Cisternostomy versus Decompressive Craniectomy for the Management of Traumatic Brain Injury: A Randomized Controlled Trial

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■ BACKGROUND: **The goal of treatment of traumatic brain injury (TBI) is to avoid secondary brain injury. Decompressive craniectomy has been shown to reduce intracranial pressure (ICP), but it actually provides an outlet for brain tissue to expand without reducing edema. Basal cisternostomy is an emerging microsurgical technique to manage cerebral edema in TBI. Cerebrospinal fluid is released from basal cisterns, which reduces cerebral edema. We compared outcomes of cisternostomy with decompressive craniectomy in a randomized controlled trial and studied the effectiveness of cisternostomy in decreasing cerebral edema.**

■ METHODS: **All enrolled patients were randomly assigned to 2 groups and assessed clinically and radiologically. TBIs were categorized as mild, moderate, and severe injuries, and Marshall computed tomography—based score was assessed. Intraoperative ICP was measured in both groups. Outcomes were assessed based on postoperative intensive care unit stay, days on ventilator support, and Glasgow Outcome Scale score.**

■ RESULTS: **There were 50 patients randomly assigned to 2 groups (25 patients in each group). Mortality rate was 32% (8 deaths) in the cisternostomy group and 44% (11 deaths) in the decompressive craniectomy group. Patients in the cisternostomy group had decreased mean days of ventilator support and intensive care unit stay. Cisternostomy resulted in significant decreases in ICP after craniotomy. Age, time from trauma to surgery, and Marshall score showed prognostic importance on outcomes.**

■ CONCLUSIONS: **Cisternostomy was effective in reducing ICP in patients with TBI. Good Glasgow Outcome Scale scores and low rates of complications were found in the postoperative period after cisternostomy. Age, presenting Glasgow Coma Scale score, Marshall score, other major injuries, and time from trauma to surgery had a significant prognostic impact on outcome in management of TBI.**

INTRODUCTION

The goal of treatment of traumatic brain injury (TBI) is mainly focused on avoiding secondary brain injury.[1] This can be achieved with meticulous control of intracranial pressure (ICP).[2] Decompressive craniectomy is the time-tested and most commonly used neurosurgical procedure available to decrease ICP in TBI. Decompressive craniectomy has been shown to reduce ICP, but it actually provides an outlet for brain tissue to expand without reducing edema.[3] Further, decompressive craniectomy itself associated with many complications and requires a second surgery in the form of cranioplasty. Therefore, a search for an effective alternative procedure that can replace decompressive craniectomy is ongoing.[4-7]

Key words
- Cisternostomy
- Decompressive hemicraniectomy
- Head injury management
- ICP
- Recent trends in traumatic brain injury
- TBI

Abbreviations and Acronyms
COVID-19: Coronavirus disease 2019
CSF: Cerebrospinal fluid
CT: Computed tomography
DHC: Decompressive hemicraniectomy
GCS: Glasgow Coma Scale
GOS: Glasgow Outcome Score
ICP: Intracranial pressure
ICU: Intensive care unit
TBI: Traumatic brain injury

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Recently, a cerebrospinal fluid (CSF) circulation model has been reconsidered, and it has been stated that CSF can be produced and absorbed throughout the entire CSF system. Pericapillary Virchow-Robin spaces play a critical role in the CSF system.[8] The glymphatic system has proven that CSF from the cisterns (and not from the ventricles) does communicate with the parenchyma through Virchow-Robin spaces.[6,7] It has been suggested that in TBI, there is a decrease in glymphatic removal of solutes from interstitial fluid, allowing CSF to be shifted from the cerebral cisterns to the brain following TBI.[9]

Cisternostomy refers to opening the basal cisterns to atmospheric pressure. Cherian and Burhan[10] described cisternostomy for the control of ICP in TBI in 2009. Using this technique, CSF is released from basal cisterns, which reduces cerebral edema and relaxes the brain in acute and subacute settings, thus allowing replacement of bone flap in otherwise irreplaceable settings. This technique has gained popularity in the last decade, and many neurosurgeons are now performing this technique of CSF release in TBI.[5,11,12] Up to now, to the best of our knowledge, no randomized controlled trials on cisternostomy have been conducted. As is well known, any new procedure has the potential danger of overoptimism initially. Randomized studies provide a way of testing the effectiveness of these procedures. Therefore, we conducted this study to determine the effectiveness of cisternostomy. To our knowledge, this is the first randomized controlled trial comparing the effectiveness of cisternostomy with decompressive craniectomy.

