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Preliminary Experience with Stent-Assisted Coiling of Aneurysms Arising from Small (<2.5 mm) Cerebral Vessels Using The Low-Profile Visualized Intraluminal Support Device

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ABSTRACT

BACKGROUND AND PURPOSE: The Low-Profile Visualized Intraluminal Support (LVIS) stent is a new device recently introduced for the treatment of wide-neck intracranial aneurysms. This single-center study presents the authors' preliminary experience using the LVIS stent to treat saccular aneurysms with parent arteries smaller than 2.5 mm.

MATERIALS AND METHODS: Aneurysms with a LVIS stent used in a small parent vessel (<2.5 mm in diameter) between October 2014 and April 2016 were included. Procedure-related complications, angiographic results, clinical outcomes, and midterm follow-up data were analyzed retrospectively.

RESULTS: A total of 22 patients was studied, including 5 ruptured and 17 unruptured aneurysms. Most of the aneurysms were located in the anterior circulation (90.9%). Stent placement in the parent arteries measuring 1.7–2.4 mm in diameter (mean, 2.1 mm) was successful in 100% of cases. Procedure-related complication developed in 1 patient (4.5%) who presented with aneurysm rupture. No permanent morbidity and mortality occurred. Immediate angiographic outcome showed complete occlusion in 8 aneurysms (36.4%), neck residual in 8 (36.4%), and residual aneurysm in 6 (27.3%). All patients underwent angiographic follow-up at a mean of 8.3 months, which revealed complete occlusion in 18 (81.8%) patients, neck remnant in 3 (13.6%), and residual sac in 1 (4.5%). No recanalization of the target aneurysm was observed. There was 1 case with asymptomatic in-stent stenosis.

CONCLUSIONS: Our preliminary results show that the deployment of LVIS stents in small vessels is feasible, safe, and effective in the midterm. Larger studies with long-term follow-up are needed to validate our promising results.

ABBREVIATION: LVIS = Low-Profile Visualized Intraluminal Support

The introduction of stent devices has greatly advanced the endovascular treatment options of intracranial aneurysms. Many aneurysms that had been previously considered untreatable because of their morphology, including those with unfavorable dome-to-neck ratios and/or location, are now amenable to coiling with the use of stents.^{1,2} However, the use of

stents for treating wide-neck distal intracranial aneurysms with small parent vessels remains challenging. Several previous studies reported relatively high rates of periprocedural thromboembolic events and in-stent stenosis.^{3–11}

The Low-Profile Visualized Intraluminal Support (LVIS) device (MicroVention, Tustin, California), a new device offering an option between conventional stents and flow diverters, is designed for the stent-assisted coil embolization of wide-neck intracranial aneurysms. There is an increasing number of publications on the use of the LVIS device.^{12–16} However, to our knowledge, no studies to date have specifically investigated the placement of the LVIS device in small vessels. Hence, we conducted this retrospective study to examine the LVIS device in terms of its safety, deployment feasibility, and treatment effectiveness in intracranial aneurysms with parent vessels measuring <2.5 mm in diameter.

MATERIALS AND METHODS

This retrospective study was approved by our hospital's institutional review board.

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Table 1: Clinical data of all patients

