Complications of Different Types of Cranioplasty and Identification of Risk Factors Associated with Cranioplasty at a Tertiary Care Centre: A Prospective Observational Study

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Indian J Neurosurg 2024;13:27–34.

Abstract

Objective Decompressive craniectomy (DC) is an urgent procedure which is done to decrease intracranial pressure. A study of the complications would suggest measures to improve the care. This study was focused on analyzing the complications after cranioplasty (CP) and to identify risk factors that may be associated with the failure of the procedure.

Method: This study was conducted over 41 months at level-1 trauma center and medical college. It included patients undergoing CP for a defect arising out of previous DC or inability to replace the bone flap (Glasgow Coma Scale $>$ 13, size $>$ 5 cm, without surgical site infection). All patients underwent CT imaging before and after the procedure. The CP technique largely depended on the patients, based on the cost of prosthesis and availability.

Result: Hundred patients were included in the study. Postoperatively, total 22 patients suffered complications of which few had more than one complication. Titanium implant appeared to be a better implant, with no complication ($p < 0.05$). Complication was common in younger age group, chemically cured PMMA (polymethyl methacrylate) and ethylene oxide) sterilized bone flap). Complications were higher among patients with multiple comorbidity and stroke patients.

Conclusion: Titanium flap had no complication and in case of autologous abdominal subcutaneous flap, apart from bone flap absorption, patients had no major complication. Therefore, both implants are preferred implants for CP. Heat-cured PMMA can be used in case of nonavailability of a better option, as it is economical feasible and can be molded at any dental lab.

Keywords
- Decompressive craniectomy
- cranioplasty
- infection
- titanium
- methyl methacrylate

Introduction

Treatment of life-threatening increase in intracranial pressure requires urgent decompressive craniectomy (DC).[1] After DC, the patients who survived and recovered need to undergo cranioplasty (CP). Several studies on CP highlight the operative aspects of the CP such as the use of synthetic materials,[2,3] preservation of bone flap,[3,4] and the timing of CP.[5,6] There are

article published online
February 23, 2023

DOI https://doi.org/10.1055/s-0043-1761603.
ISSN 2277-954X.

Thieme Medical and Scientific Publishers Pvt. Ltd., A-12, 2nd Floor, Sector 2, Noida-201301 UP, India

very few important studies enumerating the clinical outcomes and complications of CP.[7–10]

Complications after CP which is usually seen as a simple operative procedure may very well have been underreported.[7] Most patients undergoing CP would have suffered significant morbidity during the previous illness necessitating DC. Hence, it is more important to avoid further complications. Postoperative surgical site infections (SSI), cosmesis, and strength of reconstruction are factors, taken into consideration before CP.

Complications following CP increase morbidity and raise health care costs. An analysis of the complications will help us to decide steps to improve patient's wellbeing. This study was undertaken to assess the complications of different types of CP and to find risk factors that may be associated with the failure of the procedure.

Material and Methods

This prospective study was conducted over 41 months at level 1 trauma center and medical college. It included patients undergoing CP for a defect arising out of previous DC or inability to replace the bone flap.

Patients with Glasgow Coma Scale (GCS) >13 and with a craniectomy defect size of more than 5 cm without any recent infections in the surgical site were included.

All patients underwent CT imaging without contrast before and after the procedure. The CP technique largely depended on the patients based on the cost of prosthesis and availability. Appropriate consent was taken from study patients. Patient-specific data, clinical parameters, imaging features, operative finding, and postoperative course were recorded. This study was approved by the institutional ethical committee.

The patients were subsequently followed up at 1, 3, and 6 months from surgery. Complications were classified as major and minor. Infections occurring ≤30 days after surgery (or in case of implant insertion up to 1 year after) and affecting either the incision or deep tissue at the operation site were considered as SSI. Any uninfected collection in subgaleal space after the removal of drain was considered as subgaleal collection. Complications requiring surgical intervention or flap removal and those which were managed medically were also noted.

