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INTERVENTIONAL RADIOLOGY

ORIGINAL ARTICLE

Safety and efficacy of flow diverter stents in the treatment of bifurcation cerebral aneurysms: single-center experience

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PURPOSE

The use of flow diverter (FD) stents is continually expanding. Aneurysms on arterial bifurcation typically have an undesirable anatomical form, are frequently wide-necked, and include one or more side-branch arteries. In recent years, the off-label use of flow diversion in treating intracranial aneurysms beyond the internal carotid artery has become increasingly popular. This study reports our center's initial experience treating bifurcation aneurysms with FD devices, documenting occlusion outcomes using the O'Kelly–Marotta and modified Cekirge–Saatci scales, as well as the safety of FD usage in bifurcation locations.

METHODS

This retrospective, single-center study analyzed a prospectively maintained database of patients with cerebral aneurysms treated endovascularly. The study identified bifurcation aneurysms that were treated between January 2019 and May 2022 by placing an FD device covering the neck of the aneurysm.

RESULTS

Our short series suggests that flow diversion is a viable therapeutic option for bifurcation aneurysms with favorable angiographic outcomes.

CONCLUSION

In highly selective cases, flow diversion may be considered for treating bifurcation aneurysms in patients who will undergo follow-up examinations in the future.

CLINICAL SIGNIFICANCE

Flow diversion has emerged as a valuable technique in the management of bifurcation aneurysms, offering the potential for satisfactory occlusion and long-term outcomes.

KEYWORDS

Intracranial aneurysm, bifurcation cerebral aneurysm, flow diverter, O'Kelly–Marotta Scale, modified Cekirge–Saatci scale

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The majority of cerebral aneurysms can now be successfully treated with flow diverter (FD) stents, and their applications are continually expanding to include distal aneurysm locations.[1] Aneurysms located on arterial bifurcation typically exhibit undesirable anatomical morphology, involving one or more side-branch arteries and often possessing a large neck.[2] Bifurcation artery aneurysms may sometimes feature wide-neck topologies that incorporate adjacent branches, resulting in a particularly complex morphology.[3] Due to the high rate of long-term occlusion and lower surgical morbidity, despite the above-mentioned features, endovascular treatment is often considered the primary option for bifurcation aneurysms in some institutions.[4]

Nonetheless, there is a growing trend in utilizing endovascular methods to treat bifurcation aneurysms, driven by advancements in angiographic imaging, increased operator exper-

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tise, and the adoption of more sophisticated techniques. Various endovascular techniques, such as stent-assisted coiling, balloon remodeling, Y-stenting, and Woven EndoBridge devices, have been employed for bifurcation aneurysm treatment. However, the outcomes do not provide satisfactory occlusion and have some complication rates.[5]

Flow diversion has emerged as an alternative method for treating challenging bifurcation aneurysms, particularly those involving a single side branch or those with a history of endovascular or surgical failure. The effectiveness and safety of this approach are still under investigation, with ongoing debate regarding the role of flow diversion in bifurcation aneurysms.[6]

Methods

This retrospective single-center study is based on a prospectively maintained database of patients with cerebral aneurysms treated endovascularly. The study identified bifurcation aneurysms treated between January 2019 and May 2022 by placing an FD device covering the neck of the aneurysm, as shown in Figure 1.

The study's FDs were used regardless of the availability of appropriate clips or stents, with dual-trained physicians overseeing the specifics of the treatment plan. The common antiplatelet regimen was acetylsalicylic acid (100 mg daily) and ticagrelor (one 90-mg tablet twice daily). Postoperative follow-up visits were scheduled at 6, 12, and 24 months for comprehensive neurological assessments. Magnetic resonance imaging (MRI)/MR angiography was accepted if the patient was unable to undergo digital subtraction angiography (DSA).

Main points

- Flow diversion may be a viable treatment option for certain bifurcation aneurysms with complex anatomical features and challenging hemodynamics, particularly in cases when the aneurysm is off-centered or involves small distal vessels, and the patient can commit to ongoing follow-up examinations. However, this approach requires careful patient selection and thorough assessment of the potential risks and benefits in a multidisciplinary setting.
- The modified Cekirge–Saatci classification scale is highly useful in reporting aneurysms treated by flow diverter stents.
- Understanding the development and implications of neointimal hyperplasia is essential for clinicians involved in the management of bifurcation aneurysms treated with flow diversion. As research in this area continues to evolve, ongoing efforts are focused on refining techniques and identifying strategies to minimize the impact of neointimal hyperplasia while optimizing the long-term outcomes for patients undergoing flow diversion for bifurcation aneurysms.

