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Original Article

Treatment of intracranial aneurysms using the new Surpass Evolve flow diverter: Safety outcomes and six-month imaging follow-up

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ABSTRACT

Background and purpose. – Several studies have reported good long-term results in the occlusion of intracranial aneurysms with flow diverter treatment. The aim of this study was to report the safety and six-month follow-up outcomes using the new Surpass Evolve flow diverter in the treatment of intracranial aneurysms.

Materials and methods. – Consecutive patients with intracranial aneurysm treated with Surpass Evolve flow diverter in two high-volume neurovascular centers between May 2019 and January 2020 were retrospectively reviewed. Procedure-related complications, aneurysm occlusion (O'Kelly-Marotta grading scale), and clinical outcomes were assessed.

Results. – Twenty-nine patients with 30 aneurysms were included in the study. Favorable aneurysm occlusion (O'Kelly Marotta grading scale C-D) at six-month follow-up was achieved in 21/27 (78%) aneurysms. No clinical procedure related thromboembolic complications were encountered. Twenty-three out of 24 patients with unruptured aneurysms treated with Surpass Evolve remained clinically intact at clinical follow-up. There was one fatal hemorrhagic procedure-related complication (3%). In five patients with ruptured aneurysms, no early or late rebleeds occurred from the aneurysms.

Conclusions. – Surpass Evolve FD worked technically well with no intraprocedural thromboembolic complications and occlusion rates comparable to other FDs.

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Introduction

Endovascular treatment by coiling is still widely used for treating intracranial aneurysms. However, it involves a 20% risk of long-term recanalization and a 10% rate of retreatment.¹ Several studies have reported good long-term results in the occlusion of intracranial aneurysms with flow diverter (FD) treatment. The use of FDs in the endovascular treatment of cerebral aneurysms has become increasingly popular after the arrival of the first flow diverter device (Pipeline) in 2007.

Initially, the recommended treatment targets included large and giant wide-necked proximal internal carotid artery aneurysms.^{2–5}

Subsequently several investigators have described the benefits of FD treatment for even small and medium sized internal carotid artery aneurysms^{6,7} as well as for aneurysms beyond the circle of Willis.^{8–10} Various FDs with differences in material and delivery systems are currently available. Surpass Evolve is a new generation Surpass Streamline FD, with a CE mark approval awarded in March 2019.

Materials and methods

Surpass Evolve flow diverter

The older generation of Surpass flow diverter (Surpass Streamline) (Stryker Neurovascular, Fremont, California) comes packed and loaded on a microcatheter-pusher assembly. The new device uses the same kind of empty catheter technology as most of the flow diverters that are on the market. The FD itself is made of a cobalt-chromium alloy with a low porosity. As a way to improve its radio-opacity, the device has 12 platinum wires (92% platinum, 8%

Abbreviations: ACT, activated clotting time

FD, flow diverter

mRS, modified Rankin scale

OKM, O'Kelly Marotta.

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tungsten) integrated in the mesh. The Surpass Evolve possesses a lower profile and a higher braid angle. It is manufactured with 48 or 64 wires for its 2.5 and 3.25–5 mm diameters, respectively. The number of wires has been reduced, but the diversion capacity has not diminished due to the reconstructed braid angle.

Study design

This is a retrospective and observational study conducted in two high-volume neurovascular centers. We obtained local research approvals from the 2 hospitals, and the need for informed consent was waived by respective research committee because of the retrospective nature of the study.

Patients

All consecutive patients, including both elective and acutely ruptured aneurysms, treated with the Surpass Evolve flow diverter between May 2019 and January 2020 were identified and enrolled into this study. The decision to use a flow diverter was made by multidisciplinary teams consisting of neurovascular neurosurgeons, neuroradiologists and neurointerventionalists. The decision to treat with a flow diverter was made if there was (1) wide necked aneurysm, (2) a branching vessel orificing from the aneurysm that could result in the coil falling out of the aneurysm into the branch or (3) dissecting aneurysm.

