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# Efficacy and safety of endovascular mechanical thrombectomy for cerebral venous sinus thrombosis: meta-analysis

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**ADMINISTRATIVE INFORMATION**

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## INTRODUCTION

**Review question / Objective** The research objective of this study is to evaluate the efficacy and safety of endovascular mechanical thrombectomy (EMT) for patients with cerebral venous sinus thrombosis (CVST) through a meta-analytic approach. The aim is to determine whether EMT provides significant benefits or risks compared to other treatments in terms of outcomes such as death, modified Rankin Scale (mRS) score of ≤2, recurrence, and complications. The study seeks to provide a comprehensive assessment of EMT's role in treating CVST, especially considering its use in high-risk or deteriorating patients, and to identify potential factors that may influence its effectiveness and safety profile.

**Condition being studied** The condition being studied in this manuscript is cerebral venous sinus thrombosis (CVST). CVST is a neurological disorder characterized by the formation of blood clots in the venous sinuses of the brain. It is a significant cause of cerebral hemorrhage and venous infarction. The prevalence of CVST in the general population is reported to be 1.32 per 100,000 person-years. It predominantly affects women aged 31–50 years, with an incidence of 2.78 per 100,000 person-years in this demographic, accounting for approximately 0.5% of all stroke cases. CVST often occurs in young adults and is more common in individuals with prothrombotic states. The condition can extend into major cortical veins, which substantially increases the risk of cerebral edema, hemorrhage, or venous infarction. Prompt diagnosis and intervention are essential for improving the prognosis of patients with CVST.

## METHODS

**Participant or population** The review addresses participants who are patients diagnosed with cerebral venous sinus thrombosis (CVST). The

inclusion criteria for participants in the studies reviewed are as follows:

1. **Patients with CVST**: All included patients must have a confirmed diagnosis of cerebral venous sinus thrombosis.
2. **Treatment with EMT**: Participants who received endovascular mechanical thrombectomy (EMT) as a treatment modality were included. This encompasses various EMT techniques such as direct catheter thrombolysis, balloon-assisted thrombectomy, rheolytic catheter thrombectomy, aspiration thrombectomy, or stent retriever thrombectomy.
3. **Comparison Groups**: The review also included patients who received anticoagulation therapy or other endovascular treatments as controls.
4. **Outcome Measures**: Participants whose outcomes were reported in terms of death, modified Rankin Scale (mRS) score of ≤2, recurrence of thrombosis, and complications (including periprocedural and postprocedural complications such as intracranial hemorrhage, infection, headache, quadriplegia, dizziness and drowsiness, intracranial hypertension, and catheter-related complications) were considered.

The review excluded case reports, reviews, and studies with overlapping data published by the same institution, focusing on randomized controlled trials, prospective cohort studies, and retrospective cohort studies that met the specified criteria.

**Intervention** In this review, the intervention being evaluated is endovascular mechanical thrombectomy (EMT) for the treatment of cerebral venous sinus thrombosis (CVST). EMT is a procedure that involves the mechanical removal of blood clots from the cerebral venous sinuses. The specific types of EMT interventions included in the studies reviewed are:

1. **Direct Catheter Thrombolysis**: This involves the direct application of thrombolytic agents to the site of the thrombus.
2. **Balloon-Assisted Thrombectomy**: This technique uses a balloon to assist in the removal of the thrombus.
3. **Rheolytic Catheter Thrombectomy**: This method employs a special catheter that uses fluid dynamics to break up and remove the clot.
4. **Aspiration Thrombectomy**: This involves suctioning the thrombus out of the venous sinus.
5. **Stent Retriever Thrombectomy**: This technique uses a stent-like device to retrieve and remove the clot.

These interventions are compared against control groups that received either anticoagulation therapy or other endovascular treatments. The review aims to assess the efficacy and safety of EMT in terms of outcomes such as death, modified Rankin Scale (mRS) score of ≤2, recurrence of thrombosis, and complications associated with the procedure.

**Comparator** In this meta-analysis, the comparative interventions applied to the target population of patients with cerebral venous sinus thrombosis (CVST) include:

1. **Anticoagulation Therapy**: This is the standard treatment approach for CVST, aimed at preventing clot expansion and facilitating the natural dissolution of the thrombus. It serves as a control in comparing the efficacy and safety of endovascular mechanical thrombectomy (EMT).

