Brief Report

Contact Aspiration Versus Stent Retriever in Patients With Acute Ischemic Stroke With M2 Occlusion in the ASTER Randomized Trial (Contact Aspiration Versus Stent Retriever for Successful Revascularization)

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Background and Purpose—Middle cerebral artery M2-segment occlusions represent an important subgroup of patients with acute stroke with large-vessel occlusion. The safety of mechanical thrombectomy, especially contact aspiration (CA), in such distal intracranial occlusions is still under debate. We compared reperfusion, adverse events, neurological recovery, and functional outcome of patients with isolated M2 occlusions according to the first-line strategy mechanical thrombectomy devices (CA versus stent retriever [SR]).

Methods—This is a post hoc analysis of the ASTER trial (Contact Aspiration Versus Stent Retriever for Successful Revascularization). The primary outcome was successful reperfusion at the end of all endovascular procedures, defined as modified Thrombolysis in Cerebral Infarction (mTICI) scores 2b/3. Secondary outcomes were mTICI 2c/3 and mTICI 3, 90-day functional outcome, assessed with the modified Rankin Scale score. Safety outcomes included 90-day mortality and any symptomatic intracerebral hemorrhage.

Results—Seventy-nine patients were included: 48 were allocated to the CA group and 31 to the SR group. There were no significant differences between CA and SR groups in reperfusion after all endovascular procedures regarding mTICI 2b/3 (89.6% versus 83.9%; P=0.36), mTICI 2c/3 (54.2% versus 54.8%; P=0.90), and mTICI 3 (35.4% versus 41.9%; P=0.36) rates. There were no significant differences between CA and SR groups in 90-day modified Rankin Scale ≤2 rate (54.4% versus 50.0%; P=0.84), 24-hour change in National Institutes of Health Stroke Scale (mean difference, −3.9; 95% confidence interval, −7.9 to 0.01), and Alberta Stroke Program Early Computed Tomography score (mean difference, 0.9; 95% confidence interval, −0.1 to 2.0) scores. Safety parameters were well balanced between the 2 groups except for a higher 90-day mortality rate in the CA group (19.6% versus 3.3%; P=0.078).

Conclusions—First-line mechanical thrombectomy with CA compared with SR did not result in an increased successful revascularization rate in patients with acute stroke with isolated M2 occlusion. **(*Stroke*. 2018;49:00-00. DOI: 10.1161/STROKEAHA.117.019598.)**

Key Words: aspiration ■ cerebral hemorrhage ■ confidence intervals ■ safety ■ stent retriever ■ stroke ■ thrombectomy

Only a limited number of patients with middle cerebral artery M2 occlusion strokes were included in trials. They nevertheless represent an important subgroup of patients with large-vessel occlusion. Although more data are needed to address the question of mechanical thrombectomy (MT) benefit for M2 occlusions, in practice, MT is usually performed in

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*A list of ASTER Investigators is given in the Appendix.

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these cases.[1] The safety of MT in M2 occlusions remains a concern, and stent retriever (SR) may be more difficult to maneuver in the distal arteries. The comparison of results of contact aspiration (CA) versus SR is limited to date.[2] The aim of this post hoc study was to compare reperfusion, adverse events, neurological recovery, and functional outcome according to the first-line strategy in patients with an isolated M2 occlusion within the framework of the ASTER trial (Contact Aspiration Versus Stent Retriever for Successful Revascularization).

Methods

Patient Selection

Patient eligibility and methods of ASTER have been reported previously.[3] In the present analysis, we included patients with an M2-segment middle cerebral artery occlusion on the initial angiogram, according to the core laboratory analysis. The M2 segment was defined as the vertical middle cerebral artery branches in the Sylvian fissure originating at the genu and extending to the next genu at the level of the operculum. If the anterior temporal artery arises from the horizontal M1 segment, is not considered an M2 branch.[4] Institutional review board approval and written informed consent was obtained. Treatment modalities are detailed in the online-only Data Supplement. The data that support the findings of this study are available from B.L. on reasonable request.