Clinical and radiological assessments

For each patient, the relevant clinical information was recorded: patient's age, sex and previous aneurysm treatment. Anatomical details and morphological information (location, fusiform, dissecting, saccular, blood-blister like) of the aneurysms were collected. The aneurysm size was classified as small (less than 10 mm) or large (10–25 mm). Baseline data collection also included the size and number of FDs used as well as possible adjunctive coiling. In addition, information on antiplatelet therapy and values of platelet function tests were collected.

Baseline neurological status was assessed using the modified Rankin scale (mRS). This was also recorded at discharge and subsequent follow-up visits at three to six months. All procedure-related complications were recorded. The primary end points for clinical safety were the absence of death, absence of major or minor stroke, and the absence of a transient ischemic attack.

Vessel patency, aneurysm occlusion and possible thromboembolic events were reviewed after the intervention and also at the follow-up imaging. Follow-up imaging was conducted with digital subtraction angiography (DSA) or magnetic resonance (MR) angiography, according to institutional policies.

The primary end point for treatment efficacy was complete angiographic occlusion according to the O'Kelly Marotta (OKM) grading scale (A = total filling, B = subtotal filling, C = entry remnant, D = no filling) immediately after the procedure and at follow-up imaging after six months. OKM C and D were considered as referring to favorable occlusion. Because this was a retrospective study, the follow-up imaging protocol was not blinded. All imaging data were reviewed by the local centers.

Intimal hyperplasia was observed angiographically as a gap between the vessel lumen filled with contrast and the actual stent wall. When there was no appreciable gap, it was graded as no stenosis. If the parent vessel narrowing was 25–50%, we evaluated it as mild in-stent stenosis, 50–75% as moderate, and 75% as severe stenosis.

Endovascular procedure

All cases were performed under general anesthesia by experienced neurointerventionalists. The DSA imaging and treatments were performed using a biplane angiographic system (Artis zee biplane; Siemens, Erlangen, Germany) using three dimensional (3D) rotational angiography.

FD sizing was performed on the basis of measurements of the artery, acquired from the 3D rotational angiography data. The device width was chosen according to the proximal parent vessel diameter with the final decision on the device size being made by the main operator.

In addition to manual measurements, virtual sizing with the Sim&Size® simulation was performed for over half of cases using the same per-operative three dimensional angiography acquisition. The commercially available Sim&Size® software is CE marked and Food and Drug Administration approved; it is a simulation tool that predicts the physical behavior of certain endovascular devices.

Femoral access was used in all patients except one case. Mostly, the triaxial system with a 0.088" guiding sheath (Infinity (Stryker, Fremont CA) or Neuronmax (Penumbra Inc., Alameda, CA, USA) and 0.058 Catalyst 5 as an intermediate catheter was the standard protocol but in some cases, Sofia EX (one patient), Navien 058 (one patient) and Phenom Plus (one patient) were used. Radial access was achieved with a 5 F MPD guide. A 0.027" Excelsior XT-27 microcatheter (Stryker, Fremont CA) was used to deploy the Surpass Evolve FD in all of the procedures.

Adjunctive coiling was performed according to the operator's preference. The correct FD apposition to the vessel wall was assessed using DSA images in two orthogonal planes and/or dyna-CT. The procedure was considered successful if the device covered the aneurysm neck with at least 3 mm beyond both sides of the aneurysm neck.

Antiplatelet therapy

For elective cases dual antiplatelet therapy with 100 mg aspirin and 10 mg prasugrel or 75 mg clopidogrel was initiated five to seven days prior to the procedure. Platelet function was evaluated by Multiplate Analyzer (Roche Diagnostics, Mannheim, Germany) or VerifyNow testing before the procedure for elective cases. The medication was switched to prasugrel if the patient was observed to be a nonresponder to clopidogrel. During the procedure, activated clotting time (ACT) was doubled by administering a heparin bolus and ACT was controlled at 30–45 min intervals. After the procedure, heparinization was neither antagonized nor maintained. For acute SAH cases, 250–500 mg aspirin was given intravenously during the procedure and before or after the procedure, the patient was loaded with 30–60 mg prasugrel via a nasogastric tube.

Results

Patient and aneurysm characteristics

A total of 29 consecutive patients with 30 intracranial aneurysms treated with the Surpass Evolve FD from May 2019 to January 2020 were evaluated in this study. The mean age of the patients was 55.5 years (range 32–72) and 21 patients (72%) were women.