Patient No.	Age (yr), Risk		Presentation	HHG	Aneurysm Location	Aneurysm		PA Size	Initial		FU	
	Sex	Factors				Size	Neck		Angiogram Results	Complications	Angiogram Results	Time
1	42, F	NS	Chronic headaches	0	BT	8.5	8.2	1.9	RA	N/A	NR	13
2	57, M	HP	Lt hemiparesis, unconsciousness	3	MCA	8.8	5.1	1.8	NR	N/A	CO	8
3	65, M	HP	Acute onset of headaches	2	ACA	5.6	4.6	1.7	NR	N/A	NR	14
4	63, M	HP, DM	Lt UE weakness, slurred speech	0	ACoMA	2.1	1.4	2.1	CO	Rupture	CO	11
5	44, F	NS	Incidental	0	ACoMA	10.8	5.2	2.1	CO	N/A	CO	8
6	61, M	HP	Acute onset of headaches	2	MCA	4.4	3.2	2.0	CO	N/A	CO	10
7	53, M	NS	Incidental	0	ACoMA	3.6	3.1	2.1	NR	N/A	CO	6
8	40, M	HP, S	Recanalized	0	MCA	3.0	2.9	2.3	NR	N/A	CO	8
9	49, M	NS	Headaches, seizure	1	MCA	5.0	4.7	2.4	NR	N/A	NR	6
10	52, M	NS	Incidental	0	BT	4.4	3.6	1.8	CO	N/A	CO	6
11	61, M	HP, DM	Incidental	0	MCA	6.5	6.0	2.3	RA	N/A	CO	9
12	35, M	NS	Chronic headaches	0	ACoMA	6.7	3.3	2.3	CO	N/A	CO	6
13	51, F	HP	Chronic headaches and dizziness	0	MCA	4.8	2.7	1.8	RA	N/A	CO	11
14	55, F	HP, DL	Incidental	0	MCA	3.5	1.8	2.2	NR	N/A	CO	6
15	46, F	HP	Incidental	0	MCA	1.8	1.5	2.1	RA	N/A	CO	10
16	33, M	S	Recanalized	0	ACoMA	3.0	2.3	2.1	NR	N/A	CO and PA stenosis	8
17	54, M	HP	Acute onset of headaches	2	MCA	3.6	2.5	2.0	CO	N/A	CO	8
18	54, F	NS	Incidental	0	MCA	3.2	2.0	2.3	CO	N/A	CO	8
19	59, M	S, DL	Incidental	0	MCA	1.7	1.5	1.9	RA	N/A	RA	6
20	60, F	HP	Dizziness, nausea, vomiting	0	MCA	7.9	5.0	1.9	NR	N/A	CO	7
21	49, F	NS	Chronic headaches	0	MCA	3.6	2.6	2.3	CO	N/A	CO	8
22	53, F	HP	Chronic headaches	0	MCA	3.7	3.2	2.2	RA	N/A	CO	6

Note:—ACA indicates anterior cerebral artery; ACoMA, anterior communicating artery; BT, basilar tip; CO, complete occlusion; DL, dyslipidemia; DM, diabetes mellitus; FU, follow-up; HP, hypertension; Lt, left; N/A, not available; NR, neck residual; NS, not significant; PA, parent artery; RA, residual aneurysm; S, smoking; UE, upper extremity; HHG, Hunt and Hess grade.

Patients

All patients who underwent stent-assisted coiling treatment with the LVIS device at our institution from October 2014 to April 2016 were retrospectively reviewed. We identified 30 patients with 30 saccular aneurysms arising from parent arteries that were <2.5 mm in diameter with no atherosclerotic stenosis. Eight patients without angiographic follow-up were excluded. For the remaining 22 patients, clinical data, aneurysm characteristics, indication for stent use, periprocedural complications, initial angiographic results, and follow-up angiography data were carefully reviewed. Particular attention was given to vessel patency, aneurysm occlusion, and the incidence of thromboembolic events, and they were reviewed after intervention and on follow-up imaging by 2 experienced interventional neurosurgeons (Q.-H.H. and J.-M.L.). Before treatment, informed written consent was obtained from all patients after careful evaluation of risks, benefits, and treatment alternatives, including but not limited to observation, surgical clipping, and various endovascular options. Therapeutic decision-making entailed a multidisciplinary deliberation by both surgical and nonsurgical neurointervention teams.

Endovascular Treatment

All procedures were performed with patients under general anesthesia. DSA was performed on a biplane angiographic system (Artis zee Biplane; Siemens, Erlangen, Germany). A 6F guiding catheter was introduced through a femoral sheath into the internal carotid artery for anterior circulation aneurysms or into the vertebral artery for posterior circulation aneurysms. A 0.021-in internal diameter Headway microcatheter (Microvention) was used to deliver the LVIS stent in each case. The smallest 3.5-mm LVIS stent (which is different from the LVIS Jr stent) in various lengths was used

for all cases because the diameter of the parent artery was smaller than 2.5 mm. After the deployment, DynaCT (Siemens) or multiprojection fluoroscopy were performed to identify wall apposition.

