Clinical Article

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Half-Saline Versus Normal-Saline as Irrigation Solutions in Burr Hole Craniostomy to Treat Chronic Subdural Hematomata: A Randomized Clinical Trial

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Mehdi Mahmoodkhani 💿 ¹, Mohammad Sharafi 💿 ², Arman Sourani 💿 ², and Donya Sheibani Tehrani 💿 ³

¹Department of Neurosurgery, Kashani Hospital, School of Medicine, Isfahan University of Medical Sciences, Tehran, Iran

²Department of Neurosurgery, School of Medicine, Isfahan University of Medical Sciences, Isfahan, Iran ³Department of IT, Shahid Beheshti University, Tehran, Iran

ABSTRACT

Objective: This study aimed to evaluate the efficacy and safety of half-saline (HS) serum as an irrigation solution in chronic subdural hematoma (CSDH) surgery using the burr hole craniostomy (BHC) technique.

Methods: This randomized clinical trial was conducted in university hospital referral centers from 2020 to 2021. Sixty-three patients with CSDH eligible for BHC were primarily enrolled. Two patients were excluded because of concurrent stroke. Sixty-one patients were randomly allocated into case (HS=30) and control (normal-saline [NS]=31) groups. HS was used to irrigate the hematoma in the case group and NS was used in the control group. The patients were followed-up. Clinical variables including demographic and medical findings, postoperative computed tomography findings, postoperative complications, hospitalization period, recurrence rate, and functional status measured by the Barthel type B index were recorded.

Results: Forty-six of 61 patients were male (75.4%), and the patients' mean age was 65.4 \pm 16.9 years, with equal distribution between the 2 groups. Postoperative effusion and postoperative hospital stay duration were significantly lower in the HS group than in the NS group (*p*=0.002 and 0.033, respectively). The postoperative recurrence within 3 months in both groups was approximately equal (6.6%). In terms of functional outcomes and postoperative complications, HS showed similar results to those of NS.

Conclusion: HS as an irrigation fluid in BHC effectively reduced postoperative effusion and hospital stay duration without considerable complications.

Trial Registration: Iranian Registry of Clinical Trials Identifier: IRCT20200608047688N1

Keywords: Chronic subdural hematoma; Saline solution; Therapeutic irrigation; Hypotonic solution; Subdural effusion; Burr hole craniostomy



 Received:
 Jun 16, 2022

 Revised:
 Aug 8, 2022

 Accepted:
 Aug 9, 2022

 Published online:
 Sep 29, 2022

Address for correspondence: Mohammad Sharafi

Department of Neurosurgery, School of Medicine, Isfahan University of Medical Sciences, Hezar Jerib Street, Isfahan 8174673461, Iran.

Email: Sharafi.mohammad@gmail.com

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ORCID iDs

Mehdi Mahmoodkhani D https://orcid.org/0000-0001-6903-0839 Mohammad Sharafi D https://orcid.org/0000-0002-8469-5625 Arman Sourani D https://orcid.org/0000-0002-8998-9446 Donya Sheibani Tehrani D https://orcid.org/0000-0002-5893-0353

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Trial Registration

Iranian Registry of Clinical Trials Identifier: IRCT20200608047688N1

Conflict of Interest

The authors have no financial conflicts of interest

INTRODUCTION

Chronic subdural hematoma (CSDH) is defined as the timely collection of toxic blood over the cerebral hemisphere. CSDH is a neurological event in middle-aged and elderly patients. Head trauma, anticoagulant or antiplatelet consumption, alcohol consumption, chronic kidney disease, and cranial-cerebral disproportion states (brain atrophy and shunt overdrainage) are associated with a higher incidence of CSDH. However, minor head trauma is the most reported (50%–80%) cause of CSDH formation.^{11,24} Given that Virchow originally represented CSDH as pachymeningitis hemorrhage interna, the etiology of CSDH has long been regarded as involving a bleeding-resolution-inflammation cycle.^{1,20} The cardinal manifestations of CSDH include headache, dizziness, lightheadedness, vertigo, limb weakness, sphincter dysfunction, and altered levels of consciousness. Spontaneous recovery is rare and patients often require surgery.^{4,5,13,25}

Twist drill craniostomy and burr hole craniostomy (BHC) are the most popular surgical interventions for effectively treating CSDH.¹⁵⁾ BHC is more popular because of its better clinical outcomes, including lower recurrence rate and greater hematoma evacuation. In BHC, the surgeon places burr hole(s) in the skull and irrigates the CSDH using copious amounts of warm sterile crystalloids. Normal-saline (NS), lactated Ringer's solution, and artificial cerebrospinal fluid (ACF) are available options for irrigation fluids.³⁾

NS has been used as a standard and first-line irrigation fluid in cranial surgeries; however, concerns are associated with its potential efficacy and safety in CSDH surgery.¹⁾ ACF is a fluid that contains glucose and various mineral salts and resembles natural CSF.¹²⁾ The use of irrigation fluids other than NS, including ACF and lactated ringer, has been investigated, and it has been reported that it can reduce side effects such as seizures and minor bleeding; ACF also reduces the rate of cerebral edema compared with NS.⁹⁾ Since ACF is not widely available and there is controversial evidence of different irrigation fluids in the BHC technique, we used half-saline (HS), a cheap and widely available alternative irrigation fluid, as an irrigation solution in the BHC.

