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# The “Y”-configuration of double Neuroform Atlas assisted coil embolization for treatment of cerebral bifurcation wide-neck aneurysms: very long-term follow-up of a multicentric experience

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## Abstract

**Aim:** Endovascular treatment of cerebral bifurcation wide-neck aneurysms remains a therapeutic challenge in terms of safety profile and timely treatment efficacy. The aim of this study is to investigate the very long-term efficacy and safety of Y stenting-assisted coiling with Neuroform Atlas in the treatment of wide-neck bifurcation aneurysms.

**Methods:** Clinical, procedural and follow-up data were analyzed to evaluate the safety and effectiveness of the treatment with Y-stenting assisted coil strategy (with Neuroform Atlas) in wide-neck bifurcation aneurysms. Endovascular technical aspects were also investigated. Morbidity and mortality were recorded. Digital subtraction angiography (DSA) for mid-term follow-up (12-15 months) and MR-angiography (MRA) for long-term follow-up (24-36 months) and very long-term follow-up (48-60 months) were evaluated in order to assess the efficacy.



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**Results:** The study included 21 Patients (12 Females, 9 Males) aged between 41 and 78 years, with a median age of 60 years. Of the aneurysms treated, 6 belonged to the middle cerebral artery bifurcation (MCA) (28.6%), 10 to the anterior communicating artery (ACoMA) (47.6%) and 5 to the basilar artery tip (BA) (23.8%). The median aneurysm size and dome/neck ratio were 5 and 1.2 mm, respectively. Technical success was achieved in all 21 cases (100%). No complication related to stent placement was observed. The morbidity rate was 9.5% (2/21) procedure-related; 1 case of intra-procedural SAH and 1 post-procedural stroke were observed. No death was observed. Mid-term DSA, according to the modified Raymond-Roy Occlusion Classification (RROC), showed 16 Class I (76.2%), 4 II (19%), and 1 IIIa (4.8%). Long-term MRA follow-up (24-36 months) showed aneurysm complete occlusion (CO) in 17 cases (80.9%) and residual neck (NR) in 4 cases (19.1%). Very long-term MRA follow-up (48-60 months) confirmed the same rate of occlusion (CO 80.9%; NR 19.1%). Long-term and very long-term MRA follow-up showed vessels' patency in all cases (100%).

**Conclusion:** Y-stenting-assisted coil embolization represents a safe and effective technique demonstrating an adequate rate of aneurysm occlusion at long-term follow-up and very long-term follow-up.

**Keywords:** Brain aneurysm, Y-stenting, Neuroform Atlas, endovascular treatment, wide-neck aneurysm, bifurcation aneurysm.

## INTRODUCTION

Despite the technological advancements made in recent years, endovascular treatments of wide-neck bifurcation aneurysms still represent a challenge both in relation to the procedural success rate and the long-term result<sup>[1,2]</sup>. Wide-neck aneurysms are characterized by a neck size of  $\geq 4$  mm and/or a dome-to-neck ratio of  $\leq 2$ <sup>[3]</sup>.

The technical success rate, the risk of complete failure or incomplete occlusion of the aneurysm is not only related to the size, morphology and location of the aneurysm but also to the anatomical configuration of the bifurcation (i.e., basilar artery, anterior communicating artery, middle cerebral artery)<sup>[4]</sup>.

Many endovascular techniques, other than coiling, have been reported for the treatment of wide-neck bifurcation aneurysms, including balloon-assisted coiling, stent-assisted coiling, intrasaccular devices and flow diverter devices (FDD).

Balloon remodeling (or balloon-assisted coiling) includes the use of a hyper-compliant balloon that covers the aneurysm neck or two balloons in the two branches of the bifurcation ("kissing balloon technique") or a balloon parallel the neck (for example, from A1 to M1 via the anterior communicating artery for ICA terminus aneurysms)<sup>[4]</sup>. Intrasaccular devices are positioned inside the aneurysm in order to disrupt the flow inside the sac and achieve occlusion<sup>[4]</sup>.

The FDD disrupts and modifies the flow inside the aneurysm, consequently leading to intrasaccular thrombosis and aneurysmal shrinkage<sup>[5]</sup>.

Since their appearance in clinical practice, the indications for FDDs have been extended in terms of location, ruptured status, and aneurysm subtype<sup>[6-11]</sup>.

