DERIVO Embolisation Device

The Derivo® embolisation device (DED) is a new-generation flow diverter designed to treat intracranial aneurysms, consisting of a flexible structure and a surface modification that aims to reduce thrombogenicity.

The safety and efficacy of flow diverters and their long-term clinical outcome must be investigated.

Girdhar et al., reported the thrombogenic potential of the following flow diversion devices measured experimentally in a novel human blood in-vitro pulsatile flow loop model: Pipeline™ Flex Embolization Device (Pipeline), Pipeline™ Flex Embolization Device with Shield Technology™ (Pipeline Shield), Derivo Embolization Device (Derivo), and P64 Flow Modulation Device (P64). Thrombin generation (Mean ± SD; µg/mL) was measured as: Derivo (28 ± 11), P64 (21 ± 4.5), Pipeline (21 ± 6.2), Pipeline Shield (0.6 ± 0.1) and Negative Control (1.5 ± 1.1). Platelet activation (IU/µL) was measured as: Derivo (4.9 ± 0.7), P64 (5.2 ± 0.7), Pipeline (5.5 ± 0.4), Pipeline Shield (0.3 ± 0.1), and Negative Control (0.9 ± 0.7). They found that Pipeline Shield had significantly lower platelet activation and thrombin generation than the other devices tested ($p < .05$) and this was comparable to the Negative Control (no device, $p > .05$). High resolution scanning electron microscopy performed on the intraluminal and cross-sectional surfaces of each device showed the lowest accumulation of platelets and fibrin on Pipeline Shield relative to Derivo, P64, and Pipeline. Derivo and P64 also had higher thrombus accumulation at the flared ends. Pipeline device with Phosphorylcholine surface treatment (Pipeline Shield) could mitigate device material related thromboembolic complications [1)].

Case series

Kaschner et al., retrospectively analyzed all patients with ruptured dissecting and blister aneurysms treated with the Derivo between February 2016 and July 2018. Procedural details, complications, morbidity within 30 days, and angiographic aneurysm occlusion rates, initially and after six months, were assessed.

In 10 patients 11 ruptured dissecting and blister aneurysms were treated with 12 Derivos as monotherapy. No aneurysm rebleeding was observed at follow-up. One treatment-related complication occurred including a coil perforation of an additionally treated aneurysm. One patient died due to brain edema. Initial digital subtraction angiography revealed complete (O'Kelly-Marotta grading scale D) and favorable (OKM D+C) occlusion rate in three aneurysms. Six-month follow-up for digital subtraction angiography and clinical evaluation was available in 6/9 patients with complete (OKM D) occlusion in all aneurysms (6/6). Favorable (modified Rankin Scale [mRS] ≤ 2) and moderate

(mRS 3) clinical outcome after a mean follow-up of 10 months was observed in six and two patients, respectively.

Endovascular treatment with the Derivo in ruptured dissecting and blister aneurysms revealed a sufficient initial division of aneurysms from the circulation without rebleeding. The Derivo is associated with high procedural and clinical short-term safety [2)].

Kaschner et al., did a retrospective analysis of 32 patients with complex RIAs and UIAs treated with Derivo from Nov.2015 to Dec.2018. Clinical safety was defined as absence of death, transient attack, absence of minor and major stroke, and Derivo associated hemorrhage. Treatment efficacy was assessed angiographically (DSA) immediately after treatment and at 6 month follow-up according to the O'Kelly Marotta (OKM) grading scale (A=total filling to D=no filling; prolongation of stasis 1=arterial to 3=venous phase).

32 patients with 39 aneurysms were treated with 42 Derivos. In 5 aneurysms additional coiling was performed. Deployment was technically successful in all cases. Two patients developed a procedure related minor stroke (one transient). In 1 patient bleeding due to an inflammatory aneurysmatic wall process occurred 20 days after retreatment and in 1 patient a stroke due to instent thrombosis occurred when dual platelet inhibition (PI) was switched to permanent single PI 12 month after FD treatment. No treatment related deaths were observed. Initial DSA revealed OKMD,n=3; C,n=6; B,n=5; A,n=25. Six-month follow-up for DSA and clinical evaluation was available in 20/32 patients (62.5%), 26/39 aneurysms (66.7%) and revealed 73.1% complete and 3.8% subtotal occlusion (OKMD:19/26, OKMC3:1/26).

Treatment of complex RIAs and UIAs with the new generation Derivo appeared to be safe and effective in this single centre case series for ruptured and unruptured intracranial aneurysms. Immediate DSA revealed a significant flow modulation; and 6-month follow-up showed a high occlusion rate [3)].

