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Thrombectomy Using the EmboTrap Clot-Retrieving Device for the Treatment of Acute Ischemic Stroke: A Glimpse of Clinical Evidence

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ABSTRACT

BACKGROUND: The EmboTrap Recanalization Device is a novel stent retriever for thrombectomy in the setting of acute ischemic stroke due to large-vessel occlusion.

PURPOSE: Our aim was to summarize the safety and efficacy of the EmboTrap Recanalization Device in acute ischemic stroke—large-vessel occlusion through a systematic review and meta-analysis.

DATA SOURCES: Medline, EMBASE, the Cochrane Library, Web of Science, and Google Scholar were searched up to April 2022.

STUDY SELECTION: Nine observational studies using the EmboTrap Recanalization Device were selected.

DATA ANALYSIS: We adapted effect size with 95% CIs for dichotomous data. *P* value <.05 was statistically significant.

DATA SYNTHESIS: The estimated rate of successful recanalization (modified TICl 2b–3) was 90% (95% CI, 86%–95%; $I^2 = 82.4\%$); 90-day favorable outcome (mRS 0–2), 53% (95% CI, 42%–63%; $I^2 = 88.6\%$); modified first-pass effect, 43% (95% CI, 35%–51%; $I^2 = 63.7\%$); and first-pass effect, 36% (95% CI, 29%–46%; $I^2 = 10.7\%$). The rate of any intracerebral hemorrhage was 19% (95% CI, 16%–22%; $I^2 = 0.0\%$); symptomatic intracerebral hemorrhage, 5% (95% CI, 1%–8%; $I^2 = 84.6\%$); and 90-day mortality, 14% (95% CI, 9%–19%; $I^2 = 79.3\%$). Subgroup analysis showed higher rates of complete recanalization for EmboTrap II than for the EmboTrap System.

LIMITATIONS: The included studies are single-arm without direct comparison with other stent retrievers. Some of the studies recruited had a small sample size and were limited by the retrospective study design. In addition, the uncertain heterogeneity among studies was high.

CONCLUSIONS: The EmboTrap Recanalization Device is safe and efficient in treating acute ischemic stroke due to large-vessel occlusion.

ABBREVIATIONS: AIS = acute ischemic stroke; FPE = first-pass effect; ICH = intracerebral hemorrhage; LVO = large-vessel occlusion; mFPE = modified first-pass effect; MT = mechanical thrombectomy; mTICl = modified TICl; sICH = symptomatic intracerebral hemorrhage

Acute ischemic stroke (AIS) is a major cause of morbidity and mortality, and effective reperfusion of the affected tissue is

the most important defining factor for favorable outcomes.¹ Several trials have demonstrated the clinical benefit and superior reperfusion efficacy of mechanical thrombectomy (MT) using stent-retriever thrombectomy devices after AIS.^{2–4} Current guidelines recommended MT as the first-line therapy for AIS due to large-vessel occlusion (LVO).^{1,2,5} Currently, there are several types of stent-retriever thrombectomy devices studied that were used in clinical trials and nonclinical studies. Although the overall function of MT devices is similar, many aspects, such as distinct mechanisms of action, differing 3D structures, and the interaction between the stent retriever and vessel wall, may lead to different results and clinical consequences.^{6–8}

The EmboTrap Revascularization Device is an innovative stent retriever used to retrieve clots and restore blood flow.^{8–12} It offers a 2-layer structure designed with articulating petals and a distal

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capture zone for successful trapping, retention, and removal of diverse clot types to restore blood flow in AIS-LVO. The inner layer is a closed-cell stent, which aims to restore blood flow immediately. The external layer units include open inlet ports for catching clots during device retraction and articulating petals that promote clot entrapment and retention. High rates of substantial perfusion and functional independence have been demonstrated in patients with AIS-LVO from the single-arm trial, Analysis of Revascularization in Ischemic Stroke With EmboTrap (ARISE II).⁸ Thereafter, several studies tried to explore the safety and efficacy of the EmboTrap device in treating AIS-LVO based real-world data.^{11,12} In this study, we performed a systematic review and meta-analysis to evaluate the clinical benefit of the EmboTrap Revascularization Device.

MATERIALS AND METHODS

This study was conducted according to the statement of Preferred Reporting Items for Systematic Reviews and Meta-Analyses¹³ and Assessing the Methodological Quality of Systematic Reviews¹⁴ guidelines. The project has been registered in PROSPERO (https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42022327897).