MATERIALS AND METHODS

Patient Selection

All patients presenting to the Department of Neurosurgery at Sri Venkateshwara Institute of Medical Sciences in Tirupati, India, with TBI who needed surgical management and fulfilled the inclusion criteria from April 2019 to December 2020 were enrolled in this study. Inclusion criteria were as follows: 1) age >18 years and <65 years, 2) Glasgow Coma Scale (GCS) score ≥4, 3) brain parenchymal contusions with mass effect and midline shift, 4) acute subdural hematoma with mass effect and midline shift, 5) traumatic subarachnoid hemorrhage with mass effect and midline shift, and 6) posttraumatic diffuse edema with mass effect and midline shift. Exclusion criteria were the following: 1) age <18 years and age >65 years, 2) GCS score 3, 3) extradural hemorrhage, 4) nontraumatic subarachnoid hemorrhage, 5) nontraumatic intraparenchymal bleed, and 6) acute infarcts with mass effect.

Methodology

The study was approved by the institutional Thesis Protocol Approval Committee and Institutional Ethical Committee. Written informed consent from each patient or his or her family member was obtained before the study. All enrolled patients who gave consent to participate in the study were randomly assigned to a decompressive craniectomy group and a cisternostomy group. The randomization sequence was generated before the start of the study by a computer-generated (Random Allocation Software 1.0 [https://mahmoodsaghaei.tripod.com/Softwares/randalloc.html]) set of random numbers. Treatment allocation was done by the opaque sealed envelope method. After giving consent to participate in the study, the envelop of allocation of surgical procedure was opened by the corresponding author (H.N.B.) in the presence of the patient's attendants who had given consent for the surgery and to participate in the surgery. Patients not willing to participate in the study were excluded from the study. Figure 1 shows the randomization flowchart. Patients were randomly assigned into 2 groups each containing 25 patients.

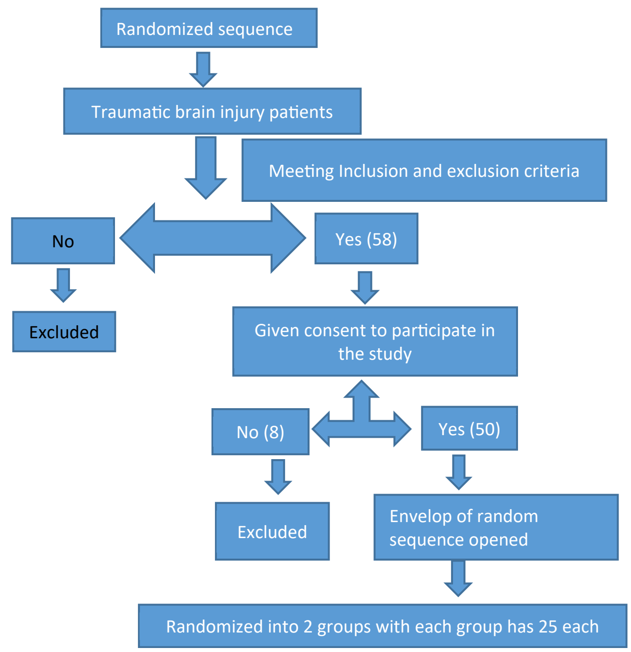

Figure 1. Flow chart of randomization.

Computed tomography (CT) of the skull was performed for every patient, as per institute protocol, to determine the type of injury, hematomas or contusions of brain, volume of hematomas, mass effect, midline shift, and the Marshall CT-based score was obtained. All TBIs were classified as mild, moderate, and severe injuries based on the clinical findings, GCS and CT findings.

Intraoperative ICP (intraparenchymal) monitoring was done in all patients. As cisternostomy was mainly based on the concept of CSF shift edema, we mainly considered measuring the parenchymal pressure instead of intraventricular pressures. Postoperatively, the patients were monitored for the number of days of ventilator support needed; number of days in the intensive care unit (ICU) with ICP monitoring; any new neurological deficits in the form of cognitive, motor, or sensory impairment postoperatively; number of days in the hospital; postoperative complications; and mortality and morbidity during follow-up after 3 months with the Glasgow Outcome Scale (GOS).

Surgery Methods

Decompressive Craniectomy. In the decompressive craniectomy group, standard decompressive craniectomy with a large flap was done with placement of bone flap in the anterior abdominal wall.