Operation characteristics

Following the induction of general anesthesia, all procedures were conducted using a biplane flat-panel DSA unit (Artis Zee, Siemens). A long 6-Fr introducer sheath was inserted into the femoral artery. A guiding catheter, either Chaperon (MicroVention) or Asahi (Asahi Intecc), and, in some cases, a more distal intermediate catheter (Fargomax, Balt; or Sofia, MicroVention), were positioned. The appropriate microcatheter (Echelon Medtronic; Headway, MicroVention; Gama-17, Balt Extrusion) was advanced into the chosen bifurcation branch using 0.014 guidewires. When positioning the FD stent, particular attention was given to covering the fewest branches as possible. Following the FD stent's deployment, adjunctive coiling was performed using a jailed microcatheter in aneurysms greater than 15 mm. The Silk FD (Balt Extrusion) was used in 11 patients, and 4 patients were treated with the P48 MW (Phenox). All aneurysms in our series were treated with a single FD stent. Three aneurysms (20%) required the use of coils as an adjunct due to their size (patients #7, #11, and #13). In one case of low-profile FD usage with the P48 stent, additional coiling was used for better occlusion (patient #12). Patient #15 had coiling initially after the rupture, and the FD was used 2 weeks later. Following extubation in the intensive care unit (ICU), the patients spent at least 2 hours in a neurovascular ICU.

Clinical and imaging assessment

At every stage, the patients underwent a clinical evaluation using the modified Rankin scale (mRS). Following treatment, clinical statuses and any neurologic impairments at discharge or follow-up were documented. At least two DSAs, including 3-dimensional selective angiography runs, were performed at 6, 12, and 24 months after the operation. The angiographic results were assessed according to the O'Kelly–Marotta and modified Cekirge–Saatci grading scales. Integrated branch changes and the presence of intimal hyperplasia were also assessed.

Written informed consent was obtained from the patients for publication and any accompanying images. The Ethical Committee of the National Center provided ethical approval for this study (number 2 of ethical approval for neurosurgery on June 19, 2024). In addition, the investigators ensured that the study conformed to the principles of the Declaration of Helsinki (last revised in 2013) and was conducted in accordance with the ICH Guidelines for Good Clinical Practice.

Results

Baseline population characteristics

There was a total of 15 patients: 7 men and 8 women, with a mean age of 54.6 ± 8.1 years (range 46–68 years). The pretreatment mRS scores were 1 for 12 patients, 0 for one patient, 3 for one patient, and 4 for one patient. Four cases involved ruptured aneurysms, two patients had multiple intracranial aneurysms, and five patients presented with headaches. Table 1 summarizes the baseline clinical characteristics.

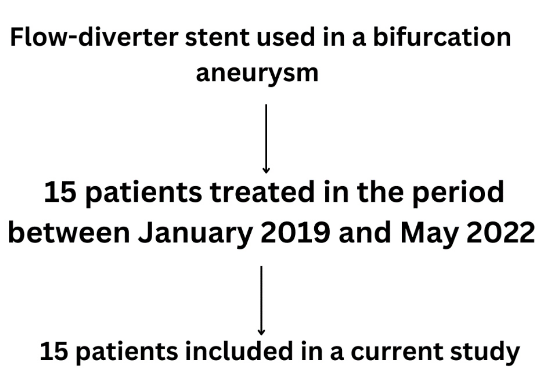

Figure 1. The flowchart of the study representing the criteria and number of patients from initial retrieval to the final study cohort.

Aneurysm characteristics

Seven patients had anterior cerebral artery distal bifurcation aneurysms, four patients had middle cerebral artery bifurcation aneurysms, three had an anterior communicating artery (ACom) aneurysm, and one had a posterior cerebral artery (PCA) bifurcation aneurysm. Two (13%) were giant aneurysms, and six (40%) were large aneurysms; the remaining aneurysms were small. We did not treat any aneurysms during the acute phase.

