Original Paper

Early Experience with the TransForm™ Occlusion Balloon Catheter: A Single-Center Study

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Key Words

Balloon-assisted coil embolization · Early experience · Intracranial aneurysms · TransForm™ occlusion balloon catheter

Abstract

Background and Objective: Balloon-assisted coil embolization has become an important adjunct in the endovascular treatment of intracranial aneurysms. The management of broad-necked cerebral aneurysms is technically perplexed due to a variety of factors, which include the difficulty in defining the aneurysm-parent vessel interface angiographically and problems in achieving complete aneurysmal occlusion. This could later predispose to regrowth or recanalization. We sought to determine the safety and efficacy of the TransForm™ occlusion balloon catheter (TOBC) for the coiling of intracranial aneurysms at our institute. **Methods:** A retrospective review was performed to identify TOBC cases between May 1, 2013, and April 30, 2014. **Results:** A total of 24 TOBC cases were identified. In 23 cases, the TOBC was used for balloon-remodeled coil embolization, and in 1 case, it was used for vasospasm treatment alone. Out of the total 24 cases in which the TOBC was used, 16 (66.6%) were ruptured aneurysms. Stents were used in 6/23 (26%) cases. In all cases, the balloon could be placed as intended. The inflation and deflation times ranged from 3 to 4 s. No serious complications were noted. In the experience of the authors, the balloon performed the intended role in most cases. **Conclusions:** This series shows that the TOBC is feasible, safe and useful in the treatment of cerebral aneurysms. The balloon was traceable to the intended site and the preparation, inflation and deflation times were short. We believe that the TOBC has effective utility in treating broad-necked and small aneurysms.

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Introduction

Endovascular management of intracranial aneurysms is the preferred treatment of choice both by clinicians and patients in most cases. The trend to opt for this minimally invasive alternative instead of open surgical techniques became more frequent after the publication of the International Subarachnoid Aneurysm Trial (ISAT) [1, 2].

Aneurysms with a complex shape, acute angles with the parent vessel, or those with wide necks are a therapeutic challenge for interventionists, with a much higher risk of recurrence [3–6]. In cases of wide-necked cerebral aneurysms, selective embolization is challenging due to the risk of coil protrusion into the parent artery. Almost 2 decades ago, Moret et al. [7] first described the early experience with balloon-assisted coil embolization (BACE), which has now become an important adjunct in the endovascular treatment of wide-necked intracranial aneurysms. The management of broad-necked cerebral aneurysms is technically perplex and challenging due to a variety of factors, which include the difficulty in defining the aneurysm and parent vessel interface angiographically, preventing coil herniation into the parent artery, and problems in achieving complete aneurysmal occlusion that could later predispose to regrowth or recanalization.

Most clinicians are reluctant to perform stent-assisted coiling in the situation of subarachnoid hemorrhage because of the need for dual anti platelet therapy. This has made the use of BACE a more prevalent and preferable approach by clinicians in the last several years to treat wide-necked intracranial aneurysms [3, 7–21]. Balloons have also been shown to help in the tamponade of the vessel in case of intraoperative perforation [22, 23] and are also used for occlusion testing before sacrifice of the vessel. Previously, Lubicz et al. [8], Mu et al. [15], Youn et al. [16] and Cekirge et al. [17] reported the use of a super-compliant balloon (HyperForm) in the treatment of wide-necked aneurysms located on arterial bifurcations and/or small arteries. The use of a coaxial dual-lumen balloon catheter (Ascent) for the treatment of wide-necked aneurysms has also been reported by Lazzaro et al. [24].

The TransForm™ occlusion balloon catheter (TOBC) was launched by Stryker Neurovascular, Fremont, Calif., USA, in 2013. The balloon has single lumen and can be navigated over a 0.014-inch wire. Micromachined hypotube design has multiple holes to inflate and deflate the balloon. This design theoretically allows a rapid inflation and deflation of the balloon. In this paper, we sought to review the safety, efficacy and performance of BACE using the TOBC of Stryker Neurovascular.