The majority i.e. 24 of the patients were elective with the remaining five suffering ruptured aneurysms in the acute phase. Twenty-two aneurysms were located in the internal carotid artery (ICA), two in the middle cerebral artery (MCA), three in the vertebral artery, one aneurysm in the basilar trunk, one in the vertebrobasilar junction and one in the posterior cerebral artery (PCA). (Table 1) Most (20) of the aneurysms were small (less than 10 mm diameter)

Table 1

Summary of aneurysm characteristics, device and last angiographic outcome (3–6 months) after flow diversion.

Pt nr	Age	Gender	Aneurysm location	An type	Acute/elective	An size (mm)	Size	Size of Surpass Evolve	Coils	last FU	OKM
1	58	F	ICA DX	Saccular	Elective	10 × 10 mm	L	4 × 15 mm	No	3 m	B
2	61	F	ICA SIN	Saccular	Elective	4 × 2 mm	S	4.5 × 20 mm	No	6 m	C
3	56	F	ICA SIN	Saccular	Elective	5 × 5 mm	S	5 × 20 mm	No	6 m	D
4	62	F	ICA DX	Saccular	Elective	6 × 5 mm	S	4.5 × 15 mm	No	6 m	D
5	52	M	ICA SIN	Saccular	Elective	4 × 3 mm	S	4.5 × 17 mm	No	6 m	C
6	52	M	MCA SIN	Saccular	Elective	4 × 3 mm	S	3.25 × 12 mm	No	6 m	B
7	66	F	Basilar trunk	Saccular	Acute	6 × 2 mm	S	4 × 12 mm, 4 × 12 mm	No	6 m	B
8	57	F	MCA SIN	Saccular	Elective	3 × 3 mm	S	2.5 × 12 mm	No	6 m	B
9	72	F	ICA DX	Saccular	Elective	10 × 6 mm	L	4.5 × 25 mm	No	6 m	D
10	59	F	Pica DX	Saccular	Acute	3 × 2 mm	S	3.25 × 17 mm	No		Clipped
11	30	F	ICA SIN	Saccular	Elective	2 × 3 mm, 3 × 3 mm	S	4.5 × 17 mm	No	6 m	D and D
12	64	F	ICA DX	Saccular	Elective	3 × 6 mm	S	4 × 12 mm	No	6 m	C
13	66	F	ICA DX	Saccular	Elective	4 × 3 mm	S	4.5 × 17 mm	No	6 m	C
14	70	F	PCA DX	Saccular	Elective	14 × 12 mm	L	3.25 × 20 mm	No	6 m	C
15	75	F	Vertebralis SIN	Saccular	Acute	4 × 9 mm	S	4 × 20 mm	No		Exitus
16	61	F	ICA SIN	Saccular	Elective	24 × 24 mm	L	5 × 20 mm	No	6 m	D
17	52	M	ICA DX	Saccular	Elective	15 × 9 mm	L	5 × 20 mm	No	6 m	D
18	48	M	ICA SIN	Saccular	Elective	4 × 4 mm	S	5 × 20 mm	No	6 m	D
19	48	M	ICA DX	Saccular	Elective	6 × 6 mm	S	5 × 20 mm	No	6 m	D
20	60	F	ICA SIN	Saccular	Elective	15 × 17 mm	L	4 × 20 mm	No	6 m	D
21	41	F	ICA SIN	Saccular	Elective	6 × 7 mm	S	4.5 × 15 mm	No	6 m	D
22	32	F	ICA SIN	Saccular	Elective	10 × 7 mm	L	4 × 17 mm	No	6 m	D
23	32	M	ICA SIN	Saccular	Elective	4 × 4 mm	S	4.5 × 17	No	6 m	C
24	70	F	ICA DX	Saccular	Elective	14 × 13 mm	L	4.5 × 15 mm, 4.5 × 12 mm	No		Exitus
25	42	M	ICA DX	Saccular	Elective	18 × 16 mm	L	4.5 × 25 mm	No	6 m	D
26	49	F	ICA DX	Saccular	Elective	7 × 6 mm	S	5 × 15 mm	No	6 m	B
27	68	F	ICA DX	Saccular	Elective	2 × 3 mm	S	4.5 × 12 mm	No	6 m	D
28	55	F	Vertebralis DX	Fusiform	Acute	5 mm × 6 mm	S	3.25 × 20 mm	Yes	6 m	D
29	52	M	Vertebrobasilar	Fusiform	Acute	28 × 19 mm	L	5 × 40 mm	Yes	6 m	B