The FDDs have been proven to be feasible in the proximal anterior and posterior circulation aneurysms, while the indications for distal circulation aneurysms are still under debate.

The flow diverter stent is another therapeutic option for wide-neck bifurcation aneurysms: in these cases, it is important to note that the neck of the aneurysm may be only partially covered and that one of the two branches will be covered from the stent<sup>[4,10,12]</sup>.

Stent-assisted coiling technique, frequently used in the treatment of unruptured aneurysms, is based on the use of different types of stents and includes the “Y-stenting configuration” technique and the “Waffle-cone” technique. In the latter, the distal extremity of the stent (usually with a “flower petal” shape) is open in the aneurysm (along the neck), while the proximal portion is in the parent vessel. Following the stent opening, the microcatheter crossing the distal edge for coiling and the “petals” prevents coils’ protrusion<sup>[4,13]</sup>. In addition, “stent-assisted coiling technique” includes the use of one (or two) stent(s) that is (are) opened between the parent vessel and one (or two) branch(es) of the bifurcation to cover the neck. In particular, when the aneurysm is centered on the bifurcation, it is useful to position two stents in the branches of the bifurcation (“Y-shape”) in order to prevent coil protrusion and protect the branches<sup>[4,14-17]</sup>.

Intracranial self-expandable stents with open or closed-cell fashion provide procedural advantages: (i) are feasible both in proximal, distal and non-homogeneous diameter branches; (ii) form a bridge across aneurysmal neck; and (iii) allow a more stable packing of coils during embolization<sup>[14,18-20]</sup>.

In this setting, Neuroform Atlas (NA) (Stryker Neurovascular, Fremont, CA, USA), a nitinol, intracranial, self-expanding open-cell stent, is a useful device that is associated with good aneurysm occlusion rate and preservation of parent artery patency<sup>[21-26]</sup>.

The main concern regarding stent-assisted coiling is the risk of recanalization. Unlike treatment with FDD, in which the aneurysm cannot regrowth or recur once it is occluded, the risk of recanalization with Y stenting-assisted coiling persists theoretically even years after the procedure.

In this setting, data regarding the efficacy of the Y stenting-assisted coiling from very long-term FUP are lacking.

The study aims to assess the safety and efficacy of the “Y-stenting configuration” technique with double NA in the treatment of wide-neck bifurcation aneurysms with very long-term follow-up.

## METHODS

### Study design

Between January 2017 and December 2017, a total of 21 consecutive patients (with ages between 41 and 78 years and a median age of 60 years) with brain bifurcation aneurysms were treated via implantation of double Neuroform Atlas stents in Y-configuration and detachable platinum coils in four experienced neuro-interventional centers.

A retrospective review of prospective collected clinical, demographic, angiographic and follow-up data was conducted on patients with brain aneurysms treated with stent-assisted coiling.

Specifically, inclusion criteria were: (i) stent-assisted coiling technique and implantation of (ii) double (iii) NA stents in “Y-stenting configuration” with (iv) availability of clinical and imaging follow-up of at least at 48-60 months (5 years).

Before the treatment, all patients underwent cerebral digital subtraction angiography (DSA) and three-dimensional reconstructions (3D-DSA) to evaluate aneurysmal sac and bifurcation branches. The largest aneurysmal diameter was measured in millimeters and aneurysms were classified according to the ISUIA study as small (< 7 mm), medium (7-12 mm), large (> 12 to 24 mm), and giant (> 25 mm)<sup>[26]</sup>.

Wide-neck aneurysms were defined as having a neck size of 4 mm and/or a dome-to-neck ratio of 2.

Intraprocedural, peri-procedural (0-30 days after the procedure), and delayed complication (from 30 days after the procedure) were recorded. In particular, morbidity was evaluated based on mild adverse events without sequelae and severe adverse events with permanent disability. Adverse events without clinical relevance were also collected.

Two interventional neuroradiologists (N.B. and V.S.) with 25 years and 11 years of experience, respectively, performed imaging follow-up evaluations according to the following scheme.

Mid-term follow-up (at 12-15 months) was assessed with DSA and angiographic occlusion was classified according to the Modified Raymond-Roy Occlusion Classification (RROC): class I (complete occlusion), class II (residual neck) and class IIIa and IIIb (residual aneurysm with a) contrast within coil interstices; b) contrast along aneurysm wall)<sup>[20]</sup>.

