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INTERVENTIONAL NEURORADIOLOGY

Coil embolization of intracranial saccular aneurysms using the Low-profile Visualized Intraluminal Support (LVIS™) device

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Abstract
Introduction The novel Low-profile Visualized Intraluminal Support (LVIS™, LVIS and LVIS Jr.) device was recently introduced for stent-supported coil embolization of intracranial aneurysms. Periprocedural and midterm follow-up results for its use in stent-supported coil embolization of unruptured aneurysms are presented herein.
Methods In this prospective multicenter study, clinical and radiologic outcomes were analyzed for 55 patients with saccular aneurysms undergoing LVIS-assisted coil embolization between October 2012 and February 2013. Magnetic resonance angiography or digital subtraction angiography was performed to evaluate midterm follow-up results.
Results The standard LVIS device, deployed in 27 patients, was more often used in internal carotid artery (ICA) aneurysms (n=19), whereas the LVIS Jr. (a lower profile stent, n=28) was generally reserved for anterior communicating artery (n=14) and middle cerebral artery (n=8) aneurysms. With LVIS-assisted coil embolization, successful occlusion was achieved in 45 aneurysms (81.8 %). Although no instances of navigation failure or stent malposition occurred, segmentally incomplete stent expansion was seen in five patients where the higher profile LVIS was applied to ICA including carotid siphon. Procedural morbidity was low (2/55, 3.6 %), limited to symptomatic thromboembolism. In the imaging of lesions (54/55, 98.2 %) at 6-month follow-up, only a single instances of major recanalization (1.9 %) occurred. Follow-up angiography of 30 aneurysms (54.5 %) demonstrated in-stent stenosis in 26 (86.7 %), with no instances of stent migration. Only one patient suffered late delayed infarction (modified Rankin Scale 1).
Conclusion The LVIS device performed acceptably in stent-assisted coil embolization of non-ruptured aneurysms due to easy navigation and precise placement, although segmentally incomplete stent expansion and delayed in-stent stenosis were issues.

Keywords Aneurysm · Coil · Embolization · Stent

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Introduction

Since the International Subarachnoid Aneurysm Trial (ISAT) and the International Study of Unruptured Intracranial Aneurysms (ISUIA), endovascular coil embolization has been widely used for treatment of intracranial aneurysms. Device improvements and advanced coiling techniques have also made it possible to treat many cerebral aneurysms with difficult configurations by this method. In particular, the introduction or evolution of various stent systems has greatly broadened the applicability of endovascular therapy in this setting [1–5]. Stent deployment provides mechanical support to prevent coil prolapse, enable dense packing of coil, and potentially divert blood flow around aneurysms, serving as a scaffold for endothelial growth and vessel healing [6–9]. The Low-profile Visualized Intraluminal Support device (LVIS™, Microvention, Tustin, CA, USA) is a novel, self-expandable stent consisting of a single, round-wire nitinol braid with radiopaque proximal/distal markers and helical

Table 1 Type and characteristics of the LVIS device

	LVIS Jr.	LVIS
Target vessels	2.0 to 3.0 mm	2.0 to 5.0 mm
	3.5 mm fully expanded diameter	3.5/4.5/5.5 mm fully expanded diameter
Cell size	1.5 mm	1.0 mm
MC for delivery	0.017 in. MC	0.021 in. MC
No. of flared end	3	4
Visualization	3 radiopaque markers (both ends)	4 radiopaque markers (both ends)
	3 radiopaque helical strands	2 radiopaque helical strands

MC microcatheter, *No.* number

strands for whole-dimension visualization. There are two variations of the devices (LVIS and LVIS Jr.) with similar structure but different characteristics, which are summarized in Table 1. Presented here is our experience with use of this device for stent-supported coil embolization of wide-neck aneurysms.

