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AJNR Am J Neuroradiol 2025, 46 (5) 915-920
doi: https://doi.org/10.3174/ajnr.A8553
http://www.ajnr.org/content/46/5/915

Stroke Thrombectomy for Large Infarcts with Limited Penumbra: Systematic Review and Meta-Analysis of Randomized Trials

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ABSTRACT

BACKGROUND: Recent randomized trials have suggested that endovascular thrombectomy (EVT) is superior to medical management (MM) for stroke patients with large infarcts. However, whether or how perfusion metrics should be used to guide optimal patient selection for treatment is unknown.

PURPOSE: To synthesize trial results to provide more definitive guidance on the role of EVT for stroke patients with large infarcts based on perfusion metrics.

DATA SOURCES: MEDLINE database from inception up to July 8, 2024. Randomized controlled trials that report the efficacy and safety of EVT for patients with large infarcts (defined by either infarct core volume greater than 50cc or Alberta Stroke Program Early CT Score [ASPECTS] less than 6) stratified by mismatch profile were included.

STUDY SELECTION: Five trials were identified – SELECT2 and ANGEL-ASPECT.

DATA ANALYSIS: The primary outcome was odds of acceptable outcomes (90-day modified Rankin scale [mRS] 0 to 3). Secondary outcome was 90-day mRS 5 or 6. Patients where then subdivided into those with mismatch ratio 1.2–1.8 or penumbra volume 10–15cc (intermediate mismatch) and those with mismatch ratio <1.2 or volume <10cc (low mismatch).

DATA SYNTHESIS: A total of 140 intermediate mismatch (75 EVT and 65 MM) and 60 low mismatch patients (23 EVT and 37 MM) were identified. EVT was significantly associated with higher odds of mRS 0–3 for intermediate mismatch (OR 2.77 [95% CI 1.11–6.89], $P = .028$), but not low mismatch (OR 1.47 [95% CI 0.44–4.94], $P = .54$). Similarly, in terms of 90-day poor outcomes (mRS 5–6), EVT for intermediate mismatch patients was significantly associated with lower odds (OR 0.49 [95% CI 0.24 to 0.99], $P = .046$), while EVT for the low mismatch cohort was not (OR 0.66 [95% CI 0.22 to 1.96], $P = .45$). There was no significant inter-study heterogeneity observed across study estimates.

CONCLUSIONS: For stroke patients with large infarcts, EVT was beneficial for patients with perfusion mismatch ratio and volume of at least 1.2 and 10cc, but not for those with mismatch ratio <1.2 or volume <10cc.

ABBREVIATIONS: EVT = endovascular thrombectomy; MM = medical management; RCT = randomized controlled trial

A series of recently published randomized controlled trials (RCTs) have demonstrated that endovascular thrombectomy (EVT) is effective for select patients with large infarcts.[1] However, whether infarct size as a stand-alone imaging marker is sufficient for EVT selection remains an area of active debate.[2–4]

Received September 2, 2024; accepted after revision October 21.

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Indicates article with supplemental data.

http://dx.doi.org/10.3174/ajnr.A8553

On one hand, results from A Randomized Controlled Trial to Optimize Patient's Selection for Endovascular Treatment in Acute Ischemic Stroke (SELECT2) have suggested that EVT may be beneficial for patients regardless of perfusion imaging profiles;[5,6] on the other hand, the Large Stroke Therapy Evaluation (LASTE) trial showed that EVT-treated patients may experience significantly reduced infarct growth after treatment,[7] suggesting that penumbra salvage may still play a central role in the efficacy of EVT.[8] Most important, while EVT for patients with a large core may be beneficial in the early time window (<6 hours from time of stroke onset), whether the procedure is safe and effective for patients in later time windows is less clear.[1] None of the large-infarct EVT trials used specific patient selection criteria based on the identification or quantification of the ischemic penumbra.[5,9] Thus, whether or how perfusion metrics should be used to guide

SUMMARY

PREVIOUS LITERATURE: Recent randomized trials have demonstrated that endovascular thrombectomy may be beneficial for patients with large territories of established infarct. However, whether this effectiveness is driven by facilitating the reperfusion of seemingly infarcted tissue or by salvaging areas of at-risk but not-yet-infarcted tissue is unclear. Current guidelines recommend the use of perfusion imaging to select patients for stroke thrombectomy beyond 6 hours of last-known-well neurologic findings. The role of perfusion imaging in selecting patients with stroke with large infarcts for thrombectomy is unknown.

