Abstract
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DÁVALOS, Antoni, et al.

Reference

DOI: 10.1161/STROKEAHA.112.663328
PMID: 22851547
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Stroke. 2012;43:2699-2705; originally published online July 31, 2012; doi: 10.1161/STROKEAHA.112.663328

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Print ISSN: 0039-2499. Online ISSN: 1524-4628

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Retrospective Multicenter Study of Solitaire FR for Revascularization in the Treatment of Acute Ischemic Stroke

Antoni Dávalos, MD; Vitor Mendes Pereira, MD; René Chapot, MD; Alain Bonafé, MD; Tommy Andersson, MD; Jan Gralla, MD; by the Solitaire Group

Background and Purpose—The purpose of this study was to evaluate safety and efficacy of the Solitaire FR device in the treatment of patients with acute ischemic stroke secondary to large artery occlusion.

Methods—We conducted a retrospective study of consecutive patients presenting with acute ischemic stroke treated with Solitaire FR as the first-line device to restore blood flow in 6 experienced European centers. This study was entirely funded and supported by Covidien Neurovascular. An independent Corelab determined modified Thrombolysis in Cerebral Infarction scores on the preprocedure and postprocedure angiograms. Complete revascularization was defined as modified Thrombolysis in Cerebral Infarction 2b or 3 post-Solitaire FR device use. Symptomatic intracranial hemorrhage was defined as parenchymal hemorrhage Type 2 associated with a decline of ≥4 points in the National Institutes of Health Stroke Scale score within 24 hours or causing death. Favorable functional outcome was considered as modified Rankin Scale score ≤2 at Day 90.

Results—We studied 141 patients (mean age, 66 years; median National Institutes of Health Stroke Scale, 18); 74 patients received intravenous tissue-type plasminogen activator before endovascular treatment. Complete revascularization was achieved in 120 of 142 occlusion sites (85%) and good outcome in 77 of 141 (55%) patients. Good outcome was more frequent in patients treated with intravenous tissue-type plasminogen activator than in those without (66% versus 42%; P<0.01). Symptomatic intracranial hemorrhage was reported in 5 patients (4%) and 29 of 141 (20%) patients died or were lost during follow-up (3 cases).

Conclusions—This retrospective study with centralized evaluation shows that the use of Solitaire FR is safe and achieves good revascularization rates and functional outcomes in patients with acute ischemic stroke and large artery occlusion. (Stroke. 2012;43:2699-2705.)

Key Words: acute ■ embolectomy ■ interventional neuroradiology ■ reperfusion ■ stroke ■ thrombectomy

The aim of stroke treatment is to restore reperfusion and ultimately achieve patient recovery. Due to the time limitation and contraindications to intravenous tissue-type plasminogen activator (IV tPA), <10% of patients with stroke receive the treatment, even in well-organized stroke networks.1 Furthermore, IV tPA recanalizes only 40% of large vessel occlusions in patients with acute stroke during the first hours after administration with even lower rates of revascularization for proximal arterial occlusions such as the terminal internal carotid artery.2 Thus, faster and more effective approaches to reperfusion are needed. Clinical results have shown that mechanical devices for clot removal provide an alternative treatment option to patients with stroke who are ineligible for thrombolytic therapy. The Merci Retriever and the Penumbra System have received US Food and Drug Administration clearance for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease within 8 hours of symptom onset.3,4

Retrievable stent-based devices are a newer generation of mechanical thrombectomy devices that achieve high and fast rates of revascularization in large vessel occlusions with the potential for improved clinical outcomes compared with the use of IV tPA. The Solitaire FR Revascularization Device
ev3-Covidien, Irvine, CA) is based on a self-expanding stent platform that offers the unique capability of being able to be fully deployed and then retrieved.5 The Solitaire FR has received the CE Mark approval for the indication for use in the flow restoration of patients with ischemic stroke due to large intracranial vessel occlusion who are ineligible for or who fail IV tPA therapy. A few European teams have published their experiences with the Solitaire FR used in acute ischemic stroke.6–16 Revascularization rates ranged between 84% and 100% and good clinical outcome between 33% and 55%.