Materials and Methods

A retrospective review was performed from May 1, 2013, to April 30, 2014. Records were reviewed for 81 patients who had 84 aneurysms treated with the endovascular technique. In 51/84 (60.7%) aneurysms, balloon assistance for coil embolization (BACE) was required. In 23/51 cases, the TOBC was used. The rest of the 28 aneurysms were treated with other balloons. In 1 case, the TOBC was used for vasospasm. Clinical data and angiograms were reviewed retrospectively in all cases. The aneurysm size, neck diameter and fundus-to-neck ratio (FNR) were noted. Aneurysms with a neck diameter ≥ 4 mm or a FNR < 2 were considered wide necked [25].

The following variables were collected on retrospective review of the charts: the visibility of the TOBC under fluoroscopy; its ability to reach the target site; assistance in coil embolization; stability during the first positioning as well as during the inflation and deflation of the balloon, and the ability of the TOBC to temporarily stop or control blood flow when indicated. When a balloon was used for vasospasm treatment, its efficacy for the resolution of vasospasm was also noted.

The aneurysm occlusion was recorded in the post-treatment angiograms, and the angiographic results were classified according to the Raymond scale, with class 1 defined as complete (total) obliteration, class 2 as residual neck/dog ear (subtotal occlusion) and class 3 as residual aneurysm (incomplete occlusion with

Table 1. Neck diameters, sac-to-neck ratios and locations of all aneurysms treated with the TOBC

Pa-tient number	Aneu-rysm number	Location of aneurysm	Procedure performed	Balloon used	Size of balloon used, mm	Stent used	Size of stent used, mm	Neck diameter, mm	Size, mm	FNR
1	1	Anterior communicating artery	BACE and angioplasty	TransForm compliant	4 × 10			3.13	5.2	1.6
2	1	Right ICA (ophthalmic)	BACE	TransForm compliant	4 × 10			1.5	4.5	3
3	1	Right ICA (PCom)	BACE	TransForm compliant	4 × 10			2	3.9	1.95
4	1	Right MCA (bifurcation)	BACE	TransForm compliant	4 × 10			5.26	6.8	1.29
5	1	Right MCA (distal to bifurcation)	BACE	TransForm compliant	4 × 10			3	5.5	1.80
	2	Left ICA (ophthalmic)	BACE and stent bailout	TransForm compliant	4 × 10	Neuro-form EZ	3.5 × 15	1.9	3.18	1.67
6	1	Left ICA (PCom)	BACE	TransForm super compliant	4 × 7			3.8	7.3	1.92
7	1	Left ICA (anterior choridal)	BACE	TransForm compliant	4 × 10			3.96	4.3	1.08
8	1	Left ICA (PCom)	BACE and stent bailout	TransForm compliant	4 × 10	Neuro-form EZ3	4.5 × 10 and 4.5 × 20	1.59	4.64	2.91
9	1	Right ICA (superaclinoid)	BACE stage 1	TransForm compliant	4 × 10			4	12.4	3.10
		Right ICA (superaclinoid)	BACE stage 3	TransForm compliant	4 × 10			4	12.4	
10	1	Left ICA (PCom)	BACE	TransForm compliant	4 × 10			2.18	4.70	2.15
11	1	ACom	BACE	TransForm compliant	4 × 10			2.3	4.45	1.93
	2	Left ICA (anterior choridal)	BACE	TransForm compliant	4 × 10			1.45	3.98	2.74
12	1	ACom	BACE stage 1	TransForm compliant	4 × 10			1.5	2.3	1.53
13	1	Right ICA (ophthalmic)	BACE	TransForm compliant	4 × 7			4.05	8.9	2.19
14	1	Right ICA (PCom)	BACE	TransForm super compliant	4 × 7			1.9	7.3	3.84
15	1	Left MCA (distal to bifurcation)	Stent-assisted coil embolization and balloon remodeling	TransForm compliant	4 × 10	Neuro-form 3	3.5 × 15	6.24	5.21	0.83
16	1	Right ICA (superaclinoid)	BACE	TransForm compliant	4 × 10			6.03	20.2	3.34
17	1	Left ICA (superior hypophyseal)	BACE	TransForm compliant	4 × 10			2.63	6.95	2.64
	2	Right ICA (superior hypophyseal)	BACE and stent bailout	TransForm compliant	4 × 10	Neuro-form EZ3	4 × 20	2.5	5.8	2.32
	3	Right ICA (superior hypophyseal)	BACE and stent bailout	TransForm compliant	4 × 10	Neuro-form EZ3	4 × 20	1.8	2.05	1.13
18	1	Left MCA (bifurcation)	BACE stent as anticipated	TransForm compliant	4 × 10	Neuro-form 3	2.5 × 20	2.98	6.21	2.08
19	1	Basilar tip	BACE	TransForm compliant	4 × 10			1.8	4	2.22
20		Basilar artery	Angioplasty	TransForm compliant	4 × 10					