The role of various factors studied regarding complications:

(1) Patient-specific parameters—age, sex, comorbidity, and neurological status.
(2) Factors related to previous surgery—indication and type of craniectomy.
(3) CT findings: pre- and postoperative.
(4) Technique of CP.
(5) Intraoperative findings.
(6) Postop status.

SPSS version 22 was used to perform statistical analysis. For estimating the statistical difference between two categorical variables, we used chi-square test or a two-tailed Fisher's exact test, whereas for checking the statistical difference between two continuous variables, we used *t*-test. The p-value < 0.05 was considered significant.

Results

The study included 106 patients who underwent CP out of which 6 patients were lost to follow-up. The remaining 100 patients were included in this study. Complications were seen in 22 out of 100 patients (22%).

Complications Postcranioplasty

Postoperatively, total of 22 patients suffered complications of which few had more than one complication. ►**Table 1** denotes complications leading to the removal of bone flap. Complications in relation to time since CP were as follows: intraoperatively, dural tear (8) and hemodynamic instability (5) were seen. In early period within a week, seizures (5), urinary tract infection (1), pneumonitis (3), deep vein thrombosis (DVT) (5), meningitis (2), subgaleal collection (3), epidural hematoma, and contusion (3) were noted. Between 8 and 30 days (intermediate) patients developed subgaleal collection (6) and SSI (1). After 1 month (late), SSI (1) and subgaleal collection persisted in two patients (►**Fig. 1**).

During the CP procedure, 28 patients had bulging dura preventing placement of flap and 23 had autologous bone flap resorption. But these findings did not change the course of procedure and were managed on the table. Due to complications, before discharge, two patients underwent bone flap removal. Major complications like SSI (2), epidural hematoma (EDH)/contusion (2 + 1), subgaleal collection (9), and seizures (5) were seen only in 13% patients. Minor complications in rest consisted of 9% patients.

Outcomes at Outpatient Department Follow-Up

At the end of 1 month, four new patients developed complications. Out of these four patients, two underwent

Table 1 Complications causing removal of prosthesis

Complication	Autologous bone flap	Synthetic prosthesis	Total	Bone flap removal
SSI	0	2	2	2
Subgaleal collection	4	5	9	4
Meningitis	1	1[a]	2	1

Abbreviation: SSI, surgical site infections.
Note: Association between occurrence of subgaleal collection and flap removal found significant ($p = 0.0008$).
[a]This patient also having SSI underwent bone flap removal.

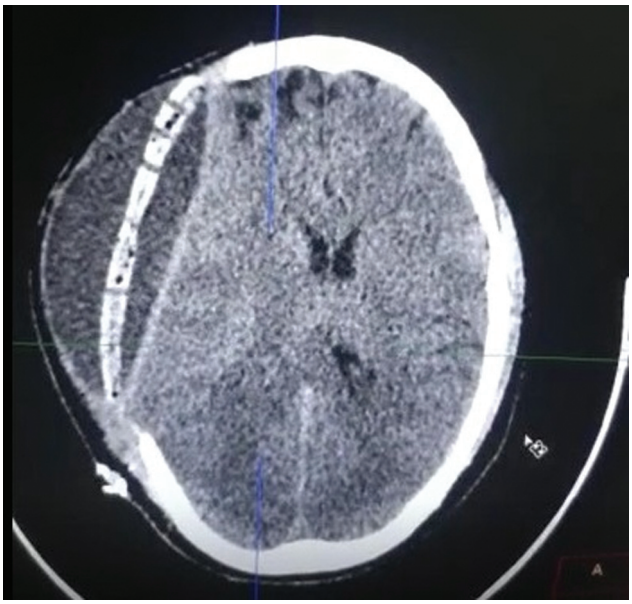

Fig. 1 Subgaleal collection in synthetic cranioplasty patient.

bone flap removal. At the end of 3 months, two patients continued to have subgaleal collection and underwent bone flap removal.

Ninety-four of the total operated patients were asymptomatic at end of 6 months.

Duration of Stay and Glasgow Outcome Score

The overall mean duration of stay was 5.27 days. In complicated patients, it was 8.95 days and in uncomplicated 4.23 days. There was no change in GOS after CP.

