Historically, most surgical cases of chronic subdural hematoma (cSDH) have been treated with placement of a bur hole in the operating room (OR), with or without placement of a subdural drain. The subdural evacuating port system (SEPS) is a minimally invasive approach to the surgical treatment of cSDH that involves twist-drill craniostomy, with subdural drainage by attachment of a hollow metal bolt and use of a closed negative-pressure drainage system.

The SEPS technique has some theoretical advantages over bur hole drainage. First, a SEPS bolt can be placed at the bedside in a monitored setting, such as the intensive care unit (ICU), and can therefore avoid use of the expensive and time-limited resource of the OR. Second, the SEPS procedure at the bedside is minimally invasive and does not involve general anesthesia.

Previous small series have established the general safety of the SEPS procedure and have compared the performance characteristics of SEPS and bur hole drainage in the operating room.
formance characteristics of SEPS and bur hole drainage. However, the small sample sizes in studies published to date have not been sufficient to establish SEPS drainage as equivalent to bur hole drainage. In addition, it is not clear whether initial experience followed by incremental modifications over time can improve the performance characteristics of the SEPS technique, consistent with Stages 2a and 2b in the Idea, Development, Exploration, Assessment and Long-term follow-up (IDEAL) framework for refinement of a new surgical procedure. We therefore examined the initial experience and the impact of incremental modifications to the bedside SEPS technique at a tertiary neurosurgical center and compared SEPS with bur hole drainage in the OR.

Methods

Subjects and Data Capture

We captured all cases of surgical treatment of cSDHs over a 7-year period (January 1, 2008, to December 31, 2014) at a tertiary neurological center within an integrated health care delivery system (Kaiser Permanente Northern California) with > 3 million members. The 7-year period began the first year in which SEPS placement was performed at our institution. All patients were treated in the context of a complete inpatient and outpatient electronic medical record (EMR) system (Epic Systems) for the full study period. Detailed information was available on all aspects of care, including comorbidities, laboratory data, and pharmacy records including inpatient medication administration data and outpatient prescription fills. To ensure complete case capture, we used a search strategy that screened operative databases and other inpatient data sources, including operative notes, using an inclusive set of key word search terms and codes. To ensure accurate case capture, we performed physician review of all captured operative notes.

Surgical Interventions

All subjects in the present study received either initial treatment of their SDH (or bilateral SDHs) by bur hole drainage in the OR or by SEPS placement in the ICU. Bur hole operations used single–bur hole technique with use of a perforator and included placement of Jackson-Pratt or Blake drains at the bur hole site with attached bulb suction, with typical drain removal 1–2 days postoperatively. SEPS procedures were performed with twist-drill cranial access according to standard techniques, with modifications introduced over time. SEPS devices were left in place and removed 1–2 days postoperatively. All procedures were performed by board-certified/board-eligible attending neurosurgeons (SEPS and bur hole drainage) or board-certified/board-eligible attending neurointensivists (SEPS). Subjects were classified into 1 of these 2 groups (bur hole in the OR or SEPS in the ICU) according to the initial procedure performed. Individual operations were considered separately. Bilateral procedures were counted as 2 separate procedures (1 left and 1 right), and outcomes for each procedure were followed separately. In all cases, choice of procedure was made by the on-call neurosurgeon. Specific features such as hematoma size, radiographic density, temporal chronicity based on history, or presence of membranes were not systematically used to determine which operative approach was used.

Measures Analyzed

We extracted data from the EMRs on age, sex, medical comorbidities as listed in Table 1, use of general anesthesia, laboratory measures including platelet count and international normalized ratio, length of stay (LOS), and occurrence of any reoperations during the same hospitalization or any subsequent hospitalization within 6 months after the initial operation.

We manually extracted data on potential complications (wound infection or dehiscence requiring operative intervention and/or antibiotic treatment, seizures, conversion to acute SDH requiring operative intervention, or intraparenchymal bleeding) from notes available in the EMR (operative notes, progress notes, and discharge summary.
notes). When necessary to adjudicate potential complications, neuroimaging studies and outpatient notes were also available for review.

Statistical Analysis

Bivariate analyses comparing subjects in the bur hole and SEPS groups were performed with the Fisher’s exact test for categorical variables and the nonparametric Kruskal-Wallis equality-of-populations rank test for continuous data. The Mantel-Haenszel chi-square test was performed to test for trends between categories. All statistical analyses were performed using Stata/MP, version 13.

