European Review for Medical and Pharmacological Sciences 2017; 21: 809-818

Chronic subdural hematoma management: clarifying the definitions of outcome measures to better understand treatment efficacy – a systematic review and meta-analysis

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Abstract. – OBJECTIVE: A long history of inconsistencies in the definitions of the outcome measures for chronic subdural hematomas (CSDHs) has contributed to the controversy over the optimal surgical strategy for CSDH treatment. Clarifying these definitions, reassess the available data, and systematically review the prior literature may provide better insight into the differences in treatment efficacy for CSDH.

MATERIALS AND METHODS: The clinical course of CSDH was described with a series of strictly defined outcome measures. PubMed, Cochrane Library, and ScienceDirect databases were searched for comparative studies of two main surgical techniques for CSDH, including burr hole craniotomy (BHC) and twist drill craniotomy (TDC). Data were collected with uniform criteria and analyzed using a random-effects model to estimate the mortality, recurrence, operative failure, and cure rates of each treatment.

RESULTS: Twelve comparative studies that examined 2,027 CSDH patients were included. The analysis results indicated that TDC and BHC treatments were similar in the mortality rates (RR, 1.25; 95% CI, 0.83-1.87; $I^2 = 0\%$; $p = 0.28$) and the recurrence rates (RR, 1.29; 95% CI, 0.87-1.92; $I^2 = 13\%$; $p = 0.21$) for CSDH patients. However, TDC had a significantly higher operative failure rate compared with BHC (RR, 0.35; 95% CI, 0.15-0.83; $I^2 = 0\%$; $p = 0.02$), whereas patients treated by a TDC approach tended to achieve higher cure rates compared with BHC (RR, 0.92; 95% CI, 0.86-0.99; $I^2 = 55\%$; $p = 0.02$).

CONCLUSIONS: The clarification of the definitions related to CSDH outcome facilitates the interpretation of differences in treatment efficacy. The TDC approach manifested a significantly higher operative failure rate compared with the BHC approach; however, TDC showed a tendency in achieving a long-term neurologic cure.

Key Words:
Chronic subdural hematomas, Burr hole, Twist drill, Closed system drainage, Subdural evacuation port system, Meta-analysis, Systematic review.

Introduction

Chronic subdural hematoma (CSDH) is one of the most common neurological diseases, with approximately 20 times higher morbidity in the elderly[1]. Although it has been well-recognized that surgical drainage via craniotomy, burr-hole craniostomy (BHC), and twist drill craniostomy (TDC) are the most effective treatments for CSDH, the optimal surgical method remains controversial[2]. BHC and TDC have many similarities compared with the significant differences between craniotomy and conservative corticosteroid treatments. However, the documented differences between the most important outcomes, including the recurrence rate and the mortality of BHC and TDC, were not significantly different for CSDH patients.

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There is no current consensus in establishing a widely accepted evaluation system of treatment outcomes for CSDH. In previous studies[3-7], the clinical events investigated as the primary endpoints, have been defined differently and represented a variety of different clinical presentations. The outcome measures of "secondary operation", "reoperation", and "complication" have often been misinterpreted as a CSDH recurrence[8]. Singla et al[9] and Neal et al[10] have discussed this issue with substantial new evidence and utilized more constructive solutions in their retrospective studies by making distinctions between reoperation, initial operation failure, and CSDH recurrence. In light of these new concepts, we have examined all comparative clinical studies of BHC and TDC through October 4, 2013, clarified the definitions of each outcome variable, and re-examined the advantages and disadvantages of the two treatments.

Materials and Methods

Search Strategy and Selection Criteria

Two independent assessors (Xu CS and Liu LY) searched PubMed, Cochrane Library, and ScienceDirect databases (from inception to October 4, 2013) using the key words "chronic subdural hematoma", "subdural hematoma", or "subdural hematoma" and "burr hole", "bur hole", "twist drill", "subdural evacuation port system", "SEPS", or "trephine". We excluded case reports, reviews, meta-analyses, comments, letters, and studies that focused on infants, very elderly individuals, and non-human species, as well as studies that used different surgical methods and outcomes not relevant to BHC and TDC. We reviewed all abstracts of the remaining articles; we excluded CSDHs not diagnosed by computed tomography (CT) or Magnetic Resonance Imaging (MRI) and included comparative studies published as full-text articles.

