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Double Stent-Assisted (Y and X) Coil Embolization of Unruptured Intracranial Saccular Aneurysms using the Low-Profile Visualized Intraluminal Support Device—Single Center Experience

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Abstract

Purpose—To study the feasibility, safety, and durability of the dual stent-assisted coil embolization (DSCE) technique using low-profile visualized intraluminal support (LVIS) device.

Methods—Retrospective review of our aneurysm database to identify all the patients treated with LVIS stent-assisted embolization between July 2015 and June 2017 was performed. 15% of the patients with Y- or X-configuration DSCE constituted the study population. Patient demographics, clinical presentation, aneurysm characteristics (location, dome, and dome/neck ratio), periprocedural complications, immediate and follow-up angiographic and clinical outcomes were reported.

Results—Twelve patients (15%) with unruptured, wide-necked branching aneurysms underwent DSCE using LVIS Junior stents. M:F—1:11. Mean age of 60 ± 11 years. 75% (n = 9) aneurysms are located in anterior circulation. Recurrent aneurysms were treated in 17% (n = 2). Mean aneurysm diameter was 8 ± 3.4 mm and the dome/neck ratio was 1.6 ± 0.4. Periprocedural complications were noted in 25% (n = 3; transient in-stent thrombus = 2 and iatrogenic rupture = 1) with no clinical sequelae. Immediate aneurysm obliteration following DSCE was noted in all (100%) patients. Mean time-of-flight (TOF) magnetic resonance angiography (MRA) follow-up was 10 ± 6 months (Range: 5–19 months). Mean clinical follow-up was 12 ± 6 months (Range: 5–21 months). Stable neck recurrence was demonstrated in 25% (n = 3). The average modified Rankin Score (mRS) at present, 24-hour poststent, and last clinical follow-up were: 0.5 (Range: 0–1), 0.75 (Range: 0–1), and 0.5 (Range: 0–1), respectively.

Conclusion—We report the first dedicated DSCE experience with LVIS Junior stents in the literature. DSCE with LVIS Junior stents for intracranial complex wide-neck branching aneurysms is feasible, safe, and effective with good clinical outcomes.

INTRODUCTION

Dual stent-assisted coil embolization (DSCE) in Y- or X-configuration was reported as an alternative technique to surgical clipping in the treatment of complex intracranial bifurcation aneurysms while maintaining the patency of branching arteries [1–3]. Since the initial reports of Y-configuration DSCE by Chow *et al.* [4] for a basilar termination aneurysm and by Sani and Lopes [5] for a middle cerebral artery bifurcation aneurysm, this technique has gained increasing acceptance for this particular subset of aneurysms. Recent retrospective multicenter DSCE experience reported low intraprocedural and periprocedural complications with a low incidence of retreatment and in-stent stenosis [1,2]. The current literature of DSCE technique is entirely based on the conventional stents of open-cell [1,2,4,6] (Neuroform; Stryker, Kalamazoo, Michigan) or closed-cell [1,2,7] (Enterprise; Codman Neurovascular, Ratham, Massachusetts) designs or combination of both [1,2]. However, the clinical experience and outcomes of this challenging technique with new generation intracranial stents is missing.

Low-profile visualized intraluminal support (LVIS; MicroVention, Tustin, CA, USA) is a new generation self-expanding braided stent device. It is cut from nitinol wire (0.056 mm), has improved radiopaque markers compared with the Enterprise and Neuroform stents, and is retrievable after up to 80% deployment. A smaller version (LVIS Jr.) is available which can be placed through a microcatheter with an inner diameter of

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0.0165 inch, which may facilitate stenting of aneurysms with smaller parent vessel diameters or creation of Y- and X-configuration stent constructs with easier navigation through the tines of a larger stent.

The purpose of this study is to determine the feasibility, safety, and short-term durability of the DSCE technique using LVIS Jr. device.

METHODS

Patient selection

The study is approved by the institutional review board (IRB) under the Humanitarian Device Exemption category. A retrospective review of aneurysm database was performed to identify 78 patients treated with LVIS stent-assisted embolization between July 2015 and June 2017. Consecutive patients who underwent DSCE for an intracranial aneurysm with a Y- or X-stent configuration constituted the study population. All patients signed an IRB approved consent form in addition to the clinical consent prior to the treatment.

Aneurysm and treatment characteristics

Aneurysm dimensions were measured on the 3D-rotational angiography reconstructed images. DSCE was deemed necessary in bifurcation aneurysms [1]: (1) when the origins of the branching arteries could not be preserved otherwise (including balloon assistance or single-stent placement); (2) when there was no identifiable aneurysm neck, and therefore, it was necessary to create a barrier for neck construction; and (3) when the aneurysm could not be packed fully otherwise and was likely to recur, particularly those of large size. Patient demographics, clinical presentation, aneurysm characteristics (size, location, dome, and dome/neck ratio), procedural details (number of stents and stent configuration), periprocedural complications, immediate and follow-up angiographic and clinical outcomes were reported.