Pt, patient; Nr, number; An, aneurysm; L, large; s, small; m, month; FU, follow-up; OKM, O'Kelly-Marotta grading scale.

but 10 were large (10 mm or more). There were 28 saccular and two fusiform aneurysms. Three of the aneurysms were located in small-diameter vessels.

Treatment

The deployment of the device was successful in all patients, i.e. 27 patients were treated with one single FD with two patients requiring two FDs. The patient with two aneurysms needed only one FD to cover both aneurysms. Additional coiling was performed in one ruptured dissective vertebral aneurysm. One ruptured vertebrobasilar junction aneurysm was treated with Evolve and coils and the other vertebral artery was also occluded with coils. No other adjunctive endovascular devices were used nor was any secondary balloon angioplasty performed.

Immediate OKM D occlusion was not achieved in any of the aneurysms (0%), OKM C in 3 (10%) aneurysms, OKM B in 7 aneurysms (23%) and OKM A in 20 aneurysms (67%).

Clinical outcome

Clinical follow-up at six months was available for 27 patients; 23 out of 24 patients with unruptured aneurysms treated with Surpass Evolve had remained clinically intact. In five patients with ruptured aneurysms, no early or late rebleeds occurred from the aneurysms. Two patients died due to the sequelae of SAH (one treated on an elective basis and one in acute phase). One acute SAH patient was transferred to her local university hospital after the endovascular procedure. The residual aneurysm was clipped there and her mRS changed from one to two. The remaining three SAH patients with posterior circulation aneurysms were independent (mRS 0 or 1) at the clinical follow up.

Angiographic follow-up

Two patients died of SAH with one having been clipped after the endovascular procedure. One patient had imaging follow-up at three months, the remaining 25 patients with 26 aneurysms underwent imaging follow-up at six months available. At the control imaging, 15/27 aneurysms showed no contrast filling (O'Kelly-Marotta (OKM) grade D), 6/27 displayed an entry remnant (OKM grade C), 6/27 showed subtotal filling (OKM grade B) but 0/27 exhibited total filling of the aneurysm (OKM grade A). Imaging was conducted by either MRA (2/26) or DSA (24/26).

In 11 patients, evidence of intima hyperplasia was observed at the DSA control. In two of these patients, it was described as mild in-stent stenosis in conjunction with distal end tapering of the stent ([Fig. 1](#)).

Complications

No intraprocedural complications occurred.

Pt 10 suffered an acute SAH from a small aneurysm with an origin in the posterior inferior cerebellar artery (PICA). She was treated by covering the PICA origin with a Surpass Evolve FD. She was neurologically intact on day five after the procedure and transferred to her own university hospital. There a CTA was performed and since the aneurysm was still filling with contrast, the aneurysm was clipped. After clipping, there was a large cerebellar infarct in CT.

Pt 11 had two paraophthalmic small aneurysms on the left side and she was treated with a single Surpass Evolve on an elective basis. She was discharged on day 2 without any neurological deficits. At the clinical control, 6 months after the procedure, she reported a transient ipsilateral visual disturbance after the endovascular procedure but MRI imaging was normal.

Pt 14 with a large PCA aneurysm had been treated with only a FD without coiling. There was remarkable stagnation of contrast medium seen immediately after the device implantation. ([Fig. 2](#))

