Initial Experience of Intracranial Aneurysm Embolization Using the Balloon Remodeling Technique with Scepter C, a New Double-Lumen Balloon

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Summary

The balloon remodeling technique (BRT) was designed for endovascular treatment of wide-necked intracranial aneurysms. To date, the balloon catheters available have had a single lumen and suitable guidewires ranging from 0.010 to 0.012 inches. We describe the first case of aneurysm embolization using the BRT with the new double-lumen balloon catheter, Scepter C®, navigable on a 0.014-inch wire, and discuss the benefit of such a device.

Introduction

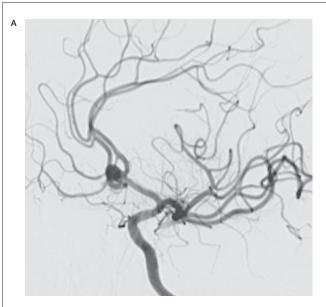
The balloon remodeling technique (BRT) used in the endovascular treatment of widenecked complex cerebral aneurysms was first described by Moret in 1994; since then, the BRT has been widely used 1. The safety of the BRT has been proven in several publications, with a higher anatomic efficacy compared to standard coiling ²⁻⁴. In this technique, a balloon is inflated temporarily to cover the neck of the aneurysm to protect the parent artery lumen during coil deployment within the aneurysm. However, several drawbacks are associated with the guide-dependent balloons currently available, such as the HyperGlide and Hyper-Form balloon microcatheters (ev3, Plymouth, MN, USA). First, the microguidewires of these balloons are unstable and offer low trackability due to their small diameter. Second, the

guidewire displacement in a single-lumen balloon catheter can lead to issues such as the wire getting glued within the balloon, the balloon failing to inflate, or the balloon deflating due to a clot in the lumen. To overcome this problem, an independent guidewire lumen can be used instead. We report the first case in which the use of a new double-lumen balloon catheter, Scepter C (MicroVention Inc., CA, USA), allowed treatment of a wide-necked anterior communicating artery (AcomA) aneurysm.

Technique

A 58-year-old man, who initially presented with a headache, was referred to our department for treatment of an unruptured AcomA wide-necked aneurysm (Figure 1). The patient had no focal neurologic deficit at the time of admission. The procedure was performed with the patient under general anesthesia and full heparinization on a biplane flat-panel angiographic unit (Integris Allura; Philips Medical Systems, Best, The Netherlands). The anticoagulation protocol during the procedure consisted of an intravenous bolus of 5000 IU heparin, with close monitoring of blood-activated clotting time (ACT) levels, which were adjusted, according to the ACT level, between 200 and seconds. The patient was given intravenous aspirin (250 mg) at the beginning of the procedure. After a full angiogram through bifemoral access, two 6F-guiding catheters (Neuropath

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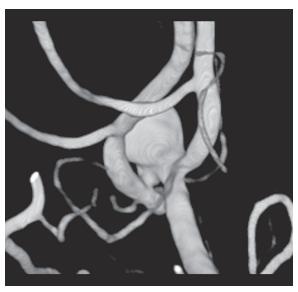


Figure 1 A) The left ICA angiogram, oblique view, shows the AcomA aneurysm with a wide neck involving both A2 segments. B) Three-dimensional image of the AcomA aneurysm, showing the left A1 segment and the left and right pericallosal arteries. The right pericallosal artery is clearly emerging from the neck of the aneurysm.

guiding catheter; Micrus Endovascular, San Jose, CA, USA) were placed at the origin of the left internal carotid artery (ICA). The balloon microcatheter, Scepter C, was conducted through a 0.014-inch guidewire and positioned in the left A1/A2 segment, across the aneurysmal neck (Figure 2). An Echelon 10 microcatheter (ev3, Plymouth, MN, USA) was placed inside the aneurysm sac through the left A1 segment. Aneurysm coiling was performed under temporary balloon inflation until its angiographic exclusion (Figure 3). We used a 50:50 contrast/saline mixture to inflate the balloon as recommended by the manufacturer. The arterial access sheaths were removed immediately after the procedure, and the puncture sites were closed with a collagen-plug hemostatic closure device (Angio-Seal; Daig/St. Jude Medical, St. Paul, MN, USA).