Search Strategy

Five databases, MEDLINE, EMBASE, the Cochrane Library, Web of Science, and Google Scholar were searched up to April 2022 by 2 independent reviewers for relevant studies. Publicly available clinical trials registers, for example, ClinicalTrials.gov, were also searched. All relevant publications since these databases were created were included in this analysis. The search strategy is provided in the Online Supplemental Data.

Study Eligibility

The criteria for the study design were specified according to The Population, Intervention, Comparison, Outcome model.

Patient-Selection Criteria. Inclusion criteria were adult patients (18 years of age or older) with AIS due to LVO, including anterior or posterior circulation occlusions, who underwent MT using the EmboTrap device. Arterial occlusion was confirmed by either CTA, MRA, or DSA. The patients had complete recanalization (defined as a modified TICI [mTICI] score of 2c–3) or successful recanalization (defined as an mTICI score of 2b–3) after MT, which was determined by postinterventional DSA. The scores of mTICI 2c–3 were combined into the complete recanalization group because patients who achieved mTICI 2c–3 scores are known to have similar clinical outcomes.¹⁵

Exclusion criteria were patients with baseline prestroke mRS scores of ≥ 3 ; patients with intracerebral hemorrhage (ICH), significant cerebellar mass effect, and acute hydrocephalus on CT or MR imaging before the thrombectomy procedure; or patients with studies that did not report the above outcomes or in which the exact number of complications was not available.

Intervention. MT was performed in patients with AS due to LVO with the EmboTrap Revascularization Device.

Outcomes. At least one of the following items was reported.

Primary Efficacy Outcomes

- 1) Favorable outcome defined as mRS of 0–2 or equal to the prestroke score at 3 months
- 2) Successful recanalization (mTICI 2b–3) determined by post-interventional DSA.

Secondary Efficacy Outcomes

- 1) Modified first-pass effect (mFPE) defined as achieving a successful recanalization (mTICI 2b–3) with a single thrombectomy device pass without rescue therapy¹⁶
- 2) The first-pass effect (FPE) defined as achieving a complete recanalization (mTICI 2c–3) with a single thrombectomy device pass without rescue therapy¹⁶
- 3) Complete recanalization (mTICI 2c–3) determined by postinterventional DSA
- 4) Rescue rate defined as using additional recanalization devices besides the EmboTrap, including intra-arterial thrombolysis, other thrombectomy devices, and pump aspiration.

Safety Outcomes. Safety outcomes were the following:

- 1) Mortality at 90-day follow-up
- 2) ICH
- 3) Symptomatic intracerebral hemorrhage (sICH) defined as intracerebral hemorrhage on imaging with a minimum increase of 4 points on the NIHSS within 24 hours postintervention by the second European Australasian Acute Stroke Study classification (ECASS II)¹⁷
- 4) Procedural complications, such as dissection or vessel perforation.

Studies. We included randomized controlled trials and observational studies including cohort studies, case-control studies, and case series with the minimum number ≥ 20 cases. The inclusion of observational studies allowed sufficient data for outcome assessment and minimization of type II errors arising from low statistical power.¹⁸ Studies not reporting the above outcomes or from which data for complications could not be extracted were excluded.

Selection of Studies and Data Extraction

Two reviewers independently searched the main databases for eligible studies. In the initial stage of screening, titles, keywords, and abstracts were reviewed, and irrelevant studies were excluded. Subsequently, full articles of all the remaining studies were obtained and carefully checked to assess eligibility, and reasons for inclusion or exclusion of studies were documented in detail. Conflicts in study selection between the 2 reviewers were resolved by a third reviewer.

Extraction of data from included studies was also performed by 2 independent reviewers following a standardized data-extraction form. The extracted information of included studies was as follows: 1) characteristics of the study, such as publication time, country, number of patients; 2) characteristics of the included patients, such as age, sex, medical history, site of occlusion by angiography, admission NIHSS score, and baseline ASPECTS; and 3) aforementioned outcomes such as any ICH, sICH, procedural complications, and favorable outcome. The resolution of

