Direct Aspiration versus Stent Retriever Thrombectomy for Acute Stroke: A Systematic Review and Meta-Analysis in 9127 Patients

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Background: The two most common approaches to thrombectomy of emergent large vessel occlusion (direct aspiration and primary stent retriever thrombectomy) have been extensively studied; however, the detailed benefit and risk comparison is largely unknown. *Objective:* To conduct a systematic review and meta-analysis to compare radiographic and clinical outcomes between the use of primary stent retrievers and direct aspiration in management of acute ischemic stroke. *Methods:* PubMed database was searched for studies between September 1, 2012 and December 31, 2017 with acute ischemic stroke patients. *Results:* We identified 64 studies with 6875 patients in the primary stent retriever group and 25 studies with 2252 patients in the aspiration group. Primary aspiration alone, without the need of rescue stent retriever devices within the aspiration cohort, was performed in 65% of 2252 patients. There was no difference in the distribution of emergent large vessel occlusion based on occlusion site, age, baseline National Institutes of Health Stroke Scale, or the use of intravenous tPA ($P = .19$, .051, .23, and .093, respectively). Successful recanalization rates, defined as thrombolysis in cerebral Infarction 2b/3, were significantly higher in the aspiration group than the primary stent retriever group (89% versus 80%, $P < .0001$). No significant difference in good clinical outcome, defined as modified Rankin scale 0-2 (aspiration 52% versus stent 48%, $P = .13$), symptomatic intracerebral hemorrhage (aspiration 5.6% versus stent 7.2%, $P = .07$), and mortality at 3 months (aspiration 15% versus stent 19%, $P = .10$). *Conclusions:* Both aspiration-first (including the subsequent use of stent retriever) and primary stent retriever thrombectomy approaches are equally effective in achieving good clinical outcomes. Our study suggests that direct aspiration with or without subsequent use of stent retriever is a safe and effective alternative to primary stent retriever in acute ischemic stroke.

Key Words: Stent—thrombectomy—aspiration—ADAPT--stroke—endovascular

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Introduction

The treatment of acute ischemic stroke (AIS) from emergent large vessel occlusion (ELVO) has been revolutionized by the advent of modern endovascular techniques. Indications for thrombectomy have been expanded, including patients with symptoms for up to 24 hours of last known normal.[1] The 2 most common approaches to mechanical thrombectomy of ELVO are the primary use of a stent retriever and direct aspiration approach. In direct aspiration, which is often referred to as the direct aspiration first pass technique (ADAPT), aspiration of the embolus (clot) is attempted first, and if aspiration only fails to achieve successful recanalization, then a rescue treatment with a stent retriever is performed.[2] The majority of patients in the recent randomized trials of endovascular stroke therapy versus medical management alone, including intravenous alteplase (tPA), were treated with the primary stent retriever approach.[3-5] Interestingly, in a survey of neurointerventionalists on real-world thrombectomy practices for ELVO, ADAPT was found to be the most common initial strategy for revascularization.[6]

There are currently significant discrepancies in recommendations on whether primary stent retriever thrombectomy should be the first-line strategy of endovascular stroke treatment. In its most recent 2018 Guidelines for the management of AIS, the American Heart Association stated that stent retrievers should remain the first choice for thrombectomy.[1] Contrary to this statement, the Society of NeuroInterventional Surgery in its statement on neuroendovascular management of emergent LVO concluded that the superiority of stent retrievers versus the primary aspiration techniques is not clearly established.[7]

We performed a systematic review and meta-analysis of published studies to compare radiographic and clinical outcomes in patients with AIS from ELVO treated with primary stent retriever thrombectomy versus the direct aspiration approach.

