a positive effect on the GCS of the bundle group patients. Using this position within the first hours of trauma can significantly reduce the ICP [30]. However, the ICP was not measured in the current study as the tools were not available in the ED**.** Improved GCS and reactive pupils in the bundle group were strong signs of maintaining ICP [31]. The results of Moriki et al., [32] are consistent with our findings regarding the positive effect of positioning. They revealed that the GCS of TBI patients improved with sitting position.

Contradicting our findings**,** the study conducted by Steiner et al., [33] assessed the effect of beginning rehabilitation once the patients were admitted to the intensive care unit (ICU) on the patients' outcomes. The authors reported that there was no statistically significant difference concerning the GCS at ICU admission between the group initially treated in a specific trauma hospital using emergency care before ICU admission and the other two groups treated in other hospitals. This discrepancy with our findings could be because different hospitals in the authors' country may provide the same quality of care for TBI patients.

4.2. Pupil assessment in the Studied Groups

Pupil size and reactivity are other significant predictors of TBI patients' outcomes [34]. As well, measuring the pupils' constriction rate might have a benefit for monitoring the consciousness level for patients with a lower GCS [35]. Dilated, non-reactive pupils are a serious sign that requires neurological emergency assessment [36], which is strongly associated with an unfavorable outcome [18] and a higher death rate [27,37]. It was reported that the total death rate increased from 16 % to 38 % when only one pupil reacted, and to 59 % when neither pupil reacted [18].

The current study found a highly statistically significant difference between the studied groups regarding pupil equality and reactivity on follow-up. Following the implementation of the care bundle, a marked improvement was noted in pupil equality and reactivity in the bundle group. Pupil reactivity is directly affected by elevated ICP [38]. Blood pressure monitoring and stabilization through fluid resuscitation, HOB elevation, and proper positioning of the neck collar can prevent increases in ICP [31]. These interventions are important components of the TBI care bundle, which contributed to the improvement of pupil reactivity in the bundle group.

The maintenance of ICP through fluid resuscitation was supported by Ong et al., [39] who revealed that the use of osmotic therapy in neurological disorder patients is significantly associated with pupil reactivity improvement. Similarly, Jahns et al., [38] study showed that appropriate fluid resuscitation decreased ICP, which was associated with an increase in neurological pupil index (a non-invasive method to assess pupil size and reactivity using automated infrared pupillometry). Also, Chen et al., [40] used the neurological pupil index as an indicator of increased ICP and declared that patients with normal pupil reactivity had lower ICP than patients with abnormal pupil reactivity.

Concerning the use of HOB elevation, the findings of Niimi et al., [35] were in agreement with our findings. They found that the sitting position increases the pupillary constriction rate (which reflects pupil reactivity improvement) in altered conscious level patients.

4.3. Comparing Patients' Survival between the Studied Groups on Follow-up

The findings of the current study revealed that no one in the bundle group died after the implementation of the TBI care bundle, compared to two patients who died in the control group. This is consistent with The results of Damkliang et al., [16] which illustrated that two patients died in the pretest group (those who did not receive the care bundle), whereas all patients in the post-test group (those who received the care bundle) were still alive, and most of them were transferred to the ICU.

Also, Imen et al., [41] found that most TBI patients (78.8%) survived after receiving resuscitation measures in the ED. In the same line, Gerber et al., [14] noted an inverse relationship between compliance with TBI guidelines and the death rate of TBI patients. Likewise, a British systemic review and meta-analysis study reported a significant reduction in death rates among patients with severe TBI in high-income countries [42]. According to the authors, this could be due to the availability of medical care, facilities, and the application of recent guidelines in these countries.

To the best of our knowledge, this is the first Egyptian study that implemented all items of TBI management and monitored the TBI patients' outcomes. It may afford the TBI management in Egypt the opportunity for rapid progress. The current study findings showed the positive effect of incorporating the evidence-based care bundle on TBI patients' outcomes. These findings support the research hypothesis of the current study.

5. Conclusion and Recommendations

The integration of the evidence-based care bundle improves TBI patients' outcomes (GCS, pupil size change and reactivity, and survival). The earlier the bundle is used, the lower the rate of mortality among TBI patients. As well, we postulated that the use of the evidence-based care bundle facilitates the implementation of organized patients' care. The effectiveness of the TBI bundle is still being investigated, hence future research integrating the TBI evidence-based care bundle in different settings, such as ICUs and rehabilitation centers, is needed.

6. Limitations

The generalization of the current research findings is limited due to the small sample size and the collection of data from one ED setting affiliated with one Egyptian hospital. In addition, it was not possible to evaluate the prehospital GCS, vital signs, and the pupil at the scene of the accident. Another limitation was the unavailability of ICP measurement tools in the ED.

Acknowledgments

We are very thankful to all ED nursing staff and patients who accepted to participate in this investigation.

Conflicts of Interest

There are no conflicts of interest.

Funding

The authors received no financial support for the research.

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