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Review Article

Which is better in the management of chronic subdural hematoma: Irrigation, or no irrigation? A systematic review and meta-analysis of randomized controlled trials

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ABSTRACT

Background: Chronic subdural hematoma (CSDH) is a prevalent neurological disorder, especially among the elderly, where blood accumulates between the brain and its outer covering. The primary treatment for CSDH involves surgical intervention, such as burr-hole craniotomy, with or without irrigation of the subdural space. The efficacy of irrigation versus no irrigation in reducing recurrence, mortality, and postoperative complications remains debated. The study aimed to compare the effectiveness and safety of irrigation versus no irrigation in the surgical management of CSDH through a systematic review and meta-analysis of randomized controlled trials (RCTs).

Methods: A systematic review and meta-analysis were conducted following Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines. Databases searched included PubMed, Scopus, Web of Science, and Cochrane Library, targeting RCTs published in English comparing irrigation with no irrigation in CSDH management. Four RCTs with a total of 843 patients met the inclusion criteria. Two reviewers extracted data independently, and the risk of bias 2 tool was used for quality assessment. The primary outcome was recurrence; secondary outcomes included mortality and postoperative complications. Statistical analyses were performed using RevMan 5.3.

Results: The meta-analysis included four RCTs with 843 patients, revealing that irrigation significantly reduces the recurrence of CSDH compared to no irrigation (odds ratios [OR] = 0.66, 95% confidence interval [CI]: 0.44–0.98, $P = 0.04$), with no observed heterogeneity ($I^2 = 0\%$). Mortality rates showed no significant difference between the irrigation and no irrigation groups (OR = 1.10, 95% CI: 0.59–2.06, $P = 0.77$), also with no heterogeneity ($I^2 = 0\%$). Postoperative complications initially showed no significant difference (OR = 0.39, 95% CI: 0.09–1.69, $P = 0.21$) and moderate heterogeneity ($I^2 = 52\%$). However, sensitivity analysis resolving the heterogeneity indicated a significant reduction in complications favoring the irrigation group ($P = 0.03$).

Conclusion: This meta-analysis suggests that irrigation during burr-hole drainage significantly reduces CSDH recurrence without increasing mortality or postoperative complications, supporting its use in clinical practice. Further, high-quality RCTs are necessary to confirm these findings and assess long-term outcomes.

Keywords: Burr-hole craniotomy, Chronic subdural hematoma, Irrigation, Meta-analysis, Recurrence

INTRODUCTION

Chronic subdural hematoma (CSDH) is a common neurological condition where blood products build up in the gap between the brain's outer layer and its protective covering.[1] This usually happens after a mild head injury or when a vein connecting the brain's surface to deeper veins ruptures.[2] This illness primarily affects older adults, with a documented yearly occurrence of about 5 instances/1000 individuals.[2] The etiology of this condition involves the slow buildup of blood and fluid, which creates a lesion that occupies space.[3] If left untreated, this can cause severe neurological problems such as focused deficits, cognitive loss, and possibly life-threatening mass effects.[4]

The primary focus of CSDH management is surgical intervention, which involves removing the hematoma and preventing its reoccurrence.[5,6] Common surgical techniques for accessing the brain include twist drill craniotomy, burr-hole craniotomy (BHC), and craniectomy.[7] Among these, BHC is the most used due to its effectiveness and less invasive nature.[8] BHC is the drilling of one or more holes in the skull to drain a hematoma, with or without extra irrigation of the subdural space.[9] The ongoing debate in neurosurgical practice is around the decision between utilizing irrigation or non-irrigation procedures.[6]

Irrigation entails the introduction of salt water or other irritants into the subdural space, either during or after the removal of a hematoma, to facilitate the removal of any remaining blood products and potentially decrease the likelihood of a recurrence.[10,11] This approach is thought to help eliminate inflammatory material and remnants of hematoma, which can lead to a more complete clearance and improved clinical results.[12] Non-irrigation procedures, in contrast, depend exclusively on mechanical drainage without introducing any additional fluid to reduce surgical complexity and potential hazards related to fluid manipulation in the delicate intracranial environment.[13]

