Original Article

Protocol-Based Early Decompressive Craniectomy in a Resource-Constrained Environment: A Tertiary Care Hospital Experience

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Abstract

Objectives: Decompressive craniectomy (DC) is an emergency life-saving procedure used to treat refractory intracranial hypertension (RICH). The authors aim to analyze their experience with protocol-based early DC (<24 h) in RICH cases diagnosed based on clinical and radiological evidence, without preoperative intracranial pressure monitoring done over 10 years. **Materials and Methods:** This is a retrospective, observational study which includes 58 consecutive patients who underwent protocol-based early DC by the senior author at a single institution between 2007 and 2017. Background variables and outcome in the form of Glasgow Outcome Score-Extended (GOS-E) at 6 months and 1 year were analyzed. **Results:** Fourteen patients had traumatic brain injury (TBI), 17 had intracranial hemorrhage (ICH), 14 had malignant cerebral infarcts (MCI), and the reminder 13 patients had other causes. At 6 months, the mortality rate was 22.4%. Good recovery, moderate disability, and severe disability were seen in 13.8%, 17.2%, and 43.1% of patients, respectively. Two patients were in vegetative state. The cutoff for favorable/unfavorable outcome was defined as GOS-E 4–8/1–3. By this application, 63.8% of patients had favorable outcome at 6 months. The favorable outcome in patients of TBI, ICH, and MCI was 57.1%, 58.8%, and 85.7%, respectively. **Conclusions:** DC helps in obtaining a favorable outcome in selected patients with a defined pathology. The diagnosis of RICH based on clinical and radiological parameters, and protocol-based early DC, is reasonably justified as the way forward for resource-constrained environments. The risk of vegetative state is small.

Keywords: *Early decompressive craniectomy, protocol-based decompressive craniectomy, refractory intracranial hypertension, resource-constrained environment*

Introduction

Acute brain injury (ABI) is a leading cause of death and disability worldwide.[1,2] The major causes of ABI include traumatic brain injury (TBI), malignant cerebral infarction (MCI), and intracranial hemorrhage (ICH). Intracranial pressure (ICP)-lowering therapies which prevent secondary brain injury are usually administered in a step-wise manner, starting with safer first-line interventions (head elevation, osmotic agents, controlled hyperventilation, hypothermia, and sedation), while reserving high-risk options for patients with refractory intracranial hypertension (RICH).[2-4] Decompressive craniectomy (DC) is one such high-risk surgical procedure in which part of the skull is removed and the underlying dura is expanded to reduce raised ICP and ensure normal cerebral perfusion.[5] Although DC is effective in reducing ICP and mortality, it is accompanied by a myriad of nontrivial complications, and there is a concern that survivors will experience permanent severe disability. DC has been evaluated in a few randomized controlled trials (RCTs) for TBI and acute ischemic stroke, which has further widened the controversy.[2-4,6] The role of DC in countries with low neurocritical care and neurosurgical resources is under scanner.[7-9] Low- and middle-income countries (LMICs) cannot afford the higher costs associated with protocol-based ICP monitoring as a requisite for diagnosing RICH for all ABI patients. Alternatively, protocol-based early DC could be offered to patients with RICH diagnosed based on clinical and radiological features.[10,11] Early DC (done within 24 h of insult) may be helpful to improve the long-term outcome of patients with RICH due to any underlying cause.[7-9] The aim of this

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retrospective, cross-sectional, observational study is to analyze our experience with protocol-based early DC without preoperative ICP monitoring in patients with clinical and radiological features of RICH over a period of 10 years.

Materials and Methods

Study design

This is a retrospective, observational case series including all the consecutive DC cases done by the senior author between 2007 and 2017 at *P* D Hinduja hospital, Mumbai, Maharashtra, India. The study group included 58 patients with clinical and radiological evidence of intracranial hypertension refractory to first-line interventions, who underwent early DC. An informed consent in a uniform format was taken from all these patients/relatives for being a part of this study and their details to be published.

