Prospective, Multicenter, Single-Arm Study of Mechanical Thrombectomy Using Solitaire Flow Restoration in Acute Ischemic Stroke

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Background and Purpose—Mechanical thrombectomy using stent retriever devices have been advocated to increase revascularization in intracranial vessel occlusion. We present the results of a large prospective study on the use of the Solitaire Flow Restoration in patients with acute ischemic stroke.

Methods—Solitaire Flow Restoration Thrombectomy for Acute Revascularization was an international, multicenter, prospective, single-arm study of Solitaire Flow Restoration thrombectomy in patients with large vessel anterior circulation strokes treated within 8 hours of symptom onset. Strict criteria for site selection were applied. The primary end point was the revascularization rate (thrombolysis in cerebral infarction ≥2b) of the occluded vessel as determined by an independent core laboratory. The secondary end point was the rate of good functional outcome (defined as 90-day modified Rankin scale, 0–2).

Results—A total of 202 patients were enrolled across 14 comprehensive stroke centers in Europe, Canada, and Australia. The median age was 72 years, 60% were female patients. The median National Institute of Health Stroke Scale was 17. Most proximal intracranial occlusion was the internal carotid artery in 18%, and the middle cerebral artery in 82%. Successful revascularization was achieved in 79.2% of patients. Device and procedure-related severe adverse events were found in 7.4%. Favorable neurological outcome was found in 57.9%. The mortality rate was 6.9%. Any intracranial hemorrhagic transformation was found in 18.8% of patients, 1.5% were symptomatic.

Conclusions—In this single-arm study, treatment with the Solitaire Flow Restoration device in intracranial anterior circulation occlusions results in high rates of revascularization, low risk of clinically relevant procedural complications, and good clinical outcomes in combination with low mortality at 90 days.

Clinical Trial Registration—URL: http://www.clinicaltrials.gov. Unique identifier: NCT01327989.

Key Words: mechanical embolectomy • stroke treatment
Stryker Neurovascular.7 Concerning the recent and upcoming randomized controlled trials on interventional versus systemic stroke treatment, more prospective data on real-world experience with this novel technology are needed.

We describe the results of the Solitaire Flow Restoration Thrombectomy for Acute Revascularization (STAR), a prospective, multicenter, single-arm trial on patients with acute ischemic anterior circulation stroke.

Methods

Study Design
The STAR trial was an international, prospective, multicenter, single-arm study. The study was designed by the principal investigators and a steering committee composed of experts in vascular neurology and interventional neuroradiology.

The study used an independent computed tomography (CT) and MRI imaging core laboratory, a separate angiography core laboratory, and an independent clinical events committee. The clinical events committee was responsible for the review and validation of all complications (ie, adverse event, procedural, or technical complication) that occurred during the course of the study and the subsequent classification of these complications as related to the device or procedure. The study data were independently monitored; study management was provided by the sponsor, Covidien Neurovascular.

Population
Patients were eligible if they presented within 8 hours after onset of an acute ischemic stroke because of a proximal intracranial arterial occlusion in the anterior circulation. Key inclusion criteria included the following: age ≥18 and <85 years, National Health Institutes Stroke Scale (NIHSS) score (8–30), modified Rankin Scale (mRS ≤2), and documented occlusion of an anterior intracranial artery (intracranial and terminus internal carotid artery and first and second segments of the middle cerebral artery) on conventional angiography.

Consent was obtained from the patient or patient’s legally authorized representative before the interventional procedure. In instances where the patient was alone and unable to make a decision, an independent physician signed the informed consent and subsequently the patient or representative signed a continuation form.

Patients were excluded if they had a life expectancy of <90 days, NIHSS >30 or comorbid uncontrolled hypertension (systolic blood pressure >185 mm Hg or diastolic blood pressure >110 mm Hg), anticoagulation with international normal ratio >3.0, platelet count <30 000, glucose >400 mg/dL, previous stroke within 30 days, unknown time of symptom onset, seizure at the onset of stroke, and associated myocardial infarction or severe infection (sepsis or endocarditis).

