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Initial single centre experience with Barrel VRD stent in large neck aneurisms

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ABSTRACT

Introduction. Despite the use of new techniques, such as Y-stenting, the waffle-cone technique and intrasaccular flow disrupters the treatment of wide-neck bifurcation aneurysms is still challenging, especially for those where adjacent branches are arising at the neck level. Moreover, the use of flow diverter stents in bifurcation aneurysms has been proposed by several teams, although the results remain controversial.

This study is reflecting initial experience in our department with a relatively new device available on the market: Barrel VRD stent. The unique design feature of the device is the "belly-like" central part of the stent which protects the adjacent branches.

Methods. We retrospectively reviewed all patients in whom stenting with braided or laser-cut stents had been performed in our center. Three patients were identified and analyzed. Technical success, complications, immediate angiographic outcomes, procedural data, are reported here.

Results. One MCA bifurcation and two basilar tip large neck aneurysms with one branch arising from the neck level have been identified. Technical success was achieved in all procedures. Overall procedure-related morbidity and mortality was 0%. In the immediate post-treatment angiography, adequate occlusion (neck remnant or total occlusion) was observed in all patients. Short- and mild-term follow-up angiography showed adequate occlusion of the aneurysms.

Conclusions. In this small case series, retrospective single-center analysis we showed

Keywords
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that Barrel VRD - stent assisted coiling is a safe and feasible technique. Moreover, it offers an elegant and effective endovascular solution for large neck basilar tip aneurysms on which the neurosurgical clipping remains challenging.

Introduction

Endovascular treatment is the standard first-line therapy for both ruptured and unruptured intracranial aneurysms [1-3]. Unfavorable anatomy as wide-neck aneurysms also require adjuvant therapy to be treated safety and efficiently [4, 5] knowing the fact that simple coiling or balloon-assisted coiling has a high risk of coil protrusion in to the parent vessel. The use of stent-assisted coil embolization for wide-necked intracranial aneurysms has significantly expanded the range of aneurysms that are candidates for endovascular treatment [6-8]. However, single stent-assisted coiling in particular situations does not provide sufficient support when the neck of the aneurysm is centered on the bifurcation branches. In these cases, the use of two stents or Y-stenting has been proposed [9-12]. From technical point of view this technique remain challenging but it has high immediate and long-term occlusion rates [11].The waffle-cone technique is a feasible alternative to Y-stenting and consists of deploying the distal end of a dedicated stent, such as pCONus (Phenox GmbH, Bochum, Germany) and PulseRider (Pulsar Vascular, San Jose, California, USA), inside the aneurysm sac and the proximal end in the parent artery. Coiling is performed through the expanded distal end of the stent. The main advantage of this technique is that both branches of the bifurcation are not involved in endovascular treatment. Small retrospective studies have evaluated and reported its safety and efficacy [13-15]. In asymmetric bifurcations where two or even three branches are arising from the neck level those techniques described above offer limited solutions and unpredictable branch protection during coiling. The use of flow diverters in wide-neck bifurcation aneurysms (WNBA) remains controversial owing to inconsistent patency of bifurcation branches covered by the stent and poor occlusion of the aneurysm at follow-up angiograms [16]. Targeted, large prospective multicenter studies are needed to evaluate the safety and efficacy of this treatment specifically for WNBA. Intrasaccular flow disruption devices, such as WEB (Woven EndoBridge; Microvention, Tustin, California, USA) are presently a feasible and efficient tool of WNBA treatment; moreover, retrospective and prospective studies confirmed the high safety level and low morbidity and mortality rates [17,18]. Despite the advantages of flow diversion in the case of complex irregular shapes and bi-lobed aneurysms or asymmetrical bifurcations, placing the WEB device proved to be unfeasible or at least very challenging even in experienced hands. In this context a single stent with "belly-like" central part which protects the adjacent branches in WNBA seems to be a promising solution for this type of aneurysms. Here, we report our single-center experience with Barrel VRD - stent assisted coiling, with clinical and angiographic peri-procedural results, in order to evaluate the safety and efficiency of this technique.

Materials and methods

Population

We retrospectively reviewed interventional neuroradiology database records to identify patients in whom stenting with laser-cut or braided stents had been performed. We identified three patients treated with this technique in our institution between April 2015 and August 2018. Demographic data, aneurysm location and size are summarized in Table 1. All aneurysms were unruptured; all of them were primary endovascular treatments. In all cases, the aneurysm neck was wide, with an average dome to neck ratio of 1.49.

