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Effectiveness of Derivo Flow Diverter Device in the Endovascular Treatment of Cerebrovascular Aneurysms

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ABSTRACT

AIM: To report our experience with flow diverter devices in the treatment of intracranial aneurysms, and to share the efficacy and clinical results of the Derivo flow diverter device in the endovascular treatment of cerebrovascular aneurysms.

MATERIAL and METHODS: This retrospective study was conducted at the Regional Training and Research Hospital between October 2015 and March 2020 after approval by the Clinical Research Ethics Committee (number 2020/22-21; dated 12/07/2020). The radiology and file records of 21 patients with cerebrovascular aneurysms treated endovascularly using a Derivo flow diverter device were examined.

RESULTS: As per our findings, flow diverter devices were used to treat 27 aneurysms from 21 cases. Among the treated aneurysms, 3, 2, and 22 were in the middle cerebral artery, anterior communicating artery, and internal cerebral artery, respectively. Eight of the patients with a mean age of 56.9 years presented with subarachnoid hemorrhage. Derivo flow diverters were used alone in 19 cases, whereas concurrent diverter device and coiling were used in only 3 patients. Complete closure of the aneurysms was observed in 3 (14.2%) cases; meanwhile, a 50% reduction in aneurysm size was observed in 2 (9.5%) cases. Complete aneurysm closure occurred in 20 cases (95%) at the 6-month follow-up. Mortality and morbidity each occurred in 1 (4.7%) case.

CONCLUSION: Flow diverter devices provide an efficient and safe method of treatment, especially for fusiform, large, giant, wide-necked intracranial aneurysms. Endovascular coil embolization treatment is deemed inappropriate for small aneurysms.

KEYWORDS: Aneurysm, Cerebrovascular, Derivo flow diverter, Endovascular

ABBREVIATIONS: DFD: Derivo flow diverter, **GCS:** Glasgow Coma Scale, **ICA:** Internal carotid artery, **SAH:** Subarachnoid hemorrhage

INTRODUCTION

The use of flow diverter devices in the endovascular treatment of cerebral aneurysms started in 2008 (3). Consequently, several flow diverter devices have been utilized clinically. The Derivo flow diverter (DFD), which is included in the last generation of flow diverter devices, has been known to be more reliable and more effective with its increased radiological visibility and optimum opening and shaping features (3). In this study, the medical records and radiological imaging information of cases were examined retrospectively to investigate the reliability and effectiveness of the DFD device.

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MATERIAL and METHODS

This retrospective study was conducted at our clinic between October 2015 and March 2020 after obtaining approval from the Clinical Research Ethics Committee (number 2020/22-211; dated 12/07/2020). The radiology and file records of 21 patients with cerebrovascular aneurysms treated endovascularly using a DFD device were examined. The last generation DFD device with increased visibility and biocompatibility was used in the endovascular treatment of cerebrovascular aneurysms. By examining the hospital records of the cases, internal carotid artery (ICA) aneurysms were evaluated according to the Bouthillier classification, while clinical outcomes were evaluated according to the modified Rankin and Raymond–Roy classification.

Demographic information of the cases, including the shape, length, and localization characteristics of the aneurysms, and Glasgow Coma Scale (GCS) information are provided in Table 1. The cases received systemic heparinization and transfemoral interventional endovascular treatment under general anesthesia. Clopidogrel loading was provided to patients with non-ruptured aneurysms before the procedure. Oral anticoagulants were administered preoperatively to patients with ruptured aneurysms presenting with subarachnoid hemorrhage, while tirofiban infusion was administered as a load and maintenance.

Through the Seldinger method, the target arterial system was reached via the transfemoral route using a triple system comprising a 6Fr long-sheath, distal access catheter, and microcatheter. Under microwire guidance, a microcatheter was passed to the distal end of the target aneurysm neck. The DFD that was advanced through the microcatheter was opened using the appropriate method and placed on the vessel wall. Serial angiograms were thereafter performed to fully visualize the main artery flow strength and aneurysm neck. After the system was removed, percutaneous sealant was used to provide femoral hemostasis. Computed tomography angiography, magnetic resonance angiography, and digital subtraction angiography control were performed on patients at the 3rd and 6th months after surgery (Figures 1–3).

