Turk Neurosurg, 2024

Original Investigation

DOI: 10.5137/1019-5149.JTN.43174-23.1

Received: 02.01.2023
Accepted: 17.03.2023

Published Online: 13.02.2024

Middle Cerebral Artery Ischemic Complications After Flow Diverter Deployment from Internal Carotid Artery Extending into M1 Segment

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ABSTRACT

AIM: To gain a better understanding of ischemia risk related to in-stent stenosis (ISS) or in-stent thrombosis (IST) of the middle cerebral artery (MCA) and lenticulostriate arteries after flow-diverting devices (FDD) deployment from the internal carotid artery (ICA) to proximal middle cerebral artery (M1).

MATERIAL and METHODS: Using data from a prospectively maintained database, we retrospectively evaluated patients who were treated with FDD between January 2015 and 2020 at a single academic center. Only patients with unruptured ICA aneurysms where the FDD was extended into M1 were included.

RESULTS: In total, 89 patients with 94 ICA aneurysms were treated with FDD. A total of 34 patients with 36 aneurysms had FDD extending into M1. Of the 34 patients, four experienced MCA, and lenticulostriate territory ischemia. Three patients had in-stent thrombosis (IST), and one patient had severe in-stent stenosis (ISS). The overall ischemic complication rate was 17.6%, which resulted in a permanent neurological deficit in 11.7% of the patients.

CONCLUSION: If the distance of the distal neck of the aneurysm to the ICA terminus (ICAT) is ≤5 mm, or if the aneurysm is located directly at the ICAT, FDD should be considered only as a last option when other treatment modalities are not suitable. In addition, in the treatment of distal ICA aneurysms, extra effort should be exerted during the procedure to deploy the FDD without extending into M1. However, when traditional microsurgical clipping and other endovascular procedures are not suitable, the use of FDD is effective in terms of high aneurysm occlusion rates and preventing aneurysm rupture.

KEYWORDS: Flow diverter, Distal internal carotid artery, In-stent stenosis, In-stent thrombosis, Aneurysms

ABBREVATIONS: FDD: Flow diverter device, **FDA:** Food, and drug administration, **ICA:** Internal carotid artery, **ICAT:** ICA terminus, **ISS:** In-stent stenosis, **IST:** In-stent thrombosis, **OphA:** Ophthalmic artery, **PcomA:** Posterior communicating artery, **AchA:** Anterior choroidal artery, **MCA:** Middle cerebral artery, **AcomA:** Anterior communicating artery, **DSA:** Digital subtraction angiography, **3-D:** Three-dimensional, **RROC:** Raymond-Roy classification, **mRS:** Modified Rankin scale, **CT:** Computed tomography, **PED:** Pipeline embolization device

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INTRODUCTION

Small, wide-neck, and giant proximal internal carotid artery (ICA) aneurysms are all challenging lesions to treat with traditional interventions such as microsurgical clipping, primary endovascular coiling, or balloon-stent-assisted coiling (1). In recent years, breakthrough flow-diverting devices (FDD) have been developed in the treatment of these aneurysms. The effect of FDD on aneurysm occlusion occurs via two mechanisms. First, owing to their low-porosity, they disrupt, and reduce the rate of blood flow entering the aneurysm sac, causing flow stagnation, and thereby inducing aneurysm thrombosis over time. Second, neointimal overgrowth reconstructs the stent and parent artery, and new endothelization covers the ostium of the aneurysm neck for permanent occlusion (12). In the United States, the Food and Drug Administration (FDA) approved clinical use of the Pipeline Embolization Device (PED) for treatment of wide-neck and giant ICA aneurysms arising from the petrous to the superior hypophyseal segments. Owing to reports on the successful use of PED in distal ICA aneurysms, the approved use was extended in 2018 to include treatment of aneurysms at the ICA terminus (ICAT).