This study provides an independent central evaluation of imaging outcome data associated with the safety and effectiveness of the Solitaire FR device when used in real-world practice to treat acute ischemic stroke.

Materials and Methods

We retrospectively evaluated all consecutive patients with ischemic stroke treated through June 2010 in 6 European centers experienced in the use of the Solitaire FR device. Patients had received Solitaire FR as the first-choice device to restore blood flow. Preprocedure, procedure, 24 to 48 hours postprocedure, discharge, and 3-month data were entered into a secure, online database. Local ethics committees approved use of patients’ retrospective data. The study was entirely funded and supported by Covidien Neurovascular.

Criteria for primary or rescue endovascular treatment were predefined in each center. In general, an intra-arterial approach was prescribed when the patient had a terminus internal carotid artery occlusion, when a middle cerebral artery occlusion was refractory to intravenous IV tPA or the patient had contraindications for systemic thrombolysis, and when the time from symptom onset was >6 hours or unknown and multimodal MRI or CT perfusion indicated salvageable brain.

Baseline and posttreatment brain and angiographic images were centrally reviewed by an independent neuroradiologist (Dr Thomas A. Tomsick, University of Cincinnati Academic Health Center). The imaging core laboratory data were hosted by Covidien. Sites provided the imaging data to Covidien and the data were verified for systematic thrombolysis, and when the time from symptom onset was >6 hours or unknown and multimodal MRI or CT perfusion indicated salvageable brain.

Baseline CT and MRI images in jpg, PDF, or Dicom were evaluated in the complete population based on examinations available for the Corelab at baseline (for 127 patients) and at 24 hours (for 124 patients). Scan image thickness was not uniform varying from 1 to 8 mm. Baseline CT in 99 patients and MRI in 10 patients were analyzed for pretreatment Alberta Stroke Programme Early CT Score (ASPECTS) score;17 scans of 16 subjects with vertebralbasilar occlusion were not included, posttreatment scans were not available for 14 subjects, and scans of 2 subjects were not measurable. Posttreatment images performed as close as possible to 24 hours were subsequently analyzed in 124 patients for additional digital measurements of parenchymal hematoma and lesion areas through manual tracing technique on each involved slice. The techniques of measurement have been described elsewhere.18 Hemorrhagic transformation was classified by the Corelab into hemorrhagic infarction Type 1 and 2, and parenchymal hematoma Type 1, Type 2, and remote according to European Cooperative Acute Stroke Study (ECASS) definitions.19 Posttreatment CT or MR investigators’ reports were used for the 17 subjects in whom Corelab evaluation was not available. Arterial patency in the preprocedure, post-Solitaire device use, and postprocedure angiograms was classified by the modified Thrombolysis in Cerebral Infarction (mTICI) scores.20 This system classifies revascularization in 5 grades: Grade 0, no perfusion; Grade 1, perfusion past the initial obstruction, but limited distal branch filling with little or slow distal perfusion; Grade 2a, partial perfusion of less than half of the vascular distribution of the occluded artery (eg, filling and perfusion in one M2 division distal to M1 occlusion); Grade 2b, partial perfusion of half or greater of the vascular distribution of the occluded artery (eg, filling and perfusion in ≥2 M2 segments distal to M1 occlusion); and Grade 3, full perfusion with filling of all distal branches.

Primary outcome success was defined as complete revascularization resulting in a mTICI Grade 2b or 3.

Neurological outcome was defined in 2 ways as follows: (1) good, when NIHSS score improved ≥4 points; and (2) dramatic improvement when NIHSS score improved ≥10 points or NIHSS was 0 or 1 at 24 to 48 hours. Favorable functional outcome was defined as a modified Rankin Scale score ≤2 after 3 months. The 3 patients who were lost to follow-up were included in the data analysis and assigned to the worst possible outcome. Mortality was also recorded at 90 days. Symptomatic intracranial hemorrhage was defined as parenchymal hematoma Type 2 by the Corelab according to imaging at 24 to 48 hours associated with a decline of ≥4 NIHSS points within 24 hours or causing death.

