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Predictive factors for cranioplasty complications – A decade's experience

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ABSTRACT

Introduction: Cranioplasty (CP) following craniectomy provides cerebral protection, improves cerebrospinal fluid dynamics, and restores cosmesis. Although often viewed as minor, CP can have major complications.
Research question: This study aims to identify the predictive factors for post-operative complications in patients undergoing CP after decompressive craniectomy.
Methods: We conducted a retrospective study at a tertiary hospital, analyzing patients who underwent CP after decompressive craniectomy (DC) from 2008 to 2019. Patient demographics, medical history, and surgery details were retrieved from hospital records. Complications included symptomatic intracerebral haemorrhage, extradural or subdural haemorrhage, hydrocephalus, infection, or bone resorption.
Results: The study included 168 patients: 139 adults (mean age 47.6 ± 12.68 years) and 29 pediatric patients (mean age 11.8 ± 5.62 years), with a slight male predominance. The overall complication rate was 26.2%, with infection being the most common (8.9%). Predictive factors for CP complications identified by binomial logistic regression, controlling for age and sex, included primary coagulopathy (14.3-fold risk increase, $p = 0.034$), intraoperative ventricular puncture (7.9-fold risk increase, $p = 0.009$), and intraoperative dural layer breach (2.8-fold risk increase, $p = 0.033$). Pre-CP home living was a protective factor.
Conclusions: CP requires vigilant management to prevent complications. Primary coagulopathy, intraoperative ventricular puncture, and dural layer breach are significant risk factors for complications.

1. Introduction

Decompressive craniectomy (DC) is a crucial procedure used to alleviate intracranial hypertension, and is often performed alongside the evacuation of extra-axial haematomas or in cases of severe medical conditions that cause elevated intracranial pressure(Smith, 2017). Surgical techniques for DC vary, ranging from unilateral hemicraniectomy to bicoronal craniectomy, with an emphasis on individualised approaches based on the underlying pathology and the surgeon's expertise (Schirmer et al., 2008).

Following DC, patients typically undergo cranioplasty (CP), a reconstructive procedure aimed at improving cerebrospinal fluid dynamics, providing cerebral protection, and enhancing neurological outcomes (Malcolm et al., 2018; Singh et al., 2019). Despite its perceived simplicity, complications associated with CP extend beyond the early stages and include post-operative haematoma, sunken bone flap, intraoperative haemodynamic instability, hydrocephalus, subgaleal collection, seizures, and empyema. While rare, severe complications like meningitis, air embolism, and death are possible and may necessitate reoperation, leading to prolonged hospital stays and increased patient morbidity(Singh et al., 2019; Gooch et al., 2009; Basheer et al., 2010; Sobani et al., 2011; Vreeburg, 2024).

Various factors have been reported to influence the outcome of CP surgery, including patient demographics, comorbidities, surgical techniques, timing of CP, cranial defect size, duration of surgery, and pre-CP cerebrospinal fluid disturbances (Singh et al., 2019; Sahoo et al., 2018).

This study aimed to analyse the factors contributing to symptomatic complications following CP surgery after DC in a ten-year cohort of patients.

2. Methods

2.1. Study design and settings

We performed an observational, retrospective, single-centre study in a tertiary hospital with a neurosurgery department that performs

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emergency DC and reconstructive CP. The study protocol has been published at ClinicalTrials.gov (number NCT04791904). The present study was written according to the STROBE statement guidelines.

2.2. Participants

All patients coded in hospital records submitted to the CP between January 2008 and December 2019 were selected. Patients who underwent DC as the primary procedure for motivated CP were included. Additionally, patients who did not undergo computed tomography (CT) before or after surgery and those lacking clinical record information on CP outcomes were excluded (Fig. 1).

All patients who underwent CP were electively scheduled. Patients who were previously treated with anticoagulants and/or platelet antiaggregants showed a reversal of their therapeutic effects before CP.

2.3. Ethical

The Local Ethics Committee approved the study protocol (approval number: 430/20). No funding was received for the preparation of this manuscript.