MATERIALS AND METHODS

Patient population

This study was a randomized clinical trial with equal allocation (1:1), conducted in Kashani referral university hospitals from 2020 to 2021. All patients who were eligible for BHC as a CSDH treatment were primarily enrolled (**FIGURE 1**).

Those who declined to participate or had concurrent intracranial lesions such as ventricular catheters, strokes, hydrocephalus, tumors, acute hemorrhagic head trauma, or uncontrolled epilepsy syndrome were excluded from the study to control for confounding bias. The remaining patients (n=61) were randomly allocated to the HS (n=30) and control (NS, n=31) groups using block randomization sequence generation. The randomization sequence was created using a statistical software (Stata[®] ver.9; StataCorp., College Station, TX, USA). Informed medical consent was obtained from patients and their first-degree relatives. Follow-up appointments were scheduled at 2 weeks, 1 month, and 3 months post operation. Neurological recovery, surgical wound status, and related events were also assessed. Follow-up computed tomography (CT) scans were obtained 3 months postoperatively.

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FIGURE 1. Flow diagram summarizing the study in a step-by-step fashion. HS: half-saline, NS: normal-saline.

Data were collected in the form of an information checklist, including demographic data, neurological findings, on admission and at discharge Glasgow coma scale (GCS), preoperative and postoperative CT scan findings (side, thickness and features of CSDH, midline shift, cisternal compression, postoperative blood residues), hospital stay duration after surgery, recurrence rate at 3 months after surgery, functional level of patients before and 3 months after treatment, and Barthel type B index.¹⁸

Postoperative subdural effusion was defined as the collection of subdural fluid on post operational CT scan, which was a remnant of the CSDH irrigation procedure and was hypodense compared to brain tissue density. Postoperative hyper-dense subdural fluid was considered a hematoma.

The thickness of the hematoma and effusion were measured by drawing a line perpendicular to the maximum diameter of the subdural hematoma on preoperative CT scans and subdural effusion on postoperative CT scans of the same site, controlled according to anatomical landmarks (**FIGURE 2**).



FIGURE 2. Axial brain computed tomography scan. Slice with maximum thickness of chronic subdural hematoma. Hematoma thickness was measured in slice with maximum thickness. (A) Pre operation, (B) post operation slice of the same patient and the same site controlled according to anatomical landmarks.



Recurrence was defined as symptom exacerbation and CSDH presentation on the same side within 3 months of the initial surgery, which required reoperation.¹²⁾ Patient performance levels before and 3 months after treatment were evaluated and recorded by the resident physician according to the Barthel type B index.¹⁸⁾ In this setting, the surgical procedure was performed under the supervision of the same neurosurgeon to obtain accurate measurements.

Due to ethical and medicolegal issues, the patient and surgical team were aware of group allocation, but a statistical analysis was blinded to the group allocation (single-blinded).

Operation

Under general anesthesia and in the supine position after prep and drape in a sterile fashion, 2 burr holes were placed ipsilateral to the CSDH side at the epicenter of collection. The dura was then cauterized and opened in a cruciate fashion. The hematoma was evacuated and irrigated with 3,000 mL of warm HS or NS through a silicone catheter over the cerebral hemisphere surfaces. A catheter was fixed to each frontal hole and attached to a zeropressure draining bag. The drain was set below the head of the bed and maintained in situ for 48 hours. A routine postoperative brain CT scan was obtained 1 day postoperatively to evaluate the intracranial status and measure the subdural effusion. All patients received prophylactic heparin (5,000 IU) subcutaneously, every 12 hours after 24 hours postoperatively for venous thromboembolism prophylaxis. All patients received levetiracetam 500 mg every 12 hours for seizure prophylaxis.

Statistical methodology

Categorical variables were presented as the number of patients with percentages. Normally distributed continuous variables were reported as means with standard deviations, and non-parametric variables are reported as medians with ranges. The χ^2 test and Fisher's exact test were used for categorical variables. The Mann-Whitney *U* test and Wilcoxon signed-rank test were used to compare non-parametric and paired non-parametric variables, respectively. IBM SPSS software (version 21; IBM Corp., Armonk, NY, USA) was used for the statistical analysis. The level of statistical significance was defined as a *p*-value ≤ 0.05 .

