Solitaire Flow Restoration device for thrombectomy recanalization of large vessel occlusions in acute ischemic stroke: A Single-Center Experience.

**Poster No.:** C-2155  
**Congress:** ECR 2015  
**Type:** Scientific Exhibit  
**Authors:**  
C. Parra-Fariñas¹, A. Tomasello¹, M. Ribó Jacobí¹, P. Coscojuela¹, E. Almazán², M. Pardo Antunez¹, C. Ortiz¹, S. Boned¹, A. Rovira-Cañellas¹; ¹Barcelona/ES, ²El Prat de Llobregat/ES  
**Keywords:** Embolism / Thrombosis, Thrombolysis, Catheter arteriography, CNS  
**DOI:** 10.1594/ecr2015/C-2155

Any information contained in this pdf file is automatically generated from digital material submitted to EPOS by third parties in the form of scientific presentations. References to any names, marks, products, or services of third parties or hypertext links to third-party sites or information are provided solely as a convenience to you and do not in any way constitute or imply ECR’s endorsement, sponsorship or recommendation of the third party, information, product or service. ECR is not responsible for the content of these pages and does not make any representations regarding the content or accuracy of material in this file.

As per copyright regulations, any unauthorised use of the material or parts thereof as well as commercial reproduction or multiple distribution by any traditional or electronically based reproduction/publication method ist strictly prohibited.

You agree to defend, indemnify, and hold ECR harmless from and against any and all claims, damages, costs, and expenses, including attorneys’ fees, arising from or related to your use of these pages.

Please note: Links to movies, ppt slideshows and any other multimedia files are not available in the pdf version of presentations.
Aims and objectives

Introduction

In patients with acute cerebral ischemia treated with intravenous thrombolysis, early restoration of blood flow is strongly associated with improved functional outcomes and reduced mortality [1]. Actually, intravenous recombinant tissue plasminogen activator (rt-PA) is the standard care for treatment of acute ischemic stroke. However, rt-PA is often ineffective, including a short therapeutic window and poor reperfusion rates, especially in large vessel occlusions, which restricts a more widespread adoption [2-5]. The use of mechanical clot retrieval devices within 8-hours from symptoms onset have been increasingly used to achieve faster and more efficient recanalization of large arterial occlusions due to increased reperfusion rates compared with intravenous or intra-arterial thrombolysis [6]. Although, mechanical devices are unable to achieve successful recanalization in as many as 20-40% of large vessel occlusion strokes [7-11].

Recent studies, as the randomized Stroke Warning Information and Faster Treatment (SWIFT) and the randomized trial Thrombectomy Revascularisation of large vessel occlusions in acute ischaemic stroke (TREVO 2), have shown the superiority of stentriever (ST), using Stentriever Technology, over other thrombectomy devices [12-13].

The Solitaire Flow Restoration (FR) device (Covidien) (Fig. 1) is a self-expanding ST, designed to restore blood flow in patients with acute ischemic brain. When the stent is deployed within the target clot in the occluded vessel, the stent struts entrap the thrombus; and when the stent is withdrawn in its unfolded state, the enmeshed thrombus is concurrently extracted from the vessel. In an animal vessel occlusion model, the Solitaire device achieved rapid and complete recanalization of target arteries without pathological evidence of vessel damage related to device deployment [14]. In several open, uncontrolled clinical series, the Solitaire device has yielded high rates of reperfusion and favourable clinical outcomes in patients with acute ischaemic stroke [11-16].

This study aims to describe the safety and effectiveness of using Solitaire retriever, as a novel mechanical thrombectomy device for large vessel occlusions in patients with acute cerebral ischemia.
Fig. 1: (A) The Solitaire FR device after complete deployment. The thrombectomy device is firmly molded to a nitinol pusher wire (arrow). Radiopaque markers at the proximal and distal end (asterisk). (B) The Solitaire FR after successful retrieval. Note the encasement of the thrombus between the stent struts and the partial re-sheathing of the stent by advancing the microcatheter just over the proximal marker before retrieval (arrow).

