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Does stent type impact coil embolization outcomes in extended follow-up of small-sized aneurysms (< 10 mm)?

Jeongjun Lee[1] · Young Dae Cho[2] · Dong Hyun Yoo[2] · Hyun-Seung Kang[3] · Won-Sang Cho[3] · Jeong Eun Kim[3] · Jusun Moon[4] · Moon Hee Han[2,3]

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Abstract

Purpose Self-expandable stents have enabled endovascular treatment of wide-necked aneurysms (ordinarily viewed as technically prohibitive), with favorable outcomes. However, the impact of stent type on occlusive stability has not been adequately investigated. In small-sized unruptured saccular aneurysms, we generated estimates of stent-assisted coil embolization outcomes during follow-up monitoring. Stent type and other risk factors linked to recanalization were analyzed.

Methods A cohort of 286 patients harboring 312 small-sized unruptured aneurysms (< 10 mm) was subjected to mid-term and extended follow-up monitoring after stent-assisted coiling. Three types of stents (Enterprise, 192; Neuroform, 27; LVIS, 93) were deployed in this population; all medical records and radiologic data of which were reviewed. Mid-term recanalization rates and related risk factors were assessed using binary logistic regression analysis.

Results A total of 49 aneurysms (15.7%) displayed recanalization at 6 months postembolization, with 34 and 15 instances of minor and major recanalization, respectively. Multivariate analysis indicated that wide-necked aneurysms (> 4 mm) (HR = 2.362; $p = 0.017$), incomplete occlusion at time of coiling (HR = 2.949; $p = 0.002$), and stent type ($p = 0.048$) were significant factors in mid-term recanalization, whereas hypertension ($p = 0.095$) and packing density ≤ 30% ($p = 0.213$) fell short of statistical significance. Compared with Enterprise (HR = 2.828) or Neuroform (HR = 4.206) stents, outcomes proved more favorable with use of LVIS.

Conclusions Above findings demonstrate that in addition to occlusive status at time of coil embolization and neck size, stent type may affect follow-up outcomes of stent-assisted coil embolization in small-sized aneurysms. LVIS (vs Enterprise or Neuroform stents) performed best during follow-up monitoring in terms of limiting recanalization.

Keywords Aneurysm · Coil embolization · Follow-up · Recurrence · Stent

Introduction

Since the landmark International Subarachnoid Aneurysm Trial (ISAT), endovascular coil embolization has assumed wide usage for treatment of intracranial aneurysms [1]. Although wide-necked aneurysms still pose a technical challenge for endovascular treatment [2], device improvements and advanced coiling techniques have made it possible to treat a large percentage of oddly configured aneurysms that ordinarily hamper endovascular coil embolization [3]. Stenting systems in particular have continued to evolve, broadening the scope of endovascular therapy considerably in this setting [2, 4]. Deployed stents provide 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 [5–8]. Once the

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✉ Young Dae Cho
aronnn@naver.com

[1] Department of Neurosurgery, Dongguk University Ilsan Hospital, College of Medicine, Dongguk University, Ilsan, South Korea

[2] Department of Radiology, Seoul National University Hospital, Seoul National University College of Medicine, 101 Daehak-ro, Jongno-gu, Seoul 03080, South Korea

[3] Department of Neurosurgery, Seoul National University Hospital, Seoul National University College of Medicine, Seoul, South Korea

[4] Department of Neurology, Korea University Anam Hospital, Korea University College of Medicine, Seoul, South Korea

Neuroform stent (Stryker, Kalamazoo, MI, USA) debuted for treatment of aneurysms, others soon followed, each intended for specific aneurysmal configurations and parent arterial patterns [9]. The properties of each device stem from configurations or manufacturing methods (e.g., open or close-cell type, laser cut, or braided type), imparting behavioral differences relative to neck protection and flow diversion. Although stents used accordingly are believed protective, preventing progression to recanalization during follow-up periods, the impact of stent type on postcoiling occlusive status of aneurysms has not been adequately investigated. Given that recanalization generally develops within 6 months of coiling [10, 11], mid-term (6-month) and more extended monitoring of aneurysms was conducted after stent-assisted coil embolization to assess recanalization rates and factors impacting recanalization, including stent type.

