

# Randomized controlled study on the curative effects of twist-drill craniotomy and burr-hole craniotomy in the treatment of chronic subdural hematoma

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**Abstract.** The present randomized controlled study investigated the differences in the curative effects of twist-drill craniotomy (TDC) and burr-hole craniotomy (BHC) in the treatment of chronic subdural hematoma (CSDH). A total of 40 patients diagnosed with CSDH via head computed tomography (CT) who required surgical decompression from January 2016 to January 2017 were enrolled in the present study, and were randomly divided into a TDC group (n=20) and a BHC group (n=20). The modified Rankin scale (mRS) scores of patients were recorded prior to the operation, and at 48 h and 3 months after the operation. The differences in the mRS score ( $V_{mRS}$ ) among the groups were calculated using the Mann-Whitney U test. The 40 patients enrolled comprised 33 males and 7 females, and there were no significant differences in the general clinical characteristics between the two groups. In the BHC group, 3 patients had a pre-operative mRS score of 5 points, among which 2 cases died at 32 and 45 days after discharge. In the TDC group, 4 patients had a pre-operative mRS score of 5 points, among which 1 case died of epilepsy and pulmonary infection at 1 month after the operation. No difference in the mortality rate was present between the two groups. During the 3-month follow-up, head CT indicated that the intracranial hematoma in a total of 4 patients, including 3 cases in the TDC group and 1 case in the BHC group, completely disappeared. In the BHC group, 3 cases required a repeated incision and drainage after the first operation, while no secondary operation was required in any of the cases of the

TDC group. The average length of stay at the hospital (LOS) after TDC was  $9.00 \pm 2.91$  days, which was significantly shorter than that after BHC ( $14.75 \pm 5.95$  days). In the total sample of 40 patients, a longer LOS was associated with a higher risk of secondary operation due to recurrence after discharge. The variation value of the mRS score at 3 months after the operation and its ratio vs. the pre-operative score in the TDC group were significantly different from those in the BHC group, suggesting that the improvement of neurological function after TDC was significantly greater than that after BHC. Although 18 patients (90%) in the TDC group were cured, there was no significant difference from the cure rate in the BHC group [15 patients (75%)]. In conclusion, no significant differences were identified in the cure rate and the mortality rate of patients with CSDH after the two types of surgical treatment. However, the mRS score in the TDC group at 3 months after the operation exhibited a significantly greater improvement compared with that in the BHC group, and the overall LOS in the TDC group was significantly shorter than that in BHC group. Therefore, TDC is superior to BHC in the treatment of CSDH (trial registration no. ChiCTR-INR-16008368).

## Introduction

Chronic subdural hematoma (CSDH) occurs frequently in middle-aged and aged people (>50 years), and the incidence rate in individuals aged >70 years is 20 times as high as that in the general population (1). Due to the global population aging, a marked increase in the number of CSDH cases is foreseeable (2). Burr-hole craniotomy (BHC) and twist-drill craniotomy (TDC) are two of the most commonly used therapeutic methods for CSDH, and the comparison of their curative effects has always been a hotspot in clinical research.

Evidence-based studies by Weigel *et al* (3) and Lega *et al* (4) indicated that BHC is more efficient and safer than TDC. However, an increasing number of studies have suggested that TDC should be used as a preferred clinical regimen. In particular, while the randomized controlled studies of Muzii *et al* (5), Gökmen *et al* (6) and Singh *et al* (7) did not prove that TDC was superior according to the major clinical

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**Key words:** chronic subdural hematoma, twist-drill craniotomy, burr-hole craniotomy, minimally invasive, modified Rankin scale score

indexes 'recurrence rate' and 'mortality rate'. However, the recent evidence-based studies by Ducruet *et al* (8) and Almenawer *et al* (9) pushed the question back to its origin, as the authors argued that TDC has more advantages due to the shorter surgery times and minimally invasive characteristics.

Previous studies generally use non-unified definitions of the outcomes, and among them, the major indexes refer to different clinical implications (3,10-20). For instance, CSDH 'recurrence', the most commonly used index to describe the major outcomes, is often confused with 'secondary operation' (5,6,18,21). To this end, the clinical evaluation system for CSDH was redesigned with the cure rate as the major evaluation index, and the present prospective clinical randomized controlled trial was designed to further determine the advantages and disadvantages of the two therapeutic methods.