Table I: Demographic Information of 21 Patients Treated with Derivo Flow Diverter Device

Variables	Number
Total number of patients	21
Male	7
Female	14
Average age	56.9
Symptoms	
Headache	10
Subarachnoid Hemorrhage	8
Limitation of outward gaze	1
Ophthalmoplegia	1
Ptosis	1
Aneurysm Morphology	
Saccular	24
Fusiform	3
Mean aneurysm size (mm)	6.5
Aneurysm Size	
Small	3
Medium	7
Large	17
Glasgow Coma Scale at the time of admission to the hospital	
Glasgow Coma Scale 15	17
Glasgow Coma Scale 12	3
Glasgow Coma Scale 8	1

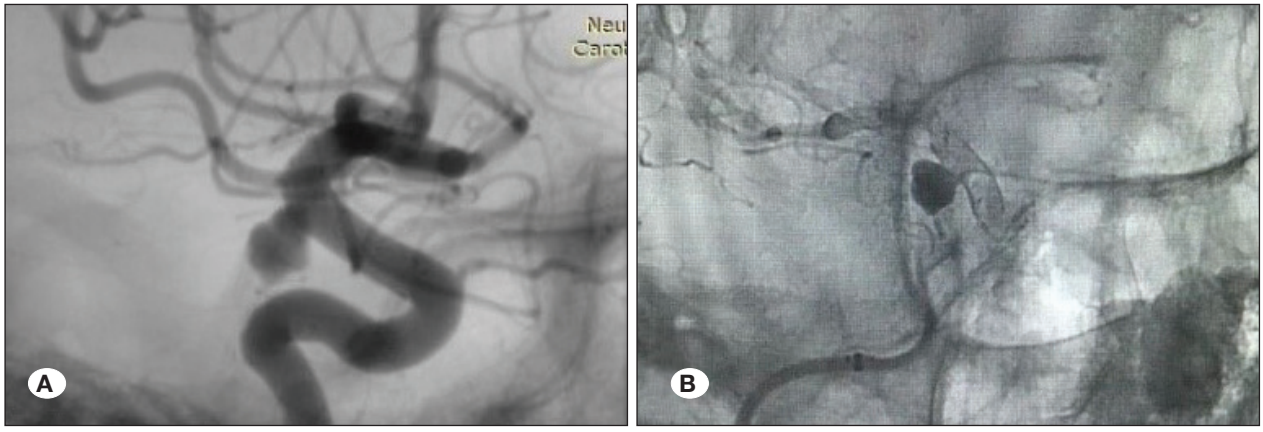

Figure 1: A) Angiography image of the internal carotid artery C7 segment aneurysm according to the Bouthillier classification. **B)** Contrast stagnation within the aneurysm following Derivo flow diverter placement.

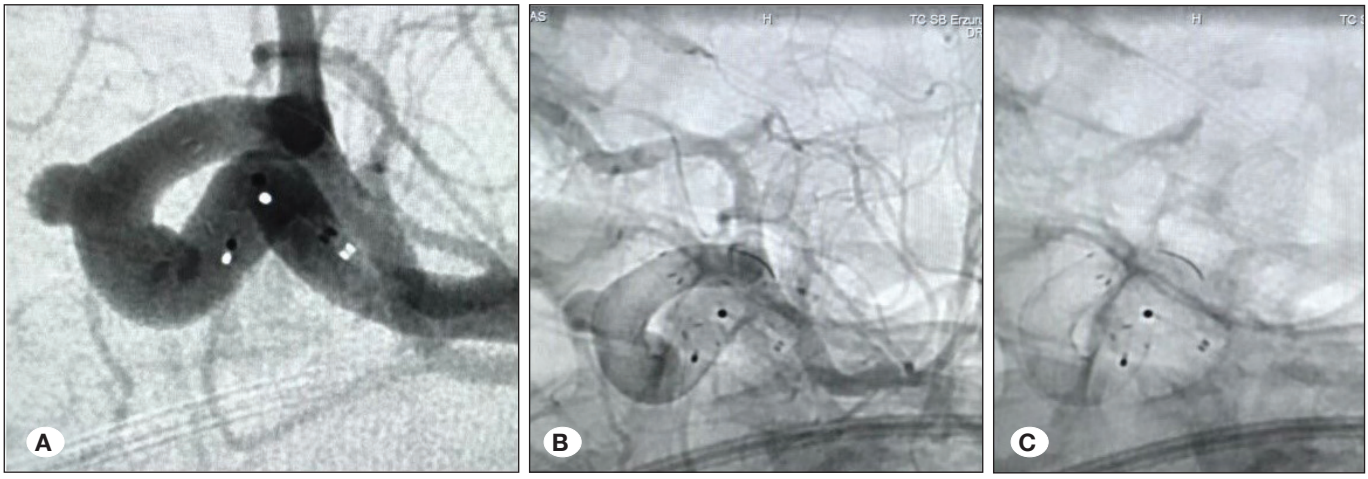

Figure 2: A) Angiography image of the internal carotid artery (ICA) C6 segment aneurysm after Derivo flow diverter (DFD) opening according to the Bouthillier classification. **B)** Angiography image of DFD remodeling of the main artery. **C)** DFD localization image conforming to ICA.

