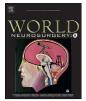
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Chronic subdural hematoma drainage using anti-thrombotic catheter technique



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A R T I C L E I N F O	A B S T R A C T		
ARTICLEINFO Keywords: Chronic subdural hematoma Drainage Catheter obstruction Surgical intensive care Blood clot	<i>Background:</i> Burr hole evacuation is a well-established treatment for symptomatic cases with chronic subdural hematoma (cSDH). Routinely postoperative catheter is left in the subdural space to drain the residual blood. Drainage obstruction is commonly seen, and it can be related to suboptimal treatment. <i>Methods:</i> Two groups of patients submitted to cSDH surgery were evaluated in a retrospective non-randomized trial, one group that had conventional subdural drainage (CD group, $n = 20$) and another group that used an anti-thrombotic catheter (AT group, $n = 14$). We compared the obstruction rate, amount of drainage and complications. Statistical analyses were done using SPSS (v.28.0). <i>Results:</i> For AT and CD groups respectively (median \pm IQR), the age was 68.23 ± 26.0 and 70.94 ± 21.5 ($p > 0.05$); preoperative hematoma width was 18.3 ± 11.0 mm and 20.7 ± 11.7 mm and midline shift was 13.0 ± 9.2 and 5.2 ± 8.0 mm ($p = 0.49$). Postoperative hematoma width was 12.7 ± 9.2 mm and 10.8 ± 9.0 mm ($p < 0.001$ intra-groups compared to preoperative) and MLS was 5.2 ± 8.0 mm and 1.5 ± 4.3 mm ($p < 0.05$ intra-groups). There were no complications related to the procedure including infection, bleed worsening and edema. No proximal obstruction was observed on the AT, but $8/20$ (40%) presented proximal obstruction on the CD group ($p = 0.006$). Daily drainage rates and length of drainage were higher in AT compared to CD: 4.0 ± 1.25 days vs. 3.0 ± 1.0 days ($p < 0.001$) and 69.86 ± 106.54 vs. 35.00 ± 59.67 mL/day ($p = 0.074$). Symptomatic recurrence demanding surgery occurred in two patients of CD group (10%) and none in AT group ($p = 0.230$), after adjusting for MMA embolization, there was still no difference between groups ($p = 0.121$). <i>Conclusion:</i> The anti-thrombotic catheter for cSDH drainage presented significant less proximal obstruction than the conventional one and higher daily drainage rates. Both methods demonstrated to safe and effective for draining cSDH.		

1. Introduction

Drainage in chronic subdural hematoma (cSDH) is widely used and is recommended to reduce hematoma recurrence and mortality rates. The incidence of cSDH is about 1.72–20.6 per 100,000 persons per year.¹ Several factors are related to cSDH recurrence as male sex, bilateral hematoma, conservative treatment, large volume, diabetes, brain atrophy and use of antiplatelet drugs.² Irrigation is generally applied to reduce recurrence. Typically, saline is used to break intracapsular fibers and remove protein-rich content allowing the brain tissue to re-expand. Interestingly, a recent meta-analysis demonstrated that procedures with and without irrigation may have similar effect regarding recurrence and complication rates.³ Recurrence is also less common in patients submitted to middle meningeal artery (MMA) embolization compared to conventional treatment (9 × 28%).⁴

The ideal draining duration is unknown, 24 h drainage was associated with shorter hospital length of stay, without significant differences in recurrence, mortality or complications when compared to 48 h duration.⁵ Moreover, it is reported that longer duration is related to higher complication rates, as infection, leakage around the drain, and subgaleal hematoma.⁵ Despite that, longer drainage periods may be required in cSDH with mixed components.⁶

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Greuter et al reported on encouraging results regarding the utilization of subperiosteal drains. They claim that this approach would be associated with lower recurrence rates, drain misplacements, parenchymal injuries, while clinical outcome and mortality would remain comparable.⁷ In a recent report, the an anti-thrombotic catheter showed 99% reduction in clotting activity with additional 89% reduction in catheter obstruction compared to regular external ventricular drainage (EVD) catheters placed for intraventricular hemorrhages.⁸ It is reasonable to hypothesize that the anti-thrombotic internal membrane in this catheter could also be advantageous in cSDH drainage.

