Solitaire Flow Restoration device versus other Stentrievers for acute stroke: comparison of Neurologic and Radiologic outcomes.

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Aims and objectives

Introduction

In recent times, endovascular stroke therapy has revolutionized the management of patients with acute cerebral ischemia and has facilitated the development of sophisticated thrombectomy devices and a multitude of stroke imaging techniques. We have observed an evolution in endovascular approaches and mechanical thrombectomy devices [1-5]; as well as the change in the way in which stroke therapists have used intravenous tissue plasminogen activator (rt-PA).

This study compare the safety, efficacy and clinical and radiological outcomes of the Solitaire Flow Restoration (FR) device (Covidien) with other devices as the TREVO Retriever (Stryker Neurovascular), the pREset LITE Thrombectomy device (Phenox) and the ERIC Retriever (MicroVention) in recanalization of patients with acute intracranial vessel occlusion (Fig. 1). These devices belong to a category known as stentrieviers (ST) because of their resemblance to intracranial stents. They apply a radial retrieval force in the centre of the thrombus and along its whole length, unlike their predecessors. A microcatheter is placed distal to the thrombus and the closed-cell stent-like nitinol device is delivered via the microcatheter. The retriever is deployed by unsheathing the microcatheter, resulting in opening of the stent and radial displacement of the thrombus against the blood vessel wall with incorporation of the clot material into the stent struts. The device is subsequently retrieved into a catheter placed in the internal carotid or vertebral arteries (Fig. 2). It has been shown in animals that some of them were very effective at achieving immediate reperfusion of occluded arteries without causing any clinically significant disruption of the vascular integrity [6].

Recent studies have shown the superiority of ST over other thrombectomy devices. The randomized Stroke Warning Information and Faster Treatment (SWIFT) trial showed in 113 patients that the Solitaire FR device is superior to the Merci retriever in achieving successful revascularization (by Corelab, 68% vs 30%; p=0.001), less symptomatic intracranial haemorrhage (2% vs 11%; p=0.06), reduced mortality (17% vs 38%; p=0.02) and increased good neurological outcome 3 months after stroke (58% vs 33%) [7].

The proposed theoretical benefits of ST over other techniques are a higher rate of recanalization and easier use leading to shorter procedural times and early flow restoration even before the clot is retrieved.
Fig. 1: (A) Solitaire Flow Restoration device (©Covidien). (B) TREVO Retriever (©Stryker Neurovascular). (C) pREset LITE Thrombectomy device (©Phenox). (D) ERIC Retriever (©MicroVention).

Fig. 2: (A) Example of 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).

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**Methods and materials**

We performed a retrospective study of patients with acute intracranial occlusion that were treated with ST endovascular procedures within 8-hours from symptoms onset prospectively included in the database of our centre.

**Clinical and Radiological Evaluation**

Clinical data including demographic, pre-existing vascular risk factors and medication history for each patient were retrieved. At admission, all patients underwent a standard neurological examination, electrocardiogram, blood pressure measure, and blood tests. Stroke severity was assessed by the National Institutes of Health Stroke Scale (NIHSS) at baseline and at 24-hours (Table 1) [8].

All patients were evaluated with cranial CT scan or multimodal MRI in patients with >4.5-hours or unknown time from symptoms onset. Vessel status was assessed by CT angiography or transcranial color-coded Duplex sonography immediately before the endovascular approach to ensure persistence of occlusion. 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.

In all cases we obtained informed consent from the patients or their relatives before the procedure.

**Endovascular procedure**

Patients eligible for intravenous tissue plasminogen activator treatment were treated according to the guidelines and procedures to start the endovascular treatment were immediately initiated. Patients were evaluated and selected to undergo endovascular procedures according to previously published protocols [9-10].

During the endovascular procedure patients were preferentially under conscious sedation and general anaesthesia was used only if severe uncontrollable agitation or airway patency concerns occurred.
According to device availability, patients were respectively and primarily treated with different ST devices. Patients treated with more than one device were excluded from the analysis.

Six-Fr intermediate guide catheter was placed into the target artery using transfemoral access. After stent deployment, we waited 3-4 min before retrieving the system.

During the procedure, each time immediately after the ST was deployed over the occlusion site an angiogram was performed and the presence or absence of flow bypassing the device and clot to distal branches was recorded. If recanalization did not occur the procedure could be repeated up to 6 passes. At the end of the procedure the interventionist assessed angiographic recanalization (Fig. 3-5).