Materials and methods

Patient selection and data collection

A total of 1652 consecutive coil embolization procedures done at a single institution between September 2012 and June 2016 were accessed for this retrospective review. Of these, 463 entailed stent-assisted coiling. Non-saccular (n = 43), recanalized (n = 65), large-sized (≥ 10 mm; n = 26), ruptured (n = 3) aneurysms were excluded, leaving 326 saccular aneurysms eligible for study. Endpoints of this study were recanalization of coiled aneurysms in follow-up imaging at 6 months and beyond. Thus, lesions lacking 6-month follow-up monitoring (n = 14) were further excluded. Ultimately, 286 patients with 312 aneurysms were investigated (Fig. 1). During this period, three types of stents (Enterprise [Codman Neuro, Raynham, MA, USA], Neuroform [Stryker], and LVIS [MicroVention Inc., Tustin, CA, USA]) were utilized at our institution. Multiple patient variables were retrieved from medical records as follows: gender, age, and medical parameters (hypertension, diabetes, smoking, hyperlipidemia). Angiographic data were also collected, namely overall dimension and neck size, location (anterior vs posterior circulation) [12], and type (side-wall vs bifurcation) of aneurysm [13]; depth-to-neck ratio (D/N ratio); packing density; and use of bioactive coils (hydrogel-modified or polyglycolic acid/lactide copolymer-coated coils). Based on length of bioactive coil engaged (relative to total length of coil inserted), aneurysms were grouped as bare (≤ 50%) or bioactive (> 50%) coil. After the procedure, coil packing density was calculated as the ratio of the total coil volume to aneurysmal volume. The aneurysmal volume was measured based on the

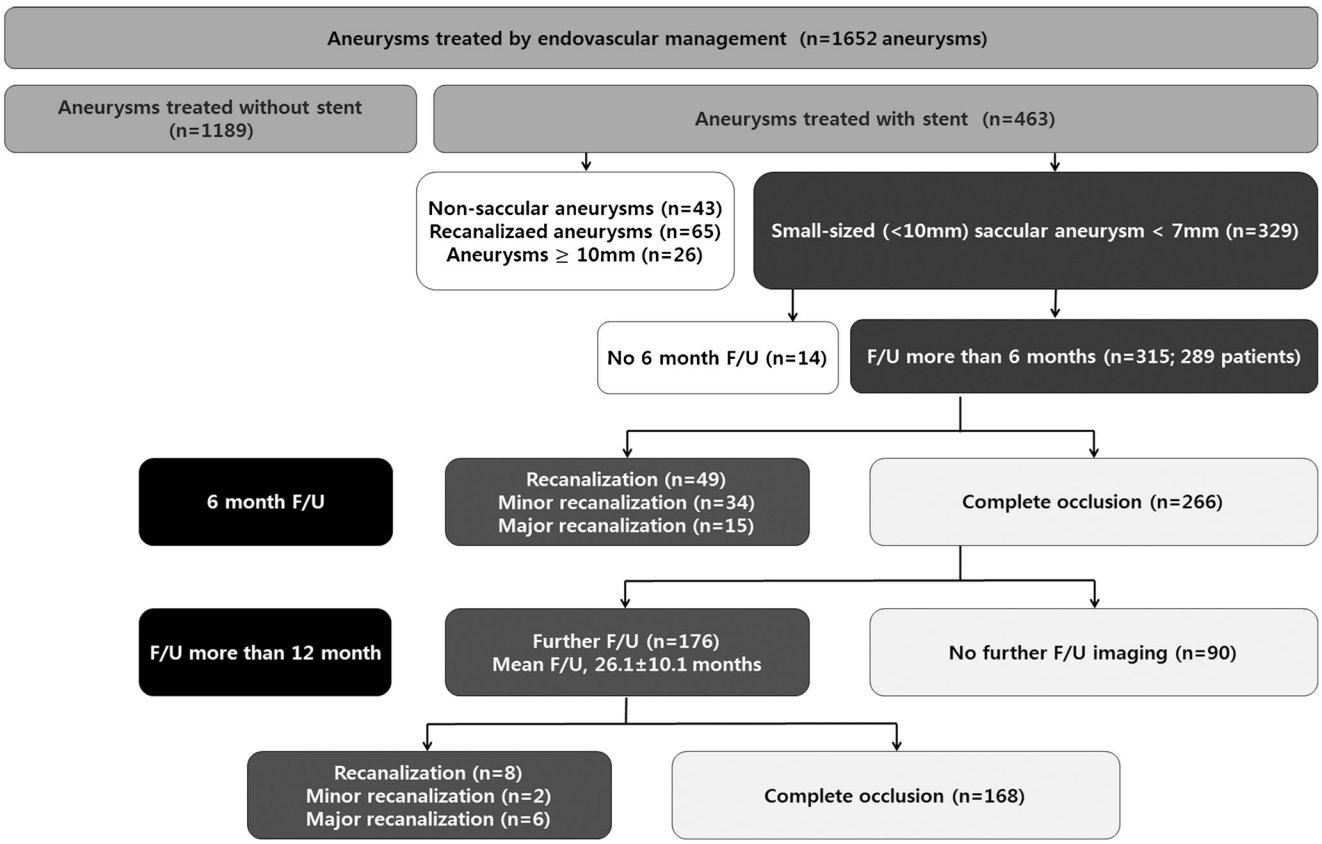

Fig. 1 Flow diagram of study design

assumption that the aneurysm was ellipsoid. In addition, the volume of the coils deployed into the aneurysm was calculated by multiplying the length of the coil by the cross sectional area. This study was conducted with approval of our Institutional Review Board. The requirement to obtain written informed consent for study participation was waived.

