Treatment of Intracranial Aneurysms with Self-Expandable Braided Stents: A Systematic Review and Meta-Analysis

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ABSTRACT

BACKGROUND: The safety and efficacy of treatment with self-expandable braided stents (LEO and LVIS) required further investigation.

PURPOSE: Our aim was to analyze the outcomes after treatment with braided stents.

DATA SOURCES: A systematic search of 3 databases was performed for studies published from 2006 to 2017.

STUDY SELECTION: According to Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines, we included studies reporting patients treated with LEO or LVIS stents.

DATA ANALYSIS: Random-effects meta-analysis was used to pool the following: aneurysm occlusion rate, complications, and neurologic outcomes.

DATA SYNTHESIS: Thirty-five studies evaluating 1426 patients treated with braided stents were included in this meta-analysis. Successful stent delivery and complete aneurysm occlusion were 97% (1041/1095; 95% CI, 95%–98%) ($I^2 = 44\%$) and 88.3% (1097/1256; 95% CI, 85%–91%) ($I^2 = 72\%$), respectively. Overall, treatment-related complications were 7.4% (107/1317; 95% CI, 5%–9%) ($I^2 = 44\%$). Ischemic/thromboembolic events (48/1324 = 2.4%; 95% CI, 1.5%–3.4%) ($I^2 = 27\%$) and in-stent thrombosis (35/1324 = 1.5%; 95% CI, 0.6%–1.7%) ($I^2 = 0\%$) were the most common complications. Treatment-related morbidity was 1.5% (30/1324; 95% CI, 0.9%–2%) and was comparable between the LEO and LVIS groups. Complication rates between the anterior (29/322 = 8.8%; 95% CI, 3.4%–12%) ($I^2 = 41\%$) versus posterior circulation (10/84 = 10.5%; 95% CI, 4%–16%) ($I^2 = 0\%$) and distal (30/303 = 8%; 95% CI, 4.5%–12%) ($I^2 = 48\%$) versus proximal aneurysms (14/153 = 9%; 95% CI, 3%–13%) ($I^2 = 46\%$) were comparable ($P > .05$).

LIMITATIONS: Limitations were selection and publication biases.

CONCLUSIONS: In this analysis, treatment with the LEO and LVIS stents was relatively safe and effective. The most common complications were periprocedural thromboembolisms and in-stent thrombosis. The rate of complications was comparable among anterior and posterior circulation aneurysms, as well as for proximal and distally located lesions.

ABBREVIATIONS: IQR = interquartile range; PRISMA = Preferred Reporting Items for Systematic Reviews and Meta-Analyses; SAC = stent-assisted coiling

The development of self-expandable stents has progressively changed the treatment strategy for most intracranial aneurysms, creating a mechanical scaffold that prevents coil protrusion and promoting neoendothelization of the neck.[1] Several self-expandable stents were introduced in the past years,[2,3] including laser-cut open-cell stents (such as the Neuroform; Stryker Neurovascular, Kalamazoo, Michigan) and laser-cut closed-cell stents (such as the Enterprise; Codman & Shurtleff, Raynham, Massachusetts).[2] The third generation of self-expandable closed stents was produced by braiding individual strands of nitinol onto a mandrel (LVIS, MicroVention, Tustin, California; and LEO, Balt Extrusion, Montmorency, France).[4,5] In addition to providing mechanical support, the braided morphology gives a relatively higher pore density than the laser-cut stents, theoretically improving the flow-diverting hemodynamic effect of these devic-

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es.[6-8] Recently, the low-profile design of the braided stents (LEO Baby and LVIS Jr) allowed delivery through a 0.0165-inch microcatheter and navigation in small vessels, with the possibility of treating distally located aneurysms.[9,10] Improved understanding of treatment-related outcomes of braided stents can help practitioners in the selection of lesions amenable to being effectively treated with these devices. Our meta-analysis examined occlusion rates and procedure-related complications after treatment with braided stents, focusing on the influence of aneurysm features, location, and treatment characteristics on the studied outcomes.