Outcomes

Table 2 summarizes the angiographic outcomes and the immediate post-procedure results. The average follow-up period for all patients in the study was 22 ± 9 months (95% confidence interval for the mean, 19–24 months). In the immediate results, we observed mostly grade C outcomes (33%) according to the O'Kelly–Marotta grading scale. During the follow-up period, 10 out of 15 patients attended their follow-up appointments. Among them, 80% achieved complete occlusion (class 1 by the modified Cekirge–Saatci grading scale) or had stable, altered angioarchitecture. Intimal hyperplasia was detected in 27% of our patients but

Table 1. Patient, aneurysm, and stent characteristics

Case no.	Presentation	Age/gender	Side/location	Size of neck/dome (mm)	Dome-to-neck ratio*	FD stent, size (mm)	Additional coiling
1	mIAs, arterial hypertension	48/F	Bilobar Small Right A1–A2	2.00 3.66 × 2.15	1.83	Silk Vista 2.50 × 20	No
2	Headache	46/F	Saccular Small Left A1–A2	2.5 3.09 × 2.97	1.23	P48 MW 3.00 × 18	No
3	Speech problems; right hemiparesis SAH in 2014	49/M	Saccular Small Right A2	2 2.5 × 2.5	1.25	Silk Vista 2.75 × 20	No
4	Left hemiparesis SAH in 2022	52/F	Small ACom	2.5 2.5 × 3.3	1.32	Silk Vista Baby 2.5 × 20	No
5	Loss of conciseness	47/F	Giant Right M1–M2	5.31 17.5 × 6.0 × 15.3	3.2	Silk Vista Baby 2.75 × 25	No
6	Headache	63/F	Large Right A1–A2	3.7 5.39 × 3.50 × 4.12	1.45	Silk Vista Baby 2.75 × 20	No
7	Vision decrease in left eye	62/M	Large ACom	6.5 10.7 × 11.4 × 15	1.75	Silk Vista Baby 2.75 × 25	Yes
8	Headache	68/M	Large Right P1–P2	9.1 11.9 × 14.0	1.5	Silk Vista Baby 2.25 × 20	No
9	Headache AH Recanalized	54/F	Large Right M1-M2	3.5 7.5 × 3.0	2.14	Silk 2.25 × 15	No
10	Hemorrhage after stent	50/F	Small Left A3	2.87 2.5 × 2.5 × 2.0	0.87	P48 1.5 × 20	No
11	Ischemic stroke in 1998	64/M	Giant Right M1–M2	3.8 21 × 12.2	5.5	Silk Vista 3.0 × 25	Yes
12	mIAs, headache	47/M	Small Right A2–A3	7.18 4.70 × 3.74	0.6	P48 MW 3.0 × 18	Yes
13	Headache	58/M	Large Left A2–A3	3.39 6.28 × 4.20 × 3.39	1.85	Silk Vista 2.5 × 15	Yes
14	SAH 2016 Recanalized	62/M	Large Left M1–M2	3.5 7.5 × 3.0	2.14	P48 MW 3.0 × 18	No
15	SAH in 2022	50/F	Recanalized Small ACom	3.0 3 × 3	1.0	Silk Vista 2.25 × 15	Yes

FD, flow diverter; F, female; M, male; ACom, anterior communicating artery.

Table 2. Immediate and latest follow-up results

Case no.	mRS before	Immediate results		Last FU result			Integrated branch site changes*	Intimal hyperplasia	Complications		mRS after
		Jailed artery(s)	O'Kelly–Marrotta grading system	O'Kelly–Marrotta grading system	Modified Cekirge–Saatci classification	MRI/MRA			Peri operative	90 days FU	
1	1	Right A2	C2	D (6, 12 months)	1	abs	No change	No	No	No	1
2	0	Left A1, A2	C2	D (6, 12 months)	1	abs	No change	No	No	No	0
3	4	Left A1, A2	A2	D (6, 12 months)	1A	abs	Changing caliber	Yes	No	No	1
4	3	Left A1, A2	A3	-	-	-	-	-	Yes[$]	-	3
5	1	Right parietal MCA	C1	-	-	-	-	-	No	-	1
6	1	Left A1, A2	D	-	-	-	-	-	Yes[+]	-	1
7	1	Right A1, A2	B3	B3	5A	Stagnation	No change	No	No	No	1
8	1	Right PCA	C2	D (6, 12, 24 months)	1	abs	No change	No	No	No	1
9	1	Right M1	A2	D (6, 12 months)	1	abs	No change	No	No	No	3
10	1	Right M3	D	D (6, 12 months)	1	abs	No change	Yes	No	No	1
11	1	Right M1	C2	-	-	abs	-	-	-	-	1
12	1	Left A1	C2	D (12 months)	2	Aneurysm neck filling (26 months)	Changing caliber	Yes	No	No	1
13	1	Left A2, A3	C1	D (6, 12, 24 months)	1	abs	No change	Yes	No	No	0
14	1	Right A2, A3	C2	-	-	-	-	-	-	-	6
15	1	Left A2	A2	D (6, 12, 24 months)	1	abs	No change	No	No	No	0