Endovascular procedure and angiographic monitoring

Most endovascular procedures were conducted under general anesthesia. All patients with UIAs were given antiplatelet medication beforehand. As stipulated at our institution, dual antiplatelet agents (clopidogrel and aspirin) were administered if stent protection was anticipated [14]. In patients responding poorly to clopidogrel, based on the VerifyNow P2Y12 assay (Accriva Diagnostics, Edison, NJ, USA), cilostazol was added. A bolus of heparin (3000 IU) was administered after femoral arterial sheath placement, supplemented by hourly boluses (1000 IU), and activated clotting time was monitored hourly. Upon completing endovascular procedures, tirofiban or heparin infusion was maintained for up to 12 h in instances of procedural thromboembolism. Sustained antiplatelet medication was recommended after procedures, using dual agents for at least 3 months and a single agent for at least 1 year.

Follow-up radiologic examinations, performed at 6, 12, 24, and 36 months post-procedure, relied on time-of-flight magnetic resonance angiography (TOF-MRA). Three tesla (T) ($n = 182$) and 1.5 T ($n = 130$) MR scanners were used for the acquisition of 3D reconstruction and source images. If MRA was not feasible or if recanalization was suspected by MRA, conventional angiography was advised to determine the need for further treatment. Anatomic outcomes of complete occlusion or recanalization were gauged according to the Raymond-Roy occlusion classification (RROC) [10]. Recanalization was defined as RROC class II (minor) and RROC class III (major), regardless of immediate postembolization angiographic results. Follow-up diagnostics were randomly scheduled, with two experienced neurointerventionists (YDC, HSK) blinded to pertinent clinical and radiologic information independently reviewing all follow-up tests, including MRA (MIP images and source images) and conventional angiography. In event of disagreement, a consensus was established by a third interventional neuroradiologist (MHH).

Statistical analyses

Continuous data were expressed as mean ± standard deviation (SD). Chi-square and Fisher's exact tests or unpaired *t* test were used to assess categorical or continuous variables, respectively. Univariate analysis of parameters impacting recanalization after coiling was conducted via binary logistic regression, using variables with p values < 0.10 in a multivariable model to determine risk factors. Average annual risk of recanalization was calculated as total of recanalized aneurysms divided by aneurysm-year total for the follow-up periods. Recanalization-free survival was estimated using the Kaplan-Meier method, and the survival rates were compared using the log-rank test. Statistical significance was set at $p < 0.05$, employing standard software (SPSS v19; SPSS Inc., Chicago, IL, USA) for all analytics.

Results

Characteristics of coiled aneurysms with stent

A total of 286 patients subjected to stent-assisted coiling of 312 small-sized unruptured aneurysms (< 10 mm) were monitored at 6 months postembolization. Subjects were predominantly female (232/312, 74.4%), with mean age of 58.7 ± 9.5 years. Most lesions involved anterior (284/312, 91.0%) rather than posterior (28/312, 9.0%) circulation. Aneurysms of anterior circulation were distributed as follows: internal carotid artery, 105; anterior communicating and anterior cerebral arteries, 72; middle cerebral artery, 77; and posterior communicating artery, 30. Side-wall and bifurcation aneurysms totaled 142 (45.5%) and 170 (54.5%), respectively. Mean estimated size of aneurysms was 5.3 ± 1.8 mm, and 150 lesions (48.1%) were ≤ 5 mm. Aneurysmal neck measured > 4 mm in 151 aneurysms (48.4%), and in 53 aneurysms (17.0%), D/N ratio was > 1.5. Mean packing density of coil was 34.1 ± 8.6%, with bioactive coil > 50% in 33 aneurysms (10.6%). Enterprise stent was applied in 192 aneurysms, Neuroform stent was in 27, and LVIS was in 93. Successful occlusion was achieved immediately after coil embolization in 181 aneurysms (58.0%). Characteristics of aneurysms studied are detailed in a Supplemental Table.