Outcomes

The primary outcome was successful reperfusion defined as a modified Thrombolysis in Cerebral Infarction (mTICI) score of 2b or 3 at the end of all endovascular procedures. Secondary technical efficacy outcomes were mTICI score 2b/3 at the end of first-line strategy, mTICI score 2c/3, and mTICI score 3 at the end of first-line procedure and at the end of all procedures. Secondary clinical efficacy outcomes were the degree of disability assessed by the modified Rankin Scale score at 90 days, change in National Institutes of Health Stroke Scale score and Alberta Stroke Program Early Computed Tomography score at 24 hours. Safety included procedure-related serious adverse events, intracranial hemorrhage on imaging at 24 hours, and death because of any cause at 90 days. All angiographic and neuroimaging readings were performed at the imaging core laboratory, blinded to procedure allocation.

Statistical Analysis

Categorical variables were expressed as frequencies and percentages and continuous as mean (SD) or median (interquartile range) for nonnormal distribution. Normality of distributions was assessed graphically and by using the Shapiro–Wilk test. Baseline characteristics were described in each treatment group, and absolute standardized differences were calculated to evaluate baseline imbalance; absolute standardized differences >20% were interpreted as meaningful imbalance. Efficacy outcomes were compared between the 2 treatment groups using a generalized linear mixed model adjusted for the randomization stratification variables by including thrombolysis as a fixed effect and center as a random effect (further details in the online-only Data Supplement). No adjustment for multiple testing was applied, and thus results are considered exploratory. Statistical testing was conducted at the 2-tailed α level of 0.05. Data were analyzed using the SAS software package, release 9.4 (SAS Institute, Cary, NC).

Results

Among 381 patients, 79 were included in the present study (Figure I in the online-only Data Supplement); 48 were allocated to the CA group and 31 to the SR group. There were several meaningful between-group differences in baseline characteristics, the greatest difference being in admission systolic blood pressure (absolute standardized differences, 48%; Table I in the online-only Data Supplement).

Successful reperfusion after all endovascular procedures was achieved in 87.3% (n=69) of overall cases, with no significant difference between the 2 groups (adjusted risk ratio for CA versus SR, 0.92; 95% confidence interval, 0.39–2.16; *P*=0.85; Table 1; Figure II in the online-only Data Supplement). There were no significant differences in near to complete reperfusion rates at the end of all procedures. Similarly, no significant difference in reperfusion rates after first-line strategy was observed. Rescue therapy was used in 15 (31.3%) of the patients with CA and 6 (19.4%) of the patients with SR (adjusted risk ratio, 1.17; 95% confidence interval, 0.81–1.6; *P*=0.38). There was no significant difference in the total number of passes (median [interquartile range], 2 [1–4] in CA versus 2 [1–3] in SR; *P*=0.75) and in the median time from puncture to reperfusion (41 minutes [interquartile range, 25–57] in the CA group and 50 minutes [interquartile range, 33–70] in SR group; *P*=0.25).

Patients with SR had a greater decrease in 24-hour National Institutes of Health Stroke scale compared with patients with CA (mean difference [CA versus SR], −3.9; 95% confidence interval, −7.9 to 0.01; *P*=0.051). A similar nonsignificant difference in 24-hour Alberta Stroke Program Early Computed CT score change in favor of SR was observed (mean difference [CA versus SR], 0.9; 95% confidence interval, −0.1 to 2.0; *P*=0.084). No difference in 90-day functional outcome was found (Table 2; Figure III in the online-only Data Supplement). Mortality at 90 days occurred in 9 patients (19.6%) in the CA group and in 1 patient (3.3%) in the SR group (*P*=0.078). Procedure-related adverse events occurred in 7 (14.6%) patients with CA and in 3 (9.7%) patients with SR (*P*=0.73). Symptomatic intracranial hemorrhage occurred in 4 patients overall.

Discussion

Our study suggests that effectiveness and safety should not be an argument in the choice of the first-line strategy for MT of isolated M2 occlusions because we observed no significant differences on reperfusion, infarct volume, clinical outcome, or adverse events. However, we found a difference of borderline significance in early imaging and clinical favorable evolution, as well as a lower 90-day mortality rate, in patients treated primarily with SR. In addition, a rescue therapy was used more frequently in CA-assigned patients, probably because of a lower mTICI 3 rate in CA group after the first-line strategy alone.

