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Original Article

A 24-month cost and outcome analysis comparing traditional fronto-orbital advancment and remodeling with endoscopic strip craniectomy and molding helmet in the management of unicoronal craniosynostosis: A retrospective bi-institutional review ☆

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ABSTRACT

Introduction: Endoscopic strip craniectomy with helmeting (ESCH) has been shown to be a safe and efficacious alternative to fronto-orbital remodeling (FOR) for selected children with craniosynostosis. In addition to clinical factors, there may be economic benefits from the use of ESCH instead of FOR.

Methods: A retrospective review of 23 patients with nonsyndromic unicoronal craniosynostosis (UCS) treated with FOR was carried out at Great Ormond Street Hospital (GOSH) for Children in London, UK. Secondary data were used for the ESCH cohort from a paper published by Jimenez and Barone (2013). Data were collected on surgical time, transfusion rates, length of hospital stay, adverse event rates, reintervention rates, and overall costs. Costs were categorized and then assigned to the appropriate data sets.

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Results: The mean age of patients undergoing FOR (vs. ESCH) was 17.4 mo (vs. 3.1 mo) with a mean surgical time of 234 min (vs. 55 min), mean transfusion volume of 221.6 mL (vs. 80.0 mL), mean transfusion rate of 14/23 (vs. 2/115), and a total immediate overnight stay of 3.13 days (vs. 97% next-day discharge). The FOR group had a higher adverse event rate (5/23 vs. 4/115, $p=<0.005$) and a higher number requiring extraocular muscle surgery (4/23 vs. 7/109, $p=0.16$). There was a substantial difference in overall costs between the two groups. Total variance cost for the FOR group was £7436.5 vs. £4951.35, representing a cost difference of £2485.15 over the 24-month study period.

Conclusion: ESCH, in comparison to FOR, appears as a more economical method in the management of USC patients, as well as having clinical benefits including reduced adverse event rate and improved ophthalmic outcomes.

Introduction

Craniosynostosis is a congenital condition in which there is premature fusion of one or more of the cranial sutures,[1] with an incidence of approximately 1:2000 live births.[2] Most patients, however, present with isolated single suture disease. A number of associations such as intrauterine constraint, maternal valproate use, maternal cigarette smoking, excessive antacid use, and metabolic diseases (e.g., hypophosphatemic rickets)[3] have been observed.

The involvement of multiple sutures[3] and extracranial anomalies suggests a unifying syndromic cause, of which mutations in FGFR and TWIST1 genes[3,4] are the most common.

Skull growth occurs perpendicular to the axis of the suture.[2] In craniosynostosis, the fused suture restricts this growth, and secondary deformities result from compensatory expansion of the unaffected sutures.[1,6] This combination of growth restriction and compensatory change results in the classical phenotypes of craniosynostosis.

Unicoronal craniosynostosis (UCS) is the second most prevalent form of synostosis[7] and deserves special attention because of its possible sequelae, of which orbital asymmetry is of particular importance. The orbital asymmetry may result in strabismus, aniso-astigmatism, 2 ocular torticollis, and amblyopia, which, if left uncorrected in childhood, can lead to blindness of the affected eye.[5,7] Strabismus is universally present in patients with identified FGFR2 or FGFR3 mutations.[5]

In addition to the orbital distortions, patients with UCS classically present with forehead and superior orbital rim retrusion, contralateral frontal bossing, and nasal deviation. These combine to form a constellation of significant facial asymmetries that are often difficult to correct even with multiple further surgeries.[7]

Fronto-orbital remodeling (FOR) surgery is the current standard management of UCS in many institutions. Despite advances in operative care, this remains a highly invasive procedure with significant morbidity and postoperative recovery requiring high-dependency care.[8]

Open strip craniectomy was initially used in the management of microcephaly and has been used in the treatment of craniosynostosis since 1927.[2] Unsatisfactory results have been attributed to the late timing of the surgery, incomplete release of involved sutures, and the lack of maintenance of the release. In 1999, Jimenez and Barone described a minimally invasive, endoscopy-assisted approach for suturectomy in combination with orthotic helmet therapy (ESCH) to treat craniosynostosis.