The different parameters affecting the outcome were studied as per the summary given in ►**Table 2**.

Age

The mean age of patients in our study was 34.32 years (range: 8–67 years). The patients of age group <20 years had relatively higher complications (42.85%) in our study group. Out of 100 patients, 87 were male and 13 were female.

Comorbidities

Single comorbidity was seen in 21 patients and multiple comorbidities in 16. The complication rate was 23.80 and 31.25% in each group.

Indication for Craniectomy

Traumatic brain injury (TBI) was the most common indication for craniectomy in 88 patients (complication rate: 20.45%), while intraoperative brain swelling in 3 (0%), infection in 3 (33.3%), and stroke was the indication in 6 (50.0%). The complication rate was maximum 50% among the stroke patients.

The type of craniectomy was unilateral fronto-temporo-parietal (FTP) 93 (complication in 21 [22.58%]), followed by bifrontal 2 (complication in 1 [50%]), temporo parietal 2, pterional 2, and frontal 1. The complication rate was maximum for bifrontal craniectomy (50%). The median time from the craniectomy procedure to CP was 177.5 days, and minimum was 32 days. Out of 56 patients who underwent CP within 6 months, 25% ($n = 14$) developed complications when compared with patients who underwent later 18% ($n = 8$).

At the time of CP, 64 patients had GCS of 15 and no deficit (25% developed complication) and 36 patients had deficits and/or GCS < 15 (16.66% developed complication).

Type of Prosthesis

Patients who underwent CP with intraoperative acrylic molds (four patients) and ethylene oxide (ETO) sterilized flaps (five patients) had a high complication rate of 75 and 40%. Among the 58 patients with abdominal bone flap, 23 patients (39.65%) had significant bone resorption. Patients with preconformed titanium implant ($n = 7$) had no complication (►**Fig. 2**). Twenty-six patients underwent prefabricated acrylic implant of which 15.38% developed complications (►**Table 2**).

Duration of Surgery and Blood Loss

Mean duration of surgery was 145.75 minutes (range: 70–285 minutes), for CP using autologous bone it was 147.32 minutes and for other techniques it was 140.95 minutes.

Mean blood loss during surgery was 185.25 mL which was 212.75 mL for autologous CP and 147.26 mL in other techniques.

Intraoperative Findings

Brain Bulge

Intraoperatively, 28 patients had brain bulge. In total, 17.85% of these later developed complications.

Dural Calcifications

In our study, 34 patients had dural calcification. Among these, 32.35% developed complications (►**Fig. 3**).

Preoperative and Postoperative Scan Findings

In preoperative image, 30% had gliosis, 1% had ex vacuo dilation, 4% had brain bulge, and in rest 65% findings were normal. In postoperative image, 2% had subgaleal collection, 2% had epidural collection, 1% had contusion, and rest 95% had no new finding.

Postoperative Fever

The occurrence of pyrexia >101°F in the postoperative period was associated with a higher rate of complication (4/8[>101°] vs. 5/20 [<101°] vs. 13/72 [normal]).

Discussion

This study being a prospective analysis of 100 patients collected over 41 months is one of the few large sample-based study. Complications leading to the failure of the procedure (removal of prosthesis) and other complications were looked up for up to 6 months post-CP. The incidence of complications after the procedure differs among reported