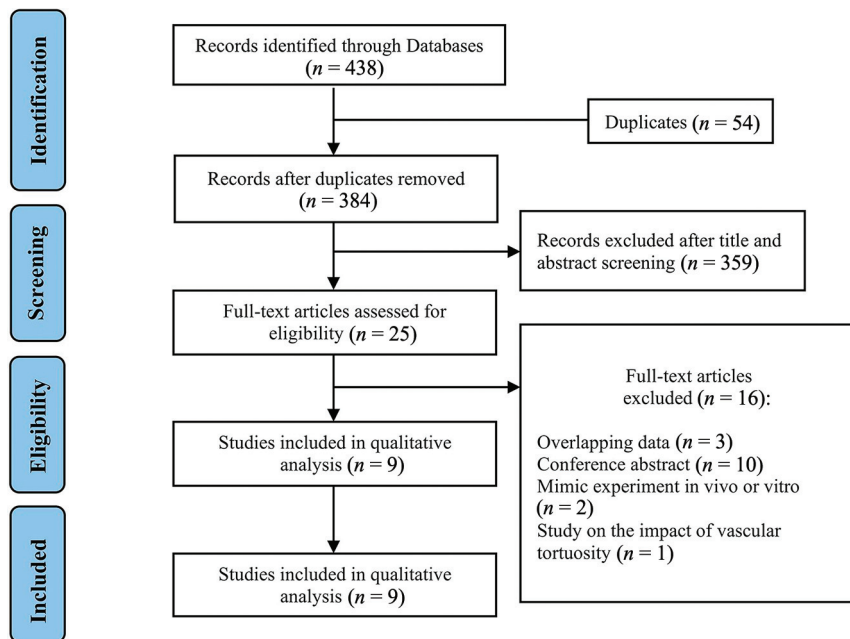


FIG 1. Flow diagram of literature for meta-analysis.

disagreement regarding data extraction was achieved through the assistance of a third reviewer. For missing or ambiguous data in the included studies, clarification of data through direct contact with the corresponding authors by e-mail was attempted.

Assessment of Risk Bias and Heterogeneity

Two reviewers independently assessed the risk of bias for each included study. The Cochrane Collaboration criteria were applied in the process of the selection of randomized controlled trials. The Methodological Index for Non-Randomized Studies scale was used for nonrandomized and single-arm studies. The heterogeneity of pooled outcomes was evaluated by the I^2 statistic. When the I^2 statistic was $>50\%$, it represented substantial heterogeneity; if the I^2 statistic was $<50\%$, it represented mild or moderate heterogeneity; and the DerSimonian and Laird method for random effects estimation was used for pooling outcomes. The Mantel-Haenszel method for fixed-effects estimation was used if heterogeneity was mild or moderate. For substantial heterogeneity of outcomes, we conducted sensitivity analysis to explore the potential source of heterogeneity.

Measures of Treatment Effect

A meta-analysis on a specific result was performed only when there were at least 2 suitable studies for analysis. If there were insufficient suitable studies for meta-analysis, results were described with narrative statistics. We adapted effect size with 95% CIs for dichotomous data and the mean differences with 95% CIs for continuous data. A P value $< .05$ was statistically significant. In addition to the meta-analyses of primary and secondary outcomes of the EmboTrap device, we also made a subgroup analysis of the EmboTrap II Recanalization Device. The STATA statistical software (Version 15.0; Stata Corp) was used for data analysis and heterogeneity assessment. The 2 independent-samples t tests by

SPSS software (Version 24.0; IBM) were used for the comparison of the EmboTrap System (the first generation of EmboTrap Recanalization Device) and EmboTrap II devices. Publication bias was assessed by visualization of funnel plots provided that the number of included studies was >10 .

RESULTS

Study Selection and Study Characteristics

We found 438 references, abstracts, and related clinical trials from the 5 main electronic databases and clinical trials registers in the first step. Among the results, 25 full-text articles were retrieved after initial checks, and 9 studies were finally eligible for inclusion in the qualitative and quantitative analyses. The process of study selection and reasons for exclusion are summarized in Fig 1, and the Online Supplemental Data show the characteristics of included

studies and patients. A total of 1230 patients were eligible for inclusion criteria.^{8-12,19-22} Among the pooled studies, 6 studies and 1070 individuals used the EmboTrap II device only, and the remaining 3 studies and 160 individuals used the EmboTrap System only. The inclusion and exclusion criteria of patients in included studies are summarized in the Online Supplemental Data. The inclusion criteria consisted of the time window and baseline neurologic and imaging evaluations. The number of patients in each included study ranged from 29 to 318, and the proportion of men was 49.4% (588/1190). The site of occlusion as determined by angiography was mostly located in anterior circulation, involving the ICA and M1 segment of the MCA.