Methods

Literature Search

Institutional board and ethics approval from our institution was not indicated due to type of study design (systematic analysis of previously published studies). The manuscript followed Preferred Reporting Items for Systematic Reviews and Meta-analysis guidelines (Fig 1). Using the PubMed database, we searched for studies including patients with acute ischemic stroke from ELVO treated with direct aspiration or primary stent retriever thrombectomy. Manuscripts were identified through the search terms "ADAPT," "direct aspiration," "stent retriever," "thrombectomy," "large vessel occlusion," "stroke" and that were published between September 1, 2012 and December 31, 2017. Only studies with ≥10 cases of stent retriever or aspiration thrombectomy technique were included in our analysis. Duplicate studies, studies utilizing thrombectomy devices other than stent retrievers or aspiration thrombectomy alone, and studies with incomplete data were excluded. When possible, authors of the original studies were contacted to provide the missing data points before the study was excluded from final analysis. All manuscripts were included in analysis that met criteria within search terms to minimize risk of bias of individual studies.

Studies selected for analysis were divided into 2 groups: primary stent retriever thrombectomy and aspiration group. If studies reported the use of a stent retriever thrombectomy in conjunction with aspiration via an intermediate catheter (example is the technique often referred to in the literature as "solumbra"[8,9] or "ARTS"[10]), such studies were classified under primary stent retriever thrombectomy for the purpose of our analysis. If the fundamental approach to recanalization relied on aspiration alone (either using aspiration pump or hand aspiration with a syringe), followed by the secondary attempts with a stent retriever if needed, such studies were included in the aspiration group, even if the authors proposed a different original name for their described technique (for example, such as "MAT"[11] or "FAST"[12]). We did not further separate studies based on the adjunct use of a balloon-guide catheter versus a conventional guide catheter.

The literature search yielded 925 studies, which was further reduced by inclusion criteria into 240 manuscripts. Total of 84 manuscripts included in data series with 5 manuscripts offering both aspiration and primary stent retriever data. Final statistical analysis was performed from data included in 64 publications with a total of 6875 patients that underwent thrombectomy using a stent retriever device and 25 publications with total of 2252 patients that underwent thrombectomy using the aspiration approach (Fig 1). A description of all manuscripts reviewed, included in the stent retriever group (Supplemental Table I), aspiration group (Supplemental Table II), and excluded studies with reason of exclusion (Supplemental Table III) are found in supplemental material.

Data Extraction

Two authors performed data extraction and analysis independently. Inter-rater agreement among the 2 independent datasets was 100%. Our study followed to the Meta-analysis of Observational Studies in Epidemiology guidelines as well as the Preferred Reporting Items for Systematic Reviews and Meta-analysis recommendations. Each study was required to report recanalization rates based on thrombolysis in cerebral Infarction (TICI) score or functional outcomes based on modified Rankin Scale (mRS). Successful recanalization rates were defined as TICI 2b/3 and good functional outcome at third month as mRS ≤2. If mRS 3-month data were not available, then clinical outcomes between 30 days and 12 months

