J Neurosurg Pediatrics 8:423–429, 2011

Minicraniotomy versus bur holes for evacuation of chronic subdural collections in infants—a preliminary single-institution experience

Clinical article

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Object. Various surgical interventions have been described to evacuate chronic subdural collections (CSCs) of infancy. These include transfontanel percutaneous aspiration, subdural drains, placement of bur hole(s) with or without a subdural drain, and shunting. Shunt placement typically provides good long-term success (resolution of the subdural fluid), but comes with well-known early and late complications. Recently, the authors have used a mini–osteoplastic craniotomy technique with the goal of definitively treating these children with a single surgery while avoiding the many issues associated with a shunt. They describe their procedure and compare it with the traditional bur hole technique.

Methods. In this single-institution retrospective study, the authors evaluated 26 cases involving patients who underwent treatment for CSC. Preoperative, intraoperative, and postoperative data were reviewed, including radiographic findings (density of the subdural fluid and ventricular and subarachnoid space size), neurological examination findings, and intraoperative fluid description. The primary outcome was treatment failure, defined as the patient requiring any subsequent surgical intervention after the index procedure (minicraniotomy or bur hole placement).

Results. Fifteen patients (10 male and 5 female; median age 5.1 months) collectively underwent 27 minicraniotomy procedures (each procedure representing a hemisphere that was treated). In the bur hole group, there were 11 patients (6 male and 5 female; median age 4.6 months) with 18 hemispheres treated. Both groups had subdural drains placed. The average follow-up for each treatment group was just over 7 months. Treatment failure occurred in 2 patients (13%) in the minicraniotomy group compared with 5 patients (45%) in the bur hole group ($p = 0.09$). Furthermore, the 2 patients who had treatment failure in the minicraniotomy group required 1 subsequent surgery each, whereas the 5 in the bur hole group needed a total of 9 subsequent surgeries. Eventually, 80% of the patients in the minicraniotomy group and 70% of those in the bur hole group had resolution of the subdural collections on the last imaging study.

Conclusions. The minicraniotomy technique may be a superior technique for the treatment of CSCs in infants compared with bur hole evacuation. The minicraniotomy provides greater visualization of the subdural space and allows more aggressive evacuation of the fluid, better irrigation of the space, the ability to fenestrate any accessible membranes safely, and continued egress of fluid into the subgaleal space. Although this preliminary report has obvious limitations, evaluation of this technique may be worthy of a prospective, multiinstitutional collaborative effort.
(DOI: 10.3171/2011.8.PEDS1131)

Key Words • **subdural hematoma** • **bur hole** • **minicraniotomy** • **infant** • **pediatric neurosurgery** • **nonaccidental trauma**

A persistent or chronic subdural collection—hygroma or hematoma—in an infant is a common problem faced by pediatric neurosurgeons. These collections evolve from an acute hematoma or a tear in the arachnoid mater, usually precipitated by blunt force trauma (accidental or nonaccidental).[4,11] Less commonly, CSCs can be caused by a leptomeningeal infection or occur spontaneously in patients with arachnoidomegaly.[28,29] Subdural collections can enlarge over time and cause accelerated head growth, compress the surrounding brain parenchyma, and produce focal or global neurological symptoms or deficits.

Abbreviation used in this paper: CSC = chronic subdural collection.

This article contains some figures that are displayed in color online but in black and white in the print edition.

From a therapeutic standpoint, CSCs pose a particularly challenging problem. A variety of procedures are commonly used to treat these collections, including percutaneous transfontanel taps, bur hole craniostomy, subdural drains, craniotomy with membranectomy, or placement of a subdural shunt system. Each of these procedures has its own risk/benefit profile and ability to eradicate the CSC.[25] Subdural shunts have a longer-term potential morbidity. Some patients develop an unrecognized subarachnoid-to-subdural connection and become dependent on the shunt, whereas others may undergo a second surgery to remove the shunt once it has been determined that it is no longer needed. In our opinion, the most desirable procedure would be one that has the greatest chance of definitively treating the CSC as a single surgery with a low risk of complications and without placing a shunt.