*No change/occlusion/changing caliber. [$]Spontaneous stent separation in the microcatheter from the delivery system, Echelon-10 replaced by HeadwayDUO; Silk Vista Baby 2.25 × 20 mm changed to Silk Vista Baby 2.5 × 20 mm. [+]Due to the difficult acute angle of detachment of the A1 segment of the left PMA and the rigidity of the distal segment of the microcatheter, gamma17_d was replaced with gamma17_DS. mRS, modified Rankin scale; MRI, magnetic resonance imaging; MRA, magnetic resonance angiography.

was not clinically significant; these patients were advised to continue dual antiplatelet therapy (DAPT).

In this study, adjunctive coiling was performed in one-third of the patient cohort. This was done by coiling the aneurysm dome while sparing the neck and then applying the stent. Some technical complications are also described in Table 2.

Unfortunately, our case series included one death: 6 months after discharge, one patient (#14) passed away from a myocardial infarction, according to the clinical history provided by the family.

One patient (#7) was lost to follow-up, and three patients (#4–6) declined follow-up during the telephone interview. One patient (#11) is currently receiving chemotherapy for cancer, but MRI shows signs of aneurysm obliteration.

Case examples

Case #1: patient #8

A 68-year-old man presented to our clinic in 2020 with a large incidental aneurysm at the junction of the posterior communicating artery and the PCA, measuring 11.9 × 14.0 mm in diameter, with a neck size of 9.1 mm. The decision was made to treat the aneurysm with FD placement. The operation was performed using a Silk Vista Baby measuring 2.25 × 20 mm. Control angiography showed aneurysm occlusion at the initial follow-up 6 months later (Figure 2). At the 3-year follow-up, the O'Kelly–Marotta grade was D and class 1A according to the modified Cekirge–Saatci classification.

Case #2: patient #7

A 62-year-old man presented with an initial complaint of decreased vision in his left eye. MRI revealed a large ACom aneurysm with maximum dimensions of 10.7 × 11.4 × 15 mm and a neck size of 6.5 mm. The management plan involved the use of an FD device, and the procedure included placing a Silk Vista Baby stent measuring 2.75 × 25 mm in the A1–A2 segment of the right anterior cerebral artery, along with additional coiling. During follow-ups at 12- and 24-months post-procedure, residual aneurysm filling with remodeling was noted. Despite this finding, the decision was made to continue observation with DAPT due to ongoing obliteration. At the 3-year follow-up, the O'Kelly–Marotta grade was 3B and class 3 according to the modified Cekirge–Saatci classification, as shown in Figure 3.

Discussion

FDs are medical devices used in the treatment of intracranial aneurysms, including those located at bifurcations.[1] Bifurcation aneurysms occur at the junction where two blood vessels divide, creating a Y-shaped structure.[2] Treating aneurysms in these locations poses specific challenges, and FDs are one of the evolving tools in neuro-interventional procedures.[3]

Schob et al.[4] conducted a retrospective analysis of patients treated with indirect flow diversion for off-centered bifurcation aneurysms. The authors found that indirect flow diversion was a safe and effective approach, with reduced perfusion of the aneurysm immediately after implantation and observable occlusion and reduction in size at follow-up.[4] The pipeline embolization device (Medtronic, Irvine, CA, USA) was granted Food and Drug Administration approval in 2011, making it the first FD approved for use in the United States market.[5] Initially, approval was intended for use in treating large or giant wide-necked aneurysms in the internal carotid artery, from the petrous to the superior hypophyseal segments, in individuals aged 22 years and older.[6] For more than 5 years, the off-label use of FD stents for the treatment of distal aneurysms has been reported, but it remains debated.[6]

In our preliminary experience, FD devices were found to be safe for use in bifurcational aneurysms. The outcomes of this assessment were documented using the O'Kelly–Marotta and modified Cekirge–Saatci scales. In our series, among the patients who attended follow-up examinations, the total occlusion rate was 53% (8/15), with 80% of these classified as class 1 by the modified Cekirge–Saatci classification. This outcome is primarily attributed to factors related to the patients, such as missed follow-up MRI appointments and one case of mortality. Some studies have reported high rates of complete occlusion with flow diversion in bifurcation aneurysms, ranging from 62% to 80%.[7,8] While high rates of complete occlusion with flow diversion in bifurcation aneurysms have been reported, it is important to consider the potential drawbacks and complications associated with this technique. Additionally, there have been reports of ischemic complications (NICE lesions) and procedure-related morbidities in patients treated with flow diversion for bifurcation aneurysms;[9] however, we did not observe any in our case series.

