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Clinical study

Re-examining decompressive craniectomy medial margin distance from midline as a metric for calculating the risk of post-traumatic hydrocephalus

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ABSTRACT

Decompressive craniectomy (DC) is a life-saving procedure in severe traumatic brain injury, but is associated with higher rates of post-traumatic hydrocephalus (PTH). The relationship between the medial craniectomy margin's proximity to midline and frequency of developing PTH is controversial. The primary study objective was to determine whether average medial craniectomy margin distance from midline was closer to midline in patients who developed PTH after DC for severe TBI compared to patients that did not. The secondary objective was to determine if a threshold distance from midline could be identified, at which the risk of developing PTH increased if the DC was performed closer to midline than this threshold. A retrospective review was performed of 380 patients undergoing DC at a single institution between March 2004 and November 2014. Clinical, operative and demographic variables were collected, including age, sex, DC parameters and occurrence of PTH. Statistical analysis compared mean axial craniectomy margin distance from midline in patients with versus without PTH. Distances from midline were tested as potential thresholds. No significant difference was identified in mean axial craniectomy margin distance from midline in patients developing PTH compared with patients with no PTH ($n = 24$, 12.8 mm versus $n = 356$, 16.6 mm respectively, $p = 0.086$). No significant cutoff distance from midline was identified ($n = 212$, $p = 0.201$). This study, the largest to date, was unable to identify a threshold with sufficient discrimination to support clinical recommendations in terms of DC margins with regard to midline, including thresholds reportedly significant in previously published research.

1. Introduction

Decompressive hemicraniectomy (DC) is a life-saving and neural tissue sparing operation performed to treat intracranial hypertension (iHTN). Allowing space for the brain to swell preserves perfusion and oxygen delivery mitigating secondary injury in severe traumatic brain injury (TBI) [1–5].

However, DC carries inherent risk. Direct injury to neural structures, persistent cerebrospinal fluid (CSF) leakage, iatrogenic infection, blood vessel injury, especially venous anastomosis and sinus injury can all significantly reduce the benefit-to-risk ratio [6]. In addition, craniectomy for treatment of iHTN has been identified as an independent risk factor in the development of post-traumatic hydrocephalus (PTH) [4,6–18]. PTH occurs at rate of 5–15% after DC [1,2], and has been linked to worse outcomes in patients surviving severe brain injury [4,10,18,19]. Variables associated with DC have been analyzed to identify procedural risk factors that may contribute to PTH. These studies have described

Abbreviations: AUC, area under the curve; CI, confidence interval; CSF, cerebrospinal fluid; CT, computed tomography; DC, decompressive craniectomy; GCS, Glasgow Coma Scale; iHTN, intracranial hypertension; OR, Odds ratio; PTH, post-traumatic hydrocephalus; ROC, receiver operating characteristic; TBI, traumatic brain injury.

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associations between PTH and dimensions of craniectomy, including medial craniectomy margin distance from midline and instrumentation [7–9,13–15,20,21]. However, in other research, DC dimensions and instrumentation have not been associated with PTH [10,19]. To date, DC margins remain a theoretical driver of PTH without high level evidence linking the two.

The aim of this research was to re-examine one dimension of DC, medial craniectomy margin distance from midline, by analyzing a single institution's 10-year experience with DC, representing the largest cohort of patients undergoing DC for TBI analyzed to date. The primary objective of this research was to determine whether average medial craniectomy margin distance from midline was closer to midline in those patients who developed PTH after DC for severe TBI compared to those that did not. The secondary objective was to determine if a threshold distance from midline could be identified, at which the risk of developing PTH increased if the DC was performed closer to midline than this threshold. In narrowing our analytical focus to this margin, our goal was to add data that can help design better studies to elucidate the underlying pathophysiology of PTH and to evaluate if there is any evidence to warrant neurosurgeons modifying one aspect of the technical approach for a highly-practiced procedure considering how valuable time is in TBI necessitating DC.