KEY FINDINGS: In this meta-analysis of randomized trial data, we show that the effectiveness of thrombectomy may not be the same for all patients with large infarcts, and there remain uncertainties regarding the safety and efficacy of thrombectomy for patients with limited areas of at-risk tissue.

KNOWLEDGE ADVANCEMENT: Our findings generally support the continued use of perfusion imaging to select patients with large infarcts for EVT if it is available at the treating institution. Future studies and trials are needed to confirm the efficacy and safety of thrombectomy for patients with large infarcts and low mismatch profiles.

EVT selection for patients with large infarcts is largely unknown,[3] especially for those presenting beyond 6 hours of stroke onset.

In this systematic review and meta-analysis, we sought to synthesize currently available RCT data on EVT versus medical management (MM) for patients with large ischemic territories and limited penumbra.

MATERIALS AND METHODS

This systematic review and meta-analysis is compliant with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.[10] RCTs that report the efficacy and safety of EVT for patients with large infarcts (defined by either infarct core volume of >50 mL or ASPECTS[11] <6) stratified by mismatch profile were included. The MEDLINE database was searched from inception to July 8, 2024, using the key words "stroke" OR "infarct," "thrombectomy" OR "endovascular," and "perfusion" OR "mismatch" OR "penumbra." This was a meta-analysis of previously published data and was exempt from institutional review board. All data used for analyses are publicly available.

Titles and abstracts of search results were screened independently by 2 investigators for eligibility, and non-English, nonhuman, and irrelevant or nonoriginal research works were excluded. Subsequently, full-text screening was conducted to identify randomized trials of EVT versus MM that reported outcomes stratified by perfusion profile. Each included study was assessed for bias using the RoB 2 tool (https://www.riskofbias.info/welcome/rob-2-0-tool)[12] by 2 independent reviewers; disagreements were resolved by consensus.

Patients from the included studies were divided into the 2 groups:

1) Intermediate mismatch: those who met the Extending the Time for Thrombolysis in Emergency Neurological Deficits-Intra-Arterial (EXTEND) criteria[13] (ratio ≥1.2 and volume ≥10 mL) but not the Endovascular Therapy Following Imaging Evaluation for Ischemic Stroke 3 (DEFUSE-3) criteria[14] (ratio <1.8 or volume <15 mL).
2) Low mismatch: those who met neither the EXTEND nor DEFUSE-3 criteria[13,14] (ratio <1.2 or volume <10 mL).

The primary outcome was odds of acceptable outcomes (90-day mRS[15] 0–3). Secondary outcome was 90-day mRS 5 or 6. The number of patients in each treatment and perfusion profile group achieving each study end point was recorded.

Statistical Methods

The number of patients achieving each end point stratified by penumbra profiles was used to calculate effect sizes in each trial and was pooled using Mantel-Haenszel fixed effects models. The decision to use fixed-effects models was due to the low expected number of included studies in which case fixed-effects models are generally recommended over random effects models.[16,17] Effect estimates were reported as ORs with corresponding 95% confidence intervals, and interstudy heterogeneity was assessed with the I^2 and Cochran Q statistics. I^2 values of ≥50% heterogeneity were considered substantial, and outcome measures with $I^2 \geq 50\%$ were deemed unsuitable for data synthesis. Publication bias was assessed using funnel plots and the Egger test as appropriate. Interaction effects between the penumbra profile and EVT effectiveness for each outcome measure were also assessed using binary logistic regression models after tabulating all patients and events across included studies. As a sensitivity analysis, random effects models were also used to confirm study findings. Statistical analyses were performed with SPSS Version 29.0 (IBM).

RESULTS

Study and Patient Inclusion

We screened 3711 studies and included 2 studies : SELECT2[6] and Study of Endovascular Therapy in Acute Anterior Circulation Large Vessel Occlusive Patients With a Large Infarct Core (ANGEL-ASPECT) (Fig 1).[18] Details regarding the study and overall patient characteristics are presented in Tables 1 and 2. Both studies were deemed to have low risks of bias based on the RoB 2 tool for the randomization process, missing outcome data, and selection of reported results; however, given that both trials were open-label, both studies had some concerns of risk of bias in terms of deviations from intended interventions and outcome measurements. Overall, both trials had low risks of bias. Three hundred thirty-six of 352 (95.5%) and 426 of 456 (93.4%) patients randomized in SELECT2 and ANGEL-ASPECT, respectively, had adequate perfusion imaging. For both studies, the definition of ischemic core based on perfusion imaging was a relative CBF of <30%; the mismatch ratio was calculated as the volume of hypoperfused tissue (time-to-maximum of 6 seconds) divided by the core volume, and the mismatch volume was calculated as the

hypoperfused volume subtracted from the core volume. In total, 140 (18.4%) patients had intermediate mismatch profiles, of whom 75 received EVT and 65 received MM. Sixty patients (7.9%) had low mismatch profiles, of whom 23 received EVT and 37 received MM.

