

Original Paper

Clinical and Angiographic Outcomes with the Combined Local Aspiration and Retriever in the North American Solitaire Stent-Retriever Acute Stroke (NASA) Registry

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Keywords

Stroke · Stent retriever · Thrombectomy · Aspiration technique

Abstract

Background: Various techniques are used to enhance the results of mechanical thrombectomy with stent-retrievers, including proximal arrest with balloon guide catheter (BGC), con-

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ventional large bore proximal catheter (CGC), or in combination with local aspiration through a large-bore catheter positioned at the clot interface (Aspiration-Retriever Technique for Stroke [ARTS]). We evaluated the impact of ARTS in the North American Solitaire Acute Stroke (NASA) registry. **Summary:** Data on the use of the aspiration technique were available for 285 anterior circulation patients, of which 29 underwent ARTS technique, 131 CGC, and 125 BGC. Baseline demographics were comparable, except that ARTS patients are less likely to have hypertension or atrial fibrillation. The ARTS group had more ICA occlusions (41.4 vs. 22% in the BGC, $p = 0.04$ and 26% in CGC, $p = 0.1$) and less MCA/M1 occlusions (44.8 vs. 68% in BGC and 62% in CGC). Time from arterial puncture to reperfusion or end of procedure with ARTS was shorter than with CGC (54 vs. 91 min, $p = 0.001$) and was comparable to the BGC time (54 vs. 67, $p = 0.11$). Final degree of reperfusion was comparable among the groups (TICI [modified Thrombolysis in Cerebral Infarction] score 2b or higher was 72 vs. 70% for CGC vs. 78% for BGC). Procedural complications, mortality, and good clinical outcome at 90 days were similar between the groups. **Key Messages:** The ARTS mechanical thrombectomy in acute ischemic stroke patients appears to yield better results as compared to the use of CGCs with no significant difference when compared to BGC. This early ARTS technique NASA registry data are limited by the earlier generation distal large bore catheters and small sample size. Future studies should focus on the comparison of ARTS and BGC techniques. © 2017 S. Karger AG, Basel

Introduction

Recent studies have shown that endovascular reperfusion therapies for acute ischemic stroke caused by proximal large vessel occlusion are safe and improve patient clinical outcome when compared to best medical therapy without endovascular intervention [1–4]. Previous studies of these endovascular rescue therapies had demonstrated that successful reperfusion and the time to successful reperfusion correlate with good clinical outcome [5–9].

Published multicenter series of endovascular stroke therapy have reported procedural or reperfusion times of 96–126 min with earlier endovascular stroke devices and strategies (defined as beginning with groin puncture to end of procedure) [10–13]. The time has improved to 36–48 min (although now defined to begin with guide catheter placement in TREVO 2 and STAR and with first guide catheter angiogram in SWIFT to TICI [modified Thrombolysis in Cerebral Infarction] score 2b reperfusion) with more recent series reporting stent retriever technologies [7, 13, 14–17]. Still, these procedural reperfusion times can represent 38% of the overall time elapsed from symptom onset to reperfusion [10] and so a therapeutic or technical strategy which significantly decreases these procedural reperfusion times may translate into clinically significant decreases in the overall time of ischemia.

Endovascular clot removal with stent retrievers can be performed without aspiration. Clot retrieval combined with aspiration techniques can be performed through a conventional large bore proximal catheter (CGC) positioned with its tip in the cervical carotid (internal carotid or common carotid), or through a balloon guide catheter (BGC) positioned with its tip in the cervical carotid, [18] or through a large bore distal access catheter positioned with its tip intracranially at the proximal clot interface (Aspiration-Retriever Technique for Stroke “ARTS” (also previously referred to as “Solumbra technique”; Fig. 1). Anecdotal reports suggest this latter technique is gaining popularity in real-world use, but there are few other reports in the literature measuring its technical and clinical outcomes [19]. We sought to evaluate the impact of local clot aspiration in a substudy of the North American Solitaire Acute Stroke (NASA) registry.