Although the surgical goals of current and past strip craniectomies were identical, there were some fundamental differences. Significant modifications in surgical access and the use of endoscopic

assistance minimized the degree of bleeding and scarring. Jimenez and Barone performed these procedures on infants within the first few months of life[8,10] and employed post-surgical cranial orthoses to capitalize on the period of rapid brain growth to achieve a symmetric cranial form.[9,10]

Published reports of ESCH suggest reduced operating times, reduced transfusion requirements, reduced hospital stay, and improved outcomes.[1,2,6–18] While additional studies have also demonstrated lower costs associated with ESCH than with FOR,[11,12,19] no studies have evaluated the costs in the UK healthcare system or the costs of specifically managing UCS. Furthermore, no study has looked at the 24-month cost, including both the primary surgical cost and additional hospital costs that may be associated with adverse events and secondary deformity.

The aims of the paper are to assess the 24-month costs associated with FOR in the management of UCS compared to ESCH, in addition to assessing the adverse event and ophthalmological surgical intervention rates.

Materials and methods

A retrospective chart review of nonsyndromic patients with UCS who underwent FOR between January 2012 and February 2015 was carried out at GOSH for Children in London, which is one of the four nationally commissioned craniofacial units in the UK. Two hundred forty-five patients were identified to have craniosynostosis. Only patients with unicoronal synostosis were selected and patients with incomplete clinical records or who had cranial remodeling or intervention before the review time period were excluded. In total, 23 patients were identified as eligible.

All patients were reviewed up to 24 months post procedure to collect data of hospital readmissions (inpatient and outpatient visits), re-intervention rates, and secondary procedures to correct associated deformities. Furthermore, perioperative data were collected for total surgical time, transfusion occurrence, transfusion amount, and overnight ward stays, which was split into high-dependency unit (HDU) stays and normal ward stays.

It was not possible to do the same for the ESCH method, as ESCH for the treatment of UCS is a method that, to our knowledge, has not yet been implemented by the hospital or any hospital in the UK. Because of this limitation, secondary data were needed for ESCH patients, which were provided through a previously published paper by Jimenez and Barone in 2013[9] (Table 2) that took place at the University of Texas Health Science Center at San Antonio, United States. Because of the significant difference in cost structure that exists between the healthcare systems in the US and UK, the perioperative data and follow-up data collected from both institutes were then applied to a UK healthcare financial model to generate an accurate cost estimate for conducting the procedure in the UK. To best estimate costs for the two interventions while using a consistent approach, costs were broken down into different cost categories (Table 1) and costs were assigned to the appropriate data sets.

Because costs differed in each fiscal year, surgical costs were calculated using the most recent hospital financial data (fiscal year 2015/2016), as costs from the eventual implementation of ESCH

Table 1
Calculation of different cost categories.

Cost	Calculation
Primary surgical cost	Theater cost of initial surgical intervention (i.e., FOR or ESCH) + transfusion cost + ward costs
Adverse event cost	Mean adverse event cost (includes all costs associated with an adverse event)
Adjusted adverse event cost	Adverse event cost × rate of adverse events
Follow-up cost for UCS patients treated with FOR	Cost of follow-up appointment*,[a] hospital follow-up rate
Follow-up cost for UCS patients treated with ESCH	(Cost of follow-up appointment*,[b] hospital follow-up rate based on proposed hospital protocol) + (helmeting and orthotist appointment costs)
Total variance cost	(Primary surgical cost) + (absorbed adverse event cost) + (follow-up cost)

[a] Hospital follow-up rate for FOR patients was based on the current hospital protocol for UCS patients treated with FOR.
[b] Hospital follow-up rate for ESCH patients based on a proposed hospital protocol for future UCS patients treated with ESCH and an average expected number of helmets required of 2.31.[12]