Procedure technique

All procedures were performed under general anesthesia with GE biplane flat-panel angiography. Femoral access with a 6F sheath and cerebral access with 6F guide catheters were secured. During the procedure, a bolus injection of 50 IU/Kg of heparin was given and a further 1000 IU of heparin was administered per hour. Anticoagulation levels were monitored to maintain an activated clotting time 2–3 times of the baseline value. DSCE consists of deployment of two LVIS Jr. self-expanding, braided stents via 0.017-inch Headway microcatheter (MicroVention, Tustin, CA, USA), one in each branch coming off from the sac or neck of the broad-based bifurcation aneurysm. The first stent is positioned in the branch with relatively more challenging access, and the second stent is placed to pass through the interstices of the first stent, thus creating a new bifurcation point below the neck of the aneurysm. This results in redirecting the blood flow toward the relevant branches and obviates the risk of coil protrusion to the parent artery. Subsequent to the stent placements, a 0.010-inch microcatheter (SL-10, Boston Scientific, Fremont, CA) or a 0.014-inch microcatheter (MicroVention, Tustin, CA, USA) was navigated over 0.014-inch microwire into the aneurysm sac through the stents.

All patients had standard antiplatelet regimen including Aspirin 325 mg and Plavix 75 mg, and platelet inhibition was confirmed with ASA and P2Y12 assays prior to the procedure. If the patient had resistance to clopidogrel after use for 1 week or the second test showed that the patient was still a low responder, the antiaggregation medicine was switched to Prasugrel. After the control angiogram was obtained in the sixth month, clopidogrel was discontinued and acetylsalicylic acid was to be taken life-long.

Angiographic and clinical follow-up

The immediate angiographic outcome was evaluated based on the final digital subtraction angiography (DSA) obtained in the embolization projection. The follow-up angiographic outcome was evaluated on time-of-flight (TOF) magnetic resonance angiography (MRA) as a standard practice at 6 months and 18 months. TOF-MRA outcomes were categorized as 100%, >90%, and <90% occlusion. Patients with TOF-MRA findings of residual aneurysm filling (>90% and <90% occlusion) were clarified with DSA. Angiographic outcomes were assessed according to the modified Raymond—Ray classification. Clinical evaluation was based on modified Rankin Score (mRS) performed at prestent, 24-hours poststent, and last clinical follow-up. Good outcome was defined as an mRS of 0–1 and poor outcome as an mRS of >1. Considering our patient cohort is constituted by the unruptured aneurysms, good clinical outcome was confined to mRS 0–1.

RESULTS

Patient characteristics

Twelve patients with unruptured, wide-necked branching aneurysms underwent DSCE using LVIS Junior stents between July 2015 and June 2017. Predominantly female (92%; M:F—1:11) with a mean age of 60 ± 11 years. Aneurysms were located in both anterior (n = 9;