2. **Other Endovascular Treatments**: These may include various minimally invasive procedures targeting the thrombus, such as intrasinus catheter-directed thrombolysis, where thrombolytic agents are directly infused into the affected venous sinus. These treatments are used as additional comparators to evaluate the specific benefits and risks of EMT.

By comparing EMT with these alternative interventions, the study aims to determine whether EMT offers superior, equivalent, or inferior outcomes in terms of mortality, functional recovery (measured by modified Rankin Scale score ≤2), recurrence of thrombosis, and complications.

**Study designs to be included** Meta-analysis.

**Eligibility criteria** In addition to the PICOS criteria, the following inclusion and exclusion criteria were applied in this meta-analysis:

### Inclusion Criteria
- **Study Design**: Randomized controlled trials, prospective cohort studies, and retrospective cohort studies were included.
- **Publication Status**: There were no restrictions on publication language or study status. Studies published in any language and with any status (e.g., published, unpublished) were considered.
- **Data Availability**: Studies that provided sufficient data to calculate effect sizes (e.g., odds ratios) for the outcomes of interest were included.

### Exclusion Criteria
- **Case Reports and Reviews**: Case reports, reviews, and editorials were excluded as they do not provide comparative data.

- **Overlapping Data**: Studies with overlapping data published by the same institution were excluded to avoid duplication of results.
- **Insufficient Data**: Studies that lacked sufficient data to assess the outcomes of interest (e.g., death, mRS ≤2, recurrence, complications) were excluded.
- **Non-Comparative Studies**: Studies that did not include a control group receiving anticoagulation or other endovascular treatments were excluded.

These additional criteria ensured that the studies included in the meta-analysis were of appropriate design and provided relevant comparative data to assess the efficacy and safety of endovascular mechanical thrombectomy for cerebral venous sinus thrombosis.

**Information sources** The intended information sources for this meta-analysis included multiple electronic databases to ensure a comprehensive search for relevant studies. Specifically, the following databases were systematically searched for eligible studies from their inception until May 2023:

1. **PubMed**: A primary database for biomedical literature, providing access to a vast collection of articles from various medical journals.
2. **EmBase**: A comprehensive database covering biomedical literature, with a focus on drug and pharmaceutical research, as well as medical device information.
3. **Cochrane Library**: A collection of high-quality, independent evidence to inform healthcare decision-making, including systematic reviews, clinical trials, and other evidence-based resources.

In addition to these databases, the reference lists of relevant reviews and original articles were manually searched to identify any additional eligible studies that might have been missed in the electronic searches. This approach ensured that all potential sources of relevant data were explored, enhancing the comprehensiveness of the study selection process.

No restrictions were placed on publication language or study status, meaning that studies published in any language and with any status (e.g., published, unpublished) were considered for inclusion. This inclusive approach aimed to minimize potential biases and ensure that all relevant data were captured for the meta-analysis.

**Main outcome(s)** The outcomes assessed in this review include death, modified Rankin Scale (mRS) score ≤2, recurrence of cerebral venous sinus thrombosis (CVST), and complications. The timing of these outcomes varied across studies, with follow-up durations ranging from a few days to several months. Effect measures were calculated using odds ratios (ORs) with 95% confidence intervals (CIs). The random-effects model was used to pool the data and account for potential heterogeneity among studies. The primary findings were as follows:

- **Death**: EMT was associated with an increased risk of death (OR: 1.84; 95% CI: 1.04–3.28; P = 0.037).
- **mRS ≤2**: No significant association was found between EMT and the proportion of patients achieving an mRS score of ≤2 (OR: 0.94; 95% CI: 0.40–2.20; P = 0.891).
- **Recurrence**: EMT had no significant effect on the risk of recurrence (OR: 0.80; 95% CI: 0.33–1.89; P = 0.605).
- **Complications**: EMT was not significantly associated with the risk of complications (OR: 1.38; 95% CI: 0.56–3.40; P = 0.487).

These results suggest that while EMT may increase the risk of death, it does not significantly impact functional outcomes, recurrence, or complications in patients with CVST.

**Quality assessment / Risk of bias analysis** The quality assessment of the primary studies included in this meta-analysis was conducted using the Newcastle–Ottawa Scale (NOS). The NOS is a widely used tool for assessing the quality of non-randomized studies in meta-analyses. It evaluates studies based on three main domains: selection, comparability, and outcome. Each domain is assigned a specific number of "stars" to reflect the study's quality, with a total possible score ranging from 0 to 9 stars.