Similar outcomes were published after MT of M2 occlusions. In a retrospective multicenter study including 117 patients with M2 occlusion treated with MT, 56% of patients achieved a 90-day modified Rankin Scale score ≤2, whereas the mTICI 2b/3 rate was 85%, and parenchymal hematoma occurred in 13%.[5] The authors observed no difference between 2 approaches (51 patients in CA group and 62 in SR group). There was no difference in reperfusion and 90-day modified Rankin Scale ≤2 rates in another small retrospective study; however, SR provided faster reperfusion.[2] Further studies are warranted.

Limitations

Our study was not powered to analyze the differences in outcomes for isolated M2 occlusions after MT, and randomization

Table 1. Effectiveness Outcomes

	Overall (n=79)	First-Line Strategy		Effect Size	Value (95% CI)	*P* Value
		Contact Aspiration (n=48)	Stent Retriever (n=31)			
Angiographic outcomes						
Reperfusion after first-line strategy alone						
mTICI 2b/3	52/79 (65.8)	31/48 (64.6)	21/31 (67.7)	Risk ratio	0.92 (0.39–2.16)	0.85
mTICI 2c/3	36/79 (45.6)	21/48 (43.8)	15/31 (48.4)	Risk ratio	0.93 (0.62–1.39)	0.73
mTICI 3	26/79 (32.9)	14/48 (29.2)	12/31 (38.7)	Risk ratio	0.84 (0.58–1.20)	0.33
Reperfusion at end of all procedures						
mTICI 2b/3	69/79 (87.3)	43/48 (89.6)	26/31 (83.9)	Risk ratio	1.60 (0.58–4.34)	0.36
mTICI 2c/3	43/79 (54.4)	26/48 (54.2)	17/31 (54.8)	Risk ratio	1.03 (0.67–1.56)	0.90
mTICI 3	30/79 (38.0)	17/48 (35.4)	13/31 (41.9)	Risk ratio	0.86 (0.63–1.18)	0.36
Use of rescue therapy	21/79 (26.6)	15/48 (31.3)	6/31 (19.4)	Risk ratio	1.17 (0.81–1.69)	0.38
Clinical outcomes						
Δ NIHSS at 24 h*	4.2 (2.1–6.3)	2.8 (0.2–5.4)†	6.8 (3.4–10.2)†	Mean difference	−3.9 (−7.9 to 0.01)†	0.051†
Δ ASPECTS at 24 h	1.2 (0.6–1.8)	1.5 (0.7–2.4)†	0.6 (−0.4 to 1.6)†	Mean difference	0.9 (−0.1 to 2.0)†	0.084†
90-d mRS score ≤2	40/76 (52.6)	25/46 (54.4)	15/30 (50.0)	Risk ratio	1.07 (0.56–2.01)	0.84
90-d mRS score	2 (1–4)	2 (1–4)	2.5 (0–3)	Common odds ratio	0.59 (0.25–1.39)	0.22

Values expressed as number/total number (%), or mean (95% CI) unless otherwise stated. Effect sizes and *P* values were calculated after adjustment for center and use of intravenous thrombolysis (*). ASPECTS indicates Alberta Stroke Program Early Computed Tomography score; CI, confidence interval; mRS, modified Rankin Scale; mTICI, modified Thrombolysis in Cerebral Ischemia; and NIHSS, National Institutes of Health Stroke Scale.

*Additional adjustment for baseline score.

†Five missing NIHSS at 24 hours (n=3 in intervention arm).

was not performed according to the occlusion location in ASTER. Despite randomization, baseline characteristics are not well balanced between 2 groups, as a higher admission systolic blood pressure level in CA group explaining its potential unfavorable outcome. However, the present analysis is the largest prospective study comparing the 2 most commonly used MT approaches, including core laboratory, within the framework of a randomized trial.