At the Children's Hospital of Wisconsin, the senior author (B.A.K.) had been using the "mini–osteoplastic craniotomy" technique to treat CSCs. The technique developed as an enlarged bur hole drainage procedure to more effectively treat loculations and to create an opportunity for extended drainage after the externalized drain had been removed. The wide dural opening presumably provides an avenue for drainage into the subgaleal space, creating a temporary subdural–subgaleal "shunt," and may function similarly to the use of subgaleal drainage in infants with intraventricular hemorrhage. Initial results suggested that this technique had a higher rate of subdural resolution.

In this study, we compare the 2 surgical techniques used most frequently at Children's Hospital of Wisconsin: this novel "mini–osteoplastic craniotomy" technique versus bur hole evacuation, both employing postoperative subdural drains. We hypothesized that the minicraniotomy, although less invasive than a larger, standard craniotomy, still allows an aggressive and thorough drainage of the CSC and thus decreases the risk of CSC recurrence and the need for subsequent procedures.

Methods

Study Design

This study was a retrospective review of all infants (age < 2 years) who were treated for a CSC at the Children's Hospital of Wisconsin from June 2002 to April 2009. The choice of surgical technique was at the discretion of the attending surgeon. Only the senior author (B.A.K.) performed the minicraniotomy, whereas all 3 staff neurosurgeons (B.A.K., S.M.L., M.Z.L.) treated patients by means of bur hole drainage. This study was approved by the institutional review board of the Children's Hospital of Wisconsin.

Preoperative clinical and radiological information was collected, including age, sex, cause of the CSC (if known), and presenting neurological signs and symptoms. The latter were classified into one of 2 groups: focal findings (for example, hemiparesis) or global findings (for example, macrocephaly defined as head circumference greater than the 98th percentile curve or rapid head growth crossing percentile curves, seizure, sun-downing, lethargy, irritability). The occipitofrontal head circumference was measured and the percentile determined. Imaging typically consisted of CT, MR imaging, or both. The location (frontal, parietal, interhemispheric) and laterality (unilateral, bilateral) of the CSC was recorded. The ventricles were classified as normal or enlarged, and the subarachnoid space was categorized as normal, absent, or enlarged. The density of the collection on CT was classified as hypodense, isodense, hyperdense, or mixed. Results from CT and MR imaging studies were used to determine the extent of parenchymal injury (for example, contusion, diffusion restriction) and whether there were any neomembranes creating loculated collections. Perioperative data included the initial appearance of the subdural fluid, the duration of postoperative drainage, the reason drainage was terminated, and the occipitofrontal head circumference at the last clinic appointment. The size of the CSC on the last imaging study was classified as resolved, improved, worse, or unchanged.

The primary outcome of this study was treatment failure, defined as the patient needing another surgical procedure (for example, replacement of a subdural drain or shunt placement) after the index procedure (minicraniotomy or bur hole placement). The secondary outcome was procedure-related complications. Because of the small sample sizes, we employed a 2-tailed Fisher exact probability test to compare the proportions of failures in each group (minicraniotomy vs bur hole). Descriptive statistics were used elsewhere.

Surgical Techniques

Bur Hole. The patient is positioned supine under general anesthesia. A small curvilinear or linear incision is made over the subdural collection, most often on the lateral aspect of the anterior fontanel along the coronal suture. The dura mater and subdural membrane are coagulated and opened enough to pass a standard or large-diameter ventricular catheter into the collection easily. The collections are copiously irrigated to remove debris and ensure that there is no active bleeding. The ventricular catheters are externalized through a stab incision and connected to standard external ventricular drainage systems. Bilateral collections are usually drained simultaneously, but through separate incisions and bur holes and with separate externalized catheters. Postoperatively, the drainage systems are kept at or below head level.