ICA = Internal carotid artery.

Table 2. Discharge status and mRS scores of all patients treated with the TOBC along with their baseline Hunt and Hess as well as Fisher grading for subarachnoid hemorrhage

Patient number	Hunt and Hess scale	Fisher grade	Baseline mRS score	Raymond scale for occlusion	Discharge mRS score	Discharge status
1	3	4	2	1	0	Home
2	n.a.	n.a.	1	1	0	Home
3	4	4	3	1	1	Home
4	2	4	2	2	0	Home
5	n.a.	n.a.	1	1	0	Home
	3	3		2		
6	1	2	2	1	1	Home
7	n.a.	n.a.	0	1	0	Home
8	2	4	2	1	1	Nursing facility
9	n.a.	n.a.	0	2	0	Home
	5	3	0	1	0	Nursing facility
10	3	4	2	1	1	Home
11	3	4	3	1	1	Home
	n.a.	n.a.		1		
12	3	4	2	2	0	Nursing facility
13	n.a.	n.a.	1	2	0	Home
14	1	3	1	1	0	Home
15	2	3	1	1	0	Home
16	5	4	5	1	6	Death
17	3	4	2	1	1	Home
	n.a.	n.a.		1		
	n.a.	n.a.		2		
18	n.a.	n.a.	1	1		Home
19	3	2	1	1	0	Home
20	n.a.	n.a.				

contrast filling the sac). The degree of disability and clinical outcome was measured using the modified Rankin Scale (mRS) at baseline and discharge.

The balloon was prepared using an Omnipaque 300 contrast at a concentration of 70% contrast and 30% normal saline. A Transcend Soft Tip wire was used for the majority of cases. Balloon preparation times were recorded. The balloon was placed across the neck of the aneurysm before accessing the aneurysm with a coiling catheter. Heparin was given before the inflation of the balloon in ruptured aneurysm cases. In an unruptured aneurysm, heparin was given immediately after groin access. The activated clotting time goal was above 250 s for both ruptured and unruptured cases. However, all activated clotting time values were not collected.

Results

The TOBC balloon was used to treat 23/51 (45%) aneurysms in 19 patients and to treat vasospasm in 2 cases. In 1 of these 2 cases, the balloon was employed for both remodeling and vasospasm, and in the other patient, it was used solely for vasospasm (table 1).

Out of the total 24 cases in which the TOBC was applied, 16 (66.6%) were ruptured aneurysms. The Hunt and Hess as well as Fisher grading for these patients was noted (table 2). A stent was used in 6/23 (26%) cases. In 4 cases, the stent was used as a bailout to support the coils from herniating into the parent vessel after balloon deflation. In the remaining 2 cases, the stent was preplanned, but BACE was used initially as there was concern about the coil loops herniating through the struts of the stent (table 1).

Fig. 1. **a** An internal carotid artery supraclinoid side-wall aneurysm before embolization. **b** Image during coil embolization demonstrating a good balloon visibility and stability. **c** Image after embolization, showing no residual or overlapping PCom origin. **d** Image of an ACom aneurysm before embolization. **e** Image made while the balloon was placed across the neck of the aneurysm (deflated). **f** Image obtained after coil embolization, showing complete obliteration and sparing of ACom.