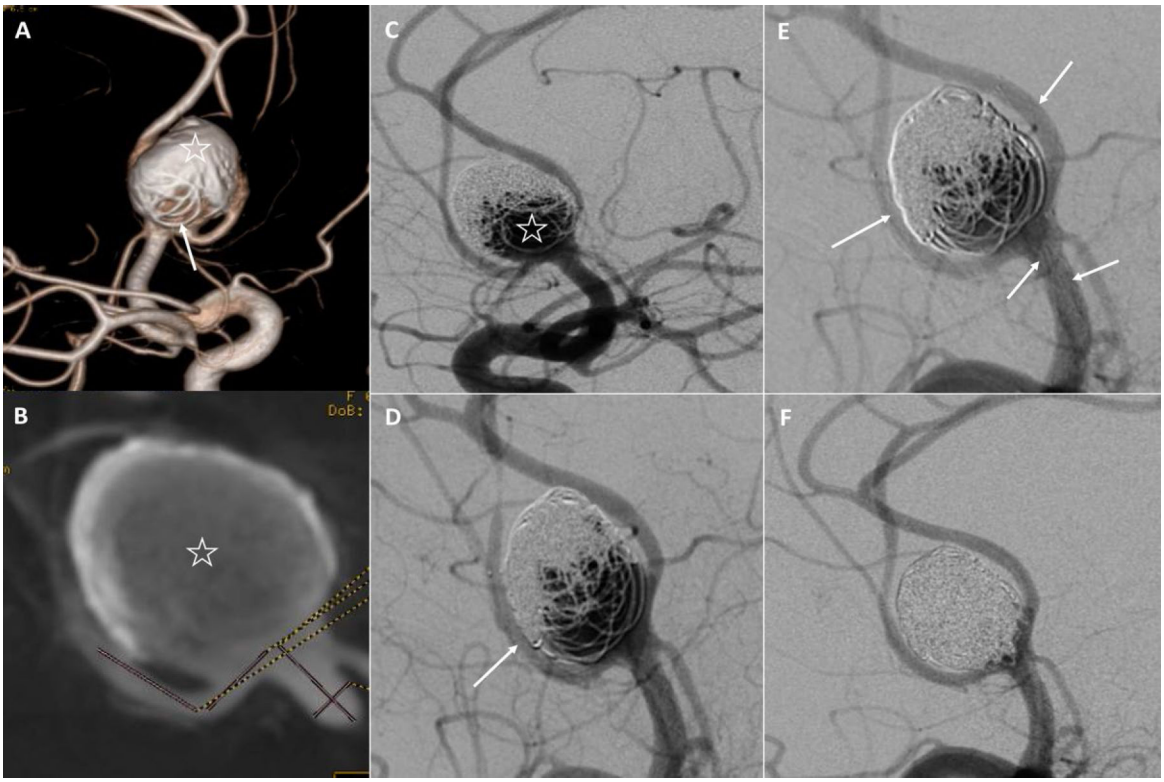

Figure 1. (A–C) Prior coil embolization (arrow) of anterior communicating artery aneurysm, presented with large recurrence (star); (D and E) Y-configuration stent embolization with two 2.5 mm × 17 mm LVIS Jr. stent extending into bilateral A2 segments and converging in dominant right A1. (F) Dome recurrence was accessed and embolized by "coil-through" technique and complete occlusion was achieved.

75%) and posterior (n = 3; 25%) circulation. Recurrent aneurysms were treated in 17% (n = 2) (Figure 1).

Aneurysm and treatment characteristics

Mean aneurysm diameter was 8 ± 3.4 mm (95% CI: 6.1–9.9 mm; Range: 4.4–13.5 mm) and the dome/neck ratio was 1.6 ± 0.4 (95% CI: 1.4–1.9; Range: 1.1–2.7). Y-configuration DSCE was noted in 92% (n = 11) aneurysms involving both anterior (Figure 2) and posterior circulation (Figure 3).

X-configuration DSCE was noted in a single patient with ACOM aneurysm (Figure 4).

Periprocedural complications were noted in 25% (n = 3; transient in-stent thrombus = 2 [Figure 5] and iatrogenic rupture with microcatheter = 1) (Figure 6) with no clinical sequelae.

Immediate aneurysm obliteration following DSCE was noted in all (100%) patients. Patient, aneurysm, and treatment characteristics are summarized in Table 1.

Angiographic and clinical follow-up

Mean angiographic follow-up with TOF-MRA was 10 ± 6 months (95% CI: 7–13 months; Range: 5–19 months). Mean clinical follow-up was 12 ± 6 months (95% CI: 9–16 months; Range: 5–21 months). Small neck recurrence (1.2–1.5 mm) was demonstrated in 25% (n = 3), confirmed on DSA, stable on follow-up MRA, and required no further treatment. The average mRS at prestent, 24-hour poststent, and last clinical follow-up were: 0.5 (Range: 0–2), 0.75 (Range: 0–2), and 0.5 (Range: 0–2), respectively. The angiographic and clinical follow-up data are summarized in Table 2.

DISCUSSION

The DSCE experience so far is largely confined to the conventional Neuroform (open-cell) [6] and Enterprise (closed-cell) [7] stents either independently or in combination [1,2]. Bartolini *et al.* [8] reported their experience in 90 DSCE patients including four patients with LVIS stents with no further details of this small subgroup. We report the first dedicated case series of DSCE with new