Table 2 Inclusion and exclusion criteria

Inclusion criteria
Subject is older than 20 years and less than 75 years of age
Target intracranial aneurysm measures <20 mm in size
Target aneurysm is unruptured and meets " wide-neck" criteria (neck width >4 mm or dome to neck ratio <2)
Subject's aneurysm arises from a parent vessel with a diameter of ≥2.0 and ≤4.5 mm
Subject or his/her legal representative understand the nature of the procedure and provides signed informed consent form
Subject is willing to return to the investigational site for the 6-month follow up evaluation
Exclusion criteria
Subject presents with ruptured aneurysm
Subject presents with an intracranial mass or currently undergoing radiation therapy for carcinoma or sarcoma of the head or neck region
Subject with International Normalized Ration (INR) ≥1.5
Subject with serum creatinine level >2.0 mg/dL at time of enrollment
Subject with known allergies to nickel titanium metal, contrast, aspirin, heparin, ticlopidine, clopidogrel, or any antithrombotics/or anticoagulant agents
Subject who has a known cardiac or other medical disorder, likely to be associated with embolic stroke
Subject who is currently participating in another clinical research study
Subject who has participated in a drug study in the last 30 days
Subject who has had a previous intracranial stenting procedure, associated with the target aneurysm
Subject is unable to complete the required follow-up
Subject is pregnant or breast feeding
Patients in whom anticoagulant, antiplatelet therapy, or thrombolytic drugs are contraindicated
Patients with anatomy that does not permit passage or deployment of the LVIS device
Angiographic criteria exclusion
- Subject has s fusiform or dissection aneurysm
- Subject harboring more than one aneurysm; more than one aneurysms requires treatment prior to completion of 6-month follow-up of aneurysm treated with LVIS
- Cerebral Diagnostic Angiogram that demonstrates an aneurysm that is not appropriate for endovascular treatment
- Subject has an arteriovenous malformation (AVM) in the territory of the target aneurysm
- Subject aneurysm is expected to require more than one stent

Methods and materials

Population

This study is a prospective, nonrandomized, multicenter clinical trial conducted at two institutions (Seoul National University Hospital and Seoul National University Bundang Hospital) in South Korea. Ethical approval was obtained from the relevant ethics committee at each institution, and all patients signed informed consents. The protocol was sanctioned by the Korean Ministry of Food and Drug Safety to seek their approval for marketing this device. The study's primary endpoint was the success rate of aneurysmal occlusion at 6 months and secondary endpoints were parent artery patency and recurrence rate at 6 months; other outcomes included device performance (stent navigation and positioning), clinical utility, and

Table 3 Characteristics of patients coiled using LVIS for intracranial aneurysms

No of patients and aneurysms	55 patients, 55 aneurysms
Mean age (years) (mean±SD)	56.7±9.6 years
Gender (female/male)	41 : 14
Aneurysm characteristics	
Aneurysm status at embolization	
Initial	52
Recanalized	3
Location	
ICA	19
AcomA	15
MCA	8
Basilar tip	6
PcomA	6
ACA	1
Aneurysm size (n=52)	
<5 mm	23
5 mm≤< 10 mm	28
10 mm ≤	1
Configuration of aneurysm	
Dome to neck ratio 1.5≤< 2	16
Dome to neck ratio 1≤< 1.5	27
Dome to neck ratio <1	12
Occlusion result	
Complete occlusion	8
Neck remnant	37
Residual aneurysm	10

ACA anterior cerebral artery, *AcomA* anterior communicating artery, *ICA* internal carotid artery except for PcomA, *MCA* middle cerebral artery, *PcomA* posterior communicating artery

adverse events (stent migration and in-stent stenosis, etc). At each facility, instructions were to use the LVIS stent within appropriate guidelines. Thus, stent deployment was limited to coil embolization of wide-neck (neck size >4 mm or dome-to-neck ratio <2) unruptured saccular aneurysms arising from parent arteries 2.0–4.5 mm in diameter. Aneurysms of extraordinarily small (<2 mm) or large (>20 mm) size and multiple, fusiform, or ruptured aneurysms were grounds for exclusion. Inclusion and exclusion criteria are summarized in Table 2. A total of 55 patients with 55 aneurysms were registered between October 2012 and February 2013. Clinical and radiologic outcomes of the stipulated treatment were assessed, with periprocedural and midterm follow-up results presented herein.

Endovascular procedure

All procedures were performed under general anesthesia. Aneurysmal configuration and arterial architecture were evaluated via Integris V (Philips Medical Systems, Best, the Netherlands) biplane system, including high-resolution 3D rotational angiography. Patients were given 75 mg of clopidogrel and 100 mg of aspirin for a minimum of 5 days before the procedure or they received loading doses of clopidogrel and aspirin (300 mg each) 1 day prior to the procedure and were supplemented (clopidogrel, 75 mg; aspirin, 100 mg) on the morning of the procedure. A bolus of heparin (3,000 IU) was also infused as the procedure began, with hourly boosting (1,000 IU) sufficient to sustain activated clotting time at 250–300 s. Dual antiplatelet agents were then routinely continued for at least 3 months afterwards, if no major related bleeding ensued. A 0.021-in. microcatheter (with LVIS) or one of 0.0165- to 0.017-in. caliber (with LVIS Jr.) was used for stent delivery.