Some emerging technologies, such as intrasaccular flow disruption devices and intrasaccular FDs, are being investigated as alternatives to traditional flow diversion techniques. These devices aim to address the limitations of standard flow diversion by providing more precise aneurysm occlusion while minimizing the risk of delayed aneurysm rupture.[10] Stent-assisted coiling was initially introduced for wide-neck aneurysms based on the hypothesis that a stent can provide a framework to hold the coils in the aneurysmal cavity, preventing coil migration.[11]

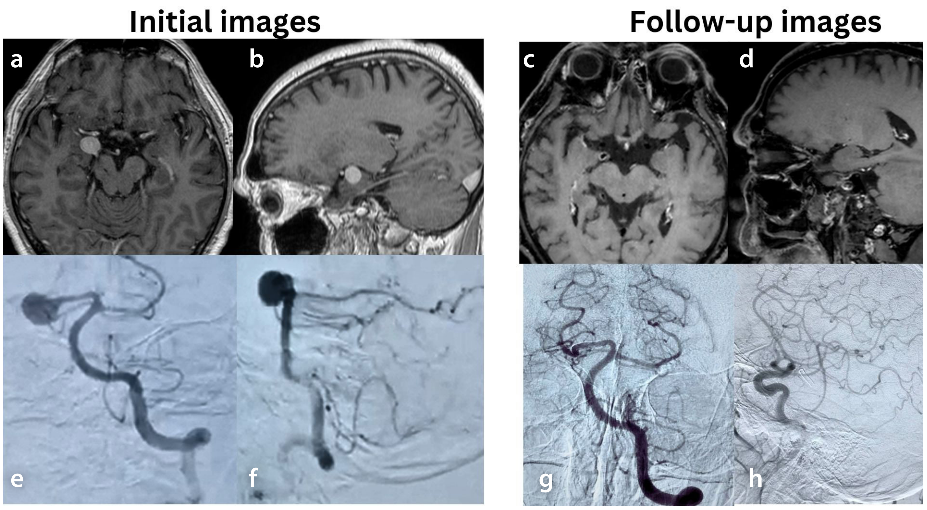

Figure 2. Patient #8. **(a)** Axial post-contrast images demonstrating a large incidental aneurysm at the junction of posterior communicating artery and posterior cerebral artery (PCA). **(b)** Sagittal images demonstrating a PCA aneurysm with adjacent brain compression. **(c, d)** Control magnetic resonance imaging/magnetic resonance angiograph demonstrating the absence of the aneurysm. **(e, f)** Pre-operative digital subtraction angiography demonstrating aneurysm sizes of 11.9 × 14.0 mm and a neck size of 9.1 mm. **(g, h)** At 3 years of follow-up, O'Kelly–Marotta grade D and class 1A according to the modified Cekirge–Saatci classification. The sequence of images illustrates the potential physiological development following flow diverter reconstruction, beginning with mechanical flow diversion and advancing to natural aneurysm thrombosis and complete occlusion. This is followed by internal parent artery repair, leading to complete anatomical restoration with the disappearance of the aneurysm-thrombus mass and a decrease in the regional mass effect.