Patient selection

All the patients reaching P D Hinduja Hospital-Emergency Department with signs of raised ICP (secondary to any pathology) were first resuscitated according to the ATLS guidelines. Computed tomography (CT) scan brain was advised immediately after resuscitation and was classified based on Marshall scoring. Patients were admitted to neuro ICU and started on first-line, ICP-lowering interventions such as head elevation, osmotic agents, controlled hyperventilation, hypothermia, and sedation. DC option was reserved for patients with RICH, diagnosed on clinical and radiological basis. Predetermined criteria for RICH and in turn the DC at our institute are *Marshall score ≥III with Glasgow Coma Scale (GCS) ≤8 or with GCS of 9–12 requiring ventilation where clinical/neurological monitoring not possible + clinical signs of herniation such as pupillary asymmetry*. No presurgery ICP monitoring was carried out. Early DC within 24 h of diagnosis of RICH was offered to all patients. Patients requiring DC along with or subsequent to evacuation of an extra-axial intracranial hematoma were excluded from the study.

Surgical technique

Either unilateral or bilateral fronto-temporo-parietal DC was offered to all the eligible patients (as per the protocol) depending on the presence of significant mass effect/midline shift either unilateral/bilateral. Standard surgical technique was employed with craniectomy flap size of at least 15 cm AP diameter. Adequate temporal decompression was achieved in every case. The dura was opened in a fan-like fashion and duraplasty was done using dura graft. A subdural ICP catheter was placed in most cases for postoperative ICP monitoring. A bone flap was either placed in the abdomen or stored in the bone bank. Cranioplasty was offered after 3–6 months depending on patient's neurological recovery.

Rehabilitation and outcome analysis

Sedation and ventilation were continued for variable periods. Postoperative brain CT was done after 24 h to see the reversal of mass effect and midline shift. Hyperosmolar therapy was continued based on postoperative ICP monitoring (ICP >20 for >15 min). Percutaneous tracheostomy was done in those cases where weaning off the ventilator was difficult. Once off the ventilator, the patient received rigorous physiotherapy and rehabilitation both in hospital and at home after discharge. Outcome in the form of Glasgow Outcome Score-Extended (GOS-E) at 6 months and 1 year were analyzed from the patient's follow-up records.[12] Nine patients were lost to follow-up at 1 year. A descriptive analysis of the clinical and demographic profile, complications, and factors associated with prognosis was done.

Results

A total of 58 patients with RICH (secondary to any pathology) who underwent early DC were analyzed. The median age of presentation was 44.1 years, and the male-to-female ratio was 39:19. Patients in the age group of 31–60 years constituted 57% (33 cases) of the total cases, followed by <30 years seen in 13 cases (22.4%) [Table 1]. The most common cause of ABI was ICH which was seen in 17 (29.3%) cases, followed by TBI and MCI, accounting for 14 (24.1%) cases each. Other causes included postoperative ICH, venous infarct, and aneurysmal hemorrhage [Table 2].

Those patients with Marshall score ≤III usually responded well to first-line interventions. Most patients who underwent DC belonged to Marshall VI seen in 44 (75.9%) cases followed by Type IV in 14 (24.1%) cases. Fifty-six cases underwent unilateral DC and two cases underwent bilateral DC [Table 1]. Thirty-eight (65.5%) cases underwent ICP monitoring in the postoperative phase. Bone flaps were placed in the abdomen in the initial fifty cases and the last eight cases had their bone flaps preserved in the bone bank.

The outcome was measured by the GOS-E at 6 months and 1 year. At 6 months, the mortality rate was 22.4% (13 patients). Eight (13.8%) patients had good recovery, ten (17.2%) patients had moderate disability, and 25 (43.1%) patients suffered from severe disability. Only two (3.5%) patients were in vegetative state [Table 3]. The cutoff for favorable/unfavorable outcome was defined as GOS-E 4–8/1–3. By this application, 63.8% of patients had favorable outcome. Outcome at 1 year was identical to that of 6 months [Table 2]. The favorable outcome in patients of TBI, ICH, and MCI was 57.1%, 58.8%, and 85.7%, respectively, with the best outcome being in MCI (not statistically significant). Though few, aneurysmal hemorrhage and postoperative ICH cases requiring DC also showed fair outcome.