The institutional review board of the Kaiser Foundation Research Institute approved this retrospective, data-only study with waiver of informed consent.

Results

Patient Characteristics

We identified 371 cases of SEPS drainage at the bedside and 659 cases of bur hole drainage in the OR (n = 1030) over a 7-year period (2008–2014). Detailed characteristics of patients according to initial procedure (including age, sex, and medical comorbidities) are presented in Table 1.

The only significant baseline difference between groups was a slightly higher Charlson comorbidity index (higher level of aggregate medical comorbidities) in the group treated with SEPS. Overall, 53.4% of SDH procedures were on the right side and 46.6% were on the left, and sidedness did not differ between the 2 procedure types (p = 0.95). Bur hole operations were more likely to be bilateral (18.7%) than SEPS operations (9.4%) (p < 0.001).

Introduction of the SEPS Procedure

Use of the SEPS procedure as initial treatment for cSDHs progressively increased across the 7 years observed in the present study (Fig. 1). In the first year of observation, SEPS accounted for 14% of the initial cSDH treatments, and by the last year of observation (2014), SEPS accounted for 80% (p < 0.001 for trend).

Reoperation Rates

The overall rate of reoperation within 6 months was higher for initial SEPS procedure (15.6%) compared with initial bur hole procedure (9.1%) (Table 2; p = 0.002). The observed overall difference was due to a higher rate of reoperation during the same hospitalization (7.0% for SEPS vs 3.2% for bur hole; p = 0.008); the difference in delayed reoperation between the 2 procedures was not significant.

As incremental modifications were made to the SEPS procedure over time (Stage 2b in the IDEAL Framework), the higher rate of reoperation during the same hospitalization seen with initial SEPS procedure was observed to significantly decrease as a function of total SEPS procedures performed (Fig. 2; p = 0.02 for trend), whereas the rate of reoperation during the same hospitalization for initial bur hole treatment did not significantly change (p = 0.40).

In the last quartile of operations performed in each group, there were no differences in the in-hospital reoperation rate, delayed reoperation rate, or total number of reoperations within 6 months (Table 2).

Multiple reoperations were uncommon. Among the 60 of 659 (9.1%) initial bur hole treatments that required ≥ 1 reoperations within 6 months, 52 (7.9%) required 1 reoperation and 8 (1.2%) required 2 reoperations. Among the 58 of 371 (15.6%) initial SEPS treatments that required ≥ 1 reoperation within 6 months, 50 (13.4%) required 1 reoperation, 7 (1.9%) required 2 reoperations, and 1 (0.3%) required 3 reoperations. For the initial SEPS treatments

### Table 2. Reoperation rates according to initial operation type

<table>
<thead>
<tr>
<th>Variable</th>
<th>Bur Hole</th>
<th>SEPS</th>
<th>All Subjects</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall cohort</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reop during initial hospitalization</td>
<td>21 of 659 (3.2)</td>
<td>26 of 371 (7.0)</td>
<td>47 of 1030 (4.6)</td>
<td>0.008</td>
</tr>
<tr>
<td>Posthospitalization reop w/in 6 mos</td>
<td>39 of 659 (5.9)</td>
<td>32 of 371 (8.6)</td>
<td>71 of 1030 (6.9)</td>
<td>0.12</td>
</tr>
<tr>
<td>Any reop w/in 6 mos</td>
<td>60 of 659 (9.1)</td>
<td>58 of 371 (15.6)</td>
<td>118 of 1030 (11.5)</td>
<td>0.002</td>
</tr>
<tr>
<td>Last quartile</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reop during initial hospitalization</td>
<td>4 of 164 (2.4)</td>
<td>3 of 92 (3.3)</td>
<td>7 of 256 (2.7)</td>
<td>0.70</td>
</tr>
<tr>
<td>Posthospitalization reop w/in 6 mos</td>
<td>7 of 164 (4.3)</td>
<td>6 of 92 (6.5)</td>
<td>13 of 256 (5.1)</td>
<td>0.55</td>
</tr>
<tr>
<td>Any reop w/in 6 mos</td>
<td>11 of 164 (6.7)</td>
<td>9 of 92 (9.8)</td>
<td>20 of 256 (7.8)</td>
<td>0.47</td>
</tr>
</tbody>
</table>
that required a reoperation, it was most often a bur hole placement (34 of 58 [59%] of first reoperations, and 5 of 7 [71%] of second reoperations).