Procedure Information

Following the Instructions for Use for the Solitaire FR, a balloon guide catheter is placed proximal to the intracranial occlusion. The Solitaire FR device is delivered and then deployed over the thrombus through an 18 to 27 microcatheter. A control angiogram is performed to determine the immediate reperfusion status. The device is left deployed before recovery for a few minutes. Before recovery, the microcatheter is advanced to cover the proximal marker of the device. Then, the balloon guide catheter is inflated to provide proximal internal carotid occlusion and flow arrest during the recovery. Subsequently, the Solitaire device and microcatheter are slowly recovered as a unit under constant aspiration with a 60-mL syringe through the balloon guide catheter (Figure). A control angiogram is performed to confirm revascularization and reperfusion. This sequence is repeated until mTICI 2b or 3 flow is established. Investigators recorded data on technical success (ability of the Solitaire FR device to reach the target lesion), the time from symptom onset to groin puncture, initial deployment and revascularization, and on the rescue device or treatment used when Solitaire FR was unable to achieve successful revascularization. Rescue therapy was done according to each institution or operator protocol.

Retrospectively defined procedure/device-related complications included vascular perforation, intramural arterial dissection, distal embolization of a previously uninvolved territory, and groin hematoma/retroperitoneal hemorrhages requiring surgery or blood transfusion.

An independent statistician (Jane C. Khoury, PhD, Associate Professor, Division of Biostatistics and Epidemiology, Cincinnati Children’s Hospital Medical Center) performed the statistical analysis. The publication was written and reviewed by the physicians.
who participated in the study. Additionally, Drs Joseph Broderick and Thomas Tomsick of the University of Cincinnati, who served as the principal investigators of the Interventional Management of Stroke (IMS) III study, were also involved in the review of the article.

**Results**

A total of 206 patients with acute ischemic stroke were treated with the Solitaire FR device according to clinical practice at the 6 institutions, which include the use of mechanical thrombectomy devices and pharmacological agents. Of the 206 patients, the Solitaire FR device was used as a first-choice device in 141 patients who are the basis for the current data analysis. The excluded patients were those who had aspiration thrombectomy or other mechanical devices used before deploying the study device. Three patients were lost to follow-up and were assigned the worst outcome at 3 months. A subgroup analysis was conducted for the patients who received IV tPA before endovascular treatment (74 patients [52%]). Results of this subgroup are provided in each table.

Baseline clinical and neuroimaging characteristics of patients are shown in Table 1. The median NIHSS score was 18 (range, 1–32). Seventy-four (52%) patients were treated with IV tPA (full dose in 82%) before the endovascular treatment, 56 (40%) had contraindications for IV tPA, and 11 (8%) without contraindications received direct intra-arterial treatment. Baseline ASPECTS score on CT/MRI examinations was readable in 113 patients with anterior circulation lesions. There were not significant differences in baseline and neuroimaging characteristics between the IV tPA and non-IV tPA groups.

A total of 143 vessel occlusion sites were identified and classified using the mTICI scores by the Corelab in the preprocedure angiogram of 138 patients (Table 1). In 5 patients, 2-vessel occlusions were found. Two patients could not be evaluated due to low-quality films and the angiogram of one patient was missing. Sixty-nine percent of occlusions were located in the terminal internal carotid artery or proximal middle cerebral artery. Similar frequencies of occlusion sites and mTICI scores were found in patients with or without previous IV tPA treatment.

**Technical Results**

The overall technical success rate, defined as the ability of the Solitaire FR to reach the occlusion site, was 97.8% (138 of 141). In 3 patients the Solitaire FR did not reach the target lesion with the first attempt. In 2 of the 3 patients, a second attempt was successful, but in the third patient, no additional passage was attempted because of a vessel dissection reported as a procedural complication. A balloon guide catheter was used in 74% of retrievals.

