ORIGINAL RESEARCH

Expanding the use of flow diverters beyond their initial indication: treatment of small unruptured aneurysms

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ABSTRACT

Background Experience with the endovascular treatment of unruptured small intracranial aneurysms by flow diverter devices is still limited.

Objective To assess the safety and efficacy of the SILK flow diverter (SFD) in the treatment of small unruptured cerebral aneurysms (<10 mm).

Methods We performed a retrospective review of a prospectively maintained database of patients treated with a SFD between July 2008 and December 2013 at 4 institutions in Spain to identify all patients with small unruptured aneurysms (<10 mm). Data for patient demographics, aneurysm characteristics, and technical procedures were analyzed. Angiographic and clinical findings were recorded during the procedure and at 6- and 12-month follow-ups.

Results A total of 109 small aneurysms were treated with a SFD in 104 patients (78 women; 26 men; mean, median, and range of age: 55.2, 57.1, and 19–80 years, respectively). A total of 60 patients were asymptomatic (57.7%). All except 7 aneurysms (6.4%) arose from the anterior circulation. The mean size of the aneurysms was 4.7±1.9 mm. At 6 months, the neuromorbidity and neuromortality rates were 2.9% and 0.9%, respectively. Imaging at the 12-month follow-up showed complete occlusion, neck remnants, and residual aneurysm in 88.5% (69/78), 7.7% (6/78), and 3.3% (3/78) of cases, respectively. No delayed hemorrhage occurred.

Conclusions The findings suggest that the indications for SFD can be safely extended to small intracranial aneurysms.

INTRODUCTION

Flow diverter (FD) stents have become an important tool in the treatment of complex aneurysms, and their efficacy, durability, and safety have been demonstrated. The indications for flow diversion are still not completely established. Few studies have been published of the use of FD stents for small aneurysms amenable to conventional endovascular techniques.[1–4] A small series has suggested the value of flow diversion treatment in very small aneurysms including blister-like aneurysms.[5] The safety and efficacy of FD for this subgroup remains unknown. Our study aimed to show the results of the largest series to date of small aneurysms treated with the SILK flow diverter (SFD) (Balt Extrusion, Montmorency, France) and assess its safety and efficacy.

PATIENTS AND METHODS

Patients and aneurysms

We retrospectively reviewed all patients with small intracranial aneurysms (<10 mm) treated with the SFD between July 2008 and February 2013 in four centers experienced in SFD use. Institutional review board approval was obtained from all participating centers. Patient selection for endovascular treatment was performed by a multidisciplinary team of interventional neuroradiologists, neurologists, and neurosurgeons. In our series, endovascular treatment was chosen when any of the following criteria were met: (1) association with a ruptured aneurysm in another location; (2) the presence of a symptomatic aneurysm; (3) a family history of intracranial aneurysms; (4) irregularities of the aneurysm profile, thus indicative of a theoretically higher risk of rupture; (5) complex aneurysms in the vicinity; and (6) the patient's desire for treatment.

The patients were informed about the complications associated with the diagnosed condition, the treatment options available, and the risks/benefits of SFD. Endovascular treatment with SFD was performed only after informed consent had been obtained.

The locations of the aneurysms were classified as follows: anterior communicating artery (ACoA), posterior communicating artery (PCoA), internal carotid artery (ICA) except PCoA, middle cerebral artery (MCA), anterior cerebral artery (ACA), vertebrobasilar system including the basilar top, superior cerebellar artery, and posterior cerebral artery (PCA).

Periprocedural strategy

All patients received clopidogrel (75 mg/day) and aspirin (150 mg/day) for at least 7 days before the procedure. Tests for resistance to clopidogrel and aspirin were not available at all hospitals and were not used. In two patients, a loading dose of 300–600 mg clopidogrel, and 300 mg oral aspirin plus 0.5–1 g intravenous aspirin, were administered. Both patients were treated as an emergency, because they presented a history of subarachnoid hemorrhage (SAH) and morphological chambers of the aneurysm.

All procedures were performed under general anesthesia and heparinization to achieve activated clotting times of approximately 300 s. After the procedure, heparin was continued for at least 24 h,

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whereas dual antiplatelet medication, including clopidogrel (75 mg/day) and aspirin (150 mg/day), was continued for at least 6 months. After this period, clopidogrel was stopped, while aspirin (150 mg/day) was continued permanently.