Mini–Osteoplastic Craniotomy. The patient is positioned supine under general anesthesia, and the head is flexed or elevated to place the anterior fontanel as the highest point. The region at and behind the coronal suture is used for the incision. On either side of the midline, a curvilinear incision is placed, with the apex of the curve just above the coronal suture (Fig. 1A). The pericranium is preserved, and the small scalp flap is held retracted. A curette is used to access the epidural space on the medial and lateral edges of the coronal suture, and the dura is stripped under the exposed parietal calvaria. The drill is inserted, with the footplate, in either the medial or lateral opening in the coronal suture, and a semicircular bone flap is created based on the coronal suture (the footplate

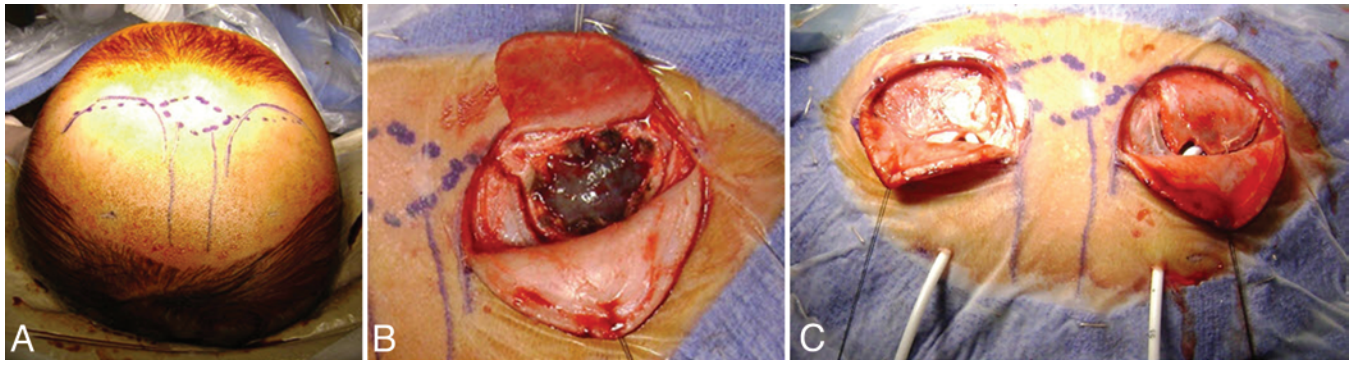

Fig. 1. Intraoperative photographs demonstrating the mini–osteoplastic craniotomy technique. **A:** The curvilinear incisions are made on the lateral aspect of the anterior fontanel with the apex of the incision just anterior to the coronal suture. A parietal bone flap is then elevated, still attached to the pericranium and the coronal suture and reflected anteriorly with a suture. **B:** The dura is then widely opened, and the edges are cauterized to keep it open. This exposes the underlying hematoma, but the exposure allows access to underlying neomembranes and loculations. **C:** Once the subdural space is thoroughly irrigated, the tips of the subdural drains are aimed anteriorly (a depth of 5 cm is usually adequate) and then tunneled posterior to the incision.

enters one opening on the coronal suture and exits the other). The bone is reflected forward, maintaining its attachment to the coronal suture, and is held in place with a suture, later used to reapproximate the bone.

The dura is coagulated widely and opened in a stellate fashion. The dural edges are cauterized with the bipolar cautery, causing them to retract and become a wide permanent opening (Fig. 1B). A subgaleal pocket is created anterior and posterior to the curvilinear incision. A ventricular catheter is used to irrigate the subdural space. The subdural collection is inspected for any visible neomembranes, and these are fenestrated if present. The ventricular catheter is externalized through a stab incision located posterior to the incision (Fig. 1C). The bone flap is reapproximated with the 3–0 Vicryl retraction suture, with an opening made to accommodate the exiting drain. The galea is closed with an absorbable suture, completing the closure as fluid is irrigated into the subdural space to minimize intracranial air.