Table 2 Summary of overall complications with statistical analysis

Characteristics	Patients who did not experienced complications ($n = 78$)	Patients who experienced complications ($n = 22$)	*p*-Value
Mean age	36.05 ± 11.91	28.18 ± 10.25	0.006[a]
Gender			
• Male	66(75.87%)	21(24.13%)	0.727[b]
• Female	12(92.31%)	1(7.69%)	
Comorbidities			0.511[b]
• Multiple	11(68.65%)	5(31.25%)	
• Single	16(76.20%)	5(23.80%)	
Indication for craniectomy			
• TBI	70(79.54%)	18(20.45%)	0.396[b]
• Intra Operative Swelling	3(100%)	0(0.00%)	
• Infection	2(66.67%)	1(33.33%)	
• Stroke	3(50.00%)	3(50.00%)	
Type of craniectomy			
• FTP	72(77.42%)	21(22.58%)	1.00[b]
• Bifrontal	1(50.00%)	1(50.00%)	
• Temporo Parietal	2(100%)	0(0%)	
• Pterional	2(100%)	0(0%)	
• Frontal	1(100%)	0(0%)	
Time elapsed since craniectomy (days)	259.50 ± 272.74	244.95 ± 187.96	0.815[a]
GCS at admission for cranioplasty			
• Full	48(75.00%)	16(25.00%)	0.334[b]
• Incomplete (with deficits)	30(83.34%)	6(16.66%)	
Type of prosthesis			
• Autologous abd S.C.	45(77.59%)	13(22.41%)	0.046[b]
• ETO	3(60.00%)	2(40.00%)	
• Acrylic	22(84.62%)	4(15.38%)	
• Titanium	7(100%)	0(0%)	
• Deputy	1(25.00%)	3(75.00%)	
Mean blood loss (mL)	179(± 124.34)	206.81(± 136.63)	0.670[a]
Mean duration of surgery (min)	143.59 ± 40.60	153.41 ± 44.25	0.328[a]
Abnormal dural calcification			
• Yes	23(67.65%)	11(32.35%)	0.073[b]
• No	55(83.34%)	11(16.66%)	
Fever			
<101°	15(75.00%)	5(25.00%)	0.013[b]
>101°	4(50.00%)	4(50.00%)	
Duration of stay (days)	4.23 ± 1.58.	8.95 ± 4.91	0.031[a]
Brain bulge			
• Yes	23	5 (17.85%)	0.601[b]
• No	55	17 (23.61%)	

Abbreviations: Autologous abd S.C., abdominal subcutaneous flap; ETO, ethylene oxide; FTP, fronto-temporo-parietal; GCS, Glasgow Coma Scale; TBI, traumatic brain injury.
[a]*p*-Value for unpaired *t*-test.
[b]*p*-Value for chi-square/Fisher's exact test.

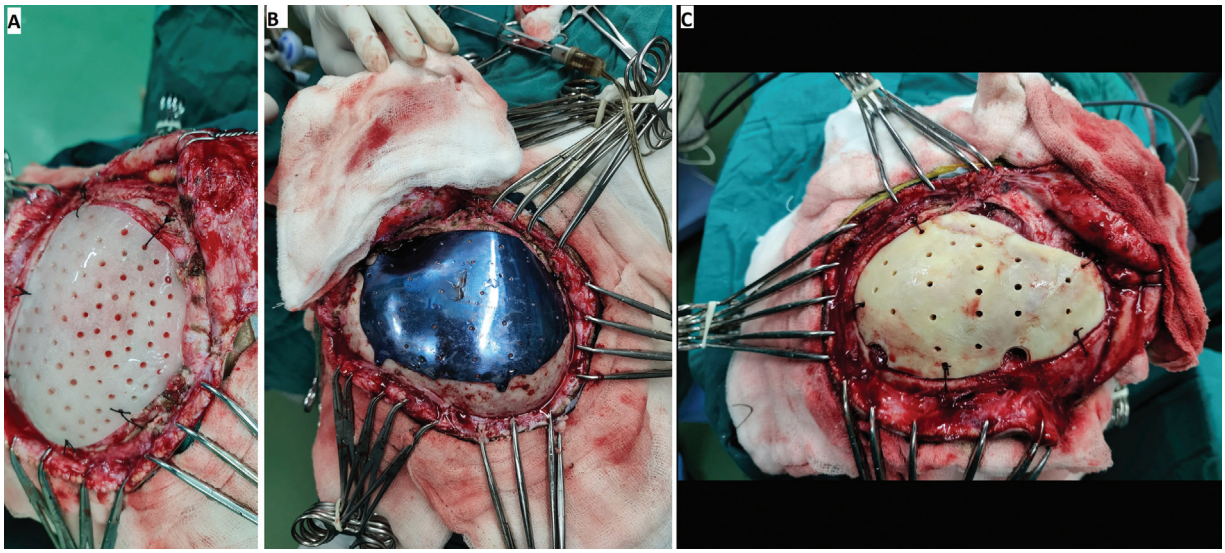

Fig. 2 Intraoperative images: **(A)** heat cured PMMA, (**B**) preconformed titanium implant, and **(C)** autologous bone flap.