2.4. Variables

Medical records were reviewed to obtain information regarding age at the time of CP (including all age groups), sex, medical history, and medications used (diabetes, high blood pressure, immunosuppression, antiaggregation, anticoagulation, and coagulopathy). The clinical context for craniectomy (trauma, stroke, ruptured aneurysm, ICH, venous thrombosis, and others) was obtained from clinical registries, such as specific cerebral spinal fluid (CSF) conditions prior to CP (hydrocephaly). Operative notes were used to retrieve craniectomy characteristics, CSF disorder treatment prior to CP (external ventricular drainage (EVD) and/or shunt), specific intraoperative techniques/maneuvers (shunt placement, EVD, ventricular puncture, and/or breach of the dural layer), choice of CP materials (autologous bone or synthetic type materials), and the existence and cause of re-intervention. The duration of the procedure was determined based on the hospital's surgical records. Time to CP was calculated as the difference between the CP and DC dates.

Discharge notes and neurosurgical follow-up examinations were thoroughly reviewed for complications related to CP (symptomatic ICH, extradural haemorrhage, subdural haemorrhage, hydrocephalus, infection, bone resorption, and death). Because it was not possible to correctly obtain data to classify each patient on the modified Rankin scale before CP, we used living status as a surrogate for functional status. All patients were classified as "Still in hospital admission", "Rehabilitation centre", "Health institution", and "At home". All the variables collected from these sources are listed in Table 1.

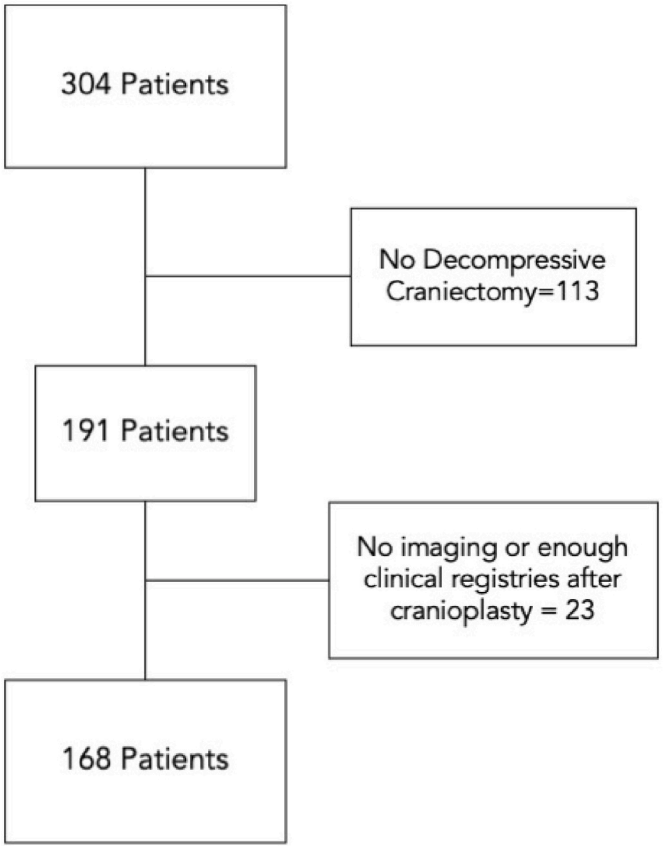

Fig. 1. Diagram of the selected patients with cranioplasty from January 2008 to December 2019 included for analysis.

2.5. Imaging data

Imaging data regarding the craniectomy procedure for each patient were collected from the CT images acquired from hospital registries. We used Sectra IDS7® software for medical imaging analysis and measurements. The assessed variables included the largest axial craniectomy dimension and deviations of both the septum pellucidum and the skin flap. All the variables were measured in the transverse (axial) plane. The following section describes how the measurements of each variable were obtained. Preoperative CT scans closer to the date of surgery were selected to study variables.

2.5.1. Largest axial craniectomy dimension

- For hemicraniectomies, the largest axial craniectomy dimension was measured in millimetres from the anterior to the posterior skull defect limits.
- For bifrontal craniectomies (with a preserved bone bridge over the superior sagittal sinus), we began by selecting the side with the most prominent bone defect, and the largest axial craniectomy dimension was measured using the method described above.
- For bicoronal craniectomies, the largest axial craniectomy dimension was measured in millimetres from the left to the right skull defect limit.
- To obtain the largest dimensions, several image slices were measured at different levels starting from the base of the cranium to the apex. The highest values are obtained.

