Mechanical Thrombectomy With the Solitaire AB Device in Large Artery Occlusions of the Anterior Circulation

A Pilot Study

Carlos Castaño, MD, PhD; Laura Dorado, MD; Cristina Guerrero, MD; Monica Millán, MD;Meritxell Gomis, MD; Natalia Perez de la Ossa, MD; Mar Castellanos, MD, PhD; M. Rosa García, NNI; Sira Domenech, MD; Antoni Dávalos, MD, PhD

Background and Purpose—To describe the safety and effectiveness of a self-expanding and fully retrievable stent (Solitaire AB; ev3 Inc, Plymouth, MN) in revascularization of patients with acute ischemic stroke.

Methods—Prospective, single-center study of 20 patients with an acute ischemic stroke attributable to a large artery occlusion of the anterior circulation within the first 8 hours from symptoms onset (median National Institutes of Health Stroke Scale, 19 [interquartile range, 15–23]). The occlusion site was middle cerebral artery in 12 patients, proximal internal carotid artery/middle cerebral artery tandem occlusion in 3 patients, and terminus internal carotid artery in 5 patients. Thrombectomy was used as rescue therapy in 2 patients who were refractory to intra-arterial plasminogen activator, and in 3 patients in whom successful recanalization with the MERCI retriever was not achieved.

Results—Successful revascularization defined as thrombosis in cerebral ischemia grade 2b or 3 was achieved in 18 of 20 (90%) treated vessels, and 16 patients showed immediate restoration of flow after stent deployment. The mean number of passes for maximal recanalization was 1.4, and the median (quartiles) time from groin puncture to recanalization was 50 (38–71) minutes. No case required adjutant therapy after deployment of the embolectomy device. No significant procedural events occurred. Symptomatic intracranial hemorrhage was found in 2 (10%) patients, 4 (20%) patients died during the 90-day follow-up period, and 45% of patients showed good functional outcome at 3 months (modified Rankin Scale score ≤2).

Conclusions—These results suggest that the Solitaire AB device can rapidly, safely, and effectively retrieve clots from the middle cerebral artery and terminus internal carotid artery within 8 hours from symptoms onset. (Stroke. 2010;41:1836-1840.)

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

The Solitaire AB (ev3 Inc, Plymouth, MN) is a self-expanding stent that offers the unique capability of being able to be fully deployed and then completely retrieved if it has not been detached.1,2 In this pilot study, we tested whether the Solitaire AB stent could be used as a novel mechanical embolectomy device for large artery occlusions of the anterior circulation in patients presenting within 8 hours from the onset of an acute ischemic stroke.

Materials and Methods

We treated 20 consecutive patients refractory or ineligible for the use of intravenous tissue plasminogen activator who met the following criteria: age 80 years or younger, National Institutes of Health Stroke Scale (NIHSS) score ≥8 or lower if there was a fluctuating neurological deficit, time from symptoms onset to the endovascular procedure of <8 hours, absence of large signs of ischemia (defined as an Alberta Stroke Program1 early CT score of <7 or MR diffusion-weighted lesion >50% of the middle cerebral artery territory), and an angiographically proven occlusion of the anterior circulation. Treatable vessels were terminus internal carotid artery (ICA), tandem proximal ICA/middle cerebral artery, and middle cerebral artery M1 and M2 divisions. Although the Solitaire AB device is approved in the European Union (EU), we used this stent in an off-label indication for mechanical thrombectomy in acute stroke. Informed consent from the patients or their relatives and local ethics committee approval were obtained accordingly.

All patients were evaluated with cranial CT scan or multimodal MR, and vessel status was assessed by MR angiography or transcranial color-coded Duplex sonography immediately before the endovascular approach. A CT scan was routinely performed at 24 to 36 hours after treatment or before if any neurological worsening ≥4 points in NIHSS score occurred.