The Barrel vascular reconstruction device

The Barrel device (Medtronic/Covidien, Irvine, California, USA) is a nitinol self-expandable, closed-cell laser cut micro-stent with electrolytic detachment system. Two main characteristics offer two this type of stent the feasibility for WNBA's treatments. Main advantage is that due to "barrel" design that is represented by the "belly-like" central part of the stent protects the adjacent branches. Secondly due to the property to be re-sheathable up to three times.

Endovascular technique

Dual antiplatelet therapy was prescribed 2 days before the procedure as in all stent-assisted coiling treatment. In all patients, endovascular treatment was performed using a monoplane angiography unit with three-dimensional rotational capability (Allura Monoplan; Philips, Best, The Netherlands) under general anesthesia and systemic heparinization.

After the procedure, dual antiplatelet therapy (Ticagrelor 2 × 90 mg/day and Aspirin 150 mg/day) was administered for the first 3 months, and aspirin 160 mg/day alone was administered for the following 9 months. In our department clopidogrel (Plavix 75 mg) was replaced by ticagrelor (Brilique 90 mg) due to multiples advantages of the last one and also knowing that 20-25% of the subjects are naturally resistant to clopidogrel. A baseline activated clotting time (ACT) was obtained prior to the bolus infusion of heparin (30 to 50 IU/kg body weight), 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. From the femoral arterial access, a 6 Fr 100 cm distal-access catheter (Envoy/Codman, USA) was placed into the internal carotid artery or in the dominant vertebral artery. In all procedures, the most challenging branch of the bifurcation was first catheterized in order to place the distal tip of the stent. Then the simple deploying by retrieving the 0.021-inch microcatheter (Rebar 18, Medtronic, Irvine, CA, USA) was performed similar to Solitaire AB stent. The convenient placement of the "belly-like" central part of the stent was analyzed during the deployment in subtracted and non-subtracted angiograms. In all procedures the Barrel stent used was BV 4065 ("belly" diameter was 6,5mm and 4 mm proximal end diameter and 3.5 mm distal diameter) and in case 1 and 3 the satisfactory positioning of the stent was achieved after a first deployment. The precise placement of the "belly-like" central part of the stent is relatively simple to archive by the first attempt (2 out of our 3 cases). In one case the good positioning was achieved after third attempt due to acute angle between left PCA basilar trunk and consecutive drop of the microcatheter whine deploying the device. Each time the Barrel stent was safely re-sheeted inside Rebar 18 microcatheter and a new catheterization of the left PCA was done. In all three cases the aneurismal sac was micro-catheterized easily through Barrel interstices after stent placement and detachment (no jailing technique was used). In all procedures, passing through both stents studs with 0.014-inch micro-guidewire was achieved without any technical incident. Finally, the aneurysm was coiled using detachable coils. After coiling in all three cases no collapse of the stent has been noticed neither thromboembolic event was noticed in the protected neck-sided branch.

Complications

No intra-procedural or delayed thromboembolic or hemorrhagic complication were noticed for all three cases treated in our department.

Follow-up protocol

At the end of the procedure, immediate control angiograms were obtained from all patients. Modified Raymond–Roy occlusion classification (RROC) was used for grading the occlusion status of coiled aneurysms. Patients underwent Angio-MRI at 3 months to reassess filling status of the coiled aneurysm, in-stent stenosis, and thrombosis. The modified Rankin scale was used for scoring neurologic status at discharge and follow-up.

Results

All three treated aneurysms were un-ruptured. Procedural details and follow-up angiographic results are shown in Table 1. Treatment was successfully performed in all three cases. Angiographic results were categorized according to the revised RROC into one of the following groups: complete occlusion (RR1), remnant neck (RR2), or residual aneurysm (RR3) by two senior neuroradiologysts in consensus. There was no evidence of in-stent stenosis or thrombosis during follow-up Angio-MRI.

Discussion

Stent-assisted coiling represents a wide world accepted solution for the treatment of wide-neck cerebral aneurysms over treatment with conventional coiling targeting higher rates of complete occlusion and lower rates of recurrence at long-term follow-up. However, treatment of WNBA and fusiform aneurysms is requiring a higher level of interventional neuro-endovascular skills and frequently requires a second stent (that is, a Y-, X- or waffle-cone-stenting configuration [19–20]) or dedicated endovascular stents such as pCONus, PulseRider, and Barrel stent [21]. There are currently little clinical data on these last three devices available.