literature, especially due to criteria used to define complications and varies from 10 to 43%[7–13]

In a study which included 94 stroke patients who underwent DC, the overall complication rate was 31.32%[11] and in another study which included several different pathologies and underwent DC, complication noted was 16.4%.[13] Prolonged wound healing and SSI was the most common complication noted in the above studies. In our study, we noted 22% complication rate and the rate of SSI was 2%, while prosthesis removal was required in 6% and reexploration in 1% which is comparable with other studies. Major complications like SSI, EDH, contusion, subgaleal collection, and seizures were seen only in 13% patients which were comparable to most studies.

Fig. 3 Dural calcification.

In our study, total nine patients who underwent craniectomy for TBI developed subgaleal collection, of these four underwent bone flap removal for persistent subgaleal collection (two patients had ETO sterilized bone and two had DePuy intraoperative molded chemically cured PMMA flap). The association between subgaleal collection and bone flap removal was found to be significant (p-value = 0.01). In one patient with acrylic and four with autologous abdominal subcutaneous (S.C.) flap, collection regressed with conservative management only.

All the above patients reporting persistence of subgaleal collection could be a part of epidural fluid collection (EFC). After CP, EFC is seen quite often than had previously been thought. EFC rarely causes neurological deficits as it tends to get spontaneously absorbed with time.[14] Causes may be due to dural calcification causing stiffness which prevents the expansion of brain parenchyma, thus forming an epidural dead space. Secondly, air acts as an irritant and leads to exudate formation due to inflammation. Third, during CP, an inadvertent dural tear can lead to cerebrospinal fluid collection or exudates generated from the dissected subgaleal region and muscle. Fourth, implants especially synthetic implants which may initiate an inflammatory process.[14,15]

The reported rate of SSI in studies found to be 1.4 to 24.4%.[16,17] In our study, 2% of patients developed SSI. Of these, one patient developed subgaleal collection with SSI and meningitis, while other was detected to have SSI only. Both underwent bone flap removal. Both these patients had craniectomy for TBI. One patient had bifrontal craniectomy. On analyzing the type of implant, we found that both the patients had a synthetic implant, one had acrylic (heat cured PMMA) and another had DePuy (chemically cured PMMA). Noticeable finding in above discussion is that none of the patient having titanium flap or autologous SC bone flap

suffered from SSI or subgaleal collection requiring bone flap removal.

Postoperatively, two patients developed EDH and one developed contusion. Of these, one patient of EDH required evacuation and the rest were managed conservatively. The occurrences of both these complications were seen within the range of the elective neurosurgical procedure.[7] Other complications seen in our study were seizures (five), meningitis (two), hemodynamic instability (five), DVT (five), and pneumonitis (three). All these complications were managed medically but caused significant morbidity in the form of increased duration of stay in the hospital, high doses of antibiotics, and ICU monitoring. However, all patients were discharged without any neurological worsening. One patient who developed meningitis with SSI required surgery for the removal of prosthesis.

Throughout the study, it was noticed that patients with an age less than equal to 20 years were associated with a maximum complication rate of 42.85% ($n = 6$), of these three patients (21.42%) required the removal of prosthesis. In other studies, however, increasing age has been shown to be associated with higher complications but these correlations are nonsignificant.[9,11] Better outcomes among younger patients in previous studies may be due to the lack of comorbid conditions. Our results are different when compared to previous studies probably due to a combination of other factors like a smaller number of patients in $\leq$ 20 years age group in the cohort and the use of synthetic or ETO sterilized flap among four out of six patients leading to a high complication rate as noted in our study. Thus, this result can be skewed, and thus, further study with larger group in this age group could give better clarity.