2.5.2. Septum pellucidum shift

- Defined as the level in which the septum pellucidum deviation was most prominent.
- To determine the septum pellucidum shift, a line was drawn between the insertion limits of the falx cerebri to define the midline of the cranium. The *septum pellucidum* shift (in millimetres) was obtained by measuring the distance between the septum and midline. It was considered positive if the septum deviation was oriented in a direction opposite to that of the bone defect (e.g. +7.5 mm) (A) in Fig. 2. On the contrary, the shift was considered negative if the septum deviation was oriented towards the bone defect, for example −4.9 (A) in Fig. 3.

2.5.3. Skin flap shift

- A skin flap shift was obtained at the level of the image where the deviation was most prominent.

Table 1
Patient demographic data according to age groups.

N	Adult [>18 years old] 139	Paediatric [0–18 years old] 29
Age at CP	47.6 ± 12.68	11.8 ± 5.62
Min-Max	18.74–79.12	1.38–17.98
Sex		
Male	82 (59%)	16 (55.2%)
Female	57 (41%)	13 (44.8%)
Context for Craniectomy		
Trauma	66 (47.5%)	19 (65.5%)
Stroke	43 (30.9%)	2 (6.9%)
Ruptured Aneurysm	11 (7.9%)	2 (6.9%)
ICH	10 (7.2%)	2 (6.9%)
Venous Thrombosis	5 (3.6%)	1 (3.4%)
Other	4 (2.9%)	3 (10.3%)
Medical History		
Diabetes	16 (11.5%)	0
High Blood Pressure	54 (38.8%)	0
Immunosuppression	1 (0,7%)	2 (6,9%)
Antiaggregation	38 (27.3%)	2 (6.9%)
Anticoagulation	47 (33.8%)	4 (13.8%)
Coagulopathy	4 (2.9%)	0
Craniectomy Characteristics		
Side		
Right	66 (47.5%)	12 (41.4%)
Left	60 (43.2%)	8 (27.6%)
Bicoronal/Bifrontal	13 (9.4%)	9 (31%)
Hemispheric (mm)		
Vertical Axis	90.0 ± 13.3	94.35 [13.8]
Axial larger axis	111.9 ± 18.40	115 [21.3]
Bicoronal (mm)		
Vertical Axis	73.1 ± 13.1	82.4 [16.5]
Axial Larger Axis	108.7 ± 19.52	121 [18.3]
CP Related Data		
Time to CP (days)	160 [208]	97 [132]
Min-Max	12–1620	32–695
Location Before CP		
Still Admitted	55 (39.6%)	10 (34.5%)
Rehabilitation Centre	20 (14.4)	8 (27.6%)
Institution	20 (14.4%)	1 (3.4%)
Home	44 (31.7%)	10 (34.5%)
Procedure Duration (min)	99.2 ± 38,09	116.1 ± 36.53
CSF Disturbance Pre-CP		
Hydrocephalus	11 (7.9%)	6 (20.7%)
EVD	6 (4.3%)	0
Shunt	4 (2.9%)	6 (20.7%)
Intraoperative Manoeuvres		
Shunt Placement	5 (3.6%)	0
EVD drainage	7 (5%)	0
Ventricular Puncture	6 (4.3%)	2 (6.9%)
Dural Layer Breach	20 (14.4%)	6 (20.7%)
CP Material		
Autologous Bone	99 (71.2%)	21 (72.4%)
Titanium Mesh	23 (16.5%)	3 (10.3%)
PEEK	17 (12.2%)	4 (13.8%)
Hydroxyapatite	0	1 (3.4%)
Complications related to CP	**36 (25.9%)** [a]	**8 (27.6%)**
Re-intervention	32 (23%)	8 (27.6%)
Symptomatic ICH	5 (3.6%)	0
Extradural Haemorrhage	5 (3.6%)	0
Subdural Haemorrhage	4 (2.9%)	0
Hydrocephalus	5 (3.6%)	3 (10.3%)
Infection	13 (9.4%)	2 (6.9%)
Bone reabsorption	0	3 (10.3%)
Related Deaths	3 (2.2%)	0

Mean ± Standard Deviation; Median [Interquartile Range]; Frequency (percentage); CSF Cerebrospinal Fluid, ICH Intracerebral Haemorrhage.