2. Methods

2.1. Patient population

Our Human Subjects Institutional Review Board waived consent for this study as only retrospective review of medical records was utilized. After receiving approval for this research from our Institutional Review Board, we conducted a retrospective review of the electronic medical records of all adult patients (18 years or older) who underwent DC for TBI at our single, high-volume, Level-1 trauma center between March 2004 and November 2014. Clinical, operative and demographic variables were collected, including age, sex, craniectomy laterality, and length of follow up. Patients were divided into 2 groups based on post-operative development of hydrocephalus as described in the medical record. Hydrocephalus was defined as clinically symptomatic ventriculomegaly requiring surgical placement of indwelling ventricular cerebrospinal fluid (CSF) diversion (i.e. ventriculoperitoneal, pleural, or atrial shunt). Patients with<30 days of follow-up were excluded from the analysis.

2.2. Definition of variables

The primary variable assessed was medial craniectomy margin distance from the midline. This measurement was performed on post-operative axial images of non-contrast head computed tomography (CT) scans, available for all patients. This distance was measured from the sagittal suture to the inner table at the edge of the craniectomy defect at the point where this was closest to the sagittal suture. When the craniectomy was carried across the midline, such as a bifrontal craniectomy, the distance from midline was recorded as zero. In cases where independent, bilateral hemicraniectomies were performed (neither crossing midline), distance from midline was recorded for both sides and the closest to midline was used for analysis. Distances were then compared using a non-parametric Mann-Whitney *U* test with significance set at $p < 0.05$.

2.3. Statistical analysis

To determine if there was a threshold distance from midline for which the risk of PTH increased, we compared the rate of PTH with DC closer or farther from every unique margin distance up to the distance farthest from midline at which a patient developed PTH in our cohort. Each of the individual axial medial craniectomy margins were treated as possible thresholds. The rates of PTH for DC closer or farther from midline for each distance were calculated as the percentage of patients with PTH with DC closer and farther from midline for each distance. These were compared with the percentage of patients not developing PTH after DC closer and farther from midline for the same distance. The difference between the rates of PTH closer to and farther from threshold distance were compared using Fisher's exact tests. Odds ratios (OR) with 95% confidence intervals (CI) were also determined.

A Monte Carlo permutation test was used to ascertain whether there was evidence that our sample contained a midline distance threshold that could be used to effectively predict hydrocephalus. First, we tested all possible thresholds and determined the lowest p-value among the 212 Fisher's exact tests performed. With this "lowest p-value" as our test statistic, we determined its true statistical significance by permuting the distances from midline in our sample 10,000 times, without regard to hydrocephalus status, yielding groups of the same size as observed (24 positives, 356 negatives), but where the distances were not related to the actual "hydrocephalus status". For each permutation, we performed the 212 Fisher's exact tests and recorded the smallest value. These 10,000 "smallest p-values" gave the distribution of this test statistic under the null hypothesis, i.e. when there is no relationship between distance and hydrocephalus occurrence. The p-value for whether there is any threshold for distance that predicts hydrocephalus is the proportion of those permuted statistics at least as small as the one observed. We reported this proportion as the p-value for the analysis.

Table 1
Demographics and craniectomy characteristics for patients with and without post operative post traumatic hydrocephalus (PTH).

	Non-PTH group	PTH group	p-value
N (Total 380)	356	24	
Age			
Mean, SD	39.6, 16.4	40.1, 21.1	0.881
Unknown (N)	1	0	
Sex (N, %)			
Male	264 (74.2%)	20 (83.3%)	0.466
Female	92 (25.8%)	4 (16.7%)	
Follow up (days)	421	440	0.327
Axial Craniectomy Margin Distance from Midline (Mean, SD)	16.6, 9.7	12.8, 8.2	0.086
Bifrontal Craniectomies Performed (N, %)			
No	345 (96.9%)	22 (91.7%)	0.195
Yes	11 (3.1%)	2 (8.3%)	

We then analyzed the utility of axial distance from midline in predicting the development of PTH with a receiver operating characteristic (ROC) curve with the true and false positive rates for each possible threshold distance. To address the possibility that bifrontal craniectomies, scored as 0 mm from midline, might affect the results, we performed a sensitivity analysis excluding all bifrontal craniectomy patients from both groups, and performed a secondary analysis of PTH rates and OR at each threshold in the same fashion as described above, and recalculated the ROC.