In this study, we compared two groups using a conventional subdural drainage and a new technique with the use of anti-thrombotic catheter approved for ventricular hemorrhage to drain cSDH.⁹ We present the efficacy and complications of this approach. We hypothesized that the use of this approach is safe, has an acceptable complication profile, and is effective for hematoma drainage for short duration.

2. Material and methods

In this retrospective cohort study, we report data on 30 patients with 34 surgeries (four with bilateral procedures) for cSDH evacuation between 2021 and 2022 in a level-1 trauma center. All the patients were retrospectively evaluated. They were divided in two groups: one (group CD; n = 20) used conventional subdural drains (Twist-drill or Codman®) Bactiseal® ventricular catheter, with 1.5 mm internal diameter) connected to a closed system. The other group (AT, n = 14) used an antithrombotic subdural catheter as subdural drain coupled to a closed system (Codman® CerebroFlo® Endexo® from Integra LifeSciences, Princeton, NJ, USA). The patients were not randomized, the data was collected from consecutive surgeries to cSDH evacuation during the period. On the AT group, 11 out of 14 procedures were burr hole surgeries in the operating room (OR) with irrigation, in the parietal and frontal areas. Three critically ill patients underwent bedside twist drill catheter placement with no irrigation. On the CD group, 6 of 20 procedures consisted in twist drill catheters, and the others were submitted to regular burr-holes and irrigation. All the procedures were performed by three experienced trauma neurosurgeons. Data were collected on basic demographics (age, sex), hematoma width, midline shift (MLS) on pre and postoperative CT scans, complications (infection, bleeding, new neurologic deficits), length of stay, seizures, recurrence, drain obstructions and reoperation. To determine the percentage of the acute component, the hematoma dimension observed on the largest width axial CT image was used, being divided in quartiles. Post-operative imaging was done until 48 h after surgery and repeated after drain removal or if any clinical worsening was noted.

This study has IRB approval from University of Miami (IRB #20081181).

Statistical analysis:

For patient characteristics, continuous variables were summarized as median with first and third quartiles (Q1 and Q3 or IQR). Variables were compared using the Fisher's exact test, Kruskal–Wallis and Man–Mhitney *U* test for categorical and continuous variables, respectively. For related samples, the Wilcoxon Signed Rank Test was performed. All statistical tests were two-tailed and a *p*-value <0.05 was considered statistically significant. Statistical analyses were done using SPSS (v.28.0).

3. Results

There were 13 patients (14 procedures) treated using the antithrombotic catheter (AT) with median age 68.23 ± 26.0 years and 17 patients (20 procedures) using conventional drains (CD) with median age 70.94 ± 21.5 years; p = 0.700, between 05/2021 and 02/2022. Data are summarized in Table 1. Median Glasgow Coma Scale (GCS) score on admission was 14 (Q1 = 13.75) for AT and 14 (Q1 = 14.0). On discharge, median GCS was 14 (Q1 = 14.25) for AT and 15 (Q1 = 15) for CD. There