Meta-analysis of Primary and Secondary Outcomes of the EmboTrap Device

According to our analysis, the rate of favorable outcome of the 90-day mRS 0–2 was 53% (95% CI, 42%–63%; $I^2 = 88.6\%$) (Fig 2). The estimated rate of successful recanalization of mTICI 2b–3 was 90% (95% CI, 86%–95%; $I^2 = 82.4\%$) (Fig 3). The rate of mFPE (mTICI score $\geq 2b$ with a single device pass without rescue) was 43% (95% CI, 35%–51%; $I^2 = 63.7\%$) (Fig 4). The above results and the outcomes of FPE (mTICI score $\geq 2c$ with a single device pass without rescue), complete recanalization (mTICI 2c–3), rescue rate, 90-day mortality, ICH, sICH, and procedure-related complications are summarized in the Table. The forest plots are presented in the Online Supplemental Data.

Subgroup Analyses of the EmboTrap System and EmboTrap II Devices

We also conducted subgroup analyses of outcomes in 1070 patients treated with the EmboTrap II Recanalization Device and 160 patients treated with the EmboTrap System (Online Supplemental Data). The 2 independent-samples t tests between the EmboTrap

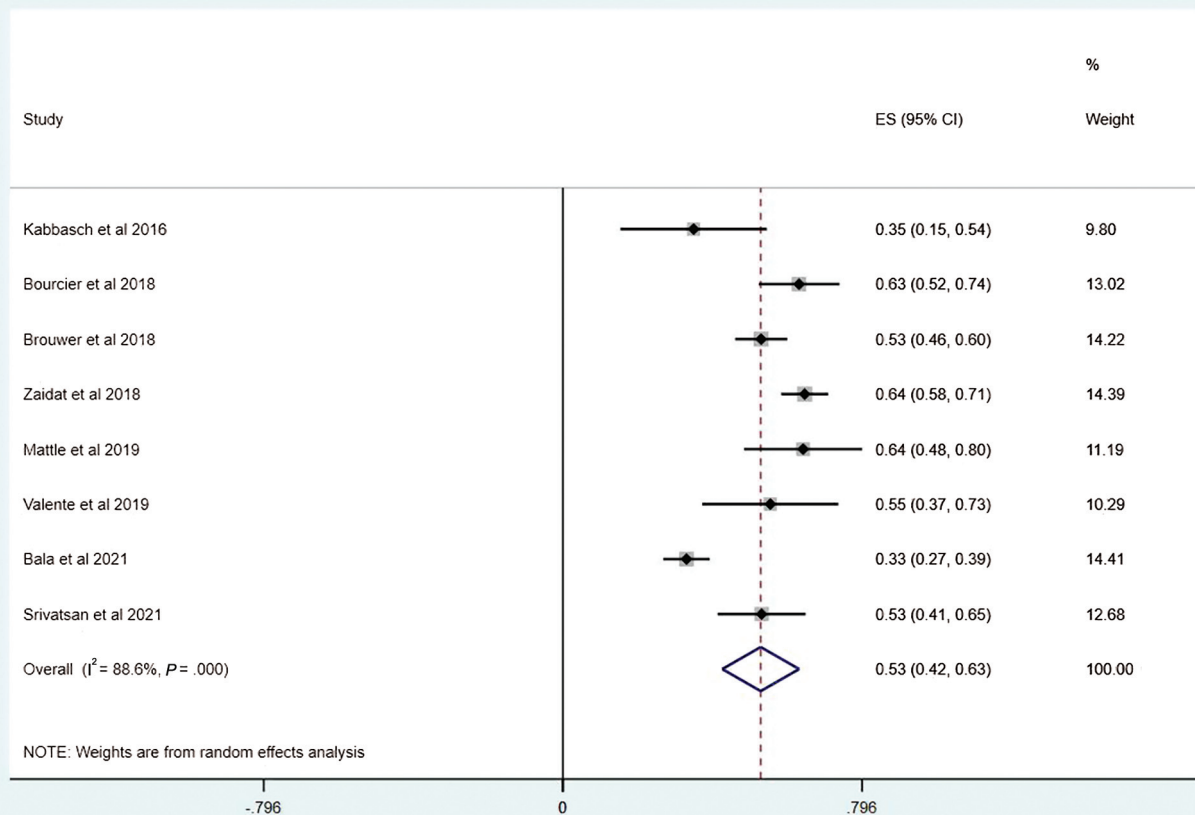


FIG 2. Forest plots of meta-analyses of favorable outcome at 90 days. ES indicates effect size.