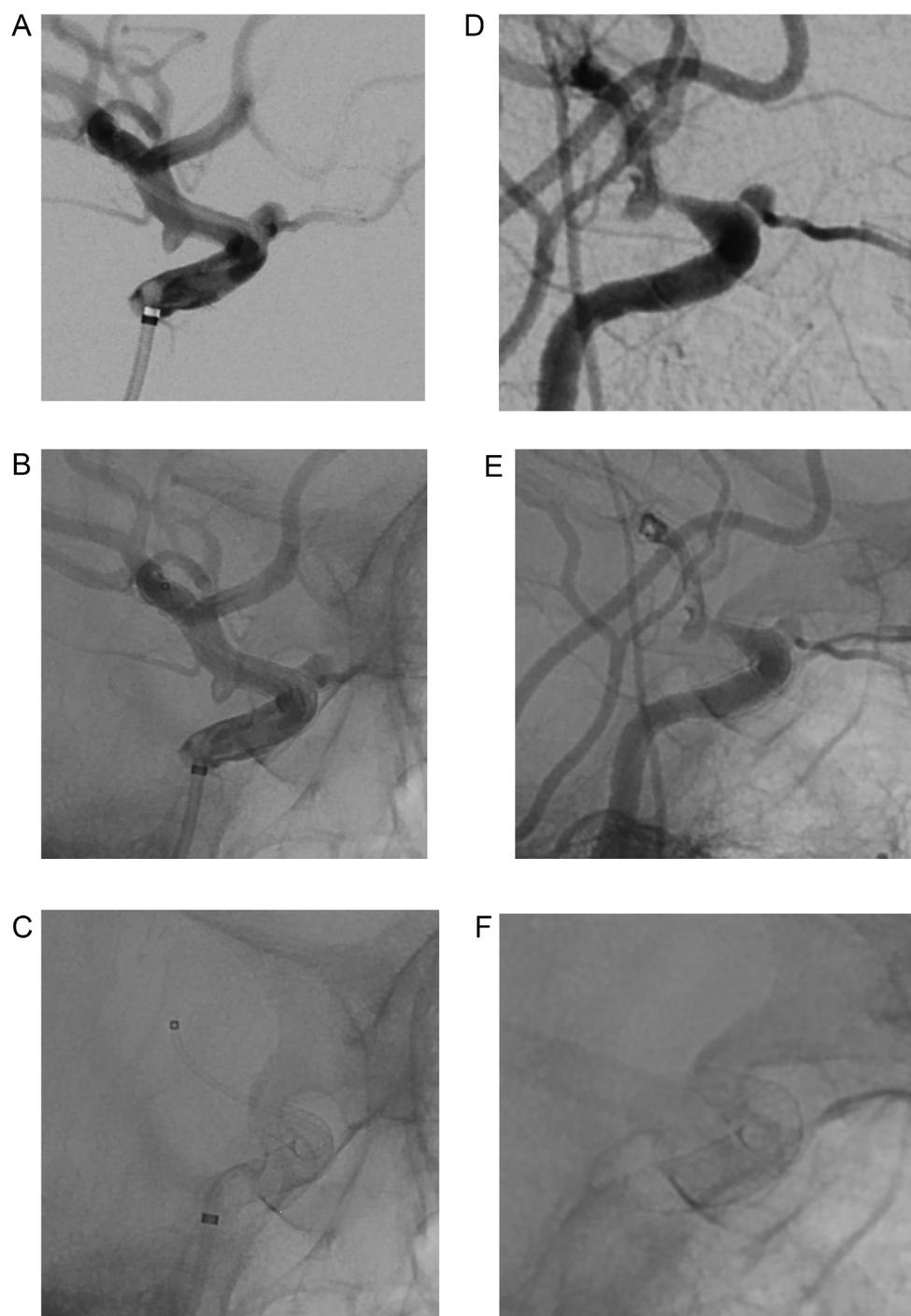


Fig. 1. Pat no. 23 with in-stent stenosis and distal stent tapering. This patient presented with an asymptomatic left carotid ophthalmic aneurysm that was treated with a single Surpass Evolve 4.5×17 mm. (A) Subtracted selective left internal carotid angiography, (B) unsubtracted selective left internal carotid angiography and (C) radiographic image obtained immediately after the intervention shows an adequately implanted device across the aneurysm neck with optimal stent wall apposition. (D) Subtracted, (E) unsubtracted and (F) radiographic images obtained at the six-month follow-up show mild in-stent stenosis and significant distal end tapering of the stent.

The patient suffered from nausea and headache on the day after procedure and MRI imaging revealed one fresh spot-like frontal infarct and the aneurysm had mostly thrombosed. She was discharged on the day 2 without any neurological deficits.