Table 1				
	Anti-thrombotic Catheter (AT)	Conventional Catheter (CD)	р	
Age	63.0 ± 30.0	67.0 ± 6.0	= 0.308	
Preoperative	21.5 ± 15.15	20.6 ± 9.6	= 0.922	
Hematoma Width (mm)				
Postoperative	$\textbf{15.6} \pm \textbf{12.9}$	$\textbf{10.9} \pm \textbf{7.8}$	= 0.491	
Hematoma Width (mm)				
Preoperative Midline shift (mm)	14.6 ± 13.45	5.2 ± 8.8	= 0.139	
Postoperative Midline shift (mm)	$\textbf{9.4} \pm \textbf{10.4}$	$\textbf{4.4} \pm \textbf{3.7}$	= 0.445	
Drainage Days*	5.0 ± 2.5	$\textbf{3.0} \pm \textbf{1.0}$	<0.001 *	
Daily Volume Drained (mL/day) *	112.5 ± 71.27	41.96 ± 50.92	= 0.04 *	
Proximal Drain	0	6 (31.6%)	= 0.039	
Obstruction*			*	
Recurrence	0	4 (21.1%)	= 0.121	
Reoperations	0	1 (5.3%)	= 0.467	

was no difference between drain location (parietal x frontal) and postoperatory pneumocephalus between groups.

3.1. Hematoma width and midline shift

For AT and CD groups respectively (median \pm IQR), preoperative hematoma width was 18.3 \pm 11.0 mm and 20.7 \pm 11.7 mm (p = 0.79) and midline shift was 13.0 \pm 9.2 and 5.2 \pm 8.0 mm (p = 0.083). After 24 h of drainage, hematoma width improved in all patients, with delta median of 4.4 \pm 5.8 mm (26.1 \pm 17.5%) for AT (p < 0.001 vs preoperative) and 7.9 \pm 9.3 mm (47.7 \pm 23.0%) for CD (p < 0.001). Midline shift improved in both groups with a delta of 6.1 \pm 7.5 mm for AT and 1.5 \pm 4.3 mm for CD (p = 0.002 and p < 0.001 intragroup compared to preoperative).

Hematoma was located (for AT and CD group respectively) on the left side in 46% and 35%, right side in 39% and 50%, and bilateral in 15% and 15%. Median MLS before surgery was 13.0 ± 9.2 mm and 24 h after surgery 6.7 \pm 7.0 mm (p = 0.002) for group AT and 5.2 \pm 8.0 mm and 4.1 \pm 4.1 mm for CD group (p < 0.001).

3.2. Hematoma drainage

Daily drainage rates and length of drainage were higher in AT compared to CD: 4.0 \pm 1.25 days vs. 3.0 \pm 1.0 days (p < 0.001) and 69.86 \pm 106.54 vs. 35.00 \pm 59.67 mL/day (p = 0.074). Median drainage duration for AT was 4.0 \pm 1.2 days and 3 \pm 1.0 days for CD (p < 0.001). Estimated density in Hounsfield Units (HU) in the predominant chronic component of the hematoma on CT was 26.0 \pm 13.8 for AT and 20.5 \pm 9.5 for CD (p = 0.105). For the acute-on-chronic component, HU was 57.0 \pm 25.3 for AT and 48.2 \pm 9.3 for CD (p = 0.048), presenting a significant higher acute component on the AT group.

3.3. Complications and outcomes

There were no complications related to the procedure including infection, bleed worsening and edema. Hospital length of stay was 12.5 \pm 10.7 days for AT and 9.3 \pm 8.0 for CD (p = 0.180). Three patients died during hospitalization on group AT and one patient in group CD due to clinical complications unrelated to the surgery (p = 0.177). There was no infection related to drainage or surgery in any group.

Distal obstruction was observed in 2 cases of the AT group (14%) and none of the CD group, both resolved after flushing the system. No proximal obstruction was observed in the AT group, but 8/20 (40%) presented proximal obstruction in the CD group (p = 0.006). Two patients on group AT presented distal obstruction that resolved after distal flushing. No intracranial irrigation was required in any patient. Median drain length until proximal drain obstruction on group CD was 2.5 \pm 1.7 days.