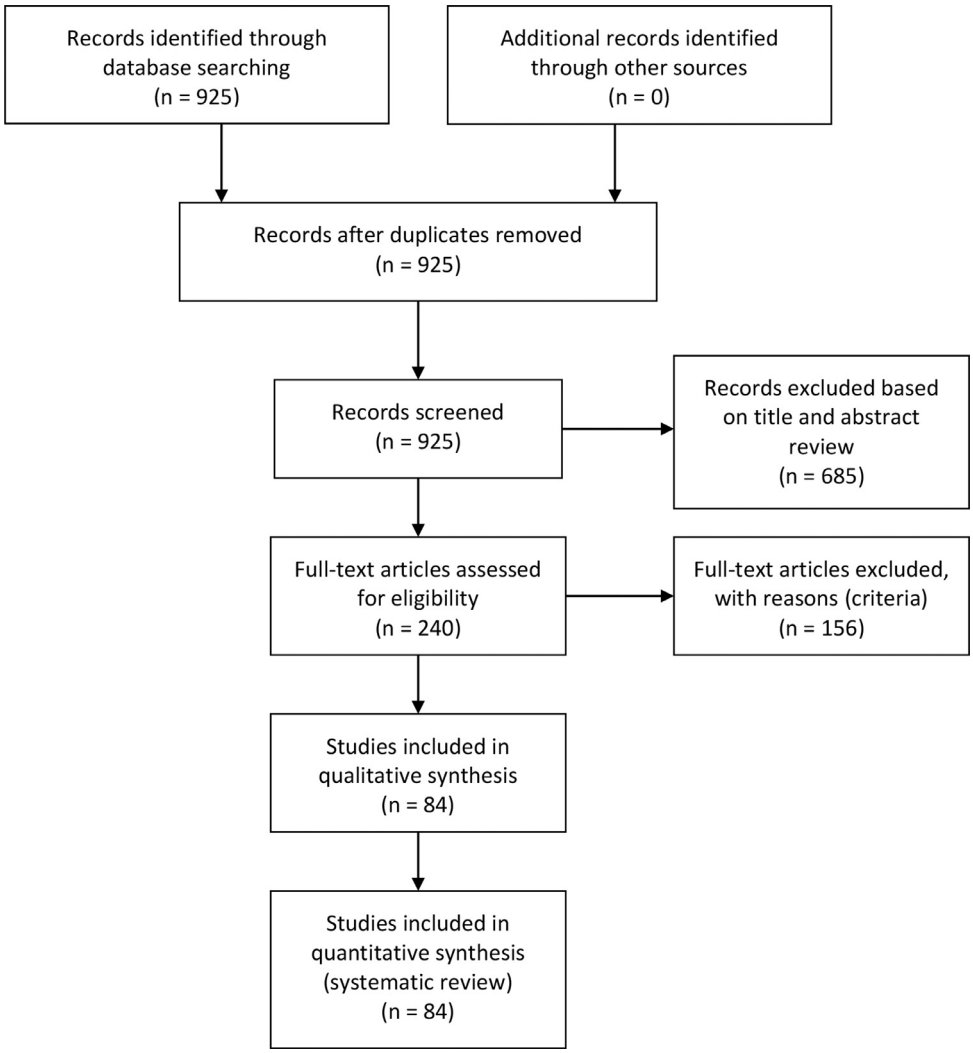

Figure 1. *Flowchart depicting data inclusion criteria and studies in final analysis.*

postintervention was utilized, when available. Symptomatic intracerebral hemorrhag was defined using the European Cooperative Acute Stroke Study II definition; however, when authors did not define hemorrhage, we considered hemorrhages associated with decline in neurological status as symptomatic.

Patient characteristics included mean age of patient, use of intravenous alteplase, National Institutes of Health Stroke Scale, and location of occlusion. ELVO sites were separated into three groups: internal carotid artery, middle cerebral artery, and posterior circulation including posterior cerebral artery and basilar artery.

Statistical Analysis

Recanalization rates and clinical outcomes were assessed using the meta-analysis program metafor.[13] A meta-analysis compared 64 stent-retriever and 24 aspiration studies for rates of successful recanalization (TICI 2b/3) and separately for good clinical outcome (3-month mRS $\leq$2). Meta-analyses on symptomatic intracranial hemorrhage (Supplemental Fig I) and mortality rates (Supplemental Fig II) were also completed and included in supplemental material.

Proportions were converted to logits for analysis and restricted maximum likelihood was used to estimate the random-effects variance component. Several studies required addition of 1 data point to prevent proportion equal to 0 or 1, respectively, due to required transformation to logit (detailed report included in the Supplemental Table I-III). Heterogeneity of effect sizes was assessed by the following statistics: Q, I^2, and tau. Meta-regression was used to test for the difference between stent retrieval and aspiration for each dependent variable. A regression test for funnel asymmetry and the trim-and-fill methods were used to examine possible publication bias (Supplemental Fig IIIA-D).

All meta-analyses were performed by using the R language for statistical programming (RStudio Team (2018). RStudio: Integrated Development for R. RStudio, Inc.,

Boston, MA URL). Statistical analyzes including chi-square and the student *t* test were performed using GraphPad Prism version 7 for Windows, GraphPad Software, La Jolla, CA, and SPSS (IBM SPSS Statistics for Windows, version 24 (IBM Corp., Armonk, NY). $P < .05$ was considered statistically significant.

