Original research

Impact of aspiration catheter size on clinical outcomes in aspiration thrombectomy

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ABSTRACT

Background Direct aspiration thrombectomy is a well-established method for mechanical thrombectomy in acute ischemic stroke. Yet, the influence of aspiration catheter internal diameter (ID) on aspiration thrombectomy efficacy is incompletely understood.

Methods A systematic literature review and meta-regression analysis was completed to evaluate the impact of primary aspiration thrombectomy outcomes based on the ID of the aspiration catheter. Primary outcome measures were: final recanalization of modified Thrombolysis In Cerebral Ischemia (mTICI) 2b-3 with aspiration only and with rescue modalities, first pass effect (FPE), need for rescue modalities, intracranial hemorrhagic complication rates, and functional outcomes of 90-day modified Rankin Scale (mRS) of 0–2.

Results 30 studies were identified with 3228 patients. Meta-regression analysis revealed a significant association between increasing aspiration catheter ID and FPE (p=0.032), between ID and final recanalization with aspiration only (p=0.05), and between ID size and recanalization including cases with rescue modalities (p=0.002). Further, subgroup analysis indicated that catheters with an ID ≥0.064 inch had a lower rate of need for rescue than smaller catheters (p=0.013). Additionally, catheters with an ID ≥0.068 inch had a higher rate of intracranial bleeding complications (p=0.025). Lastly, no significant association was found in functional outcomes overall.

Conclusions Larger aspiration catheters are associated with a higher rate of FPE, final recanalization with only an aspiration catheter, and in cases with rescue modalities, though with a higher rate of hemorrhagic complications. These findings confirm that aspiration catheter size functions as a variable in aspiration thrombectomy, which should be considered in future study and trial design.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Smaller primarily retrospective series have suggested that larger aspiration catheters might facilitate improved clinical outcomes in aspiration thrombectomy.

WHAT THIS STUDY ADDS

⇒ This is a large meta-regression analysis of the literature that provides the clearest evidence that larger aspiration catheters are associated with improved clinical outcomes, but at the possible risk of increased intracranial hemorrhage.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ This study validates the suggestion that aspiration catheter size does in fact function as a variable in stroke aspiration thrombectomy outcomes. This should be considered in future study and trial design.

INTRODUCTION

Direct aspiration thrombectomy for acute ischemic stroke is a well-established and commonly used interventional technique. Large multicenter randomized controlled trials have previously demonstrated the non-inferiority of first line aspiration thrombectomy compared with primary stent retriever thrombectomy.[1 2] Further, ongoing studies have been completed exploring variables that contribute to aspiration thrombectomy efficacy in order to maximize clinical outcomes. Several small retrospective studies have investigated how the distal inner diameter (ID) of the aspiration catheter functions as a variable in primary aspiration thrombectomy and have suggested that larger sized catheters facilitate improved technical and clinical outcomes.[3–5] While the relation between increased catheter size and aspiration thrombectomy efficacy has been purported, no large-scale studies exist evaluating if catheters with a larger ID are indeed associated with improved clinical effectiveness in acute ischemic stroke. The aim of this study was to conduct a meta-regression analysis of the current literature to evaluate if catheter ID functions as a variable that alters clinical outcomes and if increasing ID results in increased clinical effectiveness in acute ischemic stroke.

METHODS

Systematic literature review and inclusion criteria

A systematic literature review was completed to identify studies that described clinical outcomes of primary aspiration thrombectomy as a function of aspiration catheter ID. The MEDLINE and Cochrane databases were queried up to April of 2022 using the following search terms: 'thrombectomy' OR 'aspiration thrombectomy' AND 'stroke',

