Solitaire stent for endovascular treatment of intracranial aneurysms: Immediate and mid-term results in 15 patients with 17 aneurysms

Le stent Solitaire pour le traitement endovasculaire des anévrismes intracrâniens : résultats immédiats et à moyen terme chez 15 patients avec 17 anévrismes

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Keywords
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Summary
Introduction. — The Solitaire stent is the first fully retractable stent for endovascular treatment (EVT) of intracranial aneurysms. The aim of this study was to evaluate its use in a prospective series with mid-term follow-up.
Methods. — A retrospective review of our prospectively maintained database identified all patients treated with a Solitaire stent. Clinical charts, procedural data, angiographic results were reviewed.
Results. — Between June 2008 and September 2009, 15 patients with 17 wide-necked or fusiform aneurysms (16 unruptured/one ruptured) were identified. EVT was successfully performed in all but one patient in whom the stent was removed because it induced flow reduction in the 1.8-mm parent artery. Among 14 treated patients, 13 had an excellent outcome and one had a good outcome. In this latter patient, the first stent could not be delivered and was changed for another one that was successfully deployed. The patient experienced a thrombo-embolic complication 6 hours after EVT and kept a slight hand paresis. In all cases but one, the stent was thus easily navigated and positioned despite a relative poor visibility. Angiographic results included eight complete occlusions, two neck remnants, and six incomplete occlusions. Six-month control in 14 aneurysms showed 13 complete occlusions and one incomplete occlusion.
Conclusion. — The Solitaire stent is useful for EVT of complex intracranial aneurysms because it is fully retractable, easy to navigate and to precisely place. However, it should be used with caution in arteries less than 2 mm in diameter.
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Introduction

Endovascular treatment (EVT) by means of detachable coils is more and more considered as first-intention treatment for both ruptured and unruptured intracranial aneurysms (IA) [1–8]. However, in case of wide-necked or fusiform aneurysms, selective embolization remains difficult because of the risk of coil protrusion within the parent vessel. Wide-necked aneurysms may be treated by the use of the “remodeling technique”: a small balloon-occlusion microcatheter is used to protect the parent artery lumen during coils deployment within the lesion. However, this technique may fail to retain coils within the sac in aneurysms with a very large neck. Recently, several authors have shown the safety and efficacy of stent-assisted coiling for EVT of such complex aneurysms [9–23]. Among available self-expandable stents, the Solitaire stent (EV3, Irvine, CA) is the most recent one and few information is available concerning the advantages of this stent as well as its potential limitations [13,14,23]. The aim of this study was to report clinical outcome and mid-term angiographic follow-up of 15 patients with 17 aneurysms treated with the Solitaire stent.

Patients and methods

Population

Between June 2008 and September 2009, 15 patients with 17 aneurysms were treated by stent-assisted coiling with the Solitaire stent. There were 12 women and three men with a mean age of 48 years. Clinical presentation is detailed in Table 1. All but one patient had an unruptured aneurysm. One 52-year-old man (Patient 7) presented with a subarachnoid hemorrhage (SAH) that was classified as grade I [24]. Among the remaining 14 patients, 11 were asymptomatic and three presented with symptoms of mass effect including transient cranial nerve palsies (n = 2) and facial pain (n = 1). Prior to all procedures, patients underwent conventional angiography of both internal carotid arteries (ICA), vertebral arteries (VA) and a three-dimensional angiography. Aneurysms characteristics are detailed in Table 1: 16 aneurysms were wide-necked (neck > 4 mm or dome/neck ratio < 2) and one was fusiform.

Solitaire stent system

The Solitaire stent was specifically designed for neurovascular applications to support embolic detachable platinum coils within wide-necked cerebral aneurysms. It is the only self-expanding stent that can be completely retrieved prior to detachment, even when fully deployed. The stent is delivered through a standard 0.018” or 0.021” Rebar microcatheter (EV3, Irvine, CA) just like a coil. To detach the stent, the recommended electrolytic detachment system must be used (NDS-2, EV3, Irvine, CA). The available stents include a 4.0 mm in diameter with 15- or 20-mm length and a 6.0 mm in diameter with 30-mm length. The delivery procedure is roughly similar to that reported for coil placement. After the microcatheter is in place, the guidewire is removed and the stent is introduced into the hub of the microcatheter through an introducer sheath. The stent is then pushed through the microcatheter and placed across the aneurysm neck. The microcatheter is then carefully pulled back to unsheathe the stent. If repositioning is required, the stent can be resheathed and the system either advanced forward or pulled back for more accurate placement. After the stent is fully deployed, a smaller microcatheter with a distal tip of less or equal to 2.5 F can be used with a microguidewire to go through the interstices of the stent for coil occlusion of the aneurysm. Another technique is to jail the coiling catheter with the stent by the use of a double-catheter technique.