## Patients and methods

**Definition of TDC.** Skull drilling evacuation of hematoma with a skull drilling diameter of >5 mm is defined as minimally invasive craniotomy or TDC, that with a drilling diameter of >5 and >30 mm is defined as BHC and that with larger surgical wounds is defined as general craniotomy. In the flow chart in Fig. 1, the clinical course of patients with CSDH is illustrated according to previous studies (22).

**Definition of recurrent CSDH.** The recurrence of CSDH is defined as the repeated accumulation of hematoma in the ipsilateral subdural hematoma cavity confirmed by imaging after the initial treatment. Repeated treatment by decompression drainage in the case of CSDH recurrence with symptoms or aggravated symptoms is known as reoperation. The first operation frequently fails due to certain technical issues or operative complications, including acute subdural hemorrhage, ineffective shunt or poor drainage. At this point, an emergency remedial surgery is required to reconstruct the drainage for intracranial decompression, which is often performed within a short time after the first operation. In the present study, remedial surgery within 48 h was used as a short-term efficacy index for assessing the success rate of surgery. As a control, the cure rate was used as a long-term index of assessing the surgical efficacy. Patients regarded as cured from CSDH were those with improvement of neurologic impairment after the first operation, including the complete clearance of hematoma without recurrence, residual hematoma in the subdural space identified during follow-up imaging, asymptomatic or no symptom aggravation. Therefore, patients who underwent a second surgery, namely a remedial operation and reoperation, and who died during follow-up, were not deemed as being cured (22).

**Inclusion criteria.** Patients diagnosed with CSDH via head CT or magnetic resonance imaging (MRI) at Huai'an First People's Hospital (Huai'an China) between January 2016 and January 2017 were enrolled in the present study. Inclusion criteria were a clear correlation of CSDH with neurologic impairment symptoms and signs confirmed via neurological examination; the requirement of hematoma drainage and decompression; and an age >18 years for either sex. Patients with CSDH caused by systemic diseases were excluded, and

surgical contraindications were excluded through appropriate biochemical examinations, electrocardiogram and chest CT. Patients who met the inclusion criteria were enrolled and randomly grouped after they and their families were informed about the details of the present study, the surgical risks and the relevant safety measures, and provided written informed consent. The present study was approved by the Ethics Committee of Huai'an First People's Hospital.

**Random grouping method.** A total of 40 random numbers were generated using Statistical Product and Service Solutions (SPSS) v21.0 software (IBM Corp., Armonk, NY, USA). After the patients provided their signature to confirm the experimental scheme, one number was randomly selected from the 40 numbers and the patients were accordingly enrolled into the pre-set groups (23). Three clinicians were independently responsible for the grouping, surgery and follow-up, respectively.

**Surgical procedures for TDC.** According to the CT scan positioning, the center on the thickest layer was selected as a puncture point and the arteries were avoided. The electric hand drill with a 2-cm minimally invasive intracranial hematoma puncture needle was used to penetrate the skull and dura mater along the locating point to the hematoma center into the subdural hematoma cavity. The drill was then removed, the drainage hose was connected and the drill head was pulled out. The appearance of a dark red bloody fluid overflow was considered to indicate a successful puncture, and the rapid improvement in symptoms were used for verification. The highest point of drainage tube was maintained 10-15 cm higher than the head puncture point, and the symptoms were improved; the drainage tube was temporarily clipped and then opened after 2 h, and the total drainage time was 48 h. The minimally invasive puncture drainage was successful in 19 patients, and the drainage tube was removed after 48 h without the traditional irrigation according to previous studies (24-29). Through the routine post-operative review of the head CT, severe complications were excluded and the drainage tube was removed after 48 h.

**Surgical procedures for BHC.** A scalp incision with a length of ~4 cm was made with a skull drill of 12 mm in diameter and the drill was slightly expanded by using the rongeur. The dura mater was cut in a cross shape and washed with warm saline, and one drainage tube was placed into it.

**Post-operative management.** To prevent recurrence, all patients were routinely administered statins every night. After the operation, the tube was clipped for 2 h after it was opened for drainage for 48 h and hematoma was significantly reduced on CT; the symptoms were improved and the silicone drainage tube was eventually pulled out. After the operation, in a comfortable supine position, the elderly patients were required to lie in bed and rest, but they were not strictly confined to the bed (11). The incision was disinfected and the dressing was replaced once per day. All 40 patients were followed up by independent clinicians. A new head imaging was reviewed and neurological scoring according to the mRS was performed at 3 months after the operation.