Periprocedure Anticoagulation and Antiplatelet Management

Heparin was titrated during the procedure to achieve an activated clotting time of 2–2.5 times that of baseline. If stent placement was proposed for a patient with an unruptured aneurysm, dual antiplatelet drugs (aspirin, 100 mg/d plus clopidogrel, 75 mg/d) were given for at least 3 days before the procedure. However, for patients with acutely ruptured aneurysms, a loading dose of clopidogrel and aspirin (300 mg of each) was administered orally by gastrointestinal tube or per rectum 2 hours before stent placement. Regardless of whether their aneurysm was ruptured, all patients were administered a daily dose of aspirin (100 mg) and clopidogrel (75 mg) postoperatively for 6 weeks, followed by aspirin alone, which was maintained indefinitely. During the procedure, 0.1 µg/kg/min of glycoprotein IIb/IIIa antagonist (tirofiban) was injected intravenously when acute intrastent thrombosis occurred.

Clinical and Angiographic Follow-Up

The efficacy of aneurysm coiling was assessed by using the Raymond scale. MR angiography was recommended 3 months after embolization. Postprocedural DSA follow-up was performed at 6-month intervals. Hemodynamical in-stent stenosis and branch vessel stenosis were defined as equal to or greater than 50% diameter loss. Clinical outcome was assessed with the mRS based on the latest follow-up record retrieved from an outpatient department. Evidence of stroke in the treated territory identi-