Pt 15 suffered a SAH from a ruptured fusiform vertebral aneurysm at the level of the posterior inferior cerebellar artery (PICA). The patient had undergone ventriculostomy before the endovascular procedure. She was loaded with prasugrel on the angioblate before the start of the endovascular procedure. She woke up after the procedure with the same neurological condition as before the

procedure. A few hours later, the patient lost consciousness and the computed tomography scan revealed a hemorrhage around the ventriculostomy as well as in the ventricles. The ventriculostomy was changed to the other side. This patient suffered a status epilepticus after the new ventriculostomy procedure, and died 13 days later.

There was one early major procedure related complication (3%). Pt 24 presented with an asymptomatic 14×13 mm sized aneurysm. The elective treatment was performed with two Surpass Evolves. Two devices were overlapped after slight malposition of the first

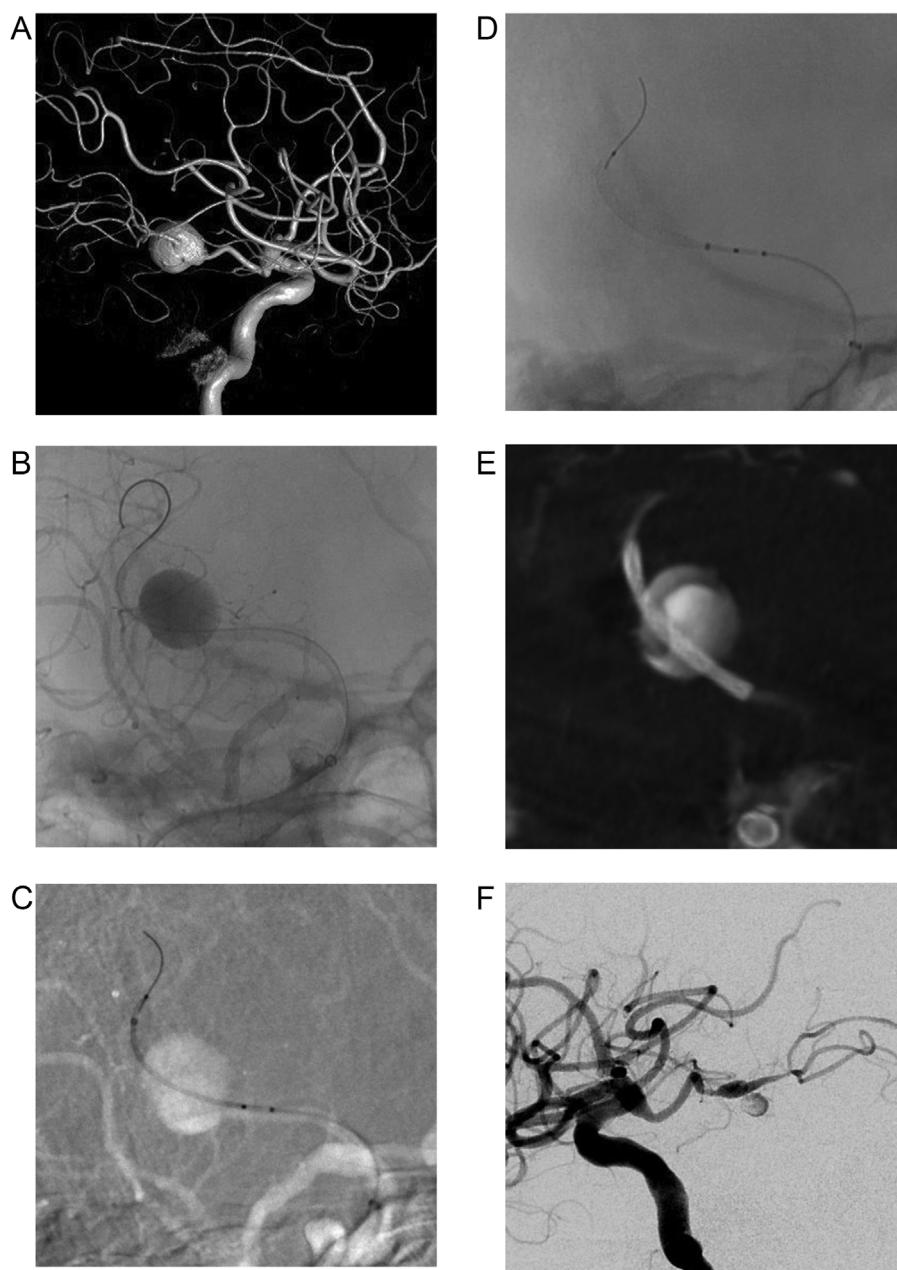


Fig. 2. (A) 3D DSA of the right internal carotid artery (ICA) with an incidentally found cerebelli posterior aneurysm that was enlarged in follow-up controls (Pt no. 14). (B) Catheterization through the aneurysm. (C) Device in the microcatheter before opening. (D) Surpass Evolve is partly opened, distal tip of the microcatheter is still beyond the "point of no return" for resheathing. (E) Post-implant deployment as assessed by dyna-CT showed good coverage of the aneurysm with Evolve 3.25 × 20 mm. (F) Right ICA DSA at the six-month follow-up revealed near complete occlusion of the aneurysm with mild intima hyperplasia.

device. No adjunctive coils were used because the aneurysm had a narrow neck. The patient remained on the ward due to headache and nausea after the procedure. On the 6th postoperative day the aneurysm was interpreted nearly thrombosed in CT. Two hours later she went unconscious and there was a large SAH and ICH. A DSA was performed, and the aneurysm was almost completely thrombosed. Despite of immediate active retreatment with two new FDs the patient died.

Discussion

To the best of our knowledge, this study reports the largest six months follow-up group of the new Surpass Evolve FD. Our results demonstrate encouraging technical success and good radiological outcomes. Favorable aneurysm occlusion (OKM C and D) at

six month follow-up was achieved in 21/27 (78%) aneurysms. The first generation Surpass Streamline is a well-known flow diverter in worldwide use and several clinical results with this device have been published.^{11,12} Our six-month imaging results are in the same range as previously reported (near-complete or complete occlusion in 62.8–80% of aneurysms). All the aneurysms with OKM grade B at six-month FU had a side-branch orifice at the aneurysm neck producing a continuous pressure gradient over the aneurysm wall. It has been described also in previous reports that aneurysms with a larger neck and those with side-branches show a longer occlusion time.¹³