**Outcome Measures**

Primary outcome was the rate of complete vascular recanalization defined as thrombolysis in cerebral infarction (TICI) grade 2b or 3 (Table 2) [11]. Good early neurological outcome was defined as NIHSS score 0-1, or improvement of #10 points in NIHSS at 24 hours. Symptomatic intracranial haemorrhage was defined as a CT-documented haemorrhage that was temporally related to deterioration in the patient's clinical condition in the judgment of the clinical investigator [12]. Functional independence was defined as modified Rankin Scale score (mRS) # 2 at day 90 (Table 3). Mortality at 3 months 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: National Institutes of Health Stroke Scale (NIHSS) [8]. 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. 3: Endovascular recanalization in 73-year old patient with acute right ACM occlusion. Radiopaque marker at distal end of the retriever device (arrow).

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Fig. 4: (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) [11] (arrow).

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Fig. 5: (A) Basal angiogram with occlusion of proximal left middle cerebral artery (arrow). (B) Trevo retriever deployment in proximal middle cerebral artery (arrow). C. Final angiogram with complete recanalization (TICI 2b) [11] (arrow).

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**Table 2:** Terminology and definition of Thrombolysis in Cerebral Infarction (TICI) Reperfusion (1a) and Arterial Occlusive Lesion (AOL) Recanalization scores (1b) [11].


<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
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<tbody>
<tr>
<td>0</td>
<td>No symptoms at all</td>
</tr>
<tr>
<td>1</td>
<td>No significant disability despite symptoms; able to carry out all previous activities, but able to look after own affairs without assistance</td>
</tr>
<tr>
<td>2</td>
<td>Slight disability; unable to carry out all previous activities, but able to look after own affairs without assistance</td>
</tr>
<tr>
<td>3</td>
<td>Moderate disability; requiring some help, but able to walk without assistance</td>
</tr>
<tr>
<td>4</td>
<td>Moderately severe disability; unable to walk without assistance and unable to attend to own bodily needs without assistance</td>
</tr>
<tr>
<td>5</td>
<td>Severe disability; bedridden, incontinent and requiring constant nursing care and attention</td>
</tr>
<tr>
<td>6</td>
<td>Dead</td>
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</tbody>
</table>

**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

According to device availability and our institutional protocol, a total of 108 patients treated with ST devices were analysed: 75 (69.4%) Solitaire FR, 33 (30.5%) other ST [22 (20.37%) TREVO Retriever, 8 (7.4%) pREset, 3 (2.7%) ERIC].

The main baseline characteristics of the study group and the occluded vessel are summarized in Table 4. No major differences were observed between the treatment groups.

Overall patients who recanalized (68.6%; n=69) presented more favourable outcome (56.5% vs 19.2%; p<0.01).

The rate of complete recanalization was 67.6% (n=48) with Solitaire vs 71% (n=21) with other ST (p=0.73) (Fig. 6, 7). In 38.6% (n=29) of patients treated with Solitaire vs 36.4% (n=12) with other ST no successful recanalization was achieved. There were no significant clinical differences between these patients and those who recanalized.

Dramatic clinical improvement rate was 42% (n=29) with Solitaire vs 38.7% (n=12) with other ST (p=0.75).

At 24 h the rate of symptomatic intracerebral haemorrhage on the control CT scan was also similar between both groups; Solitaire 9.5% (n=7) vs other ST 6.1% (n=2) (p=0.56) (Fig. 8).

The rate of favourable outcome at 3 months was: Solitaire 44.7% (n=21) vs other ST 39.3%; (n=11) (p=0.65).

Mortality at 3 months was 29.8% (n=14) Solitaire vs 28.6% (n=8) other ST (p=0.9) (Table 5).

When recanalization occurred after retrieval of the stentriever, 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.
**Table 4:** Baseline Characteristics of Patients and Occluded Vessel. SD= Standard Deviation; ICA= Internal Carotid Artery; MCA= Middle Cerebral Artery; BA= Basilar Artery.

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Fig. 6: (A) 80-year old patient with acute distal M1 occlusion is visible on the initial digital subtraction angiogram (arrow). (C) Basal angiogram shows occlusion of middle cerebral artery with poor collateral circulation (arrow). (B) After stent placement, the control series shows immediate flow restoration (TICI 2b) [11] (arrow). (D) Control CT scan shows infarction in the right nucleus caudatus head and putamen with hemorrhagic component due to the recent thrombectomy (arrow).

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Fig. 7: 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) [11] (arrow). (D) Control CT scan shows right thalamus hypodensity (arrow) and perimesencephalic and basal cisterns SAH due to contrast extravasation during endovascular procedure.