When the initial operation involved treatment of bilateral SDHs, the reoperation rate was not found to be different from that for unilateral drainage, for either bur hole drainage (9.9% for unilateral vs 6.5% for bilateral; p = 0.15) or SEPS drainage (15.1% for unilateral vs 17.4% for bilateral; p = 0.71).

### Complication Rates

Complications were uncommon; the overall complication rate was 5.0% for bur hole drainage and 3.2% for SEPS, with no significant difference between the 2 groups (Table 3; p = 0.21). Individual complications also did not differ significantly between the 2 groups.

### Length of Stay, Discharge Disposition, and Mortality

The LOS was similar (median 3 days) between the 2 groups (Table 3). Among patients, 78.4% were discharged to home or inpatient rehabilitation and 19.4% were discharged to a skilled nursing facility. There was no difference in discharge disposition between the SEPS and bur hole drainage groups.

The overall in-hospital mortality rate was 2.2%, the 30-day mortality rate was 3.9%, and the 6-month mortality rate was 8.3% (Table 3). There was no difference in any of these 3 mortality categories between the SEPS and bur hole drainage groups.

### Discussion

Techniques for treating cSDH via bur hole craniostomy were introduced in the 1930s and represented a paradigm shift in the management of this condition, that is, away from traditional craniotomy.22 The next shift in management came with the use of bedside twist drills in the 1960s for evaluating head traumas, prior to the modern era of noninvasive imaging.15 Several refinements of twist-drill craniostomy for treatment of cSDHs have been developed. The most common one in current clinical use is the SEPS method, which involves placement of a hollow metal bolt tapped into the drill hole and a closed negative-pressure drainage system.2,10

Historically, reoperation rates following surgical treatment of cSDH have generally been reported as 10%–20%.20,21 Modifications of the bur hole procedure to increase subdural fluid drainage, specifically the use of postoperative drains, have been associated with reduced reoperation rates. For example, in a randomized trial comparing subdural drain placement with no drain placement after bur hole evacuation, the rate of reoperation within 6 months was 9% with drain placement and 24% without.17

![FIG. 2. Trend in in-hospital reoperation rate as a function of quartile of procedure number. Percentages of in-hospital reoperations are presented for bur hole drainage in the OR (black bars) and for SEPS drainage at the bedside (gray bars) for each of 4 ordered quartiles of procedure number. Quartiles of procedure number are determined within each group: the 4 ordered quartiles were determined separately for bur hole drainage and for SEPS drainage.](image_url)
This reduction in recurrence rate by drain placement following bur hole craniostomy has been confirmed by meta-analysis of available trial data.1

To date, 3 small trials have compared twist-drill craniostomy to bur hole drainage and have shown similar morbidity, mortality, and cure rates for the 2 interventions.2,3,10 In a meta-analysis, combined short-term recurrence rates were not significantly different: 6% for twist-drill craniostomy and 8% for bur hole drainage.8 However, the largest of these small randomized controlled trials only had 97 patients total, limiting the statistical power of these observations.

Smaller observational studies have also compared SEPS versus bur hole drainage. Reported reoperation rates have varied widely, with reported SEPS versus bur hole reoperation rates of 26% versus 16% (21 SEPS cases),10 8% versus 12% (44 SEPS cases),12 9% versus 5% (178 SEPS cases),11 and 14% versus 9% (29 SEPS cases).3 In a recent meta-analysis of observational studies examining SEPS, an overall recurrence rate of 22.4% for SEPS was reported.4 These prior observational studies have not examined the rate of recurrence after SEPS as a function of a center’s experience with the procedure.

Compared with bur hole drainage in the OR, bedside SEPS drainage may have certain advantages. It may be commenced within a shorter period of time, because it does not require operating room (OR) time. In one series, SEPS procedures began 11.2 ± 15.3 hours from admission, whereas bur hole cases began 40.3 ± 69.1 hours from admission.3 A less invasive treatment modality could potentially result in a lower LOS. In one study, the reported LOS for SEPS was 9.3 ± 6.8 days versus 13.4 ± 10.2 days for bur hole drainage.3 However, in our series, the average LOS did not differ significantly between SEPS and bur hole drainage (Table 3). The very short LOS in our study overall (3 days for both groups) may be the result of aggressive mobilization strategies and discharge planning in the context of a tightly integrated health care delivery system. The short LOS observed may make any relative LOS benefit of SEPS difficult to detect.