All eligible articles compared the outcomes of a TDC group with a controlled BHC group and contained separate raw data. These data were extracted by two independent assessors (Xu CS and Liu LY). For each study, we recorded the following information for each group, when available: the number of patients, mean age, hospitalization duration, follow-up days, and the main operative approach. The primary endpoints were clinical events concerning death, CSDH recurrence, remedial procedures, and cure after the operative procedure of the initial surgical approach. These events have inconsistent definitions across the literature. To ensure uniformity, we defined the four primary endpoints with strict criteria. Only original data defined the same as our criteria were directly collected. Clearly described data in different definitions were transformed. We also attempted to email all nine corresponding authors to request the original records and confirm the data for included papers.

Definition of Outcomes

Openings of the skull incision limited to a diameter of 5 mm were categorized as TDC, up to 30 mm as BHC, and larger openings as craniotomy. The subdural evacuation port system (SEPS) used in two studies was categorized as a variant of TDC, with a standard skull incision of 5.8 mm in diameter[11-13].

For the first time we established a summary of the clinical course of CSDH to understand the relationship between the outcome measures (Figure 1). The primary outcome measures were defined using the strict definitions described by Singla et al[9] and Neal et al[10]. The recurrence of CSDH was defined as a subsequent radiographic relapse of hematomas in the ipsilateral subdural space with or without any clinical presentation. Reoperations were performed in patients with symptomatic recurrence. The initial operation was sometimes a failure due to technical factors or surgical complications, such as acute subdural rebleeding, insufficient evacuation, or obstructed drainage.

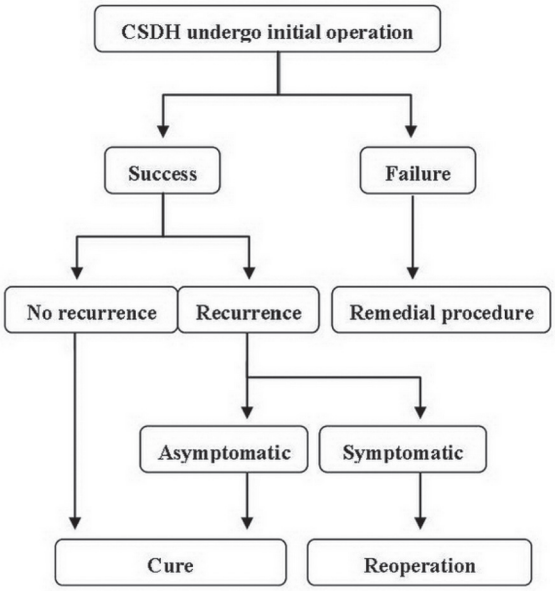

Figure 1. Summary of the postoperative course of CSDH.

A remedial surgical procedure was then required in the short-term after the first surgical procedure to re-decompress the brain region. In this article, remedial procedures were investigated as short-term clinical endpoints, which indicated the operative failures of the initial surgical operations. In contrast, we assessed cure as a long-term clinical endpoint, which was defined as CSDH patients who only underwent the initial operation and neurologically improved at the end of the follow-up period. Therefore, patients who underwent a second operation or died during the follow-up period were characterized as not cured.

Study Quality Assessment

Nine of the twelve studies included in our meta-analysis utilized a non-randomized controlled trial (nRCT) design. We used the Newcastle-Ottawa Quality Assessment Scales as our quality assessment tools[14]. We considered a study with a score of five or more to be of good quality, and all nine comparative studies met this requirement. We also undertook the Cochrane Collaboration's tool to assess the risk of bias in RCTs[15]. In general, complete blinding in surgical trials of CSDH is very difficult[16]. In the three included randomized designed studies, Muzii et al[17] and Gökmen et al[18] reported a generation of random sequences and concealed allocations, but all studies failed to ensure blinding in the intervention and follow-up periods. Almenawer[19] had an isolated third party complete the discharge and one-month follow-up forms, but failed to retain blinding in the 3-month follow-up results. Preliminary experiments were carried out to analyze the data of the nine nRCTs separately or pooled with the three RCTs to estimate the impact on the results.