Therapeutic strategy and endovascular procedure

In all cases, EVT consisted of stent delivery across the aneurysm (fusiform aneurysm) or its neck (wide-necked aneurysms) and subsequent coiling of the sac. EVT was performed on a biplane flat panel digital subtraction unit (Allura Xper 20/10, Philips, Netherlands). Medical premedication was initiated in all but one patient 3 days prior to the procedure with 160 mg of aspirin and 75 mg of clopidogrel per day. In Patient 7 who presented with SAH, a loading dose of 300 mg of clopidogrel and 500 mg of aspirin was administered one hour before treatment. Endovascular procedures were performed under general anesthesia and systemic heparinization. The adequacy of systemic anticoagulation was monitored by frequent measurements of the activated clotting time (ACT). A baseline ACT was obtained prior to the bolus infusion of 5000 IU heparin, and hourly thereafter. The bolus infusion of heparin was followed by a continuous drip (1000 to 1500 IU/h), with the purpose of doubling the baseline ACT. Systemic heparinization was prolonged for 24 h in all patients. Unilateral femoral access was obtained through a percutaneous femoral artery puncture and one 6-F guide catheter was inserted into the parent vessel. A Rebar microcatheter was then advanced over a 0.014” Transend or Synchro microguidewire (Boston Scientific, Fremont, CA) into the normal distal artery beyond the aneurysm by 1 to 2 cm. Then, the coiling catheter was navigated within the aneurysmal sac in order to jail it with the stent. The stent was introduced into the hub of the Rebar catheter and was then pushed through the microcatheter and aligned directly across the neck of the aneurysm. When proper alignment was achieved, the microcatheter was gently pulled back to unsheathe the stent, while forward tension was maintained on the stent system to keep it in place. We always waited for the distal markers to be completely open and then, the stent was fully deployed and positioning was confirmed by direct visualization. If the stent required repositioning, it was resheathed, repositioned, and then redeployed. Microplex coils (MicroVention, Aliso Vieja, CA) or Axiom coils (EV3, Irvine, CA) were delivered via the second catheter into the aneurysm [25]. After EVT, patients were transferred to the intensive care unit, and fluid balance, neurological status and blood pressure were carefully monitored. Patients were maintained on clopidogrel (75 mg/day) for a month and aspirin (160 mg/day) for 6 months.