Imaging evaluation excluded patients with signs of intracranial hemorrhage, arteriovenous malformation, or aneurysm, early ischemic changes larger than one third of the middle cerebral artery territory and according to Alberta Stroke Program Early CT (ASPECT) score (<6 points) on CT or ASPECT score (<5 points) according to diffusion-weighted imaging, angiographic evidence of carotid dissection, complete cervical carotid occlusions, vasculitis, or arterial stenosis proximal to thrombus site that may preclude safe balloon occlusion catheter placement or safe recovery of the device.

Stroke Treatment Protocol
The study protocol was approved by the local ethics committee at all study sites. Patients arriving within 4.5 hours were managed according to the center’s standard protocol. The standard indication for interventional stroke treatment at each center comprised the following:

Combined Intravenously Administered Recombinant tPA and MT
Patients who received any intravenous thrombolysis (eg, failed intravenously administered recombinant tPA, recombinant tPA bolus and initial intravenous infusion) are referred to MT. Any additional intra-arterial rtPA infusion was considered as a rescue therapy and a protocol violation for the purpose of this analysis.

Direct MT
Patients with a contraindication to intravenous thrombolysis were treated directly with MT. In addition, at some study sites, primary inclusion of patients to thrombectomy, despite eligibility for intravenous thrombolysis, was performed on the basis of local standard stroke treatment protocol.

All centers were required to maintain screening logs, which were monitored by external reviewers to ensure report of screen failures and enrollment.

Site Selection
Site selection was predefined by the steering committee to get dedicated high-volume stroke centers with extensive experience on stroke interventions, periprocedural management, and recovery care. Centers were required to have a 24-hour acute stroke emergency service with vascular neurology and interventional neuroradiology on call. At minimum, physicians were required to have treated 30 patients with stroke and 3 cases within a 4-month period using the Solitaire device following the instructions for use. Centers were not allowed to participate in a competitive stroke study during the local enrollment phase. All centers were required to provide acute rehabilitation care to all patients.

Procedure Protocol
The procedure protocol was standardized and defined per the instructions for use. The use of a balloon guide catheter and a minimum embedding time of 3 minutes with the device at the occlusion site were mandatory. Patients were included after balloon guide catheter placement at the internal carotid artery.

Successful revascularization was defined as thrombolysis in cerebral infarction (TICI) ≥2b revascularization of the target territory with a maximum of 3 passes of the study device per vessel. After the primary endpoint, outcome angiogram was performed; rescue therapy was permitted if patients in whom adequate revascularization (TICI ≥2b) had not been achieved. All cases requiring additional therapy were considered device failure treatments. Rescue therapy consisted of MT and intra-arterial thrombolysis at the interventionalist’s discretion and according to the center’s guidelines. If any rescue treatment was performed, a final procedural diagnostic angiogram was obtained. The application of anesthesia or conscious sedation followed the site’s discretion.

All patients were screened for a proximal vessel occlusion, illustrated by pretreatment imaging (CT angiography/MR angiography). Follow-up imaging was completed at 24 hours (18–30-hour window).

Experienced neurologists performed clinical neurological examinations. mRS, NIHSS score, were assessed at admission, 24-hour after procedure, 7 to 10 days or discharge and the 90-day follow-up.

Imaging Evaluation
All CT, MRI, and conventional angiography images were evaluated by an academic imaging core laboratory. CT or MRI studies were performed before the thrombectomy procedure were evaluated by an independent reader (D.S.L.), who was blinded to all angiographic and clinical data to confirm the imaging inclusion and exclusion criteria. Follow-up CT or MRI studies, acquired 24 hours (with a tolerance of 18–30 hours) after procedure, were systematically reviewed for hemorrhagic complications and final ASPECT scores.8 Hemorrhages were categorized according to the method used by Burger et al9 in the European Cooperative Acute Stroke Study trials. The angiography images were reviewed by a different independent reader (R.G.N.), who was blinded to all CT/MRI and clinical data, and graded with the TICI grading scale.10 TICI grade 0 was defined as no perfusion; grade 1 was defined as perfusion past the initial obstruction but limited distal branch filling with little or slow distal perfusion; grade 2a was defined as...
as perfusion of <1 of the vascular distribution of the occluded artery; grade 2b was defined as perfusion of greater than two thirds of the vascular distribution of the occluded artery; and grade 3 was defined as full perfusion with complete filling of all distal branches (some delay was accepted in the presence of proximal vasospasm or competitive collateral flow). Revascularization outcomes were adjudicated after every single angiographic run performed after an intervention including any passes of the Solitaire device, any use of adjunctive or rescue treatments, and at the time of procedure completion. Images were reviewed for any potential angiographic complications, including embolus to an uninvolved territory (embolic lesion to a territory that was not occluded initially or is not part of the distal territory of the previous occluded territory), perforation, dissection, vasospasm, and contrast extravasation. Collateral circulation was analyzed using the American Society of Interventional and Therapeutic Neuroradiology/Society of Interventional Radiology Collateral Flow Grading System.