Results

Preoperative Findings

A total of 26 patients underwent treatment for a CSC: 15 had a minicraniotomy as their index procedure and 11 had a bur hole created. Table 1 shows the demographics of the 2 groups; they had similar age and sex distributions. Nonaccidental trauma was the cause of the CSC in all patients except for 1 patient in each group. Both of these children with spontaneous CSC had arachnoidomegaly—the child who underwent minicraniotomy was on aspirin because of a hypercoagulable state due to congenital thrombocytosis, and the patient who had a bur hole had achondroplasia.

All patients in both groups except for one presented with global findings. One patient in the minicraniotomy group presented with a head circumference at the 98th percentile and hemiparesis (Table 1). The head circumference was greater than the 90th percentile in 53% patients in the minicraniotomy group compared with 80% in the bur hole group (the preoperative occipitofrontal head circumference was not available in 1 patient in the bur hole group).

Table 2 lists the radiographic findings. In the minicraniotomy group, there were 27 involved hemispheres (12 bilateral, 3 unilateral), while patients in the bur hole group had 18 involved hemispheres (7 bilateral, 4 unilateral). A greater percentage of patients in the bur hole group (5 [45%] of 11) had interhemispheric involvement of their collections than in patients in the minicraniotomy group (2 [13%] of 15). Hyperdensity, either alone or in combination with an isodense component, was present in 62% of patients in the minicraniotomy group (8 of 13) and in 50% of patients in the bur hole group (4 of 8). Magnetic resonance imaging revealed neomembranes and loculated collections in 2 patients who underwent minicraniotomy and 3 patients who underwent the bur hole

TABLE 1: Preoperative demographic characteristics of patients treated for CSCs*

Characteristic	Surgical Procedure	
	Minicraniotomy	Bur Hole Placement
no. of pts	15	11
sex		
M	10	6
F	5	5
mean age (mos)	5	4
neurological presentation		
focal finding	1 (7)	0 (0)
global finding	14 (93)	11 (100)
head circumference†		
>90th percentile	8 (53)	8 (80)
75th–90th percentile	5 (33)	1 (10)
<75th percentile	2 (13)	1 (10)

* Values represent numbers of patients (%) unless otherwise indicated. Abbreviation: pt = patient.

† No preoperative head circumference data were available in 1 case in the bur hole group.

TABLE 2: Preoperative radiological findings in patients treated for CSCs*

Finding	Surgical Procedure	
	Minicraniotomy (15 pts)	Bur Hole Placement (11 pts)
total hemispheres involved	27	18
bilat	12	7
unilat	3	4
location		
frontal	8 (53)	2 (18)
frontoparietal	5 (33)	4 (36)
frontoparietal & interhem	2 (13)	5 (45)
CT†		
hypodense	3 (23)	1 (13)
hypo/isodense	1 (8)	1 (13)
isodense	1 (8)	2 (25)
iso/hyperdense	7 (54)	3 (38)
hyperdense	1 (8)	1 (13)
MR imaging		
loculation	2	3
parenchymal injury	4	2
ventricular size		
normal	9 (60)	8 (73)
enlarged	6 (40)	3 (27)
subarachnoid space		
normal	5 (33)	3 (27)
absent	6 (40)	4 (36.3)
enlarged	4 (27)	4 (36.3)

* interhem = interhemispheric.

† No preoperative CT scan was performed in 2 cases in the minicraniotomy group and 3 in the bur hole group.

procedure; parenchymal injury was evident in 4 patients in the minicraniotomy group and 2 in the bur hole group. Ventricular size was enlarged in 40% of the patients (6 of 15) in the minicraniotomy group and 27% of the patients (3 of 11) in the bur hole group. Enlarged subarachnoid space (arachnoidomegaly) was present in 4 patients in each group.