Statistical Analysis

Data analysis was performed with Review Manager 5.2.6 as supplied by the Cochrane Collaboration (Oxford, UK). The pooled data assessments were carried out by a meta-analysis using the Mantel-Haenszel method to compare the BHC and TDC treatments for CSDHs by evaluating the mortality, recurrence, failure, and cure rates. Heterogeneity was assessed by the Cochran Q test and quantified by the I^2 statistic. With the degrees of freedom (df) in text, pooled data were interpreted to be homogeneous if the probability value of the χ^2 test was ≥ 0.10 and the percentage of total variation across studies with a predefined $I^2 < 50\%$. The statistical analysis for dichotomous variables was performed with a Mantel-Haenszel fixed-effects model. If the data were heterogeneous, the variables were estimated by a random-effects model using the Mantel-Haenszel method. Given that variable studies with different designs are prone to inherent heterogeneity, we used the Mantel-Haenszel random-effects model to calculate weighted pooled proportions[19]. The total effect sizes were expressed as a risk ratio (RR) and were tested by a Z test. Statistical significance was set at a p-value < 0.05 or a 95% confidence interval (CI) of the RR not including 1. Publication bias was examined by visual inspection of funnel plot symmetry.

Results

We identified 683 publications without any language restriction after the initial search. The abstracts of 52 articles that included information regarding TDC and BHC treatments for CSDH were reviewed. Fifteen comparative studies that utilized CT or MRI as the diagnostic method for CSDH were eligible for full-text assessment (Figure 2). Twelve studies were ultimately included, which contained a total of 933 patients in the TDC groups and 1,094 patients in the BHC groups. All demographic characteristics were similar. As of the submission day of this manuscript, four authors[12,13,19,20] had responded to our original data request letters, and their records are reflected in Table I.

When comparing the outcomes of BHC and TDC for CSDHs, the preliminary experiments showed that analyzing the data of the nine nRCTs separately or pooled with the three RCTs led to similarly positive results (Table II). There were no significant differences in patient mortality (total effect RR = 1.25; 95% CI, 0.83-1.87; test for overall effect $Z = 1.07$, $p = 0.28$; test for heterogeneity $\chi^2 = 6.87$, $df = 10$, $p = 0.74$, $I^2 = 0\%$) or recurrence rates (total effect RR = 1.29; 95% CI, 0.87-1.92; test for overall effect $Z = 1.26$, $p = 0.21$; test for heterogeneity $\chi^2 = 5.78$, $df = 5$, $p = 0.33$, $I^2 = 13\%$). There were significantly higher remedial procedure rates (total effect RR = 0.35; 95% CI, 0.15-0.83; test for overall effect $Z = 2.38$, $p = 0.02$; test for heterogeneity $\chi^2 = 2.28$, $df = 5$, $p = 0.81$, $I^2 = 0\%$) and cure rates (total effect RR = 0.92; 95% CI, 0.86-0.99; test for overall effect $Z = 2.32$, $p = 0.02$; test for heterogeneity $\chi^2 = 17.82$, $df = 8$, $p = 0.02$, $I^2 = 55\%$) in the TDC group compared with the BHC group (Figure 3). Furthermore, the findings from the meta-analysis logical-

