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ORIGINAL ARTICLE

Preliminary Experience with the TransForm Occlusion Balloon Catheter: Safety and Potential Advantages

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Abstract
Purpose Balloon-assisted coiling (BAC) has made the treatment of aneurysms with complex shape and broad neck possible, especially during the acute phase of hemorrhage. The authors present a prospective series of their preliminary experience with the TransForm occlusion balloon catheter (TOBC).
Methods Between September 2015 to February 2016 a total of 20 patients underwent endovascular treatment assisted by TOBC of which 19 had 20 untreated aneurysms and 1 patient harboring a meningioma was submitted to balloon test occlusion (BTO). The TOBC was used to perform BAC and BTO for the treatment of vasospasms and to cross the neck of giant aneurysms (anchor technique). All data regarding the feasibility and safety of treatment with the device were collected prospectively.
Results All patients completed treatment according to the modality previously chosen. The balloon was employed solely for remodeling in 17 patients, for anchor technique in 2, for both remodeling and vasospasm angioplasty in 1 and for BTO in 1 patient. The balloon could be navigated to the target aneurysm in all cases. Evaluation of postoperative anatomical results indicated total occlusion in 13 (72.2 %) aneurysms, neck remnants in 4 (22.2 %) and residual sac filling in 1 (5.5 %). There were two (9.5 %) complications related to treatment, all thromboembolic. No technical complications were observed.
Conclusion The TOBC was shown to be safe and effective for the treatment of intracranial aneurysms with BAC. In addition, it was successfully employed to perform angioplasty for vasospasm and BTO. Finally, it was used in the balloon anchor technique for the first time.

Keywords Aneurysm · Balloon · Coiling · Remodeling · Prospective study

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Introduction

Endovascular coiling has become the preferred treatment for intracranial aneurysms during recent years [1, 2]. Before the developmental of new devices and refinement of endovascular techniques, a great number of aneurysms, particularly larger, wide-necked aneurysms were not amenable to coiling [2, 3]. Meanwhile, balloons, stents and flow diverters have now added to the interventional neuroradiologist's armamentarium. The assistance of adjunctive techniques made it possible to treat aneurysms with complex shapes, acute angle with the parent artery and those with broad necks; therefore, almost all aneurysms are nowadays suitable for endovascular treatment. Moreover, it has improved coil packing and decreased recurrence rates in this high-risk group [1–5]. Among all devices, the balloon remains the most versatile. It can be used to prevent coil protrusion into the parent artery or branches arising from the neck or sac, to occlude vessels in cases of intraoperative perforation, to perform test occlusion, to perform intracranial angioplasty for vasospasm, to give stability to the microcatheter in acute angle aneurysms and in many others situations. Furthermore, it allows the treatment of either side wall or bifurcation aneurysms, such as ruptured and non-ruptured aneurysms [2, 4]. Although remodeling has been extensively studied, balloon technology improvements may provide better and safer results and facilitate its