3. Results

3.1. Demographics, clinical and DC characteristics of study groups

Demographic and craniectomy characteristics for patients with and without PTH are shown in Table 1. A total of 380 patients underwent DC for severe TBI. Of these, 24 (6.3%) patients developed PTH and (356) 93.7% did not develop PTH. There was no difference in average age between the 2 groups (39.6 years for PTH group vs. 40.1 years for non-PTH group, p = 0.881). A total of 16.7% of patients who developed PTH were female compared with 25.8% in the non-PTH group (p = 0.466). Mean follow-up was 440 days for the PTH group vs. 421 days for the non-PTH group (p = 0.327). The average shortest axial distance of craniectomy margin in the PTH group was 12.8 mm compared with 16.6 mm in the non-PTH group, not a significant difference (p = 0.086).

3.2. Analysis of threshold distance from midline

For the cohort of 380 patients, a total of 212 unique craniectomy margin distances from midline were identified and assessed. In 168 cases of the 380 total patients, DC margin distance from midline was duplicated by another patient within the cohort. Fig. 1 shows the rates of PTH closer to and farther from midline DC margin distance plotted for all 212 possible threshold distances from 0 mm (for craniectomies across the midline including bifrontal craniectomies) to 30.9 mm (farthest distance from midline observed in our cohort at which patients developed PTH). The rate of developing PTH was higher closer to midline at every unique potential threshold distance assessed. Distance thresholds closer to midline showed larger differences in the rate of developing PTH between the above and below threshold groups. This trend prompted deeper analysis to find whether there was a threshold with statistically significant differences in the rate of PTH that could help guide clinical treatment.

The OR for developing PTH with a medial craniectomy margin closer to versus farther from midline shown for every possible threshold in Fig. 2. For 15 of the 212 threshold distances, the p-value was <0.05 and the lower CI did not cross 1.0. Two threshold distances with nominally significant p-values and CI were very close to midline at 2.76 mm and 3.00 mm; 10 values were clustered around 7.00 mm, and 3 values were clustered around 16.70 mm.

The lowest p-value from the Fisher's exact tests of threshold distances was observed at 6.7 mm from midline (p = 0.019). Using this p-value as a test statistic, a Monte Carlo permutation test was performed. In each permutation, our observed data was randomly divided into 24 "positives" and 356 "negatives". Again, Fisher's exact tests were performed at each of the 212 unique distances from midline. In 2017 of 10,000 total permutations, the lowest p-value among the 212 Fisher's exact tests in each permutation was less than the observed lowest p-value 0.019. This permutation test measured how likely it was to generate a p-value of <0.019 when running 212 Fisher's exact tests on a similar data set, yielding a non-significant p-value of 0.201.