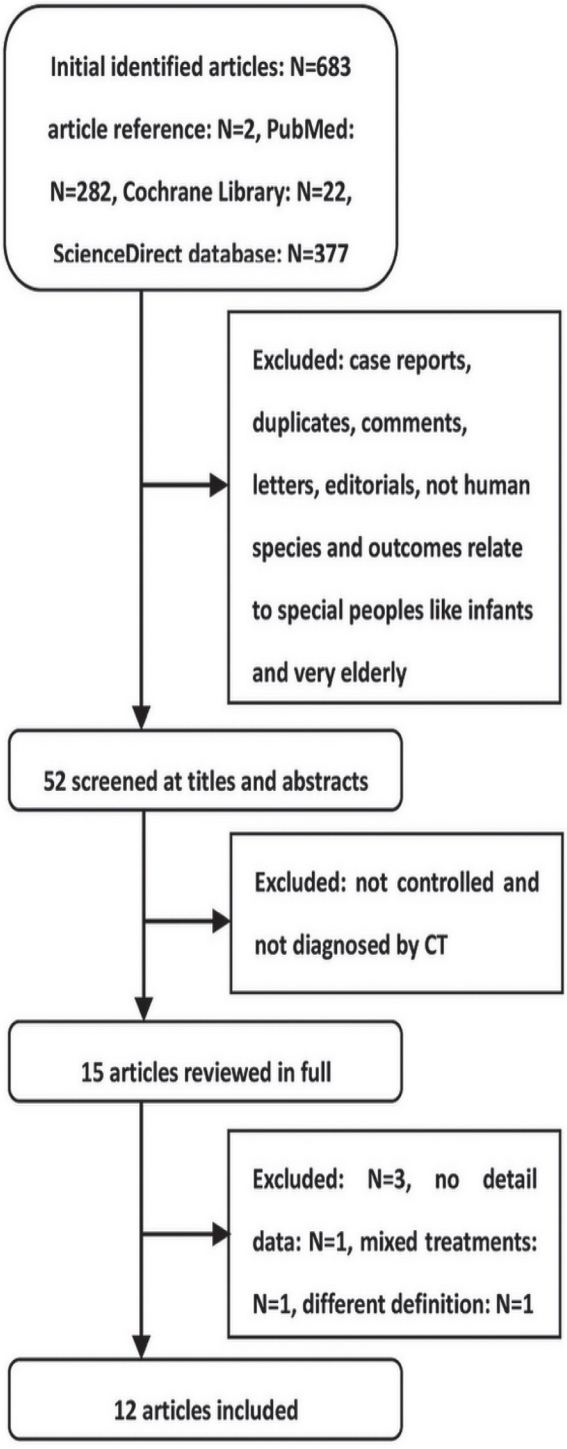

Figure 2. Summary of study selection. Summary of study selection

ly supported the summary of the clinical course of CSDH (Figure 1). When the TDC group showed significantly higher pooled failure and cure rates compared with the BHC group, there was also a higher reoperation rate in the BHC group (total effect RR = 1.66; 95% CI, 1.01-2.73; test for overall effect $Z = 2.00$, $p = 0.05$; test for heterogeneity $\chi^2 = 3.88$, $df = 4$, $p = 0.42$, $I^2 = 0\%$).

For sensitivity analyses, we employed the jackknife method. All results of the four-pooled outcomes were relatively stable in the RR value, and there were no adverse results detected from the Q and Z tests. Publication biases were examined by visual inspection of funnel plots. The four main outcomes demonstrated a high symmetry (Figure 4).

Discussion

The terms "recurrence" and "reoperation" have been used as the primary clinical endpoints to evaluate the safety and efficacy of CSDH treatments, but these terms have a variety of meanings across studies[3-8,20-24]. For example, the remedial operation performed in cases of operative failure of the initial operation was included in the secondary operation for recurrent CSDH. Furthermore, the secondary operation (reoperation) was often misinterpreted as a CSDH recurrence[5,12,17,18].

To our knowledge, the acute subdural bleeding that emerged soon after the initial operation was the result of micro bleeding from the destroyed micro-vessels, which is very commonly seen by neurosurgeons in daily practice, especially in patients with a bleeding tendency[25,26]. In general, the acute subdural bleeding persisted with the residual hematoma in the subdural space and naturally ceased and absorbed, rather than transforming into CSDH. Markwalder et al[27] observed persistent subdural fluid in 78% of cases by CT scans on the 10th day after surgery, and 27 of the 32 patients were normal when re-scanned one month later. Almenawer et al[19] and Hwang et al[28] also suggested this type of subdural bleeding rarely warranted reoperation, as it was spontaneously reabsorbed usually within a month after relieving the pressure by draining the bulk of the hematoma. The primary mechanism of this healing occurs after membrane maturation, which prevents re-bleeding from the immature fragile membranes[29]. Mori and Maeda[30] speculated that acute bleeding from the surgical scalp wound might flow directly into the evacuated subdural space and accumulate as an acute subdural hematoma.

In their observational study, the incidence was 2.6% (13 of 500), and all patients had undergone a secondary operation. Thus, the acute subdural he-

Table I. Summary of the general characteristics and available outcomes of the included studies.

