



Original research

# Technique and impact on first pass effect primary results of the ASSIST global registry

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► Additional supplemental material is published online only. To view, please visit the journal online (<http://dx.doi.org/10.1136/jnis-2023-021126>).

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Received 12 October 2023  
Accepted 19 December 2023

## ABSTRACT

**Background** Patients treated with mechanical thrombectomy (MT) for acute ischemic strokes from large vessel occlusion (LVO) have better outcomes with effective reperfusion. However, it is unknown which technique leads to better technical and clinical success. We aimed to determine which technique yields the most effective first pass reperfusion during MT.

**Methods** In a prospective, multicenter global registry we enrolled patients treated with operator preferred MT technique at 71 hospitals from January 2019 to January 2022. Three techniques were assessed: SR Classic with stent retriever (SR) and balloon guide catheter (BGC); SR Combination which employed SR with contact aspiration with or without BGC; and direct aspiration (DA) with or without BGC. The primary outcome was achieving an expanded Thrombolysis In Cerebral Infarction (eTICI) score of 2c or 3 on the first pass, with the primary technique as adjudicated by core lab. The primary clinical outcome measure was a 90-day modified Rankin Scale (mRS) score of 0–2.

**Results** A total of 1492 patients were enrolled. Patients treated with SR Classic or SR Combination were more likely to achieve first pass eTICI 2c or 3 reperfusion ( $P=0.01$ ). There was no significant difference in mRS 0–2 ( $P=0.46$ ) or safety endpoints.

**Conclusions** The use of SR Classic or SR Combination was more likely to achieve first pass eTICI 2c or 3 reperfusion. There were no significant differences in clinical outcomes and safety endpoints.

## WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ The three randomized trials, ASTER, ASTER-2 and COMPASS, were designed to assess if there was a difference in stent retrievers (SRs) to aspiration alone or with combination therapy. The studies included bail outs as part of the primary endpoints, thus making it difficult to ascertain if there is a difference in technical and clinical outcomes with the primary technique.

## WHAT THIS STUDY ADDS

⇒ By using first pass reperfusion success as a primary endpoint, the ASSIST Registry is assessing the success of the technique in the hands of operators employing their primary technique in the real world as it segments technical outcomes more effectively as the primary aim of an ideal device or technique.

## HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ The current study demonstrates the SR Classic technique leads to a higher rate of first pass effect compared with aspiration techniques. A regression analysis was performed based on patients with a complete dataset. The SR Classic arm demonstrated better 90-day outcomes which allows for future research to confirm this critical finding as it would impact clinical care and technological development.



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**To cite:** Gupta R, Miralbés S, Calleja Bonilla A, *et al*. *J NeuroIntervent Surg* Epub ahead of print: [please include Day Month Year]. doi:10.1136/jnis-2023-021126

## INTRODUCTION

The publication of several clinical trials demonstrating superior outcomes for patients receiving mechanical thrombectomy (MT) for acute ischemic strokes (AIS) due to large vessel occlusion (LVO) has dramatically improved outcomes for patients.<sup>1</sup> Unfortunately, only 26.9% of treated patients achieved a modified Rankin Score (mRS) of 0–1 and 46% an mRS of 0–2 at 90-day follow-up in a meta-analysis of five randomized controlled trials.<sup>1</sup> Successful reperfusion is critical to achieving good clinical outcomes, as a higher degree of reperfusion is linked to improved neurological recovery.

The expanded Thrombolysis In Cerebral Infarction (eTICI) score segments outcomes based on seven distinct grades.<sup>2</sup> An eTICI 2c or 3 score where >90% of the territory has undergone successful reperfusion is associated with a good 90-day mRS outcome (56.9% and 68.2%, respectively). First pass eTICI 3 score is a potential marker of measuring efficient procedural success,<sup>3</sup> and an excellent tool to compare techniques. There are several MT techniques currently employed to achieve successful reperfusion, but it is unclear whether one is superior in AIS treatment.<sup>4–6</sup>

Current techniques include the use of a stent retriever (SR) with a balloon guide catheter (BGC),<sup>7</sup> a combination of contact aspiration with an SR,<sup>8,9</sup> and direct aspiration (DA) alone.<sup>10</sup> Although each technique is commonly employed, there is limited evidence regarding which is the most effective first line strategy. The ASSIST Registry was designed as a multicenter global study in a real-world scenario to assess which technique will yield the highest rate of first pass eTICI 2c or 3.

## METHODS

### Study design and participants

The ASSIST Registry is a prospective, global, multicenter registry of anterior circulation AIS patients with an LVO who have undergone treatment with one of the interventional techniques using Stryker Neurovascular devices for the first pass in treating a target occlusion. The protocol allowed for enrollment of 1500 patients at up to 100 clinical sites globally. Seventy-one sites in 11 countries participated in the registry to enroll 1492 patients (online supplemental table 1). The institutional review boards and ethics committees at each site provided written approval of the study before recruitment of subjects into the registry. Each site was required to complete a qualification survey to determine the primary technique employed and ensure operator experience. This study is registered at Clinicaltrials.gov (number NCT03845491). The authors wrote this manuscript according to the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) cohort reporting guidelines.