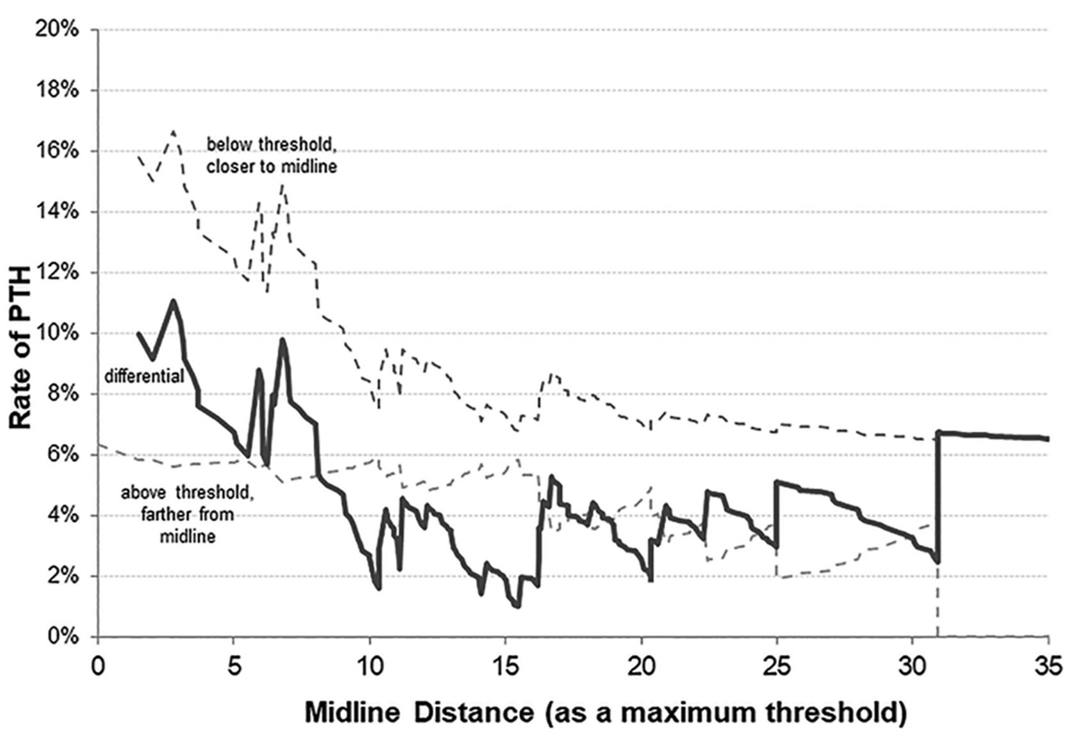

Fig. 1. Rate of post traumatic hydrocephalus (PTH) by midline distance. A linear plot of the rates at which patients developed PTH in the closer to midline and farther from midline groups at all 212 unique craniectomy medial margins measured in the cohort. Closer to midline is represented by the upper dotted line and farther from midline is represented by the lower dotted line. The solid line shows the differences between rates of developing PTH at each distance. For example, patients with craniectomy margins closer than 5 mm to midline developed PTH at rate of almost 13% (upper dotted line), while patients with craniectomy margins greater than 5 mm developed PTH at approximately 6% (lower dotted line). The difference between the rates is 6%, represented by the solid line.