3.4. Recurrence and middle meningeal artery embolization

On group AT, five patients underwent middle meningeal artery (MMA) embolization and one patient in CD group. Radiological recurrence of the hematoma was observed in two patients (14.3%) of AT group after drain removal, and in four (20%) of CD group (p = 0.454). Two patients in the CD group presented symptomatic recurrence and required re-operation (p = 0.230). One of them was treated by twist drill and had a proximal catheter obstruction during the first day (0 mL drained), and the other had two burr-holes done at the OR and didn't present drain obstruction, with a total of 190 mL drained along three days. Three out of the 14 procedures (21%) of the AT group and 6/20 (30%) on CD group were done at bedside at the neurocritical care unit. Three patients on the AT group and 2 on the CD group developed seizures after the surgery (p = 0.362).

The comparison between groups was rerun excluding patients submitted to MMA embolization on both groups. The proximal obstruction was still significantly higher on the CD group (p = 0.019) and there was no difference on distal obstruction (p = 0.054). The volume drained was higher on AT (p = 0.003). Drainage days was higher in AT group (p < 0.001). There was no difference between seizure (p = 0.961) and hematoma recurrence (p = 0.121).

4. Discussion

Bedside procedures commonly are done using twist-drill and the drain patency is very important. Most of them uses a system called SEPS™ (Subdural Evacuating Port System – Medtronic), that drains the subdural collection through a bolt inserted into the bone, connecting an external catheter with the subdural space, without a proper catheter inserted into the subdural space. It is also possible to insert a subdural catheter using a bedside twist drill, as was performed for 3 patients in the AT group. One of the cases was a 66 y/o male patient intubated for severe hepatic encephalopathy and circulatory shock requiring two pressors. The CT scan showed a large hemispheric subdural hematoma with predominant chronic component and significant mass effect and midline shift. A posterior parietal entry point at the area of maximal skull curvature was chosen to minimize the chance of parenchymal penetration as recommended by Hwang et al.¹⁰ A disposable cranial access kit was used for the drilling, which was done in a shallow angle for the same reason. Once the catheter entered the subdural space, the stylet was held in place and only the catheter advanced for five more centimeters as no resistance was felt. Three days later the catheter was removed, and the post

drainage CT showed effective brain expansion. A post removal CT was performed and showed no new intracranial hemorrhage (Fig. 1).

Other bedside case example was an 81 y/o female that presented intubated for reduced level of conscience. The workup revealed severely up trending troponin values indicating ongoing acute myocardial ischemia. The procedure was done with local anesthesia and mild sedation (Fig. 2). The post drainage scan confirmed effective brain decompression. She improved the neurologic condition opening eyes spontaneously and following commands. Nevertheless, she unfortunately developed severe mesenteric ischemia and passed away from refractory circulatory shock.

The third case using anti-thrombotic catheter at a bedside case was an 87 y/o female patient that presented with reduced level of consciousness and hemiparesis. The CT scan showed an acSDH with mostly acute component. Craniotomy was recommended but the family declined it and asked for a less invasive option. For this reason, a bedside drainage was performed. Surprisingly, the patient had a very favorable outcome returning to her baseline exam with no focal deficits and was discharged 17 days after admission (Fig. 3). Three patients died during hospitalization due to mesenteric infarct, liver failure and congestive heart failure (CHF). The cause of death was deemed not related to the procedure or catheter in all three. The mortality is congruent with the reported rate in this critical population.¹¹

In this retrospective cohort study, we had some limitations, like the non-randomization, the small sample and different acute-on-chronic component between groups. There was no long-term follow-up. The use of twist-drill treatment was significant higher in the CD group compared to AT group, and the middle meningeal artery embolization was higher in the AT group. We showed that an anti-thrombotic catheter (Codman CerebroFlo Endexo® from Integra LifeSciences, Princeton, NJ, USA), classically used for intraventricular hemorrhage are safe and effective for draining cSDH and presented significantly higher daily drainage volumes and less proximal obstruction. Our group had previously reported the first case in the literature that successfully using this anti-thrombotic catheter for acute-on-chronic SDH drainage.⁹