Long-term FUP (24-36) and very long-term FUP (48-60 months) were assessed with MRA (using time-of-flight sequence and contrast-enhanced angiography). The aneurysms were classified as complete occlusion (CO), neck remnant (NR) (occlusion > 90%, small neck remnant or “dog ear”) and partial occlusion (PO) (contrast medium - filling of the aneurysm lumen).

## RESULTS

### Aneurysm characteristics [Table 1]

We included 19 unruptured (UA) and 2 ruptured (RA) wide-neck saccular bifurcation aneurysms. The majority of them (76.2%) belong to the anterior circulation, while the rest (23.8%) belong to the posterior circulation. 6 were located at the middle cerebral artery bifurcation (MCA) (28.6%) [Figure 1], 10 on the anterior communicating artery (AComA) (47.6%) [Figure 2] and 5 at the basilar artery apex (BA) (23.8%) [Figure 3].

Within the study group, 14 aneurysms were classified as small, 5 as medium and 2 as large. The median average size of all aneurysms was 5 mm (range 3-18). The median neck size was 4.2 mm (range 2.5-8 mm) and the median dome/neck ratio was 1.2.

### Endovascular procedure

All endovascular treatments were performed under general anesthesia and via the femoral approach. Triaxial system (8F long introducer, 6F intermediate catheter and two 0.0165” microcatheters) was used in 13 procedures while, in 8 cases, coaxial system (6F guiding catheter with two 0.0165” microcatheters) was adopted.

The dimensions of the NA stent were calculated based on the chosen “landing” area by measuring (on the 3D angiographic image) the proximal caliber of the parent vessel and the distal caliber of the bifurcation branch.

**Table 1. Patients ages, aneurysms' characteristics, location**

Patients	21
Sex (male)	9 (42.8%)
Age (mean) [range]	60 yo (41-78 yo)
Aneurysm	21
Ruptured	2 (9.5%)
Unruptured	19 (90.5%)
Morphology	21 saccular (100%)
Location	6 (28.6%) MCA 10 (47.6%) AcomA 5 (23.8%) BA
Dimension	14 small (66.7%) 5 medium (23.8%) 2 large (9.5%)
Median average size	5 mm (range 3-18mm)
Median neck size	4.2mm (range 2.5-8mm)
Median dome/neck ratio	1.2

MCA: Middle cerebral artery; AComA: anterior communicating artery. BA: basilar artery apex.

First, a microcatheter was brought into the aneurysmal sac for embolization with “jailing” technique. The other microcatheter is used to deploy the first stent (parent artery - first bifurcation branch); the microcatheter was delivered inside the second bifurcation branch through the mesh of the first stent. Subsequently, the second stent was deployed (parent artery - second bifurcation branch) in order to reach the Y configuration (proximal extremities landing inside the first stent), restore the physiological bifurcation anatomy and cover aneurysmal neck. Finally, detachable platinum coils were released in the aneurysmal sac with “jailing” technique. In none of the included cases, we re-catheterize the sac because the initial position of the “jailed” microcatheter was stable for coiling.

### Pharmacological management

Patients with unruptured aneurysms received double antiplatelet therapy with acetylsalicylic acid (100 mg/day) and clopidogrel (75 mg/day) starting 7 days before the treatment. During procedures, anticoagulation was provided using intravenous administration of heparin 50 U/kg with close monitoring of blood activated clotting time (ACT): the ACT level was above 250 s.

In the two cases of ruptured aneurysms, patients received intravenous lysine acetylsalicylate (250 mg) during the release of the first stent. During positioning of the first coil (after opening the second stent), patients received glycoprotein IIb/IIIa inhibitors with an infusion rate of 0.4 mg/kg/min for the first thirty minutes and a maintenance rate of 0.1 mg/kg/min for the next twelve hours. If the brain CT scan after twelve hours was negative for new hemorrhage, double antiplatelet therapy was started with acetylsalicylic acid (100 mg) and a loading dose of clopidogrel (300 mg); subsequently, patients continued therapy with acetylsalicylic acid (100 mg/day) and clopidogrel (75 mg/day).

After a brain MRI at 3 months, in the absence of complications (ischemic or hemorrhagic), all patients discontinued clopidogrel and continued to take single antiplatelet therapy for at least another 6 months.