Because SEPS may be done without using the OR or anesthesia resources, costs may be significantly less for SEPS than for the bur hole SDH evacuation.4 An improved expense profile of bedside SEPS treatment will be an increasingly important consideration, given that the total expense of cSDH treatment in the United States has been rising, from $2.2 to $4.9 billion between 1998 and 2007.6 The US population continues to age, which is expected to further increase the incidence of this strongly age-related condition. Specific cost analyses were not performed in our study, because our financial model (that is, prepaid integrated health care delivery) does not follow the common fee-for-service model for health care delivery in the United States, and our lack of external billing makes it impossible to assign specific dollar costs to procedures.

Incremental modifications were made over time to our institutional SEPS protocol, with the intention of minimizing clotting of the closed drainage system and maximizing yield of initial subdural fluid drainage. All of these modifications, listed in Table 4, were in use during the last quarter of SEPS cases, during which time the rate of recurrence was not different from that observed with bur hole drainage (Table 2). By applying incremental modifications followed by observational comparative assessment, the current study represents Stages 2a and 2b in the IDEAL framework for evaluating new surgical techniques,14 which are essential steps prior to Stage 3 (that is, a randomized controlled trial comparing SEPS with bur hole evacuation).

The incremental modifications seem to have been important to the overall success of the SEPS procedure. The initial experience with SEPS at our institution showed a statistically significant higher rate of reoperation with SEPS compared with bur hole drainage. Only as modifications were made over time did the rates of reoperation become comparable between the 2 procedures (Table 2).

The increase over time in the number of SDH cases treated with SEPS at our institution was not prospectively determined but rather was the natural result of the perceived utility of the SEPS procedure as modifications were introduced. By the end of the 7-year period described herein, SEPS had become established at our institution as a first-line procedure, which is reflected by the majority of cases (80%) being performed in this fashion.

Our study has limitations. This was a retrospective analysis of 2 surgical approaches to the treatment of cSDHs, and the procedure choice was not randomized. Because the choice of procedure was, in all cases, determined by the on-call neurosurgeon, biases regarding case features and procedure choice may confound our analysis. Although radiographic features such as density and presence of membranes were not systematically used to make procedure choices, because of the nonrandom procedure choice, we cannot rule out individual-level confounding by such features. An insufficient number of operative re-

### TABLE 4. Modifications of the SEPS operative technique

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<td>Make 3 distance measurements from axial &amp; coronal neuroimaging (CT or MRI) to thickest/most central aspect of SDH: 1) coronal distance from midline; 2) axial (i.e., hatband) distance from midline; &amp; 3) from top of the ear (vertically &amp; then anterior or posterior)</td>
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ports provided a specific quantified amount of subdural drainage by either SEPS placement or bur hole treatment, and thus we could not determine whether low volume drained is predictive of recurrence, as has been previously suggested for SEPS.2,9

The gradual change in institutional practice from bur hole to SEPS utilization (Fig. 1) raises the possibility of confounding by other secular trends. Modifications were made specifically to the SEPS procedure, and not to the bur hole procedure, because of perceived issues with intraprocedural clotting of the low-profile SEPS system. Although we detected a lower rate of recurrence with SEPS as a function of experience with the procedure and with the adoption of several incremental modifications to the procedure, we cannot address which, if any, of these modifications were responsible for the improved performance characteristic of the modified procedure.

Conclusions

To our knowledge, we present the largest retrospective observational study to date of SEPS in the ICU versus bur hole drainage in the OR for the management of cSDHs. Outcome measures of morbidity and mortality were similar between SEPS and bur hole drainage. After modifications were implemented to minimize intraprocedural clotting of the SEPS, recurrence rates were similar between SEPS and bur hole treatment. Given the appearance of equipoise, a randomized controlled comparison of bur hole evacuation versus modified SEPS technique for cSDH treatment is warranted.

References


Disclosures

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

Conception and design: Flint, Chan, Rao. Acquisition of data: Flint, Chan, Rao. Analysis and interpretation of data: Flint, Rao. Drafting the article: Flint, Chan, Kalani, Efron, Sheridan. Critically revising the article: all authors. Reviewed submitted version of manuscript: Flint, Chan, Kalani, Efron, Sheridan. Approved the final version of the manuscript on behalf of all authors: Flint. Statistical analysis: Flint. Study supervision: Flint.

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