Four Quadrant Osteoplastic Decompressive Craniotomy versus Conventional Decompressive Craniectomy for Traumatic Brain Injury: A Randomized Controlled Trial

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Abstract

Objective Four quadrant osteoplastic decompressive craniotomy (FoQOsD) has been described as a novel technique in the management of patients with traumatic brain injury requiring decompressive surgery. There has not been a randomized controlled trial comparing its outcomes with conventional decompressive craniectomy (DECRA) as yet.

Methods A randomized controlled trial of 55 patients was conducted, of whom 29 underwent DECRA and 26 patients underwent FoQOsD. The preoperative baseline demographics, clinical conditions, and radiologic features were similar in both the groups. Clinical outcome was decided by the use of Glasgow coma outcome scale extended (GOS-e) at 3 months. Radiographic outcomes were assessed by measurement of the change in midline shift and brain width expansion (ipsilateral and contralateral to hematoma) on the postoperative computed tomographic (CT) scan.

Results No significant differences were identified in baseline demographics, clinical condition, Rotterdam CT score, and radiographic characteristics between both the groups. At 3-month follow-up, the mean GOS-e score was comparable in both the groups (3.23 in DECRA group and 3.35 in FoQOsD group, $p = 0.856$). Mortality analysis at 3 months revealed that nine patients died in the DECRA group and eight died in FoQOsD group. Postoperative imaging characteristics, including Rotterdam score, also did not differ significantly. The percentage reduction in midline shift and percentage brain width expansion on the postoperative CT scan was similar in both the groups ($p > 0.05$).

Conclusion FoQOsD appears to be at least as efficacious as DECRA in providing equivalent clinical outcomes with the added benefit of avoiding a second surgery.

Keywords
- four quadrant osteoplastic decompressive craniotomy
- conventional decompressive craniectomy
- novel decompression technique
- syndrome of trephined
- traumatic brain injury
- randomized controlled trial

Introduction

Traumatic brain injury (TBI) is the major cause of disability, death, and economic cost to our society.[1] One of the central concepts that have emerged from research is that all neurologic damage from TBI does not occur at the moment of impact but evolves over the ensuing hours and days.[2] Furthermore, improved outcome results when these secondary, delayed insults, resulting in reduced cerebral perfusion to the injured brain, are prevented or respond to treatment.

The main objective of initial treatment is to prevent an increase in intracranial pressure (ICP) so as to maintain adequate cerebral perfusion and oxygenation by intensive monitoring, thus avoiding secondary brain injury. Cerebral perfusion is reduced and poorer outcomes are

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associated with systemic hypotension and intracranial hypertension. Despite the lack of level 1 evidence, monitoring the ICP and interventions to reduce the raised ICP are frequently used.

High ICP is treated by general maneuvers (normothermia, sedation, etc.) along with a set of first-line therapeutic measures (moderate hypocapnia, mannitol, etc.). When these measures fail to control high ICP, second-line therapies are started. Among these, second-line therapies such as barbiturates, hyperventilation, moderate hypothermia, or removal of a variable amount of skull bone (known as decompressive craniectomy [DC]) are used.[3]

The Brain Trauma Foundation guidelines published in 2007 recommended that treatment should be initiated as ICP exceeds 20 mm Hg.[4] These guidelines were modified in the 4th edition published in 2012, which stated that DC can be planned when ICP readings are greater than 25 mm Hg for 1 to 12 hours.[3]

Primary DC refers to leaving a large bone flap out after the evacuation of an intracranial hematoma in the early phase after a TBI followed by cranial reconstruction at a later date.[5,6] A secondary DC is used as part of tiered therapeutic protocols that are frequently used in intensive care units (ICUs) to control raised ICP and ensure adequate cerebral perfusion pressure after TBI.[5,6]

Surgical decompression can relieve pressure by increasing intracranial compliance, thus potentially sparing normal brain parenchyma from secondary injury.[7] However, as with any invasive procedure, it is also associated with some complications. Known risks include edema, hematoma formation, infarction, lack of protection against further trauma, and strangulation of cerebral tissue at edge of bone flap. Other complications include hydrocephalus, syndrome of the trephined, and cerebrospinal fluid (CSF) leak.[8]

Of these, persistence of bony defect is of paramount importance. It is further noted among many studies that many of these complications get reversed with the replacement of the bone flap.[8] This is probably related to the restoration of normal cerebral hemodynamics. Models have demonstrated that following craniectomy, there is a reduction in the pressure of both the CSF and brain parenchyma whereas there is an increase in cerebral blood flow after cranioplasty.[9,10] This leads to improved neurologic outcomes after replacement of the bone flap. The correction of shift of central structures and protection of brain from direct atmospheric pressure also help in reversal of the morbidities, especially posttraumatic hydrocephalus, CSF leak, and syndrome of the trephined.[10]

With this background, it was our intention to study the efficacy of a novel alternative technique, four quadrant osteoplastic decompressive craniotomy (FoQOsD), and compare its outcomes with traditional or conventional decompressive craniectomy (DECRA). We hypothesized that this newer technique provides for adequate surgical decompression while retaining the bone flap that avoids many of the complications known with DECRA. Patients with TBI being planned for DC were randomized into two groups of DECRA and FoQOsD, and the outcomes were studied.