System and EmboTrap II Recanalization Devices showed a significantly higher rate of complete recanalization of EmboTrap II than of EmboTrap System (0.60 versus 0.48, $P = .043$), while other results did not show a significant difference between the 2 devices. The results of EmboTrap II and the EmboTrap System are shown in the Online Supplemental Data. The subgroup analysis outcome of FPE for EmboTrap II was not listed because it pooled the same studies as the above results. Subgroup analysis of FPE, mFPE, and 90-day mortality for the EmboTrap System was not performed due to limited data.

Risk of Bias

The Methodological Index for Non-Randomized Studies criteria were used to assess the bias risk of nonrandomized and single-arm studies, with most included studies being at low risk for bias (Online Supplemental Data). Sensitivity analyses were conducted to explore potential heterogeneity, and the results did not suggest any possible source of high heterogeneity, which may be due to the intrinsic nature of single-arm studies. Because only 8 studies were pooled, funnel plots were not used.

DISCUSSION

This is the first systematic review and meta-analysis to explore the safety and efficacy of the EmboTrap Revascularization Device

in patients with AIS and LVO. The results of our analysis were similar to those in previous reports from the ARISE II study.⁸

Several trials have demonstrated the clinical benefit and superior reperfusion efficacy of MT using stent-retriever thrombectomy devices over standard medical therapy in treating AIS-LVO.⁴⁻¹⁰ In the guidelines from American Heart Association/American Stroke Association, MT using stent retrievers has been recommended.⁵ The EmboTrap Thrombectomy Device was originally designed for more effectively trapping, retaining, and removing clots through its unique design of dual-layer and a distal capture zone. A novel stent retriever with a unique 2-layer nitinol structure and an inner 1.25-mm closed cell stent, this device theoretically creates a flow channel through the occlusion. The outer structure leaflets are designed to maintain apposition with the vessel wall to retain the captured clot during retraction, particularly through tortuous vessels. In addition, the distal-closed structure aims at reducing the risk of distal embolization. Thus, in this study, the pooled data suggesting a high successful recanalization rate (90%) and acceptable safety outcomes (ICH, 19%; sICH, 5%; and procedural-related complications, 6%) of the EmboTrap Revascularization Device support its use in the real-world setting.

Most of the recruited studies were single-arm without direct comparison with other types of stent retrievers, and 87% of pooled patients underwent EmboTrap II thrombectomy, suggesting that