Table 2
Patient Data for FOR and ESCH

	[a]FOR ($n=23$)	[b]ESCH ($n=115$)	
Side distribution (R:L)	12:11	82:33	
Gender distribution (M:F)	10:13	50:65	
Age at procedure (months)	17.37 (range 13.20–29.53)	3.1 (range 36 weeks of gestation-10)	
Surgical time (min)	234.35 (range 180–270)	55 (22–150)	
Patients requiring transfusion,	14/23	2/115	$p=<0.005$*
Transfusion amount	221.6 (range 80–308)	80 (range 60–100)	
Total immediate overnight stays	3.13 (range 2–7)	97% discharged the next day	
Immediate overnight HDU stays	1.17 (range 1–3)		
Immediate overnight Normal ward Stays	1.96 (range 1–4)		
Total secondary overnight stays	2.2 (range 0–26)		
Secondary overnight HDU stays	0.2 (range 0–5)		
Secondary overnight Normal ward Stays	2 (range 0–21)		
Total overnight stays	5.35 (range 2–28)		
Overnight total HDU stays	1.39 (range 1–6)		
Overnight total Normal ward stays	3.96 (range 1–22)		
Patients with an adverse event	5/23	4/115	$p=<0.005$*
Adverse event type	Infection ($n=2$) Hemorrhage ($n=1$) Hematoma ($n=2$) Dural Tear ($n=1$) Skin Eruption ($n=1$) Secondary FOR ($n=2$)	Class II Venous Air Embolism, not clinically significant ($n=2$) Dural Tears ($n=2$)	
Patients requiring extraocular muscle surgery	4/23	7/109	$p=0.16$

[a] FOR data were primary data collected at GOSH.
[b] ESCH data were secondary data based on results from Jimenez and Barone.[9] Although the patient population from this cohort was limited to coronal craniosynostosis, a small subset was bicoronal ($n=12$) as opposed to unicoronal ($n=103$).
* Chi-square test.

at the hospital would likely be best reflected by these data. When calculating adverse event costs for FOR and ESCH, total cost per adverse event incidence was obtained from the patient financial database at GOSH and a mean adverse event cost was calculated. This mean adverse event cost was then multiplied by the adverse event rate for FOR and ESCH patients to calculate an estimated overall adverse event cost in the UK.

Adverse events were defined as any event that resulted in a prolonged hospital stay or readmission to the hospital following the primary surgical procedure but excluded ophthalmic surgical intervention. Adverse events encountered are listed in Table 2. Follow-up costs were calculated based on the hospital follow-up protocol for UCS patients treated with FOR and a proposed follow-up protocol for future UCS patients treated with ESCH that included the cost of helmet fitting and manufacturing, using an expected rate of 2.31 helmets[12] (Table 1).

Descriptive statistics were performed for categorical and continuous data for patient demographics, postoperative outcomes, and cost analyses. Statistical analysis of categorical variables reported in both intervention groups was performed using chi-square tests. Observations with two-tailed p-values of less than 0.05 were considered statistically significant.

Results

Patient population

Twenty-three patients with nonsyndromic USC were identified through a retrospective chart review at GOSH, London, from January 2012 to February 2015. Among them, 12 and 11 patients had right- and left-sided involvement, respectively, with 10 male and 13 female patients. All patients underwent FOR, with the mean age of conducting the procedure being 17.4 months (range 13.2–29.5 months). For the ESCH group, open data were used by a paper published by Jimenez and Barone.[9] There were a total of 115 nonsyndromic craniosynostosis patients, with a right to left distribution of

82 to 33, respectively, with 50 male and 65 female patients. The mean age of conducting the procedure being 3.1 months (range 36 weeks of gestation to 10 months).

Surgical results

Average surgical time for the FOR group was 234 min, range 180–270 min (vs. 55 min, range 22–150 min). Fourteen of 23 patients required a blood transfusion (vs. 2 of 115 patients) with a mean transfusion volume of 222 mL, range 80–308 mL (vs. 80 mL, range 60–100 mL). The patients required a mean of 3.13 (range 2–7) immediate overnight stays following their primary procedure (vs. 97% discharged the next day). This was split into a mean immediate HDU stay of 1.17 (range 1–3) nights and a mean immediate overnight normal ward stay of 1.96 (range 1–4) nights.

In the FOR arm, there were 5 adverse events out of the 23 cases. Two children had wound infections that required a return to theater for washouts, 2 children had sterile subgaleal collections that did not require a return to theater, and 1 child developed postoperative RSV bronchiolitis. Of the 5 patients who experienced an adverse event, the total secondary overnight stay was 2.2 nights (range 0–26), including a mean HDU stay of 0.2 nights (range 0–5) and a mean standard bed stay of 2 nights (range 0–21).

Overall, the mean total overnight stays, including immediate and secondary overnight stays was 5.35 nights (range 2–28 nights) with a mean HDU and normal bed stay of 1.39 (range 1–6 nights) and 3.96 nights (range 1–22 nights), respectively.