Endovascular procedure

All procedures were performed by two senior interventional neuroradiologists with extensive experience in intracranial stent placement techniques. A long introducer (6F) was placed within the cervical portion of the parent artery. A Fargo intermediate catheter (Balt Extrusion, Montmorency, France) was then placed within the long introducer sheath to reach the petrocavernous segment of the ICA or the V3 segment for posterior circulation. Then, a 0.21–0.25 Vasco microcatheter (Balt Extrusion, Montmorency, France) was navigated over a Synchro 0.14 inch microwire (Boston Scientific, West Valley, Utah, USA) and placed distal to the aneurysm with a sufficient margin for maneuver and to facilitate stent introduction, positioning, and deployment. The choice of stent length and diameter was based on preprocedural and intraprocedural imaging. The SFD deployment strategy followed strict compliance with the recommendations of the SFD device manufacturer (Balt Extrusion, Montmorency, France).

Angiography was performed immediately after the procedure and at the 6-month and 1-year follow-ups to assess the aneurysm occlusion rate and the patency of the side branches covered by the SFD. Angiographic findings were classified using the Montreal grading system (Raymond–Roy classification)[6] as either complete occlusion (class 1: no contrast agent filling the aneurysmal sac) or incomplete occlusion (class 2: residual neck and class 3: residual aneurysm). Scoring of the images was done at the reference hospital by two expert neuroradiologists, both of whom had experience in image evaluation.

Clinical complications and related morbidity and mortality

Periprocedural and postoperative complications were classified according to a protocol similar to that employed by Berge *et al*[7] as acute and subacute complications (occurring within 2 weeks of the procedure), as well as delayed complications (occurring between 2 weeks and 6 months after the procedure).

Clinical outcomes were evaluated at discharge and at the 6-month follow-up using the modified Rankin scale (mRS). The primary outcomes assessed were neurologic morbidity and mortality. Neurologic morbidity was defined as a composite of the following neurologic complications: spontaneous aneurysm rupture, ipsilateral intracranial hemorrhage, ischemic stroke, stenosis of the parent artery, and cranial neuropathy. All clinical complications were evaluated by two neurologists in each center, and data were posteriorly submitted to the reference hospital for retrospective review by three senior neurologists, who categorized the events as 'major' or 'minor,' with 'major' defined as an ongoing clinical deficit at 7 days after the event. All major adverse events were considered when evaluating the overall incidence of neurologic morbidity and mortality.

Data collection and literature review

Descriptive data are presented as the mean±SD or the number and percentage of analyzed cases. In order to compare our results with those previously reported, relevant databases (PubMed, Scopus, Google Scholar, EMBASE via Ovid, and Web of Science) were searched using the keywords 'intracranial aneurysms,' 'Silk flow diverter,' and 'Pipeline+Silk flow diverters, small aneurysms, and flow diverter.' The bibliographic sections of the identified studies were searched for relevant literature published between January 2005 and November 2016. Studies with the following characteristics were included in the analysis: publication language, English; number of patients included, >20 patients; treatment using Silk or Pipeline devices; and data provided about postoperative complications and aneurysmal occlusion rates. Case reports, review articles, and technical notes were not considered.

RESULTS

Patients and aneurysms

A total of 104 patients (78 women, 75.0%; 26 men, 25.0%) with 109 aneurysms were treated between July 2008 and February 2013. The range, mean, and median age in this consecutive series of patients was 19–80, 55.2±9.6, and 57.1 years, respectively. A total of 60 patients (57.7%) were asymptomatic, whereas 44 (42.3%) were symptomatic; specifically, 26 patients (25%) underwent a diagnostic imaging test for non-specific symptoms such as headache or dizziness, 2 patients (1.9%) had cranial nerve deficits, 3 had ischemic stroke, and 4 had transient ischemic events. A total of 15 patients presented with multiple aneurysms that were treated during a single procedure.

Most aneurysms (93.6%) were located in the anterior circulation (85, ICA; 12, PCoA; 1, ACA; 2, ACoA; and 2, MCA, while the remainder (6.4%) were located in the posterior circulation (4, basilar artery; 2, vertebral artery; and 1, PCA). In terms of aneurysm morphology, 104/109 (95.4%) aneurysms were saccular, and 5/109 (4.6%) were fusiform. The size of the aneurysms ranged from 2.0 to 9.5 mm in maximum diameter, with a mean size of 4.7±1.9 mm. The dome/neck ratios ranged from 0.62 to 3.9, with a mean of 1.71±1.39.

Occlusion rate

Immediate postprocedural angiography indicated no complete occlusions (grade III) or grade II occlusions, 54 (49.5%) grade I occlusions, and 55 (50.5%) cases with no significant change in aneurysmal filling.