Despite the advantages of FDD in the treatment of wide-neck and giant aneurysms, their tightly braided, and low-porosity structure can lead to ischemic complications from occlusion of the covered side branches and perforators, as well as in-stent stenosis (ISS) or in-stent thrombosis (IST) (11,17,18). However, the fate of occluded anterior cerebral artery segment A1 and distal ICA side branches such as the ophthalmic artery (OphA), posterior communicating artery (PcomA), and anterior choroidal artery (AchA) are well studied, and most cases are reported to be clinically silent (2,5,23). Mühl-Benninghaus et al. reported that, although ISS was a common finding after FDD treatment for mild-grade ICA aneurysms, no ISS-related neurological deficits were observed (14). Wang et al. evaluated 118 patients with ICA aneurysms treated with FDD. They reported six ISS cases (5%); four of the patients were asymptomatic according to their analysis, while two presented with dizziness and one had blurred vision (25). In another study published by Townsend et al., out of 768 patients who underwent FDD placement for ICA aneurysms, only 10 (1.3%) presented with symptomatic postprocedural thrombosis. Of these, the mean mRS score at discharge was 1.3 (median, 1; range, 0–4) (21).

Although low ischemic complication rates due to IST and ISS have been reported in FDD treatment of ICA aneurysms, this is not the case for middle cerebral artery (MCA) aneurysms. A systematic review and meta-analysis of MCA aneurysm treatment with FDD reported a 16% ischemic complication rate (6). Additionally, Brinjikji et al. investigated the risk factors for ischemic complications after FDD in 793 patients, 36 of whom (4.5%) later presented with an ischemic stroke. They found that patients with MCA aneurysms had higher odds of stroke than those with ICA aneurysms (3). Therefore, the MCA location appears to be associated with a particularly high risk of ischemic injury compared to general ischemic complications associated with FDD.

The treatment of distal ICA aneurysms with FDD usually requires deployment of the device from the ICA up to M1 (13). However, few studies have evaluated ischemic complications in the MCA and lenticulostriate arteries after such FDD deployment (24). Therefore, we aimed to quantify the risk of MCA ischemic complications due to ISS or IST after ICA to M1 FDD placement.

MATERIAL and METHODS

Study Design and Patient Selection Criteria

Our instutional review board approved this study (Biruni University, Medicana International Istanbul Hospital, 2022, p196820). Using data from a prospectively maintained database, we retrospectively evaluated patients who were treated with a PED between January 2015 and January 2020 at a single academic center. All procedures were performed by a senior hybrid vascular neurosurgeon. Only patients with unruptured ICA aneurysms where the PED was extended into M1 were included. In all cases, a single PED was deployed. The reasons for treating the ICA aneurysm with PED deployed from ICA to M1 were as follows: 1) The aneurysm was located in the distal ICA with a wide-neck and would be difficult to treat with clipping and coiling. 2) The device could not be inserted without extending into M1 because of severe tortuosity of the ICA. 3) The origin of the aneurysm neck was <5 mm from the ICAT. 4) The presence of a patent anterior communicating artery (AcomA) and adequate filling of the MCA was confirmed on angiograms taken from the contralateral ICA with manual compression of the ipsilateral ICA, where the aneurysm was located.

Antiplatelet Therapy and Procedure Technique

All patients received dual-antiplatelet therapy prior to PED implantation, with a P2Y12 test confirming the level of platelet inhibition. Our instutional antiplatelet regimen protocol consists of 100 mg aspirin and 75 mg clopidogrel daily for five days before the procedure for unruptured cases, and loading doses of 300 mg aspirin and 375 mg clopidogrel two hours before the intervention for ruptured cases. If resistance to clopidogrel was detected, patients received 2x90 mg ticagrelor for elective procedures or a 180 mg loading dose for emergency procedures. The dual-antiplatelet regimen was continued for six months following PED placement, and the aspirin therapy for life. Administration of clopidogrel or ticagrelor was discontinued after six months depending on the angiographic and clinical outcomes.