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alone and combined with either 'contact aspiration', 'aspiration catheter' or 'direct aspiration'. An eventual supplementary hand search using Google Scholar was completed on the included studies' references. For initial screening, studies had to explicitly detail outcomes based on the specific size and ID of the aspiration catheter that was used. Each study also had to describe the use of primary, direct aspiration thrombectomy; instances of primary aspiration catheter combined with stent retriever were excluded from analysis. Studies in the English language with at least five patients were eligible for inclusion. Studies that were designed as a randomized control trial, observational study, and case series were included in the quantitative meta-regression. Case reports were excluded. For evaluation for potential initial inclusion, all studies that resulted from the literature review were screened by reading the abstract and/or the full manuscript if the abstract was not sufficient in delineating possible inclusion. For eventual final inclusion, all studies were evaluated by two authors, with any disagreements on inclusion settled by consensus with an additional third author. All data collected were also confirmed in the same way. Studies describing the use of direct aspiration for ischemic stroke in the distal cerebral vasculature within the same study were included; for example, studies that described the use of a specific aspiration catheter within the internal carotid artery (ICA), M1 and M2 middle cerebral artery (MCA), and basilar artery were included in the analysis. However, studies that investigated and described the use of an aspiration catheter exclusively within the distal M2 or M3 branches of the MCA were excluded from this analysis. Lastly, for final inclusion in the quantitative synthesis, each study included in the analysis had to sufficiently describe at least one of the primary outcome measures further described below.

Outcome measures

Six primary outcome measures were studied to investigate the influence of the ID of aspiration catheters on the efficacy of direct aspiration thrombectomy for acute ischemic stroke. (1) First pass effect (FPE) defined as angiographic achievement of modified Thrombolysis In Cerebral Ischemia (mTICI) 2b-3 on first thrombectomy pass using an aspiration catheter alone was investigated. (2) The rate of successful final recanalization with aspiration catheter alone defined as mTICI 2b-3 at end of the procedure was determined. (3) The rate of requirement of any rescue technique intervention, such as the addition of a stent retriever or intra-arterial thrombolytic use, was also evaluated. (4) Overall final recanalization of angiographic mTICI 2b-3, regardless of use of rescue modalities, was also investigated. (5) The rate of post-procedural intracranial hemorrhagic complications reported as symptomatic intracranial hemorrhage or parenchymal hematoma type 2 was determined. (6) Lastly, data regarding good functional outcomes defined as attainment of a 90-day modified Rankin Score (mRS) of 0–2 was collected from the included studies.

Results synthesis and statistical analysis

Two general analytic approaches were pursued for each of the outcome measures. First, a mixed-effects meta-regression was completed using a random effects model where individual study proportions were weighted by the inverse of their estimated variances in order to account for between-study variation (DerSimonian and Laird method). For each regression analysis, the pooled rate of the primary outcome measure was plotted as a function of increasing ID size of the aspiration catheter. Corresponding meta-regression bubble plots and statistical analyses were completed using OpenMeta(Analyst) from Brown University (http://www.cebm.brown.edu/openmeta/), which is based on R software. Within each bubble plot, each circle represents an individual study where the size of the circle is representative of the study weight within the meta-regression analysis.

The second analytic approach was a mixed-effects meta-regression of adjusted means sub-analysis that was performed to evaluate the pooled rate of an outcome variable based on the pooled rate being below or above a certain catheter ID. This sub-analysis was completed for each outcome variable and at all sequential increments in relation to the catheter ID. However, only significantly positive and/or pertinent negative results were reported. All graphs depicting the results of the meta-regression sub-analysis were generated using Prism 9 statistical software.

RESULTS

Systematic literature search

A total of 499 papers were identified from the initial literature search by using the aforementioned search terms. After reading through the abstracts and/or manuscripts, 35 papers met potential inclusion criteria. One additional paper was found after reviewing the 35 manuscripts and their references, for a total of 36 studies that were more robustly scrutinized for possible inclusion in the quantitative meta-regression. From this set of studies, three were eventually excluded because they did not delineate the outcome variables by ID of the aspiration catheter, one study was excluded because it did not define outcomes by aspiration only versus combined aspiration catheter and stent retriever, and one study was excluded because the outcome variables were not sufficiently detailed for inclusion. Ultimately, 30 studies including 3228 patients met final inclusion criteria for the meta-regression (table 1).[3–32] Twenty of these studies were single center retrospective analyses, while nine were multicenter and retrospective in design, and one study was a multicenter prospective study.