In the ESCH group, there were a total of 4 adverse events out of 115 cases, 2 Class II venous air embolisms, which were not clinically significant, and 2 dural tears, 1 measuring 5 mm and 1 measuring 1.5 cm. Furthermore, 4/23 FOR patients required extraocular muscle surgery for strabismus (vs. 7/109 in the ESCH group). All results are tabulated in Table 2.

Costs

There was a substantial difference in cost between FOR and ESCH in the management of UCS. The mean primary operative cost for FOR was £4705.37 (vs. £1611.20). The average adverse event cost for FOR patients was £8,165.28 (range: £2895.92–£22,779.29). Adverse event cost was then adjusted based on an adverse event rate of 5/23 for FOR patients and 4/115 for ESCH patients for adjusted adverse event costs of £1775.13 and £284.15 for FOR and ESCH patients, respectively. The average follow-up cost for FOR was £956 compared to £3056 for the ESCH group. The total estimated cost of managing a UCS patient with FOR compared to ESCH over a 24-month period (excluding extraocular muscle surgery costs) was £7436.50 (vs. £4951.35) for a difference in cost of £2485.15. The total cost was represented as a total variance cost, which is not the true total cost, but rather the total cost of expenses that were expected to differ between the two procedures (i.e., surgical cost, transfusion cost, ward stay, adverse events, and follow-up) and therefore did not include several costs that were expected to be similar, such as preoperative costs. Even when adverse events are not considered, there is still an estimated savings of £994.17 (FOR cost of £5661.37 vs. ESCH cost of £4667.2). All cost differences are reported in Table 3.

Table 3
Cost differences in the management of UCS with FOR vs. ESCH.

Cost categories	FOR cost	ESCH cost	Cost savings, $ (FOR-ESCH)	Cost savings, % (FOR-ESCH)/FOR
Mean primary operative cost	4705.37	1611.20	3094.17	66
Adjusted adverse event cost	1775.13	284.15	1490.98	84
Follow-up cost	956	3056	2100.00	−220
[a]Total variance cost	7436.50	4951.35	2485.15	33

[a] The total variance cost does not represent the entire cost of each procedure but rather the total cost of expenses that was expected to differ between the two procedures (i.e., surgical cost, transfusion cost, ward stay, adverse events, and follow-up costs) and therefore did not include several costs that were expected to be similar, such as preoperative costs.

Discussion

FOR has a successful result rate, especially in older children,[1] but has been criticized for its high adverse event and secondary surgery rate.[6,9,10,17] Furthermore, while FOR tends to show excellent initial results, past papers have concluded a decline in results over time.[9]

The results of this paper add to the growing evidence in favor of managing craniosynostosis patients with ESCH. Although the follow-up cost is expected to be substantially higher in this group owing to the number of orthotic visit and an average helmet number of 2.31,[12] this cost is offset by savings from surgical and adverse event costs. The adverse event rate from FOR in our paper was 5/23 compared to 4/115 when ESCH was used.[9] In addition to the rate of adverse events, the severity of the adverse events in ESCH was arguably less than that in FOR. Jimenez and Barone reported no hemorrhages, hematomas, or infections in contrast to our FOR patients (Table 2). The median adverse event cost in our patients undergoing FOR was £2895.92 with two patients costing £10626.03 and £22779.29 due to hemorrhage, infections, and repeated craniofacial procedures. Such adverse events may have been avoided through ESCH, thereby saving thousands of pounds. In addition to greater cost burdens, patients undergoing FOR have increased surgical times, transfusion rates, and hospital bed stays. These not only add to hospital costs but also increase the risk of comorbidities. For instance, transfusions can often be predictive of postoperative events with transfusions greater than 60 ml/kg increasing the risk for adverse events and length of hospital stay.[20] Although combining multiple blood salvage techniques (i.e., the use of tranexamic acid) may reduce the overall transfusion rates to those comparable with the endoscopic method,[3] the optimal dose for such techniques has not yet been determined.[2]