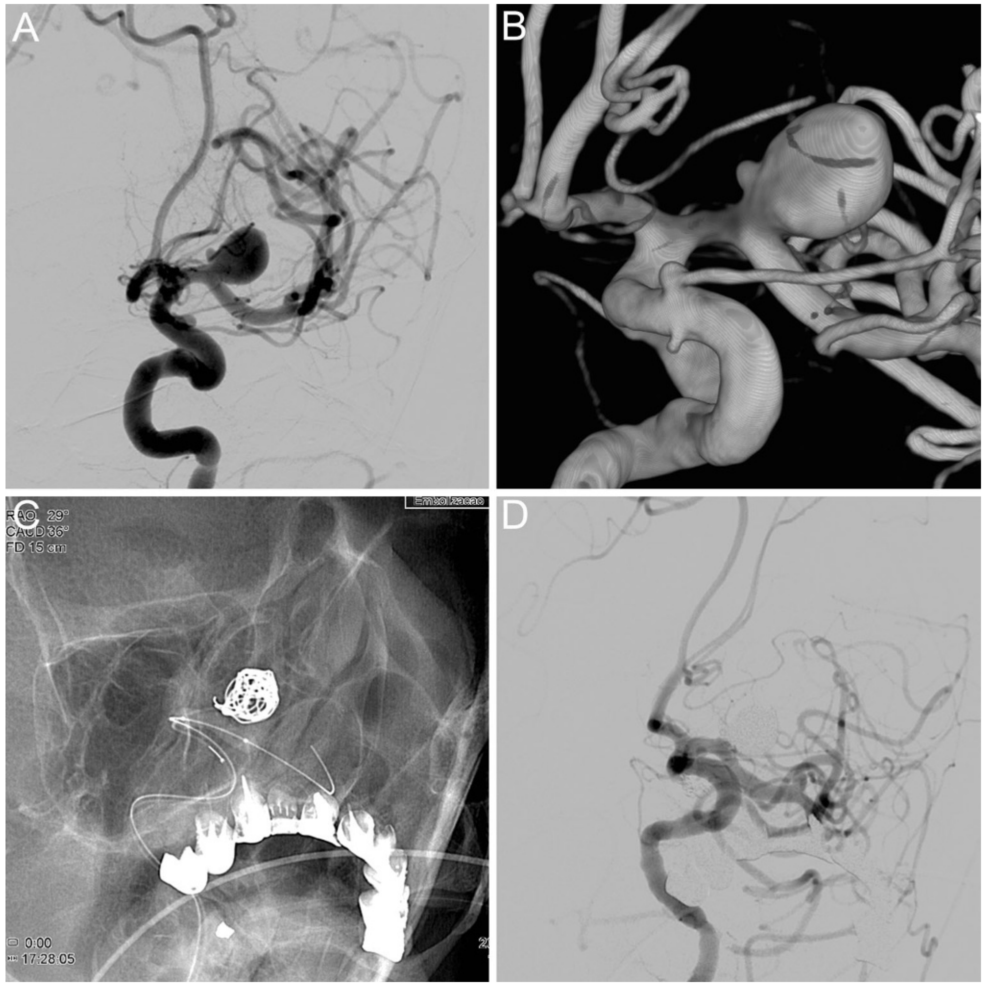

Fig. 1 Patient 6. **A** Angiography demonstrates a wide neck left middle cerebral artery (MCA) aneurysm, **B** 3-dimensional rotational angiography shows M1 segment aneurysm in detail, **C** embolization with BRT and **D** final control angiography reveals total aneurysm occlusion

use. We report our preliminary experience using the TransForm occlusion balloon catheter (TOBC, Stryker, Fremont, CA) in various situations. Additionally, clinical data were prospectively assessed to establish the safety and potential advantages of this new device.

Methods

Study Population

From September 2015 to February 2016, all patients submitted for endovascular treatment using the TOBC were prospectively assessed in order to evaluate its safety and effectiveness in a single center. Any procedure in which the TOBC was used was included in the study, regardless of the diagnosis.

Clinical and Radiological Evaluation

All patients were evaluated by a neurologist and underwent a neurological examination before and 30 days after the procedures. Computed tomography (CT) scan or magnetic resonance imaging (MRI) and catheter angiography, with three-dimensional reconstruction, were performed in all cases. An independent neuroradiologist reviewed the angiographic images, mainly to assess occlusion rates in aneurysm embolization and technical complications related to the procedure and/or balloon.

Data Collection

All data were collected prospectively. Preoperative data included age, sex, initial presentation, aneurysm localization, neck length, aneurysm size, dome/neck ratio, volumetry, branch arising from the neck or sac and modified Rankin score (mRS). Operative data included associated devices, occlusion grade (Montreal scale) and complications. Variables related to the balloon were also assessed, namely preparation facilitation, successful positioning at the aneurysm neck, visibility of the inflated balloon under fluoroscopy, stability when inflated and deflated, time to inflate and deflate and compliance. Follow-up evaluation included complications and mRS after 30 days. A wide neck