Results

We identified 64 publications with a total of 6875 patients that were treated with a stent retriever device as a primary treatment strategy and 25 publications with total of 2252 patients that underwent thrombectomy using the aspiration approach. A total of 9127 patients were included in final analysis. The design of each study included in final analysis, the total number of patients treated with primary stent retriever or aspiration thrombectomy and patient characteristics are described in Supplemental Tables I-II, respectively.

Mean age was 66.9 and 69.0 years for the stent retriever and aspiration groups, respectively ($P = .051$). There was no difference in the distribution of ELVO based on occlusion site (internal carotid artery, middle cerebral artery, or posterior circulation), baseline National Institutes of Health Stroke Scale, or the use of intravenous tPA between the two groups ($P = .19$, .23, and .09, respectively; Table 1). Primary aspiration alone, without the need of rescue stent retriever devices within the aspiration cohort was performed in 65% of 2252 patients.

The successful recanalization TICI 2b/3 rate was higher with aspiration, 88.65%, confidence interval (CI; 85.64, 91.09) than the primary stent retriever thrombectomy rate, 80.46%, CI (77.81, 82.87), $P < .0001$ (Fig 2). Recanalization rate data showed heterogeneous results (I^2 : 84.64%, tau: .6239, Q (df = 88) = 484.91, *P* value < .0001), suggesting that some studies achieved higher success rates than others. Good clinical outcome 3 months between aspiration, 52.43%, CI (48.01, 56.73), and primary stent retriever thrombectomy, 48.38%, CI (45.69, 51.09), were similar, $P = .13$ (Fig 3). Symptomatic intracranial hemorrhage (aspiration, 5.63%, CI [4.43, 7.14] and primary stent, 7.24%, CI [6.32, 8.28]; Supplemental Fig I), and mortality rates (aspiration, 18.51%, CI [16.48, 20.73], and primary stent retriever, 15.15%, CI [12.16, 18.72]; Supplemental Fig II), were similar, with $P = .07$ and .10, respectively. The effect sizes for each of these variables was also heterogeneous: mRS (I^2 : 74.70%, tau: .3544, Q (df = 88) = 332.90, $P < .0001$), symptomatic intracranial hemorrhage (I^2 : 42.02%, tau: .3466, Q (df = 84) = 167.24, $P < .0001$), and mortality rate (I^2 : 73.17%, tau: .4318, Q (df = 79) = 244.67, $P < .0001$). A detailed summary of results for each meta-analysis is shown in Supplemental Table IV.

The regression test for funnel asymmetry was significant for the collection of stent studies based on recanalization rates (z = 5.07, $P < .01$), and the trim-and-fill algorithm imputed 17 studies for the sample set of studies (Supplemental Fig IIIA). The trim-and-fill estimate for the stent studies was .77 (95% CI = .74, .80), which is a slight revision downward. The regression test for funnel asymmetry was not significant for the collection of aspiration studies (z = .93, $P = .35$), and the trim-and-fill algorithm did not impute any missing studies. Thus, there was no revised estimate for the aspiration studies. Further analyzes regarding funnel plot based on clinical outcomes, symptomatic intracranial hemorrhage, and mortality rate found in Supplemental Figure IIIB-D.

Discussion

Recanalization is strongly associated with improved functional outcomes and reduced mortality in patients with ELVO.[14] Thrombectomy device innovation, resulting in higher recanalization rates in ELVO patients, is a key element advancing the field of endovascular stroke therapy, shifting the landscape of interventional stroke studies from "negative" to "positive" trials.[15] Stent retriever thrombectomy has been the most commonly utilized primary treatment strategy for recanalization in nearly all key randomized trials of AIS endovascular therapy since the superiority of stent retrievers over Merci retrieval device was demonstrated in 2012.[16,17] In the original 5 randomized trials of mechanical thrombectomy, utilization of stent retrievers ranged from 86% to 100% of all