Outcomes

After data synthesis, EVT for patients with intermediate mismatch was significantly associated with higher odds of mRS 0–3 (OR, 2.77 [95% CI, 1.11–6.89]; $P = .028$; Fig 2), while EVT for the low mismatch cohort was not (OR, 1.47 [95% CI, 0.44–4.94]; $P = .54$; Fig 2). In terms of 90-day poor outcomes (mRS 5 or 6), EVT for patients with an intermediate mismatch was significantly associated with lower odds (OR, 0.49 [95% CI, 0.24–0.99]; $P = .046$; Fig 3), while EVT for the low-mismatch cohort was not (OR, 0.66 [95% CI, 0.22–1.96]; $P = .45$; Fig 3). There was no significant interstudy heterogeneity observed across study estimates (Figs 2 and 3), and funnel plots did not reveal significant publication bias (Supplemental Data). The Egger test was not performed due to the inclusion of only 2 studies. In interaction analysis, there were no significant interaction effects between the penumbra profile and EVT in terms of mRS 0–3 ($P = .32$) or mRS 5–6 ($P = .68$); however, statistical power is likely insufficient for detecting significant interaction effects.

For sensitivity analysis, random effects models were used to confirm findings from fixed effects models. Here, we found that EVT for patients with intermediate mismatch remained numerically associated with higher odds of mRS 0–3, with a similar effect size compared with the estimate from the fixed effects model (OR, 2.72 [95% CI, 0.75–9.91]; $P = .13$). EVT for the low-mismatch cohort remained not significantly associated with different odds of mRS 0–3 (OR, 1.47 [95% CI, 0.44–4.94]; $P = .54$). In terms of 90-day poor outcomes (mRS 5 or 6), random effects estimates were similar, where EVT for patients with intermediate mismatch was significantly associated with lower odds (OR, 0.49 [95% CI, 0.24–0.99]; $P = .047$), while EVT for the low-mismatch cohort was not (OR, 0.64 [95% CI, 0.17–2.48]; $P = .52$). The I^2 values for each estimate were 0.43, 0.00, 0.00, and 0.32, respectively, and tests for interstudy heterogeneity were not statistically significant for all 4 estimates ($P > .10$ for all).

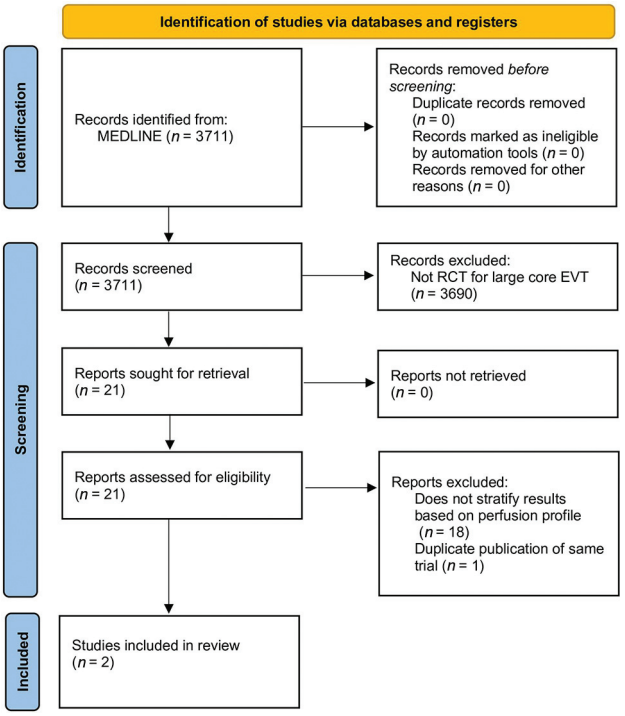

FIG 1. PRISMA flow chart.