One experienced neuroradiologist (CHS) independently reviewed angiographic results immediately following coil embolization. Using the thre-point Raymond scale, therapeutic outcomes were classified as follows: complete occlusion (no residual filling of aneurysm by contrast medium), residual neck (limited residual contrast at base of aneurysm), or residual aneurysm (any contrast filling of aneurysmal sac) [10].

The angles of stented parent arteries adjacent to the bifurcation aneurysms were measured on digital subtraction angiography (DSA), before and immediately after stent-assisted

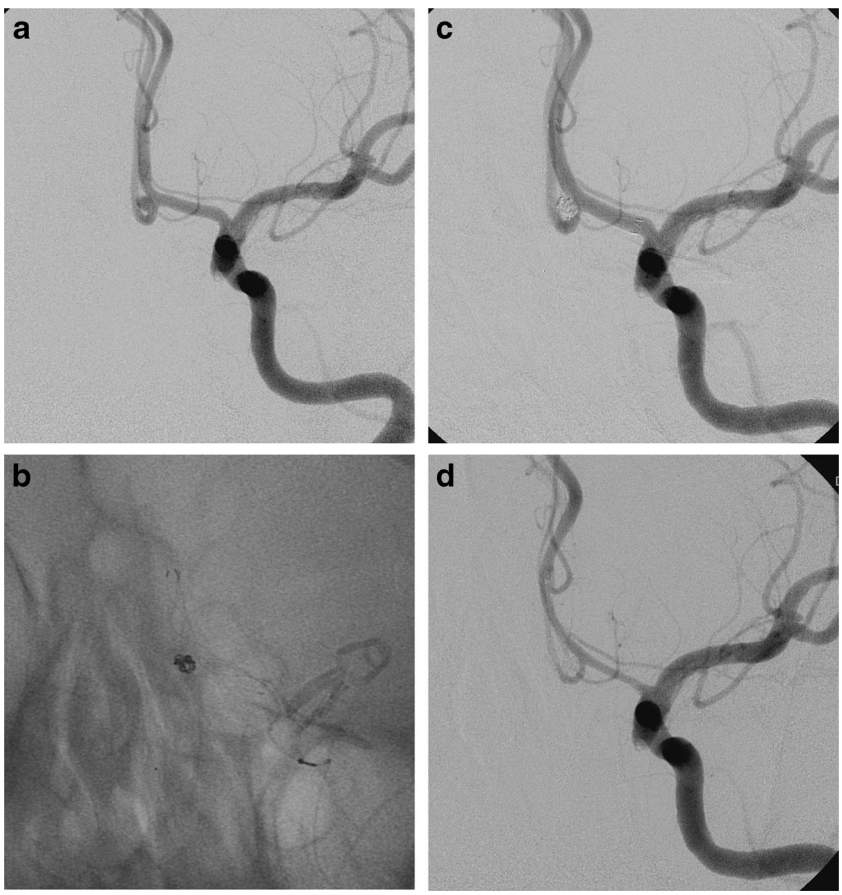

Fig. 1 **a** Conventional angiography delineating wide-necked anterior communicating artery aneurysm; **b** after microcatheter (0.017 in.) introduced into ipsilateral A2 branch for stent delivery and separate S-shaped microcatheter (fashioned using steam) advanced into aneurysmal sac for coil delivery, LVIS Jr. (2.5 mm× 16 mm) deployed from ipsilateral A2 to A1 (covering aneurysm neck) for coil insertion under stent protection; **c** successful occlusion of aneurysm visible by post-procedural angiography; **d** complete occlusion of the coiled aneurysm and in-stent stenosis visible by 6-month follow-up angiography

procedures. With the aid of 3D reconstruction images, the best available view containing the aneurysmal neck and parent artery was selected for angle measurement. The vascular angles were measured at the intersections of lines parallel to the afferent and efferent arteries [11].

Clinical and radiological follow-up

In all patients, time-of-flight magnetic resonance angiography (TOF-MRA) or conventional angiography was advised at 6 months after coil embolization. Conventional angiography was also recommended when assessing the status of treated aneurysms with MRA was not feasible, or when aneurysmal recanalization was suspected by MRA, in order to decide if further treatment was necessary.

Clinical outcomes were assessed using the modified Rankin Scale (mRS) at the time of 1- and 6-month follow-up visits by independent neurovascular surgeon (JEK). Anatomic follow-up results were also categorized using Raymond scale: complete occlusion, neck remnant, or residual sac. Repeat embolization was recommended for patients showing residual sac, considered as major recanalization.

In-stent stenosis was categorized as follows: mild stenosis (<33 % narrowing relative to non-stented parent artery), moderate stenosis (33–67 %), and severe stenosis (≥67 %) [1].