Our follow-up protocol included angiographic evaluation at 6 and 12 months after the procedure. However, because the actual timing varied among the patients in our case series, we decided to include in our analysis only the angiographic data obtained at the 12-month follow-up visit, as these data seemed the most reliable. Twelve-month angiographic follow-up data were available for 75 patients (72.1%) with 78 aneurysms. At the 1-year follow-up, complete occlusion (class 1, as described by Roy *et al*[6]) was noted in 69 of 78 aneurysms (88.5%). A residual aneurysm neck was noted in 7.7% of cases (6/78), with residual aneurysms accounting for 3.8% (3/78 aneurysms). None of the 75 patients showed in-stent stenosis within a year after the procedure.

Clinical complications and related morbidity and mortality

Seven clinical complications (6.7%, 7/104) occurred. Six adverse ischemic events (5.7%, 6/104), of which three (2.9%, 3/104) were considered to be minor events, were transient neurological deficits that resolved in less than 7 days, whereas three (2.9%, 3/104) were considered major adverse events, comprising one case with an mRS score of 3 and two cases with an mRS score of 2. The procedure mRS scores of three patients were 0. All adverse ischemic events occurred in the group of patients with anterior circulation aneurysms.

One patient with a small parophthalmic aneurysm had a SAH during the procedure owing to stent angioplasty performed to obtain adequate opening of the SFD. The patient died of SAH complications. No delayed hemorrhages occurred in the series.

Table 1 Number of patients, number of aneurysms and small aneurysms, and type of embolization device used in previous studies

Author	Journal	Patients (N)	Aneurysms (N)	Small aneurysms (N)	Flow diverter
Lylyk[10]	Neurosurgery	53	63	33	PED
Nelson[18]	AJNR	31	31	20	PED
Saatci[3]	AJNR	191	251	155	PED
Malatesta[19]	Radiol Med	28	35	25	PED, SILK
Jabbour[20]	Neurosurgery	109	120	72	PED
Piano[21]	J Neurosurg	101	104	21	PED, SILK
Briganti[22]	Eur J Radiol	35	39	32	PED, SILK
Moon[23]	Neurol Res	29	38	33	PED
Kallmes[11]	AJNR	793	906	473	PED
Lubicz[24]	AJNR	58	70	52	SILK
Strauss[25]	Acta Neurochir (Wien)	60	67	28	SILK
Wakhloo[26]	AJNR	161	186	117	SPS
Giacomini[27]	Interv Neuroradiol	77	87	30	PED, SILK
Kallmes[28]	Interv Neurol	191	207	24	PED
Chalouhi[29]	Stroke	200	200	40	PED
Pistocchi[30]	Stroke	26	33	26	PED, SILK

PED, Pipeline endovascular device; SILK, Silk flow diverter; SPS, Surpass flow diverter.

Overall, the 6-month morbidity and mortality rates were 2.9% and 0.9%, respectively.

DISCUSSION

Over the past decade (since 2007), clinical practice worldwide with FDs has demonstrated excellent effectiveness, durability, safety, and cost-effectiveness of endovascular treatment of large and giant aneurysms, with acceptable periprocedural complication rates as well as acceptable morbidity and mortality rates.[8–11] Although FDs have been used systematically for large and giant aneurysms since their approval, these aneurysms represent only a small part of all intracranial aneurysms, as 80% of aneurysms found in the general population are <10 mm in size. Considerable documentation in the literature indicates that the majority of ruptured aneurysms are <10 mm.[12 13]

Although the indications for use of FDs are still not completely established, based on the efficacy obtained in complex aneurysms, there is growing interest and data supporting the safety and efficacy of FD treatment in an 'off-label' manner for small anterior circulation aneurysms as well as for selected cases of posterior circulation aneurysms.[14 15] Recent publications suggest that use of the FD can be expanded beyond its initial indication for large and giant aneurysms. For example, it could be used for blister aneurysms that are difficult to treat with conventional clipping or coiling and to treat small distal anterior circulation aneurysms or, in selected cases, posterior circulation aneurysms.[16 17]

This expansion of the indication of FDs for small aneurysms of <10 mm is supported by several series demonstrating their durability and efficacy in the treatment of cerebral aneurysms. These studies have included a number of aneurysms smaller than 10 mm.[16 17] In all of these series, the results were described in combination with large and giant aneurysms without assessing the subgroups in relation to size and location; the periprocedural complication rate associated with FD treatment may be inferred from detailed analysis of the published results (table 1). Saatci *et al*[3] reported a series of 191 patients with 251 aneurysms treated with the Pipeline endovascular device (PED); 155 aneurysms were <10 mm, the 6-month occlusion rate was 94% for aneurysms <10 mm, and the permanent morbidity rate was as low as 1%. Taken together, these data and other case-controlled studies compared FD treatment favorably with coil embolization for both small and large anterior circulation aneurysms, indicating that use of FDs is appropriate for small aneurysms.[18] As we have become more familiar with FDs, and in view of the growing data supporting their safety and efficacy, they are now increasingly being used in the management of small and less complex aneurysms at our institutions.