Anatomical and clinical outcome

Patients were evaluated by angiography at the end of the procedure to document aneurysm obliteration. Angiographic
<table>
<thead>
<tr>
<th>Patient no</th>
<th>Age/sex</th>
<th>Clinical Presentation</th>
<th>Aneurysm type/location</th>
<th>Parent vessel Size (mm)</th>
<th>Treatment</th>
<th>Procedural complication</th>
<th>Clinical outcome</th>
<th>Aneurysm occlusion</th>
<th>6-month DSA</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>F/57</td>
<td>SAH from another aneurysm</td>
<td>S/supraclinoidalICA</td>
<td>3.6</td>
<td>Stent + coils</td>
<td>No</td>
<td>Excellent</td>
<td>Complete</td>
<td>Complete</td>
</tr>
<tr>
<td>2</td>
<td>M/49</td>
<td>Incidental</td>
<td>S/carotid-ophtalmicICA</td>
<td>3.8</td>
<td>Stent + coils</td>
<td>No</td>
<td>Excellent</td>
<td>Incomplete</td>
<td>Complete</td>
</tr>
<tr>
<td>3</td>
<td>M/47</td>
<td>Post-clipping regrowth</td>
<td>S/MCA</td>
<td>2.6</td>
<td>Stent + coils</td>
<td>No</td>
<td>Excellent</td>
<td>Complete</td>
<td>Complete</td>
</tr>
<tr>
<td>4</td>
<td>F/44</td>
<td>Post-coiling recanalisation</td>
<td>S/ICA bifurcation</td>
<td>3.3 PCA 2.3</td>
<td>Stent + coils</td>
<td>No</td>
<td>Excellent</td>
<td>Incomplete</td>
<td>Complete</td>
</tr>
<tr>
<td>5</td>
<td>F/59</td>
<td>Familial history of SAH</td>
<td>S/carotid-ophtalmicICA</td>
<td>3.3</td>
<td>Stent + coils</td>
<td>No</td>
<td>Excellent</td>
<td>Complete</td>
<td>Complete</td>
</tr>
<tr>
<td>6</td>
<td>F/50</td>
<td>Incidental</td>
<td>S/supraclinoidalICA</td>
<td>3.8</td>
<td>Stent + coils</td>
<td>No opening of the 1st stent</td>
<td>Good</td>
<td>Incomplete</td>
<td>Complete</td>
</tr>
<tr>
<td>7</td>
<td>M/52</td>
<td>SAH</td>
<td>S/supraclinoidalICA</td>
<td>3.9</td>
<td>Stent + coils</td>
<td>No</td>
<td>Excellent</td>
<td>Complete</td>
<td>Complete</td>
</tr>
<tr>
<td>8</td>
<td>F/49</td>
<td>Incidental</td>
<td>F/vertebral arteryICA</td>
<td>3.2</td>
<td>Stents + coils</td>
<td>No</td>
<td>Excellent</td>
<td>Incomplete</td>
<td>Complete</td>
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<tr>
<td>9</td>
<td>F/39</td>
<td>Facial pain</td>
<td>S/extra-intracavernousICA</td>
<td>3.1</td>
<td>Stent + coils</td>
<td>No</td>
<td>Excellent</td>
<td>Incomplete</td>
<td>Complete</td>
</tr>
<tr>
<td>10</td>
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<td>Transient CN palsies</td>
<td>S/cavernousICA</td>
<td>3.7</td>
<td>Stent + coils</td>
<td>No</td>
<td>Excellent</td>
<td>Complete</td>
<td>Complete</td>
</tr>
<tr>
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<td>S/cavernousICA</td>
<td>3.9</td>
<td>Stent + coils</td>
<td>No</td>
<td>Excellent</td>
<td>Neck remnant</td>
<td>Complete</td>
</tr>
<tr>
<td>12</td>
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<td>Incidental</td>
<td>S/basilar artery</td>
<td>3.3 PCA 2.2</td>
<td>Stent + coils</td>
<td>No</td>
<td>Excellent</td>
<td>Complete</td>
<td>Complete</td>
</tr>
<tr>
<td>13</td>
<td>F/45</td>
<td>Incidental</td>
<td>S/basilar artery</td>
<td>2.7 PCA 1.8</td>
<td>Stent placement Flow reduction in PCA</td>
<td>Excellent</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>F/50</td>
<td>Incidental</td>
<td>S/carotid-ophtalmicICA</td>
<td>3.6</td>
<td>Stent + coils</td>
<td>No</td>
<td>Excellent</td>
<td>Complete</td>
<td>Neck remnant</td>
</tr>
<tr>
<td>15</td>
<td>F/48</td>
<td>Post-coiling recanalisation</td>
<td>S/Pcom</td>
<td>3.5</td>
<td>Stent + coils</td>
<td>No</td>
<td>Excellent</td>
<td>Complete</td>
<td>NA</td>
</tr>
</tbody>
</table>

SAH: subarachnoid hemorrhage; S: saccular; F: fusiform; ICA: internal carotid artery; MCA: middle cerebral artery; Pcom: posterior communicating artery; CN: cranial nerve; PCA: posterior cerebral artery; DSA: digital subtraction angiography.
results were classified as: complete occlusion (no contrast filling the aneurysmal sac), neck remnant (residual contrast filling the aneurysmal neck), and incomplete occlusion (residual contrast filling the aneurysmal body). A senior neurosurgeon, neurointerventionalist, or neurologist (LC, MB, AD, OD) recorded the clinical course, including worsening of symptoms and death. Clinical outcome was graded according to a modified Rankin Scale (mRS) [26].

Follow-up

Our imaging follow-up protocol included a conventional angiography at 6 months. Follow-up angiograms were compared to immediate post-embolisation angiograms and were then assigned to one of three categories:

- further thrombosis, when the amount of contrast agent filling the aneurysm decreased;
- unchanged, when a similar degree of aneurysm occlusion in multiple projections was found;
- and recanalisation, when an increase of the amount of contrast filling in the aneurysm was observed.