MATERIALS AND METHODS

Literature Search

A comprehensive literature search of PubMed, Ovid MEDLINE, and Ovid EMBASE was conducted for studies published from January 2006 to February 2018. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines[11] were followed. The key words and the detailed search strategy are reported in On-line Table 1. The inclusion criteria were the following: studies reporting series of intracranial aneurysms treated with LEO and LVIS stents. Exclusion criteria were the following: 1) review articles, 2) studies published in languages other than English, 3) in vitro studies, and 4) animal studies. In cases of overlapping patient populations, only the series with the largest number of patients or the most detailed data was included. Two independent readers screened articles in their entirety to determine eligibility for inclusion. A third author solved discrepancies.

Data Collection

From each study, we extracted the following: 1) treatment-related complications, 2) occlusion rate, and 3) clinical outcome. Occlusion and complication rates were analyzed on the basis of the influence of the following parameters: 1) unruptured-versus-acutely ruptured aneurysms, 2) distal-versus-proximal location, 3) anterior-versus-posterior circulation, 4) first treatment versus retreatment, 5) stent alone versus stent-assisted coiling (SAC), and 6) single-versus-multiple stents. A subgroup analysis was performed for aneurysms treated with small low-profile braided stents (LEO Baby and LVIS Jr). Distal location was considered for lesions arising distal to the circle of Willis or located in small vessels: A2–3 segments, middle cerebral artery, posterior cerebral artery, posterior inferior cerebellar artery, anterior inferior cerebellar artery, and superior cerebellar artery. The occlusion rate was defined on the basis of the Raymond-Roy classification. Accordingly, we used the following terms: complete occlusion (class I), residual neck or near complete occlusion (class II), and incomplete occlusion or residual aneurysm (class III).[12] Treatment-related complications were divided into 2 groups: periprocedural/early events (within 30 days after treatment) and delayed events (after 30 days). Finally, good outcome was defined as a modified Rankin Scale score of 0–2 or a Glasgow Outcome Score of 4–5, or it was assumed if the study used terms such as "no morbidity," "good recovery," or "no symptoms."

Outcomes

The primary objectives of this meta-analysis were to define the safety (treatment-related complications, neurologic outcomes, mortality rate) and the efficacy (aneurysm occlusion rate) of the treatment of intracranial aneurysms with self-expanding braided stents (LEO and LVIS). The secondary objectives were to define the influence of aneurysm location, aneurysm characteristics, and factors related to the treatment on the analyzed outcomes.

Quality Scoring

A modified version of the Newcastle-Ottawa Scale[13] was used for quality assessment of the included studies. The details are reported in On-line Tables 2 and 3. The quality assessment was performed by 2 authors independently, and a third author solved discrepancies.

Statistical Analysis

We estimated, from each cohort, the cumulative prevalence (percentage) and 95% confidence interval for each outcome. Percentages were calculated with a random-effects meta-analysis. Heterogeneity across studies was evaluated using the I^2 statistic: An I^2 value of >50% suggests substantial heterogeneity. To compare the percentages and to calculate the *P* values, we used the *Z*-test for 2 proportions. Meta-regression was not used in this study. Statistical analysis was performed using OpenMeta[Analyst] (http://www.cebm. brown.edu/openmeta/).

RESULTS

Literature Review

Studies included in our meta-analysis are summarized in On-line Table 4. The search flow diagram is shown in the On-line Figure.

A total of 35 studies and 1426 patients with 1518 intracranial aneurysms treated with LEO or LVIS stents were included in our review.

Quality of Studies

Overall, 14 studies (40%) were rated "high quality" (On-line Tables 2 and 3). Three articles were prospective multicentric series, 5 studies were obtained from a prospectively maintained data base, 3 studies were retrospective multicentric, and 24 articles were single-center retrospective.