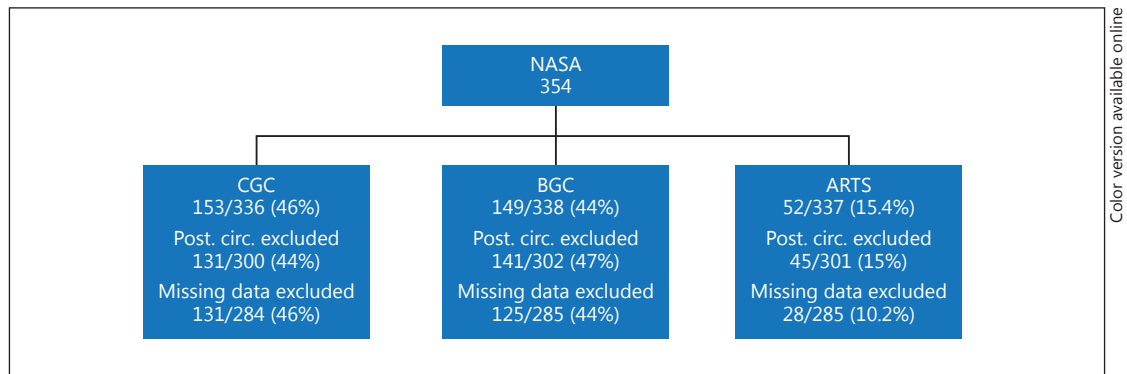


Fig. 1. ARTS NASA substudy flow chart.

Methods

NASA Design

The investigator-initiated, retrospective NASA registry collected demographic, clinical presentation, procedural details, and site-adjudicated angiographic and clinical outcome data on consecutive acute ischemic stroke patients treated with the Solitaire FR device at the 24 participating North American centers (see Appendix). Local institutional review board approval was obtained for the study protocol and retrospective data collection at each site. The stent retriever procedure was performed utilizing local protocols. Procedural details, clinical events, and outcomes were collected and reported utilizing standardized definitions provided by the registry [20].

The primary comparative groups in this substudy were the combined aspiration-retriever technique in stroke (ARTS), balloon guide catheter adjunctive technique (BGC), and conventional large bore proximal catheter (CGC) groups. The exclusion criteria (Fig. 1) were posterior circulation group, and missing data from the participating site to reach any conclusion about the most likely adjunctive technique that was used.

Procedure reperfusion time was defined as time of groin puncture to revascularization or end of procedure if revascularization of the occluded vessel was not achieved. The primary angiographic outcome was successful reperfusion defined as TICI scores of $\geq 2b$. Symptomatic ICH was defined as any intracranial hemorrhage associated with neurological deterioration of 4 points or more on the NIHSS at 24 h. Clinical outcomes also included modified Rankin Scale at 90 days and mortality.

Statistical Analysis

The NASA Registry cohort was dichotomized into those undergoing local aspiration or no local aspiration and restricted to occlusion in the ICA and MCA territories only. Baseline characteristics were compared using the Fisher exact (when small cell size) or χ^2 tests for categorical variables and Student t tests for continuous variables. The data were stored and analyzed by the central coordinating site, the Medical College of Wisconsin. Descriptive, univariate statistics were performed using JMP 11 statistical software (SAS Institute, Cary, NC, USA).

Results

There were 354 patients included in the NASA registry. Data on the combined aspiration-retrieval technique in acute ischemic stroke were available for 285 anterior circulation vessel occlusion patients in this analysis, of which 29 patients underwent the ARTS technique, 131 CGC and 125 BGC. Of those undergoing ARTS, the mean age was 63 ± 17.1 years and mean National Institute of Health Stroke Score (NIHSS) was 16.6 ± 5.9 , which were comparable to the no local aspiration cohorts of BGC and CGC (BGC 68.9 ± 14.4 , 17.3 ± 6 , and CGC 68.3 ± 15.5 , 18.2 ± 6) (Table 1). Patients undergoing ARTS technique were less likely to have a history of hypertension and atrial fibrillation, and were more likely to harbor ICA occlusions compared