Recanalization of coiled aneurysms at 6 months

A total of 49 aneurysms (15.7%) showed recanalization (minor 34; major 15) at 6-month follow-up monitoring. In the follow-up occlusion result, interobserver agreement was found to be excellent ($k = 0.818$, range 0.774 to 0.862). Baseline characteristics were as follows: female, 39/49 (79.6%); mean age, 59.6 ± 10.2 years; hypertension, 30/49 (63.3%); anterior location, 45/49 (91.8%); bifurcation aneurysm, 23/49 (46.9%), mean size, 6.0 ± 1.7 mm; packing density, 30.9 ± 9.0%; bioactive coil > 50%, 5/49 (10.2%); and D/N ratio > 1.5, 6/49 (12.2%). In decreasing order, Enterprise, 35/49 (71.4%); Neuroform, 8/49 (16.3%); and LVIS, 6/49 (12.2%) stents were used (Figs. 2, 3, and 4). Univariate analysis indicated that hypertension, aneurysmal neck size, packing density, incomplete occlusion

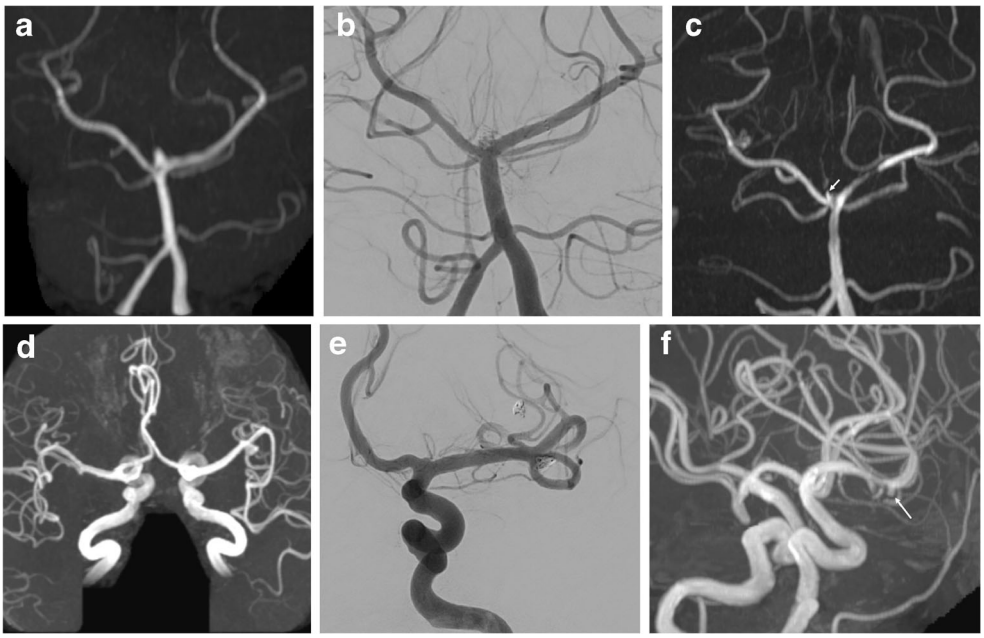

Fig. 2 Representative cases of minor (**a**–**c**) and major (**d**–**f**) recanalization in coiled aneurysm with LVIS. **a** Preembolization TOF-MRA of basilar top aneurysm. **b** Postembolization DSA. **c** Six-month follow-up TOF-MRA (arrow indicates the minor recanalized portion). **d** Preembolization TOF-MRA of the left MCA bifurcation aneurysm. **e** Postembolization DSA. **f** Six-month follow-up TOF-MRA (arrow indicates the major recanalized portion).

immediately postembolization, and stent type were associated with recanalization (Table 1). Other variables, such as female gender, age, aneurysmal location, diabetes, smoking, hyperlipidemia, bifurcation aneurysm, D/N ratio, aneurysmal size, and bioactive coil usage, did not impact recanalization significantly. In multivariate analysis, wide-necked aneurysms (> 4 mm) (HR = 2.362; $p = 0.017$), incomplete occlusion immediately postembolization (HR = 2.949; $p = 0.002$), and stent type ($p = 0.048$) were identified as significant risk factors for mid-term recanalization, whereas hypertension ($p = 0.095$) and packing density ≤ 30% ($p = 0.213$) fell short of statistical significance (Table 2). Outcomes of aneurysms bearing LVIS stents were more favorable by comparison (Enterprise, HR = 2.828; Neuroform, HR = 4.206).

Extended monitoring of coiled aneurysms completely occluded or showing minor recanalization at 6 months

Of 263 aneurysms showing complete occlusion at 6 months, 173 were further evaluated (≥ 12 months). The other 90 lesions were either recently treated (< 12 months prior; $n = 53$)