The locations where the TOBC was used to treat aneurysms were ophthalmic ($n = 3$); posterior communicating artery (PCom; $n = 5$); anterior choroidal ($n = 2$); supraclinoid ($n = 2$; fig. 1a–c); superior hypophyseal ($n = 3$); anterior communicating artery (ACom; $n = 3$; fig. 1d–f); basilar ($n = 1$), and in the middle cerebral artery (MCA; $n = 4$). The size of the 23 aneurysms treated ranged from 2.05 to 20.2 mm, with an average size of 6.07 mm. The neck diameter of the 23 aneurysms treated measured from 1.45 to 6.24 mm, with an average of 2.93 mm. The FNR of these 23 aneurysms treated with the TOBC ranged from 0.83 to 3.84 mm. Of the 23 aneurysms, 11 (48%) had an FNR < 2 . Of the 12 aneurysms with an FNR > 2 , 3 (25%) had a neck diameter ≥ 4 mm (4, 4.05 and 6.24 mm; table 1).

The average balloon preparation time was 3.6 min. In 22/23 (95.6%) aneurysms in which coiling was done, the balloon was able to be tracked to the intended side. One aneurysm required balloon placement in the contralateral A2 segment, but due to tortuosity of that segment, it could not be accessed even with a wire and hence did not contribute to the failure of balloon traceability. Watermelon seeding effect on inflating the balloon occurred in 2/23 (8.6%) cases, and 21/23 (91.3%) balloons remained very stable during inflation and deflation (fig. 1). The maximum balloon inflation time per inflation in all 23 cases ranged from 1 to 4 min.

Thrombus developed in 3/24 (12.5%) cases (2 ruptured cases and 1 unruptured case) at the neck of the aneurysm, causing partial occlusions. In all cases, the thrombus resolved completely with a loading dose of intravenous IIb/IIIa inhibitors (Reopro). There were no instances of other complications such as aneurysm or vessel perforation by coil or microcatheter, vascular dissection or stroke related to thrombus formation. Asymptomatic strokes

Table 3. Summary of the performance of the TOBC compared to other balloons reported previously in literature

	TOBC	Cekirge et al. [17]	Youn et al. [16]	Mu et al. [15]
Balloon preparation time, min	3.6	–	–	–
Visibility	good	–	–	–
Stability	good	good	good	good
Navigability and placement	good	good	good	good
Inflation time, s	4	–	–	–
Deflation time, s	3	–	–	–
Ability to treat wide-necked aneurysms in small arteries and bifurcations	good	good	good	good
Ability to stop/control blood flow	good	good	–	–
Angioplasty/ability to treat vasospasm (off-label use)	good	good	–	–
Procedure complications, %				
Thromboembolic complications	12.5	1.7	8.8	–
Vessel or aneurysm rupture	0	1.6	–	2.3
Neurological deficit	0	8.9	2.9	0
Procedural mortality	0	1.4	0	0
Mortality	0	7	0	0
Occlusion rate, %				
Class I	78	73	91.2	80.9
Class II	22	20.4	8.8	9.5
Class III	0	6.6	0	4.8

cannot be ruled out as only few patients had MRI after the procedure. Complete obliteration (class I) was achieved in 18/23 (78%) cases, while in 5/23 (22%) cases, residual neck and dog ear (class II) were left intentionally to keep a branch open at the neck.

In 2 cases, the TransForm balloon was used for vasospasm treatment as an off-label use for angioplasty. Both patients had vasospasm related to subarachnoid hemorrhage. The balloon angioplasty completely normalized the caliber of that segment of the artery. Admission and discharge mRS scores of all patients, along with their discharge status, are mentioned in table 2.

Discussion

The BACE technique is used in the endovascular treatment of wide-necked complex cerebral aneurysms [7, 9–11]. The safety and efficacy of different balloons (HyperForm; eV3 Inc. and Ascent, Codman Neurovascular) in the treatment of wide-necked cerebral aneurysms has previously been reported in the literature [8, 15–17, 24]. For the very first time in this series, we sought to determine the safety, efficacy and feasibility of the TOBC, which was launched by Stryker Neurovascular in 2013.

The TOBC is a single-lumen, over-the-wire balloon that can be navigated over a 0.014-inch wire. According to the manufacturer's instructions, the TOBC is intended to be used for test occlusions and for balloon-assisted embolization of aneurysms in the neurovasculature. We employed the TOBC for vasospasm treatment as an off-label use for angioplasty in 2 cases at our center.