Table 1. Baseline characteristics of the NASA ARTS versus BGC and CGC cohorts

	ARTS aspiration (N = 29) % (n/N)	BGC (N = 125) % (n/N)	p BGC vs. ARTS	CGC (N = 131) % (n/N)	p CGC vs. ARTS
<i>Demographics</i>					
Age, years					
Mean (SD)	63 (17.1)	68.9 (14.4)	0.09	68.3 (15.5)	0.13
Median (IQR, R)	67 (49–76.3)	71 (60–81)		70.5 (57–81)	
Gender, female	50 (14/28)	50.4 (63/125)	1	52.7 (69/131)	0.68
Race, white	64.3 (18/28)	76 (92/121)	0.2	74.6 (97/130)	0.4
<i>Risk factors</i>					
Hypertension	55.2 (16/29)	82.3 (102/124)	0.003	77.7 (101/130)	0.02
Atrial fibrillation	27.6 (8/29)	54.8 (68/124)	0.01	35.1 (46/131)	0.4
Diabetes mellitus	20.7 (6/29)	23.4 (29/124)	1	28.2 (37/131)	0.64
Hyperlipidemia	51.7 (15/29)	56.5 (70/124)	0.84	48.1 (63/131)	0.84
Smoking history	48.3 (14/29)	29.8 (37/124)	0.08	30.2 (39/129)	0.12
Coronary artery disease	31 (9/29)	36.3 (45/124)	0.83	27.5 (36/131)	1
<i>Clinical presentation</i>					
Initial NIHSS, mean (SD)	16.6 (5.9)	17.3 (6)	0.47	18.2 (6)	0.21
Occlusion site					
MCA/M1	44.8 (13/29)	68 (85/125)	0.02	62 (81/131)	0.09
ICA terminus	41.4 (12/29)	22.4 (28/125)	0.04	26 (34/131)	0.10
Initial systolic BP, mean (SD)	142.1 (26.5)	142.6 (25.7)	0.86	146 (30.8)	0.53
Initial diastolic BP, mean (SD)	76.1 (18.3)	77.8 (15.1)	0.67	77.8 (19.6)	0.66
IV tPA	39.3 (11/28)	52 (65/125)	0.41	39.2 (51/130)	1.00

to patients with BGC or CGC (41.4 vs. 22.4% in BGC, $p = 0.04$ and 26% in the CGC, $p = 0.10$). Rates of intravenous tPA administration prior to the endovascular procedure were not different between the groups (Table 1). Time from symptom onset to groin puncture was significantly shorter in the ARTS group (252.6 ± 103.1 vs. 355.7 ± 234 min in the BGC group, $p = 0.001$, and 381.4 ± 254 in the CGC group, $p < 0.001$). There was less intra-arterial tPA use (13.8 vs. 26.4%, $p = 0.23$, and 40.5%, $p = 0.002$ in the BGC and CGC groups; respectively) and a trend towards less endovascular adjuvant rescue therapy in the ARTS group (13.8 vs. 18.4%, $p = 0.6$, in BGC group, and 31.3%, $p = 0.058$, in the CGC group).

Final degree of reperfusion was comparable among the groups (TICI 2b or higher was 72 vs. 70% for CGC vs. 78% for BGC) (Table 2). Time from arterial puncture to reperfusion or end of procedure with ARTS was shorter than with CGC (54 vs. 91 min, $p = 0.001$) and was comparable to the BGC time (54 vs. 67, $p = 0.11$). Distal emboli, emboli to new territories, symptomatic hemorrhage, mortality, and good clinical outcome at 90 days were not different between the ARTS and the other 2 cohorts (Table 2). Figure 2 is an illustrative case of the ARTS technique showing complete recanalization of the dominant right MCA inferior division occlusion with accompanying cartoon illustration.

Discussion

Aspiration (or, in the vertebrobasilar system, alternative methods of achieving flow reversal) during withdrawal of a clot capture device has been proposed as an important step of the endovascular clot retrieval procedure since the earliest reported experiences with these devices [21–26]. More recent studies have demonstrated that aspiration through a BGC

Table 2. Procedural characteristics and outcomes of the NASA ARTS versus BGC and CGC cohorts