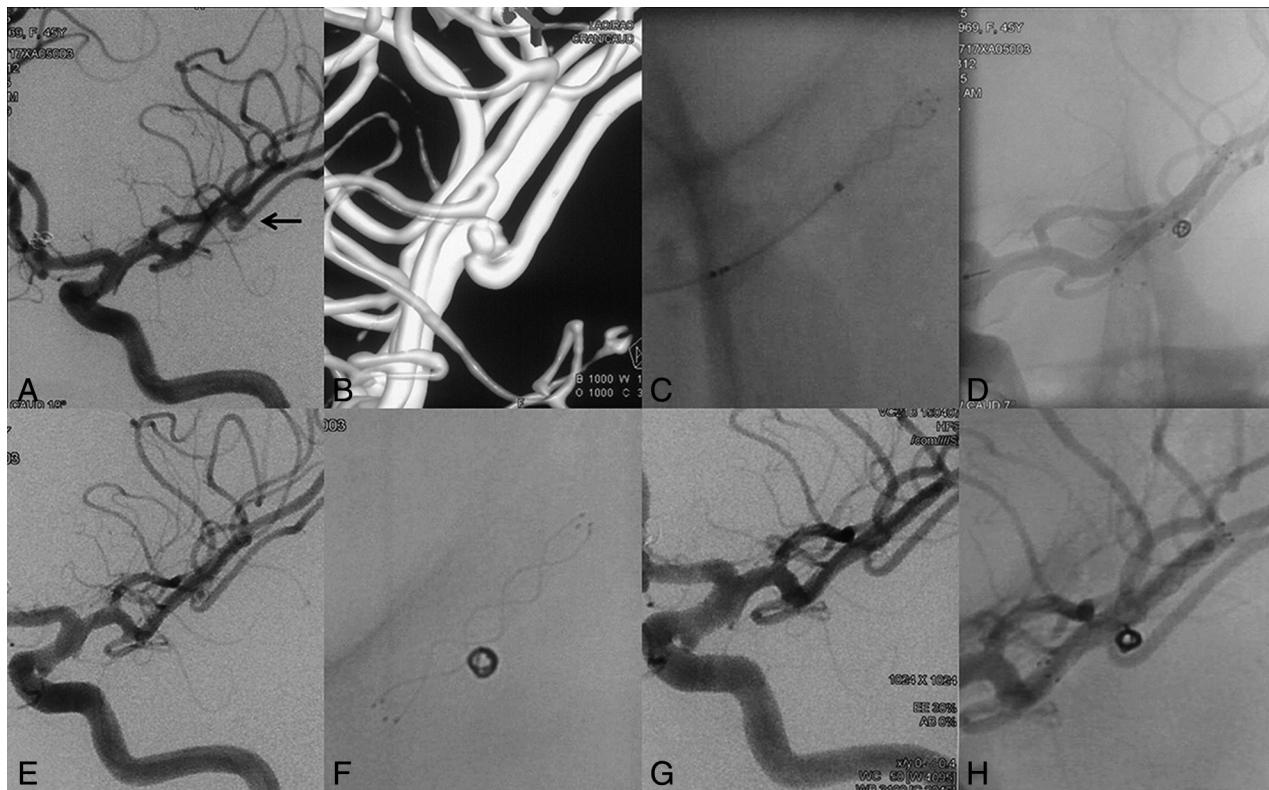


FIG 1. (Patient #15) This 46-year-old woman has a history of SAH 6 months ago, with multiple aneurysms (a ruptured anterior communicating artery aneurysm [previously coiled] and bilateral unruptured MCA aneurysms). *A*, Left ICA DSA showed a tiny saccular aneurysm at left MCA M2 bifurcation (black arrow). *B*, 3D DSA demonstrated the branch artery arising from the proximal aspect of the aneurysm sac. *C*, An LVIS stent was deployed in the MCA M2 trunk initially. *D*, A coil delivery microcatheter was navigated close to the stent interstices, but not through the interstice. Only 1 coil was introduced into the aneurysm sac. *E*, Initial angiogram after treatment showed the sac residual with patency of the parent vessels. *F*, The final fluoroscopy demonstrated that the stent was completely opened and totally covered the aneurysm neck. *G* and *H*, Follow-up angiography at 10 months demonstrated complete obliteration of the aneurysm with preserved patency of the parent and branch arteries.

fied via MR imaging, perfusion status, and stent patency was documented.

RESULTS

Clinical and demographic data of all patients are detailed in Table 1.

Study Population

A total of 22 patients (9 women and 13 men) with 22 intracranial aneurysms were included. Their mean age was 51.6 years (range, 33–65 years). Patient risk factors included hypertension (54.5%), smoking (18.2%), diabetes (13.6%), and dyslipidemia (9.1%). Five patients presented with SAH. According to Hunt-Hess grading, 1 case was classified as Hunt and Hess grade 1, 3 as grade 2, and 1 as grade 3.

Aneurysm Characteristics

Most of the aneurysms were located in the anterior circulation (90.9%), with 14 MCA aneurysms (63.6%), 5 anterior communicating artery aneurysms (22.7%), and 1 anterior cerebral artery aneurysm (4.5%). Two aneurysms were located at the basilar artery tip. Two aneurysms had been previously coiled, but recanalized, and were thus retreated with an LVIS stent. The parent vessel sizes varied from 1.7–2.4 mm (mean, 2.1 mm). The maximum sizes of aneurysms (or the circulating portion in recanalized aneurysms) varied from 1.7–10.8 mm (mean, 4.8 mm).

Immediate Outcome and Periprocedural Complications

The technical success rate of stent placement was 100%, and there was no failure in navigating or deploying the LVIS stent. Immediate postprocedural angiograms showed complete occlusion in 8 aneurysms (36.4%), neck residual in 8 (36.4%), and residual aneurysm in 6 (27.3%).

Procedure-related complications occurred in 1 patient (4.5%). This patient developed aneurysm perforation during the treatment of an anterior communicating artery aneurysm. A mild contrast extravasation from the aneurysm developed during coiling. Complete aneurysm occlusion was achieved within a few minutes, and the patient awoke with a mild headache. The postprocedural CT image revealed the contrast extravasation and SAH. This patient did not develop any neurologic deficits. No thromboembolic event was observed in our series, and there was no permanent morbidity or mortality. All patients were independent with a mRS score of 0–2 at discharge.