In this study, 21 males (24.13%) and 1 female (7.69%) got complications. The influence of gender on the outcome has always been a matter of controversy. Clinically, women have better outcomes than men.[18] Males tend to have larger frontal sinus, which gets breached while surgery, leading to a high rate of infection. We have comparable results to previous studies.[19] However, due to a very small number of female patients, any conclusion cannot be reached.

In our study, 21 patients had single comorbidity and 16 had multiple comorbidities with a complication rate of 23.8 and 31.3%, respectively. The complication rate was 19% when no comorbidity was present. In the present study, the association was not statistically significant, but studies have found higher complication rates in patients with comorbidities and increasing age.[11]

A study done by Walcott et al showed stroke patients had more infection than trauma patients after undergoing CP.[17] The indication for the craniectomy may be associated with complications.[9,17,20] Patients of CP following TBI noted to have a higher infection rate because of having scalp lacerations or skull fractures that may increase their risk for infection compared to CP following malignant stroke, tumor, or subarachnoid hemorrhage.[21,22]

Our data show a high complication rate of 33.33% among patients who underwent craniectomy for infective causes. These patients had their initial infection treated with antibiotic therapy as per recommendations, and CP was performed at a delayed time after the complete subsidence of infection.

In our study, patients with stroke had the highest complication rate of 50%. This is consistent with other published studies and most likely reflects age in combination with (vascular) comorbidities.[9,11] The number was small to assess statistical significance.

Type of Craniectomy

The rate of complication after CP in FTP defect was 22.58% (21 out of 93), while the complication rate of 50% (1 out of 2) was seen in the Bifrontal defect. The results were not statistically significant because of the smaller size of the group. The bifrontal defect is known to be associated with complications after CP.[7] Numerous factors like long incision for a bifrontal craniectomy, less availability of temporalis muscle for soft-tissue coverage, opening of the frontal sinus during surgery, and a longer surgery time may be involved. Breach of the frontal sinus is described as a definitive risk factor for infection.[7,12]

Type of Implant

The commonest implant in our study was autologous bone preserved in S.C. space. The rate of complication in the autologous abdominal bone flap was 22.41%, while the mean complication rate was 30.12% with a synthetic implant.

Complication was seen in 75% of patients with chemically cured PMMA, followed by 40% in ETO sterilized flap, 22.41% in autologous abdominal flap, 15.38% in prefabricated PMMA flap, and nil with titanium prosthesis (►**Table 2**).

The prosthesis removal rate was highest with DePuy chemically cured PMMA (75%) followed by ETO sterilized bone (40%), while it was 3.84% for heat-cured acrylic and nil for autologous abdominal S.C flap. The relationship between the implant type and complication rate was found significant (p-value = 0.046) in this study. In our study, complication rates associated with the type of prosthesis are comparable to other studies as shown in ►**Table 3**.

Time Elapsed between Craniectomy and Cranioplasty

In the present study, mean time elapsed since craniectomy till CP was 256.3 days and the rate of complication was higher in initial 6 months (25%; ►**Table 4**).

The decision regarding time interval between craniectomy and CP was decided as per clinical recovery.

Table 3 Complication rates associated with the type of prosthesis in studies

Study	Autologous prosthesis	Synthetic prosthesis	Significance
Brommeland et al[23]	39%	10%	Not significant
Tsang et al[24]	6.25%	4.45%	Not significant
Chang et al[9]	22%	15%	Not significant
Present study	22.41%	30.12%	significant

Table 4 Comparison of complication of early and late cranioplasty

Study	Complication rate in early CP	Complication rate in late CP	Remark
Chaturvedi et al[8]	45%	22.6%	Cutoff was 90 d
Kim et al[28]	10.2%	6.9%	Only SSI considered as complication
Piedra et al[10]	34.6%	35.4%	Cut off 90 d
Chang et al[9]	9%	21.5%	90 d cutoff, Significant
Present study	25%	18.18%	180 d cutoff

Abbreviation: CP, cranioplasty; SSI, surgical site infections.

Resolution of brain swelling during recovery period was one such criteria for CP which led to less number of patients undergoing CP within 3 months.