The association of favorable/unfavorable outcome at 6 months with parameters such as side of DC, preoperative

Table 1: Clinical factors and Glasgow Outcome Scale-E score at 6 months and 1 year

Parameter	GOS-E at 6 months (%)			GOS-E at 1 year (%)*	
	Favorable	Unfavorable	*P* (Chi-square)	Favorable	Unfavorable
Side					
Left	18 (31)	10 (17.2)	0.15†	15 (30.6)	9 (18.4)
Right	19 (32.8)	9 (15.5)		16 (32.7)	8 (16.3)
Bilateral	-	2 (3.4)		-	1 (2)
Pupils					
Normal	29 (50)	8 (13.8)	0.002	24 (49)	7 (14.3)
Abnormal	8 (13.8)	13 (22.4)		7 (14.3)	11 (22.4)
Preoperative GCS-motor					
M1 OR M2	3 (5.1)	7 (12)	0.014†	1 (2)	6 (12.2)
M3 TO M6	34 (58.6)	14 (24.1)		30 (61.2)	12 (24.5)
Marshall score					
IV	9 (15.5)	5 (8.6)	0.96	9 (18.4)	3 (6.1)
VI	28 (48.2)	16 (27.6)		22 (44.9)	15 (30.6)
Age (years)					
<30	9 (15.5)	4 (6.9)	0.52†	8 (16.3)	3 (6.1)
31-60	22 (37.9)	11 (19)		19 (38.8)	10 (20.4)
>61	6 (10.3)	6 (10.3)		4 (8.2)	5 (10.2)
Ventilation (days)	4.51	6.38			
ICU stay (days)	15.78	11.9			
Hospitalization (days)	28.75	19.95			

*GOS-E at 1 year has total patients of 49 due to loss to follow-up. Percentages calculated accordingly; †Chi-square test not meeting Cochran's criteria and hence not accepted; Statistically significant *P* value is highlighted with bold font. GOS – Glasgow Outcome Scale; ICU – Intensive care unit

Table 2: Diagnosis-based outcome in terms of favorability

Diagnosis	GOS-E AT 6 months (%)		Total (%)	GOS-E at 1 year (%)*		Total (%)
	Favorable	Unfavorable		Favorable	Unfavorable	
TBI	8	6	14 (24.1)	6	6	12 (24.5)
ICH	10	7	17 (29.3)	8	5	13 (26.5)
Infarct	12	2	14 (24.1)	10	3	13 (26.5)
Postoperative ICH	2	1	3 (5.2)	2	1	3 (6.1)
Venous infarct	1	2	3 (5.2)	1	1	2 (4.1)
Aneurysm	3	-	3 (5.2)	3	-	3 (6.1)
Others	1	3	4 (6.9)	1	2	3 (6.1)
Total (%)	37 (63.8)	21 (36.2)	58 (100)	31 (63.3)	18 (36.7)	49 (100)

*GOS-E at 1 year has total patients of 49 due to loss to follow-up. Percentages calculated accordingly. GOS – Glasgow Outcome Scale; ICH – Intracranial hemorrhage; TBI – Traumatic brain injury

Table 3: Glasgow Outcome Scale-E at 6 months and 1 year

GOS- extended	At 6 months (%)	At 1 year (%)*
1=Dead	13 (22.4)	15 (30.6)
2=Vegetative state	2 (3.4)	2 (4.1)
3=Lower severe disability	5 (8.6)	1 (2)
4=Upper severe disability	20 (34.5)	10 (20.4)
5=Lower moderate disability	4 (6.9)	6 (12.2)
6=Upper moderate disability	6 (10.3)	4 (8.2)
7=Lower good recovery	4 (6.9)	4 (8.2)
8=Upper good recovery	4 (6.9)	7 (14.3)
Total (%)	58 (100)	49 (100)

*GOS-E at 1 year has total patients of 49 due to loss to follow-up. Percentages calculated accordingly. GOS – Glasgow Outcome Scale

pupillary reaction, preoperative GCS-motor score, Marshall score, and age was statistically analyzed using Chi-square test [Table 1]. Those patients with normal pupillary reactions preoperatively had statistically significant better chance of having favorable outcome compared to those otherwise (P = 0.002). Rest of the parameters had no statistically significant association with favorable/unfavorable outcome. Twenty-seven (46.5%) patients underwent cranioplasty at an average of 6.07 months post DC.

Discussion

DC has been widely utilized as a modality to treat RICH since long with a controversial history.[5] The removal

of different parts of the skull has been utilized in the management of severe ABI after the first reports of this surgical technique directed at controlling ICP was published by Cushing.[5] DC can be categorized to be primary or secondary.[4,13] Primary DC is often performed in early phase after ABI and refers to the surgery leaving a large bone flap out after evacuation of intracranial lesions.[4] Secondary DC is often conducted as the last resort for RICH when medical therapies failed.[4] The most common causes of ABI are TBI, ICH, MCI, aneurysmal SAH, etc.