	ARTS aspiration (N = 29) % (n/N)	BGC (N = 125) % (n/N)	p BGC vs. ARTS	CGC (N = 131) % (n/N)	p CGC vs. ARTS
<i>Procedural factors</i>					
Time from onset to puncture, mean (SD), min	252.6 (103.1)	355 (234)	0.001	381.4 (25)	<0.001
Fluoroscopic time, mean (SD), min	37.4 (20.1)	26.7 (18)	0.03	33.4 (29.5)	0.52
Time to revascularization or end of procedure, mean (SD), min	53.5 (36.1)	67.1 (102)	0.11	90.9 (108)	0.001
General anesthesia	64.3 (18/28)	84.4 (81/96)	0.04	54 (61/113)	0.25
IA tPA	13.8 (4/29)	26.4 (33/125)	0.23	40.5 (53/131)	0.002
Rescue therapy	13.8 (4/29)	18.4 (23/125)	0.6	31.3 (41/131)	0.058
<i>Angiographic outcome</i>					
TIMI ≥ 2	86.2 (25/29)	88.8 (111/125)	1	83.1 (109/131)	0.17
TICI $\geq 2a$	93.1 (27/29)	90.4 (113/125)	1	88.6 (116/131)	0.40
TICI $\geq 2b$	72.4 (21/29)	77.6 (97/125)	0.60	70.2 (92/131)	0.98
Distal embolization	23.1 (6/26)	17.5 (21/120)	0.58	15.1 (19/126)	0.23
Embolization into new territory	7.7 (2/27)	6.4 (8/125)	0.38	5.7 (7/124)	0.48
<i>Clinical outcome</i>					
mRS ≤ 2 at 90 days	34.6 (9/26)	54.4 (56/103)	0.10	36.13 (43/119)	0.62
NIHSS at 90 days					
Mean (SD)	23.4 (19.6)	19 (12.5)	0.43	26 (18.3)	0.62
Median (IQR, R)	30 (2–42)	14 (1–42)		42 (4–42)	
Mortality at 90 days	34.6 (9/26)	25.24 (26/103)	0.1	28.6 (34/119)	0.34
sICH	11 (3/28)	12.9 (14/124)	0.75	9.9 (13/131)	0.53

in stent retriever procedures is associated with superior recanalization results, decreased need for rescue therapy, shorter procedure times and improved clinical outcome [18, 27]. The mechanism for these benefits of BGC aspiration is thought to be a reduced incidence of the clot or its fragments being displaced from the stent retriever during its withdrawal and reem-bolization into the same or a new intracranial vascular territory. However, studies have been inconsistent in demonstrating a decreased incidence of distal embolization or embolization into a new territory [17, 18, 28].

ARTS, with its local clot aspiration through a distal large bore catheter placed with its tip intracranially at the clot interface, has several theoretical advantages over aspiration through either a BGC or CGC positioned in the cervical carotid. First, the collapsible nature of the cervical vessels can work against the CGC/BGC aspiration strategy in 2 ways: complete collapse of the cervical vessel distal to the guide catheter tip but proximal to the clot being withdrawn eliminates the suction transmitted to the clot, while partial collapse of the cervical vessel reduces the diameter of the cervical vessel through which the clot must be withdrawn, ideally without fragmenting. Second, the tortuosity of the cervical vessels in elderly stroke patients often results in temporary kinks forming between the tip of the CGC/BGC and the skull base, again decreasing the diameter of the vessel at the kink through which the clot must be withdrawn. Third, there may be underlying atheroma or other baseline stenosis between the CGC/BGC tip and the target thrombus, again decreasing the diameter of the vessel to be navigated by the thrombus during withdrawal. Fourth, the CGC/BGC tip is usually separated from the target thrombus by 10–20 cm of vessel, and this intervening segment may have numerous branch vessels (petrous and cavernous branches, ophthalmic artery, posterior communicating artery, anterior choroidal artery) which can reverse flow during CGC/BGC