Published studies are filled with varied observations with respect to timing of CP. Some suggesting early surgery associated with a less complication rate,[9,12,25,26] others suggesting early being associated with higher complication rate.[6,8,10,27–29] Recent studies show similar rates between early and late cranioplasties [11,13,20,25] (►**Table 4**). Bender et al[25] and Zanaty et al[11] in their study consisting of 147 patients and 348 patients noted similar rate of complications between early and late CP. Walcott et al[17] also did not observe any difference in the postoperative complication rate among the early and late groups.

In our study, CP done within 6 months were associated with a higher rate of complications (►**Table 4**). Early CP could be associated with a higher infection rate, as microorganism can be lodged in wound or skin after craniectomy operation.[28] However, our analysis revealed no statistical significant difference in the early and late group (p-value = 0.815).

Duration of Surgery and Blood Loss

Cranioplasty using autologous abdominal S.C. flap takes more time and blood loss because of extra step, for retrieval of bone flap. It is a practice at our center to use pericranium for the augmentation of dura during DC due to which there can be increased adhesion noted during second procedure like CP, leading to increase operative time and blood loss. Mean duration of surgery was higher among patients who had complications. Similar results were observed in study done by Chaturvedi et al. It was noted longer operative time leads to a higher complication rate and blood loss.[8] However, we could not draw any statistically significant conclusion.

Intraoperative Findings and Related Complications

Brain Bulge

In our study, 28% patients had findings of bulging brain intraoperatively, which was managed with decongestants in 19%, ventricular drainage in 1%, or both in 8% and none required shunt. Of these patients, five patients (17.85%) suffered complications later; as subgaleal collection in two, one developed SSI, while rest two developed seizures in the immediate postoperative period required ICU stay for the control of seizures. Possible mechanisms for the complications could be mechanical stress over bulging brain, CSF leak due to dural tear or tapping of ventricles, and increased duration of surgery. Association between brain bulge and overall complications was statistically not significant ($p = 0.601$).

Size of Prosthesis

Twenty-three (39.65%) autologous abdominal S.C. flaps were found to be smaller than the craniectomy defect which could be due to bone flap resorption at the preservation site in abdominal wall. In one study, bone flap absorption was noted in 18 patients (16%) of the total 112 patients. Among these 18 patients, 12 patients finally needed allograft for second CP.[8] In our study, none required allograft. Five patients in our study group developed complications including one patient of subgaleal collection, which did not require surgery and was managed medically.

Dural Calcification

In total, 34 patients in our study had abnormal dural calcification out of which 11 (32.35%) suffered from complication, of these 4 patients developed subgaleal collections and 1 patient developed SSI with meningitis. Three patients underwent bone flap removal, two due to persistent subgaleal collection and one due to SSI. Lee et al in their study noted dural calcification to be related to the formation of EFC after CP.[14] The correlation between dural calcification and complication rate was insignificant in our study (p-value = 0.073, odd's ratio = 2.4).

Dural calcification is rarely seen in the pediatric age group. But we noted its presence in our 34 patients. There are two hypotheses explaining this phenomenon, one suggesting that calcifications could have developed from postoperative EDH and/or SDH because of inadequate resorption of blood, cell death, and hyalinization of connective tissues caused by vessel thrombosis and others suggesting that it could be due to neurogenic heterotopic ossification. In this, there is bone formation in soft tissue due to the presence of osteogenic precursor cells along with inducing agents.[14,30]

Conclusion

Complications related to CP are common, as noted in our study, and few factor may increase the risk. Positive relation was observed between complication and CP done using

chemically cured PMMA and ETO sterilized bone flap. Patients in younger age group, those with fever >101°F in the postoperative period, and subgaleal collection were found significantly associated with complications.

While the titanium flap had no complication and in case of autologous abdominal S.C. flaps, apart from bone flap absorption, patients had no major complication. Therefore, both implants are preferred implants for CP. Heat-cured PMMA (prefabricated) can be an economical option in case of nonavailability of other two and can be molded at any dental lab.

Conflict of Interest
None declared.

Acknowledgments
Thankful to Dr. Garima for technical assistance.

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