Patient Population

Overall, 510 aneurysms (33.5%) were treated with LEO stents and 948 aneurysms (62.5%) were treated with LVIS devices. One study with 60 aneurysms (4%) reported patients treated with LEO and LVIS stents (On-line Table 5). The mean age of patients (54.5 years; range, 7–79 years) and the male/female ratio (0.47) were comparable between the 2 groups. Overall, 83% (1172/1410; 95% CI, 81%–84%) of aneurysms were located in the anterior circulation. The mean aneurysm size was 7.2 mm (range, 2–65 mm). Most aneurysms were found incidentally (572/954 = 60%; 95% CI, 56%–63%). The mean radiologic and clinical follow-up was 10.4 months (interquartile range [IQR], 6–12 months; median, 6.5 months) and 12 months (IQR, 6–13 months; median, 8 months), respectively.

Angiographic Outcomes

Overall, the devices were successfully delivered in 97% (1041/1095; 95% CI, 95%–98%) (I^2 = 44%) of cases (On-line Table 6). The technical success rate was 97.5% (379/396; 95% CI, 95%–98%) (I^2 = 42%) and 97% (662/699; 95% CI, 95%–99%) (I^2 = 58%) for LEO and LVIS stents, respectively. During a mean angiographic follow-up of 10.4 months (median, 6.5 months; IQR, 6–12 months), the overall rate of complete/near-complete occlusion was 88.3% (1097/1256; 95% CI, 85%–91%) (I^2 = 72%): Complete/near-complete occlusion was achieved in 88.6% (410/463; 95% CI, 83%–93%) (I^2 = 69%) and 87.8% (687/793; 95% CI, 83%–92%) (I^2 = 74%) of aneurysms treated with LEO and LVIS stents, respectively.

Treatment-Related Complications

The overall complication rate was 7.4% (107/1317; 95% CI, 5%–9%) (I^2 = 44%). Complications were higher among LEO stents (46/391 = 10.5%; 95% CI, 7%–13%) (I^2 = 0%) compared with LVIS stents (54/867 = 5.3%; 95% CI, 3%–7%) (I^2 = 34%) (P = .001). The overall rate of permanent complications was 1.5% (30/1324; 95% CI, 0.9%–2%) (I^2 = 0%). Permanent complications were 2.7% (17/398; 95% CI, 1%–4%) (I^2 = 3%) and 1.3% (12/867; 95% CI, 0.6%–2.2%) (I^2 = 0%) after LEO and LVIS stent treatment, respectively (P = .002).

Most complications were periprocedural or early events (85/1324 = 5%; 95% CI, 3%–6%) (I^2 = 36%), whereas delayed complications were 1% (27/1324; 95% CI, 0.5%–1.6%) (I^2 = 0%). Both periprocedural and delayed complications were higher in the LEO group (On-line Table 6). Overall, the most common complications were ischemic/thromboembolic events (48/1324 = 2.4%; 95% CI, 1.5%–3.4%) (I^2 = 27%), followed by in-stent thrombosis (35/1324 = 1.5%; 95% CI, 0.6%–1.7%) (I^2 = 0%). After treatment with LEO stents, there was a higher incidence of ischemic/thromboembolic events (21/398 = 3.6%; 95% CI, 1.8%–5% versus 24/867 = 1.6%; 95% CI, 0.6%–1.5%) (P = .03) and in-stent thrombosis (19/398 = 3.2%; 95% CI, 1.5%–5% versus 15/867 = 0.8%; 95% CI, 0.2%–1.5%) (P = .003). Ischemic complications were related to the following events: thromboembolism (44/48 = 91%; 95% CI, 79%–97%), perforating injury due to stent coverage of lenticulostriate arteries (1/48 = 2%; 95% CI, 0.1%–10%), and platelet aggregation in the side branches covered with the stent (3/48 = 6.5%; 95% CI, 1.5%–17%). The rate of aneurysm perforation/vessel dissection during treatment and the rate of intraparenchymal hemorrhage (unrelated to aneurysm rupture) were 1.3% (22/1324; 95% CI, 0.7%–1.8%) (I^2 = 0%) and 0.5% (1/1324; 95% CI, 0.1%–1.1%) (I^2 = 0%), respectively, without differences between the 2 groups. The incidence of aneurysm rupture after treatment was 0.7% (3/1324; 95% CI, 0.3%–1.1%) (I^2 = 0%). Treatment-related mortality was 0.7% (3/1357; 95% CI, 0.3%–1.2%) (I^2 = 0%), whereas the rate of good neurologic outcome was 98% (770/78; 95% CI, 97%–99%) (I^2 = 0%).