Authors and Year	Group	No. of patients	Mean age, years	Operation procedure	Operating place and anesthesia types	Skull incision size, mm	Follow-up days	No. of events				
								Death	Recurrence	Failure	Reoperation	Cure
Smely et al (1997)	BHC	33	70	BH+IR+CSD	OR+L	11	82	3	UA	3	8	UA
	TDC	33	69.7	TD+IR+CSD	BS+L	5	81	2	UA	5	3	UA
Gabarrós et al (2000)	BHC	83	66.5	BHC+OED	OR+G	UA	365	6	10	1	UA	54
	TDC	105	67.5	TD+CSD	OR+L	5	365	3	15	3	UA	83
Williams et al (2001)	BHC	14	57.4	BH+IR+CSD	OR+L/IS	15	51.8	0	UA	0	UA	UA
	TDC	11	63	TD+CSD	BS+L	UA	35	0	UA	4	UA	UA
Muzii et al (2005)	BHC	24	76.3	BH+IR+CSD	OR+L	10	60	2	15	UA	5	17
	TDC	22	78.8	TD+CSD	BS+L	5	60	1	7	UA	1	20
Horn et al (2006)	BHC	24	65.5	BH+CSD	OR+G	11	80.5	3	UA	UA	UA	18
	TDC	55	69.1	TD+CSD	BS+L	5	80.5	4	UA	UA	UA	46
Maarrawi et al (2007)	BHC	109	61	BH+CSD	OR+G	< 5	180	1	UA	UA	UA	93
	TDC	45	61	TD+CSD	BS+L	5-30	180	0	UA	UA	UA	44
Gökmen et al (2008)	BHC	32	67	BH+IR+CSD	OR+G	13	180	2	UA	0	2	26
	TDC	38	67	TD+CSD	BS+L	4.5	180	4	UA	4	1	29
Rughani et al (2010#)	BHC	21	73.3	BH+IR+CSD	OR+17G/4L	9	45	1	4	UA	UA	UA
	TDC	21	73	TD+CSD*	7OR/14BS+3G/18L	5.8	66.8	2	5	UA	UA	UA
Lin (2011#)	BHC	270	62.34	BH+IR+CSD	OR+G	12	90	4	32	UA	32	204
	TDC	178	63.16	TD+CSD	OR+G	5	90	4	14	UA	14	158
Singh et al (2011)	BHC	52	61.2	BH+IR+CSD	OR+L/48G	15	90	0	1#	1#	1	49
	TDC	48	59.8	TD+IR+CSD	BS+L	5	90	4	3#	4#	3	42
Safain et al (2013#)	BHC	9	61	BH+IR+CSD	OR+G	5-10	111	0	2	0	UA	7
	TDC	23	68	TD+CSD*	BS+L/IS	5.8	80.5	1	2	2	UA	15
Almenawer et al (2013)	BHC	423	31	BH+CSD	OR+G	< 5	UA	31	UA	UA	UA	360
	TDC	354	18	TD+CSD	BS+L	5-30	UA	18	UA	UA	UA	315

Abbreviations: OR, operation room; BS, bedside; G, general; L, local; IS, intravenous sedation; BH, burr hole; TD, twist drill; CSD, closed system of drainage; IR, irrigation; OED, open external drainage; UA, unavailable. *Subdural evacuation port system; #author's letter.

Table II. Meta-Analysis results of all pooled studies, including RCTs and nRCTs.

Outcomes	Study type	No. of studies	Fixed-effects model		Random-effects model		Tests of heterogeneity			
			RR	95% CI	RR	95% CI	χ^2	df	p	I2 (%)
Mortality										
	All studies	12	1.18	0.80-1.74	1.25	0.83-1.87	6.87	10	0.74	0
	RCTs	3	0.49	0.16-1.45	0.58	0.15-2.29	2.41	2	0.30	17
	nRCTs	9	1.37	0.90-2.08	1.37	0.89-2.01	2.86	7	0.90	0
Recurrence (radiographic relapse)										
	All studies	6	1.26	0.89-1.97	1.29	0.87-1.92	5.78	5	0.33	13
	RCTs	2	1.47	0.78-2.77	1.05	0.18-6.17	2.58	1	0.11	61
	nRCTs	4	1.20	0.79-1.82	1.19	0.78-1.81	2.55	3	0.47	0
Failure (remedial procedure)										
	All studies	6	0.30	0.13-0.70	0.35	0.15-0.83	2.28	5	0.81	0
	RCTs	2	0.18	0.03-1.02	0.19	0.03-1.06	0.10	1	0.76	0
	nRCTs	4	0.37	0.14-0.98	0.43	0.16-1.17	1.51	3	0.68	0
Reoperation (symptomatic recurrence)										
	All studies	5	1.66	1.03-2.86	1.66	1.01-2.73	3.88	4	0.42	0
	RCTs	3	1.56	0.53-4.61	1.53	0.30-7.73	3.20	2	0.20	38
	nRCTs	2	1.68	0.98-2.87	1.68	0.98-2.88	0.66	1	0.42	0
Cure										
	All studies	9	0.92	0.88-0.96	0.92	0.86-0.99	17.82	8	0.02	55
	RCTs	3	1.01	0.90-1.12	0.99	0.83-1.19	4.35	2	0.11	54
	nRCTs	6	0.93	0.89-0.96	0.91	0.87-0.95	8.93	5	0.11	44