Meta-regression and subgroup analyses

Thirty studies with 3228 patients were included within the meta-regression analysis. Aspiration catheter IDs ranged from 0.054 inch to 0.088 inch within the included studies. Three studies included clinical outcome variables describing 0.054 inch catheters, four described 0.055 inch catheters, seven detailed 0.06 inch catheters, three described 0.064 inch catheters, eight reported outcomes of 0.068 inch catheters, 10 described outcomes for 0.07 inch catheters, five reported outcomes for 0.071 inch catheters, two detailed 0.072 inch catheters, and two studies reported outcomes of 0.088 inch aspiration catheters. The location of the occlusion was explicitly detailed in 2461 patients, with a distribution of 705 (28.6%) occlusions involving the ICA, 1242 (50.5%) M1 occlusions, 363 (14.8%) M2 or M3 occlusions, 141 (5.7%) vertebrobasilar occlusions, and 10 (0.4%) posterior cerebral artery occlusions.

Regarding the outcome measures, 13 studies and 1885 patients were included in the FPE meta-regression analysis and revealed a significant association between the pooled proportion of FPE defined as mTICI 2b-3 and with the ID of the aspiration catheter ($p=0.032$) (figure 1A). Despite this, no significant difference was detected on subgroup meta-regression of adjusted means analysis between catheter ID of <0.07 inch and ≥0.07 inch, nor between catheter ID of <0.071 inch and ≥0.071 inch (figure 2A).

From 16 studies and 1251 patients, a significant association was found between ID and final recanalization with primary aspiration thrombectomy alone ($p=0.05$) (figure 1B). Catheters with an outer ID of ≥0.064 inch (831 patients) had a higher

Table 1 Characteristics of the included studies in the meta-regression

First author	Year published	Study design	Number of patients
Frei[6]	2013	Multicenter, retrospective	63
Turk[7]	2014	Multicenter, retrospective	30
John[8]	2014	Single center, retrospective	10
Kowoll[9]	2016	Single center, retrospective	54
Vidal[10]	2016	Single center, retrospective	31
Kabbasch[11]	2016	Multicenter, retrospective	30
Suzuki[12]	2016	Single center, retrospective	24
Mohlenbruch[13]	2017	Multicenter, retrospective	85
Turk[14]	2018	Multicenter, retrospective	88
Sallustio[15]	2018	Single center, retrospective	107
Shallwani[16]	2018	Multicenter, retrospective	15
Bretzner[17]	2019	Single center, retrospective	44
Almandoz[5]	2019	Single center, retrospective	152
Jang[18]	2019	Single center, retrospective	29
Gross[19]	2019	Single center, retrospective	49
Almallouhi[20]	2019	Single center, retrospective	10
Alawieh[3]	2020	Single center, retrospective	510
Raymond[21]	2020	Single center, retrospective	92
Romano[22]	2020	Multicenter, retrospective	501
Semeraro[23]	2021	Multicenter, retrospective	321
Fredrickson[24]	2021	Single center, retrospective	20
Caldwell[25]	2021	Multicenter, prospective	27
Bolognini[26]	2021	Single center, retrospective	144
Tsuji[27]	2021	Single center, retrospective	15
Gross[4]	2021	Single center, retrospective	246
Amireh[28]	2021	Single center, retrospective	36
Bilgin[29]	2021	Single center, retrospective	148
Nogueira[30]	2021	Single center, retrospective	5
Brinjikji[31]	2022	Multicenter, retrospective	323
Romano[32]	2022	Single center, retrospective	19

proportional of final recanalization with primary aspiration thrombectomy compared with those with an ID of <0.064 inch (420 patients) (p=0.022) (figure 2B). Subgroup analysis also revealed that aspiration catheters with an ID of ≥0.071 (89 patients) had a higher pooled rate compared with an ID <0.071 (1162 patients) (p=0.007) (figure 2B).

In 25 studies and 2655 patients, there was also a significant relationship between increasing ID and rate of final recanalization defined as mTICI 2b-3 overall, including instances where a rescue technique had to be employed (p=0.002) (figure 1C). Furthermore, subgroup meta-regression demonstrated that an ID of ≥0.068 inch (854 patients) was associated with a significantly higher rate of successful overall successful final recanalization compared with an ID of <0.068 inch (1610 patients) (p=0.005) (figure 2C).