Follow-Up Results

All 22 patients underwent DSA follow-up at intervals ranging from 6–14 months (mean, 8.3 months). According to follow-up images, complete occlusion was achieved in 18 (81.8%) patients, neck remnant in 3 (13.6%), and residual sac in 1 (4.5%). None of the patients had any target aneurysm recurrence (Fig 1). One

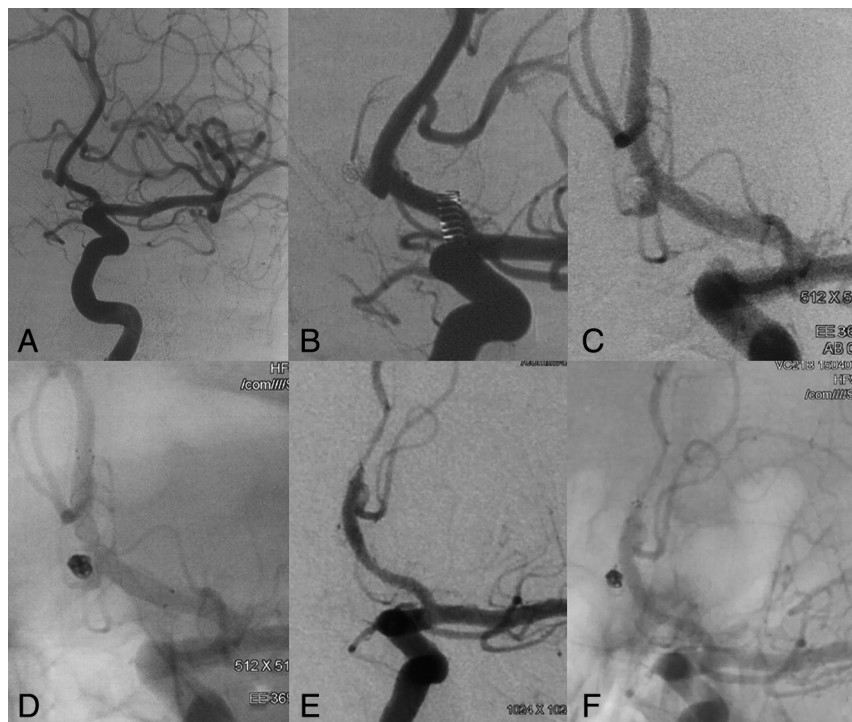


FIG 2. (Patient #16) A, Angiogram showed a ruptured anterior communicating artery aneurysm. B, The aneurysm underwent conventional coiling initially. C and D, Follow-up at 1 month revealed the residual sac filling, and an LVIS stent was then deployed in the ipsilateral anterior cerebral artery. E and F, Total aneurysm occlusion was achieved at 8-month follow-up. In-stent stenosis occurred at the distal stent marker for approximately 55%.

