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Original Article

The efficacy of postoperative middle meningeal artery embolization on chronic subdural hematoma – A multicentered randomized controlled trial

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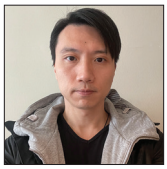

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ABSTRACT

Background: Middle meningeal artery (MMA) embolization has recently emerged as a potential treatment for chronic subdural hematoma (cSDH). Numerous retrospective studies have suggested that it can potentially reduce the risk of hematoma recurrence following surgical evacuation. We have conducted a randomized controlled trial to investigate the effectiveness of postoperative MMA embolization in reducing recurrence rate, residual hematoma thickness as well as improving functional outcome.

Methods: Patients aged 18 or above were recruited. Following evacuation through burr hole or craniotomy, patients were randomly allocated to undergo either MMA embolization or standard care (monitoring). The primary outcome was symptomatic recurrence requiring redo evacuation. Secondary outcomes include residual hematoma thickness and modified Rankin Scale (mRS) at 6 weeks and 3 months.

Results: Thirty-six patients (41 cSDHs) were recruited between April 2021 and September 2022. Seventeen patients (19 cSDHs) were allocated to the embolization group and 19 patients (22 cSDHs) were in the control group. No symptomatic recurrence was observed in the treatment group while 3 control patients (15.8%) underwent repeat surgery for symptomatic recurrence, however, it was not statistically significant (P = 0.234). Furthermore, there was no significant difference in residual hematoma thickness at 6 weeks or 3 months between the two groups. All patients in the embolization group had a good functional outcome (mRS 0–1) at 3 months, which was significantly higher than the 53% observed in the control group. No complications related to MMA embolization were reported.

Conclusion: Further study with larger sample size is required to evaluate the efficacy of MMA embolization.

Keywords: Chronic subdural hematoma, Interventional neuroradiology, Middle meningeal artery embolization

INTRODUCTION

Chronic subdural hematoma (cSDH) is a common neurosurgical condition with an estimated incidence of 20.6/100,000 persons/year.[6] Its incidence will continue to rise as a result of the aging population and the increasing use of anticoagulants and antiplatelet agents. It is estimated

that there will be approximately 60,000 new cases each year by 2030 in the United States.[2]

cSDH is classically believed to be triggered by a minor head injury, which initiates a cascade of inflammatory reactions including dural border cell proliferation, granulation tissue formation, and excessive fibrinolysis.[15] This ultimately leads to the formation of a chronic inflammatory membrane with fragile capillaries that cause microhemorrhage into the subdural space. The balance between reabsorption and rebleeding will eventually determine whether a hematoma is to progress or resolve spontaneously. Symptomatic cSDHs are generally treated with surgical evacuation including twist drill craniostomy, burr hole, and craniotomy to release the mass effect. The reported recurrence rate following surgical evacuation in the literature varies widely between 20% and 37%.[1,16]

Being the main arterial feeder to the subdural inflammatory membranes, the middle meningeal artery (MMA) has been identified as a potential treatment target for cSDH. By embolizing the MMA, it can potentially shift the balance from rebleeding toward reabsorption by reducing the arterial supply to the subdural inflammatory membranes. Numerous case reports and series over the last decade have supported the use of MMA embolization, both as a sole therapy and as an adjunct treatment to surgery.[4,5,8-12] Ban *et al*. 2018 reported a prospective study consisting of 72 consecutive cSDH patients, with 27 patients underwent MMA embolization as a sole treatment, and the other 45 patients as an adjunct treatment before surgical evacuation.[3] No treatment failures were observed among the 27 patients who underwent MMA embolization as a sole therapy. Of the 45 patients who received preoperative MMA embolization, 1 (2.2%) patient developed symptomatic recurrence at 4 months and required repeat surgical evacuation. The recurrence rate was significantly lower than the 27.5% observed in the historic control group of 469 patients. Furthermore, Kim 2017 conducted a smaller retrospective study comparing MMA embolization with redo burr hole evacuation, in 43 patients with recurrent cSDH following an initial burr hole drainage.[7] The recurrence rate in the 20 patients who underwent MMA embolization was 5%, significantly lower than the 33.3% observed in the 23 patients who underwent redo burr hole drainage. Ng *et al.* recently published a pilot study comparing surgical evacuation alone versus surgical evacuation with MMA embolization in 41 patients with cSDH.[14] The hematoma volume reabsorption at 3 months was found to be higher in the 21 patients who received MMA embolization, with a mean difference of 17.5 mL. However, 44 out of the 47 cSDHs were evacuated through twist drill craniostomy for hematoma evacuation, while the other 3 hematomas were evacuated through craniotomy. A recent meta-analysis by Yagnik *et al.* 2021 has demonstrated that twist drill craniostomy was associated with a higher reoperation rate when compared to burr hole drainage, with an odd ratio of 1.48.[17]