Role of decompressive craniectomy in various pathologies

While many studies have shown the efficacy of DC in reducing ICP and improving mortality from severe TBI, others have questioned on its usefulness.[3,4,6,14-17] A meta-analysis was published by Zhang *et al*. in 2017, analyzing four RCTs, five retrospective studies, and one prospective study in the role of DC in TBI.[4] It confirmed that DC in TBI could significantly lower ICP and reduce mortality rate, but was associated with more complications compared to medically treated patients. While DC was associated with similar risk of favorable outcome at 6 months compared with medical management, early surgery (surgery <36 h) resulted in improved outcomes in subgroup analysis for GOS-E score at 6 months. These above-mentioned results were alike for both adults and children.[4] Another meta-analysis (Kai Zhang *et al*., 2016) was published comparing outcome differences between early (<24 h) and late (>24 h) DC in TBI.[18] It concluded that early DC may be more helpful to improve the long-term outcome of patients with RICH after moderate and severe TBI. Bilateral pupil abnormality preoperatively leads to unfavorable outcome and mortality in TBI.

MCI is another common cause of ABI. The condition leads to space-occupying brain edema, resulting in raised ICP, with subsequent ischemic cell death and brain herniation.[2] The prognosis is poor, with mortality as high as 70% to 80%, and the survivors being left with severe disabilities.[17,19] Patients receive ICP-lowering therapies similar to that in TBI, with DC being reserved for those with RICH.[20,21] A meta-analysis was published by Gul *et al*. which included eight RCTs and eight non-RCTs studying the outcome of DC in MCI.[2,22] The analysis concluded that there was a significant survival advantage associated with DC in patients of all ages, when performed within 48 h of the onset of stroke.[2] However, early DC may not reduce poor functional outcome (modified Rankin score; mRS >4) in survivors, and DC performed after this time may not reduce mortality or unfavorable functional outcome.[2] Currently, there is no reason to use a watchful waiting approach for DC after a diagnosis of MCI in young patients.[2,21,23]

DC is also an acknowledged treatment measure for aneurysmal SAH leading to intractable ICP.[13] The timing and functional outcome of DC in aneurysmal SAH is heavily debated. A clinical study on mouse model by Bühler *et al*. concluded that performing DC to reduce ICP either during or acutely after SAH resulted in more severe bleeding, a higher chance of rebleeding, and poorer functional outcome.[24] Thus, elevated post-SAH ICP has a tamponade effect in controlling bleeding and should therefore not be reduced acutely. Any DC considered in SAH patients should take these effects into consideration.[24] In contrast, Jabbarli *et al*. (2017) analyzed 245 aneurysmal SAH cases who had undergone either primary or secondary DC, to report no difference in unfavorable outcome (mRS >3) between primary and secondary DC (65.5% vs. 74.3%).[13] Patients with early primary DC (<24 h) had significantly better functional outcome compared to secondary DC and even late primary DC. The data showed that early surgery improves the functional outcome of SAH patients requiring DC independently of the initial clinical condition (WFNS grade), severity of SAH, patients' age, aneurysm location, and treatment modality.[13] However, in this era of endovascular treatment, it will be challenging to select proper candidates for early DC.[13]

Cerebral venous thrombosis (CVT) is an important cause for stroke in the young where the role for DC is now well established.[25,26] Aaron *et al*. (2013) published the largest series on DC for CVT in literature to date (44 cases) and concluded that DC should be considered as a treatment option in large venous infarcts.[25] Very good outcomes can be expected especially if done early and in those below 40 years.

Decompressive craniectomy in resource-constrained environment and refractory intracranial hypertension – Clinical/radiological criterion

All the RCTs and majority of the literature available have studied the role of DC as a last-tier procedure following diagnosis of RICH based on continuous ICP monitoring. RICH is diagnosed based on a predefined ICP criterion which may vary slightly from center to center. The same is not economically feasible in most neurosurgical centers in LMICs with resource constraints. There is lack of formal prehospital setup, insurance coverage, neurocritical care, and neurorehabilitation in LMICs.[7,8] Continuous ICP monitoring may facilitate the diagnosis of RICH, but its effectiveness in improving outcomes has been questioned by the BEST TRIP trial.[11] At our center, early DC is offered to patients with RICH diagnosed on the basis of clinical and radiological evidence without ICP monitoring. A single surgery in the form of DC compared to two surgeries – one for ICP monitoring followed by another for DC if required – was economical and preferred, as health insurance is still a privilege most people do not possess. Nevertheless, our results of the protocol-based early DC in patients with ABI seems to be as good as or even better than that reported in the literature from developed countries, maybe related to the case selection