Table 1: Study characteristics

	ANGEL-ASPECT	SELECT2
Location	China	North America, Australia
Age, yr	18–80 years	18–85 years
Prestroke mRS	0 or 1	0 or 1
Site of occlusion	ICA or M1	ICA or M1
Treatment time window	Up to 24 hours	Up to 24 hours
ASPECTS criteria	CT ASPECTS 3–5	CT ASPECTS 3–5
Additional imaging criteria	Core volume 70–100 mL also qualified	Core volume ≥50 mL also qualified; patients with established infarcts were excluded

DISCUSSION

In this meta-analysis of SELECT2 and ANGEL-ASPECT, we found that EVT may be associated with superior outcomes compared with MM for those with intermediate perfusion mismatch (ratio 1.2–1.8 or volume 10–15 mL), but not for those with low perfusion mismatch (ratio <1.2 or volume <10 mL).

Perfusion imaging–based patient selection for EVT has played a major role in expanding treatment indications,[14] and current guidelines recommend a mismatch ratio ≥1.8 and volume ≥15 mL per DEFUSE-3 criteria for patients presenting in the extended time window.[14,19–21] However, despite the proved utility of perfusion imaging, recently published trials investigating the safety and efficacy of EVT for patients with large infarcts up to 24 hours of last known well did not use perfusion metrics as part of inclusion/exclusion criteria. Thus, the role of perfusion imaging metrics in selecting patients with large infarcts for EVT is largely unclear, especially in the late time window. In this meta-analysis of SELECT2 and ANGEL-ASPECT–the only 2 studies that mandated baseline perfusion imaging per protocol of the 6 recent large-infarct trials[5,7,9,22–24]– our results revealed that EVT may be beneficial for patients with an intermediate perfusion mismatch profiles that meet the EXTEND-IA criteria[13] (ratio ≥1.2 and volume ≥10 mL) but not the DEFUSE-3 criteria[14] (ratio ≥1.8 and volume ≥15 mL). These findings may reflect the fact that a modest mismatch ratio in patients with large ischemic cores may still reflect large volumes of tissue ripe for salvage, and the currently available RCT data seem to overall support the expansion of EVT use to include patients with large infarcts and mismatch ratio of ≥1.2 and volume of ≥10 mL.

While patients with large infarcts and intermediate mismatch profiles seemed to benefit from EVT, our meta-analysis did not identify a treatment benefit of EVT for patients with low-mismatch profiles (ratio <1.2 or

Table 2: Patient characteristics[a]

	ANGEL-ASPECT		SELECT2	
	EVT	MM	EVT	MM
No. of patients	230	225	178	174
Age, yr	68 (61–73)	67 (59–73)	66 (58–75)	67 (58–75)
NIH Stroke Scale	16 (13–20)	15 (12–19)	19 (15–23)	19 (15–22)
ASPECTS	3 (3–4)	3 (3–4)	4 (3–5)	4 (4–5)
0–2	8.3% (9)	9.8% (22)	5.7% (20)	
3–5	91.7% (211)	90.2% (203)	82.4% (290)	
≥6	0.0% (0)	0.0% (0)	11.9% (42)	
Initial infarct volume (mL)	60.5 (29–86)	63 (31–86)	81.5 (57–118)	79 (62–111)
Site of occlusion				
ICA	36.1% (83)	36.0% (81)	44.9% (80)	37.9% (66)
M1	63.0% (145)	63.1% (142)	51.1% (91)	57.5% (100)
M2	0.9% (2)	0.9% (2)	3.9% (7)	4.6% (8)
Tandem occlusion	17.8% (41)	15.6% (35)	31.5% (56)	25.3% (44)
IV thrombolysis	28.7% (66)	28.0% (63)	20.8% (37)	17.3% (30)
Time from onset to randomization (minutes)	453 (299–712)	463 (305–781)	544 (316–920)	587 (349–919)
Successful recanalization	81.3% (187)	–	79.8% (142)	–

Note:—The data presented are % (*n*) or Median (Q1-Q3); NIH, National Institutes of Health.
[a] Data are median (interquartile range) or No. (%).