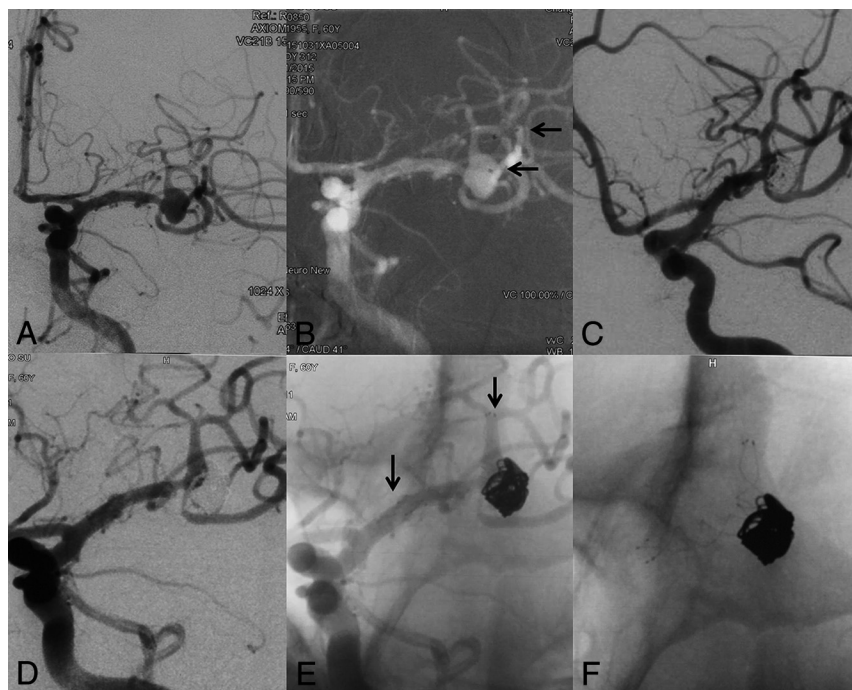


FIG 3. (Patient #21) A, Oblique left ICA angiogram showed an MCA M1 bifurcation aneurysm. B, Roadmap image revealed the coiling microcatheter and stent placement microcatheter in place (black arrows). C, Native image after stent-assisted coil embolization. D, Seven-month follow-up demonstrated complete occlusion of the aneurysm with the patency of the parent vessel. Insignificant stenosis was found in the inferior branch covered by stent. E and F, The fluoroscopy demonstrated that the stent was fully deployed, with the midsegment expanded across the aneurysm neck and good stent apposition to parent vessel wall.

asymptomatic in-stent stenosis occurred in 1 follow-up case (4.5%). The stenosis was located at the distal stent marker, and distal cerebral perfusion was normal (Fig 2). In addition, mild stenosis of branch arteries covered by the stents occurred in 1 case, and the patient did not present any neurologic deficit (Fig 3). Clinical follow-up at 6–23 months (mean, 16.1 months) was achieved in all patients, and no new neurologic deterioration or death was observed.

DISCUSSION

In our study, we describe our preliminary experience of using the LVIS stent to treat saccular aneurysms with parent arteries smaller than 2.5 mm. Overall, the results of this single-center cohort demonstrated high rates of complete occlusion at mid-term follow-up for aneurysms treated with the LVIS device. Initial in-stent thrombus and in-stent stenosis at follow-up are uncommon. We also demonstrated that procedure-related complications are acceptable, with a rate of 4.5%. No procedure-related morbidity or mortality occurred in our case series. These findings suggest that LVIS deployment in small intracranial vessels is a safe and effective means for treating intracranial aneurysms amenable to this endovascular approach. To our knowledge, this is the first reported series of patients with LVIS device placement in small vessels.

Stent-assisted coiling of wide-neck aneurysms in small parent vessels measuring <2.5 mm in diameter is a technically challenging procedure. Several studies had detailed the use of different stents, including Neuroform (Stryker Neurovascular, Kalamazoo, Michigan), Wingspan (Stryker), LEO (Balt Extrusion, Montmorency, France), and Enterprise (Codman & Shurtleff, Raynham, Massachusetts) for the treatment of wide-neck intracranial aneurysms with small vessels.^{4–9} According to the previous literature, thromboembolic events or vascular occlusions are major complications of stent-assisted coiling of these aneurysms (Table 2). Puri et al³ published a case series on the use of small flow diverters (Pipeline Embolization Device; Covidien, Irvine, California) in 7 patients, showing good safety and effectiveness. Among them, 1 patient suffered in-stent stenosis

Table 2: Clinical and anatomic results of the stent deployment in small intracranial vessels in previous studies

Series, yr	Sample Size (no.)	Vessel Diameter (mm)	Stent	Technical Success Rate (%)	Complication (%)		Near or Complete Occlusion Rate (%)	Follow-Up (%)	
					Thromboembolic	Hemorrhagic		Recurrence Rate	In-Stent Stenosis
Turk et al, 2007 ⁹	8	1.5	NF	100	25	0	100	0	N/A
Siddiqui et al, 2009 ⁸	8	1.58	EP	100	12.5	0	100	25	12.5
Yun and Cho, 2010 ⁷	11	1.6	NF	100	0	0	100	0	9.1
Zhang et al, 2010 ⁶	12	1.8	NF, LEO, WP	100	8.3	0	91.6	NA	N/A
Chung et al, 2015 ⁵	31	1.6	EP	100	9.7	0	96.3	0	11.1
Kühn et al, 2016 ⁴	44	1.7	NF, EP	93.2	13.6	2.3	88.6	9.1	6.1
Aydin et al, 2015 ¹¹	80	2.35	LEO Baby	97.5	7.5	1.3	96.3	6.5	15.6
Alghamdi et al, 2016 ¹⁰	43	2.2	LVIS Jr	100	10	5	95.3	5	17.5
Puri et al, 2016 ³	7	1.9	PED	100	0	0	N/A	0	28