### Table 1. Baseline Clinical and Neuroimaging Characteristics

<table>
<thead>
<tr>
<th></th>
<th>Overall (n=141)</th>
<th>IV tPA (n=74)</th>
<th>No IV tPA (n=67)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age, mean y (SD)</strong></td>
<td>66.3 (13.1)</td>
<td>66.2 (12.7)</td>
<td>66.4 (13.6)</td>
</tr>
<tr>
<td>[minimum–maximum]</td>
<td>[20–89]</td>
<td>[21–89]</td>
<td>[20–88]</td>
</tr>
<tr>
<td>Female sex</td>
<td>62 (44%)</td>
<td>29 (39%)</td>
<td>33 (49%)</td>
</tr>
<tr>
<td>[quartiles]</td>
<td>(n=135)</td>
<td>(n=72)</td>
<td>(n=63)</td>
</tr>
<tr>
<td>CT/MRI ASPECTS score,* median [quartiles]</td>
<td>7 [6, 9] (n=113)</td>
<td>7 [5, 9] (n=62)</td>
<td>7 [6, 10] (n=51)</td>
</tr>
<tr>
<td>Vessel occlusions†</td>
<td>(n=143)</td>
<td>(n=73)</td>
<td>(n=70)</td>
</tr>
<tr>
<td>Cervical ICA</td>
<td>6 (4%)</td>
<td>1 (1%)</td>
<td>5 (7%)</td>
</tr>
<tr>
<td>Terminus ICA</td>
<td>33 (23%)</td>
<td>20 (27%)</td>
<td>13 (19%)</td>
</tr>
<tr>
<td>M1</td>
<td>66 (46%)</td>
<td>34 (47%)</td>
<td>32 (46%)</td>
</tr>
<tr>
<td>M2</td>
<td>19 (13%)</td>
<td>12 (16%)</td>
<td>7 (10%)</td>
</tr>
<tr>
<td>Vertebral</td>
<td>3 (2%)</td>
<td>0 (0%)</td>
<td>3 (4%)</td>
</tr>
<tr>
<td>Basilar</td>
<td>13 (9%)</td>
<td>5 (7%)</td>
<td>8 (11%)</td>
</tr>
<tr>
<td>PCA</td>
<td>2 (1%)</td>
<td>1 (1%)</td>
<td>1 (1%)</td>
</tr>
<tr>
<td>SCA</td>
<td>1 (1%)</td>
<td>0</td>
<td>1 (1%)</td>
</tr>
<tr>
<td>mTICI grade</td>
<td>(n=143)</td>
<td>(n=73)</td>
<td>(n=70)</td>
</tr>
<tr>
<td>0</td>
<td>132 (93%)</td>
<td>68 (93%)</td>
<td>64 (91%)</td>
</tr>
<tr>
<td>1</td>
<td>6 (4%)</td>
<td>2 (3%)</td>
<td>4 (6%)</td>
</tr>
<tr>
<td>2a</td>
<td>4 (3%)</td>
<td>3 (4%)</td>
<td>1 (1%)</td>
</tr>
<tr>
<td>2b</td>
<td>1 (1%)</td>
<td>0</td>
<td>1 (1%)</td>
</tr>
</tbody>
</table>

Numbers are provided where not equal to No. stated in column heading.
IV tPA indicates intravenous tissue-type plasminogen activator; NIHSS, National Institutes of Health Stroke Scale; ASPECTS, Alberta Stroke Programme Early CT Score; ICA, internal carotid artery; PCA, posterior cerebral artery; SCA, superior cerebellar artery; mTICI, modified Thrombolysis in Cerebral Infarction.

