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Age at Time of Craniosynostosis Repair Predicts Increased Complication Rate

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Abstract

Objective—This study uses administrative data to assess the optimal timing for surgical repair of craniosynostosis and to identify factors associated with risk of perioperative complications.

Design—Statistical analysis of the Healthcare Cost and Utilization Project Kids' Inpatient Database (2006, 2009, 2012).

Setting—KID-participating hospitals in 44 states

Patients—Children 0–3 years of age with ICD-9 codes for surgical correction of craniosynostosis (756 and 0124, 0125, 0201, 0203, 0204, or 0206).

Main Outcome Measure—Age-based cohorts were assessed for perioperative complications. We performed a multivariable analysis to determine characteristics associated with increased risk of complications.

Results—21 million admissions were screened and 8417 visits met criteria for inclusion. Seventy-five percent of procedures occurred before age 1. Complications occurred in 8.6% of patients: 6.6% of patients at age 0–6 months, 10.3% of patients aged 7–12 months, and 13.9% of patients 12–36 months. Patients with acrocephalosyndactyly or associated congenital anomalies experienced complications in 22.9% of cases (OR 3.07, 95% CI: 2.33–4.03).

Conclusion—Craniosynostosis repair is safe, however, the risk of complications increases with age at intervention. Presence of a syndromic congenital deformity at any age carries the greatest

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Patient admissions were identified using the Kids' Inpatient Database, Healthcare Cost and Utilization Project, Agency for Healthcare Research and Quality (Rockville, MD), and statistical analysis was performed using SAS 9.4 (Cary, NC).

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increased risk of perioperative complications. This suggests that optimal timing of intervention is within the first year of life, especially in those cases with additional factors increasing perioperative risk. These data support the importance of counseling patients of the increased risk associated with delaying craniosynostosis repair.

Keywords

Craniosynostosis; Craniofacial Syndromes; Craniofacial Surgery; Kids' Inpatient Database; Administrative Data; Perioperative Complications

Introduction

The craniofacial abnormalities associated with premature fusion of the cranial sutures were initially described by Virchow in 1851 (Persing et al., 1989). Craniosynostosis is now recognized to occur in 1 in 2000 to 3000 live births (Cohen, 1979; Bruce, 2004; Ciurea and Toader, 2009). This can occur as an isolated suture closure, multiple suture synostosis, or in the presence of a craniofacial acrocephalosyndactyly syndrome such as Apert, Crouzon, or Pfeiffer syndrome (Johnson and Wilkie, 2011). The incidence of syndromic craniosynostosis is roughly 1 in 20,000 live births (Cohen, 1979; Bruce, 2004; Ciurea and Toader, 2009). Genetic causes of craniosynostosis are associated with an increased risk of associated intracranial and extracranial complications (Wan et al., 2008; Johnson and Wilkie, 2011).

The standard procedures to normalize the craniofacial dysmorphology and prevent neurologic sequela are fronto-orbital advancement (FOA), extensive cranial vault expansion/remodeling, or posterior cranial vault distraction followed by FOA at a later stage (Mehta et al., 2010; Chim and Gosain, 2011). Endoscopic strip craniectomy with helmet remodeling and other minimally invasive endoscopically-assisted procedures are becoming increasingly popular in select cases (Wan et al., 2008).

Complications of each of these reconstructive procedures are rare (Wan et al., 2008). Operative blood loss, iatrogenic dural injuries, seizure, and CSF leakage are among the most common specific complications. Anesthetic risks such as adverse drug reactions, transfusion reactions, cardiovascular arrest, air embolism, airway compromise, and hypothermia can also occur (Esparza and Hinojosa, 2008; Lee et al., 2012). Major revision procedures are required in 5.4% of patients treated for craniosynostosis. These carry a higher rate of perioperative complications than the primary procedure, regardless of the age at which they are performed (Esparza and Hinojosa, 2008; Lee et al., 2012). Rates of both perioperative complications and need for revision surgery are consistently higher in patients with syndromic cases of craniosynostosis (Wong et al., 2000; Lee et al., 2012).

Timing of surgical correction varies widely between surgeons, since some cases can remain undiagnosed until later in childhood or have mild phenotypic expression. Depending on the sutures involves, FOA and cranial vault remodeling can be performed as early as 2–4 months and as late as 4 years of age in select patients who present late to care. Many severe syndromic cases are planned as multiple-stage procedures (Marchac et al., 1994). The ideal timeframe of 4–13 months has been suggested to take advantage of the infant skull's regenerative capabilities (Wan et al., 2008; Chim and Gosain, 2011). Early procedures in this

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window are purported to take advantage of malleable bone and rapid healing, and make use of the growing brain to maintain sagittal and coronal advancement of the bone. Reported advantages of procedures occurring after the first year of life include presence of thicker bone allowing plate fixation and more precise prediction of surgical needs as most of the deformity has already occurred (Wong et al., 2000).