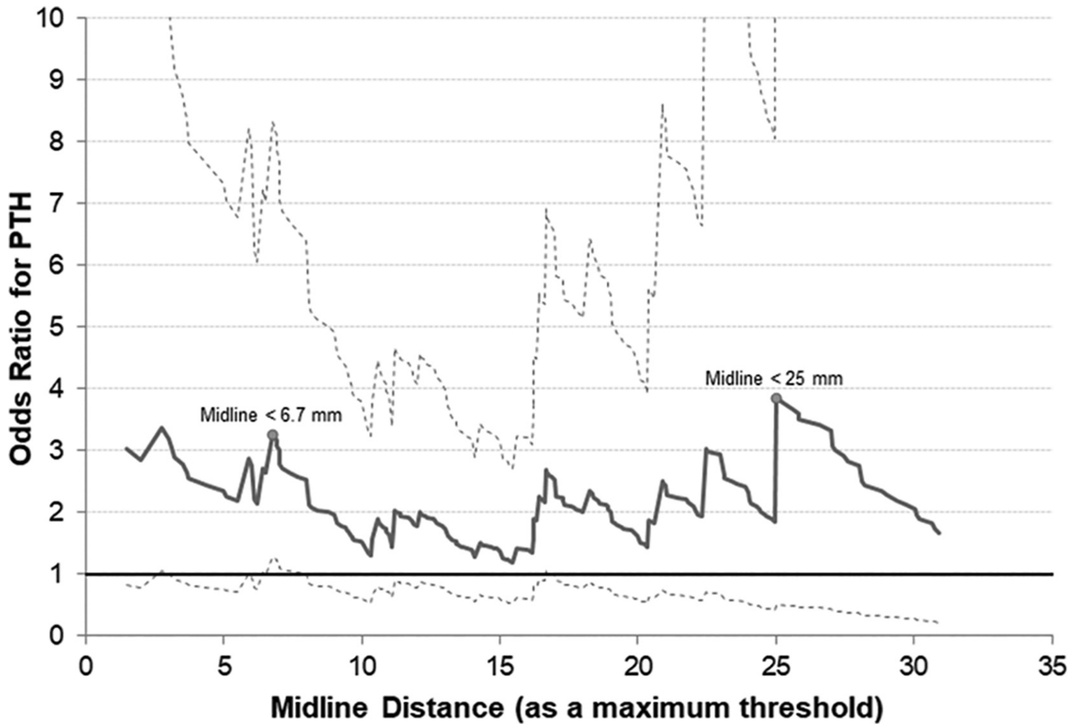

Fig. 2. Odds Ratio for post traumatic hydrocephalus (PTH) by midline distance. Odds ratios for developing PTH with a medial craniectomy margin closer to versus farther from midline are expressed at every possible threshold and represented by the solid line. 95% confidence intervals are displayed above and below the odds ratio with dotted lines. Midline of <6.7 mm indicates lowest p-value from the Fisher's exact tests of threshold distances. Midline of <25 mm is noted based on previous studies [9,13].

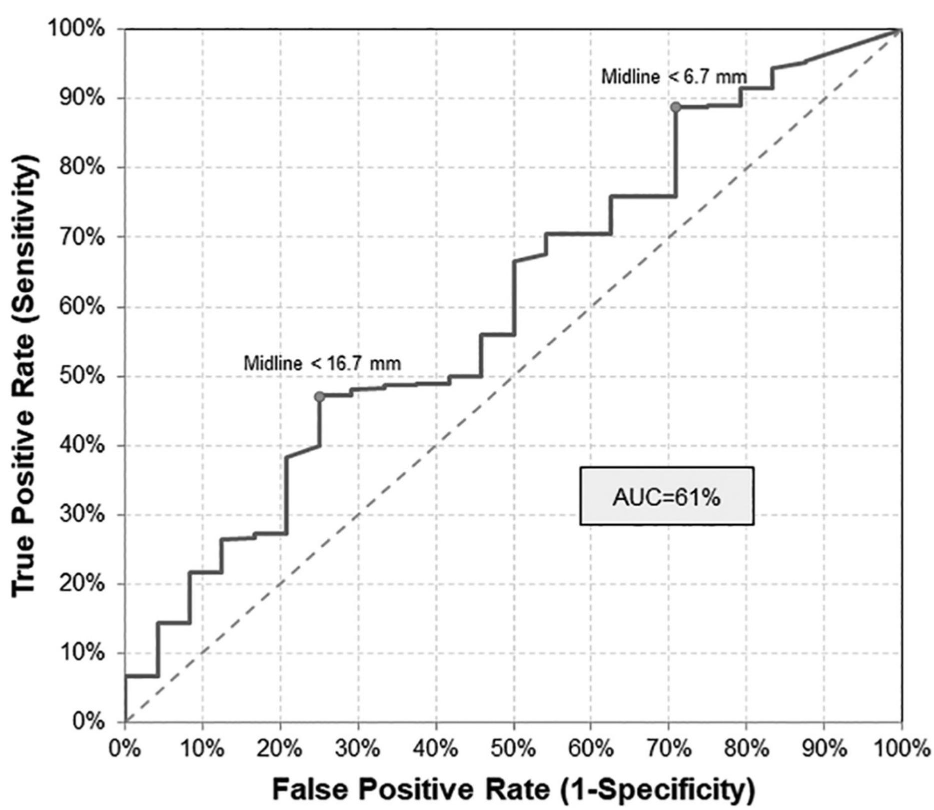

Fig. 3. Receiver operating characteristic (ROC) curve analysis. Area under the curve (AUC) estimation for midline margin as a predictive tool of risk of developing post traumatic hydrocephalus (PTH) after decompressive craniectomy (DC). Midline of <6.7 mm indicates lowest p-value from the Fisher's exact tests of threshold distances. Midline of <16.7 mm indicates the cluster of threshold distance values (n = 3) with significant results at the farthest distance from midline.

3.3. ROC curve analysis

To investigate the axial distance from midline margin as a predictive tool of risk of developing PTH after DC, we plotted a receiver operating characteristic (ROC) curve. Sensitivity and specificity were calculated at each of the 212 unique distance thresholds and plotted in the curve. Area under the curve (AUC) was 61%, indicating axial distance from midline has poor predictive ability in terms of both sensitivity and specificity across all possible threshold distances (see Fig. 3).