Data Analysis and Statistical Evaluation
The primary end point was the revascularization rate (TICI ≥ 2b) of the occluded vessel after a maximum of 3 passes of the study device as determined by an independent core laboratory. Safety was evaluated through serious adverse events (SAEs) related to the device or the procedure, adjudicated by a clinical event committee. The secondary outcome measures included the following: (1) good neurological outcome at 90 days, defined as an mRS of ≤ 2; (2) incidence of device- and procedure-related SAEs; (3) time to revascularization defined as time interval from guide catheter placement to revascularization TICI ≥ 2b or end of the procedure in case of failed revascularization; and (4) mortality at 90 days. Under the principles of intent to treat, the analysis population consisted of all patients who signed informed consent, met selection criteria, and in whom use of the study device was attempted. The worst case scenario was assigned for patients missing primary and secondary outcome data. Patients with a missing or inconclusive final angiogram data set were rated as TICI=0. Patients missing a 90-day mRS score were assigned mRS=6. Standard summary statistics were calculated for all study variables as appropriate to the type of data collected (eg, continuous versus categorical versus ordinal). No formal hypothesis testing of overall study end points was prespecified; however, subgroups of interest were identified a priori and statistical comparisons between these cohorts were performed. Statistical analysis was carried out in SAS version 9.3 (SAS Institute, Cary, NC), a validated statistical software package.

Role of Funding Source
Two academic principal investigators (J.G., V.M.P.), and an academic steering committee supervised trial design and operations. The principal investigators and the steering committee interpreted the results and wrote the report. The principal investigators and the steering committee had full access to the study data and had the final decision to submit for publication. The sponsor of the study was responsible for site management, data management, and safety reporting.

Results
Between October 2010 and May 2012, a total of 682 patients with ischemic stroke were screened at 14 international sites.
A total of 202 patients gave consent and were enrolled (Figure 1). Patients not included in the study were recorded and monitored to ensure consecutive evaluation and to avoid selection issues. The most common reasons for screen failures were proximal carotid occlusion/stenosis (20.2%), intracranial occlusion location (15.7%), unknown or >8-hour stroke symptom onset (11.5%). Nine patients did not sign informed consent or had withdrawn consent during the course of the study.

The intention-to-treat analysis included all 202 patients. Median age of patients was 72 years, 60% women, and a median NIHSS of 17 at admission. Ninety-day follow-up mRS was assessed in all patients. A total of 59% of the patients received intravenously administered rtPA before the mechanical procedure. Baseline demographics are summarized in Table 1.

The rate of the primary outcome (successful revascularization [TICI≥2b] after ≤3 passes of the study device as adjudicated by independent core laboratory evaluation) was 79.2% (160/202). In 42 patients (20.8%), TICI≥2b was not achieved within the limited number of 3 passes (device treatment failures), in 18 of these (9%) rescue therapy was performed. Additional treatment consisted of intra-arterial thrombolysis in 2 patients, MT in 13 patients. In 3 patients, combined intrarterial thrombolysis and MT was performed. After rescue therapy, core laboratory determined that 88.1% (171/194) achieved final successful revascularization (TICI≥2b). Median time from onset of symptoms to groin puncture was 238 minutes. Procedural time (guiding catheter placement to revascularization [TICI≥2b or end of the procedure] was 20 (mean, 29±27) minutes. The mean number of passes with the device was 1.5. The outcome measures are summarized in Table 2.