[a] Four patients had symptomatic ICH requiring prolonged ICU monitoring but did not undergo reintervention.

- The bone table farthest from the midline at the level of the skull defect was selected. A line parallel to the midline reference was drawn starting from the centre of the edge of the defect. The skin flap shift was obtained by measuring the distance between the line and the skin flap position at the midpoint of the craniectomy axial line (Figs. 2 and 3). It was considered positive if the skin flap measurement point did not reach the vertical line, for example, +2.7 mm (C) (Fig. 2). In contrast, the shift was considered negative if the skin flap position at the same point was lateral to the reference line (e.g. −21.2 mm (C) Fig. 3.

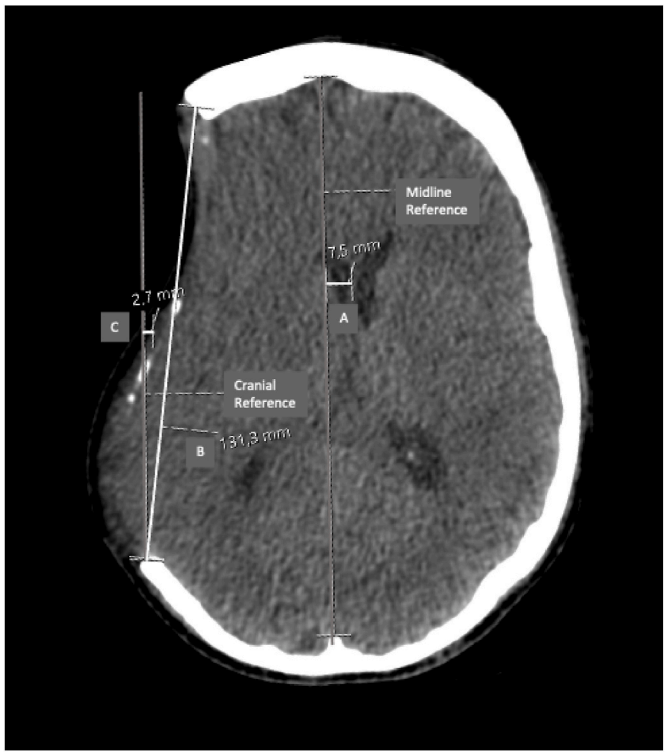

Fig. 2. CT image showing the measurements of largest axial craniectomy dimension (B), positive *septum pellucidum* (A) and skin flap deviations (C).

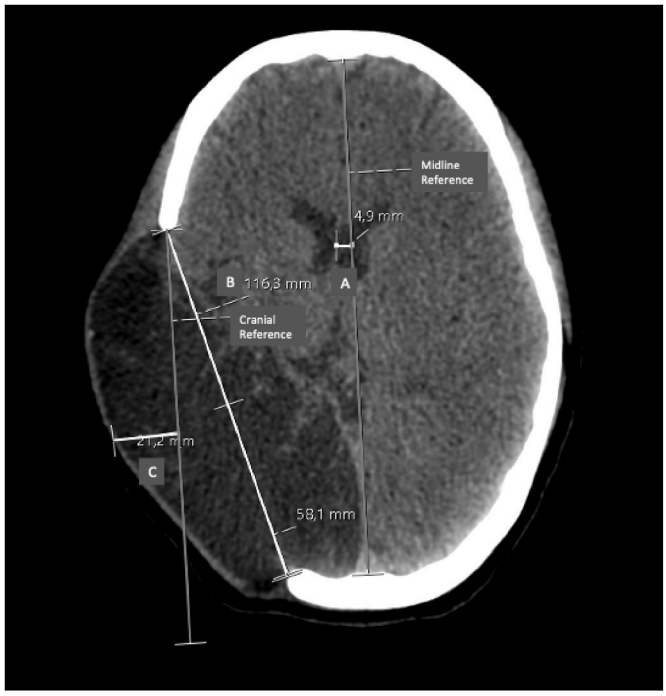

Fig. 3. CT image showing the measurements of largest axial craniectomy dimension (B) and negative *septum pellucidum* (A) and skin flap deviations (C).

- Due to brain shift, we did not use the contralateral side as a reference.

For bifrontal craniectomies (preserved bone bridge over the superior sagittal sinus), the side with the most prominent bone defect was selected, and *septum pellucidum* and skin flap shifts were measured using the same method, as in the cases of bicoronal craniectomies that displayed a shift.