For inclusion in the registry, patients must have experienced AIS with occlusion in an intracranial anterior circulation vessel. The intended treatment must be one of the pre-defined techniques using Stryker Neurovascular market-released products, the patient or legally authorized representative has signed an informed consent before or within 48 hours post-procedure, and the patient is willing to comply with the protocol follow-up requirements. Patients participating in another device trial or another clinical trial where the study procedure or treatment might confound this study's endpoint were not eligible.

The registry collected data on the following devices (including but not limited to): the AXS Infinity LS Long Sheath, the AXS Infinity LS Plus Long Sheath, the FlowGate<sup>2</sup> and Merci BGC, the AXS Catalyst Distal Access Catheters (DAC), the AXS Vecta Aspiration Catheters, the Trevo Retriever, and the Medela Dominant Flex pump.

On March 29, 2019, protocol amendment AB was approved by the steering committee to increase enrollment in the DA arm to allow for larger bore catheters given contemporaneous advances. Thus, a total of 397 patients were enrolled with AXS Catalyst 7, Vecta 71, and Vecta 74 in the DA arm.

### Procedures

After initial clinical and radiographic evaluation, patients deemed candidates for MT had a diagnostic angiogram performed on the target vessel to confirm the site of occlusion. The first technique employed was considered intention to treat with the primary technique. The procedure was completed after either successful reperfusion or an inability to recanalize the occluded cerebral vessel as per standard institutional protocols at each site. Data collected included but were not limited to demographics, pretreatment neurological assessment and radiographic parameters, technique used for each pass, clot location, angiographic imaging of each pass, and eTICI scores after each pass and final pass. Sites were requested to submit all de-identified angiographic data for enrolled subjects. Physicians were instructed to

use each device according to the intended use statement and per local regulatory approval. The procedural techniques evaluated were SR Classic, SR Combination, and DA. SR Classic combines a BGC and retrieval with the Trevo Retriever. SR Combination involves using DA, which may include a pump, applied at the clot in conjunction with proximal flow control and an SR. DA involves aspiration through the aspiration catheter, either BGC or long sheath, and may include a pump.

An independent core lab assessed the baseline non-contrast CT imaging as well as the 24 hour post-treatment CT or MRI for the type of hemorrhagic complication if present. Qualifying initial diagnostic angiography of the target vessel was also analyzed for the initial site of occlusion and reperfusion grades after each pass and final pass. The sponsor Stryker Neurovascular was responsible for data management, operations, and monitoring of each site enrolling patients in the registry.

### Primary procedural endpoint

The primary procedural outcome was the proportion of patients achieving an eTICI score<sup>2</sup> of 2c or 3 on the first pass with the primary technique as adjudicated by the independent core lab.

### Primary clinical endpoint

The primary clinical outcome measure was the proportion of patients achieving a 90-day mRS score of 0–2 which was collected by certified personnel at the centers performing the procedures.

### Secondary endpoints

Secondary procedural outcomes included an adjusted analysis of patients achieving successful reperfusion on first pass. Other procedural outcomes included eTICI scores after primary technique used, and the end of the endovascular procedure, time since groin puncture to achieve eTICI scores on first pass, and overall time from groin puncture to achieve eTICI 2c or 3 and final reperfusion. Secondary clinical outcomes included an adjusted analysis for patients achieving a 90-day mRS of 0–2, excellent functional outcome of mRS 0–1 at 90 days, as well as an early response at discharge or post-procedure day 5–7, whichever came first. This was defined as a National Institutes of Health Stroke Scale (NIHSS) drop of  $\geq 10$  points from baseline or an NIHSS score of 0 or 1.

### Safety endpoints

Safety outcomes included all-cause and stroke related mortality and device and/or procedure related serious adverse events (SAEs) during the study period. Additional outcomes included neurological deterioration at up to 48 hours (defined as an NIHSS increase  $\geq 4$  points from baseline), symptomatic intracranial hemorrhage adapted from the European Cooperative Acute Stroke Study (ECASS III),<sup>11</sup> and embolization to new territory as adjudicated by core lab. Adverse events, including SAEs, were collected from the start of the procedure to 90 days (online supplemental Table S2 and Table S3).

### Statistical analysis

Sample size considerations for the study were driven around having an adequate number of subjects to compare the rate of 90-day mRS 0–2 between any two technique arms. An overall rate of 50% for 90-day mRS 0–2 was assumed for the study, consistent with that observed in the TREVO Registry and a pooled analysis.<sup>11,12,13</sup> Assuming intra-site correlation of 0.15 and using the normal approximation to the binomial and two-sided

$\alpha$  of 0.05, a sample size of 1500 patients provides 82% power for detecting a 13% difference in the rate of 90-day mRS 0–2 (50% vs 37%) between any two technique arms.

Enrollment caps were instituted per technique to have more uniform subject enrollment and help mitigate the effect between physician and technique. Sites could enroll up to 45 patients in a single technique arm, and with sponsor permission, could enroll more. Enrollment caps per technique were 250 SR Classic, 700 SR Combination, and 550 DA.

All analyses comparing technique arms accounted for clustering within site, with the exception of the Kaplan-Meier analyses. Generalized linear mixed models with a random effect were used for continuous variables, and  $\chi^2$  tests adjusted for clustering were used for categorical variables.