The ideal management strategy for CSDH, whether to use irrigation or not, is still uncertain due to conflicting evidence and inconsistent clinical practices despite the high occurrence of CSDH and the frequent use of surgical procedures.[14] Prior systematic reviews and meta-analyses frequently incorporated non-randomized studies or lacked precision in describing surgical procedures, so constraining their capacity to offer definitive recommendations.[10,15-17] To fill this void, this work seeks to provide a comprehensive evaluation and statistical analysis specifically centered on randomized controlled trials (RCTs) that compare the use of irrigation against no irrigation in the surgical treatment of CSDH. Our objective is to assess the relative efficacy of these methods by analyzing data from well-conducted RCTs. We will focus on recurrence rates, mortality outcomes, and postoperative complications.

This meta-analysis aimed to synthesize current evidence and offer valuable insights into improving surgical techniques for managing CSDH. Our exclusive focus on RCTs is intended to increase the dependability and relevance of our findings.

MATERIALS AND METHODS

Following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines, we conducted a systematic review and meta-analysis of clinical randomized trials (RCTs) to compare the effectiveness and safety of irrigation versus no irrigation in the treatment of CSDH. By employing this method, we were able to methodically gather and examine available information, providing significant observations regarding the possible advantages of these interventions in the management of CSDH.[18]

Literature search

We performed a comprehensive literature search using PubMed, Scopus, Web of Science, and Cochrane Library databases. Our search specifically targeted RCTs published in English that evaluated the effectiveness of irrigation versus no irrigation in the management of CSDH. The search utilized keywords for irrigation, no irrigation, and CSDH. The initial search results were evaluated for relevancy by assessing the titles and abstracts. After reviewing the whole texts of papers that could be relevant, four RCTs were included in the meta-analysis.

1. Words such as "irrigation," "no irrigation," and "CSDH" were connected by the operator to ensure that all aspects of research containing these key terms were captured during search information
2. To make the search more systematic and inclusive, the two search terms, "irrigation" and "CSDH," were searched for in their synonyms and variants using the operator OR.

Study selection

The procedure of selecting studies was undertaken separately by two writers. Both individuals conducted a comprehensive assessment of the complete papers, addressing any inconsistencies or differences of opinion through mutual agreement. The selection procedure is outlined in the PRISMA diagram flowchart [Figure 1].