Need for a rescue technique/modality following failed primary aspiration thrombectomy was also investigated, which was described in 21 studies and 1667 cases. No significant association was identified overall between aspiration catheter size and a lower need for rescue technique on meta-regression (p=0.096) (figure 1D). However, subgroup analysis demonstrated that catheters with an ID of ≥0.064 inch (1161 patients) were associated with a lower rate of need for rescue compared with catheters with an ID of <0.064 inch (506 patients) (p=0.013) (figure 2D). No difference was found between catheters >0.07 inch and <0.07 inch (p=0.21) (figure 2D).

Post-procedural complications were reported in 21 studies with 1410 patients. Meta-regression indicated no significant trend between catheter ID and intracranial hemorrhagic complications (p=0.12) (figure 1E). Subgroup analysis did detect that an ID of ≥0.068 inch (759 patients) had a higher proportion of intracranial hemorrhagic complications compared with smaller <0.068 inch aspiration catheters (651 patients) (p=0.025) (figure 2E). There was no significant difference in complications when stratified by ≥0.07 inch (398 patients) and <0.07 inch (1012 patients) (p=0.174) (figure 2E).

Lastly, good clinical outcomes were evaluated defined as 90-day mRS of 0–2, which was reported in 14 studies and 1015 patients. Yet, no significant association was found between catheter size and rate of patients with a good clinical outcome on follow-up (figure 1F). Similarly, no significant association was found on subgroup analysis between aspiration catheter size of ≥0.07 inch and <0.07 inch regarding functional clinical outcomes (figure 2F).

DISCUSSION

This report is a meta-regression analysis of 30 studies and 3228 patients showing a significant association between ID of the aspiration catheter and rate of successful FPE with direct aspiration thrombectomy. There was also an association between aspiration catheter ID and final successful recanalization with aspiration only and rescue modalities, although no association was observed with functional outcomes at 90 days.

There is growing evidence that larger bore aspiration catheters improve recanalization and clinical outcomes in acute ischemic stroke. Alawieh *et al* studied 510 patients who underwent direct aspiration thrombectomy and found that Penumbra ACE64 (0.064 inch) and ACE68 (0.068 inch) aspiration catheters had significantly higher rates of successful recanalization with aspiration only, shorter procedure times, and lower rates of rescue with stent retrievers, when compared with smaller Penumbra 5MAX/ACE (0.054 inch/0.060 inch) aspiration catheters.[3] Similarly, Almandoz *et al* found significantly higher rates of FPE, recanalization with aspiration only, and lower rates of stent retriever rescue with a 0.068 inch aspiration catheter compared with smaller size catheters.[5] Gross *et al* also demonstrated that the Medtronic React 71 (0.071 inch) aspiration catheter, when compared with other 0.068 inch catheters, significantly facilitated FPE defined as TICI 2c-3 in direct aspiration thrombectomy.[4] Additionally, a recent study of 506 patients with ICA or M1 occlusions found that medium (0.064–0.068 inch) and large bore (0.071–0.074 inch) aspiration catheters resulted in higher rates of FPE, final recanalization, and faster time to recanalization compared with small bore (0.041–0.06 inch) catheters.[33]

The superior clinical impact of larger bore aspiration catheters has also been suggested in combined aspiration catheter and stent retriever thrombectomy. While cases of primary combined stent retriever and aspiration thrombectomy were not included within the presented analysis, a prior study by Perez-Garcia *et al* studied 238 patients with a combined technique and found that an ID of 0.068 inch facilitated superior FPE and final recanalization with lower complications compared with 0.06/0.054 inch aspiration catheters.[34] This is a relevant consideration given mounting evidence that a combined approach may result in superior FPE compared with direct stent retriever thrombectomy alone.[35] If the goal is to maximize FPE, it seems that choosing to use a stent