Results

Study population

Clinical and demographic patient data are summarized in Table 3. A total of 41 females and 14 males (mean age, 56.7 ±9.6 years; median age, 55 years) were studied, with maximal mean aneurysmal diameter 5.4±1.9 mm (range, 2.4–13.1 mm; median, 5.1 mm). Three recanalized aneurysms (5.4 %) were included, but all aneurysms were intact and had wide necks (mean diameter at neck, 4.3±1.5 mm (median, 4.1 mm); mean dome-to-neck ratio, 1.3±0.3 (median, 1.2)). Dome-to-neck ratio was <1.5 in 39 aneurysms (71 %). The most common sites involved were internal carotid (ICA; n=19), anterior communicating (AcomA; n=15, Fig. 1), and middle cerebral (MCA; n=8) arteries.

Procedural results

Of the 55 patients treated, a standard LVIS stent was deployed in 27 (Fig. 2), using the LVIS Jr. in 28 (Table 4). No navigation failure, stent malposition, or stent migration occurred during the coiling procedures. Immediately following coil embolization, angiographic studies indicated complete occlusion in 8 aneurysms, neck remnants in 37, and residual sacs in 10. All stents were deployed after intra-aneurysmal placement of

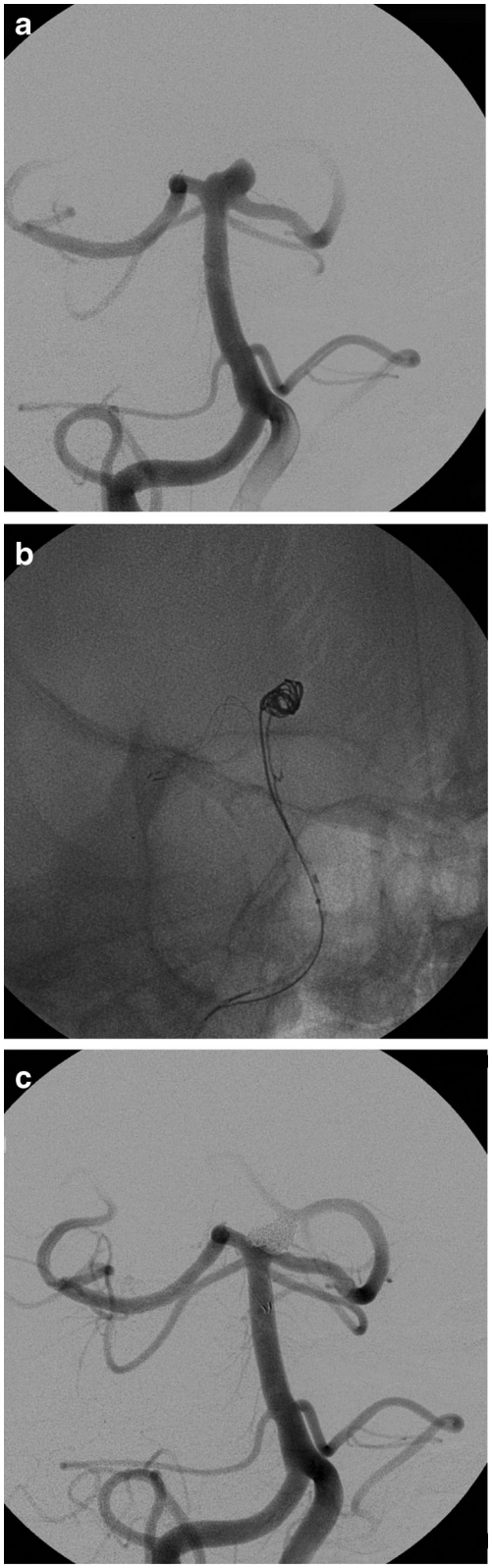

Fig. 2 **a** Conventional angiography illustrating wide-neck aneurysm of basilar tip-note right-sided shallowness of aneurysm, necessitating right posterior cerebral artery stent deployment; **b** LVIS (3.0 mm×25 mm) deployed from right P1 to basilar trunk and coil insertion via dual microcatheters under protection of stent; **c** successful occlusion of aneurysm visible by post-procedural angiography

Table 4 Type and size of used LVIS devices

Stent type and size	Number
LVIS Jr.	28
2.5×16	17
2.5×24	11
LVIS	27
2.5×25	1
3.0×15	4
3.0×25	17
4.0×35	5

microcatheters and prior to initial frame coil detachment (i.e., jailed microcatheter technique was first attempted). In three patients, the microcatheters exited during stent deployment but were re-inserted through stent struts. In 14 patients (the aforementioned included), access through stent struts was undertaken because a jailed technique either did not allow compacted filling of aneurysm or multiple microcatheters were required. In this manner, access was successful in eight patients (57 %). Success was highest in aneurysms of basilar tip (3/4, 75 %), MCA bifurcation (2/3, 67 %), and ICA (3/5, 60 %). In two AcomA aneurysms, this approach failed. Among 29 bifurcation aneurysms, mean angle change before and after stent placement was 35.1°±19.0° (range, 14–100°) (Fig. 3).