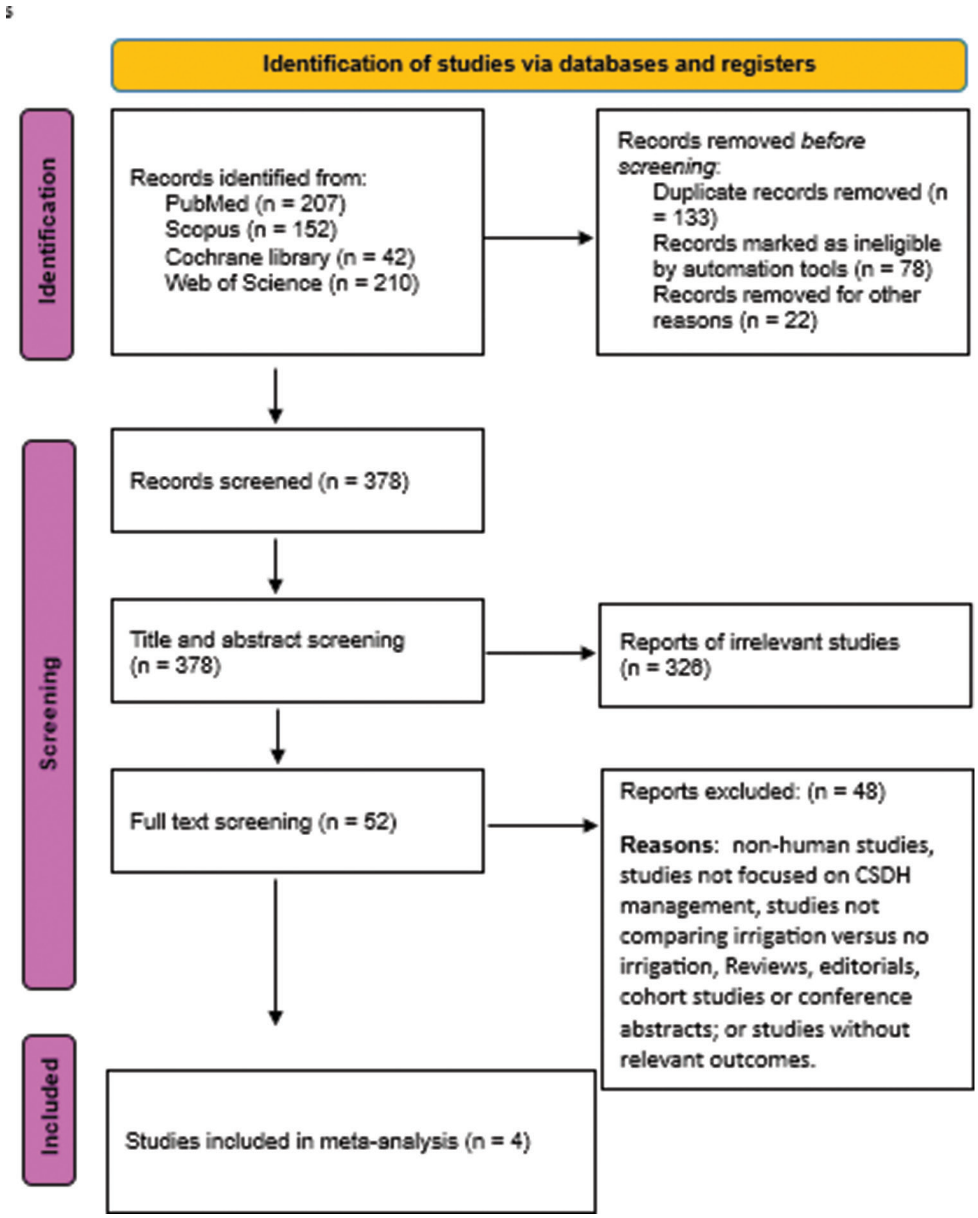

Figure 1: Identification of studies through databases and registers. This figure presents the Preferred Reporting Items for Systematic Reviews and Meta-analyses flow diagram showing the identification, screening, and inclusion process for studies included in the meta-analysis.

Initial screening

An initial search of the databases provided 611 records, which were reduced to 223 after identifying the duplicates, and 378 records were considered for screening. After identifying the titles and abstracts, both reviewers screened the studies; 326 studies were removed for not being eligible (for instance, non-RCTs or unrelated subjects).

Full-text review

Of the 52 studies, the full text was further searched to determine its suitability according to the following inclusion criteria: a randomized clinical trial that compared irrigation to no irrigation in CSDH. Of these, 48 studies were excluded on account of factors that included different interventions, study design, or lack of adequate data. Inter-observer bias was handled through conversation, or if required, the disparities were settled with a third reviewer.

Final inclusion

Out of 1264 patients, four RCTs were encompassed by inclusion criteria and applied in meta-analysis. These studies are presented in Table 1.

Table 1: Baseline characteristics of included studies.