Ethics approval

All procedures were performed under the ethical standards of the institutional and/or national research committee and the 1964 Helsinki Declaration and later amendments or comparable ethical standards. The neurosurgery department board members of Isfahan University supervised and approved this report on behalf of the Ethical Committee of Isfahan University of Medical Sciences. The study was approved by the Isfahan University of Medical Sciences, Isfahan, Iran (IR. MUI. MED. REC.1399.107) and registered in the Iranian Registry of Clinical Trials (identifier: IRCT20200608047688N1, http://www.irct.ir/). Informed consent was obtained from all the patients.

The Isfahan University Neurosurgery Department board members, in cooperation with the Isfahan University Research Board members, supervised and approved this randomized control trial (RCT) with code number 398946.

RESULTS

A total of 61 patients were reviewed in the final data analysis, 30 of whom were in the HS group and 31 were in the NS group. Seventy-five percent of the participants were male and 24.6% were female. Twenty men (66.7%) were in the HS group, and 26 (83.9%) were in the NS group (**TABLE 1**). The mean \pm SD of patients' age was 65.4 \pm 16.9 years, The mean age in the HS group was 62.8 \pm 15.9 years and in the NS group was 67.9 \pm 11.3 years (*p*=0.160).

Both age and sex showed equal distributions in the case and control groups. Medical history and anticoagulation, antiplatelet, and laterality records were negligible and exhibited no group preferences in either group.

Statistical analysis showed equal pre- and postoperative Barthel index (BI) value distribution without any group superiority. In both groups, surgery effectively improved BI (**TABLE 2**, p=0.001). The overall recurrence rate was 6.6%, which was almost the same in both the case and control groups (p=0.981, **TABLE 2**).

The mean postoperative hospital stay duration in the HS group was 4.0 ± 1.4 days, with a time range of 3 to 10 days and 5.2 ± 2.1 days in the NS group with a time range of 3 to 14 days. Statistical analysis revealed a significantly shorter postoperative hospital stay duration in the HS group than that in the NS group (*p*=0.033, **TABLE 2**).

In terms of preoperative hematoma, no significant difference was observed between the groups (p=0.524). The postoperative effusion in the HS group was significantly lower than that in the NS group (p=0.002).

| Variable | Half-Saline (n=30) | Normal-Saline (n=31) | Total (n=61) | <i>p</i> -value |
|-------------------|--------------------|----------------------|--------------|-----------------|
| Sex | | | | 0.119 |
| Male | 20 (66.7) | 26 (83.9) | 46 (75.4) | |
| Female | 10 (33.3) | 5 (16.1) | 15 (24.6) | |
| Dysarthria | 11 (40.7) | 16 (59.2) | 27 (44.2) | 0.240 |
| Hemiparesis | 7 (38.8) | 11 (61.1) | 18 (29.5) | 0.298 |
| Headache | 21 (44.6) | 26 (55.3) | 47 (77.0) | 0.198 |
| Diabetes mellitus | 4 (40) | 6 (60) | 10 (16.3) | 0.525 |
| Hypertension | 11 (44) | 14 (56) | 25 (40.9) | 0.500 |
| Anticoagulation | 2 (50) | 2 (50) | 4 (6.5) | 0.973 |
| Antiplatelet | 6 (42) | 8 (58) | 14 (22.9) | 0.590 |
| Unilateral | 24 (47) | 27 (53) | 51 (83.6) | 0.454 |
| Bilateral | 6 (54) | 5 (45.4) | 11 (18) | 0.694 |

TABLE 1. Descriptive statistics of the participants

Values are presented as number (%).

TABLE 2. Summary of variable analysis results

| Variable | Half-saline (n=30) | Normalsaline (n=31) |
|--|--------------------|---------------------|
| Barthel: 0 (scale) | 13.7±13.2 | 14.1±1.9 |
| Barthel: 3 (scale) | 18.8±1.2 | 18.8±1.5 |
| <i>p</i> -value | 0.001 | 0.001 |
| Preoperative hematoma thickness (mm) | 23.5±6.6 | 23.5±8.0 |
| Postoperative effusion thickness (mm) | 11.8±5.1 | 15.4±4.1 |
| Duration of hospitalization after surgery (days) | 4.0±1.4 | 5.2±2.1 |
| Recurrence of the disease | | |
| No | 28 (93.3) | 29 (93.5) |
| Yes | 2 (6.7) | 2 (6.5) |

Values are presented as mean \pm standard deviation or number (%).

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FIGURE 3. Summary of variable analysis results in half-saline and normalsaline

There was no significant correlation between postoperative effusion thickness and postoperative hospital stay in the HS group. The mean effusion thickness was 11 mm, and the mean postoperative hospital stay was 4 days (p=0.749>0.05). Moreover, there was no significant correlation between the postoperative effusion thickness and postoperative hospital stay in the NS group. The mean effusion thickness was 15 mm, and the mean postoperative hospital stay was 5 days (p=0.751>0.05) (**FIGURE 3**). This demonstrates that the decision to discharge patients in both groups was not dependent on postoperative effusion size.