In this multicentered randomized controlled trial, we aimed to evaluate the efficacy of postoperative MMA embolization in reducing symptomatic recurrence as well as promoting hematoma reabsorption and improving functional outcomes.

MATERIALS AND METHODS

Study design and patient selection

This is a multicentered, nonblinded, randomized controlled trial. It was designed to assess the efficacy of MMA embolization in reducing the recurrence rate of cSDH following initial surgical evacuation. The major null hypothesis was that there would be no difference in the recurrence rate at 3 months between the postoperative embolization group and the control group.

All cSDH patients admitted from April 2021 to September 2022 were screened for recruitment. cSDH diagnosis was confirmed on computed tomography (CT) scans at admission. As illustrated in Figure 1, eligible patients were adults aged 18 or above who required surgical evacuation for symptomatic cSDH with a maximal thickness of 10 mm or above. These symptoms included Glasgow Coma Scale (GCS) of 13 or less, lateralizing weakness with a power of 4 or less based on the Medical Research Council grading system, or other focal neurological deficits such as seizures. Patients were excluded if the cSDH was caused by an underlying lesion such as vascular malformations and arachnoid cysts or if they were unable to give consent to study participation themselves. Patients were randomized to embolization or control group at a 1:1 ratio using a random number generator. In patients with bilateral cSDHs, the contralateral hematoma was included if it was >10 mm in thickness and followed the randomization outcome of the larger hematoma. The contralateral hematomas were assumed to respond independently to postoperative embolization. All randomized participants underwent a CT scan following the surgical evacuation, at 6 weeks, and 3 months. Modified Rankin Scale (mRS) was recorded at admission, upon discharge, at 6 weeks, and at 3 months. Patients receiving antiplatelet or anticoagulation therapy were reversed before surgery according to individual hospital guidelines. Surgical evacuation of cSDH was performed either through single burr holes, double burr holes, or craniotomy, depending on the discretion of the treating neurosurgeon. Subdural drain on free drainage was used in all cases and removed on postoperative day 1 following a CT scan. No MMA was coagulated in patients with cSDH evacuated through craniotomy.

The trial was approved by the local Health Human Research Ethics Committee (Reference 2020.ETH.00157, REGIS