Four-vessel digital subtraction angiography (DSA) and three-dimensional (3-D) rotational imaging were performed for aneurysm diagnosis. Contralateral flow from the AcomA was confirmed. The dimensions of the PED were determined by measuring the aneurysm neck, landing zone length, and M1, and ICA diameters. In each case, the diameter of the PED was approximately 0.5 mm larger than the diameter of proximal landing zone on the ICA and similarly oversized for the distal landing zone on M1. Under general anesthesia, a 6-F long-sheath vascular introducer was inserted via a transfemoral approach, and intravenous heparin was administered

intraprocedurally to achieve an activated clotting time >250 seconds. A 5-F Navien catheter was inserted up to the carotid siphon. A 0.027 inch microcatheter was then navigated to the M1 segment. After deployment of the PED, DSA was performed immediately to evaluate the wall position of the PED and patency of the parent artery.

Angiographic Analyses

After the procedure, we performed follow-up DSA at 6, 12, and 24 months to evaluate aneurysm occlusion as described by the Raymond-Roy classification (RROC). RROC1 was defined as complete occlusion, RROC2 as a remnant neck, and RROC3 as a residual aneurysm. Patients who developed neurological deficits at any time after the procedure urgently underwent angiography, which determined if the MCA ischemic symptoms were due to ISS or IST. ISS was defined as a decrease in the diameter of the proximal M1 covered by the FDD compared with the M1 diameter measured on the pre-procedure angiography, and graded as mild (25%–50%), moderate (50%–75%), or severe (>75%). IST was defined as a partially or completely occlusive thrombus within the stent boundaries.

RESULTS

Patient and Aneurysm Characteristics

In total, 89 patients with 94 ICA aneurysms were treated with FDD. Of these, 34 (with 36 total aneurysms) had a PED that extended into M1. Two patients had bilateral aneurysms. All cases were unruptured. All patients had a modified Rankin scale (mRS) score of 0 prior to PED placement. Twenty-one of the 34 patients were female (61.7%) and 13 were male. The mean age was 62 ± 13.4 years (range: 39–78 years). Overall, 14 aneurysms originated from the ICAT or <5 mm to the ICAT (38.8%); 12, from the posterior communicating artery (33.3%); 6 from the AchA (16.6%); and 4 from the OphA (11.1%; Table I). Mean aneurysm size was 4.6 mm (range: 2.1–22 mm). The mean diameters of the ICA and proximal M1 where the distal and proximal ends of the PED landed were 3.9 and 3 mm, respectively.

Table I: Baseline Clinical Characteristics

Value	
Number of patients	34
Number of aneurysms	36
Patients with bilateral aneurysms	2
Mean age, years	62 ± 13.4
Female, n (%)	21 (61.7)
Aneurysm location, n (%)	
ICA terminus	14 (38.8)
PcoA	12 (33.3)
AchA	6 (16.6)
OphA	4 (11.1)

Angiographic Outcomes and Complications

PED were successfully inserted from the ICA to M1 in all patients. The mean angiographic follow-up duration was 13.5 months. All patients underwent short-term follow-up with angiography (6 months), at which point RROC1 was observed in 25 aneurysms (69.4%). Four patients declined long-term angiographic follow-up; of these, two had complete occlusion during short-term follow-up, one had a remnant neck, and the other had a residual aneurysm. At 24 months post-intervention, RROC1 was observed in 27 (84.3%) of the 32 aneurysms that were still being followed.

Of the 34 patients, four (17.6%) developed MCA and lenticulostriate territory ischemia. Of these, three developed IST. Patients 1 and 2 experienced completely occlusive IST 6 and 8 hours after the intervention, respectively. Patient 1 experienced aphasia and mild hemiparesis, which improved within 7 days of treatment for the thrombosis. Patient 2 experienced mild upper extremity paresis and was referred for rehabilitation on post-intervention day 2. During the mechanical thrombectomy attempt in both patients, the procedure was discontinued because the stents tended to creep proximally. Both patients were treated with intra-arterial abciximab, completely resolving the IST. Patient 3 was a 53-year-old female who was incidentally diagnosed as having a right PcomA bilobed wide-necked aneurysm (Figure 1A). After successful placement of the FDD and observation for one night, she was discharged with dual-antiplatelet medication. Eight days later, she presented to the emergency department with right facial paralysis and right hemiplegia. An emergent angiography revealed a completely occlusive thrombus in the FDD (Figure 2B). The patient subsequently underwent mechanical thrombectomy via stentriever, but convincing revascularization was not achieved. The patient was then treated with intra-arterial abciximab, after which definitive revascularization was confirmed by angiography (Figure 2C). After five days of close monitoring in the intensive care unit, computed tomography (CT) confirmed an MCA inferior trunk infarction (Figure 2D). The patient's facial paralysis completely resolved and she was referred for rehabilitation with a mRS score of 3.