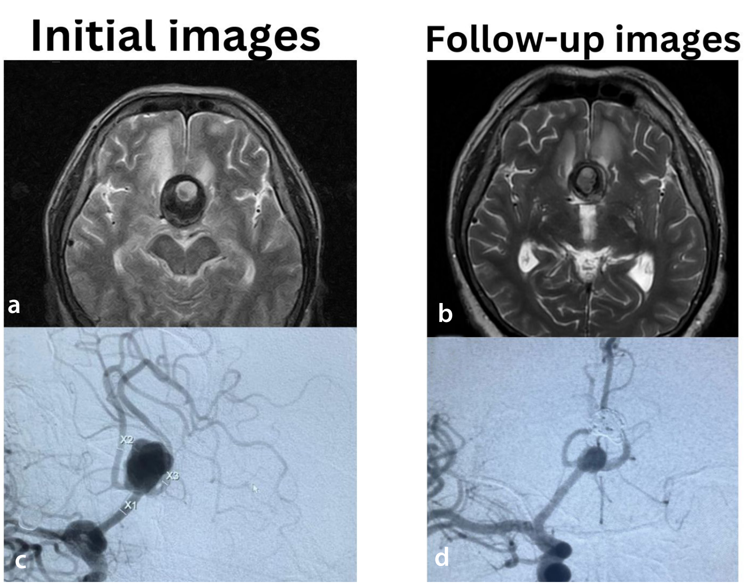

Figure 3. Patient #7. **(a)** Axial T2 Propeller magnetic resonance imaging showing a large partially thrombosed anterior communicating artery (ACom) aneurysm measuring 37 × 33 × 28 mm on initial presentation on 09/14/2022, with perianeurysmal edema. **(b)** Axial T2 image from the control presentation on 04/11/2024, showing signs of aneurysm shrinkage measuring 29 × 28 × 26 mm. **(c)** Initial angiogram in the working projection demonstrating a large contrast-filled aneurysm measuring 10.7 × 11.4 × 15 mm arising from ACom. **(d)** At 3 years of follow-up, O'Kelly–Marotta grade 3B and class 3 according to the modified Cekirge–Saatci classification.

However, some new stents are being developed specifically for this approach.[7] Patient #12 presented with a filling of the aneurysmal neck despite coiling, and the underlying cause remained unclear.

The modified Cekirge–Saatci classification, first described in 2015,[12] is an FD-specific occlusion classification that allows the subclassification of incorporated branches, aneurysm neck, and aneurysm occlusion changes in patients. However, not many centers report outcomes using this scale, which makes it difficult to assess outcomes in bifurcation or other challenging pathologies. In our series, one patient was classified as modified Cekirge–Saatci class 1A, with a reduced caliber branch due to intimal hyperplasia, although this was not clinically significant. The cause of intimal hyperplasia is the vascular endothelium, which is located at a crucial interface and becomes vasoactive in response to minute changes in hemodynamic conditions.[13]

Intimal hyperplasia is a common physiological response to vascular injury or alterations in blood flow dynamics, and it can be a significant issue when dealing with FDs, especially in the context of treating cerebral aneurysms.[13,14] Intimal hyperplasia involves the proliferation of smooth muscle cells and the accumulation of extracellular matrix within the intima, the innermost layer of the blood vessel.[14] When an FD is placed, the body may respond to the presence of foreign material and altered flow dynamics by initiating a healing response, which can include the development of intimal hyperplasia.[15]

Intimal hyperplasia has been reported with FD usage but not clearly in bifurcation aneurysms.[13,14] However, neither pore density nor metal coverage has a significant association with aneurysmal occlusion.[15] According to systematic reviews,[16] ticagrelor was associated with better survival[17] and lower neointimal hyperplasia.[18] Nevertheless, the 27% rate of intimal hyperplasia observed at the latest follow-up in our series of patients could be due to non-adherence to therapy.

This study has several limitations that need to be acknowledged. First, the retrospective single-center design introduces inherent bias, presenting descriptive data on a limited and diverse population. The retrospective nature of the research relies on previously collected data, which might introduce several biases and limitations of the single-centered study. For instance, the core lab analyses and follow-up images may be incomplete, and the study cannot control for all variables that might influence outcomes. Additionally, the retrospective nature means that the study is subject to selection bias, as it depends on cases that were previously selected for treatment or observation. These factors may affect the generalizability and accuracy of the findings. Second, subgroup analysis by FD stent type is not possible due to the limited population size. The rarity of flow diversion usage in bifurcational aneurysms further exacerbates this issue, making it challenging to conduct prospective studies or randomized trials. Consequently, it is crucial to interpret the results of this study while considering the inherent selection bias. The study's main limitation lies in its small sample size, suggesting that surgical outcomes might differ when research is conducted on a larger scale. We recommend that future researchers recruit larger sample sizes through multicenter studies.

In conclusion, flow diversion has emerged as an exceptionally valuable technique in the management of bifurcation aneurysms, providing the potential for satisfactory occlusion and favorable long-term outcomes. However, this technique requires further assessment.

Conflict of interest disclosure

The authors declared no conflicts of interest.

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