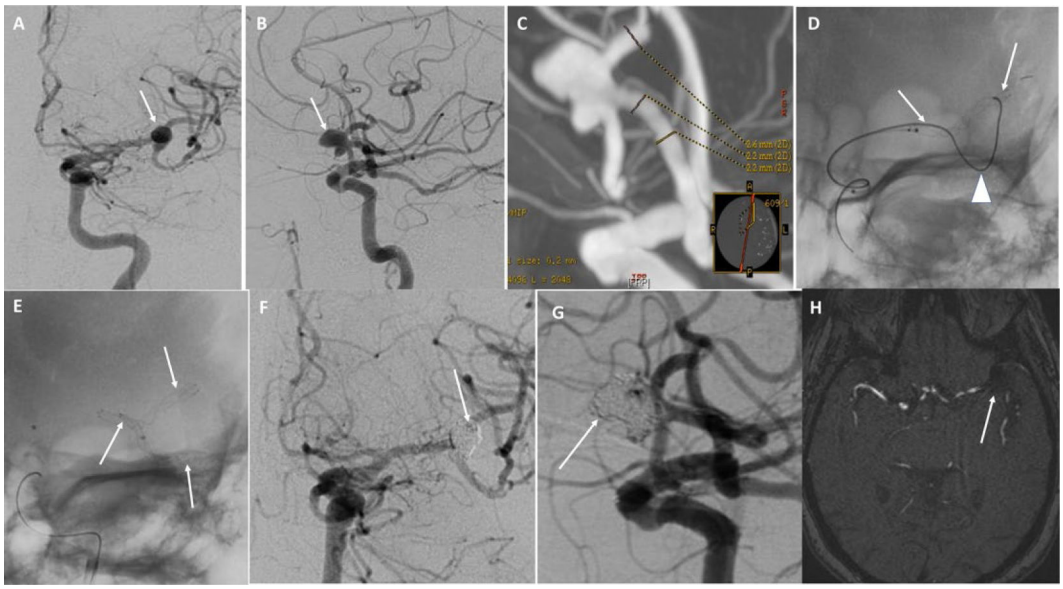

Figure 2. (A and B) Complex, wide-necked left middle cerebral artery (MCA) bifurcation aneurysm (arrows); (C) both the MCA branches are arising from the aneurysm neck; (D) 2.5 mm × 23 mm stent was deployed in to anterior division (arrows) and microwire was navigated in to the posterior division through the stent cells (arrowhead); (E) 2.5 mm × 17 mm LVIS Jr. stent was deployed in to MCA posterior division with a Y-configuration (arrows); (F and G) aneurysm embolization (arrows) using "coil-through" technique; (H) six-month TOF-MRA follow-up showing complete obliteration of aneurysm (arrow) with patent bifurcation branches.

generation braided LVIS Jr. stent devices. In our experience involving wide-necked bifurcation aneurysms of both anterior and posterior circulations, DSCE with LVIS Jr. stents is feasible, safe, and effective with no clinically significant adverse events.

LVIS Jr. stent is well visualized throughout its course compared with the Enterprise and Neuroform stents due to two radio-opaque helical strands. The three proximal and distal markers splay apart, demonstrating that the proximal and distal ends of the device are open. The two helical strands also spread into a double helix configuration, with alternating wall opposition visually on angiography. The stent can be deployed through a 0.0165-inch inner diameter microcatheter and is retrievable after up to 80% deployment, which facilitates stenting of aneurysms with smaller parent vessel diameters or creation of Y- or X-configuration stent constructs with easier navigation through the existing stent tines. The braided structure enables the stent strands to slide on each other, allowing catheterization through the interstices. The compliant small cell structure provides greater protection across the aneurysm neck and improved flow diversion compared with the currently available coil-assist stents.

DSCE is technically challenging and 10% failure rate is reported in the literature [8]. Understanding the principles of DSCE is vital to maximize the technical success. Selection of the branch to be catheterized first is extremely important for the success of the technique: (1) angle between the parent vessel and the branch vessel is the most important factor for decision-making; the one that has a sharper angle must be stented before the one with a wider angle and (2) orientation of the aneurysm neck; the side involved by the aneurysm neck for a wider segment should be stented first. Braided stents such as LVIS Jr. are prone to a characteristic deformation when the device is oversized compared to the parent artery, as commonly prescribed to prevent device migration [9]. This deformation impacts on local porosities, *in vitro* and *in vivo* [10], resulting in a transition zone (the more porous segment on each side of the compaction zone) and a compaction zone (the less porous middle segment). Crossing the first stent with a guidewire would naturally occur more easily through the transition zone, which offers pores of a larger size, and intuitively at least, would present fewer constraints to expansion of the second device. The bench-top studies to evaluate the Y-crossing of high porosity braided stents by Makoyeva *et al.* [9] at varying the angles of bifurcation (45°, 65°, and 90°) showed that deploying a second LVIS (Microvention, Tustin, CA, USA) stent through the first LVIS stent in a Y-configuration, whether through the compac-