Table 1. Demographic Data in Study

Variable	Cisternostomy Group	Decompressive Craniectomy Group	*P* Value
Age, years	44.48 ± 12.48	42.84 ± 13.90	0.663
18–30	5 (20%)	6 (24%)	
31–40	4 (16%)	4 (16%)	
41–50	9 (36%)	8 (32%)	
>50	7 (28%)	7 (28%)	
GCS	6.88 ± 1.87	7.80 ± 2.10	0.108
Mild (14–15)	0	0	
Moderate (9–3)	7 (28%)	11 (44%)	
Severe (<9)	18 (72%)	14 (56%)	
Marshall CT score	4.16 ± 1.34	4.44 ± 1.32	0.460
1	0 (0%)	0 (0%)	
2	3 (12%)	2 (8%)	
3	4 (16%)	3 (12%)	
4	11 (44%)	11 (44%)	
5	0 (0%)	0 (0%)	
6	7 (28%)	9 (36%)	
Time from trauma to surgery, hours	13.56 ± 9.15	13.48 ± 8.90	0.975
<6	3 (12%)	9 (36%)	
7–12	10 (40%)	3 (12%)	
13–24	10 (40%)	9 (36%)	
>24	2 (8%)	4 (16%)	
Associated injuries at time of presentation			
Rib fractures and hemo-/pneumothorax	3 (12%)	4 (16%)	
Long bone fractures	3 (12%)	2 (8%)	
Both	1 (4%)	0	
Intraoperative period			
Duration of surgery, hours	3.28 ± 0.52	2.90 ± 0.38	0.005
Blood loss, mL	334.00 ± 87.46	322.00 ± 45.82	0.546
Intraoperative ICP			
After 1st burr hole	27.92 ± 2.13	27.16 ± 1.59	0.159
After craniotomy	15.32 ± 3.17	16.28 ± 3.06	0.281
After cisternostomy	6.36 ± 1.91	—	
Decrease in ICP from 1st burr hole to craniotomy	12.60 ± 3.20	10.88 ± 2.99	0.055
Postoperative period			
MV support	5.68 ± 3.80	7.60 ± 4.93	0.130
Duration of ICU stay	5.48 ± 4.85	7.12 ± 3.93	0.190

Continues

Table 1. Continued

Variable	Cisternostomy Group	Decompressive Craniectomy Group	*P* Value
Total duration of hospital stay	9.76 ± 5.17	10.04 ± 5.32	0.085
GOS	3.12 ± 1.64	2.68 ± 1.65	0.349
5	7 (28%)	5 (20%)	
4	5 (20%)	4 (16%)	
3	5 (20%)	5 (20%)	
2	0 (0%)	0 (0%)	
1	8 (32%)	11 (44%)	

GCS, Glasgow Coma Scale; CT, computed tomography; ICP, intracranial pressure; MV, mechanical ventilation; ICU, intensive care unit; GOS, Glasgow Outcome Scale.

Cisternostomy. In the cisternostomy group, after craniotomy and dural opening, basal cisternostomy, including opening of the interoptic, opticocarotid, and lateral carotid cisterns, lamina terminalis, and Liliequist membrane, was done. A cisternal drain was placed and was kept for 3–5 days in the postoperative period. Duraplasty was done primarily or with a pericranial graft. The bone flap was replaced and fixed with miniplates and screws. All surgeries in both groups were performed by a single surgeon (V.V.R.C.) with 13 years of experience performing skull base and aneurysm surgeries.

Sample Size and Statistical Analysis

As we assumed cisternostomy was hypothetically better than conventional decompressive craniectomy, we used a 1-tailed hypothesis with 80% power and with moderate impact, and we studied a minimum of 25 patients from each group as per Cohen's *d* method (www.danielsoper.com/statcalc/calculator). All the data were tabulated in a Microsoft Excel 2007 (Microsoft Corporation, Redmond, Washington, USA) data sheet with proper headings. For continuous variables, data were expressed as mean ± SD. For categorical variables, data were represented as count and percentage. Comparison of means between the 2 groups was done using Student *t* test, provided that the data were normally distributed; otherwise, Mann-Whitney U test was used. Categorical variables were compared using χ^2 test. $P < 0.05$ was considered significant. Statistical analysis was done using IBM SPSS Version 20.0 (IBM Corporation, Armonk, New York, USA).