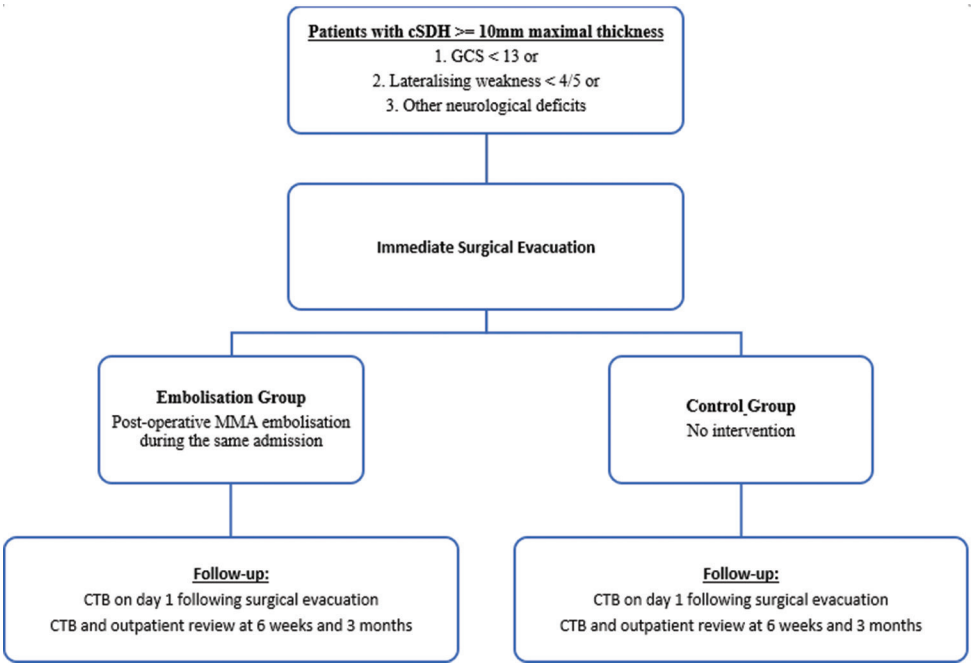

Figure 1: Study protocol. Chronic subdural hematoma, chronic subdural hematoma, GCS: Glasgow coma scale, MMA: Middle meningeal artery, CTB: Computed topography of the brain.

Reference 2020/ETH01487) and registered on Australian New Zealand Clinical Trials Registry (ACTRN12621000263897p). All participants gave written informed consent. Informed consent would only be obtained from the enduring power of attorney if the participants were incapable of providing consent and had advance health directives with permission to consent for research in place. We followed the National Statement on Ethical Conduct in Human Research in accordance with the Australian National Health and Medical Research Council Act 1992 throughout the study.

Intervention

The embolization procedure was performed by the neurointerventionists. All procedures were performed under general anesthetics following surgical evacuation during the same hospital admission. Systemic heparinization was not used. Femoral or radial access was employed at the discretion of the treating neurointerventionist. Common carotid and external carotid angiography were performed using a standard 5 or 6 French catheter. Under roadmap guidance, a microcatheter (Headway Duo 167, Terumo Microvention) or balloon microcatheter (Scepter XC, Scepter mini, Terumo Microvention) with guidewire was advanced into the MMA. MMA angiography was then performed to identify both frontal and parietal branches as well as to exclude potential dangerous anastomoses. Embolization was performed with one of the following embolic agents including Squid-12 (Balt, Montmorency, France), Onyx-18 (Medtronic, Irvine, CA, USA), Phil 25% (MicroVention, Aliso Viejo, USA), and 25% n-butyl cyanoacrylate (n-BCA) (B. Braun, Melsungen, Germany) with 75% Lipiodol (Guerbet, Villepinte, France), at the discretion of the treating neurointerventionist. When anterograde flow through MMA branches was no longer visible, the procedure was concluded.

Sample size calculation and outcome measures

Based on the current literature,[3,7] we estimated the recurrence rate of the embolization group to be about 2%, while that of the control group to be 33%. A sample size of 40 was subsequently calculated with an alpha of 0.05 and a power of 0.80.

The primary outcome was symptomatic recurrence requiring repeat surgical evacuation. Recurrence of cSDH was defined as radiologically persistent or new cSDH with persistent or new symptoms secondary to the mass effect of the cSDH. Secondary outcomes include mRS at 6 weeks and 3 months, the maximal thickness of residual cSDH as measured on CT at 6 weeks and 3 months, as well as all surgical or endovascular complications. A complication was defined as any adverse event related to surgery or embolization. It includes infection, new neurological deficits, seizures, pseudoaneurysms, retroperitoneal hemorrhage, allergic reactions to contrast or medications, stroke, intracerebral hemorrhage, carotid dissection, deep vein thrombosis, pulmonary embolism, myocardial infarction, and death.

Data collection

Clinical and radiological data were collected prospectively. The maximal thickness of residual cSDH as measured on CT at 6 weeks and 3 months was reported by independent neuroradiologists unrelated to this study. mRS at 6 weeks and 3 months was assessed during outpatient review by the researchers. All cSDHs were classified according to the imaging appearance as described by Nakaguchi *et al.* into seven types, which include hypodense, isodense, hyperdense, laminar, separated, gradient, and trabecular.[13]

Patient safety

Recruitment, blinded outcomes, and adverse events were monitored every 3 months by an independent Data Safety Monitoring Board comprised a consultant radiologist and consultant neurologist not affiliated with the study.