Table 2. Outcome Measures

<table>
<thead>
<tr>
<th>Primary measure outcome</th>
<th>Total</th>
<th>IV-IA</th>
<th>IA Only</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Successful revascularization (asssigned as TICI≥2b up to 3 passes) as per core laboratory on available data</td>
<td>84.2% (160/190)†</td>
<td>84.5% (93/110)</td>
<td>83.8% (67/80)</td>
<td>1.000</td>
</tr>
<tr>
<td>Successful revascularization (asssigned as TICI≥2b up to 3 passes) as per site investigator on available data</td>
<td>91.1% (173/190)†</td>
<td>91.8% (101/110)</td>
<td>90.0% (72/80)</td>
<td>0.798</td>
</tr>
<tr>
<td>Successful revascularization (asssigned as TICI&gt;2b up to 3 passes) as per core laboratory‡</td>
<td>79.2% (160/202)</td>
<td>78.2% (93/119)</td>
<td>80.7% (67/83)</td>
<td>0.726</td>
</tr>
<tr>
<td>Use of rescue treatment after study device</td>
<td>8.9% (18/202)</td>
<td>9.2% (11/119)</td>
<td>8.4% (7/83)</td>
<td>1.000</td>
</tr>
<tr>
<td>Final revascularization (after rescue therapy) as per core laboratory§</td>
<td>88.1% (171/194)</td>
<td>87.6% (99/113)</td>
<td>88.9% (72/81)</td>
<td>0.826</td>
</tr>
<tr>
<td>Study device TICI revascularization as per core laboratory</td>
<td>0</td>
<td>4.7% (9/190)</td>
<td>4.5% (5/110)</td>
<td>5.0% (4/80)</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>0.5% (1/190)</td>
<td>0.9% (1/110)</td>
<td>0.0% (0/80)</td>
</tr>
<tr>
<td></td>
<td>2a</td>
<td>10.5% (20/190)</td>
<td>10.0% (11/110)</td>
<td>11.3% (9/80)</td>
</tr>
<tr>
<td></td>
<td>2b</td>
<td>29.5% (56/190)</td>
<td>29.1% (32/110)</td>
<td>30.0% (24/80)</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>54.7% (104/190)</td>
<td>55.5% (61/110)</td>
<td>53.8% (43/80)</td>
</tr>
<tr>
<td>Clinical outcome</td>
<td>90-Day good outcome (mRS, 0–2)</td>
<td>57.9% (117/202)</td>
<td>62.2% (74/119)</td>
<td>51.8% (43/83)</td>
</tr>
</tbody>
</table>

IA indicates intra-arterial; IV-IA, intravenous and intra-arterial treatment; mRS, modified Rankin Scale; and TICI, thrombolysis in cerebral infarction.

†κ value=0.59.
‡Core laboratory missing primary end point data rated as TICI=0.
§Core laboratory missing primary end point data of 8 subjects.

At the 90-day follow-up visit, favorable neurological outcome (mRS, 0–2) was seen in 57.9% of patients. The distribution of mRs at 90 days is illustrated in Figure 2. Most common angiographic complication in core laboratory evaluation was vasospasm found in 23% (45/200) of patients, and as adjudicated by the clinical events committee, only 0.5% (1/202) were symptomatic. The frequency of total device- and procedure-related SAEs was 7.4%. Any intracerebral hemorrhage (ICH) was found in 18.8% patients at 24 hours and symptomatic ICH (sICH) occurred in 1.5% of the patients. The mortality rate was 6.9% with a higher proportion found in the male population (5%). A detailed summary of the safety outcomes is presented in Table 3. We performed an analysis between the collateral circulation and outcome, and we observed that a good collateral circulation (grades 3–4 American Society of Interventional and Therapeutic Neuroradiology/Society of Interventional Radiology scale) correlated significantly with good (mRS, 0–2) outcomes (P=0.034). Patients receiving rescue therapy showed a statistically significant lower rate of favorable outcome (33.3%; mRS, 0–2) compared with the comparison to those who did not (60.3%; P=0.043).