By definition, aneurysms with a neck diameter >4 mm and an FNR <2 are considered to be wide necked [25]. The TOBC performed well while coiling wide-necked intracranial

Fig. 2. **a** Image of a left MCA aneurysm before embolization. **b** Image showing balloon inflation within the Neuroform stent, demonstrating the visibility and conformability of the fusiform shape. **c** Image obtained after embolization. **d** Image of another left MCA aneurysm before embolization. **e** The TOBC in the inferior division of the left MCA (deflated). **f** Image obtained after placement of the Neuroform stent in the inferior division over an exchange length Transcend wire.

aneurysm, as shown by our data (table 1). We were able to coil aneurysms with necks as wide as 6 mm without deploying stents. Of the aneurysms successfully treated, 11/23 (48%) had an FNR <2, indicating that BACE could be an effective tool for the treatment of difficult wide-necked intracranial aneurysms without conventional stent deployment.

In a total of 4 cases, a stent was used to prevent the coils from herniating into the parent vessel after BACE. Only 2/11 (18%) aneurysms with an FNR <2 required a stent bailout, again indicating the balloon's efficacy for aneurysms with wide necks (table 1). In a previous series with the HyperForm balloon, Mu et al. [15] suggested that stent placement should be considered for aneurysms with an FNR close to 1. With the availability of complex-shape coils, a better navigability of this balloon and the conformity of shape, we believe that certain wide-necked aneurysms could be treated without stent placement using BACE.

In our series, the stent was preplanned in 2 cases. In 1 case, the aneurysm was complex fusiform, with a saccular component of the left MCA M2 division (fig. 2a–c). In the other case (fig. 2d–f), the aneurysm had a large neck with anticipated herniation of the coils without a stent. In both cases, BACE was used to supplement the stent-assisted coil embolization.

The balloon preparation was simple and quick. The average balloon preparation time was 3.6 min. The ability of the TOBC to reach the target aneurysm was appreciably fast and easy. In all cases, the balloon was able to be placed where intended except in 1 case where the tortuosity did not even allow navigation of the wire into the contralateral anterior cerebral artery and hence the balloon was kept in the A1 segment proximal to the neck of the aneurysm for safety only. In the review of their experience with the HyperForm balloon, Lubicz et al. [8], Mu et al. [15], Youn et al. [16] and Cekirge et al. [17] reported the efficacy of the BACE tech-

nique for the treatment of aneurysms located on bifurcations and small arteries. In their experience, the HyperForm balloon was able to change its cylindrical shape easily and to bulge into the origin of arterial bifurcations due to its compliant nature when placed at bifurcations. The balloon's compliance was also favorable for use in small arteries. In our use, we found the TOBC to be effective for the treatment of aneurysms located on bifurcations as well as small arteries (table 3). Due to its design of machine-slotted holes allowing rapid inflation and deflation, the balloon expands uniformly and thereby reduces the risk for a watermelon seeding effect. The super-compliant TransForm balloon allows protrusion across the ostium of branches and helps protect them from coil herniation.

In all cases, the balloon had a good visibility (fig. 1, 2). In most cases, the recommended Transcend Soft Tip wire was used with the balloon. The reliability of use of this balloon with other wires cannot be evaluated in our series.

Optimum placement and stability play a major role when using the BACE technique for the treatment of wide-necked aneurysms. In the previously reported series with the HyperForm balloon, the authors reported the balloon to be very stable [8, 15–17]. In our experience, the stability of the TOBC during the first positioning and during inflation and deflation was very steady. Only in 2 cases did the balloon experience a watermelon seeding effect. The inflations and deflations with the TOBC were prompt. The average inflation time was noted to be 4 s, while the average deflation time was 3 s. In the experience of the authors, the balloon performed the intended role in coil embolization in most cases.

The advantage of this balloon is the possibility of using a 0.014-inch wire, which increases the traceability of the balloon to distant sites. In one case, the balloon had to be used within the stent; the 0.014-inch wire allowed the exchange without losing access distal to the stent. This ensured that the balloon wire did not traverse in and out of the struts of the stent, which could result in vessel rupture and/or stent deformity. Our gold standard wire for most cases was Transend EX.014 Soft Tip, although Synchro2® Guidewires were sometimes used for tortuous anatomy and Transend 300 Floppy was used for exchanges. The reliability of use of these wires cannot be evaluated in this series due to the small number of patients.