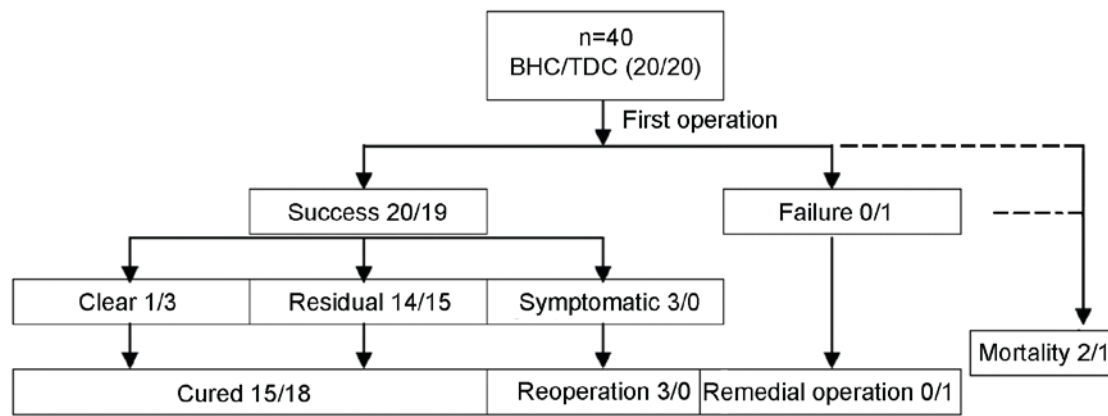


Figure 1. Clinical course of BHC and TDC in the treatment of chronic subdural hematoma. TDC, twist-drill craniotomy; BHC, burr-hole craniotomy.

**Statistical analysis.** All data from the data set were input into SPSS v21.0 for windows software (IBM Corp.). Measurement data were presented as the mean  $\pm$  standard deviation. The independent-samples t-test was used for intergroup comparison and the  $\chi^2$  test was used for enumeration data. The difference values of mRS scores prior to and after the operation and the ratio vs. the pre-operative value were compared between the two groups using the Mann-Whitney U test.  $P < 0.05$  was considered to indicate a statistically significant difference.

## Results

**Demographic data of the patients.** A total of 176 cases of CSDH were treated using different surgical methods at Huai'an First People's Hospital from January 2016 to January 2017. This population comprised 132 males and 44 females aged 19-89 years with an average age of  $63.2 \pm 10.11$  years. Definite diagnoses were made by brain CT or head MRI examination. On CT, the low-density, equal-density, slightly high-density or mixed-density crescent abnormal fluid areas in the subdural space frequently had a space-occupying effect. The brain parenchyma was pressed, the brain fissure disappeared, and the lateral ventricle and midline structure deviated to the opposite side to varying degrees. The symptoms/complaints of the patients included intracranial hypertension, psychiatric symptoms, hemiplegia and disturbance of consciousness. Among the 40 patients enrolled, 33 were males and 7 were females, and the age ranged from 19-86 years, with 34 cases (85%) aged  $>60$  years and 26 cases (65%) with a history of trauma (BHC group, 14 and TDC group, 12). The duration from injury to admission ranged from 3 weeks to 4 months. A total of 14 cases (35%) denying a history of trauma were aged  $>60$  years, and there was a significant age difference between the patients without and with history of trauma ( $72.36 \pm 6.37$  vs.  $62.73 \pm 15.36$  years;  $F = 3.81$ ;  $t = 2.23$ ;  $P = 0.03$ ). It was indicated that a history of trauma may be associated with the formation of CSDH in patients  $<60$  years, but not necessarily in patients  $>60$  years. A total of 38 (95%) out of 40 patients had unilateral hematoma, while 2 cases (5%) had bilateral hematoma; no skull fracture and brain parenchymal injury were identified during the imaging examination, and the bleeding volume was 30-210 ml.