© Covidien.
Methods and materials

We retrospectively analysed the clinical, radiological and functional outcome of 70 patients with an angiographically verified occlusion [Thrombolysis in Cerebral Infarction (TICI) grade 0] (Table 1) of the cerebral circulation that underwent thrombectomy with the Solitaire retriever within the first 8-hours from symptoms onset from July 2012 to September 2014.

Clinical and Radiological Evaluation

We retrieved clinical data including demographic, pre-existing vascular risk factors and medication history for each patient.

According to our institutional protocol, all patients underwent at admission a standard neurological examination, electrocardiogram, blood pressure measure, and blood tests. The National Institutes of Health Stroke Scale (NIHSS) (Table 2) [17] assessed stroke severity at baseline and at 24-hours. Patients were evaluated with cranial CT scan or multiparametric MRI in patients with >4.5-hours or unknown time from symptoms onset. Eligible patients were treated with rt-PA.

Vessel status was evaluated by CT angiography or transcranial color-coded Duplex sonography immediately before the endovascular procedure to ensure persistence of occlusion. We routinely performed a CT scan at 24 to 36 hours after treatment or before if any neurological worsening (#4 points increase in NIHSS score) occurred.

Informed consent from the patients or their relatives and local ethics committee approval were obtained accordingly.

Recanalization strategy

We performed all procedures according to our institutional mild sedation protocol. Once the arterial occlusion was angiographically confirmed, a 6-Fr guide catheter was placed in the ICA (Internal Carotid Artery) using a transfemoral approach and an angiogram was performed to locate the occluding clot. A saline solution was continuously perfused through the catheter during the procedure. With a large intermediate catheter (4.3, 5.5-Fr) as distal as possible, a .014-inch guide wire and a .018-inch microcatheter were advanced within the occluded intracranial vessel passing through the clot. Once the distal end of the
microcatheter was positioned a few millimetres beyond the distal aspect of the clot, the guide wire was exchanged by the Solitaire retriever. The thrombectomy device was held in place when 3 mm were out of the microcatheter. Then the microcatheter was slowly pulled back in order to deploy the endovascular device over the clot.

At that point a contrast injection through the intermediate catheter could show contrast filling of some distal branches previously occluded. The stent was kept deployed for 3-4 minutes to allow the clot to be embedded in the stent mesh. Then the microcatheter and the ST were gently withdrawn as the intermediate catheter was advanced towards the clot under continuous distal aspiration with a 50 cc syringe to create a reverse flow through the intermediate catheter. If recanalization did not occur the procedure could be repeated up to 6 passes. The procedure was terminated when recanalization was achieved or according to the treating physician criteria (usually 8-hours after symptoms onset).

A final control angiogram was performed to confirm recanalization and reperfusion (Fig. 2-4).

**Outcome Measures**

Vascular recanalization was defined as TICI grade 2b or 3 [18]. Dramatic clinical improvement was defined as a # 10 points decrease in the NIHSS at 24 hours [17]. Symptomatic intracranial haemorrhage was defined as haemorrhagic transformation on the 24-hour CT scan that was related to deterioration in the patient’s clinical condition in the judgment of the clinical investigator [19]. Functional outcome was assessed by modified Rankin Scale (mRS) (Table 3) at 3 months. In-hospital mortality was recorded.

**Statistical Analysis**

Descriptive and frequency statistical analysis were obtained and comparisons were made using SPSS 20.0 software (SPSS, Inc., Armonk, NY).
Table 1: Terminology and definition of Thrombolysis in Cerebral Infarction (TICI) Reperfusion (1a) and Arterial Occlusive Lesion (AOL) Recanalization scores (1b) [18].