ResultsInclusion criteria were met by 58 patients. For 8 patients, consent to participate in the study was not given. These patients were managed with decompressive craniectomy, as it is the standard surgical method followed at our institute for the management of TBI. The remaining 50 patients who given consent to participate were randomly assigned to 2 groups with 25 patients each. The mean age of the patients was 44.48 ± 12.48 years in the cisternostomy group and 42.84 ± 13.90 in the decompressive craniectomy group. There were 16 (64%) patients in the cisternostomy group and 15 60% patients in the decompressive craniectomy group >40 years old.

Table 2. Relation of Marshall Computed Tomography—Based Score to Presenting Glasgow Coma Scale Score and Intracranial Pressure

	Average Presenting GCS			Average ICP After 1st Burr Hole		
Marshall CT Score	Cisternostomy Group	Decompressive Craniectomy Group	*P* Value	Cisternostomy Group	Decompressive Craniectomy Group	*P* Value
1	0	0		0	0	
2	9.50 ± 0.70	10 ± 1.41	0.119	28.33 ± 0.57	26 ± 0	0.000
3	8.00 ± 1.82	10.33 ± 1.52	0.000	26.75 ± 1.70	27 ± 0	0.466
4	6.09 ± 1.64	7.45 ± 1.86	0.009	28.91 ± 2.54	27.45 ± 2.11	0.032
5	0	0		0	0	
6	6 ± 1.00	6.89 ± 1.83	0.038	26.86 ± 1.34	26.90 ± 1.37	0.917

CT, computed tomography; GCS, Glasgow Coma Scale; ICP, intracranial pressure.

The mean preoperative GCS score was 6.88 ± 1.87 in the cisternostomy group and 7.80 ± 2.10 in the decompressive craniectomy group. There were 18 (72%) patients in the cisternostomy group and 14 (56%) patients in the decompressive craniectomy group with severe head injury with GCS score <9 at the time of presentation. The mean preoperative Marshall CT score was 4.16 ± 1.34 in the cisternostomy group and 4.44 ± 1.32 in the decompressive craniectomy group.

The mean time from trauma to surgery was 13.56 ± 9.15 hours in the cisternostomy group and 13.48 ± 8.90 hours in the decompressive craniectomy group. (As our institute is a tertiary care center in our region, many cases were referred to here from peripheral centers, so transportation of the patients took some time. Thus, mean time from trauma to surgery was long in our study compared with previous studies.) The patients were categorized into 4 groups: 80% from the cisternostomy group and 48% from the decompressive group were in the 6–24 hours group (including 7–12 hours group and 13–24 hours group).

Mean duration of surgery was 3.28 ± 0.52 hours in the cisternostomy group and 2.90 ± 0.38 hours in the decompressive craniectomy group; this was statistically significant ($P = 0.005$). Mean intraoperative blood loss was 334.00 ± 87.46 mL in the cisternostomy group and 322.00 ± 45.82 mL in the decompressive craniectomy group. The mean intraoperative ICP measured after the 1st burr hole was 27.92 ± 2.13 mm Hg in the cisternostomy group and 27.16 ± 1.59 mm Hg in the decompressive craniectomy group ($P = 0.159$). The mean ICP after craniotomy was 15.32 ± 3.17 mm Hg in the cisternostomy group and 16.28 ± 3.06 mm Hg in the decompressive craniectomy group ($P = 0.281$). The mean decrease in ICP from 1st burr hole to craniotomy was 12.60 ± 3.20 mm Hg in the cisternostomy group and 10.88 ± 2.99 mm Hg in the decompressive craniectomy group. The mean duration of mechanical ventilation support was 5.68 ± 3.80 days in the cisternostomy group and 7.60 ± 4.93 days in the decompressive craniectomy group. The mean duration of ICU stay was 5.48 ± 4.85 days in the cisternostomy group and 7.12 ± 3.93 days in the decompressive craniectomy group. The mean duration of hospital stay was 9.76 ± 5.17 days in the cisternostomy group and 10.04 ± 5.32 days in the decompressive craniectomy group. Patients' demographic data are shown in **Table 1**.

The mortality rate in this study was 32% ($n = 8$ patients) in the cisternostomy group and 44% ($n = 11$ patients) in the decompressive craniectomy group. These were assigned a GOS score of 1. In this study, 50% of deaths in the cisternostomy group and 82% of deaths in the decompressive craniectomy group occurred in patients >40 years old. The mean GOS score in patients with moderate head injury was 4.57 in the cisternostomy group and 4.25 in the decompressive craniectomy group. The mean GOS score in patients with severe head injury was 2.56 in the cisternostomy group and 1.40 in the decompressive craniectomy group. The mean GOS score in patients with a Marshall CT score of 4 was 2.45 ± 1.75 in the cisternostomy group and 2.18 ± 1.47 in the decompressive craniectomy group (**Table 2**). The mean GOS score was 1 in patients who presented after 24 hours of trauma in both group. The mean GOS score in patients who presented within 6 hours of trauma was 5 in the cisternostomy group and 3.89 ± 1.36 in decompressive craniectomy group (**Tables 3** and **4**).