Materials and Methods

The study was conducted as a parallel group randomized, controlled trial for six months from November 2016 to April 2017 in the Department of Neurosurgery at King George's Medical University, Lucknow. Total 55 patients were included in the study as per selection criteria. Patients were randomized into undergoing the DECRA or the FoQOsD procedures. All patients underwent routine preoperative investigations, and after providing informed written consent, they were taken up for the surgical procedure. Approval was obtained from the ethics committee for recruiting these patients for the study. All patients were treated with established head injury protocols and preoperative ICU care. Barbiturates were administered depending on need and availability.

Inclusion Criteria

- Age more than 18 years.
- Patients with TBI with surgically evacuable lesions planned for primary DC, and following evacuation of hematoma and lax augmentation duraplasty, the brain is persistently bulging.
- ICP is persistently greater than 25 mm Hg for 1 to 12 hours in patients on ICP monitoring for TBI with surgically nonevacuable lesions (secondary DC).

Exclusion Criteria

- Refusal by caretakers to become a part of the study.
- Patients requiring mass closure due to unstable clinical condition/malignant cerebral edema.
- Patients with penetrating contaminated and/or compound fractured bone segments.

Surgical Technique

Technique of Decompressive Hemicraniectomy

For unilateral DC, the patient was placed supine with a small rolled towel underneath the ipsilateral shoulder and the head turned toward the contralateral side.

Once the site was prepped and draped, a large reverse mark incision was made starting at the level of zygoma and curving posteriorly above the ear, over the parieto-occipital region, then superiorly and anteriorly, approximately 2 cm lateral to the midline, and stopping just behind the hairline. The posterior extent of the incision was more than 15 cm behind the keyhole to allow for an adequate craniectomy flap. The superficial temporal artery was preserved and temporalis was dissected up to the zygoma to allow for maximal temporal decompression.

The anteroposterior dimension was at least 15 cm and extended down to the floor of the temporal fossa. An adequate number of burr holes were made and underlying dura was separated using a Penfield No. 3 dissector. Gigli wire saw was used to make the craniectomy and temporal extent expanded, if necessary, using a rongeur.

Hemostasis with the bone and epidural space was achieved using bone wax and dural tack up stitches, respectively, and the dura was opened carefully in a cruciate fashion. After evacuation of the hematoma, dural augmentation was done with pericranium. Scalp closure was done in layers and bone flap was placed in subcutaneous pocket in anterior abdominal wall.

Technique of Four Quadrant Osteoplastic Decompressive Craniotomy Group

The incision remains the same, and the bone work is performed after lifting the craniotomy. The bone flap is cut into four pieces using an osteotome or Gigli wire saw and loosely connected by the periosteum to the other pieces and to the opposite side. Soft tissue closure was done in two layers with a drain in situ.

Statistical Analysis

Standard statistical tests and software such as Excel, SPSS, etc. will be used when necessary. The continuous response variables were presented by mean ± standard deviation (SD), and *t*-test was applied to compare the means between the two groups. Categorical data were analyzed using chi-square test with a $p < 0.05$ taken as significant. Moreover, wherever necessary, nonparametric tests were also applied. If the data were not normally distributed, Mann-Whitney test was used to compare the two groups and Wilcoxon test was used to compare within the two groups. Two-tailed significance was kept at < 0.05.

Results

Demographics

Total 55 patients were reviewed with 29 patients undergoing DECRA and 26 undergoing FoQOsD. There was no statistical difference in any of the preoperative demographic variables: patient age, sex, mean age, surgical indication, side of decompression, pupils reactivity, Glasgow coma scale (GCS) score, and surgical procedure.

Preoperative demographics are mentioned in ►**Table 1-5**.

Both the groups were also comparable with respect to motor scores and GCS scores with *p* value of 0.985 and 0.980, respectively (not significant).

Mode of Trauma

The most common mode of trauma was road traffic accidents accounting for around 92.7% of all patients. There was no significant difference in the modes of trauma between the two groups.