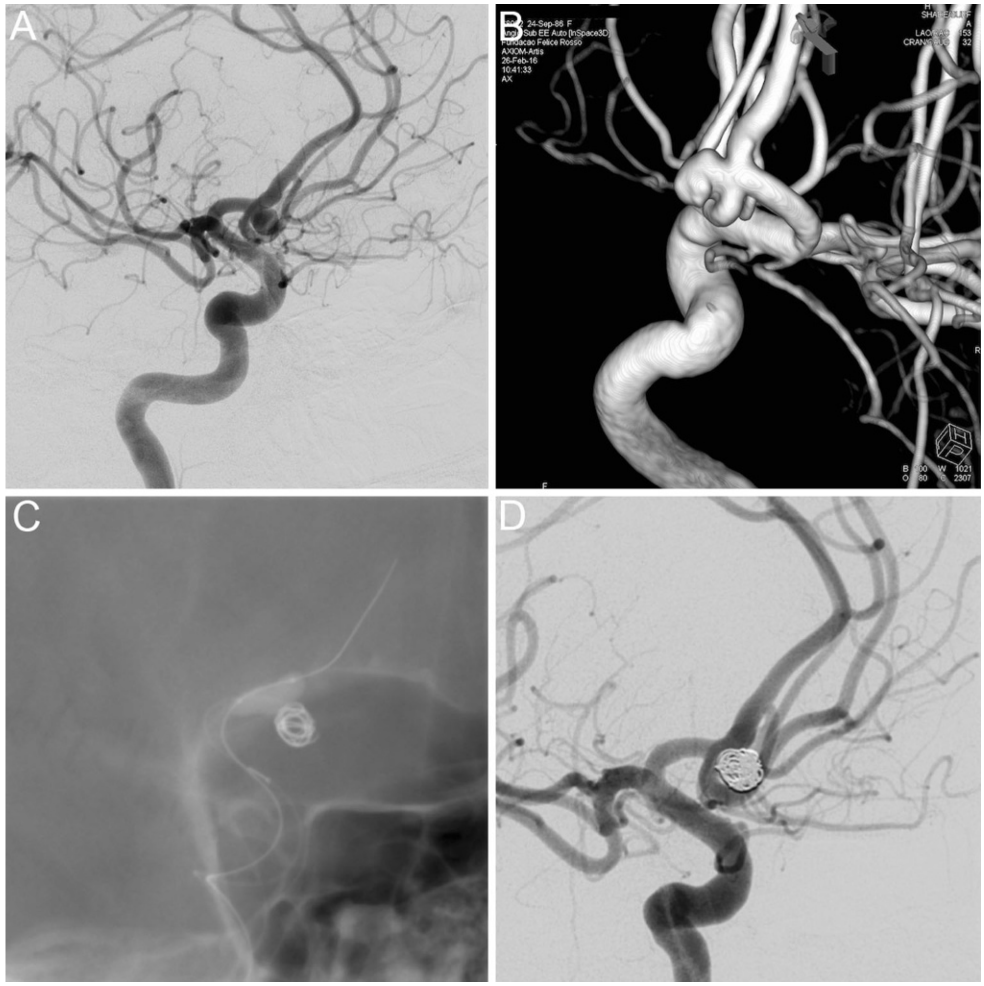

Fig. 2 Patient 16. **A** Right carotid angiography shows an anterior communicating artery (ACoA) complex aneurysm, **B** 3-dimensional rotational angiography shows the aneurysm involving right A1-A2 junction, **C** note the deformation of balloon surface toward the aneurysm neck and **D** final control angiography demonstrates total aneurysm occlusion

aneurysm was defined as having a neck size of ≥4 mm or a dome to neck ratio of <2.