Separate logistic regression models were performed for the primary procedural (eTICI 2c or 3 on first pass) and primary clinical (mRS 0–2 at 90 days) outcomes. Variables in the model were selected a priori based on the literature. Technique arm, age, baseline NIHSS, baseline Alberta Stroke Program Early CT Score (ASPECTS), history of atrial fibrillation, clot location, time last known normal to groin puncture, and intravenous tissue plasminogen activator (IV tPA) were candidate variables in the procedural outcome model. Technique arm, age, history of atrial fibrillation, baseline NIHSS, baseline ASPECTS, clot location, eTICI  $\geq 2c$  on first pass, eTICI  $\geq 2b$  at end of procedure, anesthesia, blood glucose, IV tPA, and time last known normal to end of procedure were candidate variables in the clinical outcome model. Variables that were significant ( $P < 0.05$ ) in univariate analyses were candidate variables for the multivariable model. The technique arm variable was forced into the model. Backward selection was then carried out until all variables in the model other than the technique arm were significant at  $P < 0.05$ . Models were adjusted for clustering within sites.

A Kaplan-Meier curve was generated to visualize failure to achieve eTICI 2c or 3 using the primary technique across technique arms, censoring for achievement of eTICI 2c or 3.

$P < 0.05$  was considered statistically significant. All analyses were performed using SAS 9.4 (SAS Institute Inc, Cary, NC).

## RESULTS

A total of 1492 patients were enrolled in the study, with 247 (16.6%) patients in the SR Classic arm, 697 (46.7%) patients in the SR Combination arm, and 548 (36.7%) in the DA arm (online supplemental Figure S1). The mean age of the entire population was  $70.4 \pm 14.3$  years, the median NIHSS was 14 (IQR 9–19), and 559 (37.5%) patients received intravenous thrombolytics before thrombectomy. Table 1 and online supplemental Tables S4 and S5 report the baseline demographic and procedural characteristics of patients enrolled in the study. Patients treated with DA alone were younger, more likely to harbor an intracranial internal carotid artery occlusion, presented with a lower baseline ASPECTS, and were more likely to present with a right-side intracranial occlusion.

### Primary procedural endpoint

Patients treated with SR Classic or SR Combination had a significantly higher rate of eTICI 2c or 3 after the first pass compared with DA alone (table 2). Operators using the SR Classic technique achieved eTICI 2c or greater first pass reperfusion in 47.2% of patients compared with 45.4% for SR combination and 36.5% for DA ( $P = 0.01$ ).

### Primary clinical endpoint

There was no significant difference in 90-day mRS 0–2 among the three techniques ( $P = 0.46$ ) (table 2).

### Secondary endpoints

A significantly higher proportion of patients achieved an eTICI 2c or 3 grade with SR Classic or SR Combination compared with DA before bail out or completion of the procedure (table 2). For all techniques, bail out is defined as switching to another technique for treatment of target occlusion, or to a procedural intervention other than treatment of target occlusion to improve eTICI. Bail out rate was 11.3% for SR Classic, 10.7% for SR Combination, and 37.0% for DA. The SR Classic technique achieved eTICI 2c or 3 64.9% of the time, SR Combination 60.9%, and DA 46.4% of procedures ( $P < 0.0001$ ). When assessing rates of eTICI 2c or 3 at the end of the procedure, inclusive of bail outs of the primary technique, there was no significant difference noted. Additionally, there was no significant difference in total procedure time among the techniques, inclusive of bail outs.

A regression analysis was performed to identify predictors of first pass eTICI 2c or 3 reperfusion ( $n = 1249$ ) (table 3). The use of the SR Classic technique compared with DA, higher baseline ASPECTS, and M1 middle cerebral artery occlusion location (compared with internal carotid artery (ICA)) were predictors of first pass success. SR Classic remained a significant predictor of first pass effect after adjusting for potential confounders. When compared with SR Classic, patients treated with SR Combination had similar first pass eTICI 2c or 3 rates while DA had significantly lower rates (adjusted OR 0.65, 95% CI 0.46 to 0.92,  $P = 0.02$  compared with SR Classic). An adjusted analysis was performed to identify variables associated with a 90-day mRS of 0–2 ( $n = 927$ ) (table 4). Patients who were treated under 6 hours from last known normal, with a favorable baseline NIHSS, or a higher baseline ASPECTS, had a higher probability of achieving an mRS of 0–2 at 90 days. A favorable eTICI score was also associated with a higher rate of mRS 0–2. Patients with a baseline blood glucose  $\geq 150$  mg/dL or age  $\geq 80$  years were less likely to achieve a good clinical outcome. SR Classic was a significant predictor of a good outcome after adjusting for confounders; SR Classic had better 90-day outcomes compared with SR Combination ( $P = 0.0006$ ), and marginally better results than DA ( $P = 0.06$ ).

### Safety endpoints

There were no significant differences in mortality, embolization to a new territory, or symptomatic hemorrhages among the three techniques (table 5). A total of 209 (14%) patients died within 90 days of their stroke. Embolization to a new territory was uncommon with 11 (0.7%) procedures noting this complication. The overall rate of symptomatic hemorrhages was low with 34 patients (2.3%) suffering this event. Hemorrhage types are outlined in online supplemental Table S6.

### Additional analyses

Patients treated with DA had a faster time to achieve eTICI 2c-3 with the first pass compared with both SR arms ( $19.4 \pm 12.6$  min DA vs  $23.1 \pm 13.0$  min SR Classic vs  $27.4 \pm 14.9$  min SR Combination,  $P < 0.0001$ ) (table 2). Despite the faster time for a DA pass, the rate of success was significantly less than SRs. SR Combination takes longer for each pass and does not appear to confer improved effectiveness in reperfusion compared with SR Classic.