2.6. Statistical methods

The sample size was estimated based on 10 patients for each factor included in the final multivariate logistic model of at least 15 variables, with a minimum of 150 patients.

Data were used to obtain less than 1% of the missing cells. Records before 2008 were not collected, considering the limited expected information.

The normal distribution for continuous variables was determined by Skewness and Kurtosis between −1 and 1. Normally distributed variables are presented as mean ± standard deviation, and non-normally distributed variables and time variables are presented as Median and Interquartile Range (IQR). Categorical variables were described as percentages.

A predictive model was used to determine the association and magnitude between the clinical factors and the development of complications using a binomial regression model with univariate and multivariate analyses. Multivariable model development allowed us to control for significant and clinically relevant variables that could be potential confounders. For variable selection in univariate analysis, a significant p value was considered as 0.1. Nagelkerke's R^2 was used to refer to the capability of the model to explain variances in the results. For every other statistical test, a p value of 0.05 was considered significant. Statistical analysis was performed using SPSS 28.0.

3. Results

3.1. Participants

Three hundred and four patients were identified as undergoing CP during the study period. After meeting the inclusion criteria, 168 patients were included in the analysis (Fig. 1).

3.2. Descriptive data

A total of 168 patients were analysed, consisting of 139 adult patients, with a mean age of 47.6 ± 12.68 years-old and 29 paediatric patients with a mean age of 11.8 ± 5.62 years-old. In both groups, there was a slight male predominance, and trauma was the most frequent aetiology for craniectomy in both age groups.

The median time for CP was 160 days for adults and 97 days for the paediatric population, and a large percentage of patients were still admitted to the hospital after the first event.

In CP surgery, the most frequent intraoperative manoeuvre was an unintentional dural layer breach.

CP complications were defined as any symptomatic event directly related to the procedure that may or may not necessitate re-intervention. The total complication rate for the present sample was 26.2%, and 23.8% of patients required re-intervention.

Infection was the most frequent complication, observed in 15 patients (8.9%), followed by symptomatic ICH in 9 patients (5.3%) and hydrocephalus in 8 patients (4.6%).

Table 1 represents all collected variables distributed by age groups, defined as adult (>18 years old) and paediatric (≤18 years old).

3.3. Main results

Using a Binomial Logistic Regression Model (Table 2) and considering as outcome the development of a *"CP Complication"*, a Univariate analysis identified the intraoperative need for ventricular puncture and reported breaches of the dural layer during dissection (with the need for subsequent correction) as factors associated with complications after CP. Similarly, when analysing patient factors, the presence of primary coagulopathy was associated with the outcome. Elective admission of "At Home" patients presented as a significant protective factor. This led us to re-group patients as at "Health facilities" and "At home" for the Univariate analysis (OR 0.462, p = 0.024). For the multivariate analysis, these four factors, as well as the patient's age and sex, were included so that the model could be controlled for these two variables. On multivariate analysis, a history of primary coagulopathy represented a 14.3-fold risk increase for complications (p = 0.034), as well as intraoperative ventricular puncture and dural limit violation, which increased the risk of complication 7.9 (p = 0.009) and 2.8 times (p = 0.033), respectively. Patients who lived at home at the time of CP had a reduced likelihood of post-CP surgical complications (OR 0.256, p = 0.007) (Table 2). The present model explained 20% (Nagelkerke R^2) of the variance in post-CP complications.

Table 2
Univariate and multivariate analysis for complication associated factors.

Variables	Univariate	p	Multivariate	p
Age	0.990	0.324[b]	0.992	0.444
Sex	0.632	0.194[b]	0.593	0.194
Craniectomy Aetiology		0.645		
Type of Craniectomy	0.938	0.901		
Axial Craniectomy Dimension	1.001	0.941		
Time to CP (days)	1.000	0.641		
Living Location Before CP	0.462	0.024[a]	0.256	0.007
Diabetes	1.317	0.629		
High Blood Pressure	1.127	0.747		
Immunosuppression	1.419	0.778		
Antiaggregation	0.922	0.844		
Hypocoagulation	0.315	1.453		
Primary Coagulopathy	9.000	0.060[a]	14.347	0.034
Pre-operative Hydrocephalus	1.622	0.371		
Pre-operative EVD	2.951	0.196		
Pre-operative Shunt	0.690	0.648		
Skin Flap Shift	0.986	0.162		
Septum Pellucidum Shift	1.006	0.866		
Intraoperative Ventricular Puncture	5.171	0.029[a]	7.899	0.009
Intraoperative Dural Plane Violation	2.422	0.046*	2.762	0.033