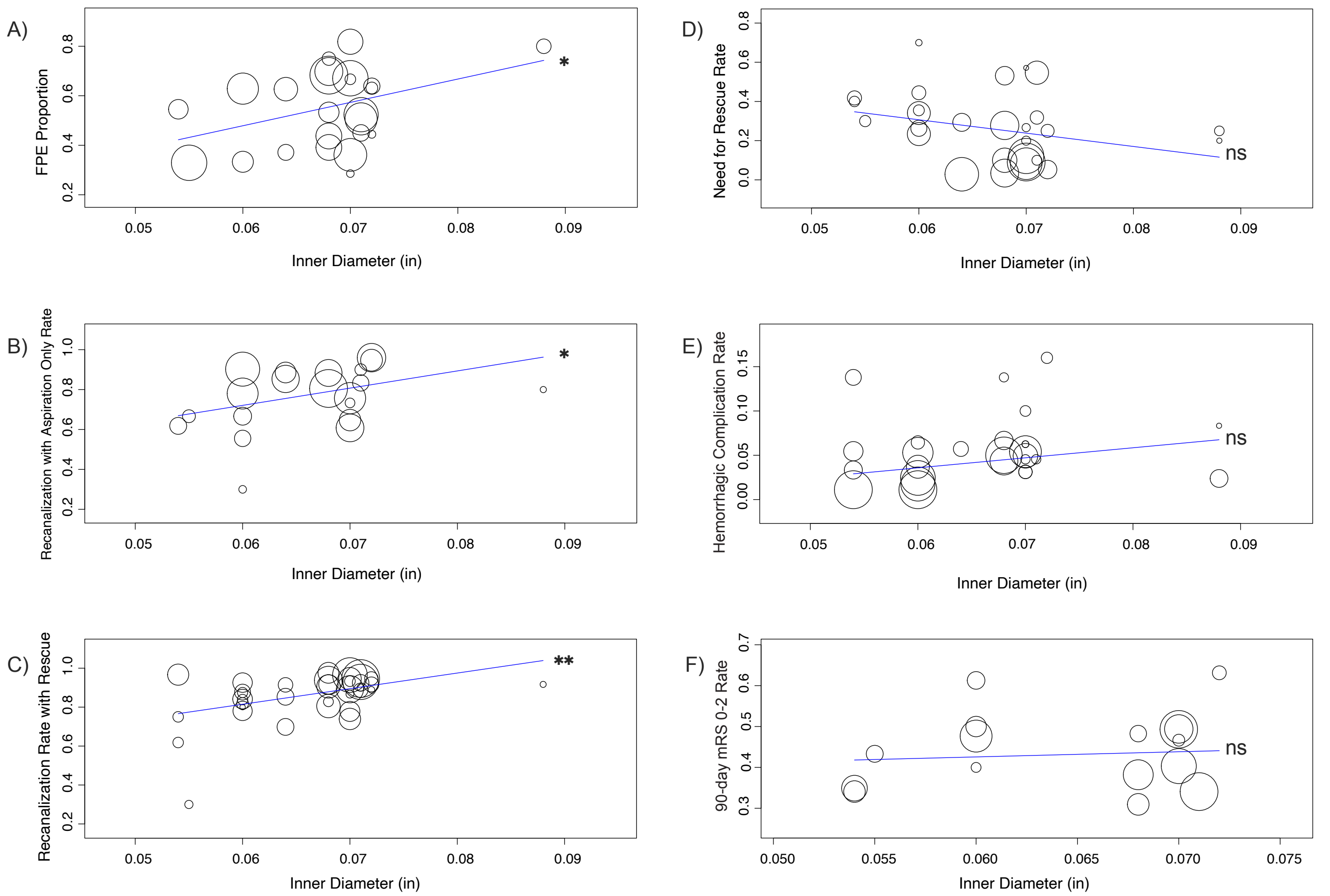

Figure 1 Meta-regression analysis of primary outcome variables. (A) Rate of achievement of FPE defined as mTICI >2b as a function of ID of the aspiration catheter. (B) Rate of final recanalization of mTICI ≥2b with aspiration catheter only as a function of ID. (C) Rate of final recanalization including cases with rescue modalities as a function of ID. (D) Rate of need for rescue modalities following primary aspiration thrombectomy as a function of ID. (E) Rate of post-procedural intracranial hemorrhagic complications as a function of ID. (F) Rate of achievement of good functional outcomes defined as an mRS of 0–2 at 90 days as a function of ID. ns ≥0.05; *p≤0.05; **p<0.01. ID, inner diameter; FPE, first pass effect; mRS, modified Rankin Scale; mTICI, modified Thrombolysis In Cerebral Ischemia.

retriever does not license the interventionalist to select a smaller more trackable aspiration catheter.