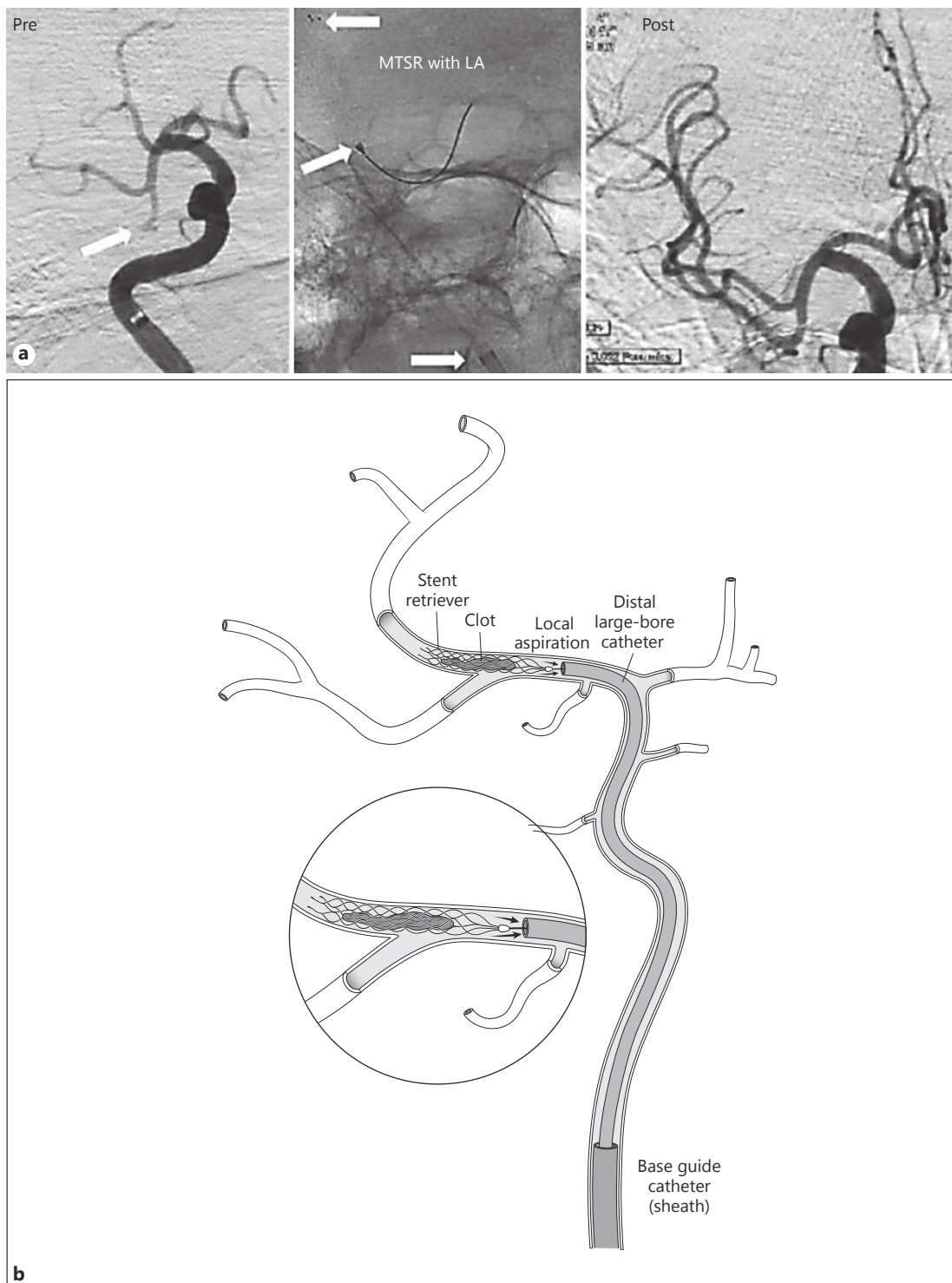


Fig. 2. a Illustrative case of mechanical thrombectomy with stent-retriever (MTSR) with local aspiration (LA) technique showing complete recanalization of the dominant right MCA inferior division occlusion. Pre-MTSR image, arrow indicates site of occlusion. MTSR with LA image, arrows (inferior to superior) indicate tip of base catheter, tip of local aspiration catheter, and tip of stent retriever. **b** Illustration of the ARTS technique.

aspiration, providing new inflow of blood into the carotid between the CGC/BGC and the intracranial thrombus with the result that there is no residual suction effect or reversal of flow at the downstream clot interface. Fifth, if the thrombus can be withdrawn leaving the large bore distal access catheter positioned immediately proximal to the original site of occlusion, there is no opportunity for the thrombus to embolize to a new territory. Sixth, local aspiration provides real-time monitoring of blood return into the distal access catheter, allowing recognition during stent retriever device withdrawal of clot “corking” in the catheter tip, such that the clot is then retrieved with a combination of both physical adherence to the stent retriever and also aspiration as a “corked” thrombus. Seventh, if the clot does not cork and the distal access catheter can be maintained at the clot interface, then any required successive passes with the stent retriever are quicker as there is no need to repeat navigation of the stent retriever delivery microcatheter through the petrous, cavernous, and supraclinoid carotid segments of the carotid artery; the stent delivery microcatheter is simply readvanced through the already positioned distal access catheter.