Segmentally incomplete stent expansion was evident in five instances where a standard LVIS was applied to ICA (Fig. 4). In each case, the stent extended from distal ICA to cavernous ICA, through carotid siphon. Proximal segment of stent was involved in four of these and distal segment in one. No apparent complications (e.g., thromboembolism) developed as a consequence, and incomplete expansion was not an issue with the LVIS Jr.

Procedure-related adverse events included asymptomatic thrombus formation (2/55, 3.6 %) and symptomatic infarction (2/55, 3.6 %). In asymptomatic patients, thrombus resolved with intra-arterial tirofiban infusion, whereas symptomatic patients suffered mild neurologic deficits (mRS 1). No fatalities occurred.

Midterm follow-up results

Follow-up imaging was performed at 6 months in 54 patients (MRA, 24; DSA, 30; follow-up rate, 98.2 %), confirming complete occlusion in 50 aneurysms (92.6 %), neck remnant in 3 (5.5 %), and residual sac in 1 (1.9 %). Among 30 patients (LVIS Jr, 18; LVIS, 12) subjected to DSA, in-stent stenosis

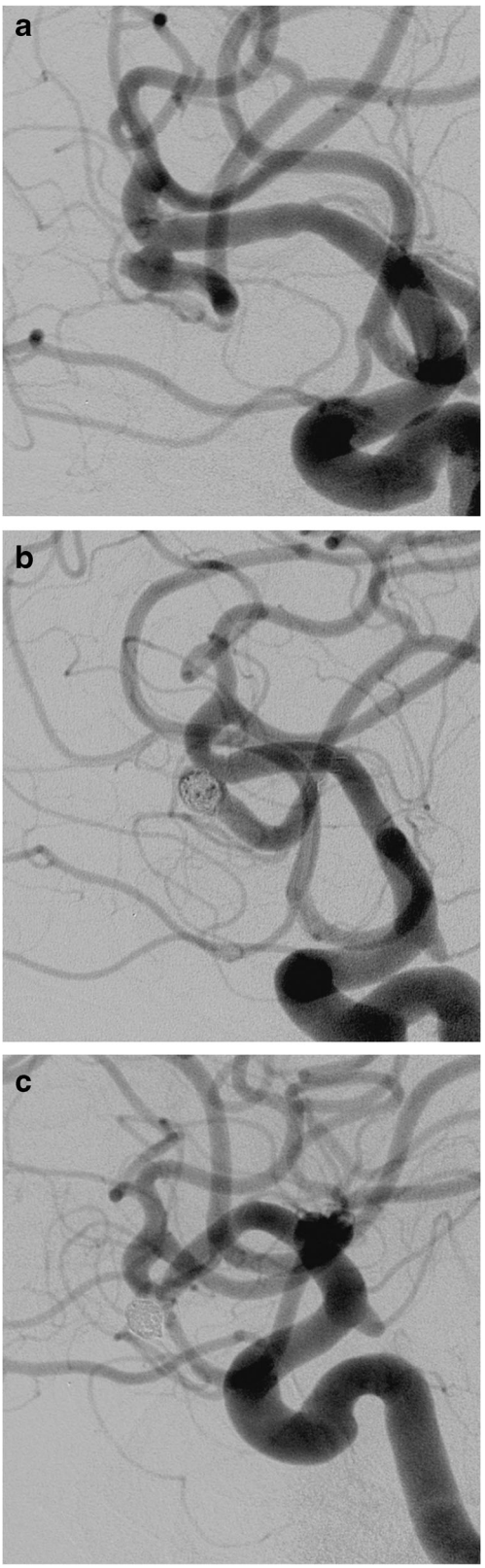

Fig. 3 **a** Conventional angiography illustrating wide-neck aneurysm of middle cerebral artery bifurcation; **b** incomplete occlusion of aneurysm visible by post-procedural angiography after coil embolization under protection of LVIS Jr (2.5 mm×24 mm); **c** complete occlusion of the coiled aneurysm (by progressive thrombosis) and in-stent stenosis visible by 6-month follow-up angiography. A series of angiography showed that the angle between the stented parent artery and the branch was straightened over time