Several studies have also investigated the underlying mechanisms that account for the apparent increased efficacy of large bore aspiration catheters. Benchtop investigations have demonstrated that larger bore aspiration catheters generate higher suction forces and flow rates relative to catheters with smaller IDs.[36 37] By using an in vitro thrombectomy model, Nogueira *et al* showed that by maximizing the catheter-to-vessel ratio with aspiration catheters, greater local flow control can be achieved with near complete antegrade flow arrest. In fact, they demonstrated that use of an 0.088 inch catheter within the MCA may result in complete antegrade flow cessation and flow reversal, obviating the need of a balloon guide catheter that shares a similar mechanism.[38] Maximization of the catheter-to-vessel ratio has also been shown to significantly correlate with successful primary aspiration thrombectomy clinically in retrospective series.[39] Using three-dimensional computational modeling from data derived from 100 patients with aspiration thrombectomy, Neidlin *et al* showed that Catalyst 7 (0.068 inch) aspiration catheters were more often successful at achieving flow reversal relative to Catalyst 6 and 5 (0.06 inch and 0.058 inch, respectively) catheters.[40] Overall, the emerging data indicate that using the largest aspiration catheter possible with high catheter-to-vessel ratios facilitates antegrade flow control and appears to mirror the technical benefits of balloon guide catheters, which similarly function by achieving proximal flow control.[41] Attributing enhanced efficacy to flow reversal rather than clot engagement implies a ceiling on inevitably escalating catheter diameters at the size of the parent vessel.

Counterbalancing the benefits of larger bore aspiration catheters is a concern for vessel injury. By using an in vivo rabbit model, Liu *et al* showed that due to the stronger vacuum forces of large bore catheters (such as 0.07 inch catheters), there is higher chance of arterial collapse during aspiration thrombectomy, which may theoretically result in absent flow and frictional arterial wall injury from the aspiration catheter.[42] Likewise, while no significant overall association was found, subgroup analysis indicated that catheters with an ID ≥0.068 inch had a higher proportion of postprocedural intracranial hemorrhage compared with smaller catheters. This is an important consideration, that while larger bore catheters may confer better clinical and technical outcomes based on angiographic criteria, there is the tradeoff for a potential higher risk of hemorrhagic complications. An additional consideration is that large bore catheters may require femoral access for maneuverability over radial access,