Twenty-four (82.7%) of 29 patients in the DECRA group and 20 (76.9%) of 26 patients in the FoQOsD group underwent a partial frontal and/or temporal lobectomy, and there was no significant variation between the two groups ($p = 0.459$).

There was no crossover in the study. We tried to get ventilator for those patients who needed it in pre- and postoperative period.

Table 1 Summary of demographic characteristics of patients undergoing DECRA and FoQOsD

Variable	DECRA	FoQOsD	*p* Value
Number	29	26	
M:F ratio	16:13	18:8	0.284
Mean age+ SD	36.21+ 12.31	39.31+ 13.71	0.381
Surgical indication			0.283
SDH	9	9	
Contusion	19	16	
Cerebral edema	1	1	
Side of decompression			
Right	9	7	
Left	19	15	
Bilateral	1	4	
Pupils			0.415
Equal/reactive	12	15	
Anisocoric	14	10	
Fixed/dilated	3	3	
Associated injuries	3	3	0.445
Opposite-side contusion	7/29 (24.13%)	8/26 (30.76%)	0.492
Presence of SAH/IVH	16/29 (55.2%)	13/26 (50%)	0.417

Abbreviations: DECRA, conventional decompressive craniectomy; F, female; FoQOsD, four quadrant osteoplastic decompressive craniotomy; IVH, intraventricular hemorrhage; M, male; SAH, subarachnoid hemorrhage; SD, standard deviation; SDH, subdural hemorrhage.

Postoperative Outcome

Glasgow Coma Scale Scores

There was significant improvement in GCS scores in both the groups before and after surgery, and this difference was *statistically significant* in the DECRA group ($p = 0.017$) while not quite significant in the FoQOsD group ($p = 0.075$).

However, there was no significant difference in the improvement of GCS between the two groups, indicating that FoQOsD may be as efficacious as DECRA ($p = 0.784$) (►**Table 6**).

Radiologic Outcome

Both the groups achieved comparable results regarding reversal of midline shift (MLS) and cerebral expansion. The reduction in MLS was comparable in both the groups with both reach groups reaching significance. While the mean increase in ipsilateral brain width in both the groups was significant, the degree of contralateral brain width expansion in the FoQOsD group had a *p* value of 0.07 that was not significant (►**Table 7**).

Table 2 Summary of GCS and motor score on admission in both groups

Group	GCS < 8	GCS 9–12	GCS 13–15	Motor score 2–3	Motor score 4–5	Motor score 6
FoQOsD	18	6	2	11	13	2
DECRA	20	6	3	13	14	2
p Value	0.985			0.980		

Abbreviations: DECRA, conventional decompressive craniectomy; FoQOsD, four quadrant osteoplastic decompressive craniotomy; GCS, Glasgow coma scale.

Table 3 Mode of injury in both groups

Mode		Group		Total
		DECRA	FoQOsD	
Assault	No.	1	0	1
	%	3.4%	0%	1.8%
FFH	No.	1	1	2
	%	3.4%	3.8%	3.6%
Fall of object	No.	0	1	1
	%	0%	3.8%	1.8%
RTA	No.	27	24	51
	%	93.1%	92.3%	92.7%
Total	No.	29	26	55
	%	100.0%	100.0%	100.0%

Abbreviations: DECRA, conventional decompressive craniectomy; FFH, fall from height; FoQOsD, four quadrant osteoplastic decompressive craniotomy; GCS, Glasgow coma scale; RTA, road traffic accident.
p = 0.403.

Table 4 Rotterdam CT score in both groups

Group	Rotterdam score 4	Rotterdam score 5	Rotterdam score 6
DECRA	1 (3.4%)	15 (51.7%)	13 (44.8%)
FoQOsD	2 (7.7%)	13 (50%)	11 (42.3%)
			p Value 0.711

Abbreviations: CT, computed tomography; DECRA, conventional decompressive craniectomy; FoQOsD, four quadrant osteoplastic decompressive craniotomy.

Table 5 Percentage of patients undergoing lobectomy

Group	Lobectomy Yes	No
DECRA	24/29 (82.7%)	5/29 (17.2%)
FoQOsD	20/26 (76.9%)	6/26 (23.0%)
p Value	0.459	

Abbreviations: DECRA, conventional decompressive craniectomy; FoQOsD, four quadrant osteoplastic decompressive craniotomy.