Balloon-Assisted Coiling Procedure

Treatment with aspirin alone was started 5 days prior to the procedure for the treatment of unruptured aneurysms when the deployment of a stent was not preplanned. All procedures were performed with the patient under general anesthesia and heparinization. The balloon remodeling technique (BRT) was performed using a compliant (Transform C) balloon for side wall aneurysms or super compliant (Transform SC) balloon for bifurcation aneurysms or when a branch arose from the neck or sac. The balloon was prepared with a mixture of 70 % Optiray 320 contrast medium (Mallinckrodt, NC, US) and 30 % saline. A Transend 14 EX (Stryker) guidewire was used in all cases. First, the balloon catheter was placed across the neck and then the microcatheter was positioned inside the aneurysm. Each occlusion time did not exceed 3 min. Embolization was performed with Target (Stryker, Fremont, CA) coils. At the end of the procedure, the microcatheter was withdrawn first (Figs. 1 and 2).

In some patients, after treatment with BRT a laser-cut stent was implanted in a standard fashion. These patients were under dual antiplatelet therapy.

Anchor Technique

In these situations an Excelsior SL-10 microcatheter (Stryker) was navigated along the inner surface of a giant aneurysm, making a loop in the dome, exiting the neck to reach the distal parent artery. Using a Transend 14, 300 cm floppy guidewire (Stryker), an exchange maneuver was performed and the catheter balloon was navigated and inflated in the distal vessel. The retraction of the balloon catheter and microwire eliminated the loop, resulting in only a wire bridge across the aneurysm neck, thereby allowing a second catheter to be brought up in a standard fashion. This catheter was used to deliver a laser cut stent or flow diverter device (Fig. 3).

Fig. 3 Patient 3. **A** Angiography demonstrating a giant cavernous aneurysm, **B** 3D-angiography reveals lack of a well-defined neck, **C** road mapping image shows a microcatheter navigated along the aneurysm inner surface, making two loops inside the sac, exiting the neck to reach the distal parent artery, **D** After an exchange maneuver a balloon is inflated in the distal vessel, **E** balloon retraction eliminates the loops and **F** a second microcatheter is positioned distally with a standard exchange maneuver

Balloon Test Occlusion

When permanent occlusion was considered to be performed, a balloon test occlusion was previously done with the patient under general anesthesia, with a Transform C balloon. A digital road map of the target vessel was obtained to control balloon inflation, which was performed under fluoroscopic view. Occlusion was confirmed by angiographic series through the guiding catheter. Angiogram series from internal carotid and vertebral arteries, depending on the vessel to be occluded, were performed after balloon inflation.

Angioplasty for Vasospasm

Patients with symptomatic vasospasm after subarachnoid hemorrhage were submitted to angioplasty with a Transform C catheter balloon if normal lumen diameter was >1.5 mm. With patients under general anesthesia and heparinization, the balloon was inflated under fluoroscopy until it reached the desired diameter at the target vessel. Control angiogram was performed to access the efficacy for the resolution of vasospasm.

Results

Patient Demographics

In this study 19 patients harboring 20 intracranial aneurysms were treated using the TOBC during the studied period (Table 1). One patient was submitted to balloon test occlusion. There were 12 women and 8 men with a mean age of 58.55 years (median 56 years, range 29–78 years).

No recanalization or previously clipped aneurysms were included. Among the aneurysms treated by remodeling technique, 11 were side wall and 7 were bifurcation aneurysms. Aneurysms treated by the remodeling technique (n = 18) were located at internal carotid artery in 9 cases, anterior communicating artery (ACA) complex in 4, middle cerebral artery (MCA) in 4, and pericallosal artery (PCA) in 1. Anchor technique was used to treat two aneurysms. Of the aneurysms 12 were non-ruptured and 8

Table 1 Summary of patients treated with the TransForm balloon occlusion catheter