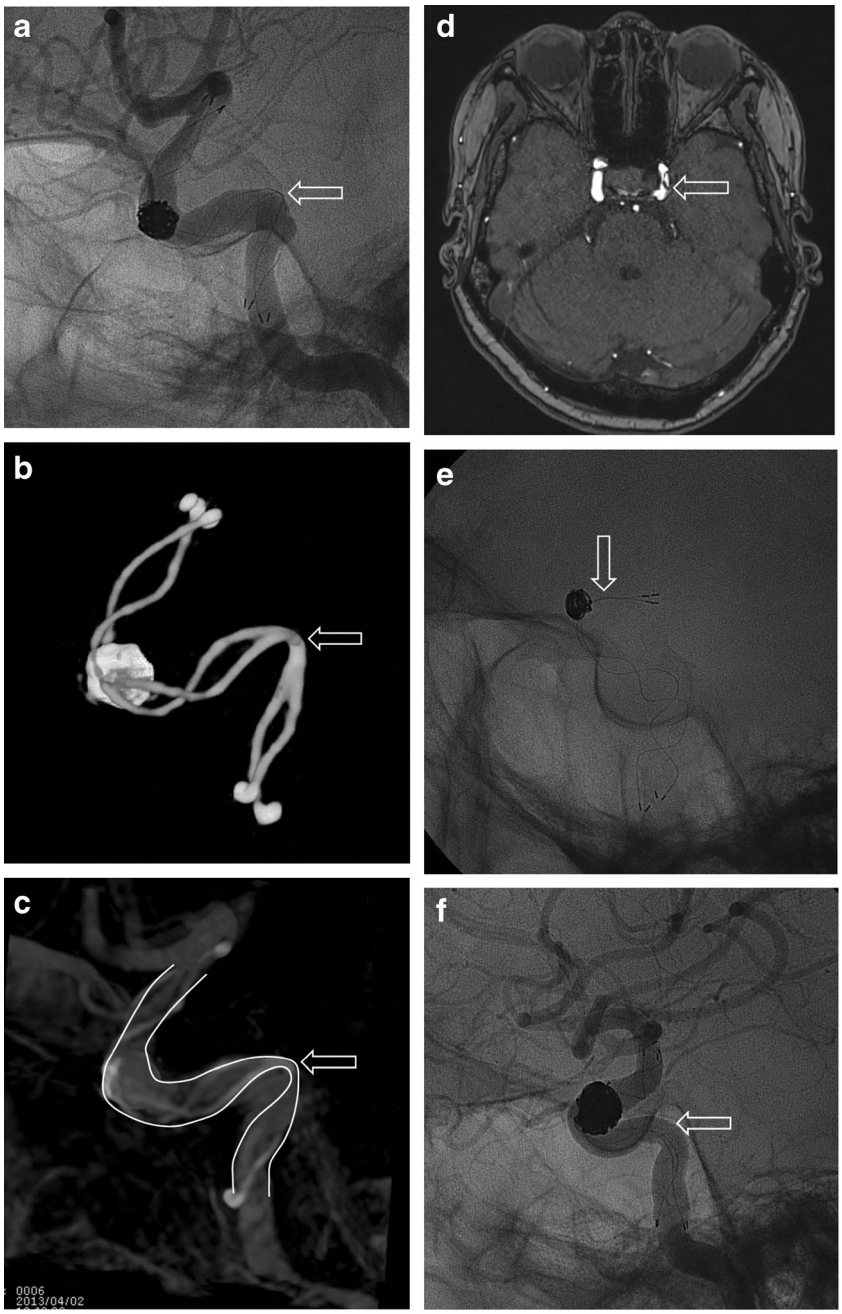

Fig. 4 Imaging of incomplete stent expansion. **a** Post-procedural angiography demonstrating cross of dual radiopaque helical strands on genu portion of cavernous ICA; **b**, **c** three-dimensional (**b**) and illustrating (**c**) images showing the incomplete apposition of the stent to parent artery; **d** floatation of the stent visible by source image of TOF MRA; **e**, **f** post-procedural angiography illustrating incomplete stent apposition of other patients. *Arrows* indicate the incomplete apposition of the stents

was documented in 26 (86.7 %) at mild (18/26, 69.2 %) or moderate (8/26, 30.8 %) levels (see Figs. 1 and 3). No severe in-stent stenosis was observed, and none of the patients affected suffered neurologic symptoms. With the LVIS Jr device, 16 aneurysms (88.9 %) showed in-stent stenosis (mean, 30.7±12.9 %), compared with 10 aneurysms (83.3 %) with the LVIS device (mean, 27.8±13.7 %). The presence and severity of stenosis did not differ statistically by stent type and aneurysm location. There were no instances of stent migration, and only one patient suffered delayed infarction (mRS 1).