Abbreviations: RR, relative risk; RCT, randomized controlled trial; nRCT, non-randomized controlled trial.

matoma should be defined as an operative complication of the first surgery, similar to an inadequate evacuation, obstructed catheter, poor decompression, or insufficient drainage. If the postoperative neurologic improvement was unsatisfactory or if it deteriorated due to an operative complication, a remedial operation was necessary to decompress the area again. This outcome was considered an initial operation failure.

However, when this micro bleeding continued and mixed with the residual hematoma, this kind of radiographic hyper-density or mixed-density subdural hematoma became very difficult to strictly distinguish from ipsilateral CSDH reaccumulation[23]. The supplement brought from the reparatory response, such as the cellular and non-cellular components necessary for tissue remodeling and healing, continued to accumulate, thereby shearing open the dural border cell layer and mixing with the blood complex[2,29,31-36]. To some extent, the natural healing process triggered by the acute bleeding failed to complete and resulted in a recurrent CSDH. This outcome was common in many elderly patients because a weak brain re-expansion cannot completely refill the subdural cavity produced by brain atrophy. This reaccumulated hematoma could be the "peace" existence in the subdural space for a long time. Clinically, if patients improved in their presentations and had no neurological deficits caused by the persistent subdural hematoma, it was defined as a cure. As a generally accepted treatment strategy, a reoperation should not be evaluated in CSDH unless the patient's condition has deteriorated markedly[9,16,27,37,38].

Therefore, a remedial operation should not be equivalent to a CSDH recurrence, and a secondary surgical procedure is not necessary to diagnose the recurrent CSDH. Many researchers had documented this issue and tried to differentiate with a series of new concepts. Oh et al[8] divided the postoperative course into seven styles in their retrospective study. This theory provided good insights into the understanding of the natural history of the postoperative course of CSDH, but lacked practicality. Singla et al[9] established a more constructive solution in a retrospective study; they made distinctions between reoperation, initial operation failure, and CSDH recurrence. In their study, 18 of the 52 included cases required a reoperation after the initial SEPS treatment within 6 months of follow-up; among these patients, 14 cases were the result of an initial operation failure, and only 4 cases presented a CSDH recurrence. Clearly, the mixed definition between reoperation and recurrence may