Study ID	Country	Design	Age		Sex				Sample size		Follow-up	Main findings
			Irrigation	No irrigation	Irrigation		No irrigation		Irrigation	No irrigation		
					Male	Female	Male	Female				
Gurelik 2017 [10]	Turkey.	RCT	59.2	58.4	28	14	22	16	42	38	8 months	There was no significant difference between recurrence rates of the two groups. Since the burr-hole drainage method is simpler to carry out, its use may be preferable.
Ishibashi 2011 [11]	Japan	RCT	77.9±8.5	79.1±10	19	15	40	18	34	58	12 months	burr hole drainage with irrigation has a significantly stronger association with good outcomes compared to drainage alone and could be a reliable and effective operative method for the treatment of CSDH with a lower recurrence rate.
Raj 2024 [18]	Finland	RCT	>18 years	>18 years	424 males in 2 groups		165 females in 2 groups		294	295	6 months	there were no differences in functional outcome or mortality between the groups, the trial favors the use of subdural irrigation.
Zakaraia 2008 [26]	Malaysia	RCT	59.7	57.6	29	11	33	9	40	42	6 months	There was no significant difference between these 2 operative techniques in relation to outcomes whether good or bad.

RCT: Randomized controlled trial, CSDH: Chronic subdural hematoma

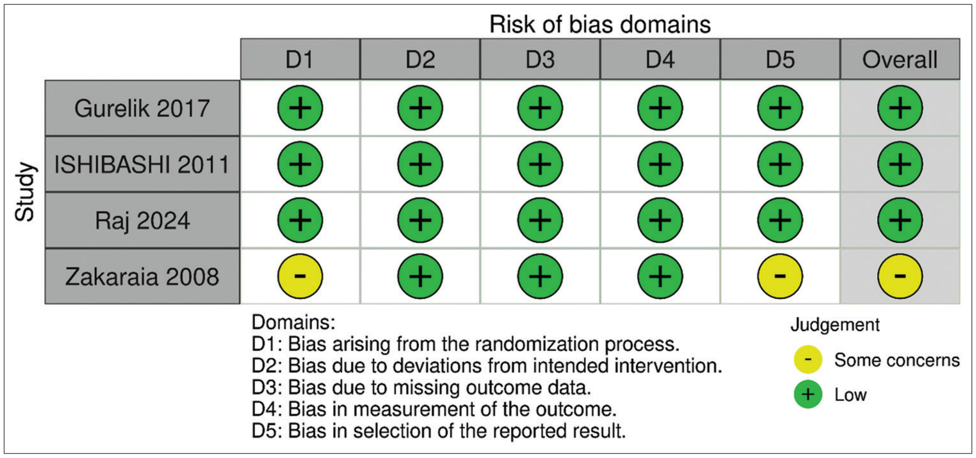

Figure 2: Quality assessment of included studies using the risk of bias 2 tool. This figure provides an overview of the risk of bias assessment for each included study, categorized as low risk, high risk, or some concerns across various domains.

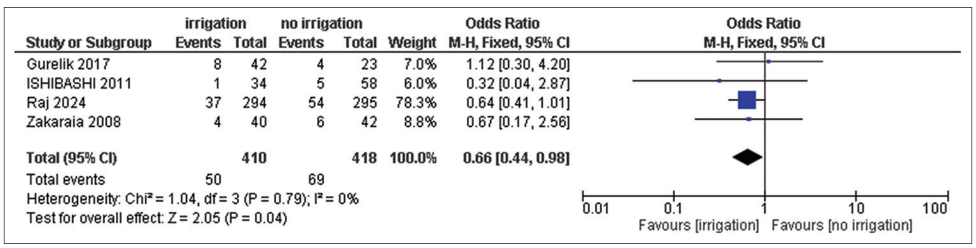

Figure 3: Comparison of outcomes between irrigation and no irrigation groups. This figure presents a forest plot of the odds ratio (OR) with 95% confidence intervals (CI) for various studies, indicating the overall effect size and heterogeneity among the included studies. M-H: Mantel-Haenszel

PRISMA flow diagram

PRISMA flow chart of study selection is presented below in Figure 1, which demonstrates the adherence to PRISMA guidelines.

Criteria for inclusion and exclusion

Inclusion criteria

1. Study design: RCTs compare the effectiveness and safety of irrigation with no irrigation in the treatment of CSDH
2. Participants: patients with CSDH who perform surgical drainage
3. Interventions: burr-hole drainage with irrigation
4. Comparator: no irrigation
5. Outcomes: Studies that reveal recurrence, mortality, and postoperative complications.