Statistical analyses

Statistical analysis was performed using Stata V17 (StataCorp. 2021. Stata Statistical Software: Release 17. College Station, TX: StataCorp LLC). Statistical significance was set at $P < 0.05$. Categorical variables were summarized using counts, while continuous variables were summarized using means. Comparisons were made between the embolization and the control group for all relevant variables. Categorical variables were analyzed using Fisher's exact tests, while continuous variables were analyzed using two-sample *t*-tests. $P < 0.05$ indicates a statistically significant difference between the two groups. Due to the small sample size, we were unable to conduct statistical comparisons for certain variables such as complications and mortality. A summary of counts is presented for these variables.

RESULTS

As shown in Figure 2, from April 2021 to September 2022, 36 eligible patients were recruited and provided consent to participate in the study. Seventeen patients (19 cSDHs) and 19 patients (22 cSDHs) were randomly allocated to the treatment group and control group, respectively. One patient in the embolization group withdrew from the study receiving embolization. All remaining patients in the embolization group (18 cSDHs) underwent MMA embolization and completed follow-up at 3 months. Similarly, 16 patients (19 cSDHs) in the control group completed follow-up at 3 months. The other three patients reached the endpoint before their follow-up at 6 weeks.

The patient demographic characteristics are summarized in Table 1. No differences were observed between the two groups in terms of gender, age, history of head trauma,

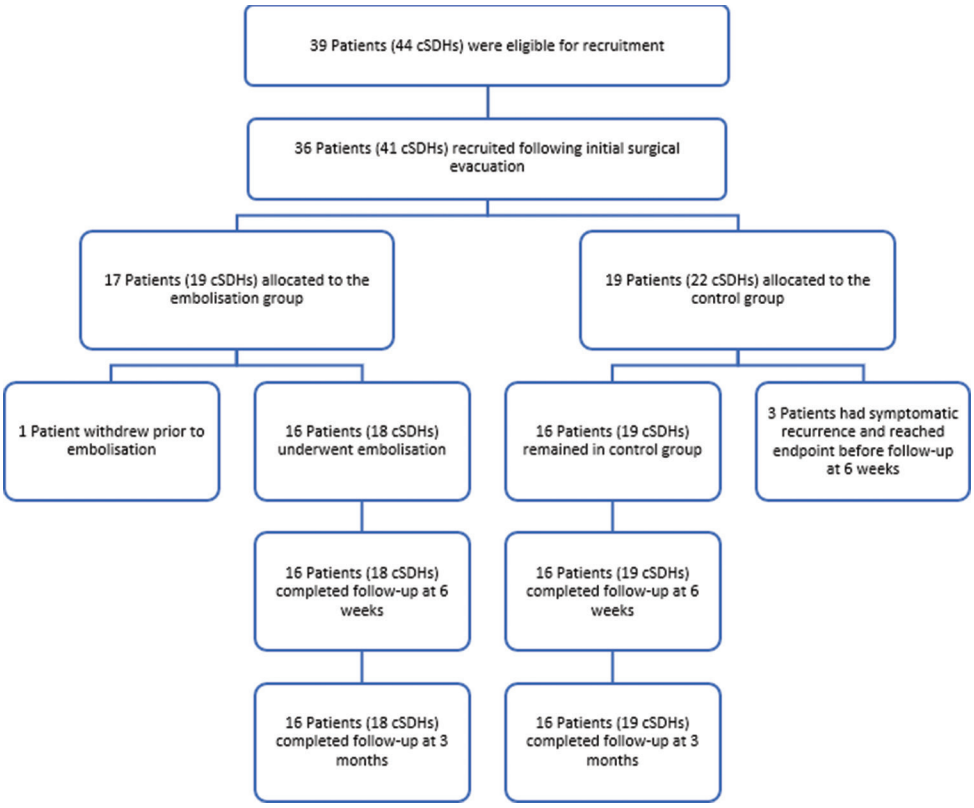

Figure 2: Recruitment flow chart. cSDH: Chronic subdural hematoma.

GCS on admission, the use of antiplatelet or anticoagulant medication, the presence of coagulopathy, and previous surgical evacuation of cSDH. The mean ages were 64.2 and 72.4 years in the embolization and control groups, respectively. There were more male patients observed in both groups (75% in the embolization group and 58% in the control group). Nineteen percentage of patients in the embolization group were on antiplatelets or anticoagulants and 13% had coagulopathy. Similarly, 21% of patients in the control group were on antiplatelets or anticoagulants and 5% had coagulopathy.