3.4. Analysis excluding bifrontal craniectomies

To evaluate the effect of including bifrontal craniectomies in the analyses, we excluded these patients and reanalyzed the data. In the PTH group, 2/24 patients (8.3%) received bifrontal craniectomies compared with 11/356 patients who did not develop PTH (3.1%). As demonstrated in Figure Supplementary figure 1, Supplementary figure 2 and Supplementary figure 3, the general pattern of the rate of developing PTH closer to and farther from midline appeared similar to analyses including bifrontal craniectomies. Excluding bifrontal craniectomies, AUC dropped from 61 to 59%.

4. Discussion

4.1. Medial DC margin distance from midline and risk of developing PTH

Several studies have reported an association of DC with an increased risk of PTH [1,4,6–10,12–14,16–18]. An early analysis of the same dataset by our group also reported a significant link between craniectomy margin and increased risk of PTH, though this report was limited by preliminary statistical analysis that incorrectly assumed similar distributions among the PTH group and non-PTH group [22]. Further, some studies have suggested that physical parameters of craniectomies are associated with the rates at which patients develop PTH after DC, including total area of the craniectomy, unilateral versus bilateral craniectomy, and a medial craniectomy margin within 25 mm of the axial midline of the skull [7–9,13–15,20,21]. Others have not found either area or distance from midline to be significant factors in the development of PTH (Table 2) [10,19]. In this study, we focused on medial craniectomy margin distance from midline, to determine if DC closer to midline was associated with developing PTH after DC for severe TBI. We also asked if a threshold distance from midline could be identified, at which the risk of developing PTH after DC increased. Utilizing the largest post-DC patient cohort reported to date, we found no association between medial craniectomy margin distance from midline and development of PTH after DC. Further, we were unable to identify a threshold distance from midline to guide clinical practice.

Our results are in contrast to previous reports. For example, De Bonis et al. showed patients with craniectomy margins within 25 mm of midline showed a statistically significant tendency to develop PTH after DC [9]. A second, larger study by the same group demonstrated a statistically significant increase in the rate development of PTH in patients with craniectomy margins $\leq$25 mm from midline as well [13]. Takeuchi et al. showed a strong but not statistically significant trend toward development of hydrocephalus after DC for hypertension-related, spontaneous intraparenchymal hemorrhage in those with craniectomy margins closer to midline ($p = 0.051$) [15]. Craniectomy distance from midline has also been reported in meta-analyses as an independent risk factor for the development of PTH [14,20].

Margin distance from midline has not been associated with PTH in all studies, however. In an Australian post-DC cohort of 166 patients reported by Honeybul and Ho, distance of craniectomy margin from midline in those who underwent unilateral decompression showed no significant association with PTH, defined as those patients requiring ventriculoperitoneal shunting for CSF dynamic impairment [10]. In our analyses, we examined each unique medial craniectomy margin distance from midline, ranging from 0 mm to 30.9 mm from midline (212 total unique distances among the 380 patients at which at least 1 patient on each side of the threshold developed PTH), and treated each distance as a potential threshold. While several of the distance thresholds were identified with nominally significant differences between rates of developing PTH in the group closer to midline, there was an inconsistent clustering pattern. Furthermore, the OR and p-values for those distance thresholds were weak for the number of tests being performed. As demonstrated by the Monte Carlo permutation test, a data distribution similar to the one observed in our study divided randomly into "positive" and "negative" groups of the same size as our study will generate at least one p-value as low or lower than our lowest observed value of 0.019 over 20% of the time if 212 Fisher's exact tests are run for each permutation. Thus, no distance from midline was observed in our study that shows a meaningfully statistical difference in the rate of developing PTH if transgressed by craniectomy margin. Notably, this includes the distance of 25 mm from midline, found to be significant in the studies noted above.