Subdural hematoma evacuation is usually required when the bleed is symptomatic and/or with associated mass effect.¹² In the elderly population as the brain parenchyma shrinks as part of the aging process, bridging veins become more distended and minor bleedings tend to occur secondary to low energy trauma. Those minor bleedings are mostly asymptomatic. With the trauma, cells in the subdural space suffer cleavage from the border dural cell layer. Cerebrospinal fluid (CSF) interposes between the broken cell layer and the rest of the dura mater. Injured cells release cytokines that promote increase in fibroblasts and vascular endothelial growth factor (VEGF). This leads to membrane formation and angiogenesis originating immature capillaries with no basal membrane hence increased fragility and permeability. Thus, fluid is

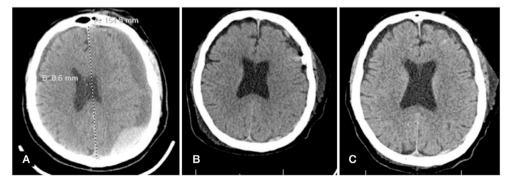


Fig. 1. Illustrates the case of a 66 y/o male (AT group, case 8) patient critically ill patient intubated with unstable hemodynamically condition. The initial CT (A) shows an acute on chronic subdural hematoma with midline shift of around 7.5 mm. B: CT shows the resolution of the mass effect three days after the bedside drainage. C: CT was performed after drainage removal and showed no new hemorrhage.

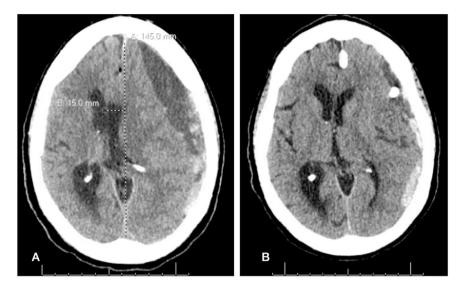


Fig. 2. Illustrates the case of an 81 y/o female patient (AT group, case 9) intubated for reduced level of conscience and with acute ongoing myocardial ischemia. A: the initial CT scan shows an acute on chronic subdural hematoma with 15 mm of midline shift. The patient underwent a bedside placement of an anti-thrombotic catheter under local anesthesia and mild sedation. After that she improved remarkably the neurologic condition and the CT scan showed effective brain decompression with no procedural related complications (B).

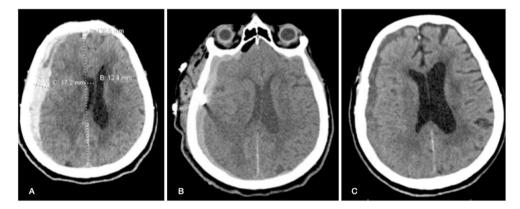


Fig. 3. Illustrates the case of an 87 y/o patient (AT group, case 7) in which the bedside drainage rendered a surprising result. The patient was extubated and returned to her baseline neurologic condition being discharged after 17 days. A: the admission CT shows a predominant acute component of the acute on chronic SDH. B: the post catheter insertion CT shows the subdural drainage in place. C: the CT performed 2 weeks later showing resolution of the mass effect and restitution of the midline.

pulled into the cavity created by the membrane in the subdural space. This process tends to repeat in a vicious cycle of capsule distention, bleeding, cell injury and cytokines release originating a chronic subdural hematoma.¹³

The content of a cSDH is more fluid than the aSDH allowing burr hole evacuation. Routinely, a postoperative drain is left in the subdural space to account for the residual fluid and to reduce recurrence.¹⁴ Nevertheless, a significant part of the cases in the clinical practice presents with a mixed finding, where an acute component is superimposed to a chronic one, in other words, an acute on chronic SDH. The acute component may offer a challenge to a less invasive approach (i.e. burr hole) as it may obstruct the subdural drain. Different types of drains can be used in the subdural space, with no consensus.¹⁵ The rate of proximal catheter obstruction is difficult to be established and may be underreported. In our study, the proximal drain obstruction on cSDH drainage was 40% using conventional drains. On the anti-thrombotic group, even with a significant higher amount of acute-on-chronic component of the SDH based on HU, no patient presented proximal obstruction. Once the cases were selected consecutively, without randomization, this can be a factor that would impact more risk to proximal obstruction on the AT group, what wasn't observed.