The final patient with ischemic complications from the procedure developed severe ISS. Patient 4 was a 47-year-old female with an ICA aneurysm diagnosed during evaluation for intermittent headaches (Figure 2A). The patient underwent intervention without immediate complications. Six months later, RROC1 was detected on follow-up angiography, and the patient was advised to stop taking clopidogrel. Approximately seven months later, the patient presented with left facial paralysis and hemiparesis. Emergency angiography revealed a severe stenosis in the distal and proximal parts of the PED, with moderate stenosis between (Figure 2B, C). In the same session, balloon angioplasty was attempted, and approximately 50% recanalization was achieved. CT confirmed an MCA superior trunk infarction (Figure 2D). The facial paralysis completely resolved, and the patient was referred for rehabil-

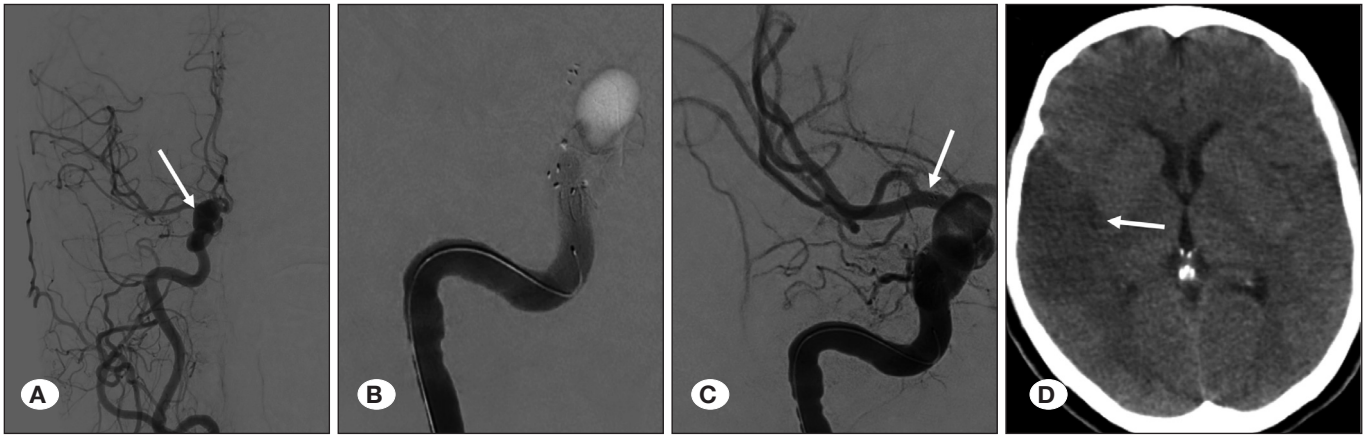

Figure 1: A) Bilobule wide-necked right posterior communicating artery aneurysm (white arrow). **B)** Current flow stagnation proximal to the stent and placement of a mechanical thrombectomy catheter. **C)** Definitive revascularization after mechanical thrombectomy and intra-arterial thrombolitic therapy (white arrow). **D)** Middle cerebral artery inferior trunk territory enfarction on a computed tomography scan (white arrow).

