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Original Research Article

Prospective Observational Study on Analysis of Complications of Different Types of Cranioplasty and Identification of Risk Factors Associated with Cranioplasty

Himanshu Kumar

Assistant Professor, Department of Surgery, Madhubani Medical College & Hospital, Madhubani, Bihar

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Corresponding author: Dr. Himanshu Kumar

Conflict of interest: Nil

Abstract

Background: In order to lower intracranial pressure, decompressive craniectomy (DC) is an urgent treatment. A review of the issues would provide ways to enhance the treatment. The analysis of post-cranioplasty (CP) problems and the identification of potential risk factors for surgery failure were the main objectives of this study.

Method: This study was carried out in Madhubani Medical College and Hospital in Madhubani, Bihar, between September 2023 and August 2025. Patients undergoing CP for a defect resulting from prior DC or incapacity to replace the bone flap (Glasgow Coma Scale>13, size >5 cm, without surgical site infection) were included. Before and after the surgery, CT imaging was performed on every patient. Based on prosthesis availability and cost, the CP approach was primarily dependent on the patients.

Result: The study involved one hundred patients. A total of 22 individuals experienced difficulties following surgery, with only a small number experiencing multiple complications. With no complications, the titanium implant seemed to be superior ($p<0.05$). Younger age groups frequently had complications with chemically cured PMMA (polymethyl methacrylate) and ethylene oxide-sterilized bone flaps. Patients with various comorbidities and stroke patients experienced more complications.

Conclusion: With the exception of bone flap absorption, patients had no significant complications from titanium flaps or autologous abdominal subcutaneous flaps. As a result, both implants are recommended for CP. When a better solution isn't available, heat-cured PMMA can be employed because it's affordable and can be molded in any dental lab.

Keywords: Decompressive Craniectomy, Cranioplasty, Infection, Titanium, Methyl Methacrylate.

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Introduction

Urgent decompressive craniectomy (DC) is necessary to treat a potentially fatal rise in intracranial pressure. [1] Following DC, cranioplasty (CP) is required for patients who have recovered. Numerous research on CP emphasize the operative features of the procedure, including the timing of the procedure, the use of synthetic materials, and the maintenance of the bone flap.[2-6]. The clinical outcomes and consequences of CP are listed in very few significant studies.[7–10]

It's possible that complications following CP, which is typically thought of as a straightforward surgical operation, have gone unreported.[7] The majority of patients receiving CP would have experienced severe morbidity during the prior illness that required DC. Therefore, preventing more issues is more crucial. Prior to CP, considerations like cosmesis, strength of reconstruction, and postoperative surgical site infections (SSI) are taken into account. After CP, complications increase morbidity and drive up medical expenses. We can make decisions about how to enhance the patient's well-being by analyzing the complications. The purpose of this study was to evaluate the consequences of various forms of CP and identify potential risk factors for operation failure.

Material and Methods

This prospective observational study was carried out in Madhubani Medical College and Hospital in Madhubani, Bihar, between September 2023 and August 2025. Patients undergoing CP for a defect resulting from prior DC or the incapacity to restore the bone flap were included.

Included were patients with a Glasgow Coma Scale (GCS) more than 13, a craniectomy defect larger than 5 cm, and no recent surgical site infections.

Prior to and following the treatment, all patients had CT scans without contrast. Based on prosthesis availability and cost, the CP approach mostly relied on the patients. Patients in the study gave their appropriate consent. Clinical factors, imaging characteristics, operational findings, postoperative course, and patient-specific data were all documented.

Following surgery, the patients were monitored for one, three, and six months. There were two categories for complications: major and minor. SSI was defined as infections that occurred within 30 days of surgery (or up to a year following implant insertion) and affected the deep tissue or incision at the operation site.

Subgaleal collection was defined as any uninfected collection in the subgaleal space following the removal of the drain. Complications that required flap removal or surgery, as well as those that were treated medically, were also recorded.

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.

The statistical analysis was done using SPSS version 22. We utilized the chi-square test or a two-tailed Fisher's exact test to estimate the statistical difference between two categorical variables and the t-test to verify the statistical difference between two continuous variables.

A p-value of less than 0.05 was considered significant.

Results

Table 1: Complications causing removal of prosthesis

Complication	Autologous bone flap	Synthetic prosthesis	Bone flap removal	Total
SSI	0	3	2	5
Subgaleal collection	4	6	4	14
Meningitis	1	1	1	3

Twenty-two (22%) of the 100 patients had complications.

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			
<101^0	15(75.00%)	5(25.00%)	0.013[b]
>101^0	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%)	

There were 87 male and 13 female among the 100 patients. Twenty-one patients had a single comorbidity, while sixteen had multiple comorbidities. In 87 patients, traumatic brain injury (TBI) was the most common reason for a craniectomy, followed by intraoperative cerebral edema in 3. 36 patients had impairments and/or a GCS of less than 15 at the time of CP, while 64 individuals had a GCS of 15. For autologous CP, the average blood loss during surgery was 206.81 mL, compared to 179 mL. A higher rate of complications was linked to pyrexia >1010F during the postoperative phase.

