Journal of Clinical Neuroscience xxx (2018) xxx–xxx

Contents lists available at ScienceDirect

Journal of Clinical Neuroscience

journal homepage: www.elsevier.com/locate/jocn

Opinion paper

Long-term outcomes of Low-profile Visualized Intraluminal Support device usage in stent-assisted coiling of intracranial aneurysm

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ARTICLE INFO

Article history:
Received 29 September 2017
Accepted 18 January 2018
Available online xxxx

Keywords:
Aneurysm
Coil
Embolization
Stent
Follow-up

ABSTRACT

Stent-assisted coil embolization technique have broadened indications for endovascular therapy of aneurysms. The Low-profile Visualized Intraluminal Support device (LVIS) is a self-expanding, nitinol single-braid and closed-cell device introduced fairly recently. We aim to evaluate long-term outcome of LVIS device in stent-assisted coiling of intracranial aneurysms.

Between October 2012 and February 2013, a total of 55 patients with unruptured wide-necked intracranial aneurysms underwent coil embolization procedures involving LVIS devices. Clinical and anatomic parameters assessed included extent of aneurysmal occlusion, stent deployment status, and delayed complications. Anatomic outcomes were evaluated via DSA, MRA, and plain radiography (PR).

Three patients were lost to follow-up after 6 months, but in 37 of 52 qualifying patients (mean follow-up, 27.1 months; range, 12–36 months) post-coiling recanalization was evaluable by DSA or MRA. Only one patient (2.7%) experienced minor recanalization, all others (97.3%) showing complete occlusion. Coil configurations were consistently stable by PR in 15 other patients (mean follow-up, 34.1 months; range, 30–39 months). No migration or altered expansion of stents was evident in 30 patients with available DSA and/or PR images. Three patients (5.8%) suffered delayed cerebral ischemia without neurologic sequelae, all as transient ischemic attacks and all related to withdrawal or change of anti-platelet medications. LVIS device usage in stent-assisted coil embolization of intracranial aneurysms provides excellent long-term results in terms of safety, efficacy and durability.

1. Introduction

The introduction of various self-expandable intracranial stents has enabled endovascular treatment of wide-necked aneurysms previously considered technically prohibitive [1–4]. The Neuroform system (Stryker, Kalamazoo, MI, USA) and the Enterprise Vascular Reconstruction Device (Codman Neurovascular, Raynham, MA, USA) are most widely used for this purpose, with long-term studies generating favorable safety, efficacy, and durability data [5–7]. The Low-profile Visualized Intraluminal Support (LVIS, Microvention, Tustin, CA, USA) device is a self-expanding, nitinol single-wire braid and closed-cell apparatus introduced in 2011. Our periprocedural and mid-term follow-up results of its use in stent-supported coil embolization of unruptured aneurysms have been reported previously [8]; and several other sources have published short- to mid-term safety and efficacy data on such devices [9–14]. However, long-term documentation is scarce. Follow-up of our initial study population was therefore extended, examining outcomes longer term for LVIS device usage in stent-assisted coil embolization of unruptured aneurysms.

2. Materials and methods

2.1. Patient population

A retrospective review was conducted, investigating clinical and radiologic records of 55 patients subjected to LVIS-assisted coil embolization for unruptured wide-necked intracranial aneurysms between October 2012 and February 2013. This cohort also served in an earlier clinical trial involving two institutions. Patient characteristics, endovascular procedural details, and follow-up results (periprocedural and mid-term) have been previously described

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https://doi.org/10.1016/j.jocn.2018.01.075
0967-5868/

[8]. Study endpoints were recanalization of aneurysms coiled via LVIS device and delayed ischemia, both as extended follow-up events. Long-term clinical and radiologic outcomes of the stipulated treatment were thus assessed for presentation herein. This study received approval of Institutional Review Boards at both institutions.

2.2. Radiological follow-up

Beyond the initial 6-month monitoring done originally, follow-up radiologic examinations were done per institutional protocol at postprocedural months12, 24, and 36 TOF-MRA with 3D reconstruction and source images. If MRA was not feasible, or if recanalization was suspected by MRA, DSA was advised to determine the need for further treatment. In patients with moderate in-stent stenosis (confirmed by 6-month postprocedural DSA), repeat DSA at 24 (or 36) months was again recommended. In some patients with completely occluded coiled aneurysms (confirmed by DSA at 6 months), plain radiography (PR) was sufficient for follow-up, given its non-invasiveness and lesser cost. PR monitoring consisted of fluoroscopic images in routine frontal and lateral views, as well as in magnified working-angle views. PR findings were compared with 6-month DSA and immediate post-embolization DSA results, checking coils and stents for changes in shape/configuration.