The learning curve with the PED has been shown to be a predictive factor for the procedure-related complication rate.¹⁴

We found the Surpass Evolve to be easier to navigate and manipulate and therefore we believe that in general, the learning

curve will be shorter in comparison to the previous generation Streamline. We experienced excellent technical success rates and procedural safety with the new generation Surpass FD.

FD treatment indications are constantly extending to aneurysms located on small vessels. The risk of thrombosis and other complications such as dissection are higher in smaller arteries. We treated three aneurysms which were located beyond the circle of Willis but encountered no major technical problems. The main advantage was the use of empty catheter device instead of the old preloaded system; at least in our hands, the old system was found to be rather stiff especially in distal vasculature.

In the early days of the FD era, criticisms were raised about the relatively high numbers of procedure-related thromboembolic complications associated with FD treatment. In the multicenter study of Pipeline flow-diversion therapy conducted by Kallmes et al.² the long-term neurologic morbidity and mortality rates were estimated as 8.4%. The morbidity and mortality rates were highest in the posterior circulation group (16.4%, 9/55) and lowest in the group that included small ICA aneurysms (size less than 10 mm) (4.8%, 14/294). Fiorella et al. reported the overall event rate as 7.8% in their meta-analysis of flow diverter treatment for small or medium sized intracranial aneurysms of the internal carotid artery.⁶ In a very recent study, Orru et al.¹⁵ summarized their experience with the new Surpass Evolve flow diverter. They described minor transitory neurological deficits in 20% of patients. They reported the use double antiplatelet therapy but they provided no evidence of pretesting the antithrombotic effect of the medication. We believe that our patients experienced fewer thromboembolic complications since we took into account the results of every individual patient's platelet function tests when deciding on the most appropriate antithrombotic medication regimen, as has been published in several reports.^{16,17}

One of our elective patients experienced the delayed aneurysm rupture and that led to death of the patient. The exact mechanism behind delayed rupture is not well established. Rouchaud et al.,¹⁸ identified delayed ruptures of 81 aneurysms after treatment with flow diverters in their systematic review article. About 20% of delayed ruptures occurred despite associated coiling. In addition giant aneurysms accounted for 46% of ruptures.