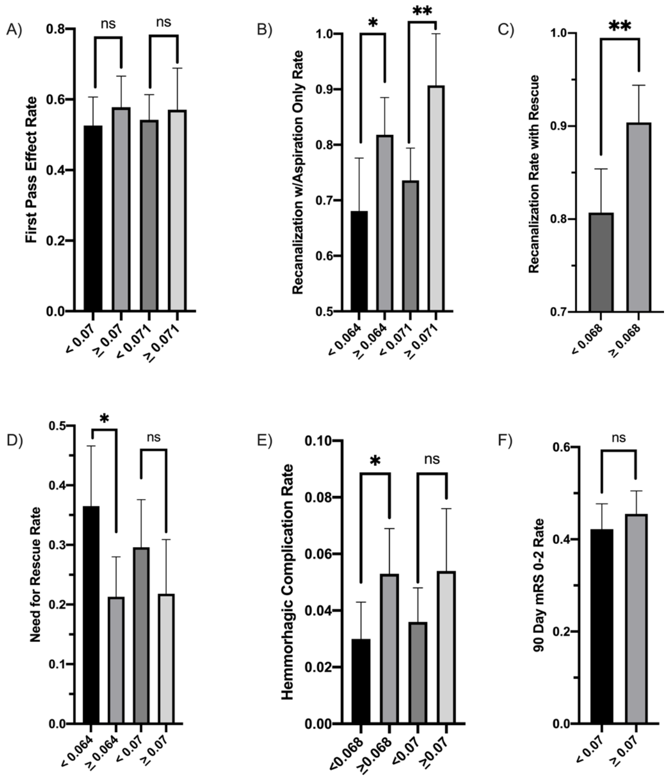

Figure 2 Meta-regression of adjusted means subgroup analyses. (A) Rate of achievement of FPE defined as mTICI >2b based on catheter ID subgrouping. (B) Rate of final recanalization of mTICI ≥2b with aspiration catheter only based on ID subgrouping. (C) Rate of final recanalization including cases with rescue modalities based on ID subgrouping. (D) Rate of need for rescue modalities following primary aspiration thrombectomy based on ID subgrouping. (E) Rate of post-procedural intracranial hemorrhagic complications based on ID subgrouping. (F) Rate of achievement of good functional outcomes defined as an mRS of 0–2 at 90 days based on ID subgrouping. Error bars represent lower and upper bounds. ns ≥0.05; *p≤0.05; **p<0.01. All x-axis number units are described in inches. ID, inner diameter; FPE, first pass effect; mRS, modified Rankin Scale; mTICI, modified Thrombolysis In Cerebral Ischemia.

which could result in a higher rate of access site complications for thrombectomy.[43] Moreover, there is the technical concern of whether the operator can actually position a larger catheter to the clot face, since larger catheters are often more difficult to navigate distally. Also, given the increased profile of large bore aspiration catheters, there may be a higher occurrence of the 'ledge effect' which may render navigation past the ophthalmic artery origin more challenging.[44] These considerations offer a potential tradeoff to the positive findings for larger aspiration catheters reported here.

The presented study has some limitations that need to be considered. First, there are several variables that influence the aspiration catheter choice, besides ID size. For example, proximal arterial tortuosity influences guide catheter choice which consequently impacts the largest possible aspiration catheter that can be used. More distal intracranial tortuosity also affects catheter trackability and can motivate choice of a smaller aspiration catheter. This could be confounding, as tortuosity may dictate selection of smaller aspiration catheters, but it may be the tortuosity and not the catheter itself which contributes to a poorer outcome. Additionally, the presented study did not account for the level and location of occlusion that likely functions as an outcome variable. Likewise, the target vessel size was not evaluated in the included studies, which likely influenced choice of catheter selection. As mentioned above, given that the catheter-to-vessel ratio is what appears to impact flow reversal, knowledge of the target vessel size would be a critical data point in evaluating the impact of catheter diameter on clinical outcomes. Similarly, the presented study did not account for the use of balloon guide catheters, which may have contributed to flow arrest and aspiration success in addition to the size of the catheter. Also, this meta-regression did not control for time to recanalization from last known well, and overall stroke burden. As a result, this could explain why there was no association with better outcomes at 90 days despite superior FPE and recanalization with larger catheters. It is also worth considering that larger catheters are relatively new devices that are continuing to evolve, and may have been used in conjunction with newer technology such as imaging, guide and selection catheters, among other innovations that may have contributed to the improved outcomes.

Another limitation of this study is that it did not consider catheter manufacturer as a variable, as catheters with the same ID may possess different efficacy and safety profiles based on the manufacturer. While Tonetti *et al* previously demonstrated that aspiration catheter manufacturer selection does not independently influence thrombectomy efficacy among similarly sized catheters, this should still be considered.[45] Furthermore, the majority of the data here consisted of catheters sized from 0.054 inch to 0.072 inch. Only two studies with 25 patients in total were included that investigated the newer 0.088 inch catheters.[25 30] As a result, caution should be taken in generalizing the findings here to the 'superbore' 0.088 inch aspiration catheters, as the significant relationships found may be non-linear in nature. Although our data do not suggest this, it should still be considered when interpreting the findings described here. Lastly, nearly all of the included studies are retrospective in design and without core-lab adjudication, which should be seriously considered given that operator reported outcomes are often over-reported compared with core-lab adjudicated imaging data.[46] Consequently, the clinical and angiographic success rates described here may be over-stated.

This was the first large-scale study to evaluate the clinical outcomes of primary aspiration thrombectomy as a function of aspiration catheter size. We found a significant association between ID and FPE, successful recanalization with aspiration only, and recanalization overall including instances with rescue techniques—though with a possible increased risk of hemorrhagic complications. Though smaller retrospective studies have suggested that larger bore catheters offer superior clinical outcomes, this study provides the most robust analysis on the topic to date. The findings here provide the clearest evidence that catheter size functions as a variable in aspiration thrombectomy efficacy, which should be considered in future study and trial design. Target vessel caliber would also serve as a critical data point in future clinical trial outcome reporting.

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