Table 2. Safety Parameters

	Overall (n=79)	First-Line Strategy		*P* Value
		Contact Aspiration (n=48)	Stent Retriever (n=31)	
Clinical events				
Symptomatic intracerebral hemorrhage	4/79 (5.1)	3/31 (6.3)	1/31 (3.2)	…
90-day all-cause mortality	10/76 (13.2)	9/46 (19.6)	1/30 (3.3)	0.078
Radiological findings				
Any intracerebral hemorrhage	30/79 (38.0)	19/48 (39.6)	11/31 (35.5)	0.71
Subarachnoid hemorrhage	4/79 (5.1)	2/48 (4.2)	2/31 (6.5)	…
Parenchymal hematoma	9/79 (11.4)	5/48 (10.4)	4/31 (12.9)	0.73
Procedural events				
Overall procedure-related adverse events	10/79 (12.7)	7/48 (14.6)	3/31 (9.7)	0.73
Embolization in a new territory	2/79 (2.5)	2/48 (4.2)	0/31 (0.0)	…
Arterial perforation	1/79 (1.3)	1/48 (2.1)	0/31 (0.0)	…
Arterial dissection	1/79 (1.3)	1/48 (2.1)	0/31 (0.0)	…
Vasospasm	4/79 (5.1)	2/48 (4.2)	2/31 (6.5)	…

Values expressed as number/total number (%) unless otherwise stated.

Conclusions

M2 occlusions MT with first-line CA did not result in an increased successful revascularization rate compared with SR.

Appendix

ASTER Trial (Contact Aspiration Versus Stent Retriever for Successful Revascularization) Investigators

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Disclosures

Dr Lapergue received a significant (>$10 K or 5%) research grant for ASTER trial (Contact Aspiration Versus Stent Retriever for Successful Revascularization) and had modest (<$10 K or <5%) speaking engagements.

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Contact Aspiration Versus Stent Retriever in Patients With Acute Ischemic Stroke With M2 Occlusion in the ASTER Randomized Trial (Contact Aspiration Versus Stent Retriever for Successful Revascularization)

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SUPPLEMENTAL MATERIAL

Contact Aspiration vs Stent Retriever in Acute Ischemic Stroke Patients with M2 Occlusion in ASTER Randomized Trial

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Supplemental Appendix

Supplemental Methods

Treatment Modalities

MT was performed using CA or SR. Operators were required to make at least 3 attempts at revascularization using the assigned endovascular technique before switching to another endovascular procedure (rescue therapy) if needed. The decisions of whether to use a rescue therapy and which therapy to use were left to the discretion of the operator. Permitted rescue techniques were CA, SR, combined CA and SR, and angioplasty with or without stenting.

Statistical Analysis

For binary efficacy outcomes, we used a generalized linear mixed model (GLMM model with binomial distribution and log-link function) with allocated group and IV thrombolysis as fixed effects and center as random effect; adjusted risk ratio (CA vs. SR) was derived from GLMM models as treatment effect size. For overall distribution of mRS (shift analysis after combining scores of 5 and 6), a mixed ordinal logistic regression model (including prior use of IV thrombolysis as fixed effect and center as a random effect) was used and common odds ratio (OR) for 1 point improvement in mRS was reported as treatment effect size. For 24-hours change in NIHSS and ASPECTS scores, a linear mixed model (including prior use of intravenous thrombolysis as fixed effect and center as a random effect) was used and adjusted mean difference was reported as treatment effect size; normality of model residuals was satisfied. Finally, a Mann-Whitney U test was used to compare the time from groin puncture to successful reperfusion and number of passes and a Fisher's exact for adverse events.

Supplemental Results

Supplemental Table. Baseline Characteristics According to the First-Line Strategy

	Overall (n=79)	First-line strategy		ASD, %
		Contact Aspiration (n=48)	Stent Retriever (n=31)	
Demographics				
Age (mean, SD)	69.6 (14.3)	69.3 (14.9)	70.2 (13.4)	6.4
Male sex	44/79 (44.3)	26/48 (54.2)	18/31 (58.1)	7.9
History				
Hypertension	48/79 (60.8)	30/48 (62.5)	18/31 (58.1)	9.1
Diabetes mellitus	19/79 (24.1)	11/48 (22.9)	8/31 (25.8)	6.7
Hypercholesterolemia	28/78 (35.9)	18/48 (37.5)	10/30 (33.3)	8.7
Current smoking	15/64 (23.4)	11/39 (28.2)	4/25 (16.0)	29.7
Coronary artery disease	19/77 (24.7)	11/47 (23.4)	8/30 (26.7)	7.5
Previous stroke or TIA	13/79 (16.5)	9/48 (18.8)	4/31 (12.9)	16.1
Previous antithrombotic medications	40/78 (51.3)	22/47 (46.8)	18/31 (58.1)	22.7
Antiplatelet	25/48 (32.1)	14/47 (29.8)	11/31 (35.5)	12.2
Anticoagulant	17/48 (21.8)	9/47 (19.2)	8/31 (25.8)	16.0
Physical				
Systolic BP, mm Hg (mean, SD)	148 (25)	152 (24)	141 (24) [1]	47.8