Only the motor function of patients' GCS was evaluated. In both groups, motor function on average was 5 preoperatively and 6 postoperatively for all patients.

In terms of post operation complications, there was no postoperative acute hematoma, tension pneumocephalus, surgical site infection, dehiscence, or acute neurological deterioration. Overall, the recurrence rate was 6.6%, with an approximately equal distribution in both the groups.

DISCUSSION

CSDH is considered one of the most prevalent pathologies in daily neurosurgical practice; however, little is known about the exact underlying pathophysiological mechanisms, and there is no consensus on the best treatment modalities, including operation nuances.^{2,6,14,21} Among these controversies, irrigation fluid selection has been less investigated and requires proper research.

Adachi et al.¹⁾ conducted a clinical study on the solution selection in the BHC irrigation phase for treating CSDH. They compared histological changes in the outer hematoma membranes after irrigation with NS versus ACF during CSDH surgery. In those irrigated with NS, the outer hematoma membranes showed architectural derangement in the extracellular matrix, cellular deformation, and eosinophilic infiltration. Conversely, in patients irrigated with



ACF, these findings were minimal or less frequent. Finally, they concluded that ACF entails fewer adverse effects on brain tissue, and hematoma membranes may reduce minor rebleeds-inflammation, thus diminishing the recurrence rate.¹⁾ The clinical and pathophysiological effects of HS or other hypotonic fluids on subdural hematoma membranes have not been thoroughly investigated in the literature.

The postoperative recurrence rate of CSDH is multifactorial; however, large postoperative pneumocephalus, anticoagulant/antiplatelet consumption, type of surgery, and medical comorbidities are associated with a higher recurrence rate. The recurrence rate varies significantly; most studies have demonstrated values of 3%–15%.^{17,23,24} Maliawan et al.¹⁶ conducted a systematic review of CSDH recurrence and deduced that 12%–13% of CSDH surgeries experience long-term recurrence.

Kim et al.¹⁰ reported a significantly lower recurrence rate in patients managed without intraoperative saline irrigation. Their study showed a large formation of pneumocephalus in the irrigation group and its correlation with recurrence. However, we would like to mention that retrospective designation, high recurrence rate of NS groups (24.6%), and a disproportionate allocation between case and control groups limit the generalizability of their study.

Whether drainage with or without irrigation is a better therapy for CSDH remains unknown. Therefore, the efficiency of intraoperative saline irrigation has not been determined.²²⁾ Ishibashi et al.⁸⁾ argued that burr hole drainage with irrigation may be an effective treatment for CSDH with a low recurrence rate. In a retrospective study, Seong et al.¹⁹⁾ reported a lower recurrence rate in patients in whom intraoperative irrigation was not employed; however, these differences were not statistically significant (0.0% vs. 8%, p>0.05). Their study was conducted in a small number of patients and in a retrospective fashion; thus, the data were not generalizable.

Extracellular iron and hemoglobin metabolites have damaging effects on brain tissues. Oxidative stress, vasospasm, neural damage, seizures, and impaired neural recovery are wellknown complications of extracellular iron-hemoglobin deposition.⁷ Irrigation is a beneficial technique for clearing blood and its degradation products and minimizing the toxic effects of iron-hemoglobin metabolites.

The current study showed a significantly shorter duration of hospital stay in the HS group than that in the NS group. Postoperative effusion in the HS group was significantly lower than that in the NS group. The authors want to mention that better brain re-expansion results in lower postoperative pneumocephalus, thus lowering the need for oxygen supplementation and the hospitalization duration. It also has beneficial effects such as better clinical recovery and lower hospitalization-associated events by reducing the admission period.

Our study showed that the Barthel type B test score for assessing personal function 3 months postoperatively was not significantly different. Meanwhile, disease recurrence was not significantly different between the 2 groups.

This study has a limitation. The authors recommend a larger RCT on this topic to improve generalizability. Tissue investigations are encouraged to better understand the effect of irrigation fluids on CSDH membranes.



CONCLUSION

As an irrigation fluid in CSDH surgery, HS can improve brain re-expansion and reduce postoperative effusion and hospitalization periods. In terms of postoperative complications, recurrence, and functional outcomes, HS is equivalent to NS as an irrigation fluid. No significant correlation was found between postoperative effusion and postoperative hospitalization in either group. A multicenter RCT study, in addition to an assessment of the pathophysiologic effects of HS on subdural membranes, is necessary to evaluate the efficacy and safety of HS as an irrigation solution in the treatment of CSDH.

ACKNOWLEDGMENTS

The authors thank the patients for their cooperation.

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