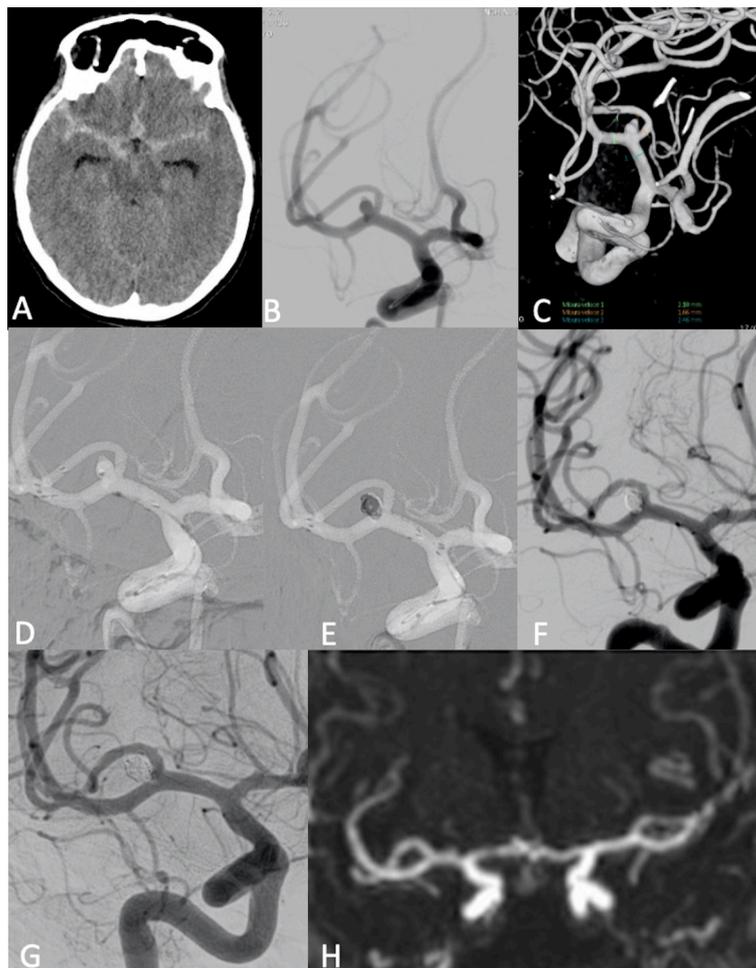
### Safety [Table 2]

The overall morbidity rate was 9.5% (2/21). In our series, we observed a single ischemic complication and a single hemorrhagic complication in two different patients. In a case of unruptured AcomA aneurysm (number 11; small aneurysm), the patient had localized subarachnoid bleeding due to microcatheter