Despite the potential benefit of single stent-assisted coiling, complex aneurysms can pose a significant challenge for achieving immediate and durable embolization. Specifically, for wide-necked aneurysms located at shallow angle arterial bifurcations, single stent-mediated coiling may provide insufficient support of the coil mass to prevent coil herniation through the aneurysm neck.

A special situation is represented by the aneurysms with branches incorporated in the aneurysm base; Kim *et al.* [22] published a study with 68 patients with 78 intracranial aneurysms treated with multiple endovascular techniques: single-catheter coiling, multi-catheter coiling, balloon-assisted coiling, stent-assisted coiling, and combined techniques. 5.8% morbidity have been reported in this study and no mortality. 10 out of 55 (18%) intracranial aneurysms had a recanalization from which six were retreated. It represents a significant proportion and, moreover, retreatments are even more challenging in this situation. In 2004, Chow *et al* detailed the Y-stent technique [12], whereby double open-cell Neuroform stents (Boston Scientific, Fremont, CA, USA) were deployed sequentially — first, proximal to the arterial bifurcation, and then into each arterial branch followed by coiling of the aneurysm sac. This represented an efficient endovascular solution for bifurcation lesions that are too complex for coiling alone, remodeling technique, or single-stent assisted coiling. Several authors have evaluated this technique in retrospective single-center studies, mostly including unruptured aneurysms [9-11]. The safety was relatively limited: Bartolini *et al.* reported 10.0% procedure-related permanent neurologic deficits and 1.0% death [10]. However, in other studies, the rate of intra-procedural complications was lower, with 4.2% in the study by Limbucci *et al*. and 2.7% in the study by Yavuz *et al.* with mortality rates of 2.1% and 0.5%, respectively [9,11]. At long-term follow-up, the rate of complete aneurysm occlusion was high with 85.8% in the Bartolini study, 95.7% in the Yavuz study, and 93.6% in the Limbucci study. Several types of stents can be used for Y-stenting; mainly open-cell stents (Neuroform, Stryker Neurovascular, Fremont, California, USA) or closed-cell stents (Enterprise, Codman, Miami Lakes, Florida, USA) have been reported. Intrasaccular flow disruption devices, such as the WEB device, are specially designed for the treatment of WNBA and have shown a high level of safety, with morbidity and mortality at 1-month post-procedure of 2.7% and 0.0%, respectively [23]. The efficacy of this technique also proved to be higher than single-stent assisted coiling, and adequate occlusion was reported in 82.0% of cases at 12 months follow-up (complete occlusion: 56.0% and neck remnant: 26.0%). Despite progressive technological improvements, such as the replacement of dual layer by single layer versions, and progressive decreases in the diameter of the micro-catheter used to deliver the device, there are still bifurcation aneurysms with challenging anatomy which are not suitable for this technique. More recently new WEB-balloon remodeling techniques have been described by Mihalea et al [24] where the WEB device can be deployed and tilted in the aneurysm sac using so called "balloon remodeling technique" and it may represent a feasible solution for this type of wide neck bifurcation aneurysms. In this category of wide neck aneurysms with branches incorporated at the neck level are technically particular and we strongly believe that Barrel stents represents a feasible and efficient solution. Moreover, it offers a solution for those anatomies where Y-stenting is not a suitable solution as in recurrent branch anatomies like in the cases presented in this report (FIGURE 1, 2 and 3). Being a nitinol self-expandable, closed-cell laser cut microstent Barrel device is definitely less thrombogenic then braided stents that can be used for Y-stenting configuration. In our experience Y-stenting demands higher technical skills and prolonged duration of treatment and from this point of view the solution to protect the both side branches of an WBNA with only one stent is more elegant and particularly less susceptible to per-operative thromboembolic complications. Several particular anatomical conditions are feasible for this technique: a dome to neck ratio below 1,5; branches incorporated at the neck level usually with a smaller diameter (not suitable for stent deployment); poly-lobed bifurcation aneurysms; and asymmetry between the aneurysm plan and the bifurcation plan.

From a technical point of view, one of the main advantages over Y-stenting is represented by the fact that the stent micro-catheter (0.021-inch internal diameter) Rebar 18 in our cases, has to be placed only once at the level of desired branch and no re-catheterization of the stent and second stent placement is needed.