Table 1. *Clinical characteristics and outcomes*

	Stent retriever (N = 6875)	Aspiration (N = 2252)	*P* value (95% CI)
Age, years	66.9 ± 4.8	69.0 ± 3.4	.0510 (−4.18 to .0089)
NHISS on admission- mean	17.41 ± 3.1	16.56 ± 2.3	.2253 (−.53 to 2.21)
IV tPA use, n (%)	2946/6083(48.4)	1220/2252(54.2)	.0933 (−17.46 to 1.38)
Location of LVO			
ICA	1522 (22.1)	602 (26.9)	.1941
MCA	4610 (67.1)	1532 (68.5)	
Posterior circulation	661 (9.6)	121 (5.4)	

Abbreviations: CI, confidence interval; ICA, internal carotid artery; IV, intravenous; LVO, large vessel occlusion; MCA, middle cerebral artery; mRS, modified Rankin Scale; NIHSS, National Institutes of Health Stroke Scale; sICH, symptomatic intracerebral hemorrhage; TICI, thrombolysis in cerebral infarction; tPA, tissue plasminogen activator.

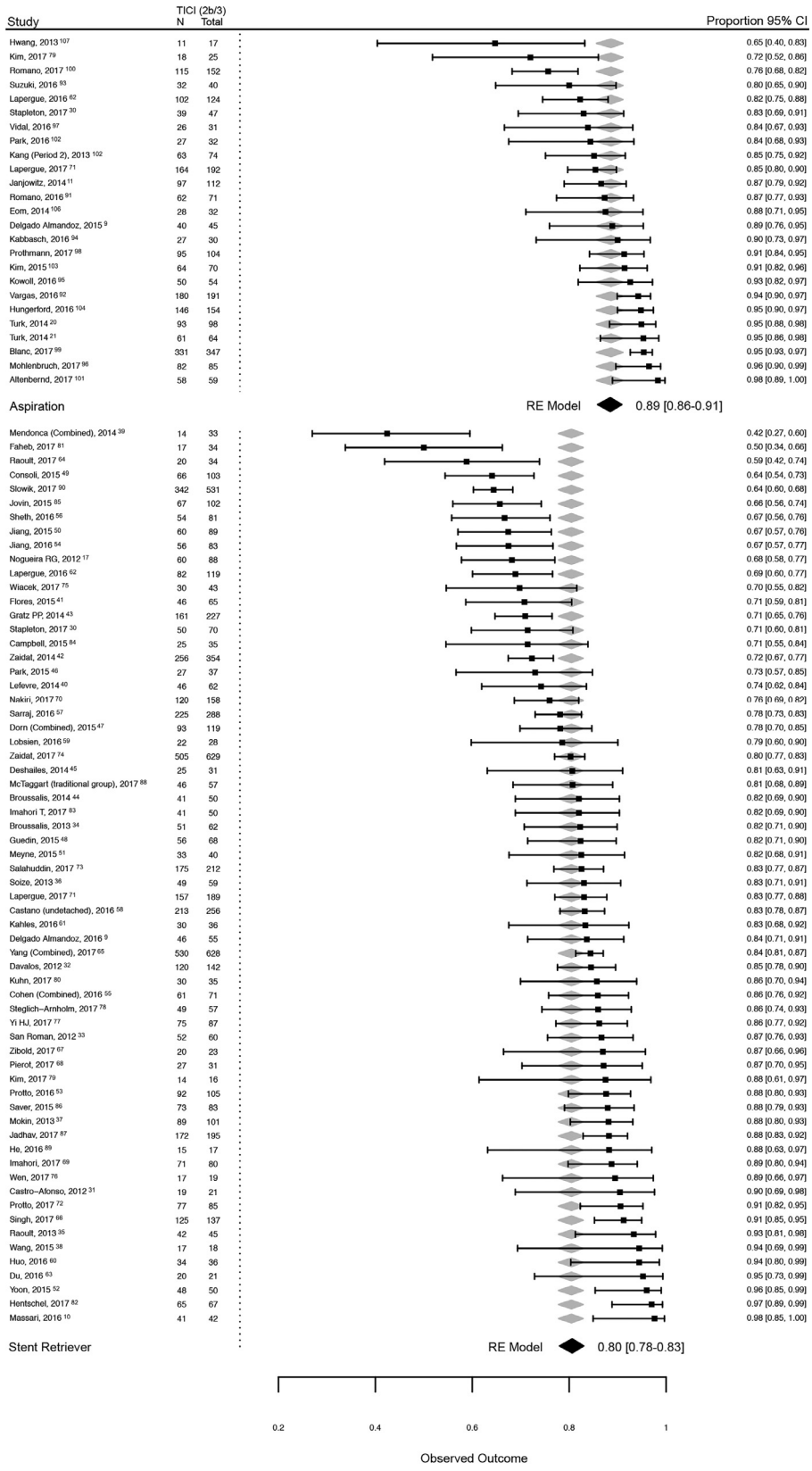

Figure 2. *Meta-analysis of aspiration versus primary stent retriever studies based on thrombolysis in cerebral infarction (TICI). Row data depicts manuscript by first author and year published, N column: # of patient's status post procedure with recanalization score of TICI 2b/3; total column: # of patient's in study; proportion: successful recanalization rate based on TICI 2b/3. Abbreviation: RE, random-effects model.*