Patient no.	Age (years) sex	Aneurysm location	Dome/ neck	HH	Branch arising from neck/sac	Technique	Transform balloon (mm)	Occlusion[b]	Complication
1	49, F	ICA clinoid	4.4/2.4	0	No	BRT	C 4 × 10	1	No
2	58, M	ACoA	8.4/5.1	0	No	BRT	SC 4 × 7	2	No
3	65, F	ICA cavernous	NA	0	No	Anchor	C 4 × 10	NA	No
4	49, M	ACoA	6.8/3.5	I	No	BRT	SC 4 × 7	1	No
5	65, M	ICA PCom	4.2/2.8	0	No	BRT	C 4 × 15	1	No
6	49, F	ICA PCom	9.9/2.6	0	No	BRT	C 4 × 10	1	No
		MCA M1	11.6/4.0	0	No	BRT	C 4 × 10	2	No
7	54, F	ACoA	6.6/5.0	II	No	BRT	SC 4 × 7	2	Thrombus
8	52, M	ICA Oph	18.1/4.8	IV	No	BRT	C 4 × 10	2	No
9	54, M	MCA bifurcation	11.2/3.7	IV	No	BRT + angioplasty	SC 4 × 7	1	No
10	69, M	ICA PCom	12.9/7.7	V	PCom	BRT	SC 4 × 7	1	Thrombus
11	50, F	ICA Oph	16.3/5.3	0	No	BRT	C 4 × 10	1	No
12	48, F	MCA bifurcation	2.3/1.8	0	No	BRT + stent	SC 4 × 7	1	No
13	71, F	ICA PCom	4.6/3.7	0	PCom	BRT	C 4 × 10	1	No
14	78, M	ICA PCom	4.2/2.5	II	PCom	BRT	SC 4 × 7	1	No
15	71, F	Basilar trunk	NA	0	No	Anchor	SC 4 × 7	NA	Alveolar hemorrhage
16	29, F	ACoA	7.2/4.2	0	No	BRT	SC 4 × 7	1	No
17	77, F	ICA PCom	2.3/3.1	II	No	BRT	C 4 × 10	1	No
18	70, F	Pericallosal	7.3/4.2	I	Callosomarginal	BRT	SC 4 × 7	3	No
19	49, F	NA	NA	NA	NA	BTO[a]	C 4 × 10	NA	No
20	64, F	MCA M1	3.6/2.3	0	No	BRT + stent	C 4 × 10	1	No

ACoA anterior communicating artery, *BRT* balloon remodeling technique, *BTO* balloon test occlusion, *HH* Hunt-Hess scale, *ICA* internal carotid artery, *MCA* middle cerebral artery, *NA* not applicable, *Oph* ophthalmic segment, *PCom* posterior communicating artery
[a]Patient harboring a foramen magnum meningioma
[b]Raymond scale

were ruptured and in 4 cases a branch arose from aneurysm sac or neck. Among balloon-remodeled aneurysms, the size ranged from 2.3 mm to 16.32 mm, with an average size of 7.88 mm. Of the aneurysms 16 had a wide neck (mean neck length of 3.89 mm, mean dome/neck ratio of 1.86) while 2 had a narrow neck (mean neck length of 3.15 mm, mean dome/neck ratio of 3.42).

Endovascular Procedure

Patient with hemorrhagic presentation were treated during the acute phase, between 1 and 14 days after bleeding. On the other hand, non-ruptured aneurysms were treated electively. All patients completed endovascular treatment according to the modality previously chosen. The balloon was employed solely for remodeling in 17 cases, for anchor technique in 2 cases, for both remodeling and vasospasm angioplasty in 1 patient and for balloon test occlusion in 1 patient.

Transform SC was used in 10 cases and Transform C in 11 cases. The average balloon preparation time was 3.2 min. The balloon could be navigated as far as the target aneurysm in all cases. In every situation the balloon remained very stable during inflation and deflation, with minimal movement. Mean inflation time was 3.8 s and mean deflation time was 2.6 s. The balloon, prepared with the mentioned mixture, could be perfectly visualized in all cases. After balloon-assisted coiling, a laser cut stent was deployed in 2 out of 18 cases. In all cases, the stent was previously planned in order to reduce the recanalization rate. No coil herniation towards the parent artery or inadvertent branch occlusion occurred during balloon remodeling. In case number 10, after balloon-assisted coiling of a MCA bifurcation aneurysm, angioplasty was performed to treat M1 segment vasospasm. The procedure resulted in normalization of artery caliber.

The anchor technique was used to cross the neck of an aneurysm located at the trunk of the basilar artery and another at the cavernous carotid artery, both giant aneurysms.