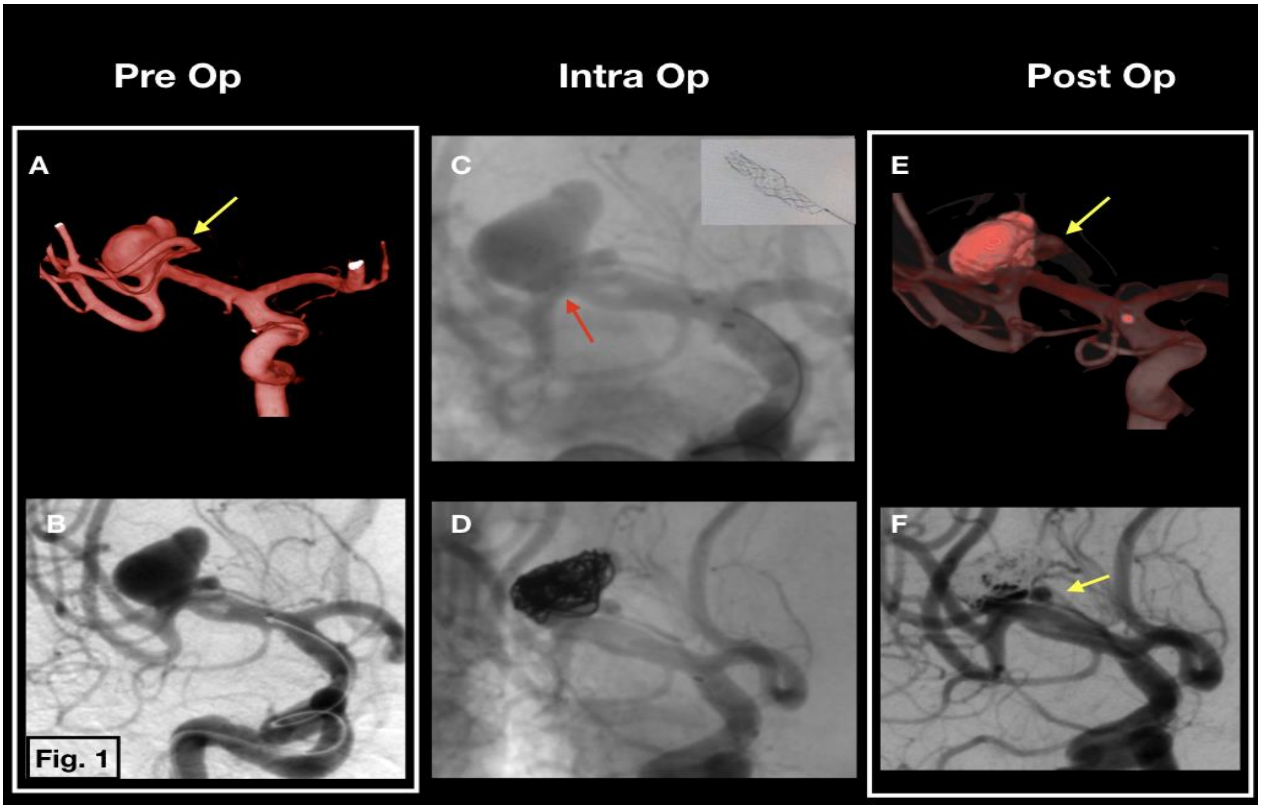

FIGURE 1. Right MCA bifurcation non-ruptured aneurysm with superior division of MCA arising from the neck level (yellow arrow). Barrel VRD was deployed in the inferior branch of the inferior division, the red arrow on Intra OP middle row (upper) indicates the radio-opaque markers protruding below the aneurysm neck. Post-Op pictures are demonstrating total occlusion of the aneurism sac and patency of the superior division of MCA.