Perioperative Results

Table 3 lists the quality of the fluid at the time of surgery (if recorded in the operative note). A greater proportion of patients having the bur hole procedure had bloody fluid (it being noted in 12 [67%] of 18 hemispheres) compared with those having minicraniotomy (noted in 11 [41%] of 27 hemispheres). All patients had subdural drains placed, except for 1 achondroplastic child in the bur hole group who had large subarachnoid spaces. Drains were typically kept in place between 3 and 6 days in both groups, but in the bur hole group, there were 3 patients whose drains were kept in place for 11 days. All but 2 patients who had minicraniotomies had their drains removed because the output had substantially decreased. Data were unavailable in 1 patient; the other patient's drains were removed after no change in the drain output over several days. Of the 10 patients in the bur hole group who had drains placed, 7 had the drains removed for decreased output, 1 patient's drain was removed when the drainage continued at a relatively high output but the fluid changed from straw-colored to clear; no data were available on 1 patient, and the patient with achondroplasia did not have a drain placed initially.

TABLE 3: Subdural fluid quality at the time of surgery in patients treated for CSCs

Fluid Quality	Surgical Procedure	
	Minicraniotomy (27 hemispheres)	Bur Hole Placement (18 hemispheres)
bloody	11 (41)	12 (67)
straw/yellow	14 (52)	3 (17)
chronic ("oil")	2 (7)	2 (11)
clear	—	1 (6)

Outcomes

The average follow-up for the minicraniotomy and bur hole groups was 7.3 and 7.4 months, respectively. The primary outcome of "treatment failure" occurred in 2 (13%) of 15 patients in the minicraniotomy group and in 5 (45%) of 11 patients in the bur hole group ($p = 0.09$, 2-tailed) (Table 4). One patient in the minicraniotomy group required replacement of his subdural drains on postoperative Day 8, and the CSC was eventually treated successfully. The other patient who had failure of the minicraniotomy had a subduroperitoneal shunt placed on postoperative Day 7.

Patients in the bur hole group had more procedures performed after the index surgery for the CSC. In 5 patients with treatment failure, a total of 9 surgeries were required. Two patients underwent reinsertion of their drains (on postoperative Days 7 and 12, respectively), and these were subsequently converted to subduroperitoneal shunts. One patient underwent placement of a shunt on postoperative Day 8 but needed conversion to a ventriculoperitoneal shunt 3 weeks later. Another patient required a formal craniotomy on postoperative Day 3 to evacuate residual loculated hematoma and strip neomembranes. That same patient underwent another craniotomy with further membrane stripping on postoperative Day 19. The 5th patient was a child with achondroplasia who needed a cranioplasty at the site of his bur hole 8 months postoperatively for a leptomeningeal cyst. Eventually most patients in both groups had resolution of their CSC on their last imaging study (Table 4), and clinically most children with macrocephaly on presentation were improved.

There were no complications, such as infection or bleeding, related to any surgical procedure. One child died 13 months after presentation, a 2-month-old victim of severe nonaccidental trauma with diffuse bihemispheric parenchymal injury on MR imaging and bilateral isodense subdural hematomas. On admission, he was pulseless and not breathing; he was resuscitated and eventually underwent a minicraniotomy. He remained in a vegetative state and died at hospice 13 months later.

TABLE 4: Postoperative outcomes of patients treated for CSCs

Outcome Variable	Surgical Procedure: Minicraniotomy (15 pts)	Surgical Procedure: Bur Hole Placement (11 pts)
treatment failure*	2 (13)	5 (45)
replace drain	1	2
subdural shunt	1	1
craniotomy	—	1
cranioplasty	—	1
radiographic†		
resolved	12 (80)	7 (70)
improved	1	—
no change	1	3
worse	1	—
head circumference‡		
>90th percentile	5 (33)	2 (25)
75th–90th percentile	2 (13)	2 (25)
<75th percentile	8 (53)	4 (50)
follow-up in mos		
mean	7.3	7.4
range	2.2–13.8	1.6–26.5

* Refers to the first intervention performed after the index procedure. There were some patients who had more than one procedure performed after the index procedure.

† No radiographic outcome data were available in 1 case in the bur hole group.

‡ No head circumference outcome data were available in 3 cases in the bur hole group.