### Assessment Domains:
1. **Selection**:
- **Representativeness of the exposed cohort**: Assessing whether the study population is representative of the general population.
- **Selection of the non-exposed cohort**: Evaluating how well the control group was selected.
- **Ascertainment of exposure**: Determining the reliability of the exposure assessment.
- **Demonstration that the outcome of interest was not present at the start of the study**: Ensuring that the study accounted for pre-existing conditions.

2. **Comparability**:

- **Adjustment for important confounders**: Evaluating whether the study adequately controlled for potential confounding variables.
- **Comparability of cohorts on the basis of the design or analysis**: Assessing whether the study design or analysis accounted for differences between groups.

3. **Outcome**:
- **Assessment of outcome**: Determining the reliability of the outcome assessment.
- **Follow-up period**: Evaluating the adequacy of the follow-up duration.
- **Completeness of follow-up**: Assessing whether the study accounted for losses to follow-up.

### Scoring:
Each study was assigned a score based on the number of stars it received across these domains. The scores were used to evaluate the overall quality of the studies, with higher scores indicating better quality. The quality assessment helped to identify potential biases and limitations in the included studies, thereby providing a more accurate interpretation of the pooled results.

In this meta-analysis, the quality assessment using the NOS revealed that there were eight studies with six stars and eight studies with five stars, indicating generally good quality among the included studies.

**Strategy of data synthesis** The data analysis in this meta-analysis was conducted using a comprehensive and systematic approach to assess the efficacy and safety of endovascular mechanical thrombectomy (EMT) for patients with cerebral venous sinus thrombosis (CVST). The primary methods and steps involved in the analysis are described as follows:

### Effect Measures and Statistical Analysis
- **Effect Estimates**: The efficacy and safety of EMT were assessed using odds ratios (ORs) with 95% confidence intervals (CIs). These measures were chosen to quantify the association between EMT and the outcomes of interest, including death, modified Rankin Scale (mRS) score ≤2, recurrence, and complications.
- **Random-Effects Model**: The random-effects model was applied to calculate the pooled effect estimates. This model was selected to account for potential heterogeneity among the included studies, acknowledging that different studies might have varying effects due to differences in patient populations, study designs, and interventions.

### Heterogeneity Assessment
- **$I^2$ and Cochran Q Statistic**: These were used to assess heterogeneity among the studies. An $I^2$ value of ≥50.0% or a P value <0.10 was considered to indicate significant heterogeneity. This assessment helped to determine whether the observed variation in effect sizes was due to chance or to true differences between studies.

### Sensitivity and Subgroup Analyses
- **Sensitivity Analysis**: This was performed to determine the robustness of the pooled conclusions. The analysis involved sequentially removing a single study to see if the overall results were significantly altered. This step helped to identify any individual studies that might be disproportionately influencing the results.
- **Subgroup Analyses**: These were conducted to explore potential sources of heterogeneity and to assess the impact of various factors on the outcomes. Subgroup analyses were performed based on study design (prospective vs. retrospective), sample size, mean age, male proportion, control group characteristics, follow-up duration, and study quality. The differences between subgroups were compared using interaction P tests.

### Publication Bias Assessment
- **Funnel Plots**: These were used to visually assess for publication bias. Funnel plots graphically display the effect size against a measure of study precision, helping to identify asymmetry that might suggest publication bias.
- **Egger and Begg Tests**: These quantitative methods were used to statistically assess for publication bias. The P values from these tests indicated whether there was significant evidence of publication bias.

### Software and Significance Levels
- **Statistical Software**: All statistical analyses were performed using STATA (version 12.0; Stata Corporation, College Station, TX, USA). This software was chosen for its robust capabilities in handling meta-analytic data and performing the necessary statistical tests.
- **Significance Levels**: The reported P values for pooled conclusions were two-sided, with a significance level set at P <0.05.

Overall, the data analysis was designed to provide a comprehensive and rigorous evaluation of the efficacy and safety of EMT for CVST, accounting for potential biases and heterogeneity among studies.

**Subgroup analysis** Subgroup analyses were conducted to explore the potential impact of various factors on the efficacy and safety of endovascular mechanical thrombectomy (EMT) for cerebral venous sinus thrombosis (CVST). These analyses aimed to identify whether specific study characteristics or patient demographics influenced the outcomes.