Earlier arguments against ARTS techniques were largely based on the decreased chance of withdrawing a thrombus intact through distal access catheters, which had inner diameters (IDs) dramatically smaller than the IDs of BGCs. With newer technologies, however, it is possible to safely navigate distal large bore catheters from several manufacturers into the middle cerebral artery. These newer catheter technologies have distal IDs up to 0.070”, IDs which are more than 80% of the IDs of commonly used BGCs in the earlier reports.

The effect of aspiration strategy on distal embolization upon mechanical thrombectomy for large-vessel occlusion rates has been studied in vitro [28, 29]. In contrast, previous clinical reports addressing either local clot aspiration, base catheter aspiration, or nonaspiration techniques have not allowed direct comparisons of these techniques [30–33].

To our knowledge, this is the first multicenter report comparing the technical and clinical results of stent retriever use with ARTS with a contemporaneous cohort undergoing stent retriever use without ARTS. This report, which compares the 2 techniques within a single registry, may allow a comparison benefitting from contemporaneous multicenter enrollment and standardization of the definitions for the results and outcomes. These distal-access large-bore catheter technologies have improved since the NASA registry, and we expect to see higher rates than our 10% utilization of ARTS in future studies.

Limitations

The NASA registry [20, 34–36] was an investigator-initiated, retrospective registry of consecutive acute ischemic stroke patients treated with the Solitaire FR device at 24 participating North American centers. The stent retriever procedure was performed utilizing local protocols.

Limitations of this nonrandomized registry include a heterogeneous stroke population and site adjudication of angiographic and other imaging results. Variation between the participating institutions in choice of aspiration techniques may be linked to variation between institutions in patient selection criteria and other procedural variables. As such, the clinical impact of the ARTS technique in this retrospective registry would require confirmation in a prospective, multicenter, randomized trial with more homogeneous patient selection criteria and standardization of procedural protocols. We do not, however, believe these limitations of a retrospective registry are likely to bias actual or reported differences in procedural reperfusion times between the aspiration techniques.

There are imbalances in the 2 groups that should be addressed: patients undergoing ARTS technique had less hypertension and atrial fibrillation (known to adversely affect outcomes) and had more ICA occlusions (known to be more challenging with worse prognosis) compared to patients without ARTS.

Conclusion

Stent retriever use with ARTS in a cohort that had more ICA occlusions was associated with shorter time to reperfusion and less use of intra-arterial tPA than CGC, with a similar risk profile in comparison to stent retriever use with alternative aspiration through a CGC or a nonaspiration technique. ARTS appears to lead to better results as compared to the use of aspiration through CGCs or nonaspiration techniques. Future studies should focus on the comparison of ARTS and BCG techniques.

Appendix

Site Investigators/Team

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Disclosure Statement

Dr. Malisch, Covidien (DSMB service for SWIFT Trial) and Stryker Neurovascular (CEC service for DAWN Trial); Dr. Taqi, Stryker Neurovascular (consultant) and Penumbra Inc. (consultant); Dr. Abraham, Stryker Neurovascular (consultant), Boehringer Ingelheim (speaker's bureau); Dr. Nogueira, Stryker Neurovascular (PI for Trevo-2 Trial, PI for DAWN Trial), Covidien (Steering Committee for SWIFT Trial, Steering Committee for SWIFT-PRIME Trial, Core Lab for STAR Trial), Penumbra Inc. (Executive Committee for 3-D Separator Trial); Dr. Mueller-Kronast, Medtronic Neurovascular (consultant); Dr. Yoo, Penumbra Inc. (consultant) and Neuravi Inc. (consultant). The other authors report no conflicts.

Author Contributions

All authors listed contributed data to this registry and participated in the writing of the manuscript.

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