Table 1: Patient demographics.

Characteristic	Embolization group (*n* = 16)	Control group (*n* = 19)	*P*-value
Gender			
Male	12	11	0.476
Female	4	8	
Mean age	64.2	72.4	0.084
Head trauma	13	16	1.000
GCS[1] on admission			
15	11	10	0.726
13–14	4	8	
8–12	1	1	
7 or less	0	0	
Antiplatelet medication			
None	14	17	0.778
Aspirin	1	2	
Aspirin+Ticagrelor	1	0	
Anticoagulants			
None	15	17	0.341
Warfarin	1	0	
Rivaroxaban	0	2	
Coagulopathy	2	1	0.582
Previous cSDH[2] Evacuation	0	1	N/A

P < 0.05 was considered statistically significant, [1]GCS: Glasgow coma scale, [2]cSDH: Chronic subdural hematoma, *n*: Number of patients

The radiological and treatment characteristics are shown in Table 2. Bilateral cSDHs were observed in 56% of patients in the embolization group, which was significantly more than the 21% observed in the control group (*P* = 0.043). No differences were observed in mean preoperative (21.1 mm vs. 20.9 mm) and postoperative (11.2 vs. 11.2 mm) cSDH thickness between the two groups. Burr hole evacuation was more common in both embolization and control groups (63% vs. 79%) when compared to craniotomy (38% vs. 21%), but there were no differences between the two groups. No significant difference in the type of cSDH was observed between the two groups.

As illustrated in Table 3, various embolic agents were used including Squid, Onyx, PHIL, and 25% n-BCA/75% Lipiodol. Bilateral MMA embolization was performed in 56% of the patients in the embolization group.

The results of the primary and secondary outcomes are summarized in Table 4. At 3 months, no symptomatic recurrence was observed in the embolization cohort. In comparison to the control group, a recurrence rate of 15.8% was observed with 3 out of the 19 patients required

Table 2: Radiological and treatment characteristics.

Radiological characteristic	Embolization Group (Patients = 16) (cSDHs = 18)	Control Group (Patients = 19) (cSDHs = 22)	*P*-value
cSDH[1]			
Unilateral	7	15	0.043
Bilateral	9	4	
Mean pre-op cSDH thickness (mm)	21.1	20.9	0.929
Mean postoperative cSDH thickness (mm)	11.2	11.2	0.969
Surgery			
Burr-hole	10	15	0.454
Craniotomy	6	4	
Classification			
Hypodense	2	7	0.099
Isodense	5	3	
Hyperdense	0	1	
Laminar	6	2	
Separated	1	3	
Gradient	1	5	
Trabecular	3	1	

P < 0.05 was considered statistically significant, [1]cSDH: Chronic subdural hematoma

repeat surgical evacuation before follow-up at 6 weeks. Despite the trend toward a higher recurrence rate in the control group, it failed to reach statistical significance (P = 0.234). No significant differences were observed between the embolization group and the control group in residual cSDH thickness at 6 weeks (6.56 mm vs. 9.2 mm, P = 0.089) and at 3 months (2.14 mm vs. 3.76 mm, P = 0.102). Mean cSDH reduction at 6 weeks and 3 months was also evaluated and found to be no difference between the two groups. Furthermore, all patients in the embolization group had a good functional outcome at 3 months, with an mRS of 0–1. This was significantly higher than the 53% observed in the control group (P = 0.018). No complications or mortality were reported in either group. The CT scans and angiograms of a participant in the embolization group are demonstrated in Figure 3.

Table 3: Embolization characteristics.