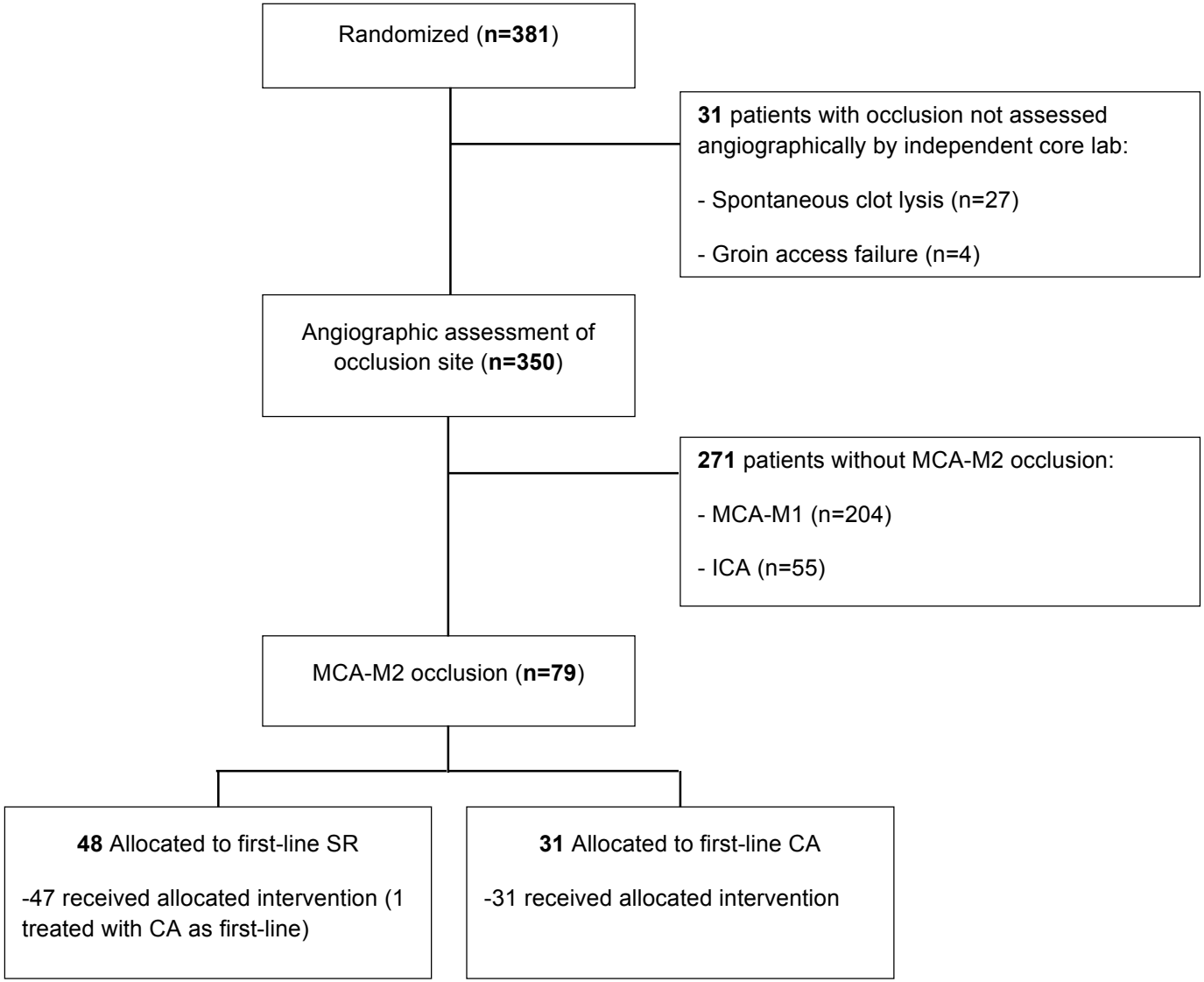
NIHSS (mean, SD)	13.4 (6.3)	13.2 (6.1) [2]	13.7 (6.5)	7.0
Neuroimaging				
ASPECTS (median, IQR)	8 (6-9)	8 (6-9)	7 (6-9)	9.3
Clot length, mm	9 (7-12)	9 (7-12) [3]	9 (8-11) [4]	8.7
Favorable collaterals at baseline angiograms	18/71 (25.4)	11/45 (24.4)	7/26 (26.9)	5.7
Suspected stroke cause				
Large artery atherosclerosis	6/79 (7.6)	5/48 (10.4)	1/31 (3.2)	33.8
Cardioembolic	33/79 (41.8)	21/48 (43.8)	12/31 (38.7)	
Other or Unknown	40/79 (50.6)	22/48 (45.8)	18/31 (58.1)	
Logistics and treatment details				
tPA pretreatment	54/79 (68.4)	31/48 (64.6)	23/31 (74.2)	21.0
General anesthesia	9/79 (11.4)	5/48 (10.4)	4/31 (12.9)	7.8
Onset to groin puncture time, min (median, IQR)	230 (166-270)	240 (161-270) [2]	228 (190-271) [2]	1.4
Onset to imaging	99 (77-130)	104 (77-130) [2]	95 (75-137)	11.9
Imaging to groin puncture	129 (58-160)	113 (55-160)	133 (67-150) [2]	12.0