Discussion

The development of self-expanding stents dedicated to intracranial use has significantly broadened the applicability of endovascular therapy to include many intracranial aneurysms otherwise unsuitable for this method [12]. After the Neuroform™ stent (Stryker) debuted for treatment of aneurysms, others soon followed, each one dependent on aneurysmal configuration and pattern of parent artery for use. The Neuroform device is a self-expanding open-cell nitinol stent, which has the capacity for segmental expansion and designed

Fig. 5 Differential cell sizing: LVIS and two comparable stents (microscopic images)

to promote stent anchorage and stability. Its competitors, including Enterprise™ (Codman), Leo™ (Balt), and Solitaire™ (eV3), are retrievable stents of closed-cell type, intended to augment navigation, delivery, and stent positioning [1–5, 13, 14]. Because each and all stents differ fundamentally, and none are superior in all functional and physical aspects, the selection of a device is an individualized process based on clinical and technical indications [15]. The LVIS device is a novel, self-expandable braided stent of smaller cell size (~0.9 mm) than any currently available for treatment of intracranial aneurysms (Fig. 5) [16]. It may provide better protection against coil protrusion and yields improved flow diversion (see Fig. 3). Despite the fact that this trial was largely limited to small aneurysms (<10 mm), progressive occlusion was demonstrated during follow-up in a majority of aneurysms that initially showed incomplete occlusion (Fig. 6). However, our success rate in accessing aneurysms through stent struts was fairly low, especially in side-wall aneurysms with tortuous parent arteries (i.e., ICA or AcomA). Its lower porosity may simply equate with a closed-cell stent. Hence, a jailed microcatheter technique should be tried first, given the challenging LVIS construct. The overall risk of procedure-related thromboembolism with use of the LVIS (7.5 %, 4/55) is comparable to rates cited for competitor stents [1–5].

Another advantage of LVIS stents is the capability of delivery through smaller caliber microcatheters. With the standard LVIS stent, a 0.021-in. microcatheter can be used (0.017 in. with LVIS Jr.). This feature facilitates microcatheter navigation (in stent delivery) and accurate stent placement, as shown in our series. The LVIS Jr. is even compatible with the coaxial double lumen balloon catheter system (e.g., Scepter C™, Microvention) [6].

The LVIS stent is well-visualized throughout its course, owing to dual radiopaque helical strands (a triad in LVIS Jr.). Four distal markers (three in LVIS Jr.) are evenly spaced about the device circumference, whereas its four proximal markers are paired. Stability of the stent after deployment is excellent as well. Procedural stent migration never occurred, although incomplete expansion of the stent was evident in five of our patients. In each instance, a higher profile LVIS stent was deployed in ICA, extending through carotid siphon and genu of cavernous ICA. No complications resulted, but the following hazards are possible: (1) delayed thromboembolism due to stent flotation, (2) unprotected coil by floating of stent in

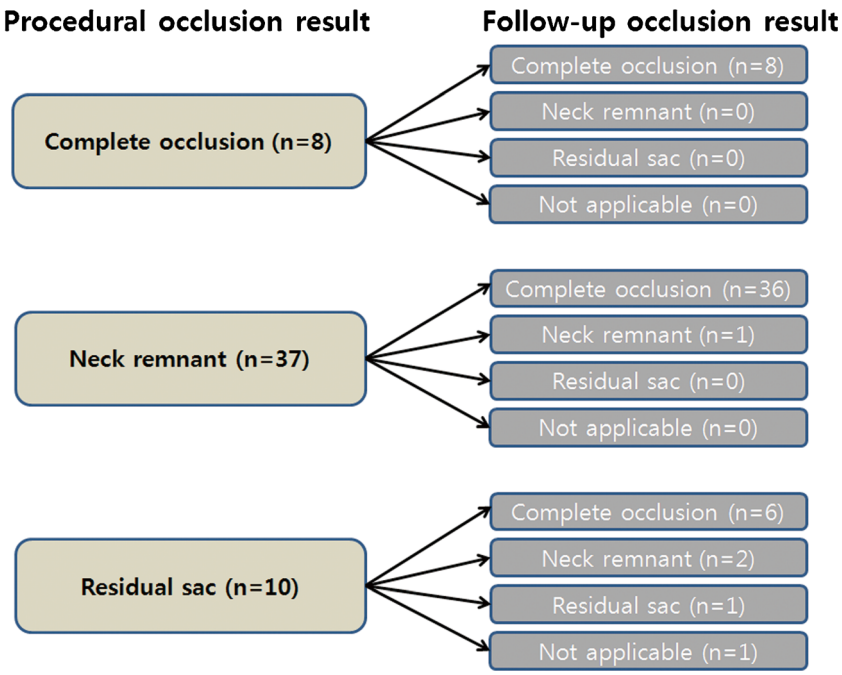

Fig. 6 The flow chart showing change of aneurysmal occlusion result during follow-up period