DISCUSSION

Severe TBI is a life-threatening condition that causes substantial morbidity and mortality.[13] In the setting of TBI, the development of uncontrolled ICP is associated with a poor prognosis. Management of TBI is mainly focused on controlling the damage caused by secondary brain injury, which occurs mainly as a result of raised ICP. Decompressive craniectomy has proved to be effective in reducing ICP and mortality, but its effects on outcomes are still under debate.[14]

In TBI, CSF rapidly shifts to the brain parenchyma. It is supported by the nonvisualization of cisterns and compressed ventricles. Therefore, external ventricular drainage is very difficult, and the CSF is not drained from brain parenchyma effectively.[15] Cisternostomy has been recently proposed in the setting of severe TBI as an adjuvant surgical technique that may have a potential for effectively improving ICP control and outcomes.[16,17] In this study, we randomly assigned 50 patients to a decompressive craniectomy group and a cisternostomy group (25 patients in each group). We studied these groups in terms of their outcome and effect of prognostic factors on them. Both groups were comparable in terms of age, presenting GCS score,

Table 3. Relation of Intracranial Pressure to Glasgow Outcome Scale

	Mean ICP after 1st Burr Hole (mm Hg)			Mean ICP Craniotomy (mm Hg)		
GOS	Cisternostomy Group	Decompressive Craniectomy Group	*P* Value	Cisternostomy Group	Decompressive Craniectomy Group	*P* Value
5	27.71 ± 2.98	26.80 ± 0.83	0.148	14.86 ± 3.33	13.40 ± 1.67	0.056
4	28.40 ± 2.30	27 ± 0.81	0.006	14.00 ± 3	14 ± 3.74	1.000
3	27.20 ± 1.48	27.60 ± 2.70	0.519	15.40 ± 3.84	16 ± 3.39	0.561
2	0	0				
1	28.25 ± 1.75	27.18 ± 1.60	0.029	16.50 ± 2.87	18.55 ± 0.82	0.001

GOS, Glasgow Outcome Scale; ICP, intracranial pressure.

Marshall CT score, time from trauma to surgery, duration of surgery, intraoperative blood loss, and ICP after placement of the first burr hole (Table 1).

Intraoperative and Postoperative Period

According to Cherian et al.,[16] the average time for cisternostomy from dural opening is approximately 20 minutes with extra time needed in the case of posterior clinoid drilling or any other additional unforeseen circumstances associated with severe head injuries. In our study, the mean duration of surgery was 3.28 ± 0.52 hours in the cisternostomy group and 2.90 ± 0.38 hours in the decompressive craniectomy group. This result was similar to the study by Cherian et al., but the extra time for cisternostomy was statistically significant ($P = 0.005$). In the study by Cherian et al., the mortality rate 13.8% for cisternostomy and 34.8% for decompressive hemicraniectomy (DHC), and in our study, the mortality rate was 32% in the cisternostomy group and 44% in the DHC group. Even though the mortality rate was high in our study, it was less in the cisternostomy group.[16] The mean duration on ventilator support and ICU care in this study was more compared with a study by Cherian et al. in 2013,[16] but it was lower in the cisternostomy group compared with the decompressive craniectomy group.

Glasgow Outcome Scale

According to Cherian et al.,[16] the mean GOS score was 2.8 for patients treated with DHC and 3.9 for patients treated with cisternostomy. Our study results were comparable to their results with a mean GOS score of 2.68 in the DHC group and 3.12 in the cisternostomy group.[16] These results were also supported by Giammattei et al.[11] in a retrospective series of 40 patients who underwent either basal cisternostomy or decompressive craniotomy alone. The GOS scores were also significantly better for basal cisternostomy patients at 6 months (61% for basal cisternostomy vs. 35% for decompressive craniotomy). In a study by Parthiban et al.,[18] basal cisternostomy alone had a favorable GOS score compared with basal cisternostomy combined with decompressive craniotomy (82% vs. 62%). Goyal et al.[19] published a cohort of 9 patients who underwent both basal cisternostomy and decompressive craniotomy. They demonstrated a significant difference between opening and closing parenchymal pressures. Their study supported the CSF shift edema and suggested that both basal cisternostomy and decompressive craniotomy should be provided for patients with head injuries with severe edema.