**Table 1** Demographic, clinical and procedural characteristics

	SR Classic	SR Combination	DA	P value†
Age (years), mean (SD)	71.4 (14.3)	71.8 (13.1)	68.1 (15.4)	0.0004
Female, n (%)	121 (49.0)	379 (54.4)	281 (51.3)	0.24
Medical history, n (%)				
Hypertension	166 (67.5)	505 (74.6)	372 (68.6)	0.03
Congestive heart failure	33 (13.5)	99 (15.2)	68 (12.6)	0.50
Atrial fibrillation	93 (38.1)	233 (34.4)	164 (30.4)	0.05
Previous ischemic stroke	33 (13.6)	102 (15.3)	73 (13.8)	0.78
Previous intracerebral hemorrhage	4 (1.6)	14 (2.2)	10 (1.9)	0.87
Diabetes mellitus	50 (20.4)	154 (23.0)	129 (23.8)	0.60
Dyslipidemia	108 (44.1)	309 (47.8)	254 (47.1)	0.75
Current/past smoker	87 (38.2)	243 (41.3)	206 (42.7)	0.65
IV tPA administered, n (%)	79 (32.0)	285 (40.9)	195 (35.6)	0.32
Time last known normal to groin puncture, mean (SD)	7.5 (9.7)	7.5 (8.0)	8.5 (11.8)	0.21
Pre-stroke mRS, n (%)				0.02
0	178 (73.0)	448 (67.3)	390 (75.9)	
1	21 (8.6)	98 (14.7)	64 (12.5)	
2	21 (8.6)	43 (6.5)	30 (5.8)	
3	20 (8.2)	55 (8.3)	23 (4.5)	
4 or 5	4 (1.6)	22 (3.3)	7 (1.4)	
NIHSS score, mean (SD)	15.3 (6.6)	13.6 (6.7)	14.6 (6.2)	0.14
Baseline CT ASPECTS, mean (SD)	7.8 (1.4)	7.7 (1.4)	7.3 (1.5)	0.0002
Procedural characteristics				
Tandem occlusions, n (%)	26 (10.5)	108 (15.5)	78 (14.2)	0.42
General anesthesia, n (%)	69 (27.9)	242 (34.7)	271 (49.5)	0.19
Pre-procedure eTICI (core lab), n (%)				0.91
Grade 0 or 1	230 (93.9)	647 (93.4)	510 (94.1)	
Grade ≥2a	15 (6.1)	46 (6.6)	32 (5.9)	
Right side, n (%)	97 (39.6)	353 (50.9)	285 (52.3)	0.01
Site of occlusion (core lab), n (%)				<0.0001
ICA	38 (15.4)	129 (18.5)	156 (28.5)	
M1	145 (58.7)	341 (48.9)	300 (54.7)	
M2	63 (25.5)	215 (30.8)	90 (16.4)	
Distal vessel occlusion (A1, A2, M3)	1 (0.4)	12 (1.7)	2 (0.4)	
Number of passes to treat target occlusion using primary technique, mean (SD)	1.4 (0.9)	1.5 (0.9)	1.4 (0.8)	0.27
Number of passes to treat target occlusion after primary technique, mean (SD)*	1.5 (1.8)	1.0 (1.4)	1.3 (1.1)	0.19
BGC use	247 (100.0)	354 (50.8)	106 (19.3)	N/A‡
24 hour CT ASPECTS, mean (SD)	6.5 (2.1)	6.1 (2.2)	5.8 (2.3)	0.0013

\*Limited to 303 subjects who switched techniques.

†Means and frequencies are reported where the P value is from the generalized linear mixed model or  $\chi^2$  test adjusted for clustering.

‡P value cannot be calculated due to 100% cell count.

ASPECTS, Alberta Stroke Program Early CT Score; BGC, balloon-guide catheter; DA, direct aspiration; eTICI, expanded Thrombolysis In Cerebral Infarction; ICA, internal carotid artery; IV tPA, intravenous tissue plasminogen activator; mRS, modified Rankin Scale; NIHSS, National Institutes of Health Stroke Scale; SR, stent retriever.

When assessing success rate by primary technique (figure 1), the estimated median time to bail out or failure by primary technique was 50.0 min (95% CI 40.0 to 59.0 min) for SR Classic, 29.0 min (95% CI 27.0 to 31.0 min) for DA, and 55.0 min (95% CI 50.0 to 59.0 min) for SR Combination. In this analysis, to best assess the effectiveness of the primary technique, use of bail out by the operator was considered a failure to achieve reperfusion. Thus, despite each individual DA pass being faster, it was less effective compared with SRs and thus led to a lower

chance of successful eTICI 2c or 3 as the primary technique during the procedure.