Exclusion criteria

1. Non-RCTs: Studies that are not RCTs, including observational studies, case reports, reviews, or meta-analyses
2. Additional treatments: Research investigating the comparison of different irrigation solutions or studies investigating other approaches
3. Non-English studies: Exclude articles that are not available in English to prevent potential translation bias
4. Insufficient data: Research studies that lack complete outcome data or essential information that was unattainable from the authors.

Data extraction

We collected pertinent data from the chosen research and arranged it systematically in a specialized spreadsheet. The provided material encompassed crucial details, including the study's design, the nation in which it was conducted, the sample size for each group, the age of participants (represented by the mean and standard deviation), the sex of each group, follow-up duration, and main findings. The data extraction was undertaken by two independent reviewers, who resolved any inconsistencies by discussion or third-party assessment.

Evaluating quality using risk of bias 2 (ROB2) tool

The ROB2 tool, a verified instrument for evaluating the propensity for bias in RCTs, was utilized. The evaluation encompasses bias arising from the randomization process, variations from intended interventions, missing outcome data, outcome assessment, and selection of the reported result [Figure 2]. Two experts evaluated the quality of nine pertinent research publications. All inconsistencies in the evaluations were handled by discussion and agreement, resulting in a thorough assessment of the methodological quality of the studies that were included.[3]

Measured outcomes

The primary outcome assessed in this study was the recurrence. The secondary outcomes examined were mortality and postoperative complications.

Statistical analysis and heterogeneity

The statistical analysis was conducted using the RevMan 5.3 software. The Mantel–Haenszel method was used to combine dichotomous variables (recurrence, mortality, and post-operative complications) into odds ratios (OR). The study employed a fixed effects model, which is characterized by a larger standard error, higher weighting of smaller studies, and broader confidence intervals.

Heterogeneity in the forest plots was determined through visual inspection, while the I^2 and Chi-square (χ^2) tests were employed to quantify it. The χ^2 test was used to examine the presence of significant heterogeneity, and if heterogeneity was detected, it was measured using the I^2 test. The interpretation of the I^2 test follows the standards outlined in the Cochrane Handbook for meta-analysis. According to these guidelines, an I^2 value of 0–40% may not be considered significant, 30–60% may indicate moderate heterogeneity, 50–90% may suggest substantial heterogeneity, and 75–100% may indicate significant heterogeneity.

RESULTS

Literature search

Figure 1 depicts a flow chart illustrating the process of selecting and including papers according to PRISMA

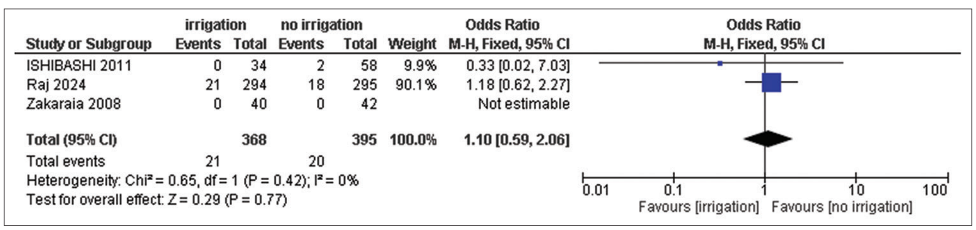

Figure 4: Comparison of adverse events between irrigation and no irrigation groups. This figure presents a forest plot of the odds ratio with 95% confidence intervals (CI) for various studies, indicating the overall effect size and heterogeneity among the included studies. M-H: Mantel-Haenszel