Previous studies have sought to suggest ideal timing of repair based on long-term neurological development of patients following surgery (Patel et al., 2014). In contrast, our work seeks to use perioperative morbidity as a metric by which to determine timing. This offers the advantages of both greater generalizability and a clear and direct causation between timing of surgery and the outcomes in question. We hypothesized that regardless of procedure, increased age leads to an increased risk of perioperative complications. We also hypothesized that syndromic abnormalities additionally increase this risk.

Methods

The Kids' Inpatient Database (KID, Healthcare Cost and Utilization Project (HCUP), Agency for Healthcare Research and Quality), offers the largest publically available administrative dataset for pediatric inpatient care. The data is comprised from institutions in 44 states and includes roughly 3 million discharges, or 7 million visits when weighted. The collected data is weighted to project national estimates with pediatric admissions. The information in the currently available data sets is based on ICD-9 coding submitted at discharge. This database has been produced every 3 years since 1997 and includes the de-identified information of patients ages 20 or younger. Variables in the database include diagnoses, procedures, discharge status, patient and hospital demographic data, total charges, length of stay, and severity/comorbidity measures.

Childhood inpatient visits were identified using KID files 2006, 2009, and 2012 meeting the following criteria: 1) ICD-9 diagnosis code 7560 (congenital abnormality of the skull/face bones) and 2) ICD-9 Clinical Modification (CM) procedure code for a craniosynostosis repair procedure including craniotomy, craniectomy, opening of cranial suture, skull flap formation, bone graft to skull, or other cranial osteoplasty (0124, 0125, 0201, 0203, 0204, 0206).

Collected data included patient age, gender, race, income, primary method of payment, hospital characteristics, admission data including length of stay and cost of admission, and information regarding perioperative surgical complications. All patients were additionally assessed for the presence of comorbidities which are prevalent in this population (Table 1). Special attention was given to the presence of acrocephalosyndactyly (755.55), a set of craniofacial syndromes associated with craniosynostosis.

Patients were grouped by age at time of repair of 0–6 months, 7–12 months, and 1–3 years. As the age in months variable was unavailable for KID 2012, this dataset was not included in the analysis of specific age-related complication rates when separated by month of age. Procedures performed at age 4 years or greater were considered less likely to be primary repair procedures and more likely to include secondary revision surgeries and therefore were

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excluded from this analysis. Additionally, patients with ICD-9-CM codes 852, 853, and 854 (intracranial hemorrhage following injury, intracranial injury of other and unspecified nature) were excluded to remove craniotomy procedures that may have been performed in trauma situations.

Statistical Analysis

Patient and visit characteristics for the study population were presented as counts and percentages. Univariable and multivariable logistic regression models were specified to determine the significance of associations of demographics and presence of associated syndromic congenital anomalies with perioperative complications. Length of stay and hospital costs were not modeled directly due to collinearity with the primary outcome of perioperative surgical complications. All analyses accounted for the complex design of the KID database using survey procedures in SAS 9.4 (Cary, NC). All analyses determined statistical significance using a 95% confidence interval ($p < 0.05$).

Results

There were 8417 weighted visits for surgical repair of craniosynostosis that met criteria for inclusion in this study (Table 2). Of these, 65.3% of patients were identified as male, 64.7% were identified as White, 20.8% were identified as Hispanic, and 5.0% were identified as Black. The primary payer was private insurance in 52.8% of patients and Medicaid in 39.1% of patients. Hospital length of stay following craniosynostosis repair was 2–3 days in 47% of visits, and only 3.6% of visits lasted greater than 1 week. The most commonly coded procedure was cranial osteoplasty (58.1%) followed by opening of cranial suture (38.0%). Craniectomies were only coded for in 4.6% of cases. Over one third of repair procedures included in this study were listed with multiple procedure codes (35.3%). Patients were diagnosed with a coexisting syndromic congenital abnormality in 6.5% of cases (Table 2).

Surgical repairs occurred prior to age 12 months in 75.4% of cases (Table 2). The procedure commonly performed earliest was opening of cranial suture with an average age at the time of procedure of 6.99 months. Eighty-five percent of these procedures occurred before age 1. Craniectomy and procedures involving bone grafting to the skull were performed on the oldest children with mean ages of 11.16 and 12.29 months respectively (Table 3).