Discussion

There is a large volume of neurosurgical literature on the treatment of chronic subdural hematomas in adults. For example, reported risk factors for subdural recurrence have included the presence of bilateral chronic subdural hematoma, postoperative pneumocephalus, a mixed-density subdural hematoma, a low subdural drain output, and a poor Glasgow Outcome Scale score.[2,14,26] The effectiveness of various surgical techniques (including bur hole craniostomy alone, bur holes with subdural drains, bedside twist drill craniostomy with drain placement, and formal craniotomy) have been extensively evaluated.[5,6,10,15,20,21,31,33] Variations of each of these techniques have also been studied, including the duration of subdural drainage,[32] location of the subdural catheter after bur hole drainage,[22] the number of bur holes,[24] bur holes with passive subperiosteal drainage system,[33] and the position of the head after bur hole placement[1] or twist-drill treatment.[18]

A recent randomized controlled trial showed that the use of a subdural drain with a bur hole was strongly associated with a reduced risk of recurrence and mortality at 6 months compared with a bur hole alone.[23] Recurrence occurred in 10 (9.3%) of 108 patients with a drain and 26 (24%) of 107 without a drain. In fact, the trial was terminated because of the significant benefit afforded by the reduction of recurrence.

By comparison, the pediatric literature on the management of CSC is not as extensive. Chronic subdural collections of infancy, which are either hygromas secondary to a tear in the arachnoid membrane or an evolving hematoma or a combination of both, are most commonly the result of abuse and usually present in a delayed fashion after the trauma. Most of the literature evaluates the effectiveness and complications associated with individual surgical interventions. Each intervention comes with its own profile of advantages and disadvantages. Transfontanel taps are the least invasive, can be performed quickly at the bedside, and may be repeated, but they can only be performed for a limited period of time (usually up to 2 weeks) as the cumulative risk of causing an intracranial hemorrhage, infection, or injury to the parenchyma (for example, porencephaly) increases with each tap. These taps do not address multiple, loculated subdural collections. Litofsky et al.[17] found a recurrence (or "failure") rate of 78% with transfontanel taps. Tolias et al.[25] had a 42% failure rate, and 25% of the patients suffered subdural empyemas.

Placement of a subdural drain—either at bedside or in the operating room—is one of the most commonly performed procedures for CSC in infants. It is a straightforward procedure with a low risk of procedural complications; however, at least several days of drainage are typically required, compartmentalized collections are not easily drained, and there are risks of recurrence and infection. Failure rates vary widely, from 6% to 48%, with one paper reporting an infection rate of 8%.[4,7,9,16,17,27]

Bur hole evacuation is slightly more invasive but is also straightforward. It requires general anesthesia and allows the surgeon to irrigate the subdural space and leave a drain in place if necessary; however, it still has the disadvantage of limited exposure and thus a relative inability to deal adequately with loculated collections. Recurrence rates of 13% and 50% have been reported.[7,25]

Placement of a subdural shunt can be used as the primary treatment, and it is often the procedure of choice when the other interventions have failed. It has been repeatedly shown to be the most effective long-term treatment for CSC,[3,12,13,30] and early shunt placement has been advocated by some.[12] It has the lowest rate of failure, with several studies reporting a 0% failure rate, but comes with numerous well-known short- and long-term complications.[8,13,30] In some cases, the shunt may be removed after resolution of the CSC.[8,12,13,17,25]

Craniotomy for CSC is a relatively infrequent procedure and is typically reserved for cases in which the CSC is loculated. In the series reported by Caldarelli et al.,[4] only 3 (4%) of 72 children underwent a craniotomy with resection of neomembranes. Although craniotomy is the most invasive procedure, the greater exposure afforded allows the surgeon to fenestrate or resect neomembranes and gain access to compartmentalized subdural collections. Although there is some literature documenting its effectiveness in adult patients,[20,31] there has been very little reported on this procedure in the pediatric literature.