Patients treated with smaller bore catheters compared with larger bore catheters in the DA arm were compared as part of the expansion of this arm of the study. A total of 548 patients were treated in the DA arm, with 146 (26.9%) treated with a small-bore catheter compared with 397 (73.1%) with larger bore catheters. In a post-hoc analysis, patients treated with the smaller bore catheters were more likely to achieve an mRS of

**Table 2** Angiographic and clinical efficacy outcomes

	SR Classic	SR Combination	DA	P value*
Primary clinical endpoint				
90-day mRS 0–2, n (%)	140 (59.1)	351 (52.7)	273 (54.0)	0.46
Secondary clinical endpoints				
90-day mRS 0–1, n (%)	112 (47.3)	264 (39.6)	209 (41.3)	0.17
Early response, n (%)	156 (66.1)	376 (58.2)	294 (58.0)	0.25
Primary procedural outcome (core lab)				
eTICI 2c or greater on first pass for treatment of target occlusion, n (%)	110 (47.2)	309 (45.4)	193 (36.5)	0.01
Secondary procedural outcomes (core lab)				
eTICI 2c or greater after primary technique, n (%)	157 (64.9)	417 (60.9)	248 (46.4)	<0.0001
eTICI 2c or greater at end of procedure, n (%)	171 (69.8)	449 (64.9)	357 (65.6)	0.61
Overall time from groin puncture to first pass efficacy for those who achieved first pass efficacy, mean (SD)	23.1 (13.0)	27.4 (14.9)	19.4 (12.6)	<0.0001
Overall time from groin puncture to final reperfusion (eTICI 2c or 3, mins) for treatment of target occlusion (mins), mean (SD)	29.2 (19.3)	31.3 (17.5)	27.1 (19.2)	0.68
Overall time from groin puncture to end of procedure (mins), mean (SD)	35.5 (24.3)	40.5 (29.4)	33.0 (24.1)	0.54
Overall time from last known normal to eTICI 2c or greater in passes for treatment of target occlusion (hours), mean (SD)	7.7 (9.7)	8.1 (9.0)	8.0 (10.2)	0.94
Overall time from last known well to end of procedure (hours), mean (SD)	8.3 (10.0)	8.2 (8.1)	9.0 (11.9)	0.39

\*Means and frequencies are reported where the P value is from the generalized linear mixed model or  $\chi^2$  test adjusted for clustering. DA, direct aspiration; eTICI, expanded Thrombolysis In Cerebral Infarction; mRS, modified Rankin Scale; SR, stent retriever.

**Table 3** Regression analysis with eTICI 2c or 3 on first pass as outcome

	Univariate analysis		Multivariable analysis	
	OR (95% CI)	P value	OR (95% CI)	P value
Technique group		0.01		0.02
SR Classic	Reference		Reference	
SR Combination	0.85 (0.59 to 1.22)	0.38	0.91 (0.63 to 1.31)	0.61
Direct aspiration	0.58 (0.40 to 0.85)	0.005	0.65 (0.46 to 0.92)	0.02
Age	1.01 (1.00 to 1.02)	0.02		
Baseline NIHSS	0.99 (0.98 to 1.01)	0.36		
Baseline ASPECTS total score	1.19 (1.10 to 1.29)	<0.0001	1.18 (1.09 to 1.27)	<0.0001
History of atrial fibrillation	1.12 (0.90 to 1.38)	0.30		
Clot location		<0.0001		<0.0001
ICA	Reference		Reference	
M1	2.08 (1.58 to 2.72)	<0.0001	1.93 (1.49 to 2.49)	<0.0001
M2	1.63 (1.17 to 2.26)	0.005	1.28 (0.91 to 1.79)	0.15
Time last known normal to groin puncture		0.07		
<6 hours	Reference			
6–24 hours	0.78 (0.64 to 0.96)	0.02		
>24 hours	0.81 (0.40 to 1.64)	0.55		
IV tPA	1.05 (0.86 to 1.30)	0.61		

Analysis was performed on subjects with non-missing data for all variables in the univariate analysis (n=1249). ASPECTS, Alberta Stroke Program Early CT Score; eTICI, expanded Thrombolysis In Cerebral Infarction; ICA, internal carotid artery; IV tPA, intravenous tissue plasminogen activator; NIHSS, National Institutes of Health Stroke Scale; SR, stent retriever.

0–2 at 90 days compared with the large bore group (66.2% vs 49.6%,  $P<0.0001$ ). However, patients in the larger bore group presented with higher NIHSS, lower ASPECTS, and a higher percentage of patients with clots in the ICA. There was no significant difference in first pass eTICI 2c or 3, with the smaller bore group achieving this endpoint 35.2% of the time compared with 37.4% in the larger bore group ( $P=0.66$ ).

## DISCUSSION

The current study demonstrates patients treated with the SR Classic or SR Combination techniques had a higher probability of achieving eTICI 2c or 3 during the first pass compared with DA. Although an individual DA pass was shorter in duration compared with the other two techniques, there was a significantly higher rate of bail out and less successful reperfusion using DA compared with SR. Additionally, patients treated with the SR Combination technique had longer times for each individual pass compared with DA and SR Classic. Patients treated with DA, if successful, achieved faster eTICI 2c or 3 with the first pass, but this rate of success was significantly lower than both SR techniques. Moreover, the efficacy of each successive DA pass does not appear to increase success rates compared with SRs (figure 1). The ASSIST Registry is to our knowledge the largest prospective dataset to assess the impact of technique on first pass reperfusion success based on the proceduralists' preferred primary technique.