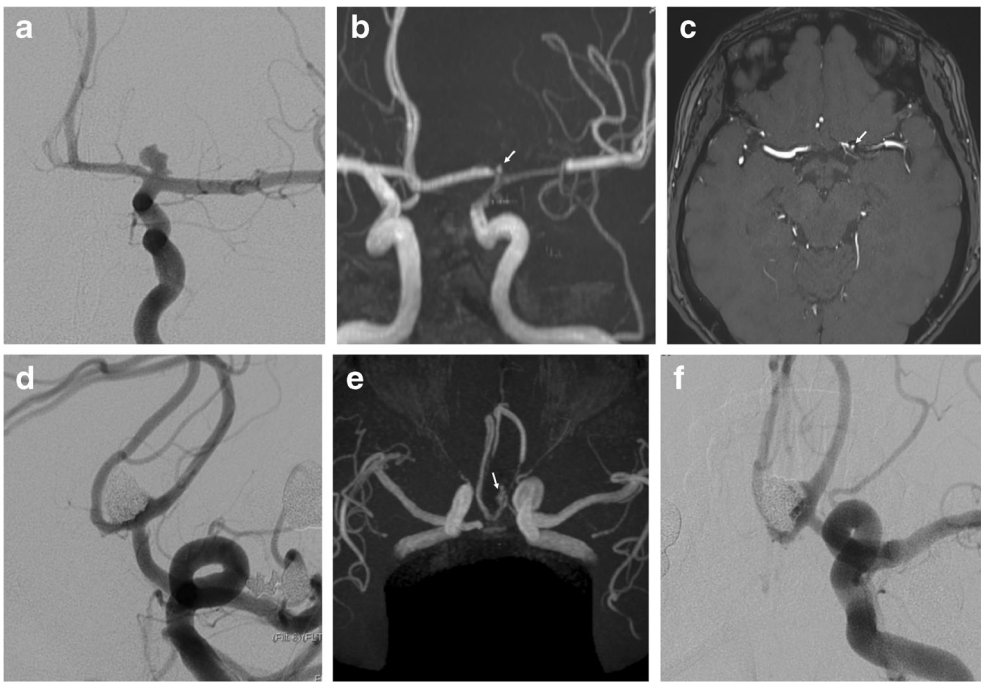

Fig. 3 Representative cases of minor (**a**–**c**) and major (**d**–**f**) recanalization in coiled aneurysm with Enterprise stent. **a** Preembolization TOF-MRA of internal carotid artery bifurcation aneurysm. **b**, **c** Six-month follow-up TOF-MRA (arrow indicates the minor recanalized portion; **b** MIP image; **c** source image). **d** Postembolization TOF-MRA of the anterior communicating artery aneurysm. **e**, **f** Six-month follow-up angiography (arrow indicates the major recanalized portion; **e** TOF MRA; **f** DSA).

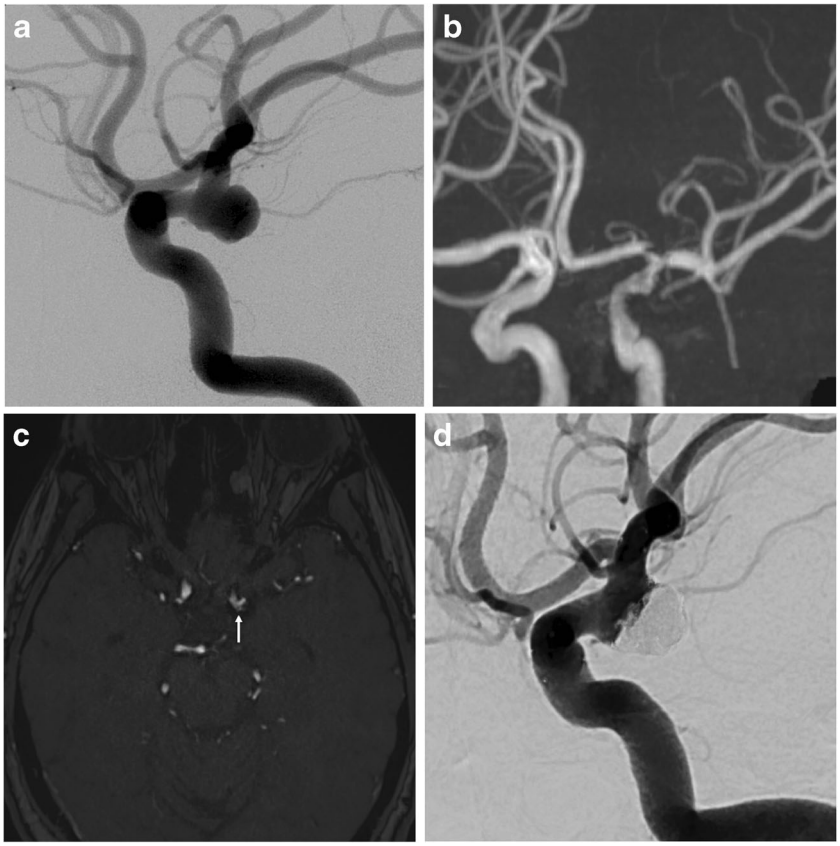

Fig. 4 Representative case of minor recanalization in coiled aneurysm with Neuroform stent. **a** Preembolization DSA of posterior communicating artery aneurysm. **b**–**d** Six-month follow-up TOF-MRA (arrow indicates the minor recanalized portion; **b** MIP image; **c** source image; **d** DSA).