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From Unit of Interventional Neuroradiology (C.C., M.R.G.) and Acute Stroke Unit (C.C., L.D., C.G., M.M., M.G., N.P.d.I.O., M.R.G., A.D.), Service of Neurology, Department of Neurosciences, Hospital Universitari Germans Trias i Pujol, Badalona, Universidad Autónoma de Barcelona, Barcelona, Spain; Acute Stroke Unit (M.C.), Service of Neurology, Hospital Doctor Josep Trueta, Girona, Spain; Institut de Diagnostic per la Imatge (S.D.), Hospital Universitari Germans Trias i Pujol, Badalona, Barcelona, Spain. Correspondence to Dr Carlos Castaño, Department of Neurosciences, Hospital Universitari Germans Trias i Pujol., Universitat Autònoma de Barcelona, Ctra Canyet s/n, CP 08916 Badalona, Barcelona, Spain. E-mail ccastanod@gmail.com © 2010 American Heart Association, Inc.

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Revascularization Procedure

All procedures were performed under general anesthesia. Using a transfemoral approach, an 8-Fr balloon guide catheter was placed in the proximal internal carotid artery. A heparinized saline solution was continuously perfused through the catheter during the procedure. With the balloon of the guide catheter deflated, a 0.014-inch guide wire was advanced coaxially over a Rebar 18 microcatheter (ev3 Inc, Irvine, CA) within the occluded intracranial vessel and navigated distal to the clot. The Rebar 18 microcatheter was then advanced over the wire through the clot, and the guide wire was exchanged for the embolectomy device. Then, the Solitaire AB was advanced and deployed with the distal portion of the stent placed a few millimeters distal to the clot (Figure). This resulted in immediate flow restoration distal to the thrombus if the clot length was shorter than the stent (20 mm). In those cases in which the stent was deployed in an occluded M1 segment, angiographic flow restoration in lenticulostriate arteries was noted.

The stent was kept deployed for 1 or 2 minutes before retrieving it, and then the balloon of the guide catheter was inflated and the microcatheter and the embolectomy device were gently withdrawn outside the body through the guide catheter under continuous proximal aspiration with a syringe. A control angiography was performed to confirm recanalization and reperfusion (Figure).

If the patient had a tandem occlusion of the proximal ICA, then angioplasty before distal mechanical thrombectomy and stenting after thrombectomy were performed in the ICA.

Outcome Measures

Primary outcome was the rate of vascular recanalization defined as thrombolysis in cerebral infarction grade 2b or 3.4 Prospectively established device-related complications were vascular perforation, intramural arterial dissection, or embolization of a previously uninvolved territory. Symptomatic intracranial hemorrhage was defined as any hemorrhagic transformation on the 24-hour CT scan associated with a decline of ≥4 points in the NIHSS score within 24 hours or leading to death, or any subarachnoid hemorrhage.

Functional independence was defined as modified Rankin Scale score ≤2 at day 90, and good early neurological outcome as NIHSS score 0, 1, or improvement of ≥10 points at day 7 or at discharge if occurred within the first week.

Results

Baseline characteristics and procedural techniques are shown in Table 1. Ten patients were treated with intravenous tissue plasminogen activator before the neurointerventional approach. The median (quartiles) baseline NIHSS score was 19 (15–23), the median time from onset of symptoms to neurointerventional treatment (groin puncture) was 352 (212–394) minutes, and the time from the decision to intervene to groin puncture was 70 (47–95) minutes.

In most patients, the device was used as the unique method (n=15) and in 5 cases it was used after unsuccessful recanalization with MERCI retriever (n=3) or intra-arterial tissue plasminogen activator (n=2). Stenting of extracranial ICA was required after thrombectomy in 2 patients. Successful revascularization was achieved in 18 of 20 (90%) patients (thrombolysis in cerebral infarction grade 3 in 17, thrombolysis in cerebral infarction grade 2b in one). No cases required adjuvant therapy after deployment of the embolectomy device or intracranial stenting. The flow was restored immediately in all but 4 patients with terminus ICA occlusion in whom the stent could not overlay all the thrombus length.
The mean number of passes until achieving maximal recanalization was 1.4. The median (quartiles) time from groin puncture to recanalization was 70 (45–112) minutes in the total series (n=20) and 50 (38–71) minutes when the Solitaire AB was the first endovascular approach (n=15). Distal embolization to the middle cerebral artery territory occurred in 2 patients, but no patient has thrombus migration to a different territory. No arterial rupture or dissections were encountered.