Table 2: National Institutes of Health Stroke Scale (NIHSS) [17]. The NIHSS is a tool used by healthcare providers to objectively quantify the impairment caused by a stroke. The NIHSS is composed of 11 items, each of which scores a specific ability between a 0 and 4. For each item, a score of 0 typically indicates normal function in that specific ability,
while a higher score is indicative of some level of impairment. The individual scores from each item are summed in order to calculate a patient’s total NIHSS score. The maximum possible score is 42, with the minimum score being a 0.


Fig. 2: Endovascular recanalization in 73-year old patient with acute right ACM occlusion. Radiopaque marker at distal end of the retriever device (arrow).

© 2014 Department of Neuroradiology, Vall d’Hebron Hospital. Barcelona, Spain.
**Fig. 3:** (A) Basal angiogram with acute occlusion of middle cerebral artery, M1 segment (arrow). (B) Solitaire deployment in proximal middle cerebral artery (arrow) where the clot is compressed against the down vessel wall. (C) Final angiogram with complete recanalization and reperfusion (TICI 3) [18] (arrow).

© 2014 Department of Neuroradiology, Vall d’Hebron Hospital. Barcelona, Spain.

**Fig. 4:** (A) Basal angiogram with occlusion of proximal left middle cerebral artery (arrow). (B) Stentriever deployment in proximal middle cerebral artery (arrow). Note some contrast passing thought the stent. (C). Final angiogram with complete recanalization (TICI 3) [18] (arrow).

© 2014 Department of Neuroradiology, Vall d’Hebron Hospital. Barcelona, Spain.
**Table 3:** Modified Rankin Scale (mRS). The mRS is a commonly used scale for measuring the degree of disability or dependence in the daily activities of people who have suffered a stroke or other causes of neurological disability, and it has become the most widely used clinical outcome measure or stroke clinical trials.

Results

From July 2012 to September 2014, 70 patients were treated with Solitaire retriever (36 female, 34 male). Mean age was 67±15.8 years.

On the first angiogram the occlusion site was identified in the middle cerebral artery (MCA) in 39 (55.7%) patients, in the internal carotid artery (ICA) in 27 (38.6%) patients and in the basilar artery (BA) in 4 (5.7%) patients.

The main baseline characteristics of the study group and the occluded vessel are summarized in Table 4.

Successful recanalization was achieved in 46 (65.7%) patients, TICI grade 3 in 16 (22.8%) patients and grade 2b in 30 (42.8%) patients (Fig. 5, 6). In 7 (10%) patients no recanalization was achieved (TICI 0-1). There were no significant clinical differences between these patients and those who reanalysed.

When recanalization occurred after retrieval of the ST, fragments of the clot could usually be identified embedded in the stent. However, in some cases the clot was only seen in the aspiration syringe and in a few of the cases recanalization was achieved despite no clot being found either in the stent or in the syringe.

Dramatic clinical improvement was found in 25 (35.7%) patients. Symptomatic intracranial haemorrhage occurred in 6 (8.6%) patients (Fig. 7). Of 56 (80%) patients who completed the 90-day follow-up period, 19 (27.1%) achieved functional independence. In hospital mortality rate was 8.6%, 6 patients (Table 5).
Table 4: Baseline Characteristics of Patients and Occluded Vessel. SD= Standard Deviation; ICA= Internal Carotid Artery; MCA= Middle Cerebral Artery; BA= Basilar Artery.

© 2014 Department of Neuroradiology, Vall d’Hebron Hospital. Barcelona, Spain.
**Fig. 5:** 74-year old patient with acute right proximal MCA occlusion. (A) Hyperdense MCA sign (arrow). This increase attenuation of the proximal portion of the MCA is often associated with thrombosis of the M1 MCA segment. It is one of the early signs of ischaemic stroke. (B) Digital subtraction angiogram before deployment of the stent shows M1 occlusion (arrow) with poor collateral circulation. (C, D) Angiograms after deployment of the stent shows complete recanalization (TICI 3) [18] (arrows).