Overall, 959 (9.8%) patients who underwent corrective procedures experienced a surgical or perioperative complication. The most common complication type was post-operative bleeding (n=274, 3.3%), followed by accidental punctures or lacerations (n=103, 1.2%), pneumonia (n=100, 1.2%), and seizure (n=99, 1.2%) (Table 4). Presence of any perioperative surgical complication was directly correlated to increased length of stay and increased cost of hospital admission

Surgical complications increased with age, with complication rates of 6.6% in ages 0–6 months, 10.3% in ages 7–11 months, and 13.9%, 18.3%, and 17.5% at ages 1, 2, and 3 years of age respectively (Table 5).

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Adjusted odds ratios (OR) were calculated from multivariable logistic regression for factors increasing the risk of perioperative surgical complications (Table 6). The factors that resulted in an increased risk of perioperative complications were age (OR=2.53 at 3 years vs < 1, 95% CI: 1.67–3.82), presence of a comorbid congenital anomaly (OR=3.07, 95% CI: 2.33–4.03), and a procedure type of craniotomy or skull flap formation (OR 1.56, 95% CI: 1.18–2.06; OR=1.45, 95% CI: 1.06–1.98 respectively). There was no significant difference in complication rates between genders or any race.

Discussion

The analysis of large administrative datasets is becoming an increasingly valuable method of studying conditions with low incidence and even lower complication rates. A study by Nguyen et al. (2013) used KID years 2003–2009 to recognize factors associated with an increased length of stay in patients undergoing surgical correction for craniosynostosis. This study demonstrated an increase in length of stay and hospital cost associated with both increasing age at the time of the procedure and presence of congenital comorbidities. Our study uses additional statistical modeling with the most recent datasets available to assess the isolated effects of each of these factors, as well as a number of ancillary variables.

Other national databases are available that focus specifically on surgical populations, such as the National Surgical Quality and Improvement Project database and the pediatric subset (Peds NSQIP). This has the advantages of using CPT coding that is more specific for craniosynostosis procedures, and measuring outcome data directed specifically towards the surgical population. Lin et al. (2015) compared Peds NSQIP and KID for the analysis of perioperative complications in primary craniosynostosis repair. They demonstrated the rates of all perioperative complications in both datasets to be similar, and consistent with published clinical series data reported in the literature.

Patient demographics in our study were similar to those previously reported in the literature, demonstrating that procedures for the repair of craniosynostosis occur most commonly in insured, white, male patients, and are performed predominantly in tertiary care hospitals in large urban centers (Nguyen et al., 2013). This is consistent with our experience as these procedures are rarely performed emergently, providing parents with time to research and travel to high volume pediatric surgical centers for care.

Our study demonstrates an overall complication rate of 8.6%, consistent with previously reported data (Esparza and Hinojosa, 2008; Lee et al., 2012; Nguyen et al., 2013; Lin et al., 2015). Postoperative bleeding was the most common surgical complication occurring in 3.3% of cases, with the next most common complications being accidental lacerations (1.2%), pneumonia (1.2%) and seizures (1.2%).

Syndromic acrocephalosyndactyly or presence of any of the additional congenital abnormalities in these patients resulted in clear differences in patient outcomes, as this was the factor most associated with perioperative complications. A complication occurred in 22.9% of these patients, which is three times the rate seen in patients without a comorbid condition.

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The ideal timing for the repair of craniosynostosis is still under debate (Marchac et al., 1994; Bruce, 2004; Patel et al., 2014) however, our data suggest that at least in terms of the risks of perioperative surgical complications, patients that are younger at the time of surgery experience better outcomes with less complications. The multivariable analysis shows that when controlled for procedure type and presence of comorbidities, procedures performed after the age of 12 months have an increased risk of complications (OR 1.61, 95% CI: 1.27–2.06) as compared to those performed prior to 12 months. When performed after the child is older than 36 months that risk rises to an OR of 2.53 (95% CI: 1.67–3.82). This trend was also consistent when broken down by age in months prior to 1 year of age, showing that age at procedure of 0–6 months carried a complication rate of 6.6% and this rate increased to 10.3% at age 7–11 months. Patel et al. (2014) recently demonstrated that in addition to a decreased risk of perioperative complications, patients who have these procedures performed at a younger age have improved long term neurological, psychiatric, and intellectual outcomes. Furthermore, these outcomes diminish directly with age at the time of procedure.