We believe, as do other pediatric neurosurgeons,[19] that every effort should be made to avoid placing a shunt in a child, given the well-known short- and long-term complications and potential for it to become a life-long

device. Ersahin et al.[8] reported their complications with subduroperitoneal shunts in 97 patients. Complications including obstruction, migration, skin necrosis over the reservoir, inadequate drainage of bilateral collections, and infection occurred in 35 patients (36%). In one of the larger series, Kurschel et al.[13] reported a complication rate of 22.4% (36 of 161 patients); the most common complications were obstruction, inadequate drainage requiring a contralateral shunt, infection, disconnections, migration, and wound complications. They found that predictors of shunt-related complications were status epilepticus at presentation and presence of hyperdense subdural fluid on CT imaging. Vinchon et al.[30] had a complication rate of 15.5% (38 of 244 patients). On the other hand, some authors have strongly advocated against performing a craniotomy with membranectomy because they consider it overly invasive with poor long-term results, despite these complications with shunt placement.[3]

Although the difference in the primary outcome in our study—treatment failure as defined by a need for repeat surgery—did not reach statistical significance, there was a trend favoring the minicraniotomy technique. More striking was the difference in the total number of surgeries required after the index procedure. The minicraniotomy group had 2 patients each requiring 1 surgery after their first operation for recurrent fluid, but the bur hole group had 5 patients who had treatment failure and needed a total of 9 subsequent surgeries: replacement of subdural drains (2), placement of subduroperitoneal shunts (3) or ventriculoperitoneal shunt (1), craniotomy with membranectomy (2), and cranioplasty (1).

Study Limitations and Future Direction

The major limitation of this study is the small number of patients. With a larger sample size, the effect of potential confounding factors and imbalances between the treatment groups that may have a direct impact on the primary outcome can be controlled for. For example, in our study, there were more patients in the craniotomy group with hyperdense components to their subdural collection, but the bur hole group had more patients with an interhemispheric subdural collection and blood at the time of surgery. The implications of these differences cannot be answered with this preliminary study. If we assume that the observed difference in the failure rates between the 2 groups from this study is real (45% vs 13%), based on a post hoc sample size analysis (assuming $\alpha = 0.05$ and $\beta = 0.2$, 1-sided test), a total of 48 patients would be needed to detect this difference: 24 patients randomized to the minicraniotomy arm, 24 to the bur hole treatment arm. Another limitation was the relatively short follow-up period (about 7 months for each treatment group). Although failure of the index procedure is usually evident within days to weeks, a longer follow-up time would be beneficial to document outcomes such as recovery of neurological function and late recurrences.

Conclusions

In this small, retrospective clinical study, we compared the effectiveness of "minicraniotomy" surgery with that of bur hole evacuation (both with subdural drains) for the treatment of CSCs in infants. Forty-five percent of the patients who underwent placement of a bur hole required another procedure, compared with 13% of the patients who underwent minicraniotomy. Furthermore, the patients who had treatment failure in the bur hole group often required more than 1 subsequent procedure. We believe that the minicraniotomy technique has the potential to treat infants with CSC with long-term efficacy and minimal morbidity, but a larger, prospective study is needed to confirm our findings. Given the encouraging results of this small study, we plan to continue evaluating the minicraniotomy technique, but it would be an ideal study for a collaborative, multicenter effort. If such a study demonstrates the same effectiveness, a wide acceptance of this procedure could result in a significant reduction in subsequent surgeries, morbidity, and cost.

Disclosure

The authors report no conflict of interest concerning the materials or methods used in this study or the findings specified in this paper.

Author contributions to the study and manuscript preparation include the following. Conception and design: Kaufman, Matthews, Lew, Zwienenberg-Lee. Acquisition of data: Kaufman, Matthews. Analysis and interpretation of data: Kaufman, Klimo, Matthews. Drafting the article: Kaufman, Klimo, Matthews. Critically revising the article: all authors. Reviewed submitted version of manuscript: all authors. Approved the final version of the manuscript on behalf of all authors: Kaufman. Statistical analysis: Klimo. Study supervision: Kaufman.

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Manuscript submitted February 16, 2011.
Accepted August 3, 2011.

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