**Table 2. Patients follow-up**

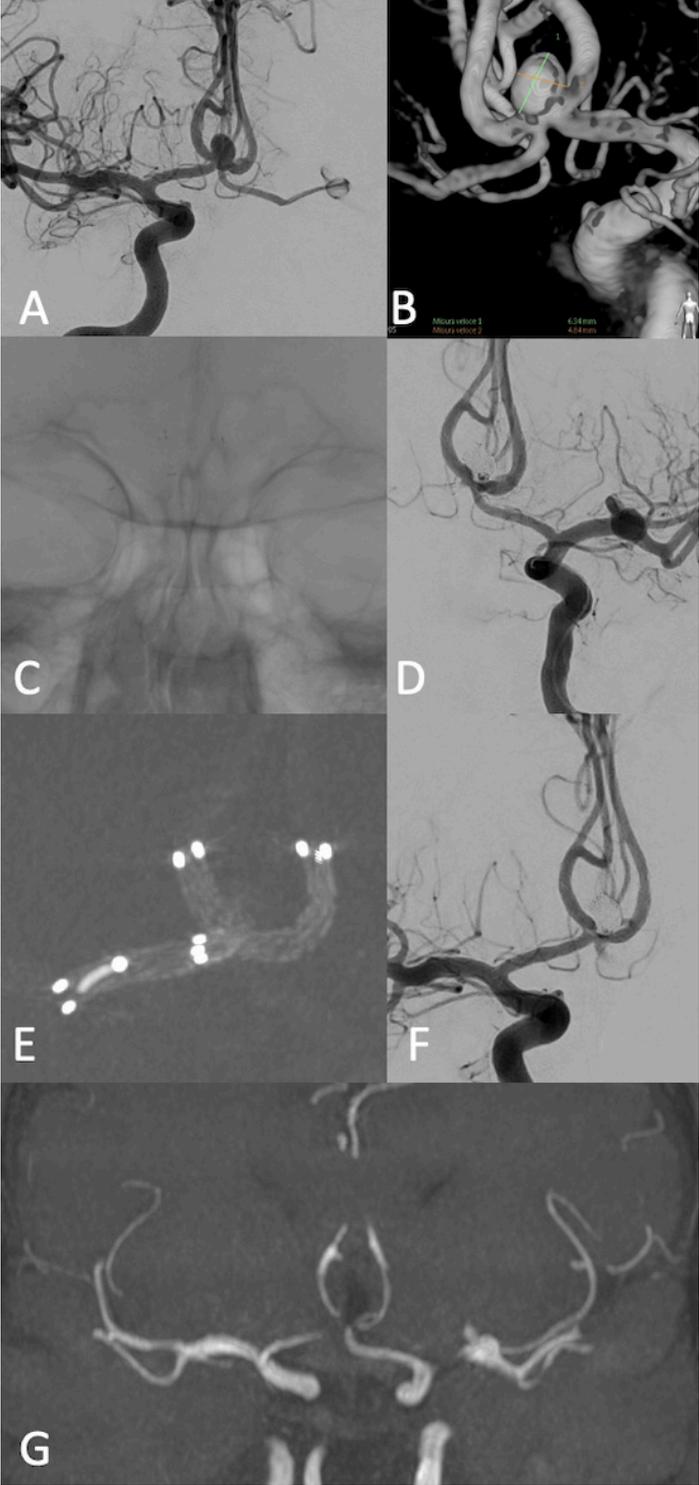
Final procedural DSA (RROC)	20 Class I (95.2%) 1 Class II (4.8%)
Mid term follow-up with DSA (12-15 months)	16 Class I (76.2%) 4 Class II (19%) 1 Class IIIa (4.8%)
Long term follow-up (24-36 months) with MRA	17 CO (80.9%) NR 4 (19.1%)
Very long term follow-up (48-60 months) with MRA	17 CO (80.9%) NR 4 (19.1%)

DSA: Digital subtraction angiography; RROC: raymond-ROY OCCLUSION CLASSIFICATION; CO: complete occlusion; NR: neck remnant; MRA: MR-angiography.



**Figure 1.** Female, 40 y.o., with subarachnoid hemorrhage (HH1, GCS 14, Fischer 2, WFNS 5) and right MCA bifurcation small ruptured aneurysm. (A) CT demonstrated diffuse SAH. (B) Diagnostic angiography and (C) 3D reconstruction better disclosed the morphology of the MCA ruptured aneurysm. (D) Coil-microcatheter was positioned inside the sac and then two NA stents were deployed in the two M2 branches. (E and F) Final angiograms showed the complete occlusion of the aneurysm. (G) 12-month DSA showed complete occlusion which was confirmed at (H) very long-term MR FUP (50 months).

perforation during coils placement (specifically, first coil): he experienced a headache for 10 days and required an extension of hospitalization (seven more days) with a Modified Rankin Scale (mRS) 1 at discharge and an mRS 0 at follow-up (both at 12 and 24 months). In another case of unruptured Acoma



**Figure 2.** Female, 60 y.o., with an asymptomatic AcomA wide-neck aneurysm. (A) Diagnostic angiography and (B) 3D reconstruction demonstrated the aneurysm. (C) Two NA stents were deployed in the right A1-A2 branches with a Y configuration and then (D) coils were released inside the aneurysmal sac. (E) XperCT better showed the Y configuration of the two stents. (F) 12-months DSA showed complete occlusion which was confirmed at (G) very long-term MR FUP (48 months).



**Figure 3.** Female, 70 y.o., with an asymptomatic BA wide-neck aneurysm. (A) Diagnostic angiography. (B) Two NA stents were deployed in the basilar artery - posterior cerebral arteries with a Y configuration and assisted coiling was then performed. (C and D) 12-month DSA showed complete occlusion which was confirmed at (E and F) very long-term MR FUP (48 months).

aneurysm (number 18; small aneurysm), the patient developed acute right hemiparesis ten days after the treatment: MRI showed ischemia in the left precentral gyrus although the next urgent DSA demonstrated patency of the stents. This patient was discharged with an mRS 3, while at the next follow-up (both at 12, 24 and 48 months), he had an mRS 1. In our series, based on a very long follow-up of up to 48-60 months, we do not record any treatment-related deaths.

