

INPLASY PROTOCOL

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None declared.

Mechanical thrombectomy with or without intravenous thrombolysis in patients with acute ischemic stroke: a systematic review and meta-analysis

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Review question / Objective: The objective of this systematic review was to evaluate the efficacy and safety of mechanical thrombectomy with or without intravenous thrombolysis in patients with acute ischemic stroke.

Condition being studied: Acute ischemic stroke.

Information sources: Clinicaltrials.gov and three main databases including MEDLINE, EMBASE, and Cochrane Library.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 24 March 2021 and was last updated on 24 March 2021 (registration number INPLASY202130094).

INTRODUCTION

Review question / Objective: The objective of this systematic review was to evaluate the efficacy and safety of mechanical thrombectomy with or without intravenous thrombolysis in patients with acute ischemic stroke.

Condition being studied: acute ischemic stroke.

METHODS

Search strategy: Two independent investigators (XW and YG) systematically searched the Clinicaltrials.gov and three

main databases including MEDLINE, EMBASE, and Cochrane Library to identify relevant studies published until March 2021. The following search strategy was used: (mechanical thrombectomy[Title/Abstract]) OR (intravenous thrombolysis[Title/Abstract]) AND (acute ischemic stroke [Title/Abstract]) for MEDLINE; `mechanical thrombectomy'/exp OR `intravenous thrombolysis '/exp AND `acute ischemic stroke'/exp for EMBASE; "mechanical thrombectomy" OR "intravenous thrombolysis" in Title Abstract Keyword AND "acute ischemic stroke" in Title Abstract Keyword for Cochrane Library; “mechanical thrombectomy or intravenous thrombolysis | acute ischemic stroke” for Clinicaltrials.gov. Additionally, the reference lists of RCTs, relevant systematic reviews and meta-analyses were also screened independently and manually to ensure a more comprehensive search.

Participant or population: Adult patients diagnosed with acute ischemic stroke.

Intervention: Patient undergoes intravenous thrombolysis before mechanical thrombectomy.

Comparator: Patient does not undergoes intravenous thrombolysis before mechanical thrombectomy.

Study designs to be included: Only randomized controlled trials will be included.

Eligibility criteria: We set the inclusion criteria as follows: (1) study type: RCT; (2) language restriction: only available in English; (3) participants: adult patients diagnosed with acute ischemic stroke; (4) intervention: mechanical thrombectomy with or without intravenous thrombolysis; (5) outcomes: our primary outcome was patients achieving functional independence (modified Rankin Scale, mRS, 0 to 2) at 3 months. Secondary efficacy outcomes included patients achieving excellent outcome (mRS 0-1) at 3 months, patients achieving reperfusion at final angiogram or follow-up CT or MRI, the change of national

institutes of health stroke scale (NIHSS) score from baseline to 24h or 5-7 days and the score of European Quality of Life 5-Dimension 5-level scale (EQ-5D-5L) at 3 months. Safety outcomes including death (mRS 6), patients with at least 1 serious adverse event, any intracranial hemorrhage (ICH), symptomatic ICH (according to the definition used in each study), large or malignant middle cerebral artery (MCA) infarction, respiratory dysfunction, patients with at least 1 procedure-associated complication, clot migration, contrast extravasation, puncture access complications and arterial dissection. Included RCTs were not requested to supply all the outcomes mentioned above.

Information sources: Clinicaltrials.gov and three main databases including MEDLINE, EMBASE, and Cochrane Library.

Main outcome(s): Our primary outcome was patients achieving functional independence (modified Rankin Scale, mRS, 0 to 2) at 3 months.

Additional outcome(s): Secondary efficacy outcomes included patients achieving excellent outcome (mRS 0-1) at 3 months, patients achieving reperfusion at final angiogram or follow-up CT or MRI, the change of national institutes of health stroke scale (NIHSS) score from baseline to 24h or 5-7 days and the score of European Quality of Life 5-Dimension 5-level scale (EQ-5D-5L) at 3 months. Safety outcomes including death (mRS 6), patients with at least 1 serious adverse event, any intracranial hemorrhage (ICH), symptomatic ICH (according to the definition used in each study), large or malignant middle cerebral artery (MCA) infarction, respiratory dysfunction, patients with at least 1 procedure-associated complication, clot migration, contrast extravasation, puncture access complications and arterial dissection. Included RCTs were not requested to supply all the outcomes mentioned above.

Quality assessment / Risk of bias analysis: The risk of bias plot for individual studies was assessed with the Review Manager 5.3

software. The uniform criteria to assess the risk of bias for RCTs of the Cochrane Collaboration was applied, which included: selection bias, performance bias, detection bias, attrition bias, reporting bias, and other potential biases. Each bias criterion was classified as “low”, “high”, or “unclear” after independently judged by the third reviewer.

Strategy of data synthesis: Review Manager 5.3 software was used to assess the data. For the dichotomous outcomes, the risk ratio (RR) and odds ratio (OR) were analyzed and calculated with a random effect model. Mean difference (MD) was used for the continuous outcomes. For all the analyses, two tailed tests were performed and a P value < 0.05 was considered to be statistical significant.

Subgroup analysis: Not applicable in this study

Sensitivity analysis: Heterogeneity was estimated via the I² statistic, which was as follows: I² < 30% suggests “low heterogeneity”; I² between 30% and 50% means “moderate heterogeneity”; I² > 50% denotes “substantial heterogeneity”. Sensitivity analysis was used to explore the stability of the consolidated results.

Country(ies) involved: China.

Keywords: mechanical thrombectomy, intravenous thrombolysis, acute ischemic stroke.

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