**Clinical manifestations.** A total of 17 cases (42.5%) had chronic progressive medical characteristics of intracranial hypertension, including headache, nausea and optic disc edema. A total of 29 cases (72.5%) presented with focal neurologic impairment due to the hematoma compression, including hemiparesis, epilepsy, alalia and eating difficulty, including 6 cases (15%), in which the impairment was severe with manifestations including disturbance of consciousness, psychiatric symptoms, behavioral abnormalities and mental retardation, and 5 cases (12.5%) with urinary incontinence prior to admission, but whose consciousness as well as respiratory pulse and other vital signs were stable. The medical history of the cases was as follows: 20 cases (50%) were complicated with varying degrees of hypertension and diabetes mellitus, and 2 cases (5%) had a history of underlying cerebrovascular disease with unilateral hemiplegia. Furthermore, 2 cases (5%) had a history of tumor, 1 case (2.5%) had a history of renal insufficiency and 1 case (2.5%) used to take antiplatelet drugs, e.g., aspirin, prior to admission. In all patients enrolled in the present study, statin drugs were used to prevent hematoma recurrence. No significant differences in the general clinical characteristics were identified between the two groups (Table I).

**Major outcomes.** One case in the TDC group received the remedial operation due to no obvious improvement of symptoms and poor hematoma drainage on head CT review at 48 h after the operation (TDC vs. BHC;  $P = 0.31$ ; Table I). However, it cannot be reasoned that the failure rate of TDC was significantly higher than that of BHC. In the BHC group, 3 patients had a pre-operative mRS score of 5 points, among which the hematoma of 2 cases was significantly improved on head CT review at 48 h after the operation, but the mRS score was still 5 points. Furthermore, 2 patients died at 32 days after discharge (36 days post-operation) and 45 days after discharge (49 days post-operation). In the TDC group, 4 cases had a pre-operative mRS score of 5 points, among which 1 case was discharged 5 days after admission, but his mRS score was 4 points, and he died of epilepsy and pulmonary infection after 1 month. The hemiplegia symptoms of one 80-year-old case were not alleviated, the patient could not take care of themselves, and the head CT at the 3-month follow-up indicated no increase in the hematoma. No difference in the mortality rate was identified between the

Table I. Comparison of general clinical characteristics and outcomes between the BHC and TDC groups.

Parameter	BHC	TDC	P-value
n	20	20	
Age (years)	66.00±16.74	66.20±10.11	0.96
Male sex	17 (85)	16 (80)	0.68
Medical characteristics			
Trauma	14 (70)	12 (60)	0.51
Hypertension	5 (25)	10 (50)	0.10
Diabetes	1 (5)	0	0.31
Aspirin	0	1 (5)	0.31
mRS score			
Pre-operation	2.55±1.47	2.74±1.49	0.70
48 h post-operation	1.35±1.53	1.42±1.35	0.88
3 months post-operation	1.40±1.98	0.74±1.67	0.27
Outcomes			
Remedial surgery	0	1 (5)	0.31
Hematoma clear	1 (5)	3 (15)	0.29
Hematoma residual	14 (70)	15 (75)	0.67
Secondary operation	3 (15)	0	0.07
Death	2 (10)	1 (5)	0.55
LOS (days)	14.75±5.95	9.00±2.91	0.00

Values are expressed as the mean ± standard deviation or n (%). BHC, burr-hole craniotomy; TDC, twist-drill craniotomy; mRS, modified Rankin scale; LOS, length of stay at hospital.

two groups ( $P=0.55$ ). In addition, the head CT at the 3-month follow-up indicated that the intracranial hematoma of a total of 4 patients in the two groups was completely removed, including 3 cases in the TDC group and 1 male case aged 19 years in the BHC group (TDC vs. BHC;  $P=0.29$ ; Table I). In the remaining patients, residual hematoma was present after 3 months (Fig. 2). The BHC group contained 3 cases of intracranial hypertension, 2 of which were diagnosed with a recurrence of CSDH, and received the secondary operation at 30 and 47 days after the first operation. One other case was diagnosed with a secondary intracranial infection and received the incision and drainage again due to fever, scalp incision swelling and other central nervous system infection symptoms, as well as a mixed-density shadow in the subdural space on head CT. In the TDC group, those patients with improved symptoms within 48 h of surgery had stable symptoms until the 3-month follow-up, and none of the patients was required to undergo a secondary operation (TDC vs. BHC;  $P=0.07$ ). It was also identified that patients with a high pre-operative score retained these increased scores at 48 h after the operation ( $P<0.001$ ), indicating that the symptoms may be obviously improved by the two types of surgery within 48 h. The average LOS after TDC was  $9.00\pm2.91$  days, which was significantly shorter than that after BHC ( $14.75\pm5.95$  days;  $P<0.01$ ). To further compare the curative effects of the two types of operation, the differences in mRS scores prior to the operation vs. 48 h post-operation ( $V_{\text{pre-48 h}}$ ), prior to the operation vs. 3 months post-operation ( $V_{\text{pre-3 m}}$ ) and 48 h vs. 3 months after the operation ( $V_{48 \text{ h-3 m}}$ )