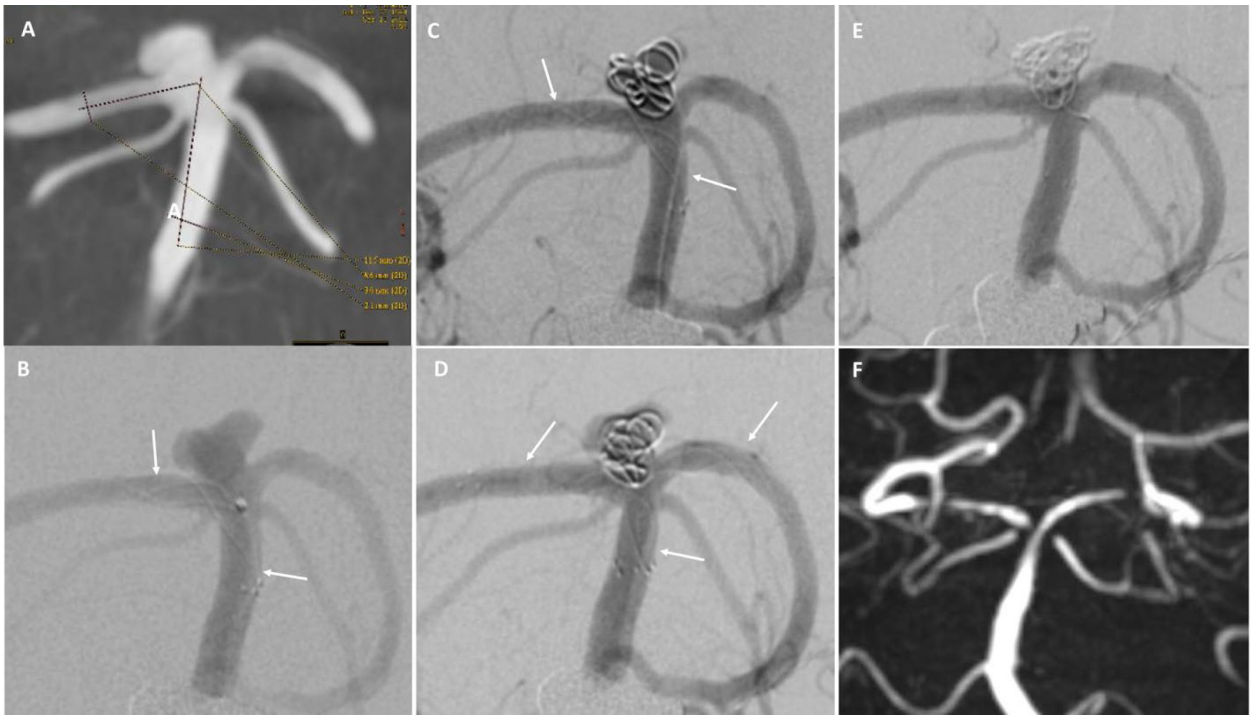

Figure 3. (A) Basilar termination aneurysm with dysplastic basilar apex involving bilateral posterior cerebral arteries (PCAs), right > left and right superior cerebellar artery; (B) single 3.5 mm × 18 mm LVIS Jr. deployed from right PCA in to basilar termination (arrows); (C) aneurysm embolization by "coil-through" technique showed protected right PCA by stent (arrows), but coil loops prolapsed coil loops towards the unprotected left PCA origin; (D) the coiling microcatheter was jailed and left PCA was stented with second 3.5 mm × 18 mm LVIS Jr. stent (arrows); (E) dome secured with coil embolization; (F) six-month follow-up MRA confirmed complete obliteration of the aneurysm.

tion or the transition zone, did not cause any significant stenosis (≥30%) at the point of crossing. Varying the parent vessel diameter while keeping the distal branch diameter constant at 2.5 mm demonstrated a proportional relationship between parent artery diameter and the diameter of the second device at the point of crossing. In our experience, DSCE technique with LVIS Jr. stents is 100% feasible for bifurcation aneurysms attributed to the combination of aneurysm selection, procedural approach, operator experience, and technological advancement. The decision of Y- or X-configuration is based on the aneurysm location and anatomic relation of the parent and branch vessels to the aneurysm.

Even with the optimal placement of both stents, the threat of thrombus formation and possible embolization is very real. The intraprocedural thrombus formation is well reported with the conventional Neuroform and Enterprise stents despite optimal platelet suppression with the dual antiplatelet regimen and full heparinization during the procedure [1,2,8]. In the series of 19 Y-stent-assisted coiling cases by Spiotta and colleagues [11], three intraprocedural (16%) and two delayed (11%) thromboembolic occurred. Chalouhi *et al.* [12] reported equivalent thromboembolic event rates (16%) Y-stent-assisted coiling procedures (16 cases) in their series. We have two patients (16%) with transient nonocclusive in-stent thrombus formation (Figure 5) subsequent to the deployment of the second stent. We confirmed adequate heparinization with repeat ACT measurement and continue with coil embolization at this point while closely monitoring for the thrombus progression. Once the aneurysm is secured, the persistent stent thrombus was treated with a bolus dose of intraarterial Reopro administration of 0.25 mg/Kg. Both patients woke up neurologically intact and had maintenance dose of Reopro (0.125 mcg/Kg) for the next 12 hours to minimize the subsequent risk of thromboembolic events in the acute phase.