We recognize a number of limitations to the present study. Large-scale cross-sectional inpatient administrative data only captures complications that occur within the hospital stay and fit criteria for a billing code. Additionally, assessment of the need for subsequent revision surgery is a germane outcome measure for these procedures. By using cross-sectional data that is published only in 3 year increments, long term follow up and differentiation between primary and revision procedures for this indication become difficult. We attempted to eliminate revision procedures by using an age cutoff of 3 years, though it is possible some revisions may have been captured. ICD-9 coding limits our ability to separate craniosynostosis from other craniofacial abnormalities that may require these procedures, therefore, even though craniosynostosis is largely the most common, other craniofacial syndromes may be captured in the 756.0 code. To our knowledge, there has not been a study to date assessing the positive predictive value of the ICD-9 code for craniosynostosis. Using strictly ICD-9 coding, we were also unable to differentiate cases by which individual sutures were fused. In other words, differences in craniosynostosis repair based on the location of the affected suture cannot be distinctly accounted for in this model. An additional limitation to the database coding is that all syndromic acrocephalosyndactyly, regardless of a wide range of phenotypes, are grouped together and outcomes for degrees in phenotypic severity could not be accounted for.

All KID files released after the 2016 dataset will utilize ICD-10 coding. This allows greater specificity in the diagnosis of craniosynostosis, the location of fusion, and the procedures performed, which will be beneficial to future studies. Longitudinal studies focusing on these identified risks as pertain to long term and lifetime revision rates will be of immense benefit to surgical care of patients with craniosynostosis going forward.

Conclusions

Craniosynostosis repair continues to be safe, however, the risk of complications increases linearly with age at intervention. Presence of a syndromic congenital deformity at any age carries the greatest increased risk of perioperative complications. This suggests that surgery should ideally be performed prior to age 12 months by a multidisciplinary team of surgical

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specialists. This timing will reduce the risk of perioperative complications that increase patient morbidity, hospital length of stay, and healthcare costs. Special attention should be given to patients with additional comorbidities to ensure they receive adequate care early in their infancy, as they are already at a high risk of perioperative complications. The results of this study expand on previous patterns seen at the institutional level that suggest it may be prudent to counsel patients seeking treatment of the increased risks associated with delaying craniosynostosis repair.

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Table 1

ICD-9 codes used for data collection

Complications	ICD-9 Codes
Hematoma	99812
Elevated ICP/Papilledema	37700 37701 37702
Post-op bleeding	99811
Other nervous system complication	99709
Accidental puncture or laceration	9982
Airway or respiratory failure	51881
Pneumonia	481 4821 48281 486 5180 99731
Post-operative infection	6820 73008 73009 73098 73099 99859 99851
Post-operative stroke	99702
Seizure	34510 3453 34540 34550 34551 34560 34580 34590 34591
Wound disruption	99830 99831 99832
Graft failure	99652
Wound infection	99859
Meningitis	3200 3201 3202 3203 3209
Other bone infection	73028
Pulmonary or air embolism	9991
Trauma	85220 85221 85226 85241 85301
Comorbid condition *	75555 74100 74101 74103 74190 74191 7420 7421 7422 7423 7424 7428 7429 7449 74601 74602 74609 7463 7464 7466 7467 74681 74685 74686 74687 74689 7469 7580 7581 7582 75831 75832 75833 75839 7585 7586 7587 75889 7589

* acrocephalosyndactyly, anomalies of pulm valve, chromosomal abnormalities, congenital encephalocele, congenital hydrocephalus, microcephalus, other specific anomaly of brain, other specified anomalies of the nervous system, reduction deformities of brain, spinia bifida w/ hydrocephalus, unspecified anomaly of face/neck, unspecified anomaly of brain/spinal cord/nervous system

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Table 2

Characteristics of patients with craniosynostosis who underwent corrective procedures