The following anatomic parameters were evaluated by imaging modality as specified: 1) extent of occlusion or recanalization (DSA, MRA); 2) stent migration and configuration – ie, kinking, fracture, or altered expansion (DSA, PR); 3) in-stent stenosis (DSA); 4) stability of coil shape (PR, if DSA, MRA unavailable). To assess extent of occlusion, the Raymond scale was applied: complete occlusion, minor recanalization, or major recanalization. Follow-up diagnostics were interpreted by two experienced neurointerventionists. In the event of disparate readings, a third-party consensus prevailed.

2.3. Clinical follow-up

According to our institutional protocol, dual antiplatelet agents were administered routinely for at least 3 months after stent-assisted coil embolization (if no major related bleeding), and single-agent therapy was maintained for at least 1 year. Clinical outcomes were gauged via modified Rankin Scale (mRS), assessed by independent neurovascular surgeon at the time of follow-up visits. Any symptoms of delayed cerebral ischemia were checked, as were antiplatelet medication regimens and durations. An MR imaging work-up was done to confirm any lesions related to delayed symptom development.

3. Results

Of the 55 patients enrolled at onset of the original clinical trial, three patients were lost to neurovascular surgical follow-up at 6 months postembolization, leaving 52 patients (94.5%) for long-term follow-up of clinical and radiologic parameters. LVIS was applied in 26 patients, while LVIS junior was in the other 26 patients. In one patient, major recanalization was observed 6 months after coil embolization (during original clinical trial), with coil embolization repeated 12 months after the initial procedure. Follow-up periods in such patient was calculated from dates of second procedures for assessing extent of aneurysmal occlusion, using initial procedure date to analyze all other variables.

3.1. Radiologic follow-up results

Demographic patient data and radiological follow-up results are summarized in Table 1. Evaluation for recanalization of coiled aneurysms was available in 37 patients using DSA and MRA, with mean follow up of 27.1 months (range, 12–36 months). One patient (2.7%) showed minor recanalization on MRA image 24 months after the coil embolization procedure. All other patients (97.3%) showed complete occlusion (Fig. 1). PR image was available in remaining 15 patients (27.3%) in whom DSA or MRA was not available, with mean follow up time of 34.1 months (range 30–39 months). The coil shape and configuration were stable in all 15 patients.

Stent migration and configuration was evaluated with DSA or PR in 30 patients with mean follow up time of 32.2 months (range 18–40 months). There was no case of stent migration. Of the five patients in whom we have previously reported the incomplete expansion of the stent, four patients were eligible for evaluation of stent expansion state. The stent remained incompletely expanded with no change in conformation in mean period of 29.8 months (range 18–36 months).

Among six patients with DSA follow-up images (mean follow-up, 25.8 months; range, 12–36 months), no in-stent stenosis was evident. Three patients did develop moderate in-stent stenosis (during earlier trial), as shown by 6-month postprocedural DSA. However, stenosis had resolved for all three patients in follow-up DSA images (see Fig. 1).

3.2. Clinical follow-up results

In the 52 qualifying patients, mean clinical follow-up was 34.6 months (range, 24–41 months). No patients developed bleeding long-term, but three patients (5.8%) in total suffered delayed cerebral ischemic symptoms. Transient ischemic attacks occurred in two patients at 9 and 12 months, respectively after coil embolization. The ischemic events coincided with changes in medication, switching from dual (aspirin and clopidogrel) to aspirin-only antiplatelet regimens. Upon conservative management and reinstatement of both agents, these patients recovered without residual neurologic deficits or further ischemic symptomology. Another patient, suffering an attack 15 months after coil embolization, had discontinued clopidogrel for spinal surgery. Again, recovery was complete and uneventful. The brain MRI study at the time of

Table 1
Demographic patient data and radiological follow-up results.

Number of patients	52
Age (at the time of coil embolization)	55.5 (30–75)
Gender (female/male)	39:13
Aneurysm location	
Internal carotid artery	19
Anterior communicating artery	15
Middle cerebral artery	7
Basilar tip	5
Posterior communicating artery	5
Anterior cerebral artery	1
Imaging modality available	
DSA	6 (11.5%)
MRA	36 (69.2%)
PR	27 (51.9%)
Occlusion state (MRA or DSA)	
Complete occlusion	36/37 (97.3%)
Minor recanalization	1/37 (2.7%)
Coil stability (PR, when DSA or MRA unavailable)	
Stable coils	15/15 (100%)
Stent migration or configuration change (DSA or PR)	0/30 (0%)
In-stent stenosis (DSA)	0/6 (0%)

PR = plain radiography.

Please cite this article in press as: Yoo DH et al. Long-term outcomes of Low-profile Visualized Intraluminal Support device usage in stent-assisted coiling of intracranial aneurysm. J Clin Neurosci (2018), https://doi.org/10.1016/j.jocn.2018.01.075