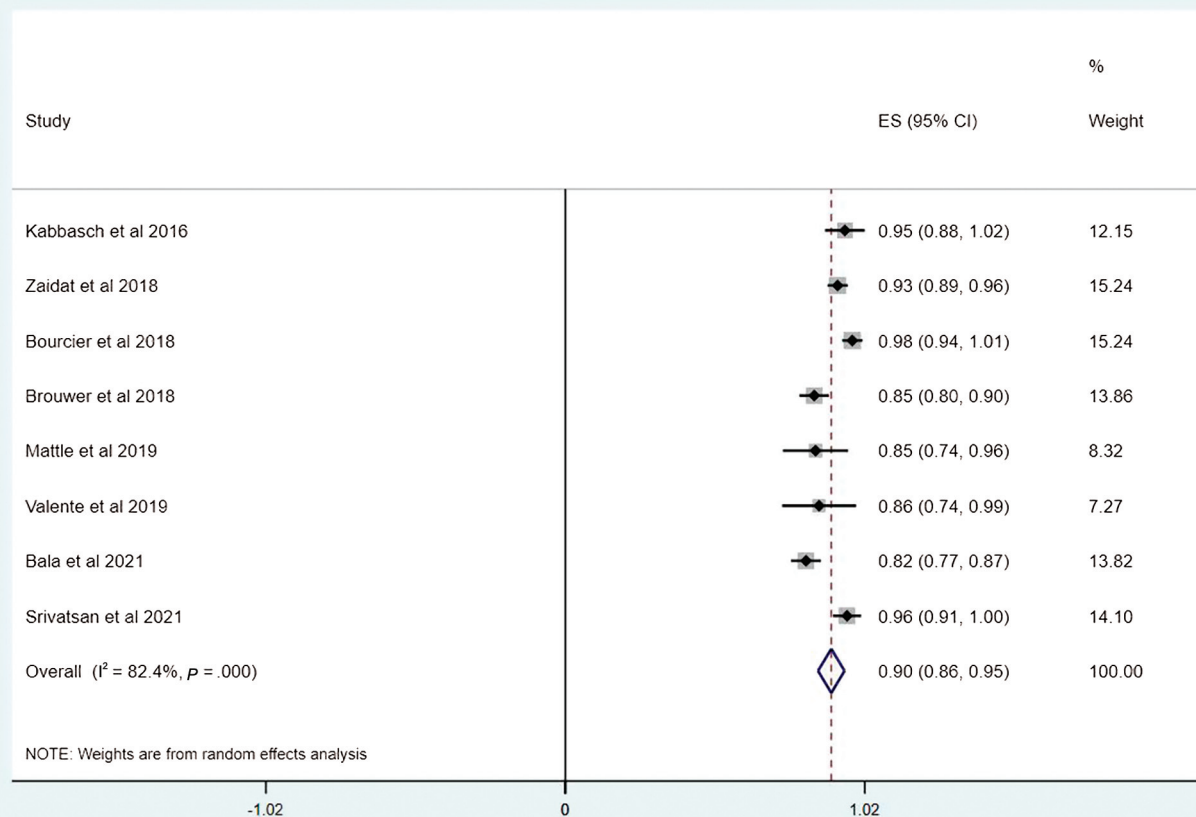


FIG 3. Forest plots of meta-analyses of successful recanalization. ES indicates effect size.

the data are more generalizable with that device. The second generation of stent retrievers, principally Solitaire (Medtronic) and Trevo (Stryker), have been widely adopted with their high efficacy in achieving reperfusion rates and clinical outcomes in AIS-LVO compared with medical therapy in early clinical trials.^{7,23,24} Compared with pooled results from randomized controlled trials using Solitaire and Trevo stents (ie, Highly Effective Reperfusion evaluated in Multiple Endovascular Stroke [HERMES]),²⁵ the EmboTrap device appears to have a greater chance of achieving successful recanalization (88% versus 71%) without increasing the safety events (sICH, 5% versus 4.4%). The procedural-related complication risk was also acceptable (6% in both the total population and subgroup analysis of EmboTrap II). Additionally, in the ARISE I study, the authors compared their EmboTrap arm with a meta-analysis of 8 randomized controlled trials, which yielded similar revascularization rates and good clinical outcomes.²⁰ Thus, further trials with direct comparison between the EmboTrap device and other devices may be warranted to better clarify the superiority of the EmboTrap device.

FPE (mTICI score $\geq 2c$ with a single device pass without rescue) is a new metric to evaluate the efficacy of thrombectomy devices.¹⁶ Previous meta-analyses reported better clinical outcomes of FPE or mFPE (mTICI score $\geq 2b$ with a single device pass without rescue) compared with a multiple-pass effect in patients with AIS

and LVO.²⁶ In our study, the rate of mFPE in EmboTrap II subgroup analysis was 43%, which was higher than that in other stent retrievers reported.²⁷ The higher rate of mFPE of EmboTrap II may be due to several reasons: As a new generation device, it has a new structure with a double proximal marker, which could hypothetically facilitate correct positioning and optimal device capture. The addition of 2 more structural units may further improve its capturing capability.¹² The unique design of an inner blood channel theoretically ensures temporary-but-rapid reperfusion of ischemic brain tissue. This may be validated by the higher favorable outcome of EmboTrap II observed in this study than of Solitaire and Trevo in the study of HERMES collaborators (51% versus 46%).²⁵

This study has certain limitations. Some of the studies recruited had a relatively small sample size and were limited by the retrospective study design. In addition, the heterogeneity among studies was high. Most studies were single-arm without direct comparison with other stent retrievers. We included studies that did not control the use of balloon-guide catheters, occlusion location, and onset-to-puncture time, among numerous other variables that may function as variables in outcomes and likely contribute to the high degree of interstudy heterogeneity. Furthermore, patients with occlusion of both the anterior or posterior circulation were recruited, potentially leading to the heterogeneity of the study population. Because the