Intraoperative ICP

In this study, we measured ICP intraoperatively. There was a significant decrease in ICP in both groups from 1st burr hole to craniotomy. When compared in both groups, this decrease in ICP did not have any statistical significance. In the cisternostomy group, the ICP further decreased significantly after cisternostomy. In our study, the mortality rate proportionally increased with the delay in surgery in both groups, as patients who presented within 6 hours from trauma to surgery had good outcomes, and all patients who presented after 24 hours had worst outcomes in both the groups. Patients with poor prognosis in our study had high ICP after craniotomy compared with patients who showed good prognosis in both groups. However, patients in the cisternostomy group had significantly lower ICP ($P = 0.001$) after craniotomy, including patients with poor prognosis compared the decompressive craniectomy group (Table 3).

Relation to Prognostic Factors

In our study, the Marshall CT score did not show any significant difference in ICP at presentation. Patients in both groups with poor Marshall CT scores of 4 and 6 had poor GCS scores at presentation and poor GOS scores. Patients with increased age showed poor outcomes in both groups, but outcomes were better in the cisternostomy group compared with the decompressive craniectomy group. Patients with severe head injury (presenting GCS score <9) showed poor outcomes in both groups, but outcomes were better in the cisternostomy group, which was statistically significant compared with the decompressive craniectomy group ($P = 0.002$) (Table 4). Association with other major injuries such as long bone and rib fractures showed worst outcome in both groups.

Limitations

Our study was limited because it was a single-center study. Another limitation was the small number of patients, which was due to a smaller number of trauma cases in view of restrictions secondary to coronavirus disease 2019 (COVID-19).

Table 4. Relation of Prognostic Factors to Glasgow Outcome Scale

Prognostic Factor	Average GOS		
	Cisternostomy Group	Decompressive Craniectomy Group	*P* Value
GCS			
Mild (14—15)			
Moderate (9—13)	4.58 ± 0.78	4.25 ± 0.75	0.134
Severe (<9)	2.56 ± 1.54	1.40 ± 0.82	0.002
Marshall CT score			
1	0	0	
2	4.33 ± 1.15	5 ± 0	0.005
3	4.25 ± 1.70	4.67 ± 0.57	0.223
4	2.45 ± 1.75	2.18 ± 1.47	0.558
5	0	0	
6	2.57 ± 1.39	2.25 ± 1.38	0.418
Age, years			
18—30	4.00 ± 1.32	4 ± 1.09	1.000
31—40	2.75 ± 2.06	3 ± 1.77	0.000
41—50	2.57 ± 1.61	2 ± 1.41	0.189
>50	2.60 ± 1.67	1.43 ± 1.13	0.006
Time from trauma to surgery, hours			
<6	5 ± 0	3.89 ± 1.36	0.6880
7—12	3.09 ± 1.51	2.75 ± 2.06	0.509
13—24	3 ± 1.66	2.13 ± 1.24	0.041
>24	1	1	1

GOS, Glasgow Outcome Scale; GCS, Glasgow Coma Scale; CT, computed tomography.

CONCLUSIONS

Cisternostomy was effective in reducing ICP in patients with TBI, as there was a significant decrease in ICP after cisternostomy. Patients have a good GOS score and a low rate of complications in the postoperative period following cisternostomy. Cisternostomy decreases the number of days of ventilator support and the length of ICU stay. Cisternostomy avoids the need for second surgery in the form of cranioplasty and its associated morbidity. The Marshall CT score does not show any significant difference in ICP at presentation. However, patients with poor Marshall scores of 4 and 6 had poor GCS scores at presentation, poor GOS scores, older age, other major injuries, and long intervals from trauma to surgery, all of which had a significant prognostic impact on the outcome in the management of TBI, though outcomes were better in the cisternostomy group. Therefore, basal cisternostomy seems like a promising procedure, but performing cisternostomy in TBI is challenging, which requires expertise of the surgeon in skull base surgeries and availability of a microscope. With this single randomized controlled trial, we cannot state that it is an alternative procedure for decompressive craniectomy to treat patients with TBI. More large multicenter randomized trials are needed to establish the effectiveness of cisternostomy in the management of TBI.

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