Y- and X-configuration DSCE may be performed by "coil-through technique" or "jailing" the coiling microcatheter within the aneurysm, followed by deploying the stent or by coiling the aneurysm first and then deploying stents afterward, "coil-stent technique" [11]. "Coil-through technique" has the advantage of navigating one

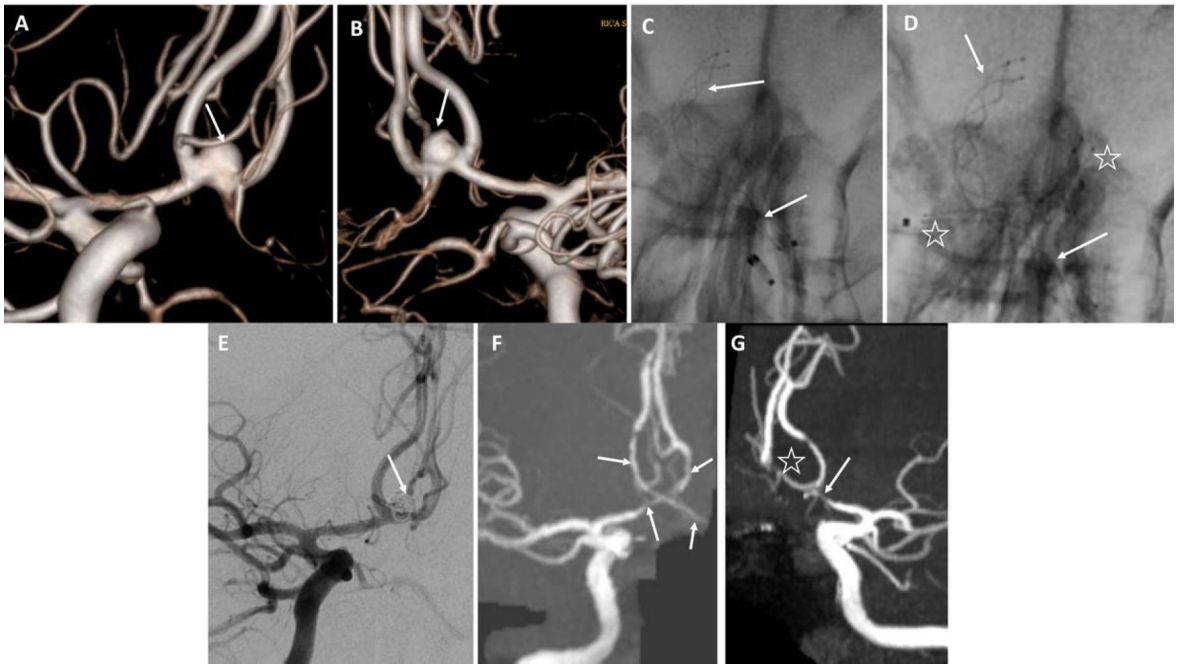

Figure 4. (A and B) Wide-necked ACOM aneurysm, aneurysm neck incorporating bilateral A1/2 junctions (arrows); (C and D) X-configuration stents were deployed from right A2 to left A1 (arrows, 2.5 mm 34 mm) and from left A2 to right A1 (stars, 2.5 mm 23 mm); (E) complete obliteration aneurysm with coil embolization; (F and G) six-month follow-up TOF-MRA shows aneurysm remains occluded (star). Note the artifactual luminal narrowing in the stent regions due to susceptibility (arrows).

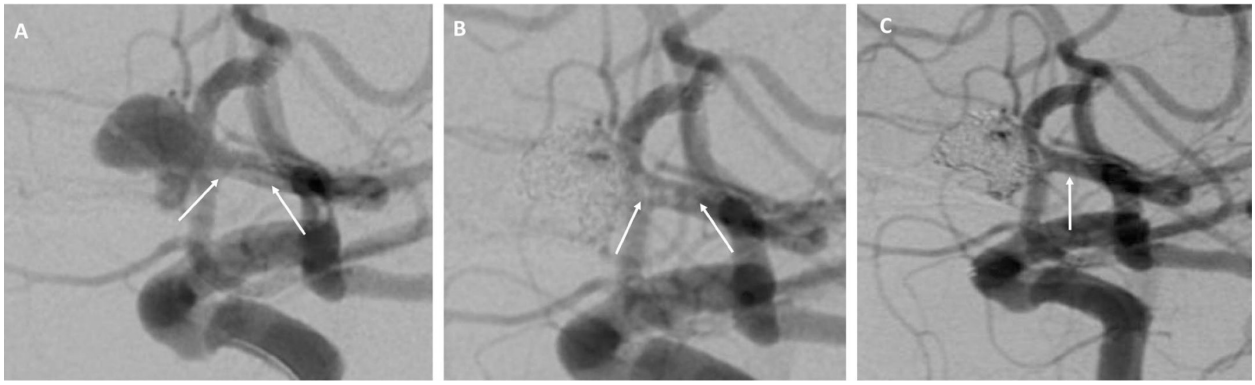

Figure 5. MCA bifurcation aneurysm, (A) following Y-configuration of two LVIS Jr. stents nonocclusive flow-limiting thrombus noted in the proximal overlapping stent construct (arrows); (B) aneurysm secured with coil embolization first and follow-up angiogram confirmed residual thrombus in the proximal stent (arrows); (C) once aneurysm is secured, intraarterial Reopro was given through the microcatheter, resulted in complete resolution of thrombus (arrow).