or had been followed for 6 months only ($n = 37$). Eight aneurysms (Enterprise, 5; LVIS, 3) developed recanalization (minor, 6; major, 2) during 381.5 aneurysm-years of monitoring (mean follow-up period, 26.1 ± 10.1 months; median, 18 months). Overall recanalization rate of coiled aneurysms completely occluded at 6 months was 2.1% per aneurysm-year. Of 34 aneurysms showing minor recanalization at 6 months, 27 aneurysms were monitored further (mean follow-up period, 27.6 ± 0.4 months; median, 30 months). Three aneurysms (all Enterprise stents) progressed to major recanalization during 62.1 aneurysm-years. The overall annual rate of major recanalization in coiled aneurysms with minor recanalization at 6 months was 4.8% per aneurysm-year. Kaplan-Meier estimates of cumulative survival without recanalization are presented in Fig. 5. Overall recanalization-free survival rate at 24 months was 83.2% (Neuroform, 70.4%; Enterprise, 80.0%; LVIS, 92.5%; $p = 0.043$).

Discussion

The use of self-expandable stents has contributed to advancement of endovascular techniques used for intracranial aneurysms [4, 15–17]. It became possible to treat difficult aneurysms, particularly those with complex morphologies, wide necks, or lower dome-to-neck ratios, by preventing protrusion or migration of coils and enabling dense coil packing [17, 18]. Outcomes of coil embolization also have proved more favorable with (vs without) stent assistance [4, 17, 19–21]. As reported by Cho et al. [17], recanalization rates in coiled aneurysms with (vs without) stents deployed were significantly lower at 6 months after coil embolization (1.9 vs 10.2%, respectively) or at last follow-up (8.3 vs 18.5%, respectively). In one meta-analysis [18], recurrence was more than halved by stent-assisted coil embolization (12%), compared with coiling-only (27.9%). These data suggest that stents divert saccular flow, inducing stasis and progressive thrombosis [6, 19, 22, 23]. They may well provide scaffolding for endothelialization of aneurysmal necks, severing them from parent arteries [15, 24]. On this basis, we analyzed various factors (including stent type) with a potential to influence mid-term anatomic outcomes of small aneurysms subjected to stent-assisted coiling.

Incomplete initial occlusion, large lesion size, low packing density, and rupture have been previously identified as factors in recanalization [4, 10, 19, 25–27]. Raymond et al. [10] found significantly lower risk of recurrence in instances of complete initial occlusion, whereas wide-necked aneurysms showed significantly greater risk of recurrence in long-term angiographic monitoring. In multivariate analysis of stent-assisted coiling, Chalouhi et al. [28] further demonstrated that incomplete aneurysmal occlusion at time of treatment is predictive

Table 1 Demographic and angiographic characteristics of coiled aneurysms with stent ($N = 312$)

6-mo occlusion result Variables	Complete occlusion ($n = 263$)	Recanalization ($n = 49$)	p value
Clinical variables			
Female	193	39	0.476
Age, years	58.6 ± 9.4	59.6 ± 10.2	0.493
Hypertension	116	31	0.027
Diabetes	27	5	0.990
Smoking	22	5	0.725
Hyperlipidemia	87	12	0.216
Aneurysmal variables			
Anterior location	239	45	0.829
Bifurcation An	147	23	0.276
D/N ratio (> 1.5)	47	6	0.411
Maximum size (mm)	5.2 ± 1.8	6.0 ± 1.7	
> 5 mm	133	29	0.280
Neck size (mm)	4.2 ± 1.3	5.3 ± 1.9	
> 4 mm	118	33	0.003
Procedural variables			
Stent			0.004
LVIS	87	6	
Enterprise	157	35	
Neuroform	19	8	
Bioactive coil > 50%	28	5	0.926
Incomplete occlusion	100	31	0.001
Packing density	34.7 ± 8.5	30.9 ± 9.0	0.004
> 30%	189	24	0.002

mo month, *D/N ratio* dome-to-neck ratio

of recanalization. In our series, multivariate analysis indicated that wide-necked aneurysms (> 4 mm), incomplete initial occlusion (at coil embolization), and stent type were significant factors in mid-term recanalization. Hence, stent type does have bearing on outcomes of stent-assisted coil embolization in follow-up monitoring of small-sized unruptured aneurysms.