Table 6 Pre- and postoperative clinical results

Group	GCS (at admission)(mean+ SD)	GCS (pre-surgery)(mean + SD)	GCS (post-surgery)(mean + SD)	*p* Value
DECRA	7.52 +2.89	7.45 + 2.88	9.45 + 3.38	0.017 (S)
FoQOsD	7.60 + 2.85	7.62 + 2.88	9.20 + 3.35	0.075
p Value	0.295	0.830	0.784 (NS)	

Abbreviations: DECRA, conventional decompressive craniectomy; FoQOsD, four quadrant osteoplastic decompressive craniotomy; GCS, Glasgow coma scale; NS, not significant; SD, standard deviation; S, significant.

Table 7 Pre- and postoperative radiologic comparisons

Variable	FoQOsD Preoperative	FoQOsD Postoperative	*p* Value	DECRA Preoperative	DECRA Postoperative	*p* Value
Mean MLS	8.92+2.09	3.63+1.87	< 0.0001 (S)	9.24+2.15	3.28+1.12	< 0.0001
Mean I/L brain width	55.70 + 4.28	58.01 + 3.86	< 0.0001 (S)	56.19 + 3.11	58.93 + 3.20	0.001 (S)
Mean C/L brain width	46.70 + 4.67	49.15 + 4.98	0.07 (NS)	44.82 + 3.80	48.10 +4.42	0.037 (S)

Abbreviations: C/L, contralateral; DECRA, conventional decompressive craniectomy; FoQOsD, four quadrant osteoplastic decompressive craniotomy; I/L, ipsilateral; MLS, midline shift; NS, not significant; S, significant.

Glasgow Outcome Score Extended Outcome

In the DECRA group, seven patients were dead by the 1-month follow -up period, which increased to 9 at the 3-month period. Both these patients were older than 50 years and had a GCS score of 12 on discharge. The probable cause was aspiration while cardiac events could not be ruled out. Sudden neurologic deterioration from syndrome of the trephined was also a possibility. There was no added death in the FoQOsD group (►**Table 8**).

This could mean that once the edema resolves and the brain starts to sink in, the presence of a bone flap will prevent any acute neurologic deterioration.

Mortality

See ►**Table 9**.

Complications

Twenty-two (84.6%) of 26 patients in the FoQOsD group had no significant complications in the *perioperative period*

Table 8 Primary outcome of GOS-e at 3 months

GOS-e at 1 mo	DECRA (n = 26)[a]	FQOsD (n = 28)[a]	GOS-e at 3 mo	DECRA (n = 17)[b]	FQOsD (n = 17)[b]
1 Dead	7	8	1 Dead	9	8
2 Vegetative state	1	0	2 Vegetative state	0	0
3 Lower severe disability	6	5	3 Lower severe disability	1	1
4 Upper severe disability	5	7	4 Upper severe disability	1	0
5 Low moderate disability	2	2	5 Low moderate disability	1	2
6 Upper moderate disability	5	3	6 Upper moderate disability	2	6
7 Low good recovery	0	0	7 Low good recovery	2	0
8. Upper good recovery	0	0	8 Upper good recovery	1	0

Abbreviations: DECRA, conventional decompressive craniectomy; FoQOsD, four quadrant osteoplastic decompressive craniotomy GOS-e, Glasgow outcome scale extended.

[a]Three patients lost to follow-up in DECRA group and one in the FoQOsD group.

[b]A further three patients in each of the FoQOsD and conventional DECRA groups were lost to follow-up at 3-month period. A total number of six patients in the DECRA group and five in the FoQOsD group have not yet reached the 3-month follow-up period.

Table 9 Mortality analysis in both groups

Variable	DECRA	FoQOsD	p value
Mortality at 7 d			0.089
Dead	2	6	
Alive	27	20	
Mortality at 3 mo			0.843
Dead	9	8	
Alive	17	17	

Abbreviations: DECRA, conventional decompressive craniectomy; FoQOsD, four quadrant osteoplastic decompressive craniotomy.

following surgery whereas 20 (68.9%) of 29 patients had no complications in the DECRA group (p = 0.223).

In the postoperative period in the DECRA group, five patients developed infection of the abdominal wound and subsequently underwent bone flap removal. Only one patient of the FoQOsD group developed surgical site infection needing antibiotics.

One patient in each group developed hydrocephalus requiring CSF diversion.

Seven patients (four in DECRA group and three in FoQOsD group) developed ventilator-associated pneumonia and/or sepsis and required prolonged ICU stay and antibiotics.

Discussion

The management of intracranial hypertension is a subject of great debate for a neurosurgeon. DC has emerged as a valuable surgical option in such cases. The results of the RESCUEicp (Randomized Evaluation of Surgery with Craniectomy for Uncontrollable Elevation of Intracranial Pressure) trial show that secondary DC for refractory intracranial hypertension reduces mortality.[11] Primary DC is also a frequently practiced surgical procedure. However, there is a varied spectrum of complications associated with DC because of the absence of a bone flap.[8] The main complications that may occur following a DC include vulnerability of the underlying brain to direct injuries due to the loss of bone and a higher incidence of infection, hydrocephalus, syndrome of the trephined, etc.