UCS carries an increased prevalence of strabismus, especially in those with FGFR2 or FGFR3 mutations,[5] adding to the cost of patient care. The extraocular muscle surgical rate was 4/23 in our group of patients, with literature stating manifestation of strabismus incidences from 50% to 65% and occurrence more frequently on the contralateral side to the synostosis.[5] Extraocular muscle surgery for strabismus was not included in our total variance cost estimate due to not being able to find a comparative 24-month rate in ESCH patients. Although not included, it is expected to contribute to an increase in the total variance cost for FOR due to lower strabismus surgery rates in ESCH patients.[9] Despite the orbital rims being more symmetrical after FOR, the ocular motility dysfunction remains.[5] This is likely due to FOR not being able to address the problems that lead to orbit dysmorphology such as the constriction of the anterior cranial fossa, deviation of the anterior fossa midline, elevation of the orbital floor, and straightening of the lesser sphenoid wing.[21] FOR has an unpredictable effect on extraocular muscle function and may lead to new-onset strabismus.[21] MacKinnon et al. observed 9/22 patients treated by FOR requiring strabismus surgery compared to 2/21 patients in the ESCH group. The odds ratio of having strabismus surgery with FOR compared to ESCH was 6.3:1 (95% CI, 1.09–69.34).[22] It is not yet known, however, whether the difference in ophthalmic outcomes is due to differences in timing or differences in the two procedures.[22] If early intervention is critical in reducing the rate of strabismus in children with UCS, then this would strengthen the argument for the use of an earlier surgical intervention that may be possible with FOR, such as ESCH.

ESCH is primarily limited by the age of the patient due to reliance on brain growth and remodeling of the head with a helmet. ESCH therefore requires intervention at an earlier age, ideally before 4 months.[22] This is in contrast with FOR, which should be performed around 6–7 months for best binocular function,[23] 6–12 months for the least need for any secondary surgery, or older than 12 months for the lowest incidence of readvancement.[24] While some units have reported improved intellectual outcomes for conventional vault remodeling vs. strip craniectomy techniques,[25] these studies are retrospective and include heterogeneous populations. Currently, there are no reliable prospective data on the effect of surgical treatment for single-suture synostosis on neuropsychological outcome, and published studies are at variance.[26,27]

Additionally, performing FOR at less than 6 months of age compared to 23 months greatly reduces the incidence of strabismus from 67% to 19%.[22] However, FOR at such an early age has been associated with greater operative morbidity and increased likelihood of relapse.[22,24] Timing of FOR therefore needs to be carefully assessed.

There were several limitations to our paper: First, no data were available before 2012 owing to changes in the ward and data storage methods at the hospital, thereby limiting patient recruitment and follow-up duration. A major limitation in our study was the study design. While an ideal study would be to conduct a randomized controlled trial comparing the outcomes of FOR to ESCH in a single institute that routinely performs both procedures, this was not possible due to the ESCH technique not yet being routinely used at our institute or any institute known to us in the UK. To our knowledge, we are not aware of other studies relying on literature-derived data. Relying on published data by Jimenez and Barone[9] meant we did not have access to individual patient data preventing formal adjustments for population differences that may exist between the UK and the US. We do not, however, expect this to significantly impact our findings due to both groups limiting the patient population to nonsyndromic craniosynostosis. It is important to address that a small subset of patients within the Jimenz and Barone population (12 out of 115) had bicoronal craniosynostosis as opposed to unicoronal synostosis. This, however, is not expected to significantly change operative costs. Significant differences may be expected in the need for extraocular surgery; however, as costs associated with extraocular surgery were not included in our cost calculations for either group, we do not expect this small population group to have a significant impact on our findings.

Our FOR results were similar to results stated in the literature regarding other craniosynostosis patients treated by FOR. Although follow-up costs were calculated, follow-up did not include ophthalmological visits, as secondary data were unavailable for this parameter. Given the higher incidence of ophthalmic surgical intervention in the FOR cohort, it is expected that this would contribute to a further increase in the total variance cost for FOR compared to ESCH. Finally, a future study will aim to utilize primary data of ESCH patients once ESCH is implemented in the hospital as an intervention method for craniosynostosis patients. At such a point, total costs will be possible to obtain for the two groups to allow direct comparisons as well as including any costing gaps that currently exist, such as ophthalmic costs.

Conclusion

ESCH therapy is a more economical method than frontal orbital advancement in the management of unilateral coronal synostosis. It is associated with short surgical times, reduced blood transfusion rates, few adverse events, short inpatient stays, and few ophthalmic interventions. However, ESCH therapy may not be suitable for children who present after the age of 6 months, where FOR is likely to remain the method of choice. Further studies are warranted to compare the use of FOR and ESCH in the management of UCS at an institute where both methods have been routinely used.

Ethical statement

This study is registered and approved by the Great Ormond Street Hospital (GOSH) for children research and audit department.

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Conflicts of interest statement

None.

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