© 2014 Department of Neuroradiology, Vall d’Hebron Hospital. Barcelona, Spain.
Fig. 6: 60-year old patient with acute occlusion of basilar artery (BA). (A) Initial angiogram shows complete occlusion of the BA. (B) Small infarct in the right thalamus in the MRI (arrow). (C) After 2 ST passes successful recanalization was achieved (TICI 3) [18] (arrow). (D) Control CT scan shows right thalamus hypodensity (arrow) and perimesencephalic and basal cisterns SAH due to contrast extravasation during endovascular procedure.

© 2014 Department of Neuroradiology, Vall d’Hebron Hospital. Barcelona, Spain.
**Fig. 7:** Intracranial haemorrhage after successful mechanical thrombectomy (TICI 3) [18] in a 65-year old patient with an acute left proximal MCA occlusion.

© 2014 Department of Neuroradiology, Vall d’Hebron Hospital. Barcelona, Spain.

<table>
<thead>
<tr>
<th>Outcome Measure</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recanalization (TICI 2b-3)</td>
<td>46 (65.7)</td>
</tr>
<tr>
<td>2b, n (%)</td>
<td>30 (42.8)</td>
</tr>
<tr>
<td>3, n (%)</td>
<td>16 (22.8)</td>
</tr>
<tr>
<td>Dramatic clinical improvement, n (%)</td>
<td>25 (35.7)</td>
</tr>
<tr>
<td>Symptomatic intracranial haemorrhage, n (%)</td>
<td>6 (8.6)</td>
</tr>
<tr>
<td>90 days follow-up period completed, n (%)</td>
<td>56 (80)</td>
</tr>
<tr>
<td>Patients Independent, n (%)</td>
<td>19 (27.1)</td>
</tr>
<tr>
<td>Intra-hospital mortality, n (%)</td>
<td>6 (8.6)</td>
</tr>
</tbody>
</table>

**Table 5:** Outcomes Measures. TICI: Thrombolysis in Cerebral Infarction (Table 1) [18]. Dramatic clinical improvement: # 10 points decrease in the NIHSS at 24 hours. Symptomatic intracranial haemorrhage: haemorrhagic transformation on the 24-hour CT scan that was related to deterioration in the patient’s clinical condition in the judgment of the clinical investigator. Functional independence: mRS score # 2 at 3 months.

© 2014 Department of Neuroradiology, Vall d’Hebron Hospital. Barcelona, Spain.
Conclusion

Endovascular procedures aim to increase and advance in time the rates of reperfusion in patients with acute ischaemic stroke due to large intracranial vessel occlusion.

In this study, we present our experience with the Solitaire retriever system on a cohort of acute intracerebral ischemia patients undergoing endovascular therapy.

Our data show that this mechanism can safely, timely, and efficiently induce recanalization in certain severe stroke patients with an intracranial occlusion.

The observed rates of successful recanalization, in almost two-third of patients (77%), and the clinical outcomes in the present study are comparable to previously published results with other endovascular devices [7-11] (Table 6).

Limitations

Our results should be interpreted with caution due to the small number of patients, but we believe that this mechanism could be a step forward in reperfusion therapies representing a simple, safe, and effective therapeutic alternative. Although, the high rate of recanalization observed should be considered with care since our cohort represents a selected series of cases.
Table 6: Comparison of Outcome between Previously Published Data on Endovascular Treatment and Our study. #TICI classification was used instead of 2b-3 (Table 1) [18]. †If it was associated with a clinical deterioration of 4 points on the NIHSS or 1-point deterioration in the level of consciousness. ‡Four-point or greater decline in the NIHSS score within 24 hours with any blood products on head CT at 24 hours (petechial bleeding, hematoma, or subarachnoid haemorrhage) or any intracranial haemorrhage in which no further NIHSS scores were available beyond baseline and the patient died.

© 2014 Department of Neuroradiology, Vall d´Hebron Hospital. Barcelona, Spain.
**Personal information**

Carmen Parra-Fariñas, MD.
Department of Radiology.
Vall d’Hebron Hospital.
Barcelona, Spain.
carmenparrafarinas@gmail.com