Characteristic	Embolization group (n = 16)
Embolic agents	
Squid™	5
Onyx™	1
PHIL[1]™	3
25% n-BCA[2]/75% lipiodol	7
Unilateral embolization	7
Bilateral embolization	9

[1]PHIL: Precipitating hydrophobic injectable liquid, [2]n-BCA: n-butyl cyanoacrylate, n: Number of patients

DISCUSSION

The results of this study did not demonstrate a significant reduction in recurrence rate following postoperative MMA in patients with cSDH. This is similar to the findings of the randomized controlled trial by Ng *et al.* 2020.[14] However, Ban *et al.* 2018 compared 72 prospectively enrolled patients who received MMA embolization with a retrospective control cohort of 469 patients and found a significant reduction in recurrence rate (1.4% vs. 27.5%).[3] This discrepancy can be partially explained by the relatively higher recurrence rate (27.5%) in the control group in Ban *et al.* 2018 study, in comparison to the 4% reported by Ng *et al.* 2020 and 15.8% observed in our study.[3,14] It is worth noting that two patients who did not consent to participate in the study also experienced recurrent subdural hematoma requiring reoperation before 6 weeks from index surgery.

Our results also did not show a difference in residual hematoma thickness at 6 weeks and 3 months between the embolization group and the control group. Ng *et al.* 2020 used cSDH volume instead of maximal thickness in their study and showed that postoperative MMA embolization was associated with a higher volume of hematoma resorption

Table 4: Primary and secondary outcomes.

Outcome	Embolization group (Patients = 16) (cSDHs = 18)	Control group (Patients = 19) (cSDHs = 22)	P-value
Symptomatic recurrence	0	3	0.234
Residual cSDH[1] thickness (mm)			
6 weeks	6.56	9.2	0.089
3 months	2.14	3.76	0.102
Mean cSDH[1] thickness reduction (mm)			
6 weeks	5.28	2.27	0.110
3 months	9.32	7.5	0.218
mRS[2] on admission			
0–1	6	6	
2–3	5	4	0.417
4-6	5	9	
mRS[2] at 3 months			
0–1	16	10	
2–3	0	6	0.018
4–6	0	0	
Median hospital length of stay (day)	7	7	0.737
Complications[3]	0	0	N/A
Mortality	0	0	N/A

[1]cSDH: Chronic subdural hematoma, [2]mRS: Modified Rankin scale, [3]Complications include infection, wound dehiscence, neurological deficits, seizures, deep vein thrombosis, pulmonary embolism, myocardial infarction, pseudoaneurysm formation, retroperitoneal hematoma, allergic reaction to contrast, stroke, intracerebral hemorrhage