A variety of self-expanding neurovascular stents (Neuroform, Leo, Enterprise, Solitaire, and LVIS) is currently available for stent-assisted coil embolization. At our facility, Enterprise, Neuroform, and LVIS devices are used preferentially for endovascular treatments. The Neuroform stent (Stryker) was the first self-expandable laser-cut stent designed to treat cerebral aneurysms. Its reputed limitations include low radial force, difficulty of deployment, saccular cell dislocation, and lack of retractability [15, 29–32]. The Enterprise device (Codman Neuro [DePuy Synthes]) was the second laser-cut, closed-cell stent to be marketed, and the Low-profile Visualized Intraluminal Support device (LVIS; MicroVention [Terumo]) is a novel, self-expandable braided stent with closed-cell design. Its helical strands (for whole dimension visualization) aid in full deployment and appropriate wall apposition.

There are notable differences in these three stents. By design, they are either open-cell (Neuroform) or closed-cell (Enterprise, LVIS) type. It is conceded that open-cell stents are superior to closed-cell counterparts in terms of wall apposition, although saccular protrusion and low radial force may be problematic [30, 32]. Both LVIS and Enterprise stents are

Table 2 Logistic regression model assessing the risk of recanalization in coiled aneurysms with stent

Variables	Odds ratio	95% CI	p value
Neck size > 4 mm	2.362	1.165–4.791	0.017
Incomplete occlusion	2.949	1.500–5.796	0.002
Packing density ≤ 30%	1.552	0.778–3.096	0.213
Hypertension	1.762	0.907–3.422	0.095
Stent type			0.048
Enterprise	2.828	1.108–7.216	0.030
Neuroform	4.206	1.202–14.721	0.025
LVIS	Reference		

CI confidence interval

*$p < 0.05$ is significant

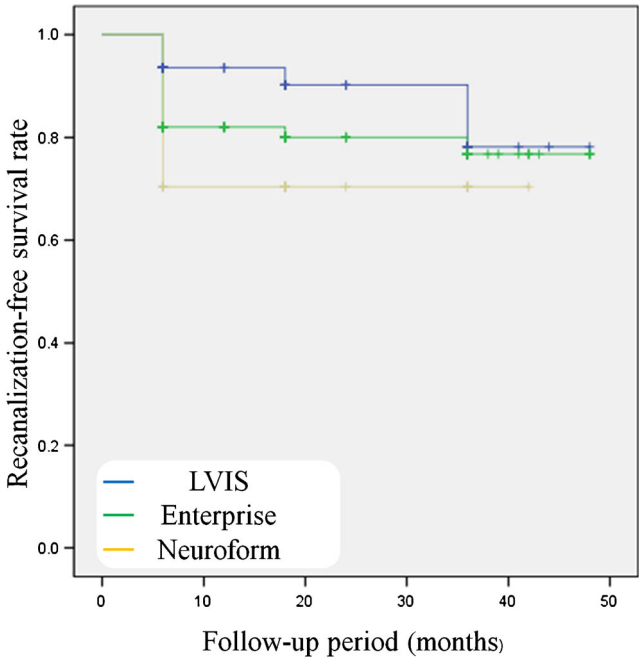

Fig. 5 Kaplan-Meier 24-month estimates of cumulative survival (without recanalization) in coiled aneurysms with stent, shown by risk factors of stent type (Neuroform, 70.4%; Enterprise, 80.0%; LVIS, 92.5%; $p = 0.043$)

capable of being partially deployed, recaptured, and redeployed. However, an important advantage of the LVIS stent is its metal coverage of aneurysmal neck, which is significantly greater than the others afford. In clinical practice, it is difficult to appreciate exactly how these differences might affect outcomes of endovascular treatment.

Many studies have reported angiographic follow-up monitoring of occluded aneurysms by stent type. In terms of occlusion rates, LVIS stents [9, 33–37] (68–92.6%) have fared better than Enterprise (42.7–74.2%) [38–41] and Neuroform (46–74.19%) stents [41–44], and earlier studies have shown slightly better outcomes in follow-up monitoring of LVIS usage. Still, there are some limitations. A mean follow-up period of only 6–7.52 months is cited in the literature on LVIS stents, compared with much longer mean durations for Enterprise (5.8–20.6 months) or Neuroform (12.0–37.1 months) stents. Extended monitoring increases detection of eventual recanalization and may explain the comparatively poorer outcomes of the latter two devices [4, 10]. Furthermore, classifying of intracranial aneurysmal occlusion (as in previous studies) is a subjective process likely to vary from one neurointerventionist to the next. Although rates of occlusion clearly seem lower in follow-up assessments of LVIS (vs Enterprise or Neuroform) stents, direct comparison by standard means is needed for validation.

Some researchers have compared stent-assisted coiling by Enterprise and Neuroform devices, analyzing outcomes in follow-up monitoring. One particular analysis, addressing 4238 aneurysms in 4039 patients, revealed higher reported rates of complete occlusion for coil embolizations using Enterprise (vs Neuroform) stents (74.7 vs 61.1%, respectively), and the recanalization rate was higher when deploying Neuroform stents [41]. Durst et al. [45] likewise reported slightly higher recanalization and retreatment rates for Neuroform (vs Enterprise) stents. In still other studies, the Neuroform (as opposed to Enterprise) stent emerged as a statistically significant independent factor in recanalization and retreatment of aneurysms [28, 45].