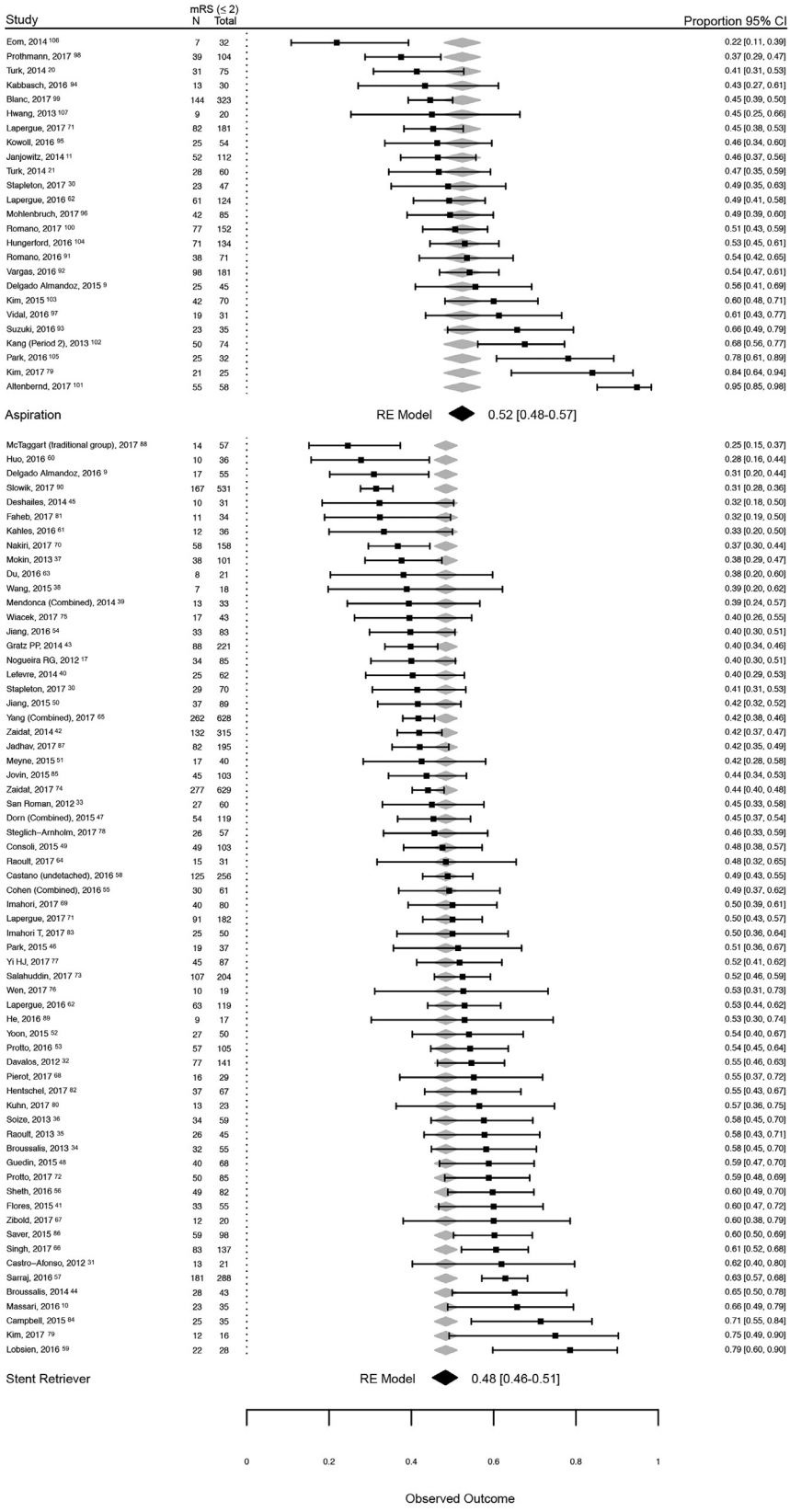

Figure 3. *Meta-analysis of aspiration versus primary stent retriever studies based on modified Rankin Score. Row data depict manuscript by first author and year published, N column: # of patient's with mRS 0-2 at third month after intervention; total column: # of patient's in study; proportion: proportion of good clinical outcomes based on mRS 0-2. Abbreviation: RE, random-effects model.*

interventions.[18] Similarly, in the more recent trials of thrombectomy in patients with expanded time window, stent retrievers were used in 98% of interventions in the DAWN trial,[3] and 82% of interventions in the DEFUSE3 trial.[19]

Meanwhile, an alternative technique relying on direct aspiration alone emerged and has gained increased popularity among neurointerventionalists.[6] In this approach to thrombectomy, most commonly referred to as the ADAPT technique, a flexible large-bore catheter is placed in direct contact with the clot to perform aspiration, and allows immediate use of a stent retriever as a rescue therapy if aspiration alone fails to achieved successful recanalization.[2,20] Proponents of ADAPT report improved time to recanalization and cost-effectiveness of direct aspiration over stent retriever thrombectomy.[21] There is also evidence that thrombectomy with a stent retriever may be more damaging to the arterial wall, especially the endothelium, than vessel changes caused by aspiration catheter alone.[22,23]

Pooled data from all of the studies included in our analysis suggest that direct aspiration and primary stent retriever thrombectomy result in similar rates of good clinical outcome and mortality rates. We found a small yet statistically significant difference in the rates of TICI2b/3 recanalization favoring the use of direct