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The Experience of the Derivo® Embolisation Device in Intracranial Aneurysms

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ABSTRACT

AIM: To investigate the safety and efficacy of Derivo® embolisation device (DED), a new-generation flow diverter designed to treat cerebrovascular aneurysms, and its long-term clinical outcomes.

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.

RESULTS: 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.

CONCLUSION: The DED device is a new-generation flow diverter with excellent opening behaviour and navigational benefits. Our 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.

KEYWORDS: Derivo® embolisation device, Cerebrovascular, Intracranial aneurysms, Flow diverter, Subarachnoid hemorrhage, Intracranial stent

ABBREVIATIONS: ACA: Anterior cerebral artery, **Acom:** Anterior comunican artery, **ASA:** Acetyl salicylic acid, **CT:** Computerize Tomography, **DED:** Derivo® embolisation device, **FD:** Flow diverter, **GCS:** Glasgow Coma Scale, **ICA:** Internal carotid artery, **MCA:** Middle cerebral artery, **MRA:** Magnetic resonance angiography, **mRS:** Modified Rankin scale, **N/A:** Not avaliable, **PCom:** Posterior communicating artery, **R:** Ruptured, **RR:** Raymond-Roy classification, **SAH:** Subarachnoid Haemorrhage, **Sup:** Superior, **UR:** Unruptured

INTRODUCTION

The SILK flow diverter (Balt Extrusion, Montmorency, France), which is used for the treatment of cerebral aneurysm, was first introduced in 2008. Thereafter, several different types of flow diverters have been introduced into clinical practice (10,11,17,22). The Derivo® embolisation device [DED (Acandis GmbH, Pforzheim, Germany)] is a newer generation flow diverter manufactured by the modification of

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the first-generation Derivo® device by enhancing its visibility and mechanical properties (1,13). This study aimed to describe the clinical and imaging results of aneurysm treatment with the latest generation of DED. Moreover, the clinical outcomes after treatment were assessed.

MATERIAL and METHODS

This retrospective study was performed by evaluating the medical records of patients with cerebral aneurysms treated with our neurovascular team at two institutions. Three operators (ED, AA, IA) performed DED placement. Patients whose intracranial aneurysms were treated by the more recently developed generation DED were identified. DED was preferred flow diverter initially for ICA aneurysms particularly for visibility, deployment characteristics and size advantage over 5.5 mm for initial cases. This device differed from the first-generation device because platinum is incorporated within the struts to enhance visibility. The surface of the device is treated with a thin surface layer of titanium oxide and oxynitrides to enhance biocompatibility (7). All aneurysms located at or above the petrous and V4 segments of the anterior and posterior circulations, respectively, were included consecutively. The clinical and angiographic data of the patients were assessed. ICA aneurysms were evaluated according to the Bouthillier classification. Moreover, the records of patients were evaluated to obtain data about age; sex; presenting symptoms; location, size and configuration of aneurysm and Glasgow Coma Scale (GCS) upon admission. The modified Rankin (mRS) and Raymond–Roy classifications (RR) were utilized to define relevant outcomes.

All patients were treated under general anaesthesia and systemic heparinization via a transfemoral arterial approach. Unruptured cases were preloaded with clopidogrel (or prasugrel) and acetyl salicylic acid (ASA) based on the previously published regimens (10). Patients with acutely ruptured aneurysms were administered oral antiaggregants during the immediate perioperative period, and tirofiban infusion (0.4 microgram/kg/min loading dose and 0.1 microgram/kg/min maintenance dose) was also administered in these cases.

For the general description of the procedure, a triaxial system comprising of a 6-Fr-long introducer sheath, a distal access catheter and a microcatheter with a 0.027–0.028-inch inner diameter, Headway 27 (Microvention, Terumo, the USA), Rebar 27 (Covidien, Medtronic, the USA), XT 27 (Excelsior, Streyker Inc., the USA), Neuroslider (Acandis GmbH, Germany) or Vasco 25 (Balt Extrusion, Montmorency, France) was used to access the target arterial segment. If adjunctive intrasaccular aneurysm treatment was planned or if further proximal support was needed, larger bore sheaths were used. After the navigation of the microcatheter across the aneurysm neck over a cerebral microguide wire, a variety of previously described techniques were used to deploy DED and to appose it to the vessel wall as much as possible (8). After placement, the microcatheter was advanced over the delivery wire to recapture the delivery system in most cases. If needed and as per the choice of the individual operators, adjunctive techniques, such as balloon angioplasty, intrasaccular embolization, telescopic placement of a second DED or intracranial stent placement for device apposition, were used. Once a good apposition of the device was achieved, the total coverage of the aneurysm neck and patency of the parent artery were ensured by serial angiograms and flat-panel computed tomography (CT) angiograms. Moreover, heparinization was reversed via the intravenous administration of protamine, and femoral haemostasis was achieved using percutaneous closure devices.

The patients were advised to be re-admitted for follow-up magnetic resonance angiography (MRA) 1–3 months after the initial treatment and cerebral angiography after 6 months. Patients with residual aneurysms were subjected to close MRA follow-up at 6-month intervals; otherwise, the patients came back for yearly MRA examinations. Retreatment was advised if there was no significant reduction of aneurysm opacification after 6 months–1 year follow-up. Minor neck remnants were not considered for close follow-up or retreatment. Patients were asked to discontinue clopidogrel or prasugrel after 6 months and continue ASA indefinitely.