#### **Efficacy data [Table 3]**

In all 21 patients, successful stent deployment in Y configuration was achieved. At the end of the procedure, the complete occlusion of the aneurysmal sac was achieved in 20 cases (95.2%), while in 1 case, a small neck remnant was left (4.8%). Mid-term FUP with DSA documented 16 Class I (76.2%), 4 Class II (19%), and 1 Class IIIa (4.8%), according to RROC. No cases of intra-stent stenosis or thrombosis were reported.

Long-term MRA follow-up (24-36 months) showed aneurysm CO in 17 cases (80.9%) and NR in 4 cases (19.1%). Very long-term MRA follow-up (48-60 months) confirmed these data (CO 80.9%; NR 19.1%). No occlusion of stents or intra-stent stenosis was recorded at the long-term and very long-term MRA follow-up.

**Table 3. Safety and complication**

Overall	Mortality 0/21 (0%) Morbidity 2/21 (9.5%)
Location-Morbidity	MCA 0/21 (0%) AComA 2/21 (9.5%) BA 0/21 (0%)
Type of complication	1/21 Ischemic (MAE) 1/21 hemorrhagic (MAE)

MCA: Middle cerebral artery; AComA: anterior communicating artery; BA: basilar artery apex; MAE: mild adverse events without sequelae.

## DISCUSSION

Despite considerable advances in the endovascular strategies for cerebral aneurysms, the treatment of wide-neck bifurcation aneurysms remains a challenge, given the difficulty in terms of safety and efficacy. Treatment options for wide-neck bifurcation aneurysms are multiple: coiling, remodeling, stent-assisted coiling, intrasaccular flow disruption devices, or FDDs. The latter work on the diversion of flow across the wide neck in order to achieve the exclusion of the aneurysmal sac from the circulation; conversely, in the other endovascular treatments, the occlusion of the aneurysm is obtained by deposition of endovascular “materials” inside the sac.

Therefore, the main concerns regarding wide-neck bifurcation aneurysms are related to the necessity to obtain the complete occlusion and durable occlusion of the sac with the preservation of the parent artery and the bifurcation branches (especially when they arise from the neck)<sup>[2,4,22]</sup>. The use of two self-expandable neurovascular stents in a “Y” configuration, combined with coil embolization, has already been demonstrated to be a safe and effective strategy for this type of aneurysm<sup>[23-25,27]</sup>.

Compared to the single stent-assisted coiling or balloon-assisted coiling, the “Y” configuration reduces the risk of contralateral bifurcation branch exclusion and/or occlusion<sup>[28]</sup>, allows anatomy reconstruction of the bifurcation and forms a more stable scaffold for subsequent coils embolization. In addition, “Y” stent configuration provides partial flow redirection in the bifurcation branches<sup>[23]</sup> and aids healing of the aneurysm by providing scaffolding for the endothelialization along the neck of the aneurysm<sup>[17,23,29]</sup>. In “Y” configuration, both closed-cell and open-cell stents, which are associated with coils embolization, enable a safe coil packing with a low risk of protrusion<sup>[19]</sup>. Compared to closed-cell stents, open-cell stents, such as NA, are more adaptable stents in unfavorable anatomies and in non-uniform diameters and allow easier placement of the second stent<sup>[20,25,27,30]</sup>.

An important procedural risk is the occlusion of a bifurcation branch due to inadequate opening of the contralateral stent. In our opinion, it is useful to place the first stent between the main artery and the most challenging bifurcation branch for catheterization in order to have, then, a more favorable anatomy to pass through the meshes and open the second stent<sup>[26,31]</sup>.

In our series, technical success (opening stents and coiling) was obtained in 100% of patients with an occlusion rate (RROC class I/II) of 95.2% at the end of the procedure. Mid-term FUP shows an occlusion rate of 76.2% (RROC class I/II). These results are almost comparable with the other series previously reported. Very long-term MRI follow-up (48-60 months) showed complete occlusion in 80.9% of cases and neck remnant in 19.1% of cases. Interestingly, the occlusion rates increased over time. This result could be explained by the flow diversion effect<sup>[23]</sup> and the scaffolding support for the endothelialization induced by the Y-stenting configuration<sup>[17,29]</sup>.