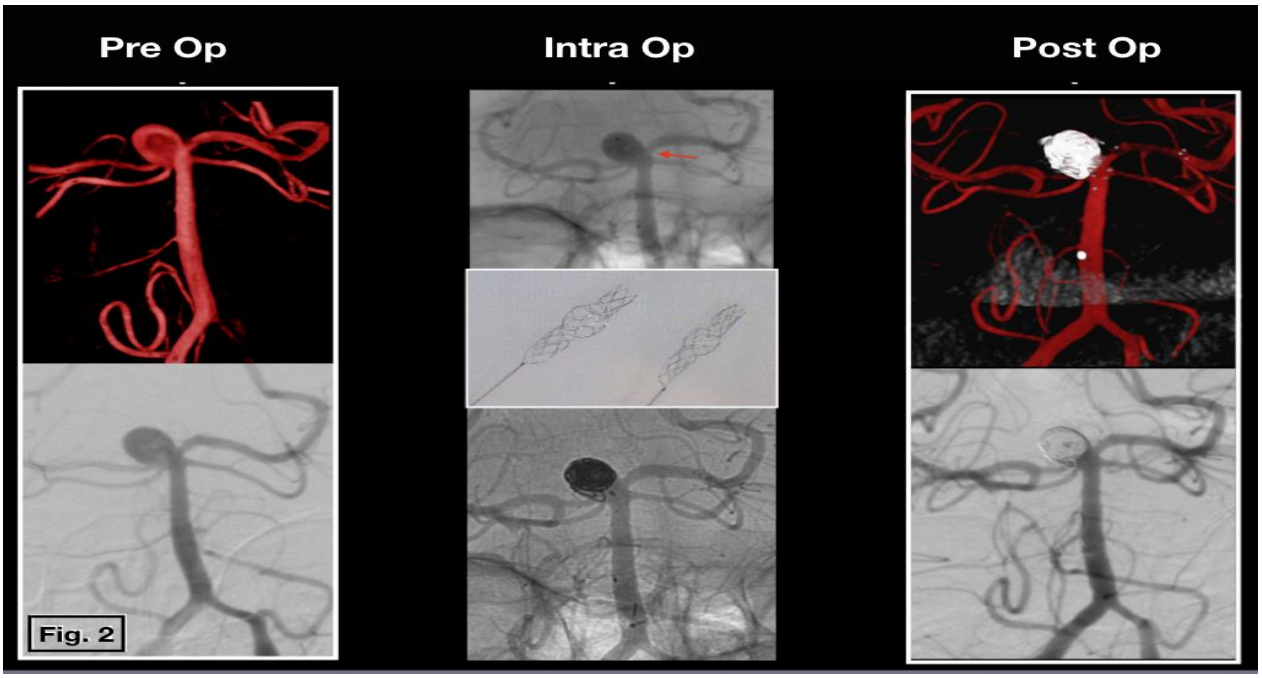

FIGURE 2. Basilar tip non-ruptured aneurysm with both PCA's arising from the neck level; Barrel VRD was deployed between the P1-P2 segment of left PCA and the middle third of basilar artery. Post-Op pictures (3DRA and subtracted 2D images) are demonstrating total occlusion of the aneurism sac and patency of the both PCA's and SCA's arteries.