### Factors Considered in Subgroup Analyses:
1. **Study Design**: Studies were categorized as prospective or retrospective to assess whether the method of data collection influenced the outcomes.
2. **Sample Size**: Subgroups were created based on sample size (≥100 vs. <100) to determine if larger studies had different results compared to smaller ones.
3. **Mean Age**: Subgroups were formed based on the mean age of the included patients (≥40.0 years vs. <40.0 years) to explore the potential impact of age on treatment outcomes.
4. **Male Proportion**: Subgroups were created based on the proportion of male patients (≥50.0% vs. 6.0 months) to evaluate the impact of follow-up duration on outcomes.
7. **Study Quality**: Subgroups were created based on the quality score assigned using the Newcastle–Ottawa Scale (NOS) to assess whether higher-quality studies had different results compared to lower-quality ones.

### Key Findings from Subgroup Analyses:
- **Death**: EMT was associated with an increased risk of death in subgroups with prospective design, mean age ≥40.0 years, male proportion ≥50.0%, and follow-up duration ≤6.0 months.
- **mRS ≤2**: The effect of EMT on the proportion of patients achieving mRS ≤2 was influenced by study design, sample size, mean age, male proportion, and control group characteristics. Specifically, EMT was associated with a reduced proportion of mRS ≤2 in studies with a sample size ≥100.
- **Recurrence**: No significant differences were observed in the risk of recurrence across any of the subgroups.
- **Complications**: The effect of EMT on the risk of complications was influenced by sample size and male proportion. EMT was associated with an increased risk of complications in studies with a sample size ≥100, while it was associated with a reduced risk of complications in studies with a male proportion ≥50.0%.

These subgroup analyses provided insights into the potential factors that may influence the efficacy and safety of EMT for CVST. However, the results.

**Sensitivity analysis** Sensitivity analysis was performed to assess the robustness of the pooled conclusions in this meta-analysis. The analysis involved sequentially removing a single study from the dataset to determine whether the overall results were significantly altered by any individual study. This approach helped to identify potential outliers or studies that might be disproportionately influencing the pooled effect estimates.

### Key Findings from Sensitivity Analysis:
1. **Risk of Death**:
- The pooled conclusion that endovascular mechanical thrombectomy (EMT) was associated with an increased risk of death (OR: 1.84; 95% CI: 1.04–3.28; P = 0.037) was found to be not stable. Sequential removal of individual studies revealed that the pooled result could be significantly affected by certain studies. This suggests that the association between EMT and increased mortality may not be consistent across all studies and could be influenced by specific studies with higher mortality rates.

2. **mRS ≤2**:
- The pooled conclusion that EMT had no significant effect on the proportion of patients achieving a modified Rankin Scale (mRS) score of ≤2 (OR: 0.94; 95% CI: 0.40–2.20; P = 0.891) was robust. The sensitivity analysis showed that the pooled result was not significantly affected by the removal of any single study. This indicates that the overall finding regarding functional outcomes (mRS ≤2) is stable and not driven by a particular study.

3. **Recurrence**:
- The pooled conclusion that EMT had no significant effect on the risk of recurrence (OR: 0.80; 95% CI: 0.33–1.89; P = 0.605) was also stable. The sensitivity analysis confirmed that the pooled result remained unchanged regardless of which individual study was removed. This suggests that the finding regarding recurrence is consistent across the included studies.

4. **Complications**:
- The pooled conclusion that EMT was not associated with the risk of complications (OR: 1.38; 95% CI: 0.56–3.40; P = 0.487) was stable. The sensitivity analysis showed that the pooled result was not altered by sequentially excluding individual studies. This indicates that the finding regarding complications is robust and not influenced by any particular study.

### Conclusion:
The sensitivity analysis provided insights into the stability of the pooled results. While the finding that

EMT increased the risk of death was not stable and may be influenced by specific studies, the results regarding mRS ≤2, recurrence, and complications were robust. This suggests that the overall findings for these outcomes are reliable and not driven by individual studies. However, further investigation is needed to understand the factors contributing to the variability in the mortality results.

**Country(ies) involved** China.

**Keywords** endovascular mechanical thrombectomy; cerebral venous sinus thrombosis; prognosis; safety profile; meta-analysis.

**Contributions of each author**
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