*ASPECTS score by Corelab evaluation in patients with anterior territory infarction and readable CT or MR at baseline.
†Corelab evaluation: a total of 143 occlusion sites were evaluated in 138 patients (see text for explanation).
Revascularization Results

Table 2 outlines procedural characteristics and the final patient mTICI scores post-Solitaire use. Successful revascularization (mTICI 2b or 3) was reported by the Corelab in 120 of 142 (85%) arterial occlusions. The number of passes until achieving complete or maximal revascularization was reported in 138 patients. The median number of passes for all patients was one (range, 0–7) and 77% of procedures achieving complete or maximal revascularization was reported by the Corelab in 120 (85%) arterial occlusions. The median number of passes until achieving successful revascularization within one or 2 passes was 39 (28–54). In 7 (4.9%) patients (3 patients with prior IV tPA and 4 without), a rescue device or pharmacological intraarterial thrombolysis was used because Solitaire FR was unable to achieve successful revascularization. mTICI 2b to 3 was achieved in 3 cases and 2a in one.

Clinical Outcome

Table 3 shows clinical outcomes. In review of records, it was noted that NIHSS recordings were missing in 6 patients at baseline and in 15 at 24 to 48 hours postprocedure. They were considered as nonresponders. Accordingly, good early neurological outcome at 24 to 48 hours (NIHSS improvement ≥4 points) was found in 78 (55%) patients and 58 patients (41%) showed a dramatic improvement of ≥10 points or full neurological recovery (NIHSS 0–1). At 3 months, 26 patients were dead (18%) and 3 patients were lost to follow-up (2%). Good functional outcome (modified Rankin Scale ≤2) at 3 months was achieved in 77 of 141 (55%) patients in the total series and in 75 of 134 (56%) patients who did not need rescue endovascular treatment. The rate of neurological recovery (NIHSS 0–1) from 24 hours after the procedure up to 3 months of follow-up was significantly higher in patients treated with IV tPA than in those without, and this resulted in a higher rate of favorable functional outcome at 3 months (IV tPA, 66%; no IV tPA, 42%; P<0.01). Proportions were similar in the subset of patients in whom only the Solitaire was used.

Complications and Deaths

Hemorrhagic transformation as per Corelab evaluation was found in 45 of 124 (36%) patients with available CT/MRI at 24 hours (Table 4). Symptomatic intracranial hemorrhage was reported in 5 patients (4%). There were no significant differences between patients previously treated with IV tPA and those who were not. All 17 patients without available posttreatment CT or MR for the Corelab evaluation had follow-up CT or MRI at 24 to 48 hours and no symptomatic intracranial hemorrhage was reported by the local investigators. Subarachnoid hemorrhage was reported in 12 patients by Corelab evaluation (10%) and in 7 patients by site evaluation. Fatal isolated subarachnoid hemorrhage was reported in one patient and in 4 cases it was associated to parenchymal hematoma Type 2. Subarachnoid hemorrhage was related to a technical issue (device manipulation in a small vessel) in a single patient.

Vessel dissection occurred in 2 patients, in one case leading to cerebral ischemia after intrastent thrombosis of the stent placed (an Enterprise stent; Codman Neurovascular, Boston, MA) to treat the dissection. Pseudoaneurysm formation at femoral access was reported in 2 patients and vasospasm in 5 without clinical sequelae. The Corelab reported distal emboli not present at onset for 9 patients. Two of the 9 patients had new ischemia with clinical impact: the first had a new infarct on the posterior internal carotid artery with the initial target vessel being M1 to M2 and the second a new infarct on the posterior internal carotid artery with the initial target vessel being the basilar artery.

Mortality was reported in 26 patients (18%) after 3 months (20 were in-hospital deaths) and 3 additional patients were classified as deaths due to lost follow-up, resulting in an overall 20% mortality rate. Causes of death were stroke-related (11 patients, 5 due to intracerebral hemorrhage), systemic bleeding (2), cardiac-related (3), pulmonary diseases (5 cases), disseminated cancer (3), glottic edema (one),
and renal failure (one). No death was attributed to the Solitaire device.