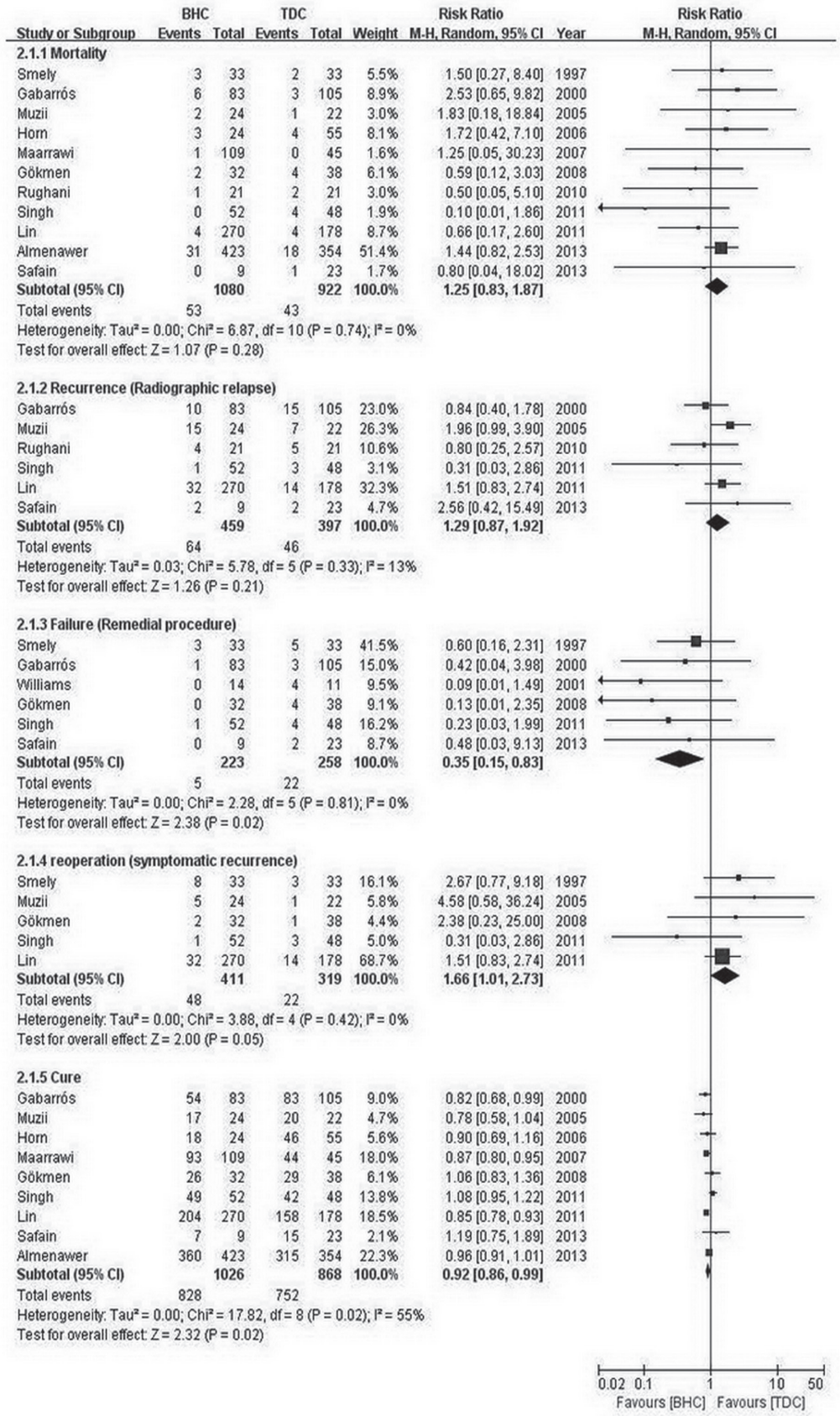

Figure 3. Results comparing mortality, recurrence, failure, reoperation, and cure rates of BHC and TDC treatments for CSDHs.