were determined, and the ratio of these three variables vs. the pre-operative mRS score was also calculated [ $V_{(\text{pre-48 h})/\text{pre}}$ ,  $V_{(\text{pre-3 m})/\text{pre}}$  and  $V_{(48 \text{ h-3 m})/\text{pre}}$ , respectively]. The Mann-Whitney U test was performed and the results indicated that the variation values  $V_{\text{pre-3 m}}$  and  $V_{48 \text{ h-3 m}}$  of the mRS score at 3 months after the operation and the ratios  $V_{(\text{pre-3 m})/\text{pre}}$  and  $V_{(48 \text{ h-3 m})/\text{pre}}$  in the TDC group were obviously different compared with those in the BHC group ( $P<0.05$ ; Table II), suggesting that the improvement of neurological function in the TDC group after the operation was more obvious than that in the BHC group. According to the traditional definition, the remedial operation (1 case in the TDC group) and secondary operation (3 cases in the BHC group) were considered to indicate a recurrence of CSDH in the present study, and the recurrence rate was not significantly different between the two groups ( $P=0.29$ ; Table I). Although 18 patients (90%) in the TDC group were cured (the operation was successful and the survival time was  $>3$  months without recurrence), there was no significant difference in the cure rate compared with that in the BHC group ( $P=0.21$ ).

## Discussion

CSDH is a common neurological disease and frequently occurs in the elderly. With the global population aging, its incidence rate is high. BHC and TDC are the two most commonly used drainage techniques for subdural hematoma. Due to non-unified definitions and inconsistent evaluation indexes, previous studies as a whole have not convincingly demonstrated which



Table II. Comparison of  $V_{mRS}$  between the two surgery groups.

$V_{mRS}$	BHC			TDC			P-value
	n	Mean	Sum	n	Mean	Sum	
$V_{pre-48 h}$	20	19.93	398.00	20	21.08	421.00	0.72
$V_{pre-3 m}$	20	16.40	328.00	19	23.79	452.00	0.04
$V_{48 h-3 m}$	20	16.23	324.50	19	23.97	455.50	0.03
$V_{(pre-48 h)/pre}$	20	22.03	440.50	20	18.98	379.50	0.40
$V_{(pre-3 m)/pre}$	20	16.68	333.50	19	23.50	446.50	0.03
$V_{(48 h-3 m)/pre}$	20	15.70	314.00	19	24.53	466.00	0.01

The Mann-Whitney U test was applied. BHC, burr-hole craniotomy; TDC, twist-drill craniotomy; mRS, modified Rankin scale;  $V_{mRS}$ , change in mRS score; pre, prior to surgery; 3 m, 3 months after treatment.