In the first case the balloon was inflated in the PCA and in the latter in the MCA. In both situations the balloons could perform the loop inside the aneurysm sac with no difficulty in navigation.

Immediate Anatomical Results

Evaluation of postoperative anatomic ($n = 18$) results indicated total occlusion in 13 (72.2 %) aneurysms, neck remnants in 4 (22.5 %) aneurysms and residual sac filling in 1 (5.9 %). All branches that arose from the sac, 3 fetal posterior communicating arteries and 1 callosomarginal artery, were kept patent.

Complications

We had two (9.5 %) complications related to treatment, all thromboembolic events (1 ruptured and 1 non-ruptured aneurysms). These patients were submitted to the balloon remodeling technique. A thrombus developed adjacent to the aneurysm neck without distal embolization in both cases. Despite normal flow across the thrombus site, a loading dose of intravenous GP IIb/IIIa inhibitor was infused and resulted in total dissolution. One patient (number 16) experienced diffuse alveolar hemorrhage due to negative pressure post extubation. No technical complications related to the TBOC were observed.

Clinical Outcome

Patient number 10 died due to an alveolar hemorrhage and 1 patient (number 12) with a ruptured internal carotid artery aneurysm died secondary to complications of subarachnoid hemorrhage. All patients harboring non-ruptured aneurysms treated with BRT had an uneventful recovery and were asymptomatic on discharge. Of the patients 16 (80 %) had a good outcome (mRS < 3) among which 15 were totally asymptomatic and 1 with a slight disability (mRS = 2). Excluding the two deaths, no further deterioration of patients occurred after treatment. No rehemorrhage was observed.

Discussion

The shape of intracranial aneurysms, particularly the width of the neck, is no longer a limitation for endovascular treatment [2, 3]. The use of balloon-assisted coiling has made it possible to treat more complex aneurysms. The remodeling technique was promoted by Moret et al. in 1992 and is now a routine technique [4].

Balloon-assisted coiling has been shown to be safe and effective. Results in the literature suggest that aneurysm coiling supported by balloon remodeling is not associated with a statistically significantly increased risk of thromboembolism compared with traditional unassisted methods. Additionally, BRT seems to be associated with the quality of postoperative aneurysm occlusion [1, 6].

In the ATENA study [6], the overall rate of adverse events related to the treatment of non-ruptured aneurysms was 10.8 % for treatment with coils alone and 11.7 % for the remodeling technique. On the other hand, when dealing with ruptured aneurysms, the overall rate of treatment-related complications in the CLARITY study [1], with or without clinical manifestations, was 17.4 % with coil embolization and 16.9 % with remodeling.

The TOBC was launched by Stryker Neurovascular (Fremont, CA) in 2013 [3]. Since then, only two series have been reported about the use of TOBC [3, 5]. Quadri et al. [3] used the TOBC for balloon-remodeled coil embolization in 23 cases and for vasospasm treatment in 1. In all cases, the balloon could be placed as intended. Thrombi developed in 3 cases (12.5 %) and complete aneurysm occlusion was achieved in 78 %. On the other hand, Bartolini et al. [5] retrospectively analyzed 33 patients harboring 36 intracranial aneurysms treated by BRT. In all cases, the balloon was placed in a correct position and all treatment was successful. Two thromboembolic complications were observed and no rebleeding occurred.

The present series describes the initial experience with the TBOC in different situations, even beyond balloon-assisted coiling. In most cases, the balloon was used to perform remodeling technique (18 out of 21 cases). In two cases it helped to allow access to the distal parent vessel with a microcatheter in order to deploy a stent (anchor technique). Finally, it was employed to perform angioplasty for vasospasm in one patient and occlusion test in another. Both ruptured and non-ruptured aneurysms were treated.

The overall success rate in positioning the balloon at the aneurysm neck was 100 %. The inflated balloon could prevent coil herniation and keep the microcatheter stable inside the aneurysm in all cases treated with BRT, either sidewall or bifurcation aneurysms. In four cases, in which fetal posterior communicating arteries and a callosomarginal artery arose from the aneurysm sac or neck, the inflated super compliant balloon was able to deform sufficiently and prevent inadvertent occlusion of these branches.