Asymptomatic intracranial hemorrhage occurred in 6 patients, and 2 patients (10%) had symptomatic intracranial hemorrhage within 24 hours after the procedure (1 fatal parenchymal hemorrhage and 1 subarachnoid hemorrhage). Mortality was recorded in 4 patients (20%) during the follow-up period of 90 days (1 patient died within the first week). Good early neurological outcome was found in 10 (50%) patients, and 9 patients (45%) were functionally independent at 90 days. Favorable functional outcome was associated with younger age (59±12.8 vs 70.9±8.5; P=0.023), lower stroke severity at baseline as measured by the NIHSS score (15 [3–21] vs 22 [17–24]; P=0.016) and treatment with intravenous tissue plasminogen activator before the neurointerventional approach (77.8% vs 27.3%; P=0.025), although the latter effect was confounded by a lower stroke severity before the endovascular procedure in patients pretreated with systemic tissue plasminogen activator (mean NIHSS, 13 vs 21; P=0.027). No other variables, such as procedure duration, time from symptoms onset to groin puncture or to recanalization, and cardioembolic etiology, were significantly associated with outcome in the univariate analysis.

**Discussion**

This pilot study shows that the self-expanding and fully retrievable stent Solitaire AB can rapidly, safely, and effectively retrieve clots from the proximal middle cerebral artery and terminus ICA within 8 hours from symptoms onset. Remarkably, immediate flow restoration occurred in 80% of patients after stent deployment, and in most of them only 1 pass was required to fully retrieve the clot and achieve complete revascularization. Hence, the mean number of pass attempts (1.4) was lower than in the MERCI studies (2.9 passes), whereas the mean time from groin puncture to recanalization was shorter.5,6 Because time to reperfusion is important for brain survival, the ability to restore flow immediately, even if temporary, may be of great advantage.7 However, the length of thrombus is an important factor influencing the ability to reach this goal with the Solitaire AB device exemplified by our 4 patients with thrombus length longer than the stent in whom thrombus retrieval was needed before flow restoration.

We enrolled patients who were able to receive mechanical thrombectomy up to 8 hours after symptoms onset and had potential salvageable brain. The frequency of successful revascularization and good clinical outcome in the present study was higher than that previously shown in thrombolytic trials published so far, whereas the rate of symptomatic intra-arterial hemorrhage and mortality was comparable (Ta-
ble 2).5,6,8–12 Age and NIHSS score were predictors of good outcome, as has been recently reported in patients undergoing thrombectomy.13

Embolectomy with the Solitaire AB was safe. None of the devices fractured during the procedures. There was no angiographic or clinical evidence of vascular injury or emboli into previously uninvolved arteries. The rate of complications was not higher than that reported in larger thrombectomy trials, ranging between 2.4% and 4.3%.5,9,11

Our preliminary observations suggest that the Solitaire device is a valuable addition to the armamentarium of acute stroke intervention tools. However, the high proportion of good outcomes obtained in our group of patients may be influenced by the fact that 3 of the patients who achieved good outcomes had very low NIHSS score at baseline (3 or 4). Although the decision to treat was adopted because the probability of neurological worsening with infarct expansion and long-term dependence increases 7 odd in patients with minor or moderate symptoms and proximal occlusions,14,15 most studies of intra-arterial thrombolysis presented in Table 2 did not include patients with such low NIHSS scores. Another limitation of our study is that investigators who evaluated the clinical outcome were not blinded to the revascularization results, and an independent committee did not evaluate angiographic data and potential adverse events.

This is a small pilot study, so the results should be interpreted cautiously. However, we believe that our findings may represent a step forward in reperfusion therapies because Solitaire AB achieved a very high rate of rapid revascularization of distal branches, with the potential for excellent clinical outcomes.

Table 2. Comparison of Baseline Stroke Severity and Outcome Variables Between This Study and the Intra-Arterial Thrombolytic and NINDS Trials

<table>
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<th></th>
<th>N</th>
<th>NIHSS Basal</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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sICH indicates symptomatic intracerebral hemorrhage; TIMI, Thrombolysis in Myocardial Infarction.
*Parenchymal hematoma type II.
†TICI 2b-3 classification was used instead of TIMI 2–3.

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Disclosures
None.

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