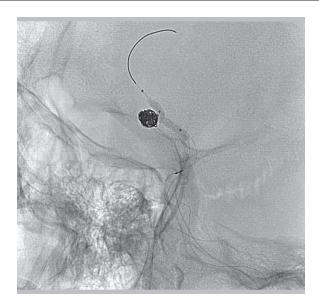
Discussion

For endovascular management of widenecked bifurcation aneurysms, various adjunctive techniques, such as the BRT or, as recently reported, Y- or X-stenting, have been proposed to permit safe endovascular occlusion 5-7. In 2003, the use of a new super-compliant balloon (HyperForm; ev3) was reported in the treatment of four complex wide-necked aneurysms in which a regular and less compliant balloon would not have conformed to the anatomy 8. More recently, another technique the neurovascular self-expanding stent (stentassisted coiling) - has been employed in the endovascular treatment of complex artery aneurysms 9. The major advantage of the BRT over stent-assisted techniques lies in the fact that the dual antiplatelet therapy during and following treatment recommended in stent-assisted techniques is not needed; the use of these agents may be a concern, especially in ruptured aneurysms. Stent-assisted coiling has been associated with hemorrhagic or thromboembolic complications, with permanent neurologic deficits in up to 7.4% of cases 10.

The balloons currently available for the BRT, HyperForm and HyperGlide (ev3, Plymouth, MN, USA), have a single lumen and navigate guide wires ranging from 0.010 to 0.012 inches. However, the small diameter of the microguidewires makes them more unstable with lower trackability. Moreover, guidewire displacement in a single-lumen balloon catheter can lead to issues such as the wire getting glued within the balloon, the balloon failing to inflate, or the balloon deflating due to a clot in the lumen.

The New Scepter C Occlusion Balloon Catheter is a dual coaxial lumen catheter with a nondetachable low inflation pressure compliant balloon attached to the distal end of the

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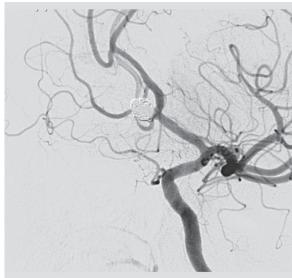


Figure 2 The left unsubtracted ICA angiogram, oblique view, shows the inflated Scepter C balloon in the left pericallosal artery. The balloon bulges into the origin of the right A2 segment. The Traxcess 14 guidewire is positioned distally into the left A2 segment.

Figure 3 The left ICA final angiogram, oblique view, shows total aneurysm occlusion, with patency of both A2 arteries.

Table 1 Comparison of technologies available.

	HyperForm / HyperGlide	Scepter C
Intended use	For use in the blood vessels of the peripheral and neurovasculature where temporary occlusion is desired. These catheters offer a vessel selective technique of temporary vascular occlusion which is useful in selectively stopping or controlling blood flow for balloon-assisted embolization of intracranial aneurysm	Same
Lumen configuration	Single Lumen	Dual coaxial lumen
Inner configuration	0.010	0.0165
Outer diameter	2.2-2.8F	2.6-2.8F
Balloon diameter	3-5 mm/10-30 mm	4 mm/10-20 mm
Material	Polyether block amide, polyolefin, stainless steel, PTFE, chloroprene	Polyether block amide, polyolefin, stainless steel, PITE, polyurethane elastomeric alloy
No. of markers	2	3
Coating	Hydrophilic coating	Same
Guidewire compatibility	0.010-0.012	0.014 or smaller

catheter. The catheter is designed to track over a steerable 0.014-inch guidewire. Radiopaque marker bands are located at the ends of the balloon and the distal tip of the catheter to facilitate fluoroscopic visualization. The outer surface of the catheter is coated with a hydrophilic polymer to increase lubricity. The double-lumen construction increases kink resistance for reliable balloon deflation and decreases the potential risk of balloon dysfunction by clotting in the lumen. Moreover, the large guidewire lumen allows enhanced distal navigability, due to better support. Another advantage is that this new balloon catheter is mounted on a 0.014-inch guidewire, the same size of the catheters generally used to deploy an intracranial stent. Thus, if it is necessary to deploy a stent after the BRT, it is possible thanks to docking-type guidewires such as Traxcess (MicroVention, Tustin, CA, USA) to exchange the balloon with the stent without the need for another catheterization of the aneurysm parent artery. In addition, the Scepter C has three radiopaque markers, compared to a single-lumen balloon, facilitating visualization (Table 1). Two cases of wide-neck aneurysm treatment using a different double-lumen balloon catheter Ascent (Micrus Endovascular, San Jose, CA, USA) were recently published ^{11,12}. However, the balloon Scepter C used in our report is the only balloon 0.014 inches in diameter available to date with hydrophilic coating, which significantly improves trackability in tortuous vessels. Moreover, the tip of the Scepter C is twice as soft as the Ascent balloon, with, probably, a lower risk of perforation in the case of the single-catheter BRT ^{11,12}. The high compliance property allows easy bulging into the origin of the arterial branches emerging from the aneurysm neck.

Conclusion

We describe the first case of a large-necked intracranial aneurysm successfully treated with the BRT, using the new double-lumen balloon Scepter C. The device proved to be safe and effective for aneurysm occlusion. More experience and longer follow-up periods are required to further assess the value of this new neurovascular device.

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