The ideal technique would achieve eTICI 3 reperfusion with the first pass, as this has been linked to improved clinical outcomes and reduced complications.<sup>14 15</sup> A meta-analysis demonstrated a 28% rate of first pass effect when analyzing 9082 patients and the analysis did not demonstrate a difference among the three techniques. Care must be taken in interpreting these results as several of the studies were not adjudicated by an independent core lab, which is more stringent than site adjudication.<sup>16</sup> A first pass complete reperfusion was associated with better functional recovery compared with incomplete reperfusion.<sup>15</sup> The current

**Table 4** Regression analysis with mRS 0–2 at 90 days as outcome

	Univariate analysis		Multivariable analysis	
	OR (95% CI)	P value	OR (95% CI)	P value
Technique group		0.05		0.002
SR Classic	Reference			
SR Combination	0.73 (0.52 to 1.03)	0.07	0.52 (0.36 to 0.75)	0.0006
Direct aspiration	0.67 (0.46 to 0.96)	0.03	0.63 (0.39 to 1.01)	0.06
Age ≥80 years	0.45 (0.32 to 0.61)	<0.0001	0.29 (0.20 to 0.43)	<0.0001
History of atrial fibrillation	0.70 (0.52 to 0.95)	0.02		
Baseline NIHSS	0.88 (0.86 to 0.90)	<0.0001	0.87 (0.85 to 0.89)	<0.0001
Baseline ASPECTS total score	1.30 (1.18 to 1.44)	<0.0001	1.23 (1.10 to 1.38)	0.0003
Clot location		<0.0001		
ICA	Reference			
M1	1.37 (0.99 to 1.89)	0.06		
M2	2.19 (1.55 to 3.10)	<0.0001		
eTICI 2c or greater on the first pass for treatment of target occlusion	2.03 (1.47 to 2.80)	<0.0001	1.93 (1.31 to 2.84)	0.001
eTICI 2b or greater at end of procedure	4.33 (1.92 to 9.77)	0.0006	4.16 (1.63 to 10.61)	0.004
General anesthesia	1.01 (0.65 to 1.55)	0.98		
Blood glucose ≥150 mg/dL	0.57 (0.41 to 0.80)	0.001	0.56 (0.38 to 0.82)	0.003
Time last known normal to end of procedure		0.0008		0.01
<6 hours	Reference			
6–24 hours	0.64 (0.50 to 0.82)	0.0006	0.66 (0.48 to 0.92)	0.01
>24 hours	0.30 (0.13 to 0.69)	0.005	0.27 (0.10 to 0.72)	0.01
IV tPA	1.57 (1.16 to 2.13)	0.004		

Analysis was limited to subjects with baseline mRS 0–2.  
 Analysis was performed on subjects with non-missing data for all variables in the univariate analysis (n=927).  
 ASPECTS, Alberta Stroke Program Early CT Score; eTICI, expanded Thrombolysis In Cerebral Infarction; ICA, internal carotid artery; IV tPA, intravenous tissue plasminogen activator; mRS, modified Rankin Scale; NIHSS, National Institutes of Health Stroke Scale; SR, stent retriever.

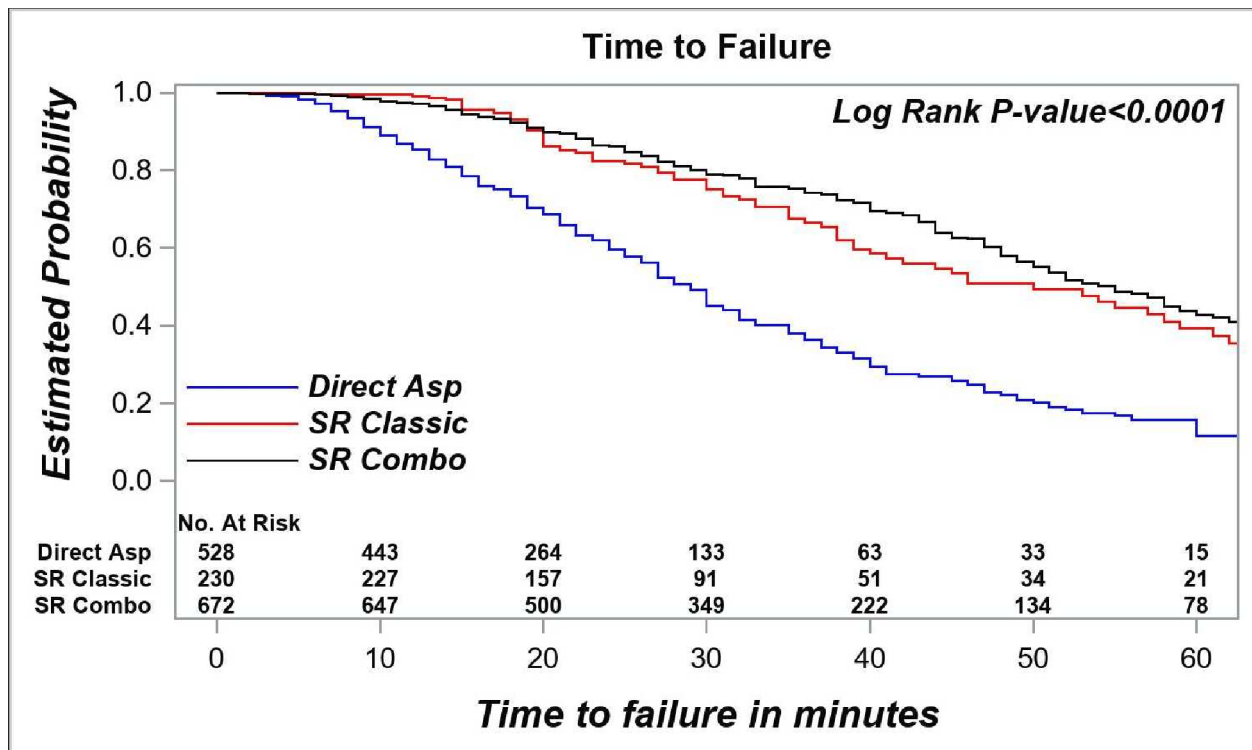
study demonstrates patients treated with an SR with or without concomitant contact aspiration were more likely to achieve first pass eTICI 2c or 3 reperfusion compared with DA. The ASTER study was designed to assess the superiority of successful revascularization of DA compared with SR alone. The study did not assess first pass reperfusion, but compared the two arms with regards to final successful mTICI 2b or 3 reperfusion. When comparing mTICI 3 by primary technique without bail out, the SR arm achieved this end point in 35.5% of patients compared with 28.7% for DA alone (P=0.16).<sup>5</sup> Although the study was underpowered for assessing this endpoint, the trends noted are consistent with the ASSIST Registry. The second ASTER study assessed whether SR Combination was superior to SR alone with