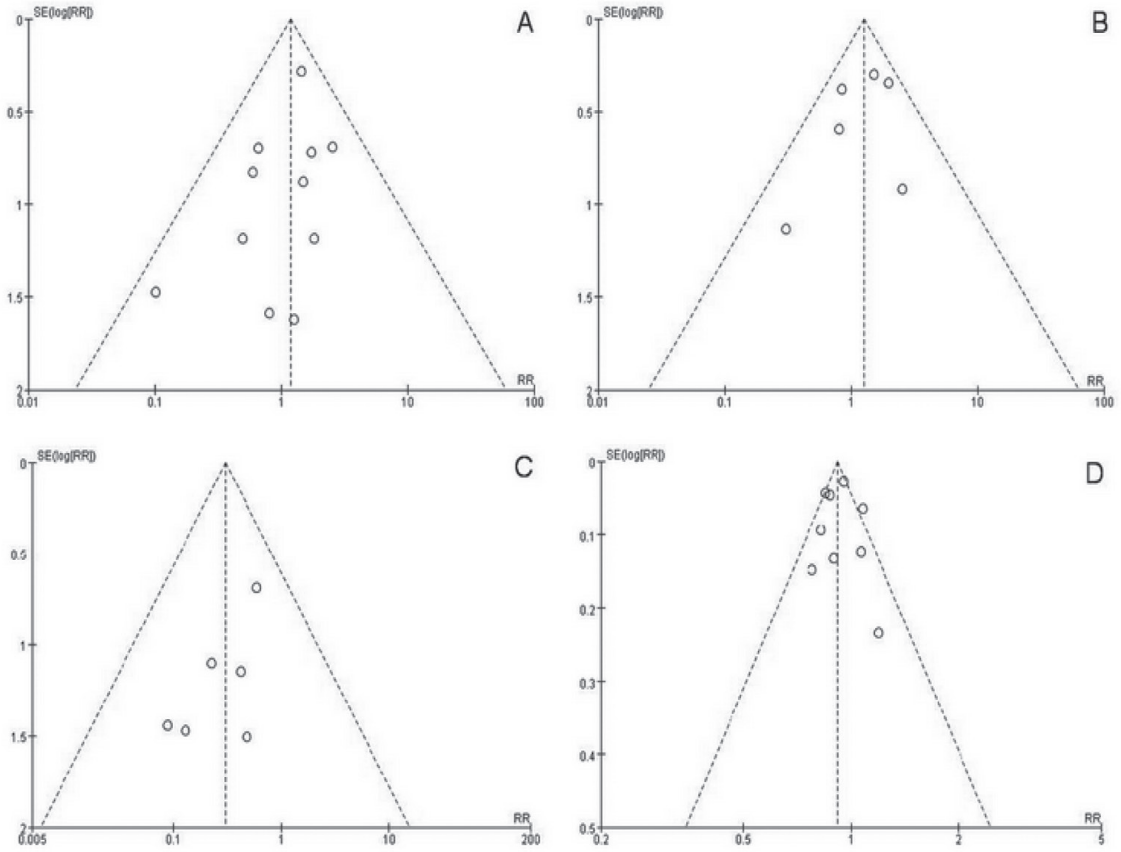

Figure 4. Funnel plots indicating publication biases for the mortality ***(A)***, recurrence ***(B)***, failure ***(C)***, and cure ***(D)*** rates for BHC and TDC treatments for CSDHs.

exaggerate the recurrence rate of CSDH and neglect the high operative failure rate of the TDC approach.

In the current study, we utilized criteria similar to Singla et al[9]. Because of these different definitions, the data analyzed in each group of comparisons did not include all reported findings of the 12 selected articles. There were only three studies that separately reported a remedial procedure, radiographic recurrence, symptomatic recurrence or improvements in detail[13,16,39]. Other authors reported one or two outcomes consistent with our definitions[40]. Our results on the comparison of recurrence and mortality rates of the two treatments were not different from previous studies[7,41]. However, this did not mean BHC and TDC were equal in safety and efficacy. We assessed the remedial procedure rate to reflect the initial operative failure rate of a certain surgical approach. We calculated an overall failure rate of TDC treatment in the included six studies as 8.5%, which fell within the reported TDC surgical failure rate range (0%-36.4%)[41,42]. TDC treatment clearly has a higher overall operative failure rate in contrast to BHC treatment. This situation may have an association with variant conditions of the individual patients, the proficiency of the neurosurgeons, or technical factors. Recognizing this difference may have a positive impact on further research to avoid surgical failures caused by technical factors. This study also utilized the cure rate as a primary outcome to measure the overall efficacy of the two treatments. Our results demonstrated the TDC groups tended to achieve higher cure rates compared with the BHC groups; these findings were similar to recent articles[41]. To some extent, the higher pooled reoperation rate in the BHC groups stressed the rationality and completeness of our summary of the postoperative course of CSDH as an evaluation system. However, we did not think the reoperation rate should be measured as a primary outcome here because its value was logically equal to the value of the recurrence minus the cure rate, and it lacked clinical practicality for patients.

Conclusions

Clarifying the definitions of the primary outcome measures may facilitate a better understanding of the treatment efficacy for CSDHs. TDC treatment had a tendency to produce better results compared with BHC treatment on achieving a long-term neurological cure rate. The current study provides a rationale to recommend the use of failure and cure rates as the two primary clinical endpoints to evaluate the multiple types of treatments for CSDHs. However, the quality of the included studies weakens the persuasiveness of the findings. Thus, additional, prospective randomized controlled studies are needed to confirm these results.

Acknowledgements

This work was supported by the Key Project of Science & Technology Development Fund of Nanjing Medical University (No. 2015NJMUZD074).

Conflict of Interest

The Authors declare that they have no conflict of interests.

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