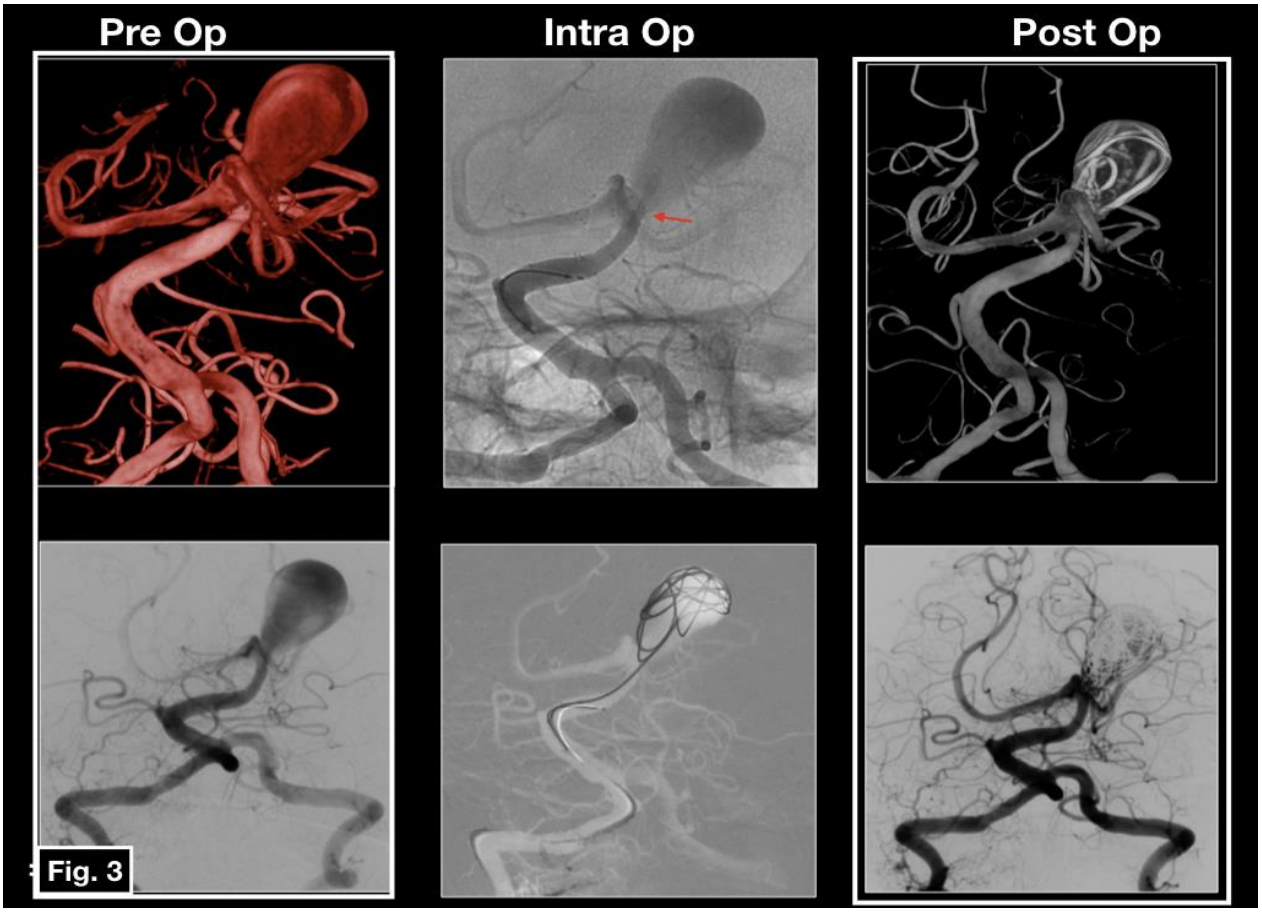

Fig 3. Giant basilar tip non-ruptured aneurysm with both PCA's arising from the neck level; Barrel VRD was deployed between the P1 segment of right PCA and the middle third of basilar artery. Red arrow indicating adequate apposition of the "belly" of the stent at the neck level with protection of both origins of PCA's. Post-Op pictures (3DRA and subtracted 2D images) are demonstrating adequate occlusion of the aneurism sac and patency of the both PCA's and SCA's arteries.

There is high visibility of the markers and positioning of the "barrel" at the neck level is clearly controlled under Road Map in conjunction with non-subtracted fluoroscopy (FIGURE 1 and 3; Intra-Op – middle row, upper image). In the same time the operator has to be aware that in angulated anatomies the stent positioning can be challenging and it requires re-shiting of the stent. Is always preferable the more distal start of deploying than more proximal one. In this way we adjusted permanently the "barrel" part till the best matching with the neck is achieved. In all cases the stent has been detached once the deployment was proper and in the second time micro-catheterism through the stent struts was done without any technical difficulties with an 0,017 coiling microcatheter (Echelon 10/Medtronic,USA) . Coiling of the aneurysm sac was achieved using coils that were 1 mm smaller than aneurysm maximal diameter. This strategy allowed safe coiling of the sac and also avoided the micro-catheter expulsion from the aneurysm. In the current study, the initial immediate angiographic result was complete occlusion in all cases, and no recanalization occurred during follow-up. We found that this type of technique is useful in cases of asymmetrical WNBA, in which a WEB device is not a feasible solution and is less challenging than Y-stenting technique. In the same time, we are aware of the strong limitation of our small number of aneurysms treated by this technique and certainly further prospective studies comparing this technique with Y-stenting or WEB technique is needed in order to quantify the potential complication rates, long term angiographic outcomes.

CONCLUSION

WNBA remains challenging to endovascular treatment, although new devices that are dedicated

to this type of anatomy are available. Barrel stent seems to be a promising device and difficult anatomies where Y-stenting or WEB device were only technical solution are now suitable for this technique. Main advantage of the device is the possibility to protect complex bifurcations or even trifurcations and branches incorporated at the neck level. However, further study using this technique in a prospective study with a large population and a long follow-up period is warranted.

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Competing interests statement

No Competing Interests to declare.

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