The rate of device-/procedure-related SAEs was not significantly elevated in the subgroup of patients receiving rescue therapy (11.1% versus 7.2%).

Discussion

The STAR study showed that the Solitaire Flow Restoration device was effective in achieving successful cerebral revascularization (TICI≥2b within 3 passes) in patients presenting with acute ischemic stroke harboring anterior circulation proximal occlusions. Our results also demonstrated a significant improvement in patient’s clinical outcomes, as well as low rates of mortality and sICH. This is the largest prospective multicenter study on MT for acute ischemic stroke to date. Key elements of this study include the predefined procedure...
protocol, center selection, independently monitored data acquisition, and core laboratory review using TICI scores to define successful reperfusion.

The revascularization rates are among the highest reported in the literature; however, procedural characteristics of the study reflected the experience of study centers with MT and, particularly, with the study device. Sites selected for the study were high-volume stroke centers with multidisciplinary and certified teams with experienced neurointerventionalists, vascular neurologists, and neurorehabilitation facilities. Furthermore, interventionalists were required to have expertise in general stroke interventions and experience using the study device per the instructions for use. Most international normal ratios in Europe had used the device for years before this study since clearance in April 2009. Two recent randomized MT trials that were performed for Food and Drug Administration clearance of 2 stent retrievers required few cases using the stent retriever device per site before enrollment. The impact of the experience with the study device can be observed also on the rate of device- and procedure-related SAEs that was lower compared with previous studies with stent retrievers. In addition, the number of passes, rescue treatments, and the shorter procedural times were comparably lower as well.

The study showed a high rate of favorable clinical outcome, which was comparable (58 versus 55%) with a previously published retrospective Solitaire study reporting the initial experience with the Solitaire device as first line device in 6 European centers. In the SWIFT trial, treatment with the Solitaire Flow Restoration device presented a favorable clinical outcome in 36%. From our point of view, the higher rate of good clinical outcome in our study can be attributed to the higher revascularization rate, as well as selection of patients with exclusively anterior circulation stroke using ASPECT score for selection, prestroke mRS 0 to 2, and comprehensive patient management after the treatment. Furthermore, our population presented a slightly lower initial NIHSS and lower relevant comorbidities compared with other studies using stent retrievers.

In addition, the number of passes, rescue treatments, and the shorter procedural times were comparably lower as well. The rate of sICH was comparably low but within the range of the SWIFT trial (2%). Previous studies on other MT devices have shown higher rates of sICH. We, therefore, postulate that the use of stent retrievers may impact the rate of hemorrhagic transformation. Another recent stent retriever, the Trevo device (Stryker Neurovascular, Mountain View, CA) reported a 7% sICH rate, significantly lower compared with the Merci device. In addition to a high revascularization rate and low rate of sICH, this STAR study demonstrated a low mortality rate at 90 days. This may be because of imaging-based patient selection, limitation to anterior circulation strokes, and low complication rate. Furthermore, a subgroup analysis showed a significantly higher rate of mortality in the male study population which was unrepresented.

Our study has limitations. It was a single-arm study limited to only anterior circulation occlusions. The neurological