microcatheter at any point of time either stenting or coiling unlike "jailing" that needs close scrutiny on jailed microcatheter in aneurysm dome while dealing with stent microcatheter or potential risk of coil herniation or migration at aneurysm neck with "coil-stent technique." However, "coil-through technique" has the risk of abrupt microcatheter movement while crossing the overlapping stent tines. We had one intraprocedural rupture (8%) from microcatheter during coil-through technique (Figure 6), prompt identification and coiling secured the

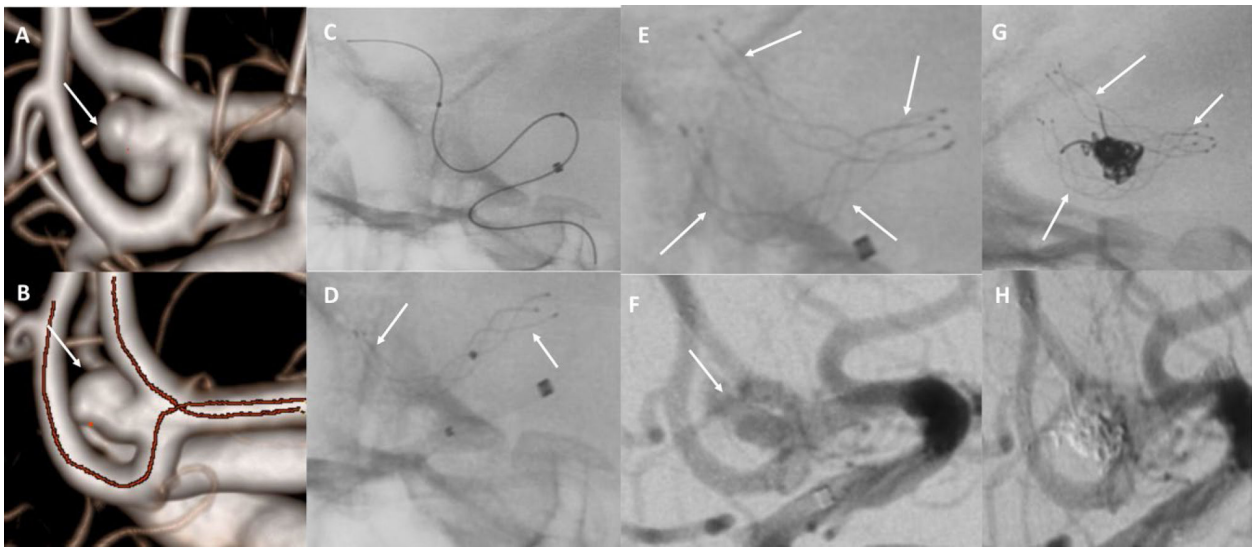

Figure 6. (A and B) Incidental bilobed, wide-necked ACOM aneurysm (arrows); (C–E) 0.017-inch microcatheter navigation over 0.014-inch microwire and Y-configuration stent deployment (arrows); (F) access in to aneurysm dome by "coil-through" approach resulted in sudden microcatheter jump and aneurysm rupture resulting in contrast extravasation (arrow); (G and H) immediate coil embolization resulted in secured aneurysm with complete occlusion.

Table 1. Summary of patient demographics, aneurysm characteristics, and procedural techniques

Patient no.	Location	Size (mm)	D/N ratio	Presentation	LVIS Jr. stent configuration	LVIS Jr. stent size (mm)	Immediate occlusion (MRR)	Periprocedure complications
1	ACOM	5.5	1.2	Unruptured	X-stent	2.5 × 34 2.5 × 23	1	None
2	PICA anastomosis	8.7	2.0	Unruptured	Y-stent	2.5 × 17 2.5 × 23	3A	None
3	M1 bifurcation	8.0	1.8	Unruptured	Y-stent	2.5 × 17 2.5 × 23	1	Transient in-stent thrombus (IA Reopro)
4	ACOM	12.7	2.7	Recurrence	Y-stent	2.5 × 35 2.5 × 23	1	None
5	ACOM	4.9	1.8	Unruptured	Y-stent	2.5 × 23 2.5 × 17	3A	Iatrogenic rupture with microcatheter
6	Basilar termination	7.0	1.5	Unruptured	Y-stent	3.5 × 18 3.5 × 18	1	None
7	M1 bifurcation	5.8	1.3	Unruptured	Y-stent	3.5 × 18 2.5 × 17	1	None
8	ACOM	4.4	1.1	Recurrence	Y-stent	2.5 × 232.5 × 23	1	Transient in-stent thrombus (IA Reopro)
9	M2 bifurcation	13.0	1.2	Unruptured	Y-stent	3.5 × 33 3.5 × 33	3A	None
10	ICA terminus	4.7	1.7	Unruptured	Y-stent	3.5 × 18 3.5 × 18	3A	None
11	Basilar termination	7.8	1.5	Unruptured	Y-stent	3.5 × 18 3.5 × 18	3A	None
12	M1 bifurcation	13.5	1.7	Unruptured	Y-stent	2.5 × 23 2.5 × 17	1	None

MRR: modified Raymond–Roy score

aneurysm with no immediate morbidity or delayed neurological sequelae.