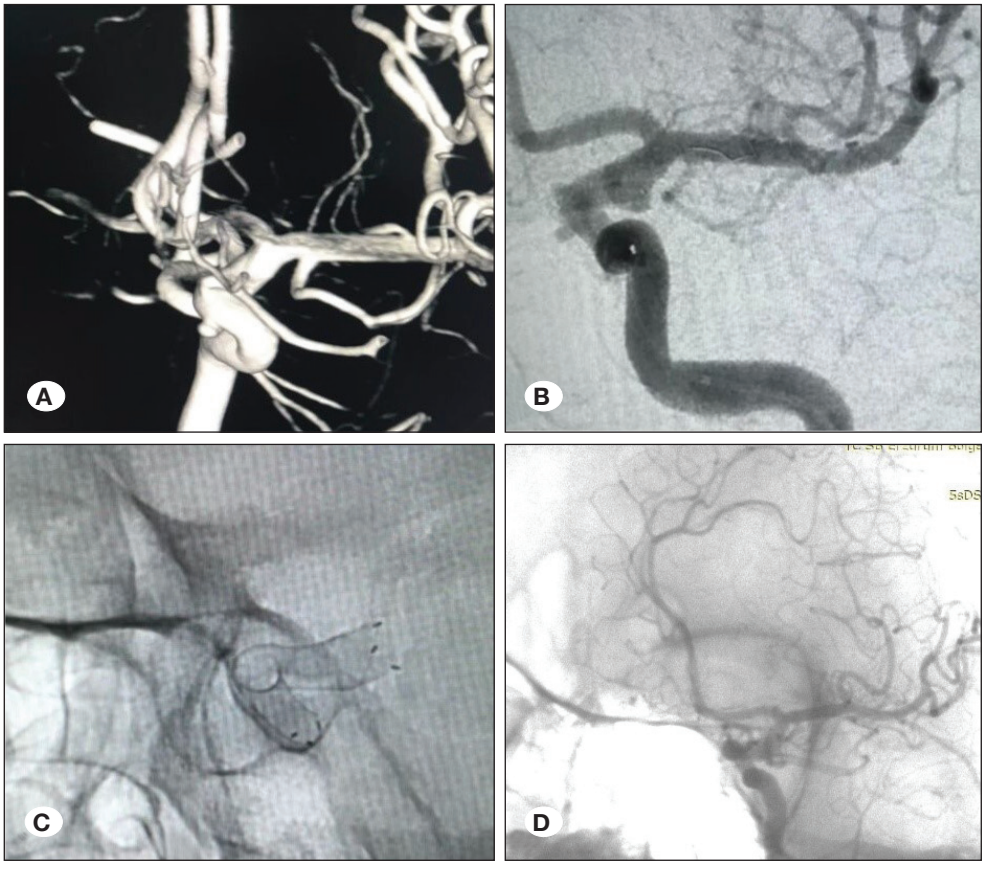

Figure 3: A) 3D angiography image of the internal carotid artery (ICA) C6 segment ruptured aneurysm according to Bouthillier classification. **B)** 2D angiography image. **C)** Derivo flow diverter localization image adapted to the ICA. **D)** Six-month follow-up angiography image with complete closure of the aneurysm.

RESULTS

In this current study, we have analyzed a total of 27 aneurysms from 21 patients treated with DFD. The age increment of the 14 female and 7 male patients, whose ages ranged from 41 to 72 years, was 56.9 years. Among the included patients, 8 presented with subarachnoid hemorrhage (SAH), 10 with headache, 1 with ptosis, 1 with ophthalmoplegia, and 1 with outward gaze limitation. Of the patients presenting with SAH, 3, 1, and 8 had a GCS of 12, 8, and 15, respectively. While the aneurysms in the 8 SAH cases with ruptured aneurysms were treated urgently, the remaining 13 patients were treated for aneurysms under elective conditions. After morphological examination of aneurysms, fusiform aneurysms were determined in 3 cases and saccular aneurysms in 18 cases. All three patients