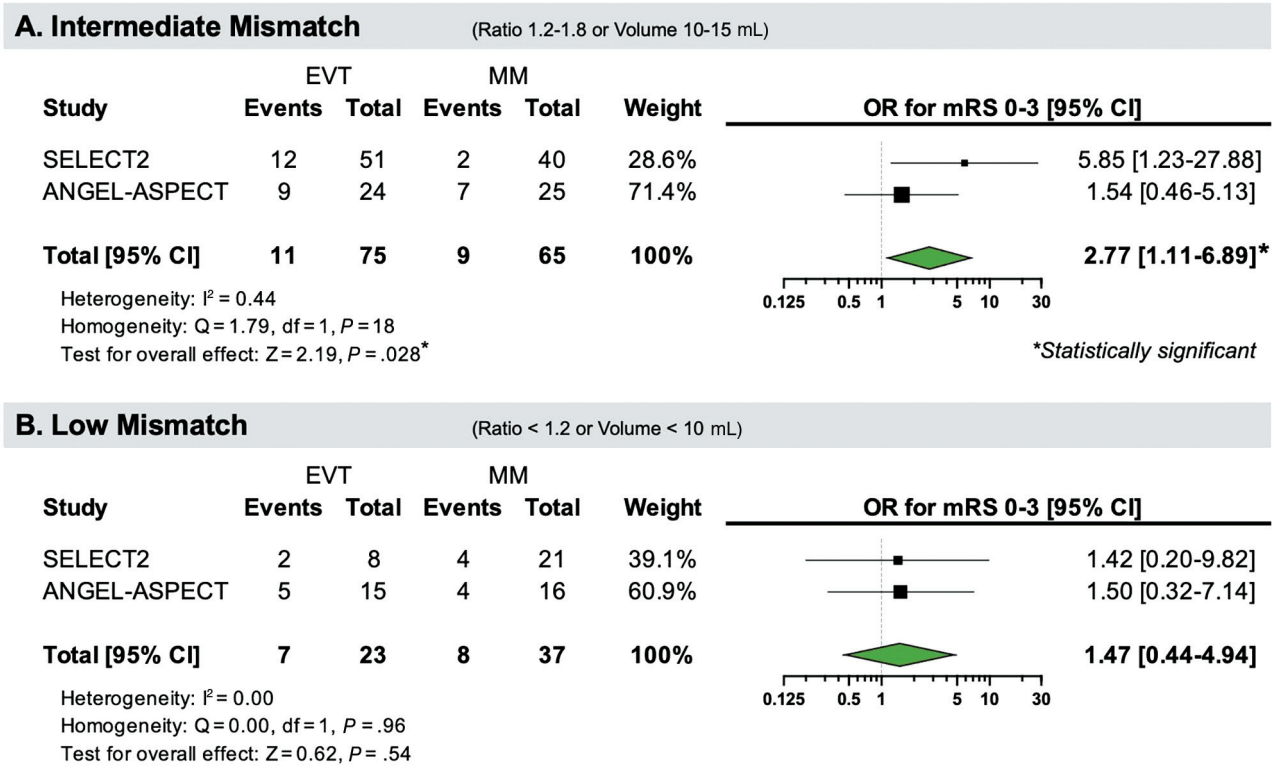

FIG 2. Individual and pooled estimates for the odds of good outcomes (mRS 0–3).

volume <10 mL). This finding may be due, in part, to the limited sample size. Prior observational studies have investigated the safety and efficacy of EVT for patients with a low mismatch; however, results have been mixed.[25,26] Most important, the wide confidence intervals of pooled effect sizes seen in our analyses not only suggest a lack of clear efficacy for EVT but also raise concern for potential harm. Reperfusion of infarcts with no radiologically demonstrable viable tissue could increase the rate of hemorrhage and brain edema. Thus, the results of our study establish the clinical equipoise of EVT for patients with large infarcts and low mismatch, and randomized controlled trials are now needed to further assess the safety and efficacy of EVT in this population.

Overall, we believe our synthesis of currently available RCT data generally supports the use of perfusion imaging to select patients with large infarcts for EVT if it is available at the treating institution. Before the availability of more definitive data from dedicated randomized trials demonstrating the superiority or noninferiority of EVT for patients with large infarcts and low mismatch profiles (ratio <1.2 or volume <10 mL), we do not believe