Few studies have been published on the use of the FDs for small aneurysms amenable to conventional endovascular techniques. To our knowledge, only three studies have specifically assessed the safety and efficacy of the Pipeline device for small aneurysms (table 2).[14 29 30] Griessenauer *et al*[31] evaluated the safety and efficacy of the PED in a multicenter cohort of 117 patients with 149 small aneurysms ≤7 mm (vs ≤10 mm in our study), with complete occlusion in 87% and a mortality and morbidity rate of 0.9% and 8.7%, respectively. Lin *et al*[14] retrospectively reviewed a prospective database to identify 41 patients with 44 aneurysms <10 mm reporting a mortality and morbidity rate of 2.3% and 6.9%, respectively, with an occlusion rate as high as 80%. Chalouhi *et al*[32] retrospectively assessed the safety and efficacy of the PED in 100 small intracranial aneurysms (≤7 mm), reporting a mortality and morbidity rate of 0% and 3%, respectively, with an occlusion rate of 77.7%.

In this study, we aimed to determine in a large series of patients whether treatment of small aneurysms with SILK is safe and effective. We found that SILK treatment is associated with excellent clinical outcomes and can be performed with a complication rate of 6.7%, implying a neuromortality and neuromorbidity as low as 0.9% and 2.9%, respectively. Of interest, the occlusion rate with SILK was as high as 88.5%, which confirms the high efficacy of the device in this subgroup of patients. These findings suggest that it is safe to offer FD therapy to patients with aneurysms <10 mm when treatment is considered necessary.

Our experience with SILK treatment of small aneurysms is comparable to results of other published reports (table 3). The

Table 2 Previous studies examining small aneurysm characteristics, number of patients, number of aneurysms, mean age, aneurysm size, and percentage of unruptured aneurysms

Author	Centers	Design	Patients(N)	Aneurysms(N)	Age(years)	Size(mm)	Unruptured (%)
Griessenauer[31]	M	Pros	117	149	54	7	90
Chalouhi[32]	S	Retr	100	100	17–80	7	93
Lin[14]	S	Retr	41	44	54.9	10	100

M, multicenter; Pros, prospective, Retr, retrospective; S, single center.

Table 3 Complete occlusion percentage, morbidity, mortality, aneurysm location, and type of device in previous studies examining small aneurysms

Author	Complete occlusion grade (%)	Morbidity (%)	Mortality (%)	Anterior circ. (%)	FD	In-stent stenosis (%)	SAH (%)	IPH (%)	Ischemic events (%)
Griessenauer[31]	78.1	8.7	0.9	92	PED	NA	NA	NA	8.7
Chalouhi[32]	72	3	0	95	PED	NA	0	3	6
Lin[14]	66.7	6.9	2.3	100	PED	5.4	2.3	2.3	0
Our results	88.5	2.9	0.9	93.6	SFD	NA	0.9	NA	5.7

FD, flow diverter; IPH, intraparenchymal hemorrhage; NA, not available; PED, Pipeline endovascular device; SAH, subarachnoid hemorrhage; SFD, SILK flow diverter.

2.9% morbidity and the 0.9% mortality in our series of 104 patients are close to the 8.7% and 0.9% observed by Griessenauer *et al*,[31] the 6.9% and 2.3% observed by Lin *et al*,[14] and the 3% and 0%, respectively, reported by Chalouhi *et al*[32] Our occlusion rate of 88.5% was similar to that observed in the series of Griessenauer *et al* (87%),[31] Lin *et al* (80%),[14] and Chalouhi *et al* (77.7%).[32]

The 2.9% rate of minor complications in this report is lower than the minor complication rate reported for PED treatment of large and giant aneurysms.

When FDs are used for large and giant aneurysms mortality rates up to 5.5% have been reported,[3 10 11 20 26] whereas we reported a mortality rate up 0.9%. Our occlusion rates are comparable to those observed for FD treatment of large and giant aneurysms. Although the safety and efficacy of FDs in the subgroup of small aneurysms remain unknown, the findings of this study add to other published results, showing that the treatment of small aneurysms (<10 mm) with FD may be better than endosaccular modalities, which inherently carry a risk of procedural rupture during access of the aneurysm sac or coil placement.

Limitations

As with the study of Chalouhi *et al*,[32] the main limitations of this report are related to its retrospective design and absence of a control group.

CONCLUSIONS

The findings of this study are in agreement with other published results and suggest that the treatment of unruptured small intracranial aneurysms with SILK is safe and highly effective. Larger studies and long-term follow-up are necessary to determine the optimal treatment of small aneurysms.

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