Note:—N/A indicates not available; NF, Neuroform stent; EP, Enterprise stent; WP, Wingspan stent; PED, Pipeline Embolization Device.

at follow-up. Recently, 2 low-profile self-expandable microstents, LEO Baby and LVIS Jr, were introduced. These stents can be delivered and deployed in small distal arteries via a 0.017-in microcatheter and are dedicated for the endovascular treatment of aneurysms with small parent arteries from 2–3.5 mm. Thus, surgeons have recently been using the Leo Baby and LVIS Jr stents in small cerebral arteries. However, according to 2 case series reported by Aydin et al¹¹ and Alghamdi et al,¹⁰ thromboembolic events and in-stent stenosis are also not negligible in the deployment of the LEO Baby and LVIS Jr stents in small cerebral arteries. In addition, the LEO Baby and LVIS Jr stents have not been approved for aneurysm treatment in our country. Similar to the design of LEO Baby and LVIS Jr, a higher-profile LVIS stent is a self-expandable braided stent that provides higher metal coverage rate and higher radial force. The safety and efficacy of the LVIS device deployment in small vessels is worthy of attention.

Incomplete stent expansion and poor wall apposition are common causes for the thromboembolic events.^{17,18} Increased metal surface coverage might also increase the risk of thromboembolism when stents are deployed in small arteries. The LVIS stent, with braided morphology and full-length visualization design, allows greater flexibility and visibility to provide operators more control for stent deployment. The higher radial force of LVIS stents could facilitate better apposition to vessel wall. Moreover, the minimum size of the LVIS device is 3.5 mm in diameter; therefore, when an LVIS stent is deployed in a vessel smaller than 2.5 mm, it may be elongated, and the stent cells may become larger. Decreased metal surface coverage might lower the vascular stimulation and, hence, decrease the risk of thromboembolism. In our study, no periprocedural thromboembolic complications occurred. One asymptomatic in-stent stenosis occurred in 1 follow-up case (4.5%). The stenosis was located at the distal stent marker, which might result from vascular injury by the distal flares during stent manipulation and then neointimal hyperplasia at the distal stent marker segment.

Endovascular treatment of wide-neck bifurcation cerebral aneurysms is challenging, especially with small arteries involved. The special design of the LVIS device provides more bulging capability at bifurcation. Therefore, we use the so-called “barrel technique” to expand a segment of the stent into the aneurysm neck, providing greater neck coverage and changing a wide-neck aneurysm into a narrow-neck one, which consequently protects the parent vessel and the bifurcation (Fig 3).¹⁹ In addition, the

stent was pushed at the aneurysm neck to make a denser metal surface coverage and improve flow diversion effect, which may facilitate aneurysm thrombosis and enable more complete rate of occlusion during the long-term follow-up. Our results showed only 1 aneurysm that demonstrated residual sac filling and no case of recanalization on follow-up angiography examinations. However, pushing the stent microcatheter may change the tension of the coil microcatheter and then increase the related risk of perforation, so caution must be used in the manipulation of microcatheters when pushing the stent. In our study, 1 intraprocedural aneurysm rupture developed during the stent deployment in an anterior communicating artery aneurysm.

Limitations of this study include its retrospective design, limited number of cases from a single institution, the nonblinded authors’ interpretation of the radiographic results, and the relatively short angiographic follow-up.

CONCLUSIONS

This study shows that the LVIS stent is a safe and effective device for endovascular treatment of intracranial aneurysms with small parent vessels. Periprocedural thromboembolic complications and in-stent stenosis are uncommon. Larger studies with long-term follow-up are needed to validate our promising results.

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