In a retrospective study of 59 consecutive patients (mean age: 53 years, 81% women) treated with the DED for 59 aneurysms (mean size: 8.1 mm) between November 2015 and February 2018 at 3 German tertiary care centers. Goertz et al., evaluated the rate of ischemic stroke, functional outcome, and angiographic results during a 1-year follow-up period.

Deployment of the DED was successful in all cases. Adverse events were observed in 6 procedures (10.2%), of which 2 were symptomatic (3.4%). No delayed ischemic or hemorrhagic events occurred during the 1-year follow-up and there were no deaths. Permanent morbidity due to in-stent thrombosis and consecutive ischemic stroke occurred in 1 patient (1.7%). Complete (O'Kelly-Marotta grading scale D) and favorable (O'Kelly-Marotta grading scale C+D) aneurysm occlusion was obtained in 70.5% (31/44) and 88.7% (39/44) at 6 months and 82.8% (24/29) and 100% (29/29) at 12 months, respectively.

The results demonstrated that treatment of intracranial aneurysms with the DED is associated with low rates of ischemic complications and adequate aneurysm occlusion at 1-year follow-up [4)].

Between February 2016 and March 2018, 10 patients (median age 54.5 years, seven women) with 11

aneurysms were treated with the DED at three neurovascular centers. Procedural details, complications, morbidity, and aneurysm occlusion (O'Kelly-Marotta scale, OKM) were retrospectively reviewed.

Among 11 aneurysms treated, there were nine anterior circulation and two posterior circulation aneurysms. Aneurysm morphology was saccular in four cases, dissecting in three, blister-like in three, and fusiform in one. In each case, a single DED was implanted and deployment was technically successful without exception. Adjunctive coiling was performed in two aneurysms. We observed one in-stent thrombosis, presumably due to low response to clopidogrel 4 days after the procedure, which remained with a mild hemiparesis after aspiration thrombectomy. No further thromboembolic or hemorrhagic events occurred. Favorable outcome (modified Rankin scale score ≤2) at last follow-up was achieved in all patients. Among 10 aneurysms available for angiographic follow-up, complete aneurysm occlusion (OKM D) was obtained in nine cases (90.0%).

In this pilot study, endovascular treatment of ruptured intracranial aneurysms with the DED was feasible and not associated with any incidence of rebleeding [5].

In a study, the clinical outcomes of using the DED on 182 aneurysms are presented Material and Methods: In total, 146 patients with 182 aneurysms were treated with DED. The mean age of the participants was 51.5 years; among them, 46 (31.5%) presented with acute subarachnoid haemorrhage. The mean aneurysm size was 8.3 mm, and 12 aneurysms were involved the vertebrobasilar system. Ophthalmic aneurysms account for most internal carotid artery (ICA) aneurysms.

The Glasgow Coma Scale (GCS) score of 12 patients was 15. DED was associated with a mortality rate of 2.7% and permanent morbidity rate of 3.4%, and a complete aneurysm occlusion rate was achieved in 78.7% of cases after 7.02 months

The DED device is a new-generation flow diverter with excellent opening behaviour and navigational benefits. The results indicated a safe aneurysm occlusion with optimum morbidity and mortality values despite the fact that almost one-third of the patients presented with subarachnoid haemorrhage [6].

Akgul et al. treated 34 aneurysms using 26 devices in 24 patients with wide-necked, mostly medium-sized, and fusiform aneurysms. Fourteen of the patients included in the study were women and the other 10 were men. Headache was the most frequent symptom. Although 31 (91.2%) aneurysms were in the anterior circulation, 3 (8.8%) were in the posterior. Intracranial stent medication was accomplished in all patients. All patients were evaluated 1 day later for any ischemic lesion with diffusion-weighted imaging. The first and second follow-up angiograms were planned to be performed after 3 and 9 months.

In all patients, the treatment was successful. No hemorrhagic complication was seen on computed tomography scan performed immediately after the procedure. All patients were discharged without any neurologic deficit. Although 20 (71.4%) of 28 aneurysms in 20 patients were totally closed on the 3-month follow-up angiogram, 14 (77.8%) of 18 aneurysms in 9 patients were totally closed on the 9-month follow-up. General morbidity was 8.4%, and mortality was 4.3%.

The DED seems effective and safe in the treatment of different kinds of intracranial aneurysms [7].

Case reports

Martínez-Galdámez et al., presented the first clinical use of the largest flow diverter available, the 6×50 mm DERIVO embolization device (Acandis GmbH & Co. KG, Pforzheim, Germany), into the arterial circulation for a cervical internal carotid artery endovascular reconstruction. This is a new device for large or fusiform aneurysms requiring flow diversion, especially located in the vertebrobasilar system or extracranial segments [8].

References

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