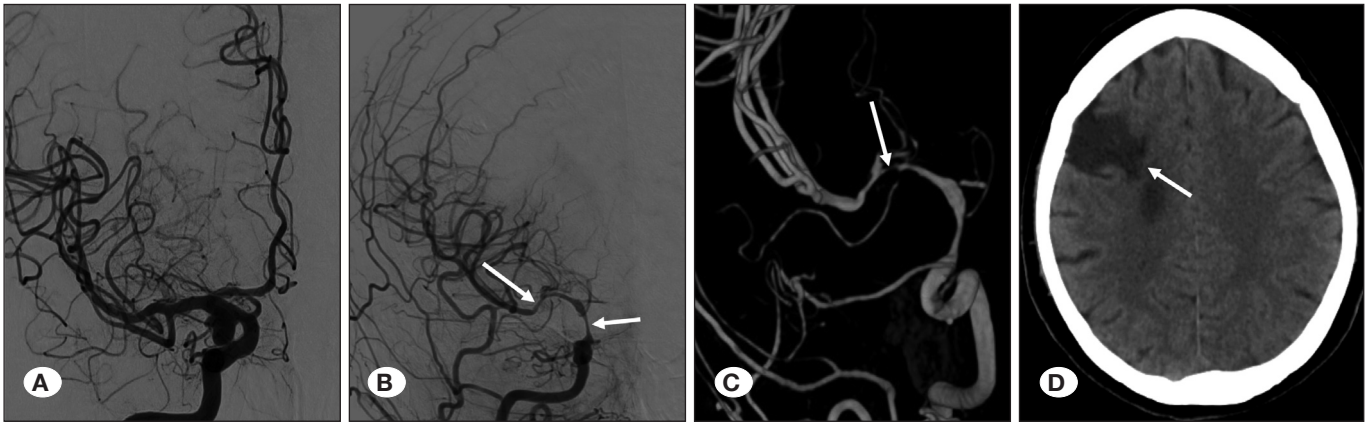

Figure 2: A) Posterolateral projecting right bilobule posterior communicating artery aneurysm (white arrow). **B)** Severe in-stent stenosis (white arrows). **C)** Severe stenosis demonstrated on a three-dimensionally reconstracted image (white arrow). **D)** Middle cerebral artery superior trunk territory enfarction on a computed tomography scan (white arrow).

Table II: Summary of MCA Ischemic Complications

Patient No	Age, Sex	Complication	Management	mRS core on Discharge
1	51, F	in-stent thrombosis	Abcixsimab	0
2	49, F	in-stent thrombosis	Abcixsimab	2
3	60, M	in-stent thrombosis	Abcixsimab	2
4	53, F	in-stent thrombosis	Thrombectomy + Abcixsimab	3
5	54, M	in-stent stenosis	Ticagrelor instead of clopidogrel	0
6	47, F	in-stent stenosis	Balloon angioplasty	2

itation under dual-antiplatelet therapy with a mRS score of 2. All complications are summarized in Table II.

DISCUSSION

FDD have become a primary choice in the treatment of small, wide-necked, and giant ICA aneurysms, with low rates of complication and high rates of occlusion (22). For adequate attachment of the FDD to the ICA and effective disruption of blood flow into the aneurysm sac, the major portion of the FDD, except for 5 mm proximally and distally, should cover the aneurysm neck (16). If the aneurysm being treated is in

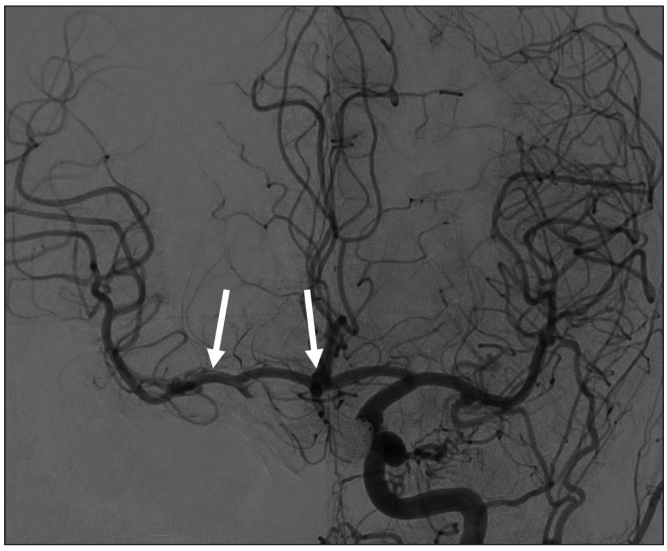

Figure 3: Incidental bilateral opthalmic artery (OphA) aneurysm. The left OphA aneurysm was coiled. The right OphA aneurysm was treated with flow-diverting devices. A completely occlusive in-stent thrombosis was observed on 6-month follow-up angiography. A patent anterior communicating artery and adequate filling of the middle cerebral artery were observed (white arrows). The patient was neurologically intact and had no ischemic symptoms.