Conventional angiographies were reviewed for all patients by three neurointerventionalists together (LC, GR, AB).

Results

Selective embolization was successfully performed in all but one patient. In Patient 13 with a wide-necked basilar tip aneurysm, stent placement from the basilar trunk into the left posterior cerebral artery (PCA) led to flow reduction within the PCA. This latter artery had a 1.8-mm diameter and several controls confirmed the initial findings of decreased flow. Therefore, the stent was removed and the patient was treated with a smaller stent from another manufacturer (2.5/18 mm Leo stent, Balt, Montmorency, France). No complication occurred during this attempt and the patient could successfully be treated with an excellent outcome.

Fourteen patients with 15 aneurysms were thus successfully treated with a Solitaire stent and 13 had an excellent outcome (mRS = 0) including three who were symptomatic (transient cranial nerve palsies and facial pain disappeared within 24 to 48 hours). In Patient 6, a technical complication occurred during EVT: this 50-year-old woman, with multiple incidental aneurysms, was treated for a left supracerebral ICA wide-necked aneurysm. Endovascular procedure went on very well until deployment of the Solitaire stent in front of the aneurysm neck. Once the distal part of the stent was delivered and fully open, we continued the deployment and observed the closing of the distal part when the Rebar catheter was pulled back to unsheathe the stent. We have tried three times to reposition and re-deploy the stent without success because of this phenomenon. The stent was removed and another Solitaire stent was used and normally deployed without any problem. Then, coiling of the sac was performed achieving a satisfying aneurysm occlusion. The patient woke up with a normal neurological exam but developed a few hours later a thrombo-embolic complication in the left middle cerebral artery territory. An early angiographic control was performed and showed no vessel dissection or spasm. At discharge 10 days later, she had a slight paresis of the right hand (mRS = 1).

In all cases, the delivery Rebar microcatheter was easily navigated and positioned with a Transend 14 or Synchro 14 microguidewire past the aneurysm neck. Then, the stent could precisely be positioned across the aneurysm neck because of the possibility to reposition it. However, concerning the visibility of the stent, we found that only proximal and distal markers could clearly be seen and that the stent itself was invisible. Nevertheless, no stent misplacement occurred. Detachment of the stent was obtained after one attempt in 11 cases and after two attempts in five cases. Mean detachment time occurred after 45 seconds. Detachable coils were then easily delivered, in all but one case (Patient 7), through the microcatheter within the aneurysmal sac without any protrusion through the stent struts. No arterial dissection/rupture or spasm occurred during all endovascular procedures.

Anatomical results at the end of EVT consisted of eight complete occlusions, two neck remnants, and six incomplete occlusions. Six-month angiographic follow-up was available in 14 cases and showed seven stable results and seven further thrombosis (Patients 1, 4, 6, 7, 8, 9, 11). Final results included 13 complete occlusions and one incomplete occlusion. No significant parent artery was seen at 6-month follow-up.

Discussion

This study shows that the Solitaire stent is a useful tool for EVT of complex IA. It has a major advantage that is the possibility to fully retrieve the stent whenever necessary. However, it should be used with caution in parent artery of less than 2 mm in diameter.

Intracranial stenting

Several authors [9–23] reported the feasibility and efficacy of stent-assisted coiling in wide-necked IA. The first self-expandable intracranial stent is the NeuroForm stent (Boston Scientific, Fremont, CA) that has been evaluated in several series [9–11,18]. It has proved its efficacy and its safety as procedure-related morbidity-mortality rates were low in these studies. However, the Neuroform stent presents some limiting characteristics including the impossibility to reposition it when it is partially delivered, a low radial force, and some deployment difficulties [9–11,18]. Therefore, new stents have recently been developed to circumvent these limitations. The first retractable stent to be released was the Leo stent that has been evaluated by Kis et al. [12] and Lubicz et al. [15] who showed the major advantage of this retrievability. Moreover, of 36 aneurysms treated in these two series, there was only one stent placement failure and these authors reported very good clinical and anatomical outcomes in almost all patients. Last but not least, the Leo stent has two radiopaque markers along its total length that makes it very visible during deployment. Nevertheless, the Leo stent presents a limiting characteristic that is the need for progressively larger and stiffer delivery catheters.
to place larger stents. The second retractable and recently released stent is the Enterprise stent that has been evaluated in few series [16–19, 22]. The Enterprise stent seems to be the easiest to navigate and to place thanks to its delivery system that is a conventional coiling catheter. However, it has also limitations: its poor visibility and the fact that it must be used in artery between 2 to 4 mm to avoid coil protrusion.