Due to the anti-thrombotic catheters' intrinsic properties, we found less frequent occurrence of clot related obstruction. Its inner walls are composed by a technology called "Endexo®" (Evonik Canada Inc.), a membrane modified to improve hemocompatibility and reduce clot related obstruction. *In vitro* experiments demonstrated that this technology was successfully used in hemodialyzers for the same purpose.¹⁶

Drainage obstruction is undesirable basically for two reasons. Firstly, because the lack of drainage leads to the accumulation of subdural fluid which may be related to therapy failure and/or symptomatic hematoma recurrence.¹⁷ Secondly, obstructions are troubleshot with catheter flushing, what can be inconvenient and carry the risk for intracranial infection. Having a subdural drain less prone to clot obstruction is particularly interesting in critically ill patients. In those patients, the evacuation is often only possible at bedside in the neurocritical care unit, with twist drill. Two cases using conventional subdural drainage presented symptomatic hematoma recurrence and demanded new surgical treatment. One patient was first treated using twist drill, the hematoma didn't improve, and the drain was obstructed since it was implanted, this patient was successfully treated using the same technique again (Fig. 4). The other patient was operated with regular two burr-holes and conventional drain at the OR, drained 190 mL and had the drain removed on day 3, but presented symptomatic recurrence, and required a mini-craniotomy (Fig. 5), with improvement.

This first cohort study reporting the use of a subdural placed antithrombotic catheter didn't show any complication related to the catheter itself in both groups. It indicates that the new catheter can be used safely for this new indication. There was no infection or hemorrhage

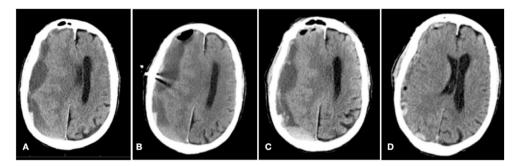


Fig. 4. Male patient 86 y/o treated by a bedside drainage (group CD, case 23). A: Preoperative. B: Postoperative day 1, conventional catheter had proximal obstruction since its insertion. C: Postoperative day 2 with symptomatic recurrence. D: Improvement on day 1 after a new bedside procedure using conventional drain without obstruction.

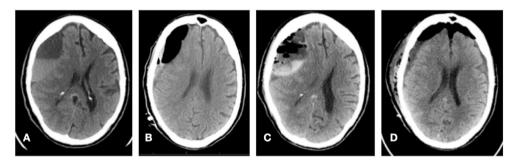


Fig. 5. Male patient 86 y/o (group CD, case 29) treated by two burr-holes at the OR. A: Preoperative. B: Postoperative day 1 with pneumocephalus and small residual hematoma, conventional drain working properly. C: Symptomatic hematoma recurrence (after drain removal) on day 4. D: Postoperative day 1 after minicraniotomy.

related to the catheter placement on both groups. All patients received prophylaxis with levetiracetam for the first 7 days. Three patients on the AT group and 2 on the CD group developed seizures after the surgery. No reoperation was demanded on the AT group versus 10% of the CD one. A randomized study with larger samples should clarify if the antithrombotic catheter could really diminish the symptomatic recurrence.