the ICAT or the distance from the distal neck of the aneurysm to the ICAT is ≤5 mm, the FDD should be inserted from the ICA extending to M1 (4). This confers a risk of MCA and lenticulostriate territory ischemia due to IST or ISS. In this study, we have demonstrated a relatively high incidence rate of MCA ischemic events, despite appropriate platelet inhibition. Three patients had acute or subacute IST, and even when complete resolution of the thrombus was achieved with intra-arterial thrombolysis or mechanical thrombectomy, patients were referred to rehabilitation with permanent neurological deficits. An additional patient had severe ISS, and was referred to rehabilitation with a mRS score of 2. The overall ischemic complication rate of 17.6% was not negligible and resulted in permanent neurological deficits in 11.7% of patients.

PED are tightly braided and low-porosity stent-like devices (15). This structure, despite the use of dual-antiplatelet medication, initially raised concerns about the risk of developing IST or ISS. This initial reservation was quelled by the low rates of ischemic complication that were initially reported after PED treatment for ICA aneurysms (7,8,19). We observed, however, a markedly higher rate of ischemic complications when PED were used in the treatment of MCA aneurisms.

In our study, although a P2Y12 test was performed for all patients to confirm the level of platelet inhibition before the procedure, IST developed in four patients with appropriate platelet inhibition levels in the acute/subacute period. Therefore, the use of platelet inhibition tests prior to the procedure does not guarantee prevention of thrombotic complications (20). This could be partially due to the diurnal platelet reactivity fluctuations induced by clopidogrel. Some studies have shown that clopidogrel reactivity varies at different times of the day, and that peak platelet reactivity is generally measured in the morning (9,10). These findings suggest uncertain efficacy of the platelet inhibition tests and that other factors may play a role in patients' risk of developing thromboembolic complications.

Overall, we demonstrated that when the FDD was extended into M1 in the treatment of distal ICA aneurysms, the risk of developing ischemic complications in the MCA territory increased due to IST or ISS. Therefore, in the treatment of distal ICA aneurysms, extra effort should be made during the intervention to avoid deploying the FDD from the ICA all the way to M1. If the FDD is confined only to the ICA, even if IST, or severe ISS develops, the presence of a patent AcomA and adequate flow will protect the MCA territory from ischemia (Figure 3).

The main limitations of this study are its retrospective nature, single-center data, and small number of patients. Owing to the limited sample size, we found no statistically significant data. Additionally, some selection bias occurred as the patients were treated with FDD according to the surgeons' preference.

CONCLUSION

If the distance from the distal neck of the aneurysm to the ICAT is ≤5 mm or the aneurysm is located directly at the ICAT, FDD should be considered only as the last resort when other treatment modalities are not suitable. In addition, in the treatment of distal ICA aneurysms, effort should be made during the procedure to deploy the FDD without extending to M1, which should help avoid MCA ischemic complications due to IST and ISS. However, when traditional microsurgical clipping and other endovascular procedures are not possible, the use of FDD is effective in terms of high aneurysm occlusion rates and preventing aneurysm rupture.

Disclosures

All authors have participated in conception and design of the study, analysis and interpretation of the data, drafting the article or revising it critically for important intellectual content, and approval of the final version. This manuscript has not been submitted to, nor is it under review at, another journal, or other publishing venue. The authors have no affiliation with any organization with a direct or indirect financial interest in the subject matter discussed in the manuscript.

AUTHORSHIP CONTRIBUTION

Study conception and design: EB
Data collection: EB
Analysis and interpretation of results: AT
Draft manuscript preparation: OC
Critical revision of the article: OC
Other (study supervision, fundings, materials, etc...): AT
All authors (EB, AT, OC) reviewed the results and approved the final version of the manuscript.

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