### Discussion

This multicenter retrospective study shows that the self-expanding and fully retrievable stent-based mechanical thrombectomy device, Solitaire FR revascularization device, can safely and effectively retrieve clots from the large arteries in the anterior and posterior cerebral circulation. Successful revascularization (mTICI 2b or 3) was achieved in 85% of arterial occlusions, resulting in 55% of patients with good functional outcome (modified Rankin Scale 0–2) at 3 months. The good functional outcome was significantly higher in patients treated previously with IV tPA compared with those without. This association may be due to a higher rate of successful revascularization in patients with prior tPA (86% versus 81%) because age, NIHSS score, baseline ASPECTS score, and time to treatment were comparable between groups.

Remarkably, 77% of patients achieved revascularization with ≤2 passes of the device. Hence, the mean number of pass attempts (1.8) was lower than in the previously reported Mechanical Embolus Removal in Cerebral Ischemia (MERCI) studies (2.9 passes), resulting in a shorter median time from groin puncture to revascularization (40 versus 96 minutes [72–138]). Because time to reperfusion is important for brain survival, the ability to restore flow immediately, even if temporary, may be of great advantage. Solitaire was the unique procedure used in most patients because a rescue device or treatment was needed in only 4.9% of cases.

Mechanical thrombectomy with the Solitaire FR device appeared to be safe. Mortality and intracerebral hemorrhage rates were comparable to those previously shown in intra-arterial thrombolytic and thrombectomy trials (see online-only Data Supplemental Table I).

This is a retrospective study that should be interpreted carefully. Patients were treated in 6 institutions according to their own clinical protocols; thus, time from symptom onset to the endovascular treatment was variable (up to 15 hours) and different paradigms were used to identify salvageable brain. Better outcomes could be due to highly selected patients with multimodal MRI or CT perfusion that may represent a different population included in prior reported studies. Furthermore, investigators who evaluated the clinical outcome were not

### Table 3. Neurologic and Functional Outcomes During Follow-Up

<table>
<thead>
<tr>
<th>Neurologic outcome</th>
<th>Overall (n=114)</th>
<th>IV tPA (n=74)</th>
<th>No IV tPA (n=67)</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Baseline 24 H Discharge 3 Mo</td>
<td>Baseline 24 H Discharge 3 Mo</td>
<td>Baseline 24 H Discharge 3 Mo</td>
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<td>Neurologic outcome</td>
<td>Neurologic outcome</td>
<td>Neurologic outcome</td>
<td>Neurologic outcome</td>
</tr>
<tr>
<td>NHSS valid cases, no.</td>
<td>135</td>
<td>126</td>
<td>114</td>
</tr>
</tbody>
</table>
blinded to the revascularization results and did not consistently undergo certification/training for modified Rankin Scale or NIHSS. A major strength of this study is the central evaluation through a core laboratory of brain and angiographic imaging.

Our results agree with those recently reported in clinical trials using stent retrievers. The randomized Stroke Warning Information and Faster Treatment (SWIFT) trial has shown in 113 patients that the Solitaire FR device is superior to the MERCI Retriever in achieving successful revascularization (by Corelab, 68% versus 30%; P < 0.001), less symptomatic intracranial hemorrhage (2% versus 11%; P = 0.06), reduced mortality (17% versus 38%; P = 0.02), and increased good neurological outcome 3 months after stroke (58% versus 33%; J. Saver, ISC, New Orleans, LA, 2012). To be noted is that the selection criteria in SWIFT were not image-based other than greater than one third hypodensity by CT, without requirement on when the CT was obtained, and the duration of treatment was longer. TREVO has also shown a high rate of revascularization (by Corelab TICI 2a, 2b, or 3; 90%) and favorable outcome (57%) in a multicenter single arm trial of 60 patients with acute stroke (N. Wahlgren N, ISC, New Orleans, LA, 2012) and in a recent single center experience (TICI 2b or 3, 73%; good outcome, 45%).