with fusiform aneurysms presented with SAH. The mean size of the aneurysms was 6.5 mm (range, 2 to 15 mm). Among the aneurysms, three were in the middle cerebral artery, two were in the anterior communicating artery, and the rest were in the ICA. While DFD was used alone in 18 cases, DFD and coiling were utilized together in three cases. Among the treated aneurysms, 3, 7, and 17 were small, medium, and large, respectively. Complete closure of the aneurysms was observed in 3 cases (14.2%) at the 3-month follow-up, while 50% closure was observed in the aneurysms in 2 cases (9.5%). Partial filling was observed in the neck of the aneurysm in 1 case at the 6-month follow-up, and complete closure of the aneurysms was observed in 19 cases (90.4%). Despite the development of aphasia and hemiparesis due to temporary occlusion of DFD in one patient, complete clinical recovery was achieved after antithrombotic therapy. One patient died due to complications related to SAH in the early perioperative period. No early or late complications were observed in the 19 cases.

DISCUSSION

SAH, which is the most common clinical presentation of intracranial aneurysms, remains an important health problem due to its high mortality and morbidity rates (1,6). There have been long-standing debates regarding which open surgery and endovascular methods are better in terms of treating cerebral aneurysms. According to the findings of the International Subarachnoid Aneurysm Trial (ISAT), endovascular treatment promoted significantly better sequela-free survival rates over the first year in patients with bleeding intracranial aneurysms. The endosaccular coiling method is an accepted method for treating cerebral aneurysms. However, the increased risk of recurrent bleeding from the aneurysm from clipping after coiling still remains a concern and thus often requires retreatment (11).

Endovascular occlusion with coils has been a frequently used treatment approach for intracranial aneurysms. However, this procedure has been associated with a long-term risk of recanalization development (annual rebleeding risk of 0.7%). In addition, wide-necked aneurysms with complex anatomy may not be treated using the coiling method alone (2).

While cerebral aneurysms have been treated endovascularly, more durable treatment methods aside from the coiling and occlusion method are being investigated. Endovascular treatment modalities that provide reconstruction by targeting the parent artery wall rather than treating the aneurysm sac are probably more effective and may reduce recurrences (11).

In addition, coil embolization alone is insufficient for the reconstruction of a non-existing wall in wide-necked aneurysms. Several studies have shown low complete occlusion rates in angiographic control performed after coil embolization treatment. Raymond et al. found a complete occlusion rate of 38.3% in first year control angiographies of 353 aneurysms treated with coil embolization (10). After the standard coil treatment, new techniques were developed for the treatment and reconstruction of particularly complex aneurysms (9).

Fujimura et al. have presented 23 cases of unruptured aneurysms treated using DFD. At their 6-month follow-up, 73.9% of the cases showed total occlusion without any complications (3). Goertz et al. presented a study of 10 cases of ruptured aneurysms that presented with SAH and were treated using DFD. These cases revealed a total occlusion rate of 90% and a complication rate of 20% (4). In this current study, 8 cases presented with SAH with 3 fusiform and 5 wide-necked ruptured aneurysms. On their 6-month follow-up, we found an occlusion rate of 90%. Flow diverters have been widely used since their introduction in the era of endovascular treatment. Their main indications have been wide-necked unruptured aneurysms that are often challenging to treat with conversative endovascular and surgical procedures (7,8). They achieved further acceptance for their successful occlusion rates and periprocedural advantages. Owing to concerns regarding the lack of evidence on rebleeding risk due to antithrombotic treatment, which is mandatory for DFD procedures, their usage has generally been limited to unruptured aneurysms (5,7,8). However, some series, as in our study and that by Goertz et al., DFD treatment in ruptured cases (4). Nonetheless, no clear evidence has been available regarding the risk of rebleeding of ruptured aneurysms due to antithrombotic therapy, which is mandatory for DFD usage. Despite some limitations due to the few cases, our findings showed that DFD treatment may be safe in ruptured aneurysms.

CONCLUSION

Flow diverter devices are known to provide an efficient and safe method of treatment, especially for fusiform, large, giant, wide-necked intracranial aneurysms. However, endovascular coil embolization treatment remains inappropriate for small aneurysms, aneurysms that give offside branches or perforating arteries, and other intracranial aneurysms that show recurrent aneurysmal filling after the treatment. A high rate of stable occlusion can be achieved at long-term follow-up.

AUTHORSHIP CONTRIBUTION

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

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