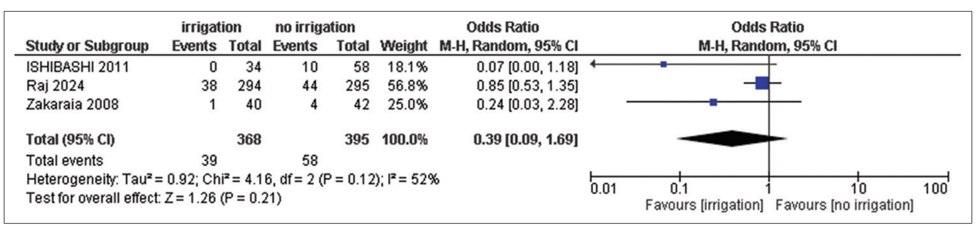

Figure 5: Comparison of surgical complications between irrigation and no irrigation groups. This figure presents a forest plot of the odds ratio with 95% confidence intervals (CI) for various studies, indicating the overall effect size and heterogeneity among the included studies. M-H: Mantel-Haenszel

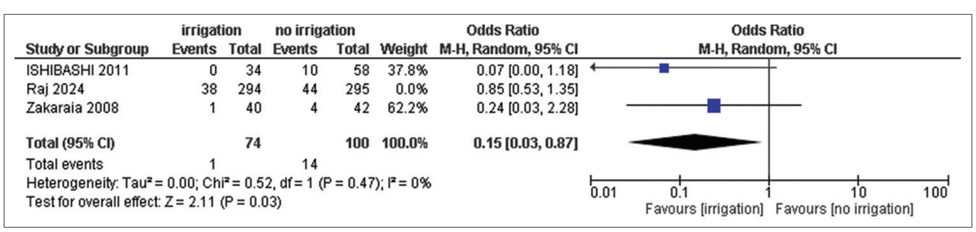

Figure 6: Comparison of postoperative infection rates between irrigation and no irrigation groups. This figure presents a forest plot of the odds ratio with 95% confidence intervals (CI) for various studies, indicating the overall effect size and heterogeneity among the included studies. M-H: Mantel-Haenszel

guidelines.[18] An electronic search of databases yielded 611 records. Out of these, 378 records were considered for title and abstract screening, while the remaining 223 were found to be duplicates. In addition, 326 records were discarded since they did not match our inclusion criteria. We performed a comprehensive examination of the complete texts of the 52 relevant studies. After conducting a thorough examination of the whole texts, we identified 4 studies that matched our specific criteria for inclusion in our analysis. These studies involved a total of 843 patients and are depicted in Figure 1.

Characteristics of the included studies

The 4 studies that were included in the analysis involved a combined total of 843 patients. These studies were conducted in various countries indicating the generalizability of our results. The interventions in these studies differed, comparing the use of irrigation versus no irrigation in the management of CSDH. A summary of characteristics can be found in Table 1**.**

Quality assessment evaluation

The methodological quality of each trial was thoroughly evaluated using the Cochrane ROB Tool for Randomized Trials.[19] Three of the studies included in the analysis were assessed as having a low ROB in all areas, showing a robust and rigorous methodology, while one study showed some concerns in at least one domain.

The ROB2 tool evaluates the ROB across several subdomains, including

1. Bias arising from the randomization process: Guarantees that participants were correctly assigned into the groups they participated in, thus controlling for selection bias
2. Bias due to deviations from intended interventions: Assessing the role of the performance bias by comparing the participants' and investigators' adherence to the intended intervention strategies
3. Bias due to missing outcome data: Encourages the understanding of how missing data reduces the accuracy of the study's findings
4. Bias in the measurement of the outcome: Reviews the measures employed in determining the outcome in regard to both consistency and objectivity
5. Bias in the selection of the reported result: This helped in making sure that all pre-specified outcomes were reported hence reducing reporting bias.

Data analysis

Recurrence

The analysis included data from four RCTs involving a total of 843 patients to assess the recurrence of CSDH following irrigation versus no irrigation treatments. The pooled (OR) for recurrence favored irrigation, with an OR of 0.66 (95% CI: 0.44–0.98), indicating a statistically significant difference in favor of irrigation (P = 0.04). There was no heterogeneity among the studies (I^2 = 0%) [Figure 3].