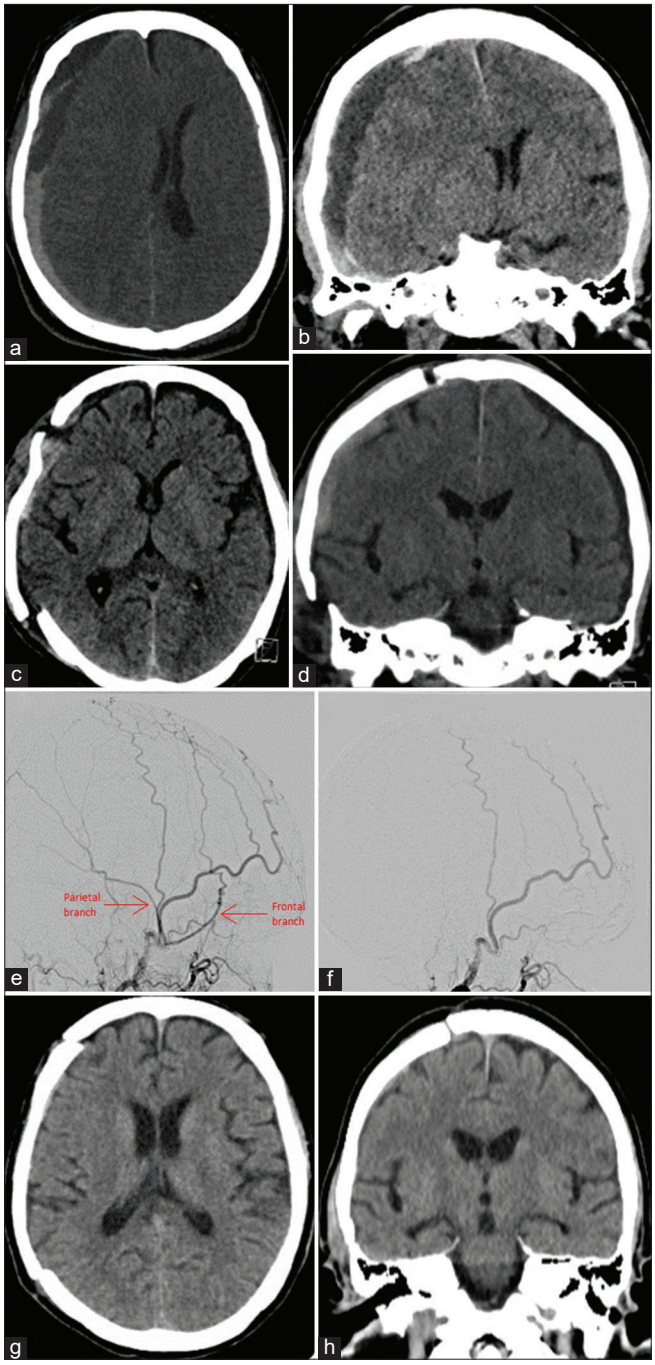

Figure 3: Example of a participant in the embolization group. (a) Pre-op axial computed tomography (CT) demonstrating a right convexity chronic subdural hematoma. (b) Pre-op coronal CT. (c) Postopereative axial CT. (d) Postoperative coronal CT. (e) Right middle meningeal artery (MMA) angiogram demonstrating flow in the frontal and parietal branches. (f) Post-embolization angiogram demonstrating occlusion of the right MMA branches. (g) Axial CT at 6 weeks demonstrating complete resolution. (h) Coronal CT at 6 weeks.

at 3 months when compared to the control group (52.6 mL vs. 35.1 mL). Even though hematoma volume is potentially a more sensitive way in detecting any subtle changes in hematoma size, we believe that maximal thickness carries more clinical relevance as it directly reflects the local mass effect.

Finally, a significantly higher proportion of patients with good functional outcomes (mRS of 0 or 1) was seen in the embolization group when compared to the control group. Headache was the most common symptom reported among patients in both groups and it could partially be related to dural irritation secondary to the inflammatory responses within the hematoma. By limiting its vascular supply to the chronic inflammatory membranes, MMA embolization might be able to reduce such inflammatory responses and therefore dural irritation.

The major limitation of this study is that it is underpowered. According to the current literature, the recurrence rate of cSDH following surgical evacuation was ranging widely from 10% to 37%.[1,16] Our initial sample size calculation was based on an estimated recurrence rate of 33%, which was higher than the observed recurrence rate of 15.8% in our control group. This could be at least partially related to the fact that all our patients underwent burr hole drainage or craniotomy while other studies in the literature included patients with twist-drill craniostomy, which has been shown to be associated with a higher recurrence rate.[17] Based on our observed recurrence rate in the control group, a revised sample size of 106 patients with 53 patients in each group is estimated. Recruitment will, therefore, continue for the current study to further evaluate the effectiveness of MMA embolization in reducing the recurrence rate of cSDH following surgical evacuation.

One criticism leveled at this study is that the embolization procedure was not standardized in the current study; neither was the surgical technique. Various embolic agents were used depending on the discretion of the treating neurointerventionist. This was a conscious decision in the design of the study, which aimed to demonstrate the efficacy of the treatment endpoint (embolization of the MMA) and not a specific embolic agent. Furthermore, patients at TCH received MMA embolization that was ipsilateral to the side of the cSDH and bilateral embolization only in case of bilateral cSDHs. On the other hand, all patients at PAH received bilateral embolization regardless of the laterality of the cSDH. Nevertheless, there is insufficient evidence from the literature to suggest the superiority of a particular embolic agent over the others or whether bilateral embolization would be more effective than unilateral embolization for patients with unilateral cSDH. Further studies are required to answer these questions.

CONCLUSION

Our interim results have demonstrated MMA embolization as having a potential role to serve as a postoperative adjunct

treatment for cSDH. We demonstrated that postoperative MMA embolization is associated with an improved functional outcome at 3 months. However, an ongoing study with a larger sample size will be required to confirm its efficacy in reducing the recurrence rate as well as facilitating the resolution of residual hematoma. Once its efficacy is confirmed, it would be a particularly useful treatment for patients with recurrent cSDH or those with the significant risk associated with prolonged cessation of anticoagulation therapy.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent.

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Conflicts of interest

There are no conflicts of interest.

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