Factors Related to Aneurysm Occlusion

Overall, the occlusion rate of distally located aneurysms and more proximal lesions was 89.5% (237/272; 95% CI, 86%–93%) (I^2 = 0%) and 77% (90/124; 95% CI, 66%–87%) (I^2 = 57%), respectively (P = .001) (On-line Table 7). Complete/near-complete occlusion in the anterior circulation (149/174 = 88.5%; 95% CI, 82%–94%) (I^2 = 34%) was higher compared with the posterior circulation (26/37 = 70%; 95% CI, 53%–86%) (I^2 = 47%) (P = .003). Occlusion after retreatment with braided stents of aneurysms recanalized after previous treatments was lower (31/42 = 75%; 95% CI, 54%–94%) (I^2 = 57%) compared with the occlusion rate of the first treatment (179/203 = 88.9%; 95% CI, 83%–94%) (I^2 = 23%) (P = .01). Differences in occlusion rates were not statistically significant in relation to single-versus-multiple overlapping devices. SAC was more effective compared with treatment with a stent alone: a complete/near-complete occlusion rate of 90% (807/898; 95% CI, 86%–93%) (I^2 = 67%) versus 63% (19/26; 95% CI, 40%–90%) (I^2 = 48%), respectively (P = .0001). In the stent-alone group, 58% (15 aneurysms) and 42% (11 aneurysms) of patients were treated with single and double stents, respectively.

Factors Related to Complications after Treatment

The complication rate was higher for ruptured aneurysms treated in the acute phase (12/75 = 14.5%; 95% CI, 7%–21%) (I^2 = 0%) compared with unruptured lesions (54/675 = 6.6%; 95% CI, 4.8%–4%) (I^2 = 0%) (P = .01). There was no statistically significant difference in complication rates among distal-versus-proximal locations and anterior-versus-posterior circulation. Similarly, treatment-related complications were comparable among first treatment versus retreatment, SAC versus stent alone, and single-versus-multiple stents.

Angiographic Outcomes and Treatment-Related Complications for Low-Profile Braided Stents (LEO Baby and LVIS Jr)

Low-profile braided stents were successfully delivered in 96% (601/638; 95% CI, 94%–98%) (I^2 = 41%) of cases, without differences between the LEO Baby and LVIS Jr (On-line Table 8). Overall, 61% (318/521; 95% CI, 56%–65%) of low-profile braided stents were deployed in small and distal vessels, whereas 39% (203/521; 95% CI, 34%–43%) were used to treat proximally located aneurysms. In addition, LEO Baby and LVIS Jr were mostly used for the treatment of anterior circulation aneurysms (296/399 = 74%; 95% CI, 69%–78%) compared with posterior circulation lesions (103/399 = 26%; 95% CI, 21%–30%). Overall, complete/near-complete occlusion was 88.6% (507/580; 95% CI, 84%–92%) (I^2 = 63%) and was higher with the LEO Baby (135/143 = 96.3%; 95% CI, 93%–99%) (I^2 = 0%) compared with LVIS Jr (372/437 = 86%; 95% CI, 80%–91%) (I^2 = 65%) (P = .005). The overall complication rate was 7.2% (54/636; 95% CI, 5%–9%) (I^2 = 0%) with 1.9% (13/636; 95% CI, 0.9%–2.9%) (I^2 = 0%) permanent events. LEO Baby devices were associated with a 3.7% (4/148; 95% CI, 0.7%–6%) (I^2 = 0%) permanent complication rate, whereas LVIS Jr stents had 1.6% (9/488; 95% CI, 0.5%–2.8%) (I^2 = 0%) (P = .7). The most common complications were ischemic/thromboembolic (22/636 = 1.8%; 95% CI, 0.7%–2.8%) (I^2 = 0%) and in-stent thrombosis (21/636 = 1.6%; 95% CI, 0.6%–2.6%) (I^2 = 4%). In-stent thrombosis was higher among LEO Baby (9/148 = 5%; 95% CI, 2%–8%) (I^2 = 0%) compared with LVIS Jr (12/488 = 1.1%; 95% CI, 0.2%–2%) (I^2 = 0%). Treatment-related mortality and good neurologic outcome