Mortality

Mortality outcomes were analyzed across the same 3 RCTs with 763 patients. The pooled OR for mortality was 1.10 (95% CI: 0.59–2.06), indicating no significant difference between irrigation and no irrigation groups in terms of mortality risk (P = 0.77). There was no heterogeneity among the studies (I^2 = 0%) [Figure 4].

Postoperative complications

The analysis of postoperative complications included data from the 3 RCTs with 763 patients. The pooled OR was 0.39 (95% CI: 0.09–1.69), suggesting no significant difference in the risk of postoperative complications between irrigation and no irrigation groups (P = 0.21). Heterogeneity among the studies was moderate (I^2 = 52%) [Figure 5]**.** This heterogeneity was resolved after removing Raj *et al.*[18] in sensitivity analysis and the pooled analysis of OR became significant favoring the irrigation group (P = 0.03) indicating lower complication in irrigation group [Figure 6].

DISCUSSION

In this systematic review and meta-analysis, four RCTs involving 843 patients were included, comparing irrigation versus no irrigation techniques in CSDH management. These trials, conducted globally, presented consistent surgical approaches but varied in irrigation use. Using the Cochrane ROB Tool, three studies demonstrated robust methodologies, while one showed minor concerns. The meta-analysis indicated a significant benefit of irrigation in reducing recurrence rates (P = 0.04), with no heterogeneity observed. Mortality outcomes did not significantly differ between groups and initial moderate heterogeneity in post-operative complications was resolved post-sensitivity analysis, suggesting potential advantages with irrigation (P = 0.03).

Aljabali *et al.*[5] meta-analysis, involving 12 studies and 1550 patients, reported no significant difference in recurrence rates between irrigation and no irrigation groups (OR = 0.94, 95% CI: 0.55–1.06, P = 0.81) despite observing initial heterogeneity. Mortality outcomes also showed no significant difference,[15] while our systematic review and meta-analysis, encompassing 4 RCTs with 843 patients, found irrigation significantly reduced recurrence rates (OR = 0.66, 95% CI: 0.44–0.98, P = 0.04) without heterogeneity. Mortality outcomes did not differ significantly between groups, and initial moderate heterogeneity in complications was resolved post-sensitivity analysis, suggesting potential benefits with irrigation ($P = 0.03$).

In our systematic review and meta-analysis of four RCTs involving 843 patients, irrigation significantly reduced the recurrence of CSDH compared to no irrigation (OR = 0.66, 95% CI: 0.44–0.98, $P = 0.04$), with no observed heterogeneity ($I^2 = 0\%$). This underscores irrigation's potential benefit in reducing recurrence rates, supporting its clinical utility. Conversely, Zhu *et al.*'s comprehensive meta-analysis of 402 studies found no significant association between irrigation and recurrence ($P = 0.81$), suggesting variability in findings across broader study contexts.[27] Our analysis also revealed no significant difference in mortality outcomes between irrigation and no irrigation groups ($P = 0.77$), aligning with Zhu *et al.*'s emphasis on patient-related factors influencing mortality risk in CSDH surgery.[27] Initial findings of no significant difference in postoperative complications ($P = 0.21$), with resolved heterogeneity favoring irrigation post-sensitivity analysis ($P = 0.03$), suggest potential advantages of irrigation in reducing complications.[19]

Our findings contrast with the findings of Yuan *et al.*,[25] who conducted a meta-analysis of seven retrospective cohort studies and two RCTs involving 993 participants and found no significant difference in recurrence rates between burr-hole drainage with irrigation (BHDI) and without irrigation (BHD) (OR = 1.27, 95% CI: 0.61–2.63, $P = 0.53$). In addition, Yuan *et al.* reported no significant difference in recurrence when analyzing the two RCTs separately (OR = 1.14, 95% CI: 0.16–8.24, $P = 0.95$). Our results also indicated no significant difference in mortality ($P = 0.77$), aligning with Yuan *et al.*'s findings (OR = 0.94, 95% CI: 0.14–6.16, $P = 0.95$).[25] However, while we found initial findings of no significant difference in postoperative complications ($P = 0.21$) with heterogeneity resolved in favor of irrigation post-sensitivity analysis ($P = 0.03$), Yuan *et al.* observed no significant difference in pneumocephalus rates (OR = 5.91, 95% CI: 0.61–56.86, $P = 0.12$).[25]