Discussion

The rate of post-procedure problems varies from 10 to 43% across reported literature, primarily because of the criteria employed to characterize difficulties. [7–13] The overall complication rate was 31.32% in a research involving 94 stroke patients who received DC [11], whereas the complication rate was 16.4% in another study involving several diseases with DC.13 The most frequent consequence identified in the aforementioned trials was prolonged wound healing and SSI. Comparable to earlier studies, we found a 22% complication rate, a 2% SSI rate, a 6% prosthesis removal requirement, and a 1% reexploration rate. Similar to most studies, only 13% of patients experienced major complications such as SSI, EDH, contusion, subgaleal collection, and seizures.

Four of the nine patients in our study who had craniectomy for traumatic brain injury received bone flap excision for persistent subgaleal collecting (two had ETO sterilized bone, and two had DePuy intraoperative molded chemically cured PMMA flap). Subgaleal collection and bone flap removal were found to be significantly correlated (p-value −0.01). With conservative treatment alone, collection regressed in four patients with autologous abdominal subcutaneous (S.C.) flaps and one patient with acrylic. Epidural fluid collection (EFC) may be a component of the aforementioned patients' persistent subgaleal collection.

EFC is more common than previously believed after CP. Since EFC tends to be absorbed spontaneously over time, it rarely results in neurological impairments.[14] One possible cause is dural calcification, which results in stiffness that stops brain parenchyma from expanding, creating an epidural dead spot. Second, air irritates the skin and causes inflammation, which results in the production of exudate. Third, cerebrospinal fluid accumulation or exudates from the dissected subgaleal region and muscle may result from an unintentional dural tear during CP. Fourth, implants, particularly synthetic ones, have the potential to cause inflammation. [14, 15]

Studies indicated that the reported SSI rate ranged from 1.4 to 24.4%. [16, 17] 2% of subjects in our research experienced SSI. Of these, one patient had meningitis and subgaleal collection with SSI, whereas another was found to have SSI alone.

Both had their bone flaps removed. For TBI, both of these patients underwent craniectomies. A bifrontal craniectomy was performed on one patient.

After examining the implant type, we discovered that both patients had synthetic implants; one had DePuy (chemically cured PMMA) and the other had acrylic (heat cured PMMA).

One noteworthy finding from the discussion above is that none of the patients receiving autologous SC bone flaps or titanium flaps experienced subgaleal collection or SSI, necessitating the removal of the bone flap. Two patients experienced EDH and one experienced a contusion following surgery. One of these EDH patients needed to be evacuated, while the others were treated conservatively. Both of these problems were observed during the elective neurosurgery treatment.[7] Seizures (five), meningitis (two), hemodynamic instability (five), DVT (five), and pneumonitis (three) were other problems observed in our investigation. Despite being treated medically, all of these issues resulted in considerable morbidity, including longer hospital stays, higher antibiotic dosages, and ICU monitoring. All patients, however, were released without experiencing any worsening of their neurological conditions. One patient needed surgery to remove their prosthesis after developing meningitis with SSI.

Patients under the age of 20 were found to have a maximum complication rate of 42.85% (n=6) throughout the research; three of these patients (21.42%) needed to have their prostheses removed. However, growing older has been linked to more difficulties in other research, while these associations are not statistically significant.[9, 11] The absence of concomitant illnesses may be the reason why younger individuals in earlier research had better outcomes. Our findings differ from those of other studies, most likely because of a number of other factors, such as the cohort's smaller number of patients in the ≤20 age group and the fact that four out of six patients used synthetic or ETO sterilized flaps, which resulted in a high complication rate. As a result, this result may be skewed; therefore, more research with a bigger sample size in this age range may provide more clarification.

One female (7.69%) and twenty-one males (24.13%) experienced issues in this study. There has always been debate regarding how gender affects the result. In terms of clinical results, women outperform men.[18] Males often have larger frontal sinuses, which might be compromised during surgery, increasing the risk of infection. Our findings are similar to those of earlier research.[19] However, it is impossible to draw any conclusions because there are so few female patients.

With a complication incidence of 23.8 and 31.3%, respectively, 21 patients in our study had a single condition and 16 had multiple comorbidities. In the absence of comorbidity, the complication rate was 19%. Although the connection was not statistically significant in this study, other research has shown that individuals with comorbidities and advanced age have greater incidence of complications.[11]

Following CP, stroke patients had higher infections than trauma patients, according to a research by Walcott et al.[17] There may be difficulties related to the craniectomy indication.[9, 17, 20] Compared to CP following malignant stroke, tumor, or subarachnoid hemorrhage, patients with CP after traumatic brain injury (TBI) were shown to have a greater infection rate due to scalp lacerations or skull fractures that may increase their risk for infection.[21, 22] According to our statistics, patients who had craniectomy for infectious reasons had a significant complication risk of 33.33%.

As advised, these individuals received antibiotic therapy for their initial infection, and CP was administered after the infection had completely subsided.

Stroke patients had the highest complication rate (50%) in our study. This is in line with other research that has been published, and it most likely represents the combination of aging and (vascular) comorbidities.[9, 11] There wasn't enough data to determine statistical significance.

Conclusion

According to our analysis, CP-related complications are frequent, and a few factors may raise the risk. Complications and CP using chemically cured PMMA and ETO-sterilized bone flap were found to be positively correlated.

Complications were observed to be substantially correlated with younger patients, those with fever >101^{0}F throughout the postoperative period, and subgaleal collection.

Aside from bone flap absorption, patients did not have any significant complications with autologous abdominal S.C. flaps or titanium flaps. As a result, both implants are recommended for CP. If the other two are not available, heat-cured PMMA (prefabricated) can be a cost-effective alternative that can be molded at any dental facility.

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