aneurysm neck (aneurysmal neck escaped or was overridden by the floating segment in our patients), (3) unfavorable effect in terms of post-procedural endothelization and flow diversion, or (4) access difficulty of re-embolization in instances of major recanalization. Our results suggest that the stent may fold or twist within a tortuous and complex carotid siphon, without full flaring of the braided closed-cell structure. According to Valdivia y Alvarado et al. [17], wire-braided stents have two major mechanical drawbacks: (1) inward crimping of distal and proximal ends of the stents ("fish mouth" or "tulip" phenomenon) during stepwise bending and (2) flattening of the midsection at a curvature, which compromises the stent radius. Although the precise means of incomplete expansion observed in our patients remains elusive, we likewise contend that inherent characteristics of the braided-stent are responsible. It is notable that all such events involved in standard LVIS deployed through long segments of tortuous and large-sized arteries. Thus, caution advised in this context.

It is well-known that stent placement across bifurcation aneurysms leads to significant biphasic angular remodeling [18]. Progressive stent-induced angular remodeling has the potential to alter peri-aneurysmal hemodynamics, independent of the flow-diverting properties of stent struts, thereby shifting the balance of hemodynamic forces in favor of progressive aneurysmal occlusion [19]. In our series, the angular change in bifurcation aneurysms after LVIS stent deployment was remarkable (mean, 35.1°±19.0°), exceeding that of the Enterprise stent at our institution (mean, 27.8°±18.5°) [11].

At midterm follow-up (by DSA), there were no instances of LVIS migration, which was notable (4.5 % rate with Enterprise stent) [1], and although the rate of delayed in-stent stenosis was high (86.7 %), instances were mild (18/26, 69.2 %) or moderate (8/26, 30.8 %) only. Previously, we reported a 13.3 % rate of in-stent stenosis with the Enterprise device [1], for which Mocco et al. [20] cited a 3 % rate of significant (>50 %) in-stent stenosis. Fiorella et al. [21] likewise confirmed a 5.8 % rate of delayed in-stent stenosis with Neuroform stents, and Kanaan et al. [22] found that the incidence of stenosis with the Enterprise stent exceeded that of the Neuroform stent. Despite the limited size of our study population, we have shown that the risk of in-stent stenosis is much greater with the LVIS than with the Enterprise stent. In-stent stenosis typically is seen within 3–6 months after stent deployment [23]. Despite its unclear pathophysiology, endothelization and intimal ingrowth are putative factors. Chalouhi et al. [24] reported that younger patients are more likely to develop the stenosis and the neointimal response induced by stent placement is more robust in younger patients. The following influences have also been implicated: (1) background atherosclerosis, (2) endothelial injury after stent deployment, and (3) allergy to metal stent components [1, 20, 25, 26]. The spontaneous resolution of in-stent stenosis was reported by Fiorella et al. and they insisted that the watchful waiting might be effective because some patients experienced partial or complete resolution of the stenosis at follow-up [21]. Recently, Gao et al. [27] reported that Enterprise stent deployment causes a significant dynamic and spontaneously resolvable in-stent stenosis of the parent artery that peaks at 4–6 months and resolves by 12–24 months post-treatment. Similar to the Enterprise device, none of the LVIS-treated patients exhibiting in-stent stenosis suffered ischemic symptoms during follow-up. Long-term DSA monitoring is needed to determine whether or not such stenosis will progress.

Conclusion

The LVIS device performed acceptably in stent-assisted coil embolization of non-ruptured aneurysms, navigating with ease and assuring accurate placement by virtue of lower profile microcatheters. On the other hand, segmentally incomplete expansion of the stent may occur with use of the higher profile LVIS in lesions stemming from tortuous parent vessels, and the high rate of delayed in-stent stenosis warrants follow-up monitoring. Finally, the process of entering an aneurysm with a microcatheter deployed through a stent is a fraught with technical difficulty and may prove challenging.

Acknowledgments This study was supported by Microvention Inc. for clinical trials of LVIS devices.

Ethical standards and patient consent We declare that all human and animal studies have been approved by the Institutional Review Board of Seoul National University Hospital and have therefore been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments. We declare that all patients gave informed consent prior to inclusion in this study.

Conflict of interest We declare that we have no conflict of interest.

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