The waffle-cone technique has been reported in small series [13,14] as a valid alternative to Y- and X-stent placement when the latter cannot be performed due to an unfavorable distal limb configuration. In this technique, the distal part of the stent is placed inside the aneurysmal sac and the blood flow is direct into the aneurysmal sac. This technique is technically easier than Y stent placement but probably presents a higher risk of coil protrusion due to the incomplete neck coverage. The major drawback is the risk of recurrence due to the redirection of the flow inside the aneurysm.

Computational fluid dynamics analysis revealed changes in the hemodynamic forces acting on a bifurcating aneurysm model after stent placement with a Y-configuration, marked reduction in the residual motion inside the aneurysm sac together with effectively repressed the temporal and spatial variations and the magnitude of wall shear stress [15]. Cekirge *et al.* [3] described a

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Table 2. Angiographic and clinical follow-up summary of the patient cohort

Patient no.	Location	Pre-stent mRS	Post-stent mRS	MRA follow-up (months)	Follow-up occlusion (MRR)	Clinical follow-up (months)	Follow-up mRS	Morbidity and mortality
1	ACOM	1	1	19	2	19	1	None
2	PICA anastomosis	0	1	11	1	12	0	None
3	M1 bifurcation	0	1	7	1	19	0	None
4	ACOM	0	0	13	2	13	0	None
5	ACOM	0	1	6	1	18	0	None
6	Basilar termination	1	0	7	1	7	0	None
7	M1 bifurcation	0	0	6	1	6	0	None
8	ACOM	0	1	5	1	14	1	None
9	M2 bifurcation	0	0	6	2	6	0	None
10	ICA terminus	1	1	5	1	5	1	None
11	Basilar termination	1	1	19	1	21	1	None
12	M1 bifurcation	1	1	18	1	7	1	None

MRR: modified Raymond–Roy score; mRS: modified Rankin scale

"flow remodeling effect" in aneurysms treated by Y-configuration closed-cell stent placement with aneurysm occlusion at follow-up. Retrospective multicenter experience of DSCE reported a 92% grade I or II occlusion and a 10% retreatment because of recanalization (10%) at 10-month follow-up. Yavuz *et al.* [2] reported 186 DSCE aneurysms with follow-up and reported an overall aneurysm recanalization rate of 2.2%, 3.8% for large aneurysms and 40% for giant aneurysms. In our series with a mean angiographic follow-up of 10-months (Range: 5–19 months), stable neck recurrence (Class-II) was noted in three patients (25%), confirmed on DSA, stable on follow-up MRA, and required no further treatment.

Despite the technical challenges associated with stent-assisted coil embolization of bifurcation aneurysms using Y- and X-configuration, DSCE technique appears to be safe with low morbidity and mortality [1,2]. In a large retrospective series of 193 bifurcation aneurysms, by using mostly closed-cell stents, the authors reported a low rate of permanent morbidity (1.1%) and mortality (0.5%) [2]. Bartolini *et al.* [8] reported a relatively high rate of complications, with a mortality rate of 1.0% and permanent neurologic morbidity of 10.0% among 105 patients, attributed to increased localization of aneurysms in the ACOM and MCA bifurcation aneurysms (75%). In a retrospective series of Y- and X-configuration stents involving ruptured and unruptured aneurysms by Fargen *et al.* [1], good outcome (mRS 0–2) was reported in 93% of the patients. In our small cohort of 12 unruptured patients with 75% anterior circulation aneurysms, following Y- and X-configuration DSCE, no mortality or morbidity was encountered. Good clinical outcome (mRS 0–1) was unchanged in our patients at 24-hours postembolization and follow-up.

The study has inherent limitations of a retrospective study, small patient population, lack of long-term follow-up, and the absence of an independent core laboratory for imaging review, detection of complications, or determination of clinical outcome status.

CONCLUSION

Double stent-assisted embolization in Y- and X-configuration using LVIS Junior stents is a feasible and safe endovascular treatment option for complex wide-necked intracranial bifurcation aneurysms, with the good clinical and angiographic outcome. We recommend independent confirmation of our findings by larger prospective multicenter studies.

Acknowledgements

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