were 0.8% (1/636; 95% CI, 0.4%–1.5%) ($I^2 = 0\%$) and 98.3% (406/415; 95% CI, 96%–99%) ($I^2 = 0\%$), respectively.

Study Heterogeneity

Analysis of the angiographic outcomes and treatment-related complications showed high heterogeneity in 10% of the reported results (4 of 39 studied outcomes) (On-line Table 6). The analysis of the factors related to complications and occlusion (On-line Table 5) showed high heterogeneity in 18% of the studied events (4 of 22 reported outcomes). The rate of high heterogeneity among complications and angiographic outcomes after LEO Baby and LVIS Jr (On-line Table 7) was 9% (3 of 33 reported results).

DISCUSSION

With the advent of the SAC technique, most complex, wide-neck intracranial aneurysms can be efficiently treated endovascularly.[14] Compared with other intracranial stents that are laser-cut from nitinol hypotubes, LEO and LVIS stents are braided from a single nitinol wire with a closed-cell design.[6,8] Because of the increased use of these devices, understanding the safety and efficacy of treatment with braided stents is important in the management of lesions amenable to SAC treatment.

Angiographic Outcomes

In combining aneurysmal occlusion rates from 35 series, our analysis provides more representative data on angiographic outcomes than any single study. We demonstrated high rates of complete/near-complete occlusion for both LEO (88.6%; 95%, CI 83%–93%) and LVIS devices (87.8%; 95% CI, 83%–92%). Meta-analysis of aneurysms treated with SAC using different devices showed 61% long-term occlusion.[15] The high rates of occlusion after treatment with braided stents can be related to the smaller cell size, higher metal coverage and flow-diversion effect than other conventional self-expandable stents.[6,8,16] Computational fluid dynamics studies showed that LVIS stents allowed more flow reduction than laser-cut devices, and double LVIS stents resulted in a better flow-diverting effect than the Pipeline Embolization Device (PED; Covidien, Irvine, California).[8] Aydin et al,[16] investigating the flow-diversion effect of low-profile braided stents used as stent monotherapy, reported 75% complete occlusion during follow-up. In the subgroup of aneurysms treated with double stents, the authors showed a slightly higher rate of complete occlusion (82%). In our study, braided stents used as stent monotherapy allowed a 63% (95% CI, 40%–90%) complete occlusion rate, which was significantly lower compared with the treatment with stent plus coiling (90%; 95% CI, 86%–93%) ($P = .0001$). Most interesting, lesions treated with SAC with single or multiple stents had comparable rates of occlusion, showing that in most cases, a single stent is enough to achieve complete aneurysm occlusion, avoiding the ischemic complications related to the higher metal density in the vessel.