Syndrome of the trephined is a rare complication seen in DECRA due to the effect of atmospheric pressure on the exposed brain. There is a reduction in the cerebral blood flow and velocity following decompressive surgery.[9,10] Restoration of the bone flap is associated with reversal of these complications. Ergodan et al demonstrated via transcranial ultrasound that blood flow velocity ipsilateral to the cranial defect was significantly increased following cranioplasty.[9]

We had two patients who were discharged with a GCS score of 12 and above and both expired suddenly within 24 hours of deterioration. Though cardiac causes and aspiration were a possibility, neurologic deterioration from syndrome of the trephined was also considered.

Restoration of cerebral hemodynamics as an explanation for neurologic recovery after cranioplasty was proposed by Richaud et al as early as 1985.[12] Cranioplasty avoids the effect of the atmospheric pressure on the brain and increase the cerebral blood flow as well as improve the cardiovascular functions. It is seen that many patients who receive an earlier cranioplasty tend to have better neurologic outcomes.[9,10]

Therefore, keeping this in mind and also understanding the need for cerebral decompression, many modifications of the DECRA have emerged over the past two decades. These include hinge craniotomy, floating resin craniotomy among others.[13–16] These modifications are specifically aimed at reducing the morbidity associated with the removal of bone flap while achieving adequate cerebral decompression.

Peethambaran et al in 2015 presented a pilot study on a new technique called four quadrant osteoplastic decompressive craniotomy and found that this technique and DECRA were similar regarding survival and brain expansion on CT scan.[15] We conducted a similar study in April 2016 in our center and found a success rate (defined as improvement in GCS and GOS) in 7 (58.3%) out of 12 patients.

Infection rates following DC and cranioplasty vary between 3 and 5%. The significant factor associated with increased rates of infection is the stored bone flap. Storage of the bone flap in a freezer for prolonged periods also increases the risk of infection.[15] In this study, five patients in the DECRA group developed infection of the abdominal wound that

required bone flap removal. Our procedure avoided these complications.

In this study, one patient in each group developed hydrocephalus that was managed by CSF diversion. The mechanism of hydrocephalus is attributed to obstruction of the arachnoid granulations by surgical debris. Early cranioplasty would restore normal ICP dynamics and probably normalize the hydrocephalus.[15]

Kenning et al performed volumetric analysis and CT morphometrics to assess the CT scans in operated cases of DECRA and hinge craniotomy. They found that the degree of cerebral expansion and extracerebral herniation was lower in the hinge craniotomy group, which was not statistically significant. However, their results reached statistical significance when the extracerebral herniation was expressed as an index.[16]

They further speculated that the higher extracerebral herniation index and change in direction of MLS in patients with DECRA may be responsible for postoperative brain deformation.[16] As demonstrated by Flint et al, the rapid cerebral decompression may increase the chance of parenchymal contusion and venous congestion.[17]

In both the groups, the mean reduction in MLS before and after surgery was comparable. The change in ipsilateral and contralateral brain expansion was also similar in both the groups.

In comparison to a hinge craniotomy, this technique allows for greater cerebral expansion. There is less resistance, and the brain usually bulges out in a hemispheric pattern. The four pieces protrude in four different directions offering least resistance to the brain.[15] While in floating resin and hinge craniotomy, there is some resistance offered by the bone flap.

There were two big limitations to our study. First, ICP monitoring was not done. Due to limited resources, ICP monitoring was only practiced in patients undergoing secondary DC. The second is that long-term follow-up has still not been achieved, and a follow-up CT scan is mandatory to look for bony fusion. Small sample size is another limitation.

Our study is first to evaluate cerebral decompression techniques of FoQOsD and DECRA through a comparative analysis. We have found that FoQOsD is as efficacious as DECRA in improving the clinical outcome and producing adequate decompression. Furthermore, FoQOsD avoids late mortality due to acute neurologic deterioration from the absence of a bone flap and the morbidity of wound infection.

Conclusion

FoQOsD could replace DECRA in a select category of patients. With comparable clinical and radiologic outcomes, we feel that FoQOsD can avoid the economic burden of a second surgery and improve the psychology of patients. Furthermore, in a high-volume center such as ours, avoiding second surgery will increase patient turnover and this will improve health care.

It would also be prudent to consider measuring ICP in both the groups to assess the degree of ICP fall. Larger samples are also required.

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