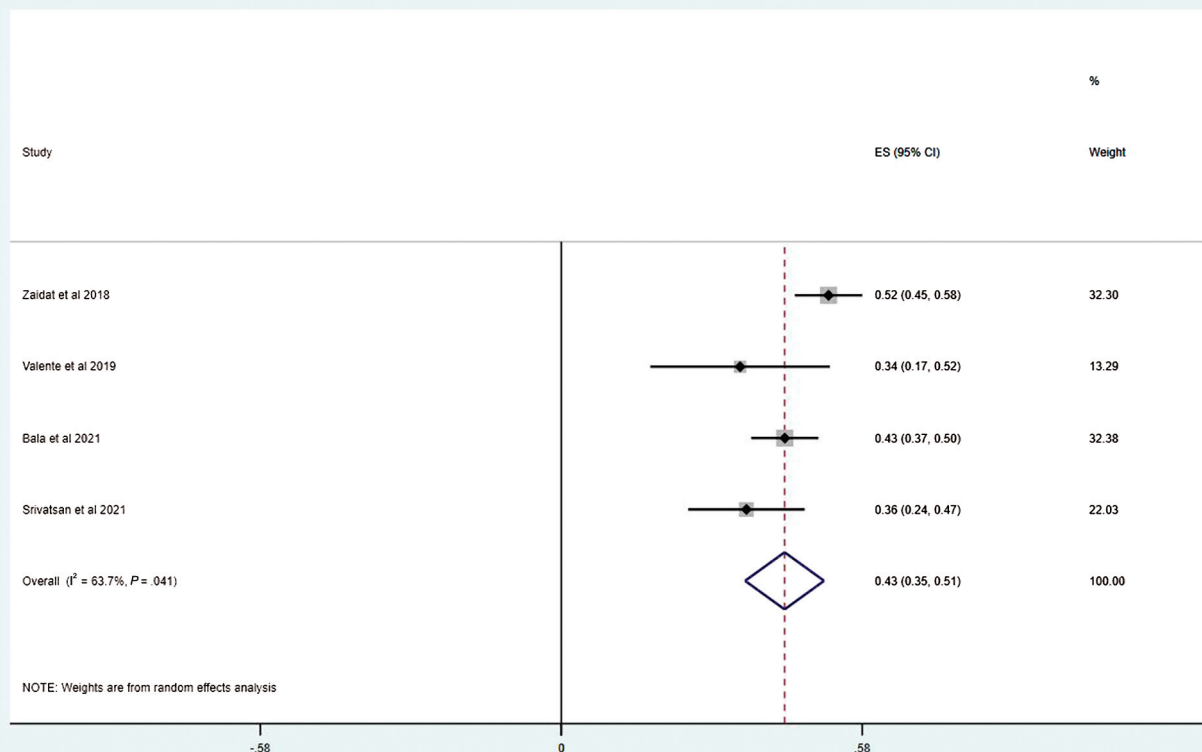


FIG 4. Forest plots of meta-analyses of mFPE. ES indicates effect size.

The primary and secondary outcomes of the EmboTrap Recanalization Device

Outcomes	ES (95% CI)	I^2	P Value ^a
Favorable outcome at 90 days	0.53 (0.42–0.63)	88.6%	<.001
Rate of successful recanalization	0.90 (0.86–0.95)	82.4%	<.001
Rate of complete recanalization	0.55 (0.46–0.64)	77.1%	.004
mFPE (mTICI score $\geq 2b$)	0.43 (0.35–0.51)	63.7%	.041
FPE (mTICI score 2c–3)	0.36 (0.30–0.42)	10.7%	.326
Rescue rate	0.14 (0.08–0.21)	88.4%	<.001
90-day mortality	0.14 (0.09–0.19)	79.3%	<.001
Any ICH	0.19 (0.16–0.22)	0.0%	.510
Symptomatic ICH	0.05 (0.01–0.08)	84.6%	<.001
Procedure-related complications	0.06 (0.05–0.08)	0.0%	.529

Note:— I^2 indicates the variation attributable to heterogeneity; ES, effect size.

^a P value indicates the significance of heterogeneity.

recruited studies were conducted in European countries and the United States, racial generalizability could be limited. Also, trials with direct comparison between EmboTrap and other devices may be required to further validate the results of this systematic review and meta-analysis.

CONCLUSIONS

For patients with AIS due to LVO, MT with the EmboTrap Recanalization Device is at least as safe and effective as the current generation of stent retrievers. This new device may also be associated with a higher FPE without an associated increase in safety events.

Disclosure forms provided by the authors are available with the full text and PDF of this article at www.ajnr.org.

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