Considered p-value of 0.1 in univariate analysis as the minimum value for multivariate model selection.
EVD, External Ventricular Drainage.
[a] Variables included in the multivariate binomial logistic regression model.
[b] Variables included in the multivariate binomial logistic regression model for clinical relevance.

4. Discussion

Our aim was to analyse the predictive factors for CP complications following DC. Given that CP is often regarded as a minor procedure and is associated with major complication rates, we paid special attention to the intraoperative manoeuvres that might affect CP outcomes. We found that intraoperative ventricular puncture and dural breach increased the risk of CP complications. Additionally, individual patient factors were analysed, and we found that a history of primary coagulation disorders increased the risk of CP complications.

Interestingly, our analysis showed that patients within the context of returning to their domicile before elective CP procedures displayed better outcomes. This might function as a surrogate for better family support and socioeconomic and/or functional status, which were not assessed in this study.

Also, and in line with one of the largest cohorts most recently published, the time for cranioplasty did not emerge as a predictive factor for

CP complication (Vreeburg, 2024).

These findings are comparable to those of the studies mentioned below. Together, they offer key insights for the improvement of intraoperative particularities and management of specific patient factors.

4.1. Coagulation disorders

Our study found that the presence of primary coagulation disorders significant (14.3-fold) increase the risk of complications. Four patients presented with primary coagulation disorders characterised by a hypercoagulable state responsible for cerebral venous sinus thrombosis (three patients) and ischaemic stroke (one patient). Three of these patients experienced haemorrhagic complications following CP. A case report by Akamatsu et al. described a patient with haemophilia A diagnosed between the DC and CP who presented with persistent wound bleeding, epistaxis, and asymptomatic massive intracranial haematoma (Akamatsu et al., 2018). Riyaz et al. conducted a retrospective chart review of five infants of less than one year of age who underwent DC. Of these five patients, four were coagulopathic and three survived CP. One patient who presented with coagulopathy developed hydrocephalus requiring ventricular-peritoneal shunt (VPS) colocation 3 months after CP(Riyaz et al., 2015). These findings highlight the impact of altered coagulation status on the outcomes of CP procedures. We recommend meticulous observation and follow-up for patients with primary coagulation disorders who undergo CP.

4.2. The need for intraoperative ventricular puncture

Patients who undergo craniectomy have been described as having a particularly high risk of developing CSF disorders due to brain exposure to atmospheric pressure(Heo et al., 2014; Oh et al., 2008). Such disturbances, and the presence of hydrocephalus, are usually managed by CSF diversion through the placement of a VPS or EVD.

Although one study concluded that simultaneous CP and VPS placement may be safe in patients with TBI, cranial defects, and hydrocephalus (Ting et al., 2020), others have shown that it is associated with an increased risk of infection (Yang et al., 2017; Mustroph et al., 2017; Jung et al., 2020), resorption (Mustroph et al., 2017), and reoperation (Yang et al., 2017). A systematic review and meta-analysis showed that simultaneous VPS placement during CP increases the risk of overall complications, CP infection, and bone resorption in adult patients(Mustroph et al., 2017). Another meta-analysis indicated that the concurrent placement of VPS alongside CP leads to increased complications, including higher rates of surgical site infections and potentially post-operative symptomatic haemorrhage, attributed to cerebrospinal fluid over-drainage, causing brain depression and sustained dead space at the surgical site. (Jung et al., 2020). Based on the present findings, these two studies recommend staging rather than simultaneous VPS placement. Our results enhance these findings, showing that some types of CSF dysfunction requiring intraoperative ventricular puncture significantly increased (7.9 times) the risk of CP complications. We underline the importance of careful intraoperative decision-making regarding the risk-benefit ratio of any procedure that involves ventricular puncture. Avoiding such procedures may benefit CP outcomes.