aspiration over the primary stent retriever thrombectomy. Our findings suggest that both treatment approaches are safe and effective for the treatment of ELVO. Only preliminary results of a randomized trial comparing the ADAPT technique to stent retriever as the first line approach (COMPASS, a COMParison of direct ASpiration versus Stent retriever as first approach) were available at the completion of our systematic analysis, therefore, the study was not included in our analysis.[24] COMPASS study was designed to test the noninferiority of the ADAPT approach in patients with anterior circulation LVO for AIS within 6 hours of symptoms onset. Based on its preliminary results, the ADAPT approach to thrombectomy is noninferior to primary stent retriever thrombectomy, with comparable rates of final reperfusion and procedure times.[25]

Limitations

Our study has several limitations. Most of publications included in our analysis were retrospective studies and registries with imaging data interpreted locally without adjudication by a central core lab. There is a tendency to overestimate the reperfusion success when self-reported TICI scores are compared to core lab adjudicated results.[26] Centers had variations in treatment protocols, which should be considered when interpreting the results of our systematic analysis. For instance, type and brand of aspiration catheter, the use of manual aspiration or aspiration pump, and the number of aspiration attempts before switching to rescue therapy with a stent retriever may influence the efficacy of the approach and thus might explain some of the heterogeneity in our results. Similarly, for primary stent retriever thrombectomy, the choice of the device and the use of a balloon-guide catheter may affect the success rate of thrombectomy.