Treatment-Related Complications

In general, treatment-related complications and morbidity after SAC are 12% and 5%, respectively.[17,18] In our analysis, treatment with braided stents was relatively safe, with overall rates of complications and morbidity of 7.4% (95% CI, 5%–9%) and 1.5% (95% CI, 0.9%–2%), respectively. This is in accordance with a recent prospective, multicentric study of LVIS devices that reported approximately 5% treatment-related morbidity.[19] Most interesting, the overall complication rate was higher after treatment with LEO (10.5%; 95% CI, 7%–13%) compared with LVIS stents (5.3%; 95% CI, 3%–7%). The higher rate of complications was related to higher ischemic/thromboembolic events (3.6%; 95% CI, 1.5%–5% versus 1.6%; 95% CI, 0.6%–2.5%) and in-stent thrombosis (3.2%; 95% CI, 1.5%–5% versus 0.8%; 95% CI, 0.2%–1.5%). After we investigated the literature, the rate of in-stent thrombosis after treatment with laser-cut stents was 1%,[2] which is lower compared with the overall rate of both braided stents and low-profile braided stents (1.5% and 1.6%, respectively). Similar to that in flow-diverter stents, the higher incidence of acute occlusion of braided stents compared with laser-cut devices can be explained, at least in part, by the higher mesh density and more condensed pores of these devices. However, in our meta-analysis, LVIS and LVIS Jr had a low incidence of acute in-stent occlusion (0.8% and 1.1%, respectively), which appears quite comparable with that in the laser-cut stents.

Knowledge of the safety of braided stents in relation to the location and characteristics of the aneurysms has important therapeutic implications. Most interesting, we found comparable rates of complications between proximal (ICA and circle of Willis) and distal aneurysms beyond the circle of Willis or in small vessels. The rate of complications for distal aneurysms treated with flow-diverter stents ranges between 15% and 20%.[20,21] Feng et al[22] reported 5% complications after SAC of MCA aneurysms with LVIS Jr stents. Similarly, Aydin et al[16] reported a high occlusion rate and a low incidence (5%) of complications after flow-diversion treatment of aneurysms at or distal to the circle of Willis, with low-profile braided stents used as stent monotherapy.

Although the occlusion rate was lower in the posterior circulation (70%; 95% CI, 53%–86% versus 88.5%; 95% CI, 82%–94%), treatment-related complications were comparable between anterior (8.8%; 95% CI, 3.4%–12%) and posterior circulation aneurysms (10.5; 95% CI, 4%–16%) ($P = .7$). Similarly, Johnson et al,[23] in a large series of 486 aneurysms treated with Neuroform and Enterprise stents, reported comparable rates of complications among anterior (11.5%) and posterior circulation lesions (12.7%). Contrariwise, flow diversion in the posterior circulation is associated with not negligible rates of ischemic complications related to perforators infarcts. In the International Retrospective Study of Pipeline Embolization Device, the rates of morbidity and mortality after flow diversion treatment were higher among posterior circulation (16.5%) compared with anterior circulation lesions (5%–9%).[24]

Finally, our subgroup analysis of >600 aneurysms treated with low-profile braided stents (LEO Baby and LVIS Jr) demonstrated comparable results in terms of the safety (complication rate = 7.2%; 95% CI, 5%–9%) and efficacy (complete/near-complete occlusion = 96.3%; 95% CI, 93%–99%) of these devices usually used in smaller and distal vessels because of the possibility of being delivered through a 0.0165-inch microcatheter.

Strength and Limitations

Our study has limitations. Most series are retrospective studies and single-institution experiences. Details of the antiplatelet therapy were infrequently specified. The smaller number of cases in some subgroup analyses may not provide sufficient power to demonstrate a statistically significant difference among the studied outcomes. However, although retrospective data are low in quality, our meta-analysis is the best available evidence to guide the treatment management of aneurysms with braided stents.

CONCLUSIONS

In our study, treatment with the LEO and LVIS stents was relatively safe and effective. Most of the complications were related to periprocedural thromboembolic events and in-stent thrombosis. We found comparable rates of treatment-related complications among anterior-versus-posterior circulation aneurysms and for proximal-versus-distally located lesions. These findings can guide practitioners in the treatment, management, and selection of aneurysms amenable to treatment with braided stents.

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