Previous studies have suggested that patients treated with EVD before CP are at increased risk of developing CP complications. One study showed an association between the presence of EVD and the risk of bone resorption in paediatric patients(Rocque et al., 2018), whereas another study found that patients who underwent EVD placement and removal before CP were more likely to develop complications. They explained that this may simply be due to the relatively severe injuries that these patients presented with(Sobani et al., 2011). Goedemans et al. recently reported that patients with preoperative symptomatic disturbances in CSF flow (patients with CT-confirmed hydrocephalus treated with a VPS, lumbar-peritoneal shunt, or EVD) had a higher risk of developing symptomatic epi/subdural haemorrhage after CP (Goedemans et al., 2020). Our study did not confirm an association among preoperative CSF disturbances, EVD placement (an infrequent occurrence in our sample), and CP complications.

4.3. Intraoperative dural limit violation

To adequately prepare the site where the CP material should be placed, the surgeon must dissect and reproduce the correct tissue planes. Accidental or intentional dural lacerations may occur during this process. Hng et al. reported that dural breaches and CSF leakage into the surgical site during CP increased the risk of complications such namely infection (Hng et al., 2015). Jeong et al. found that CSF leakage during CP was associated with an increased risk of symptomatic and recurrent extradural fluid collection in patients with trauma who had undergone decompressive hemicraniectomy. They believed that repair and subsequent massive irrigation of the CSF leakage site could prevent recurrent extradural fluid collection and the need for bone flap removal(Jeong et al., 2016). The results of our study are in accordance with these findings, as dural limit violations significantly increased (2.8 times) the risk of CP complications. Even if dural lacerations are subsequently corrected using the same procedure, the risk of complications remains high. Therefore, we emphasise the relevance of meticulous dissection of tissue planes during DC and CP, with a focus on preserving their integrity.

4.4. Living location previous to CP

As the mRankin scale score before CP could not be rigorously collected for all patients, we selected the variable *Living Location Before CP* as a surrogate for functional status. Patients who were still within their first hospital admission, at a rehabilitation centre, or at a continuous care facility were compared to those who were already living at home with family support. This last factor presented itself as a protective aspect, since patients living at home before CP had a significantly lower likelihood of developing CP complications (OR 0.256, $p = 0.007$). This factor should not in itself be interpreted as a causal factor, but its significance still regards it as sufficiently relevant to merit a description.

4.5. Study limitations

This study was limited by its retrospective nature, which restricts the quality and reliability of the abstracted data.

As previously mentioned, it was difficult to reliably define the functional status of all the patients included in the analyses. Additionally, the patients included in this study did not have a predefined follow-up period, which narrowed down any late CP complications that could have been included in the analysis.

Moreover, the real-life setting did not allow a homogeneous time for the preoperative CT scan. Imaging data variables were extracted from a zero—to two-month period prior to CP, limiting data extraction to a purely uniform fashion. Due to this limitation, the variability is representative of daily practice.

As this was a unicenter study, the analysis was limited to applied surgical techniques and materials.

4.6. External validity

Considering the broadness of the analysed individuals, as well as the inclusion of a paediatric population and all types of DC aetiologies, we are confident that the analysed sample may represent a tertiary hospital's CP population. The aforementioned limitations of this retrospective single-centre study did not nullify the importance of the identified factors.

However, we believe that progression to a multicentre study with a wider sample size would contribute to the dissection of these and other

relevant predictors of direct surgical complications of CP.

5. Conclusion

CP after DC is associated with significant complication rates. Our goal was to identify the potential risk factors for CP complications that may be modifiable in future procedures. In the analysed population, primary coagulation disorders, the need for intraoperative ventricular puncture, and intraoperative dural limit violation were associated with CP complications. Additionally, the elective admission of a patient living at home was a significant protective factor.

Author contributions

All authors contributed to the conception and design of the study. Pedro Silva and Ana Ferreira were responsible for material preparation, Victor Viegas collected the data, and Ferreira performed the analysis. The first draft of the manuscript was written by Ana Ferreira and Victor Viegas, and all authors commented on the previous versions of the manuscript. All the authors have read and approved the final version of the manuscript.

Conflict of interest

The authors declare that they have no conflict of interest.

Ethical approval

The study was approved by the local Ethics Committee of Centro Hospitalar Universitário de São João (number 430/20).

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.bas.2024.102925.

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