The data on procedure times, average number of passes and rates of TICI 3 only were excluded from the analysis. A new thrombectomy metric, called first pass effect (FPE) has recently been introduced.[27] The manuscript describes the ability of a certain thrombectomy device or approach to achieve a complete recanalization with a single device pass. Variations in exact definition of FPE and limited number of publications reporting this measure prevented us from conducting meta-analysis of FPE between aspiration and stent retriever thrombectomy. Data from registries and single center studies estimates 25%-52% rate of FTE with stent retrievers[27,28] and 34% with direct aspiration.[29] Finally, many of the studies included in our analysis studied did not provide outcome rates of the aspiration only component of ADAPT; therefore, we only reported the overall safety and efficacy of aspiration, including cases where rescue therapy with stent retrievers was required.

Conclusions

The direct aspiration and primary stent retriever approaches to thrombectomy resulted in similar rates of good clinical outcome and mortality. Our study indicates that the aspiration-first, including the subsequent use of stent-retriever, is a safe and effective alternative to primary stent retriever in ELVO.

Competing Interests Statement

Primiani, Vicente, Brannick: None.

Levy: shareholder/ownership interests−Intratech Medical Ltd., Blockade Medical LLC, Medina Medical. Principal investigator: Covidien US SWIFT PRIME Trials. Honoraria for training and lecturing−Covidien. Consultant−Pulsar, Medina Medical, Blockade Medical. Other financial support−Abbott for carotid training for physicians.

Mocco: Investor: Rebound Medical, Viseon,Cerebrotech, Endostream, Apama, The Stroke Project, Comet Medical, Serenity, 3Rivers Medical, and Synchron. Consultant: Rebound Medical, Viseon, Cerebrotech, Endostream, The Stroke Project, Serenity, 3Rivers Medical, and Synchron.

Mokin: Consultant-Toshiba/Canon Medical.

Siddiqui: grants−National Institutes of Health/NINDS/NIBIB, University at Buffalo−none related to present study; financial interests−Hotspur, Intratech Medical, StimSox, Valor Medical, Blockade Medical, and Lazarus Effect; consultant−Codman & Shurtleff, Inc., Concentric Medical, ev3/Covidien Vascular Therapies,

GuidePoint Global Consulting, Penumbra, Stryker, Pulsar Vascular, MicroVention, Lazarus Effect, Blockade Medical; speakers' bureau−Codman & Shurtleff, Inc. speakers' bureau; National Steering Committee−Penumbra Inc.'s 3D Separator Trial, Covidien's SWIFT PRIME trial, MicroVention' s FRED trial; advisory boards—Codman & Shurtleff, Covidien Neurovascular; honoraria−Abbott Vascular, Codman & Shurtleff, Penumbra Inc.

Turk: Codman, consulting, research grants; Penumbra, consulting, research grants; Microvention, consulting, researchgrants; Blockade, stock, consulting; Pulsar Vascular, stock, consulting, research grants; Medtronic, consulting, research grants; and Siemens, consulting.Investor: Cerebrotech, Endostream, Apama, The Stroke Project, Serenity, 3RiversMedical, and Synchron. Consultant: Cerebrotech, Endostream, The Stroke Project,Serenity, 3Rivers Medical, and Vastrax.

Authors' Contribution

MM—study concept, initiated project. MM and CTP—drafted, revised manuscript, monitored data collection, and study design. MB and CTP—statistical analysis. ACV—data collection and independent analysis. MM, CTP, AT, JM, EL, AS, MB, ACV—All authors participated in data collection, analysis, and approved the final version.

Supplementary Materials

Supplementary material associated with this article can be found in the online version at doi:10.1016/j.jstrokecerebrovasdis.2019.01.034.

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