eTICI 2c or 3 at the end of the procedure. There was no significant difference between the two groups inclusive of bail outs, but in secondary analysis the investigators found that patients with combination treatment were significantly more likely to achieve eTICI 2c or 3 with the assigned treatment alone (86.2% vs 72.3%, P<0.001). Moreover, first pass eTICI 2c or 3 trended higher for combination therapy (40.9% vs 33.7%, P=0.12), although the study was not powered to detect a difference.<sup>5</sup> The COMPASS trial was a non-inferiority design to assess if there was a difference between primary aspiration and the use of SR. A large majority of patients in the SR arm were concomitantly treated with an aspiration catheter.<sup>4</sup> There were no significant differences between the two arms with regard to clinical

**Table 5** Safety

	SR Classic	SR Combination	DA	P value†
All-cause mortality at 90 days (±14 days), n (%)	28 (11.3)	105 (15.1)	76 (13.9)	0.46
Stroke-related mortality at 90 days (±14 days), n (%)*	19 (7.7)	63 (9.0)	38 (6.9)	0.54
Device and/or procedure related SAEs at 90 days (±14 days), n (%)	16 (6.5)	40 (5.7)	23 (4.2)	0.46
Embolization to new territory during procedure (core lab), n (%)	2 (0.8)	6 (0.9)	3 (0.6)	0.81
Symptomatic ICH up to 48 hours post-procedure, n (%)	5 (2.0)	15 (2.2)	14 (2.6)	0.84
Neurological deterioration (NIHSS ≥4) up to 48 hours post-procedure, n (%)	13 (5.3)	52 (7.5)	47 (8.6)	0.29
Access site complications up to 48 hours post-procedure, n (%)	3 (1.2)	10 (1.4)	2 (0.4)	0.14

\*5 subjects died of a new stroke that occurred post-procedure that was not the index stroke.  
 †Means and frequencies are reported where the P value is from the generalized linear mixed model or  $\chi^2$  test adjusted for clustering.  
 DA, direct aspiration; ICH, intracranial hemorrhage; NIHSS, National Institutes of Health Stroke Scale; SAEs, serious adverse events; SR, stent retriever.



**Figure 1** Survival analysis time to failure. Direct Asp, direct aspiration; SR, stent retriever.

outcomes, first pass TIC1 2b or greater reperfusion, or final reperfusion grade.

In the ASSIST Registry, the use of BGC was within the range of the ASTER and COMPASS randomized clinical trials.<sup>4,5</sup> It is likely reflective of real-world practice. However, given BGC use may improve outcomes, future studies comparing DA and SR may be warranted with BGC use being mandated in both arms.

There have been advances with larger aspiration catheters to enhance effectiveness. Larger bore catheters provide a higher force on the clot, potentially increasing effectiveness, but have not been proven in core lab adjudicated studies.<sup>17,18</sup> The advent of larger bore 0.088 inch catheters are being tested as potential first line treatment for LVO. Limited reports exist, but a recent report with the TracStar LDP (Imperative Care) demonstrated the catheter can be placed at the target occlusion site 73% of the time.<sup>19</sup> The SUMMIT NZ trial was prospective and core lab adjudicated and reported preliminary results using the 088 HiPoint catheter. In this small study, 17 out of 38 patients (44.7%) achieved eTIC1 2c or 3 first pass reperfusion.<sup>20</sup> These results are in the range of what was seen for the SR procedures in the current study. A recent meta-regression analysis demonstrated a higher rate of first pass reperfusion TIC1 2b or 3 with increasing diameters of the catheter, but this effect was not seen in binary comparison of 0.071 inch or larger compared with less than 0.071 inch catheters. Moreover, the authors found a higher rate of symptomatic hemorrhages with larger bore catheters.<sup>21</sup> Patients enrolled in the DA arm of the ASSIST Registry did not have a significant difference in first pass reperfusion with larger bore catheters compared with smaller bore catheters.

In unadjusted analysis, there were no differences seen in clinical outcomes among the three techniques. When an adjusted analysis was performed of a complete dataset the patients treated with the SR Classic technique had better clinical outcomes than SR Combination, and a trend was noted for better outcomes than DA. Caution must be taken in interpreting the adjusted analysis

as roughly one third of the patients could not be included in the analysis. Nonetheless, the difference does help generate an opportunity for future research to determine if there are clinical outcome differences based on technique.