The recurrence of CSDH following surgery may be attributed to multiple factors, including the pathophysiology of CSDH, advanced age, reduced brain re-expansion, bilateral CSDH, and large hematoma size. This may be attributed to a multitude of variables that contribute to the development of CSDH, including the specific pathophysiology of CSDH, advanced age, decreased brain re-expansion following surgery, bilateral CSDH, and the presence of a big hematoma.[21] The presence of an early hematoma, as well as the administration of anticoagulant medication, have been documented in previous studies.[22,23] The presence of inflammatory mediators, such as interleukin 6, is evident. It has been proposed that the presence of growth factors in the subdural fluid increases the chances of recurrence. Furthermore, the historical account of the recurrence of CSDH is associated with the presence of malignant tumors and a specific form of hematoma identified in computed tomography (CT) examination.[24]

The FINISH trial, conducted by Raj *et al.*, was a Finnish, nationwide, multicenter, randomized, controlled, non-inferiority trial comparing burr-hole drainage with and without irrigation for the treatment of CSDH. Enrolling 589 patients from five neurosurgical units, the study aimed to determine if non-inferiority of the no-irrigation approach could be established. The primary outcome was the reoperation rate within 6 months, with a non-inferiority margin set at 7.5%. The trial found that 18.3% of participants in the no-irrigation group required reoperation compared to 12.6% in the irrigation group, with a difference of 6.0 percentage points (95% CI 0.2–11.7; $P = 0.30$), indicating higher reoperation rates without irrigation. There were no significant differences in functional outcomes or mortality rates between the groups, nor in the number of adverse events. These findings suggest that while functional outcomes and mortality are similar, burr-hole drainage with irrigation reduces the need for reoperation, thereby favoring the use of subdural irrigation.[25]

Limitations

This meta-analysis has several limitations that should be acknowledged. First, the relatively small number of included RCTs (four) and the total sample size (843 patients) may limit the generalizability of the findings. In addition, the studies varied in terms of their methodologies, patient populations, and definitions of outcomes, which could introduce heterogeneity and affect the results. The potential for publication bias is another concern, as studies with non-significant results might be underreported. Furthermore, the included trials did not consistently report on all secondary outcomes, such as detailed postoperative complications, which may lead to an incomplete assessment of the safety profile of the interventions.

CONCLUSION

This systematic review and meta-analysis of four RCTs indicate that burr-hole drainage with irrigation significantly reduces the recurrence rate of CSDH compared to burr-hole drainage without irrigation. Our findings support the use of irrigation during CSDH surgery as it may lower the need for reoperations without significantly impacting mortality or increasing postoperative complications. Despite the limitations, this analysis provides valuable evidence favoring the incorporation of irrigation into surgical protocols for CSDH management. Further, large-scale, high-quality RCTs are warranted to confirm these results and to explore the long-term outcomes and safety of irrigation in diverse patient populations.

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Author's contributions

Conceptualization, Writing – original draft, Writing – review and editing: All authors.

Data availability statement

All data are available on the internet.

Ethical approval

Institutional Review Board approval is not required.

Declaration of patient consent

Patient's consent is not required as there are no patients in this study.

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Conflicts of interest

There are no conflicts of interest.

Use of artificial intelligence (AI)-assisted technology for manuscript preparation

The authors confirm that there was no use of artificial intelligence (AI)-assisted technology for assisting in the writing or editing of the manuscript and no images were manipulated using AI.

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