Values expressed as no/total no. (%) unless otherwise indicated.

[1] n=2 missing values; [2] n=1 missing value; [3] n=16 missing values; [4] n=5 missing value.

ASD indicates absolute standardized difference; ASPECTS, Alberta Stroke Program Early Computed CT Score; IQR, interquartile range; NIHSS, National Institutes of Health Stroke Scale; tPA, tissue-type plasminogen activator; TIA, transient ischemic attack; SD, standard deviation.

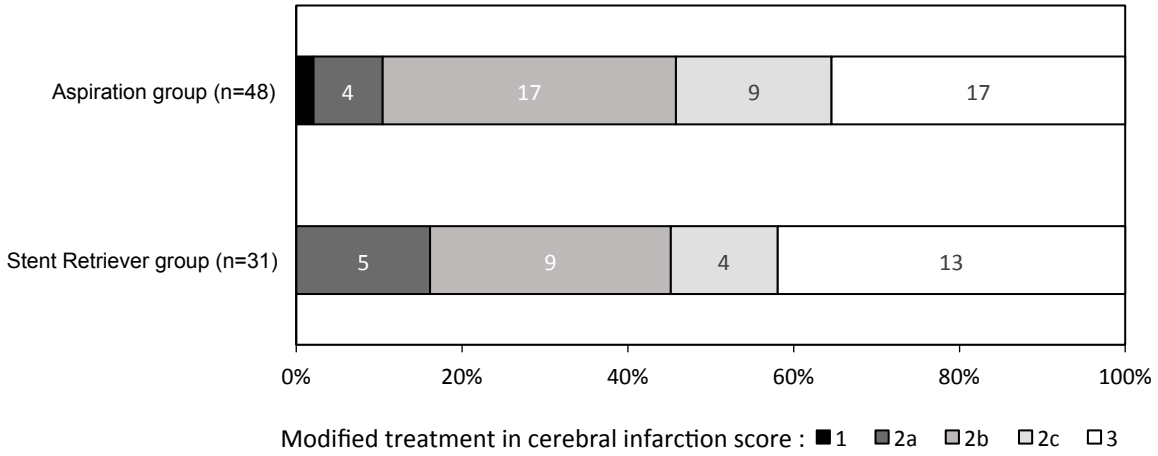
Supplemental Figure I. Study Flow-Chart



CA indicates contact aspiration; SR, stent retriever; ICA, internal carotid artery; MCA, middle cerebral artery.

Supplemental Figure II. Modified Treatment In Cerebral Infarction score at the End of all Endovascular Procedures.

Outcomes are compared for the Contact Aspiration group versus Stent Retriever group.



Supplemental Figure III. Modified Rankin Scale at 90 Days.

Outcomes are compared for the Contact Aspiration group versus Stent Retriever group.