We did not encounter any clinical procedure related thromboembolic complications. All the patients were tested with Multiplate or VerifyNow analysis, and their medication was adjusted according to these results. This is probably not only due to the small number of patients but also due to the fact that all procedures were conducted by experienced operators.

In a very recent article, Piergallini and colleagues reported that the use of Sim&Size software was associated with a reduced need for corrective intervention, procedural time, radiation dose and the length of the stent.¹⁹ At the time of our first interventions, not all the various sizes of Surpass Evolve were available. For that reason, the software measurements did not decrease the length of devices that we placed, but did help to choose the most optimal device with the stent proximal and distal ends to be situated on a straight vessel segment. In addition, the simulation of the pushing force applied by operator also enhanced the precision of the deployment.

Most investigators have concentrated on the aneurysm occlusion rate when publishing their results. Instead, the rate of in-stent-stenosis or stent tapering has been rather infrequently analyzed. The cause for the stent tapering phenomenon is still not clearly understood. Cohen et al.²⁰ reported the incidence of in-stent stenosis to be similar in the Silk and Pipeline device groups (6/16, 38% and 7/18, 39%, respectively). Stent tapering and location changes were reported in 2/16 patients with implanted Silk Flow Diverter stents (13%) as compared with no changes in the Pipeline device group. The endothelial damage, resulting from the balloon dilation and the electrochemical effects of the implanted metallic

stent on the vessel wall, have been shown to promote the activation of macrophages, smooth muscle cells, and fibroblasts. This might ultimately lead to an overgrowth of neointimal tissue and in-stent stenosis.²¹ John et al.²² treated 80 patients with Pipeline flow diverters. They report 16 patients (31%) with intimal hyperplasia and 5 patients (9.8%) with in-stent stenosis in their angiographic six-month follow-up that was available for 51 patients. Additional follow-up angiography was available in 2 of the 5 stenosis patients, showing marked improvement. They observed more in-stent stenosis in the cohort of balloon angioplasty patients, although the difference was not statistically significant. Instances of recurrent stenosis following the in-stent balloon dilation have been reported by Vajda et al.²³ They detected a substantial difference in the rate of recurrent stenosis when comparing conventional balloons and drug-eluting balloons, i.e. recurrent stenosis rates of 50% and 9%, respectively. It has been shown that inflammatory fibrointimal proliferation following FD implantation can cause a focal decrease in the diameter of FD that is constrained and distorted by an inflammatory reaction. This can modify even an initially well wall-apposed and fully expanded FD.²⁴ Incorrect FD sizing has also been suggested to predispose to stent tapering. In our series, the number of patients with DSA imaging verified intimal hyperplasia was 11/24 (45%) although it is worth noting that we reported the intimal hyperplasia with a very low threshold. Two of these patients (8%) had a focal decrease in distal FD diameter at the six month control DSA with no clinical consequences. Our results are comparable to the previous publications²¹ but still without a clear understanding of why stent tapering occurred in two of our patients. The mild intimal hyperplasia that was observed did not change the medical management of these patients.

Our study has some limitations. First of all, the number of treated aneurysms was not large enough to allow a reliable statistical analysis. Secondly the majority of treated aneurysms were classified as small. This makes it more difficult to compare our results with the previous studies, where most of the aneurysms have been classified as large. Finally, the angiographic results were not analyzed by a core laboratory, which would make more reliable the interpretation of angiographic imaging.

Conclusions

Surpass Evolve FD worked technically well with no intra-procedural thromboembolic complications and occlusion rates comparable to other FDs.

Authors' contribution

Riitta Rautio: conceptualization, methodology, writing – original draft preparation, investigation.

Kemal Alpay: visualization, writing – review & editing.

Matias Sinisalo: writing – review & editing.

Jussi Numminen: investigation, writing – review & editing.

Disclosure of interest

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