All stents employed were previously preplanned. Procedure-related complications occurred in 9.5 %, all of which were thromboembolic but with no clinical manifestation. No dissections, vessel rupture or aneurysm perforation were observed.

Several balloons are available in the market as single or double lumen [2–5]. All of them are designed to be tracked over a guidewire. Single lumen balloons are only inflated by inserting a compatible guidewire into the distal seal. Furthermore, they are available in a compliant version, dedicated to remodeling of sidewall aneurysms, occlusion test and angioplasty for vasospasm and a super compliant version, dedicated to treatment of bifurcation aneurysms [2–5].

Preparation and navigation of Transform C and Transform SC are very similar. The compliant version is often inadequate for protection of both neck and arterial branches of complex bifurcation aneurysms. On the other hand, the super compliant balloon has the property to change its cylindrical shape to the anatomy of the vessel in which it is inflated, allowing the treatment of those aneurysms [2–5]. The TBOC is similar in design to other balloons. It comprises a single lumen catheter with a non-detachable open-ended balloon attached at the distal end; however, it is compatible with a 0.014-inch guidewire. Additionally, different from other balloons the hypotube has multiples holes to inflate and deflate the balloon [3, 5]. Preparation of the balloon was fast and easy. No difficulty was observed regarding balloon visibility under fluoroscopy and road mapping image. Even in the cases of anchor technique, the balloon could be navigated inside the aneurysm sac, performing a loop with no resistance. Retraction of balloon catheter in order to eliminate the loop was also very smooth [7]. Finally, the balloon remained considerably stable over the aneurysm neck, during inflation and deflation, with minimal need for repositioning.

Balloons that operate on 0.010-inch platforms, such as Hyperform and Hyperglide (Covidien, Irvine, CA), are less stable and provide inferior torque to overcome difficult anatomy but the 0.014-inch wire used in TOBC and Scepter (Microvention, Tustin, CA) induces more deformation of the cerebral arteries during navigation [2–4]. Compared to TOBC, balloons with two independent lumens, such as Scepter and Ascent (Micrus, San Jose, CA) give the operator the opportunity to navigate coils or some low profile stents through one lumen, even with the balloon inflated; however, they are more dense and stiffer. Furthermore, Hyperform and Hyperglide balloons have only two inflation holes, which reduces the speed of inflation and deflation and limits the concentration of contrast medium used [2–4].

In summary, some potential advantages were observed due to TransForm balloon catheter design: (1) the 0.014-inch guidewire compatibility improves the support for navigation, increases stability and allows exchange maneuvers using a stiff wire without losing distal access (e.g. anchor technique), (2) it is possible to choose the guidewire of choice, depending on vessel anatomy and or personal choice and (3) a hypotube with multiples holes allows rapid inflation and deflation, even with a 70 % contrast medium concentration (which undoubtedly increases visibility) [3, 5].

Long-term follow-up is not available. The objective of the present series was to report feasibility, safety and efficacy of the treatment with TOBC. Long-term results regarding occlusion, recanalization and rebleeding rates associated to BRT have been well-defined in other studies.

Conclusion

The TBOC was shown to be safe and effective for the treatment of intracranial aneurysms with BRT. In addition, it was successfully employed to perform angioplasty for vasospasm and BTO. Finally, it was used in the for the first time balloon anchor technique. A greater number of cases are necessary to allow stronger conclusions to be drawn on the usefulness and safety of this device.

Compliance with ethical guidelines

Conflicts of interest F.P. Trivelato, M.T. Salles Rezende, L.V. Fonseca, L. Bonadio and A. Cordeira Ulhoa state that there are no conflicts of interest.

This study was carried out with the approval of the responsible the ethics committee. All procedures were carried out in accordance with national law and the Helsinki Declaration of 1975 (in its current revised form). Informed consent was obtained from all patients included in the study.

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