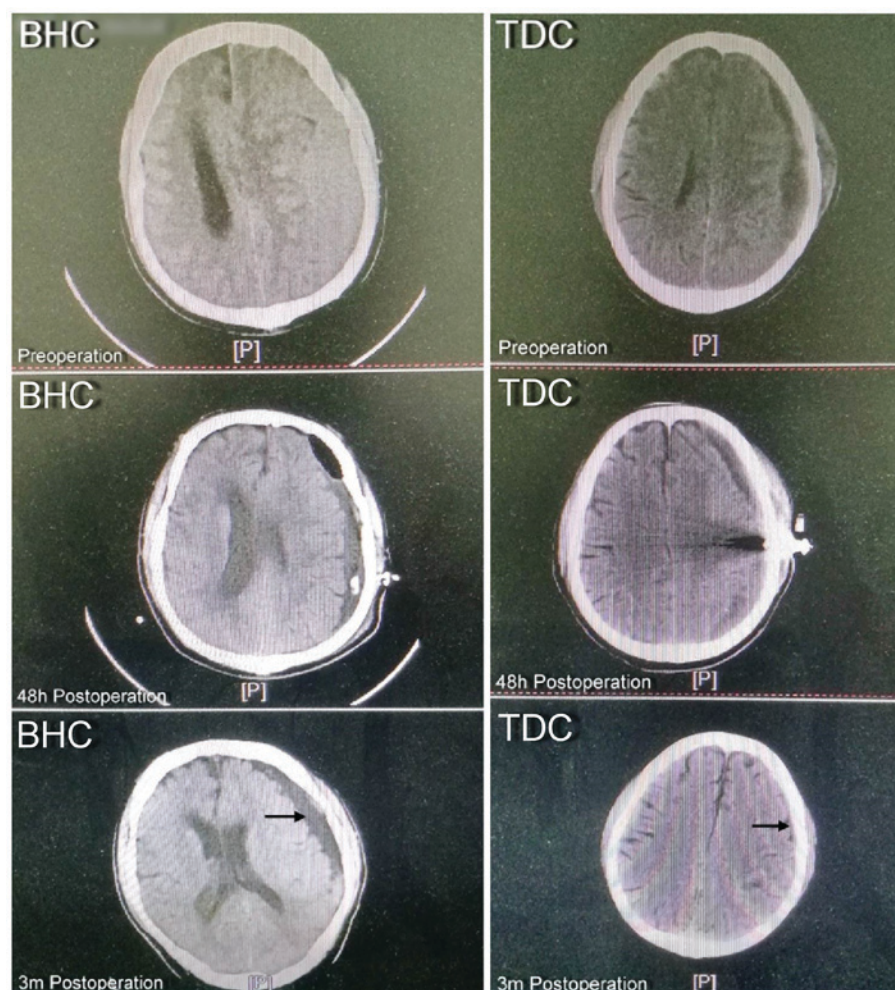


Figure 2. Computed tomography images prior to the operation and at 48 h and 3 months after BHC and TDC. Residual hematomas were observed in the BHC group. TDC, twist-drill craniotomy; BHC, burr-hole craniotomy; [P], posterior.

one of the two techniques provides more benefits (22). Three randomized controlled studies had the following shortcomings: The definition of recurrence in the study by Muzii *et al* (5) was based on the imaging results, which is different from the traditional evaluation based on symptom recurrence; however, the other indexes in their study were evaluated in a similar manner. In the study by Gökmen *et al* (6), the recurrence

of CSDH was considered as requirement for a secondary operation. The study by Singh *et al* (7) had similar clinical implications to Gökmen *et al* (6), but the detailed description of definitions was lacking. Oh *et al* (14) identified in a review that as an inconsistency, the definition of 'recurrence' mainly included remedial operation, remnants and secondary operation. Although the recurrence rate has been a major index for

evaluating the efficacy in the past, it has also been the most inconsistently defined parameter.

The definition of recurrence based on residual hematoma may be the major cause for the variety of results. In the present study, the proportion of patients with clear intracranial residual hematoma on head CT at the 3-month follow-up after the operation was 72.5%, which was consistent with the results of Weigel *et al* (3,20). In previous studies, the presence of post-operative residual hematoma is the most common clinical outcome for patients receiving treatment for CSDH. At present, it remains to be clarified whether the residual hematoma is the unabsorbed hematoma after the first onset and treatment, compensatory product formed due to the difficult re-expansion and failed filling of residual cavity in patients with brain atrophy or new subdural hematoma. Since the recurrence of CSDH was determined based on residual hematoma in the past (11,24-29) and monitoring of the changes in residual hematoma varies, the definition of 'recurrence' is not consistent among studies.

In order to avoid confusing results due to the unclear definition of recurrence, the terminology of the present study was based on studies by Neal *et al* (30) and Singla *et al* (31), and a novel index system was established. As one of the major indexes for evaluating the long-term efficacy of surgery, patients with removal of CSDH or residual CSDH without any new neurologic impairment in the follow-up imaging after 3 months were deemed as cured. The cured patients only underwent one operation. No additional surgery was required based on the examination outcomes, including various criteria for assessing the recurrence and reasons for determining a secondary operation. The cure rate was used as the major index for evaluating the efficacy, which has applicability in the clinic.