Our data were aligned with the above, showing a lower recanalization rate at the 6-month follow-up mark for coiling of aneurysms using an Enterprise (35/195, 17.9%) vs Neuroform (8/27, 29.6%) stent. On the other hand, there are few studies comparing the LVIS device with these other stents. We have identified only one published report of direct LVIS and Enterprise stent comparison in clinical practice. Ge et al. [46] documented progressive thrombotic occlusion during follow-up monitoring in 33% of patients subjected to LVIS stenting, compared with 14.3% of those receiving Enterprise stents. Although not statistically significant, recurrence rates for LVIS and Enterprise stent deployment did diverge (2.8 and 10.7%, respectively). In our series, the LVIS stent proved superior, showing a significantly lower recanalization rate (6/93, 6.5%; $p = 0.048$) by comparison. In multivariate analysis, outcomes of treated aneurysms involving LVIS stents were more favorable in follow-up monitoring than those involving Enterprise (HR = 2.828) or Neuroform (HR = 4.206) stents.

Self-expanding neurovascular stents were originally designed as scaffolding to bridge aneurysmal necks and protect against coil protrusion or migration. Subsequently, flow diversion effect and the potential for progressive postembolization thrombosis gained considerable attention. Dholakia et al. [47] discovered better flow reduction in LVIS and Enterprise stents (vs Neuroform stents) during computational simulations of fluid dynamics (82 vs 65% reduction in kinetic energy). Thus, they contended that the open-cell design of Neuroform stents may confer aneurysmal neck coverage and flow resistance to the least extent, whereas closed cell LVIS and Enterprise stents perhaps alter hemodynamic parameters, promoting saccular thrombosis and endothelialization of aneurysmal necks [28].

The LVIS stent offers a high degree of metal coverage (~ 23%), much denser than that incorporated in more conventional Enterprise and Neuroform (8–11%) stents [48]. The porosity of a neurovascular stent is also important for control of circulatory hemodynamics. Interwire spacing dictates resistance to blood flow, allowing for stasis in aneurysms and thrombotic facilitation [7, 49, 50]. Indeed, blood flow velocity and wall shear stress are proportional to metal stent coverage [51]. The superior flow reduction effect of the LVIS stent has been confirmed by Wang et al. [48], who demonstrated that a

single LVIS stent surpassed even double Enterprise stenting in reducing intra-aneurysmal velocity and wall shear stress. Even double LVIS stent showed more reduction in wall shear stress and velocity compared with a single Pipeline. Excessive wall shear stress and high blood flow velocity at necks of treated aneurysms are considered contributory factors in eventual recanalization [52, 53]. Although this particular study relied on computational fluid dynamics and therefore is of limited value in a clinical setting (given the host of complexities), its relevance in follow-up monitoring of occlusion rates after stent-assisted coil embolization of aneurysms may be considerable.

Our study has several limitations, one being the retrospective collection of data at a single center. Thus, there is a potential for bias in choice of stent. For instance, Enterprise and Neuroform (rather than LVIS) stents were more often selected for aneurysms of internal carotid artery, and the aneurysms in which they were deployed tended to be a bit larger. Choice of stent was weighed in each instance, based on merits and drawbacks, but only large-scale prospective studies will provide needed clarification. In addition, three types of stents became available at different times for a certain period, and level of coiling technique might be different in each stent. Another limitation is that TOF-MRA was used routinely for follow-up monitoring (per institutional protocol), without performing baseline MRA studies immediately postembolization. Despite the utility of TOF-MRA in gauging extent of recanalization, the stent artifacts encountered may obscure minor features [54–57], and the size of the residual flow in coiled aneurysms with stent may be underestimated, in particular in small-sized aneurysms. In our cohort, rates for aneurysms of posterior circulation (28/312, 9.0%) and of bioactive coils > 50% (33/312, 10.6%) were low. Therefore, coiled aneurysms of posterior circulation or aneurysms of bioactive coils > 50% may not be represented well in this sampling.

Conclusions

In stent-assisted coil embolization of small-sized (< 10 mm) aneurysms, stent type, as well as occlusive status at time of coiling and aneurysmal neck size, may impact outcomes during follow-up monitoring. LVIS stents seem beneficial for reducing recanalization rates in this setting, more so than Enterprise or Neuroform stents.

Compliance with ethical standards

Funding No funding was received for this study.

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

Ethical approval All procedures performed in the studies involving human participants 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 consent For this type of study formal consent is not required.

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