### Table 3. Safety End Points

<table>
<thead>
<tr>
<th>End Point</th>
<th>Total (n=202)</th>
<th>IV-IA (n=119)</th>
<th>IA only (n=83)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device- or procedure-related serious adverse events</td>
<td>7.4% (15/202)</td>
<td>6.7% (8/119)</td>
<td>8.4% (7/83)</td>
<td>0.786</td>
</tr>
<tr>
<td>Procedure-related serious adverse events</td>
<td>5.4% (11/202)</td>
<td>5.9% (7/119)</td>
<td>4.8% (4/83)</td>
<td>1.000</td>
</tr>
<tr>
<td>Solitaire device-related serious adverse events*</td>
<td>2.5% (5/202)</td>
<td>2.5% (3/119)</td>
<td>2.4% (2/83)</td>
<td>1.000</td>
</tr>
<tr>
<td>Embolus to uninvolved territory</td>
<td>1.0% (2/202)</td>
<td>0.0% (0/119)</td>
<td>2.4% (2/83)</td>
<td>0.168</td>
</tr>
<tr>
<td>Intracranial hemorrhage</td>
<td>1.0% (2/202)</td>
<td>1.7% (2/119)</td>
<td>0.0% (0/83)</td>
<td>0.513</td>
</tr>
<tr>
<td>Vessel dissection</td>
<td>1.0% (2/202)</td>
<td>0.8% (1/119)</td>
<td>1.2% (1/83)</td>
<td>1.000</td>
</tr>
<tr>
<td><strong>Secondary</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intracranial hemorrhage as per CEC adjudication</td>
<td>18.8% (38/202)</td>
<td>18.5% (22/119)</td>
<td>19.3% (16/83)</td>
<td>1.000</td>
</tr>
<tr>
<td>HI-1</td>
<td>9.4% (19/202)</td>
<td>8.4% (10/119)</td>
<td>10.8% (9/83)</td>
<td>0.627</td>
</tr>
<tr>
<td>HI-2</td>
<td>5.0% (10/202)</td>
<td>5.0% (6/119)</td>
<td>4.8% (4/83)</td>
<td>1.000</td>
</tr>
<tr>
<td>PH-1</td>
<td>3.0% (6/202)</td>
<td>4.2% (5/119)</td>
<td>1.2% (1/83)</td>
<td>0.404</td>
</tr>
<tr>
<td>IVM+PH-2</td>
<td>0.5% (1/202)</td>
<td>0.8% (1/119)</td>
<td>0.0% (0/83)</td>
<td>1.000</td>
</tr>
<tr>
<td>SAH</td>
<td>3.0% (6/202)</td>
<td>2.5% (3/119)</td>
<td>3.6% (3/83)</td>
<td>0.691</td>
</tr>
<tr>
<td>Symptomatic per CEC adjudication†</td>
<td>1.5% (3/202)</td>
<td>1.7% (2/119)</td>
<td>1.2% (1/83)</td>
<td>1.000</td>
</tr>
<tr>
<td>Death from any cause by 90 days</td>
<td>6.9% (14/202)</td>
<td>5.9% (7/119)</td>
<td>8.4% (7/83)</td>
<td>0.577</td>
</tr>
</tbody>
</table>

CEC indicates clinical events committee; HI, hemorrhage infarction; IA, intra-arterial; IV-IA, combined intravenous and intra-arterial treatment; IVM, intra-ventricular hemorrhage; PH, paracymal hemorrhage; and SAH, subarachnoid hemorrhage.

*1 patient presented 2 events.
†Classified according to European Cooperative Acute Stroke Study trials definition.
examination was conducted by a neurologist not blinded to the study device. Selection bias could not be excluded because of the study’s nonrandomized design. However, we used several independent committees to design the study, monitor, and adjudicate outcome measurements. The recruitment rate (31%) of the present study was higher compared with previous randomized control trials on MT (SWIFT trial, 21%; Trevo trial, 19%). Baseline characteristics (age, NIHSS at admission, occlusion sites) are in line with previous studies.

Conclusions
This single-arm prospective study suggests that treatment with the Solitaire Flow Restoration device for stroke because of intracranial anterior circulation occlusions by comprehensive and experienced stroke centers results in a low risk of clinically relevant procedure- and device-related complications, high revascularization rates, and good clinical outcomes. These data support further investigation of this device in randomized controlled trials against best medical treatment alone.

Appendix
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Disclosures
Dr Pereira, global PI STAR, consultant for Covidien; Dr Gralla, global PI STAR, consultant for Covidien; Dr Chapot, consultant for Covidien. Microvention and Balt; Dr Liebeskind, consultant to Stryker and Covidien, National Institutes of Health grant support; Dr Nogueira, Covidien—Steering Committee (SOLITAIRE With the Intention For Thrombectomy and Solitaire FR With the Intention For Thrombectomy as Primary Endovascular Treatment for Acute Ischemic Stroke Trials). Core Laboratory (STAR Trial). Physician Advisory Board. Penumbra—Executive Committee. Reverse Medical—Core Laboratory. Dr Liebig, consults for Covidien and Stryker; Dr Goyal, consultant for Covidien. The other authors report no conflicts.

References
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