In patients with severe vasospasm proximal to the aneurysm, Cekirge et al. [17] reported using the HyperForm balloon for angioplasty before using the same balloon for remodeling. Though not indicated by the manufacturer, apart from the balloon occlusion test (BOT) and BACE, we used the TOBC as an off-label use for angioplasty in 2 cases to treat vasospasm. In both cases, a significant improvement in vasospasm was noted without any complications. In this series, we did not use the TransForm balloon specifically for testing occlusion, but when angiographic images were performed to confirm flow cessation during active embolization, no flow was noted.

In our series, overall class I occlusion was obtained in 78% (18/23) and class II occlusion in 22% (5/23) of the aneurysms with the TOBC, as compared to 73% (class I) and 20.4% (class II) reported by Cekirge et al. [17], 91.2% (class I) and 8.8% (class II) reported by Youn et al. [16] and 80.9% (class I) and 9.5% (class II) reported by Mu et al. [15] with the HyperForm balloon.

BACE has proved to be effective and safe. Procedural complications known to be associated with BACE include a higher rate of thromboembolic events and increased risks of aneurysm or vessel rupture [26, 27]. Other complications such as vessel dissection, neurological deficits, permanent morbidity and procedure mortality have also been reported [8, 15–17].

In the BACE technique, the use of balloons for coil embolization may tentatively lead to an increased incidence of thrombus formation and thromboembolic events due to blood stasis and platelet aggregation in the parent vessel. In addition, the repeated inflations and deflations of the balloon may lead to intimal injury in the vasculature [7]. In a literature review, Shapiro et al. [28] reported the incidence of thromboembolic complications at 8.1% during BACE. In their series with the HyperForm balloon, Youn et al. [16] and Cekirge et al.

[17] reported 8.8 and 1.7% of thromboembolic events, respectively. In our series with the TOBC, thrombus developed in 3/24 (12.5%) cases (2 ruptured and 1 unruptured case) at the neck of the aneurysm, causing partial occlusions. In all cases, thrombus resolved completely with a loading dose of intravenous IIb/IIIa inhibitors (Reopro). To avoid thromboembolic complications, a combination of aspirin and clopidogrel before the start of the intervention has been suggested by Youn et al. [16]. The higher rate of thrombus formation in our cohort can be explained by the larger proportion of ruptured aneurysms in our series.

The TOBC appears to have short inflation and deflation times (3–4 s). Since no previous case series have reported inflation and deflation times, an objective comparison cannot be made with other balloons. Since short inflation and deflation times allow shorter times of cessation of flow resulting in a lower risk of thromboembolic complications, we suggest notification of this variable in future studies. Its improvement can prove to be of significance in lowering the periprocedural complications.

No vascular dissection, vessel rupture or aneurysm rupture occurred in our case series with the TOBC. In their series with 864 patients, Cekirge et al. [17] attributed 1 case of vessel occlusion and neurological deficit to the dissection of the superior trunk of the MCA. Our case series had a significantly smaller number of patients, and the incidence of such complication could not be ruled out in this series.

All our patients except 1 were discharged with an mRS of 0 or 1. The mortality rate was 5.2% (1/19) in patients treated with BACE. The death of 1 patient (patient 16) was not procedurally related but rather due to the degree of preprocedural subarachnoid hemorrhage, with the family finally opting to withdraw life support.

Conclusion

In this early experience of 24 aneurysms, the TOBC was safe and useful. In our single-center study, balloon-remodeled coil embolization of aneurysms using the TOBC was not associated with any serious complications. The balloon was traceable to the intended sites, and the preparation time was short. We believe that the TOBC has a good utility in treating broad-necked aneurysms that are otherwise suboptimally managed by conventional coil embolization. Additional studies with long-term follow-up are essential to gain further real-life experience of the TOBC and to better define the place of this relatively new balloon in the therapeutic armamentarium for the treatment of wide-necked and complex cerebral aneurysms. Limitations of the study are the small sample size, retrospective design and lack of long-term follow-up.

Disclosure Statement

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