There are several limitations to the current study. The first is the patients were not randomized, but each site declared their preferred technique during an initial survey phase of the study, allowing for planning of the number of patients anticipated in each arm. Although randomization may be a preferred strategy, the current trial accounted for the technique the operator is most familiar with in their current practice and averts a bias of reduced experience by forcing a technique they may not be accustomed to. Second, centers were highly encouraged to enroll consecutive patients but this did not always occur due to the inability to obtain consent or one of the Stryker devices not being used as first line treatment. Third, some patients or their legally authorized representatives consented retroactively after completion of the procedure. It is possible this created a bias where patients with poor outcomes were not consented, but this would have been consistent across all arms of the study. Fourth, rescue or bail out therapy was allowed during the study and operators may have employed this strategy at various points after their first pass with the primary technique. There was no a priori study protocol for number of passes before failure of a technique, but switching techniques was considered a bail out or failure of the primary technique. Fifth, device technology is constantly evolving, and the current study design did not assess aspiration catheter sizes larger than the Vecta 074 inch catheter. Sixth, the current study assessed the Trevo SR and Catalyst and Vecta aspiration catheters manufactured by Stryker Neurovascular. There may be inherent differences in designs of various current technologies that may yield differing results. Lastly, the analysis for the primary outcomes was based on available data. However, in sensitivity analyses where patients missing outcome data were designated as having poor outcomes, the results did not

change (online supplemental Table S7). Additionally, although a regression analysis could only be performed in patients with complete data, SR Classic may be associated with better clinical outcomes compared with the other two techniques after adjustment. Further investigation is required to confirm this trend.

In conclusion, the ASSIST Registry demonstrates patients treated either with SR Classic or SR Combination are significantly more likely to achieve a first pass eTICI 2c or 3 compared with DA and no significant differences in functional outcomes or safety.

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**Contributors** RG and MM drafted the initial manuscript and are responsible for the overall content as the guarantors. LLP analyzed the data. All authors were involved and made substantial contributions to the conception or design of the work, or the acquisition, analysis, or interpretation of the data; revising it critically for important intellectual content; final approval of the version published; and agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The corresponding author as well as all authors had access to the full dataset and the interpretation and writing of the manuscript was under the discretion of the authors.

**Funding** The ASSIST Registry was sponsored and funded by Stryker Neurovascular.

**Competing interests** RG serves as Principal Investigator (PI) for the ASSIST Registry (Stryker), PI for the RECLAIM II Study (Zoll), Clinical Events Committee (CEC) for the MIND Trial (Penumbra), Data Safety Monitoring Board (DSMB) Membrane Study (Cerenovus), ELEVATE Study (Medtronic) consultant and stock options for Vesalio, Rapid Medical. AM serves as a consultant for Stryker. AS received research grants from Penumbra, Stryker, Medtronic, Avail, Rapid AI, Brain Aneurysm Foundation, consultant for Penumbra, Stryker, Terumo, RAPID AI, DSMB Brain Aneurysm Foundation, Stock options for Avail. CL is a consultant for Penumbra, Phenox, Stryker. DV received a research grant from Microvention, is a consultant for Medtronic, receives payment or honoraria for lectures from Cerenovus, travel support from Microvention and Medtronic. LD is a consultant for Stryker. LLP is an employee of Stryker and holds Stryker stock. LD is a consultant for Cerenovus, Genentech, Medtronic, Rapid Medical, Stryker, and Vesalio. MM received research grants from Acandis, Balt, Medtronic, Microvention, Phenox, Stryker\* (\*industry payments are made to the research fund of the institution), receives payment or honoraria for lectures from Balt, Medtronic, Stryker\* (\*industry payments are made to the research fund of the institution).

**Patient consent for publication** Not applicable.

**Ethics approval** This study involves human participants and was performed in compliance with the World Medical Association's Declaration of Helsinki. This study was approved by Advocate Health and Hospitals 'Western Institutional Review Board Puyallup, WA' 20191803; Buffalo University 'Western Institutional Review Board Puyallup, WA' 20191803; Kaiser Permanente – LA 'Kaiser Permanente Southern California Institutional Review Board Pasadena, CA' 12330; Medical University of South Carolina 'Institutional Review Board for Human Research (IRB) Office of Research Integrity (ORI) Medical University of South Carolina Palmetto Place Office Park Charleston, SC' Pro00089838 Thomas Jefferson University 'Western Institutional Review Board Puyallup, WA' 20191803; U Mass 'Western Institutional Review Board Puyallup, WA' H00020421\_2; West Virginia University Hospital 'West Virginia University Office of Human Research Protections Morgantown, WV' 1908690661; Semmes Murphey Foundation 'University of Tennessee Health Science Center IRB Memphis, TN' 20-07240-XP; Riverside Methodist – OHRI 'Western Institutional Review Board Puyallup, WA' Institution Tracking: 1555244; IRB Tracking: 20191803; UC Irvine 'Western Institutional Review Board Puyallup, WA' Institution

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**Provenance and peer review** Not commissioned; externally peer reviewed.

**Data availability statement** The data supporting the findings of this study are available from the corresponding author on reasonable request.

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