	Unweighted No. Visits (n=5469)	No. (%) Weighted Visits (n=8417)
Age		
< 1 year	4088	6296 (75.4)
1 year	685	1048 (12.5)
2 years	478	733 (8.8)
3 years	175	275 (3.3)
Female	1878	2886 (34.7)
Race		
White	2921	4476 (64.7)
Black	229	343 (5.0)
Hispanic	943	1443 (20.8)
Asian or Pacific Islander	86	130 (1.9)
Other	343	531 (7.7)
Comorbid condition[1]	362	550 (6.5)
Region		
Northeast	759	1154 (13.7)
Midwest	1303	1981 (23.5)
South	1873	2915 (34.6)
West	1534	2366 (28.1)
Payer		
Medicaid	2143	3286 (39.1)
Private	2879	4439 (52.8)
Other	441	683 (8.1)
Length of stay		
≤ 1 day	402	620 (7.4)
2–3 days	2564	3956 (47.0)
4–7 days	2305	3535 (42.0)
> 7 days	198	306 (3.6)
Procedure type		
Craniotomy	549	839 (10.0)
Craniectomy	245	391 (4.6)
Opening of cranial suture	2061	3195 (38.0)
Skull flap formation	726	1131 (13.4)
Bone graft to skull	1137	1761 (20.9)
Cranial osteoplasty	3183	4887 (58.1)
Multiple procedures	1917	2975 (35.3)

[1] acrocephalosyndactyly, anomalies of pulm valve, chromosomal abnormalities, congenital encephalocele, congenital hydrocephalus, microcephalus, other specific anomaly of brain, other specified anomalies of the nervous system, reduction deformities of brain, spinia bifida w/ hydrocephalus, unspecified anomaly of face/neck, unspecified anomaly of brain/spinal cord/nervous system

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Table 3

Age by procedure type

Procedure type	Mean (SE) Age in months	% under 1 year old
Craniotomy	10.61 (0.48)	69.4%
Craniectomy	11.16 (0.82)	74.8%
Opening of cranial suture	6.99 (0.36)	85.1%
Skull flap formation	10.42 (0.51)	69.3%
Bone graft to skull	12.29 (0.70)	66.1%
Cranial osteoplasty	10.22 (0.36)	72.3%

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Table 4

Surgical complications for patients with craniosynostosis who underwent corrective procedures

	Unweighted No. Visits (n=5469)	No. (%) Weighted Visits (n=8417)
Complication	472	726 (8.6)
Hematoma	21	33 (0.4)
Elevated ICP/Papilledema	34	51 (0.6)
Post-op bleeding	177	274 (3.3)
Other nervous system complication	29	45 (0.5)
Accidental puncture or laceration	64	103 (1.2)
Airway or respiratory failure	28	42 (0.5)
Pneumonia	66	100 (1.2)
Post-operative infection	18	27 (0.3)
Post-operative stroke	21	32 (0.4)
Seizure	67	99 (1.2)
Wound disruption	13	19 (0.2)

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Table 5

Surgical complications by age

	Weighted No. Visits (n=4039)	% with Complications
Age		
0–6 months	1598	6.6%
7–11 months	1539	10.3%
1 year	572	13.9%
2 years	193	18.3%
3 years	136	17.5%

Note: Estimates based on KID 2006–2009 files only. Weighted estimates of number of visits and percent with complication by age provided in Table 4.

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Table 6

Odds ratios for associations of patient characteristics with surgical complications

	% with Complications	Unadjusted Odds Ratio (95% Confidence Interval)	Adjusted Odds Ratio (95% Confidence Interval)
Overall	8.6%		
Age			
< 1 year	7.2%	1	1
1 year	13.0%	1.93 (1.52, 2.45) ‡	1.61 (1.27, 2.06) ‡
2 years	11.1%	1.61 (1.11, 2.33) †	1.33 (0.91, 1.96)
3 years	19.4%	3.12 (2.12, 4.60) ‡	2.53 (1.67, 3.82) ‡
Gender			
Female	9.0%	1.06 (0.86, 1.30)	0.96 (0.79, 1.18)
Male	8.5%	1	1
Race			
Non-white	8.8%	1.05 (0.83, 1.33)	1.02 (0.80, 1.31)
White	8.5%	1	1
Comorbid condition			
Yes	22.9%	3.60 (2.74, 4.75) ‡	3.07 (2.33, 4.03) ‡
No	7.6%	1	1
Procedure type			
Craniotomy	13.8%	1.84 (1.41, 2.39) ‡	1.56 (1.18, 2.06) ‡
Craniectomy	13.0%	1.63 (1.20, 2.21) ‡	1.43 (0.99, 2.04)
Opening of cranial suture	6.6%	0.64 (0.51, 0.82) ‡	0.87 (0.65, 1.15)
Skull flap formation	11.0%	1.37 (1.04, 1.81) †	1.45 (1.06, 1.98) †
Bone graft to skull	10.3%	1.29 (0.99, 1.67)	1.18 (0.89, 1.56)
Cranial osteoplasty	9.5%	1.30 (1.04, 1.62) †	1.24 (0.94, 1.65)

† $p<0.05$

‡ $p<0.01$