Based on the above, the results of the present study indicated that 75 and 90% of patients in the BHC group and TDC group, respectively, were cured, and there was no statistically significant difference between the two groups. However, it is indicated that BHC and TDC do not have the same effectiveness. Therefore, the improvement level of the mRS score, expressed as the  $V_{\text{mRS}}$  value, was used as another evaluation index with the aim to clarify the effectiveness of the two surgeries through further evaluating the overall changes in mRS scores prior to and after the two types of operation in each group.

The differences in mRS scores between the time-points prior to the operation, at 48 h and 3 months after operation were calculated ( $V_{\text{pre-48 h}}$ ,  $V_{\text{pre-3 m}}$  and  $V_{48 \text{ h-3 m}}$ ), and the ratio of these three variables to the pre-operative mRS score was also calculated [ $V_{(\text{pre-48 h})/\text{pre}}$ ,  $V_{(\text{pre-3 m})/\text{pre}}$  and  $V_{(48 \text{ h-3 m})/\text{pre}}$ ]. The Mann-Whitney U test was performed and the results indicated that the variation values  $V_{\text{pre-3 m}}$  and  $V_{48 \text{ h-3 m}}$  of mRS score at 3 months after the operation and the ratios  $V_{(\text{pre-3 m})/\text{pre}}$  and  $V_{(48 \text{ h-3 m})/\text{pre}}$  in the TDC group exhibited obvious differences compared with those in the BHC group ( $P < 0.05$ ), suggesting that the improvement of neurological function in the TDC group at 3 months after the operation was more obvious than that in the BHC group. Therefore, it may be assumed that with the increase of sample size, the long-term cure rate in the TDC group may be superior to that in BHC group. This present result is superior to that of the recent study by Wang *et al* (32), which indicated that TDC and BHC have comparable clinical outcomes in the treatment of patients with CSDH.

As previous studies, the present study identified no significant difference in the mortality rate of CSDH patients after treatment with the two different surgeries (3,8). In the present study, the overall failure rate of TDC was 5%, which was within the previously reported range (0-36.4%) (8). The present study also proved that the success rate of the first BHC was higher (100%), but it did not suggest that the failure rate of TDC is higher than that of BHC ( $P = 0.31$ ). The failure rate may be associated with factors including the surgical conditions, proficiency of the surgeon, technical factors and the overall condition of the patients.

In the present study, the rate of symptom recurrence and secondary operation within 3 months after BHC was up to 15%, which was consistent with the fact that the long-term improvement in mRS score after the operation in the BHC group was lower than that in the TDC group, proving the rationality and completeness of the evaluation system applied. However, it may not be reasonable to use the secondary operation rate as a major clinical index to assess the efficacy of the first operation. In addition, as mentioned above, among previous studies, the definition of 'secondary operation' is as inconsistent as that of 'recurrence', and it lacks the practicality for clinical use as an index for measuring the surgical efficacy.

In the present study, no significant differences were identified in the cure rate and the mortality rate of patients with CSDH after the two types of surgical treatment. However, the mRS score in the TDC group at 3 months after the operation was significantly more improved compared with that in the BHC group, and the overall LOS in the TDC group was significantly shorter compared with that in the BHC group. Therefore, the TDC regimen was indicated to be superior to the BHC regimen.

In conclusion, the effectiveness of TDC in the treatment of CSDH is not lower than that of BHC, and it is characterized by a simpler operation and smaller damage; at the same time, the LOS of patients receiving TDC is also obviously shorter than that of patients after BHC, and the improvement of neurological score of patients who received TDC was better in the long-term. Therefore, TDC is superior to BHC for the treatment of CSDH.

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## Availability of data and materials

All data generated or analyzed during this study are included in this published article.

## Authors' contributions

CX, BC, LXu, LXi and XY were involved in the study design; MW, XH, QC, JZ, ML and ZL were involved in data collection; XT, GC and FX were involved in data analysis; CX and

ML prepared the manuscript. All authors read and approved the final manuscript.

### Ethics approval and consent to participate

This study was approved by the Ethics Committee of Huai'an First People's Hospital. Written informed consent was obtained from the patients and/or their guardians.

### Patient consent for publication

Patients or their guardians provided written informed consent for publication.

### Competing interests

The authors declare that they have no competing interests.

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