The utilization of the anti-thrombotic catheter in the subdural space was feasible, without any case of proximal obstruction effectively promoting brain decompression, and maybe it was related to the observed significantly higher amount of daily drainage volume and longer catheter permanence in the anti-thrombotic group compared to the conventional one. Nevertheless, the coupled external tubing does not share the same properties. For this reason, distal obstruction occurred in two cases from AT group, requiring extracranial irrigation towards the bag, and none distal obstruction was observed on the CD group. We hypothesize it would be advantageous to have the external tubing manufactured with the same material. We could not identify literature data regarding subdural drains occlusion rates before. Maybe this lies on the fact that if not salvageable, subdural drains are simply removed differently from EVDs that are typically replaced. On average, it is expected that 41% of EVDs obstruct among patients with vascular neurosurgical pathologies,¹⁸ and this number is similar to our finding of 40% of proximal obstruction on the CD group. This can lead to maneuvers as catheter flushing and/or exchange, increasing the incidence of infection, intracranial hemorrhage and clots.19

Another pertinent aspect is that anti-thrombotic catheters are not antibiotic/silver coated. Although no infection was observed, future catheters should combine the anti-thrombotic with antibiotic/silver coating. The anti-thrombotic catheter cost is almost 30% higher compared to a traditional EVD catheter. It also has a harder consistency compared to the traditional one, demanding to be submerged on warm saline to e softer during insertion, to avoid parenchymal damage.

This study has several limitations. This is a single center study, nonblinded and non-randomized, using a small sample. This limits the generalization of this technique to other centers. We believe this approach is safe and should be further explored in randomized clinical trials comparing the technique with other catheters. This technique might also be useful to combine with middle meningeal artery embolization and possibly at the bedside when indicated to avoid OR related time and costs. Although the AT group presented higher rates of drainage and less obstructions. Two patients on the CD group presented symptomatic recurrence of the cSDH demanding a re-operation and none in the AT group.

5. Conclusion

This retrospective cohort study demonstrated that an anti-thrombotic catheter for cSDH drainage presented significantly less proximal obstruction than the conventional one and higher daily drainage rates. Both methods demonstrated to be safe and effective for draining cSDH. Forty percent of the conventional subdural drains got proximal obstruction.

Ethical approval

This study has IRB approval from University of Miami (IRB #20081181).

CRediT authorship contribution statement

Joacir Graciolli Cordeiro: Writing – review & editing, Writing – original draft, Supervision, Methodology, Investigation, Formal analysis, Conceptualization. Bernardo Assumpcao de Monaco: Writing – review & editing, Writing – original draft, Validation, Software, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. Ronald Benveniste: Writing – review & editing, Writing – original draft, Supervision, Investigation, Formal analysis. Ayham Alkhachroum: Writing – review & editing, Writing – original draft, Visualization, Validation, Supervision, Investigation, Formal analysis. **Evan M. Krueger:** Writing – review & editing, Visualization, Methodology, Formal analysis. **Kristine O'Phelan:** Writing – review & editing, Visualization, Supervision, Formal analysis. **Jonathan R. Jagid:** Writing – review & editing, Writing – original draft, Visualization, Validation, Supervision, Methodology, Investigation, Formal analysis, Conceptualization.

Declaration of competing interest

Dr. Alkhachroum is supported by an institutional KL2 Career Development Award from the Miami CTSI NCATS UL1TR002736 and by the National Institute of Neurological Disorders and Stroke of the National Institutes of Health under Award Number K23NS126577. All other authors don't have conflicts of interest to declare.All authors certify that they have no affiliations with or involvement in any organization or entity with any financial interest or non-financial interest in the subject matter or materials discussed in this manuscript. This study doesn't have funding support.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://do i.org/10.1016/j.wnsx.2023.100215.

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Abbreviations list

acSDH: acute-on-chronic subdural hematoma CHF: congestive heart failure cSDH: chronic subdural hematoma CSF: cerebrospinal fluid CT: computerized tomography EVD: external ventricular drainage GCS: Glasgow Coma Scale IQR: interquartile ratio MLS: midline shift OR: operating room Q1: quartile 1 Q3: quartile 3 SDH: subdural hematoma VEGF: vascular endothelial growth factor