4.2. Definitions of PTH

Interpretation of published research on this topic has been challenging, in part because there is considerable variation in the definition of PTH. In our study, we define PTH as clinically symptomatic ventriculomegaly requiring surgical placement of indwelling ventricular CSF diversion. This definition is similar to that used by Honeybul and Ho, in which no association between PTH and DC margin distance from midline was observed [10]. However, in both studies by De Bonis et al. hydrocephalus was defined by radiographic criteria only: progressive dilation of ventricles, an Evans index of >0.3 and narrowing of CSF spaces at the convexity [9,13]. In the study of DC for spontaneous intraparenchymal hemorrhage by Takeuchi, post-intervention hydrocephalus

Table 2
Studies reporting association of decompressive craniectomy (DC) and post-traumatic hydrocephalus (PTH).

Research Study	Year	N	Reported Association of DC and PTH
Choi et al. [7]	2008	33	Larger DC size is associated with PTH.
De Bonis et al. [9]	2010	41	Statistically significant association between PTH and DC medial margin <25 mm from midline.
Honeybul et al. [10]	2012	166	No association between DC margin and PTH.
De Bonis et al. [13]	2013	64	Logistical regression analysis showing DC margin <25 mm from midline only associated risk factor for PTH.
Takeuchi et al. [15]	2013	21	Association between shorter DC margin from midline and ventriculomegaly suggesting hydrocephalus.
Su et al. [19]	2019	143	No association between DC margin and PTH.
Fotakopoulos et al. [21]	2016	126	Increased DC size is significantly associated with PTH.

was also defined by the same set of radiographic criteria above in isolation from clinical criteria [15].

4.3. Incidence of PTH

Further, interpretation of the results of studies describing risk factors in the development of PTH after DC is complicated by wide variation in the reported incidence of PTH after DC. For example, Ding et al. reported no relationship between PTH and admission Glasgow Coma Scale (GCS) score, while Shi et al. found that patients with low admission GCS scores tended to develop PTH after DC [16,17], largely a result of great variability in inclusion criteria of patients. Additionally, Ding et al. reported incidence of hydrocephalus as a range of 0–88.2%, dependent on the inclusion criteria and characterization of hydrocephalus [16].

4.4. Directions for future research

Moving forward, more complex analyses of craniectomy dimensions will be necessary, as the medial craniectomy margin distance from midline may be a poor proxy for other craniectomy margins and/or the area of the craniectomy. Multivariate studies of TBI mechanism, specific radiographic markers of TBI and craniectomy margin as well as the role of and timing of cranioplasty could also offer more insight into the relationship between DC and PTH. Predetermined definitions of PTH with agreed upon clinical criteria for diagnosis and standardized treatment protocols across multiple institutions would afford future studies greater consistency and generalizability, as well as aid in the ability to collect better prospective data.

4.5. Limitations

This study has some limitations, including its retrospective design, with potential for selection bias, and the small total number of patients manifesting PTH. The study criterion for the diagnosis of PTH was the need for permanent CSF diversion. Criteria to warrant placement of a CSF shunt vary from surgeon to surgeon, thus our patient cohort will reflect this variability. However, placement of a permanent shunt is a more robust indicator of true hydrocephalus than isolated radiographic or CSF pressure measurement. Post-operative infection has been associated with PTH and this variable was not analyzed since information was not consistently available. Study data are derived from a single institution, limiting generalizability. Finally, PTH is a rare outcome, in our study occurring in 6.3% of patients. This is the largest series yet published examining PTH relative to DC distance from midline, however the relative infrequency of the outcome of interest limits generalizability; a larger series combining data and analysis across multiple institutions is desirable. However, the ten-year study timeline encompassed more than 20 surgeons with varying surgical technique, reflecting this real-world clinical setting.

5. Conclusions

In the largest retrospective study performed to date, patients that developed PTH had craniectomy margins closer to midline than those that did not, however the difference between groups was not significant. Analyses were unable to identify a threshold with sufficient discrimination to support clinical recommendations in terms of DC margins with regard to the midline, including those thresholds reported to be significant in previously published literature. Based on this analysis and other published literature, technical modifications to alter DC medial margin for prevention of PTH is not warranted.

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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.jocn.2021.02.025.

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