The Solitaire stent is the first stent that is fully retractable. It is also the most recent one even if its first generation, the so-called SOLO stent (EV3, Irvine, CA), has already been evaluated in two series [14, 23]. Very recently, Klisch et al. [13] reported the first and only series of patients treated with the definitive version of the stent, the so-called Solitaire stent (EV3, Irvine, CA). These studies showed the safety and efficacy of the stent and they did not show significant limitations. Even if our study confirms the advantages of this stent, it also pointed out some limitations that must be known when planning to treat patients with this device. First, the stent should be used with caution in parent artery of less than 2 mm in diameter. In the present series, we have experienced a significant slow reduction in a 1.8 mm PCA (Patient 13) and we had to change for a smaller stent from another manufacturer. This phenomenon might be related to the higher radial force of the stent when compared to the other available stents. Indeed, a high radial force might be an advantage in some situations (e.g. avoiding dislocation after placement, which has been reported more frequently for the Enterprise stent) or an disadvantage in some other situations like extremely oversizing of a stent-system resulting in permanent vasospasm. However, within these scenarios a stent should always be used with caution — but retractability of a system is a main advantage to react in this fashion described before. The second limitation concerns the relative poor visibility of the stent that is common with other available stents (NeuroForm, Enterprise) except with the Leo stent. The last relative limitation was related to the stent detachment system that is the only one that uses an electrolytic system: in 11 cases out of 16, one attempt was enough but in five cases out of 16, two attempts were needed.

On a clinical and anatomical point of view, similar results than those published with this stent and with other available stents were obtained in our study [9–23]. Indeed, an excellent outcome was achieved in all but one patient as well as satisfying anatomical results at 6-month follow-up. Moreover, no significant parent artery was seen highlighting the good tolerance of the stent.

**Stent selection**

Based on the previous paragraph, we are selecting our stent according to these following criteria:

- stent retractability;
- parent vessel diameter;
- stent length;
- arterial tortuosities;
- stent radiopacity.

Therefore, we don’t use the NeuroForm stent that is not retractable. In small vessels (< 2.5 mm), we are using the Leo stent that has many available diameters including a 2.5-mm one. In large vessels (> 4 mm), we are using the 6-mm Solitaire stent and the Leo stent (4.5 or 5.5 mm in diameter) to avoid coil protrusion between the stent and the vessel wall. In medium-sized vessels (between 2.5 and 4 mm), the Enterprise and the Solitaire are the one we are always choosing. Thanks to longer length availability when compared to the Solitaire stent, the Enterprise stent is our first choice in case of fusiform aneurysms.

**Treatment indications**

In our department, patient selection for EVT with self-expandable stent mostly includes unruptured IA that can not safely be treated by the use of the remodeling technique. Indeed, use of this technique avoids a permanent intravas-

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**Figure 1** Unruptured aneurysm in a 49-year-old woman with multiple incidental aneurysms. A. Conventional angiography shows a fusiform aneurysm of the left vertebral artery. B, C. Stent-assisted coiling with incomplete but satisfying aneurysm occlusion. D. Angiographic control at 6 months shows a further thrombosis with complete aneurysm occlusion and patency of the parent artery. No significant stenosis is seen.
cular implant and long-term antiplatelet medication. On the other hand, our study reinforces the idea that stenting is improving and stabilising anatomical results of coiled aneurysms (Fig. 1) that has recently been published in three series [17,20,21]. Therefore, its indication might enlarge in the future. Nevertheless, future larger series with long-term follow-up are required to determine the exact place of this stent in the therapeutic armamentarium of IA.

Conclusion

Our preliminary study shows that the Solitaire stent is a very useful tool for the treatment of complex IA. It has a major advantage that is the possibility to fully retrieve the stent whenever necessary. However, it should be used with caution in parent artery <2 mm in diameter.

Conflicts of interest

The first author is a proctor and consultant for ev3.

References