as per our mentioned criteria. Our institute's clinical and radiological criterion for diagnosis of RICH coincides with that of the statistically proven criterion given by Alali *et al*. in 2018.[10,11] Alali *et al*. used data from BEST TRIP and COBRIT trials from South and North America, respectively, to compare concordance/discordance between ICP prediction on clinical and radiological basis with that of continuous ICP monitoring.[10,11,27] They advocated a clinical decision of RICH if the patient satisfied 1 major or ≥2 minor criteria [Table 4]. This criterion-based clinical decision was found to have high sensitivity but modest positive predictive value at traditional ICP cutoff levels (ICP 22 mmHg) and sensitivity reached 100% at ICP of 30 mmHg.[10] As rightly argued by the authors, sensitivity of the criterion was of utmost significance as undiagnosed RICH could lead to worse outcomes.

A small prospective study involving ten patients of traumatic head injury was published from Nigeria by Ojo *et al*. They studied the role of early DC based on radiological and clinical signs of raised ICP in a resource-poor center. The outcome reported was 40% mortality with 20% each of low disability (GOS 5), moderate disability (GOS 4), and severe disability (GOS 3).[9] The study concluded in favor of early DC without ICP monitoring as a justifiable alternative in resource-poor centers. A similar study by Adeleye *et al*. from Nigeria examined the role of "prophylactic DC" in cases of TBI with clinical and radiological evidence of raised ICP. The study included 17 patients with 23.5% of mortality. The outcome using GOS-E revealed 29.4% of upper severe disability and 47.1% of lower moderate disability or higher. The conclusion drawn was that DC may have a role to play in the developing countries in the preemptive treatment of posttraumatic raised ICP.[7] Results of both these studies are in line with that of ours. A review of neurosurgical literature pertaining to the outcome of DC in LMICs was published by Clavijo *et al*. in 2019. It noted a common trend of benefit from the DC procedure in majority of the reviewed literature but was unable to draw statistically significant conclusions from the same because of low methodological quality of these studies.[8]

Table 4: Clinical criterion rule for raised intracranial pressure as per Alali *et al*. (2018)

A) Major criteria
Compressed cisterns (Marshall III)
Midline shift >5 mm (Marshall IV)
Nonevacuated mass lesion (>25 cm^3)
B) Minor criteria
GCS motor score ≤4
Pupillary asymmetry
Abnormal pupillary reactivity
Marshall II (i.e., basal cisterns are present with midline shift of 0-5 mm and/or high- or mixed-density lesion of ≥25 cm^3)

ICP – Intracranial pressure; GCS – Glasgow Coma Scale

A recent systematic review of quality of life of patients after DC reported that most disabled patients (mRS >3) and caregivers were satisfied with their lives and would opt to have the procedure again.[28,29] This confirms that DC is here to stay as the last-tier option for RICH. An institutional review of DC from a tertiary corporate hospital like ours is unique in a way, as the results reflect in a descriptive way how DC is used in real practice in developing countries than can be evaluated by RCTs.

Limitations

We recognize the various limitations of our study. Our study being a retrospective, observational study from a single tertiary care center, with a small sample size and no control group, leads to insignificant statistical results. Inclusion of RICH cases due to any underlying pathology adds to the difficulty of arriving at statistically significant conclusions about DC for any single pathology. We hope that this article will contribute to keeping the discussion alive regarding the place of DC in ABI, especially in LMICs, and to stimulate the initiation of further studies.

Conclusions

Despite its limitations, DC clearly demonstrates a survival benefit in patients with ABI with RICH in all age groups, though there are conflicting inferences regarding the incidence of favorable outcome following DC.[2-4,6,21] DC helps in obtaining a favorable outcome in selected patients with defined pathology. Our case series provides reasonable justification that protocol-based early decompression without preoperative ICP monitoring is the way forward for resource-constrained environments. Risk of vegetative state was small in our series. For clinicians, it is imperative to communicate the potential range of outcomes and the expected quality of life with the next of kin before DC. It is clear that DC is here to stay as the last-tier option against RICH in ABI and can be used preemptively in developing countries for patients with clinical and radiological signs of RICH.[10] Hence, future studies that consider quality of life and psychological states of patients following are warranted.

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Conflicts of interest

There are no conflicts of interest.

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