Newer revascularization concepts like the use of stent-based thrombectomy devices achieve revascularization rates of 90%; however, there still remains a mismatch between revascularization and clinical outcome, particularly in cases with delay in initiation and successful revascularization with intra-arterial therapy. The Solitaire FR device is a valuable addition to the armamentarium of acute stroke intervention tools because complete thrombus removal is safely achieved in many patients within a short time. To date, no intra-arterial device or revascularization approach has been demonstrated to improve clinical outcome as compared with IV tPA within 4½ hours. However, this study demonstrated similar rates of positive outcome in patients who had either failed IV tPA or were not candidates to IV tPA. This represents substantial advancement of outcome in a more severe subgroup who before had few, if any, options. Obviously, recruitment in randomized trials of endovascular therapy as compared with standard therapy is urgently needed. Inclusion of these devices in IMS III²³ and other randomized trials is ongoing.

### Appendix

#### Hospitals and Collaborators Participating in the Solitaire Group

Carlos Cañasto, Laura Dorado, Aitziber Aleu, and Rosal García, Hospital Germans Trias i Pujol, Badalona, Spain; Roman Sztajzel, Karl-Olof Lovblad, Ana Marcos Gonzalez, and Ana Paula Narata, Hospital Universitario Genève, Geneva, Switzerland; Conrad Venker, AKK Hospital, Essen, Germany; Paolo Machi, Carlos Riquelme, and Vincent Costalat, Hôpital Gui de Chauliac, Montpellier, France; Michael Soderman and Ake Holmberg, Karolinska University Hospital, Stockholm, Sweden; and Caspar Brekenfeld, Heinrich P. Mattle, and Gerhard Schroth, Inselspital University Hospital, Berne, Switzerland.

#### Acknowledgments

We thank ev3-Covidien Inc and Patricia Boyer for their support in this study.

#### Sources of Funding

This study was entirely funded and supported by Covidien Neurovascular.

#### Disclosures

All primary authors are consultants on clinical or educational projects for ev3-Covidien Inc.

#### References


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<tr>
<th></th>
<th>n</th>
<th>NIHSS</th>
<th>Successful recanalization (TIMI 2-3)</th>
<th>mRS 0-2 at day 90</th>
<th>90-day mortality</th>
<th>sICH</th>
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<td><strong>Intraarterial thrombolysis</strong></td>
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<tr>
<td>PROACT II [1]</td>
<td>121</td>
<td>17</td>
<td>66%</td>
<td>40%</td>
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<td>10%</td>
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<tr>
<td>IMS-I [2]</td>
<td>62</td>
<td>18</td>
<td>56%</td>
<td>43%</td>
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<td>6%</td>
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<td>IMS-II [3]</td>
<td>55</td>
<td>19</td>
<td>60%</td>
<td>46%</td>
<td>16%</td>
<td>10%</td>
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<td><strong>Mechanical thrombectomy</strong></td>
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<tr>
<td>Multi MERCI [4]</td>
<td>164</td>
<td>19</td>
<td>68%</td>
<td>36%</td>
<td>34%</td>
<td>10%</td>
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<tr>
<td>Penumbra (pivotal) [5]</td>
<td>125</td>
<td>18</td>
<td>82%</td>
<td>25%</td>
<td>33%</td>
<td>11%</td>
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<tr>
<td>Solitaire™ FR</td>
<td>141</td>
<td>18</td>
<td>85%*</td>
<td>55%</td>
<td>20%</td>
<td>4%†</td>
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<tr>
<td>Pooling analysis of</td>
<td>1391</td>
<td>11</td>
<td>NA</td>
<td>49%</td>
<td>13%</td>
<td>5-9%†</td>
</tr>
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<td>intravenous tPA trials within</td>
<td></td>
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<tr>
<td>6 hours (tPA) [6]</td>
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</table>

ICH: symptomatic intracerebral hemorrhage; * mTICI 2b-3 classification was used instead of TIMI 2-3. † Parenchymal hemorrhage type II.
References for Table online