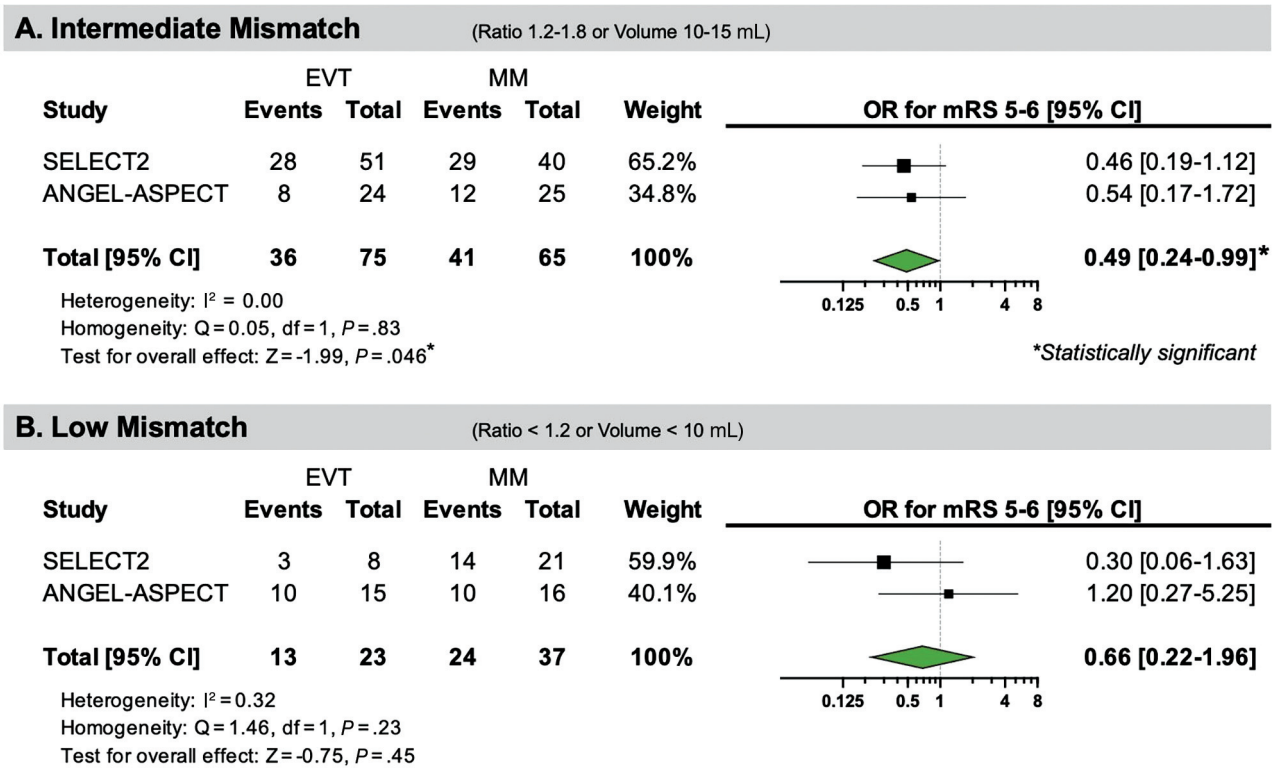

FIG 3. Individual and pooled estimates for the odds of poor outcomes (mRS 5–6).

providers should forgo perfusion imaging altogether during acute stroke triage, particularly in the extended time window.

Our study has several limitations. While included studies reported patient outcomes stratified by the mismatch profile, the details regarding patient characteristics were not uniformly reported, and we do not have individualized or summary data describing the infarct size, time window, or demographic information of patients with intermediate and low mismatch. Furthermore, the sample size in our study is limited, particularly for the low-mismatch subgroup; thus, our study is likely underpowered to detect significant differences. Also, given that there are only 2 studies that met the inclusion criteria for our meta-analysis, we could not adequately assess interstudy heterogeneity. While the low number of patients and trials impact the generalizability of our estimates, we believe our findings are still important, given that they are based on the only available RCT data and that the overall dearth of available clinical data strengthens our call for dedicated trials of EVT in the low-mismatch population. Individual patient data meta-analysis may also be informative. Finally, our ability to statistically assess publication bias was also limited; however, to our knowledge, ANGEL-ASPECT and SELECT2 are the only 2 prospectively registered RCTs for large-infarct EVT that required CTP imaging per protocol; thus, we believe the risk of publication bias is low.

CONCLUSIONS

In this meta-analysis of currently available RCT data, EVT appeared likely beneficial for patients with large infarcts and a perfusion mismatch ratio ≥1.2 and penumbra volume ≥10 mL. The efficacy and safety of EVT for patients with large infarcts and low mismatch (ratio <1.2 or volume <10 mL) remain uncertain and require further investigation.

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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