Few studies assessed the efficacy and the safety of Y-stent-assisted coil in the treatment of wide-neck bifurcation aneurysms. However, data from the very long-term FUP are missing.

Ciccio *et al.* report a complete obliteration/residual neck (RROC class I/II) in 74.5% (41/55 patients) to final DSA after treatment with an occlusion rate at FUP (mean duration 16 months) of 94.7% of 38 patients available at the FUP<sup>[25]</sup>.

Ten Brinck *et al.* analyzed a series of 27 consecutive patients who were treated with 37 Neuroform Atlas stents (62.9% treated with SAC and 37% with Y-stenting)<sup>[32]</sup>. Overall, they described RROC class I/II in 69.2% at six months follow-ups. In a series of 473 patients, Kim *et al.* observed 3.2% (15 patients) with wide-necked bifurcation aneurysms treated with Y-stent-assisted coiling and two NA stents<sup>[33]</sup>. In the final DSA after treatment, complete occlusion was obtained in 46.7%, neck remnant in 13.3%, and incomplete occlusion in 40% of cases. At follow-up (with DSA), complete occlusion was observed in 73.3%, neck remnant in 6.7%, and incomplete occlusion in 20%<sup>[33]</sup>.

In our series, we reported a morbidity rate of 9.5% (2/21), all related to the treatment. Specifically, one with an aneurysm perforation during coiling of the sac and one pre-rolandic ischemia occurred 10 days after the procedure.

In the literature, the adverse events rates range from 2% to 25% in patients treated with Y-stenting with NA<sup>[29]</sup>.

Bartolini *et al.*, in their experience of 105 aneurysms treated with Y and X SAC, report permanent neurological deficit in 10%<sup>[15]</sup>, while Ciccio *et al.*, on the other hand, assess a 12.7% of symptomatic complications (7/55 patients), including 2 cases (3.6%) of permanent neurological handicaps<sup>[25]</sup>. Aydin *et al.* treated 30 aneurysms with NA Y stenting and reported complications in 6.7% of cases, resulting in permanent morbidity in 3.3% of patients<sup>[34]</sup>.

In the “multi-centric European post-market follow-up study of the Neuroform Atlas Stent System” (ATLAS EU PMCF)<sup>[34]</sup>, 19/106 patients were treated with Y-stenting assisted coiling. Aneurysm occlusion was achieved in 95.1% at the end of the procedure and reached 98.9% at the 12 months FUP. In the 12-month follow-up, they observed 1% of major stroke (1/102 patients). Moreover, 3% (3/102 patients) of minor strokes resulted in an mRS of 2<sup>[35]</sup>.

### Limitations of study

The limitations of this study are its retrospective design, the non-randomized nature, and the small number of patients. Another limitation regards the small number of large and giant wide-neck aneurysms that were treated, which are known to present a higher risk of recanalization.

In Conclusions, Y reconstruction-assisted coil embolization with two open-cell NA stents represents a safe and effective therapeutic approach for the treatment of wide-neck bifurcation aneurysms, being applicable even in difficult arterial anatomic configurations with good preservation of parent vessels patency and being associated with a high rate of aneurysm occlusion. Moreover, based on our very long-term follow-up (48-60 months), we found that Y-stenting-assisted coil embolization demonstrated an adequate rate of aneurysm occlusion at long-term follow-up that is almost stable at the very long-term follow-up.

## DECLARATIONS

### Authors' contributions

Contributed to the conception of the work: Semeraro V, Lozupone E, Vidali S

Have drafted the work: Ganimede MP, Marrazzo A

Have made contributions to the acquisition and analysis of data: Pedicelli A, Alexandre A, Lauretti DL, Palmisano V, dalla Malva G

Performed data interpretation: Di Stasi C, Burdi N, Gandini R

Revised the work: Lozupone E

### Availability of data and materials

Not applicable.

### Financial support and sponsorship

None.

### Conflicts of interest

All authors declared that there are no conflicts of interest.

### Ethical approval and consent to participate

All procedures performed were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. Patient written informed consent was acquired before each procedure. Ethical committee approval of a retrospective study was acquired.

### Consent for publication

Not applicable.

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