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**Fig. 8:** Intracranial haemorrhage in right centrum semiovale and basal ganglia after mechanical thrombectomy in a 75-year old patient with an acute right MCA occlusion.

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<table>
<thead>
<tr>
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<th>Solitaire (n=75)</th>
<th>Other ST (n=33)</th>
<th>p</th>
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<tr>
<td>Recanalization (TICI 2b-3), n (%)</td>
<td>48 (67.6)</td>
<td>21 (71)</td>
<td>0.73</td>
</tr>
<tr>
<td>Dramatic clinical improvement, n (%)</td>
<td>29 (42)</td>
<td>12 (38.7)</td>
<td>0.75</td>
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<tr>
<td>Symptomatic intracranial haemorrhage, n (%)</td>
<td>7 (9.5)</td>
<td>2 (6.1)</td>
<td>0.56</td>
</tr>
<tr>
<td>Functional independence, n (%)</td>
<td>21 (44.7)</td>
<td>11 (39.3)</td>
<td>0.65</td>
</tr>
<tr>
<td>90-day mortality, n (%)</td>
<td>14 (29.8)</td>
<td>8 (28.6)</td>
<td>0.9</td>
</tr>
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</table>

**Table 5:** Outcomes Measures. TICI= Thrombolysis in Cerebral Infarction (Table 1) [11]. 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.

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Conclusion

The close correlation between reperfusion and clinical outcomes in acute cerebral ischemia is time-dependent [13]. In this setting, the ability of ST to achieve faster and higher rates of recanalization may play an important role [1-5].

The recent publication of the IMS 3 study showed no benefit of endovascular procedures over standard endovenous thrombolytic treatment [14]. In the endovascular arm of this study the rate of successful recanalization (TICI 2b-3) was <45%; however, only 4 out of 151 patients were treated with ST. Our results encourage the use of ST in future randomized trials for acute ischemic stroke in order to increase the recanalization rate. To date, several case series of ST have consistently reported a favourable outcome in approximately 50% of treated patients [15-16].

The successful recanalization rates observed in our study, in almost two-third of the patients (Solitaire: 61.7%; other ST: 71%), and the clinical outcomes are similar to previously published results with other endovascular devices [1-5] (Table 6). In addition, according to previous studies, describing the superiority of ST over other strategies in acute endovascular treatment of stroke [7, 17], our study shows that the rates of complete recanalization with ST are highly suggestive of the effectiveness of these new devices.

Limitations

Our results should be interpreted with caution because in our study, the patients were not randomly assigned to the treatment groups. Our patients were sequentially treated according to device availability in our centres and interventionist preferences, however, in the authors' subjective opinion any ST offer an easy delivery, a short deployment time, a fast flow restoration and a high rate of clot retrieval.

We can conclude that in acute endovascular treatment of stroke the use of ST may increase recanalization rates and reduce time to reperfusion leading to improve outcomes without significant differences between the Solitaire retriever and the other ST in complete recanalization as recent studies have shown [18].
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<td><strong>N</strong></td>
<td>121</td>
<td>151</td>
<td>164</td>
<td>125</td>
<td>20</td>
<td>75</td>
<td>33</td>
</tr>
<tr>
<td><strong>Age, years (mean)</strong></td>
<td>64</td>
<td>67</td>
<td>68</td>
<td>64</td>
<td>66</td>
<td>67</td>
<td>77</td>
</tr>
<tr>
<td><strong>Recanalization (TIMI 2-3) %</strong></td>
<td>66</td>
<td>48</td>
<td>68</td>
<td>82</td>
<td>90*</td>
<td>68*</td>
<td>71*</td>
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<tr>
<td><strong>Symptomatic IC %</strong></td>
<td>10.9 †</td>
<td>7.8‡</td>
<td>9.8‡</td>
<td>11.2</td>
<td>10</td>
<td>9.5</td>
<td>6.1</td>
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<tr>
<td><strong>90-day mRS ≤ 2 %</strong></td>
<td>40</td>
<td>27.7</td>
<td>36</td>
<td>25</td>
<td>45</td>
<td>44.7</td>
<td>39.3</td>
</tr>
<tr>
<td><strong>90-day mortality %</strong></td>
<td>25</td>
<td>43.5</td>
<td>34</td>
<td>32.8</td>
<td>20</td>
<td>29.8</td>
<td>28.6</td>
</tr>
</tbody>
</table>

**Table 6**: Comparison of Outcome between Previously Published Data on Endovascular Treatment and Our study. #TICI classification was used instead of 2b-3 . †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.

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References