Fisher's exact test was used to compare categorical variables.

RESULTS

In total, 146 patients (96 women and 50 men with a mean age of 51.5 years) with 182 aneurysms were treated with the DED; 46 patients had a history of subarachnoid haemorrhage (Table I); among them, 20 were treated electively for their recurrent aneurysms. Mean while, 26 patients were directly treated with DED owing to acutely ruptured aneurysms (Figures 1A-F; 2A-H).

The aneurysm morphology was saccular in 162 of 182 patients, and the remaining aneurysms were classified as dissecting, blister or fusiform. The size of the aneurysms was between 2 and 28 mm with a mean of diameter of 8.3 mm (Table I). In total, 124 aneurysms were small, of which 50 were between 10 and 25 mm in size and 8 were large. Anterior circulation aneurysms were observed in majority of patients (170/182 aneurysms), and the remaining 12 were posterior circulation aneurysms. Table II shows the location of the treated aneurysms, and Table I shows the clinical status of the patients at presentation. The GCS score was 15 in 134 of 146 patients. Four of the patients presented with a GCS of 14, 4 with 13, 2 with 10, 1 with 9 and 1 with 8 (Table I). Moreover, 6 of the 100 patients who presented without symptoms of subarachnoid haemorrhage (SAH) had a residual or recurrent aneurysm treated with DED (Table III).

Two technical failures were observed, both of which were related to the inability to reach the target arterial segment with DED rather than difficulties in deployment. Among the microcatheters used for deployment, Headway 27 and XT 27 were best suited for the navigation and deployment of DED (it was also adviced by the producer company) (1).

In total, 8 clinically significant adverse events occurred during the perioperative and follow-up periods, excluding the complications related directly to SAH (Table IV). One patient died owing to perforation of the aneurysm during

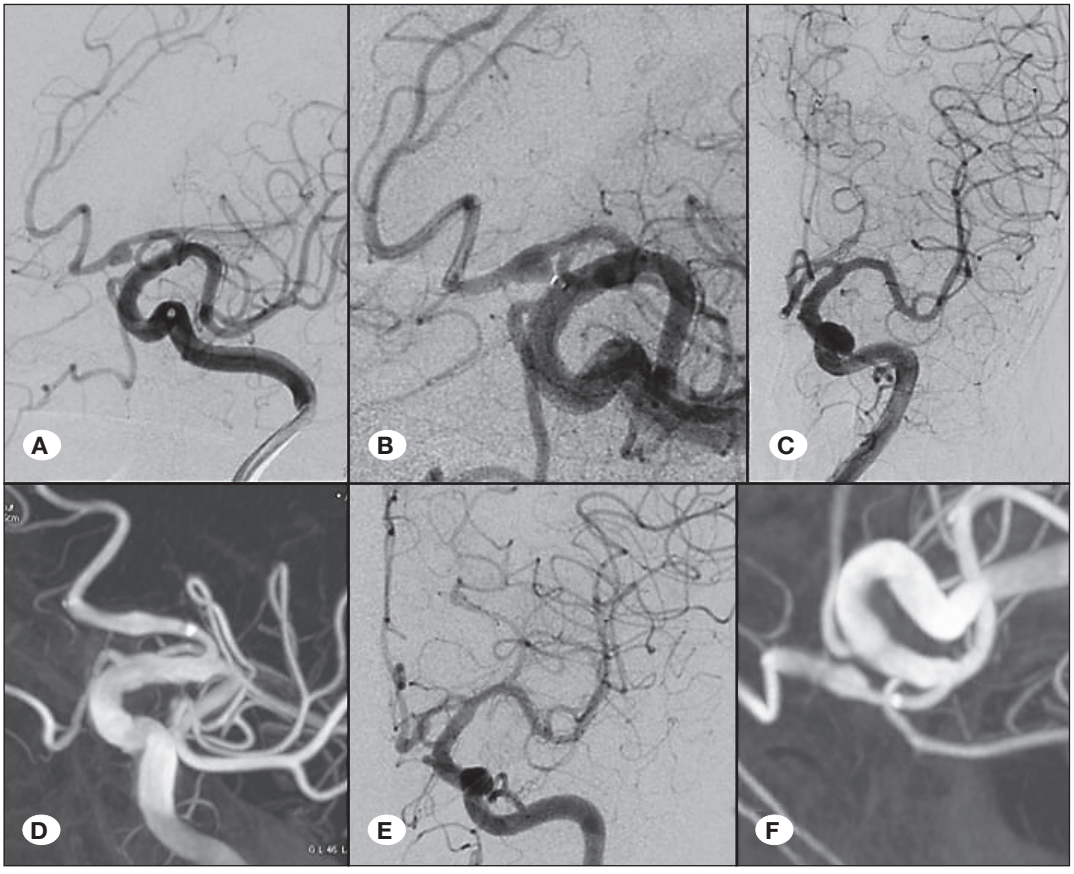

Figure 1: Pre **(A)** and post deployment **(B)** digital subtraction angiographic views of left A1 blister aneurysm presenting with symptoms of SAH a day ago. Postoperative AP digital subtraction angiographic view **(C)** and postcontrast digital subtraction angiography reconstructed image **(D)** two days after deployment of Derivo® embolisation device AP control angiogram **(E)** and post contrast digital subtraction angiography reconstructed image **(F)** obtained six months after treatment demonstrated complete obliteration of the aneurysm.

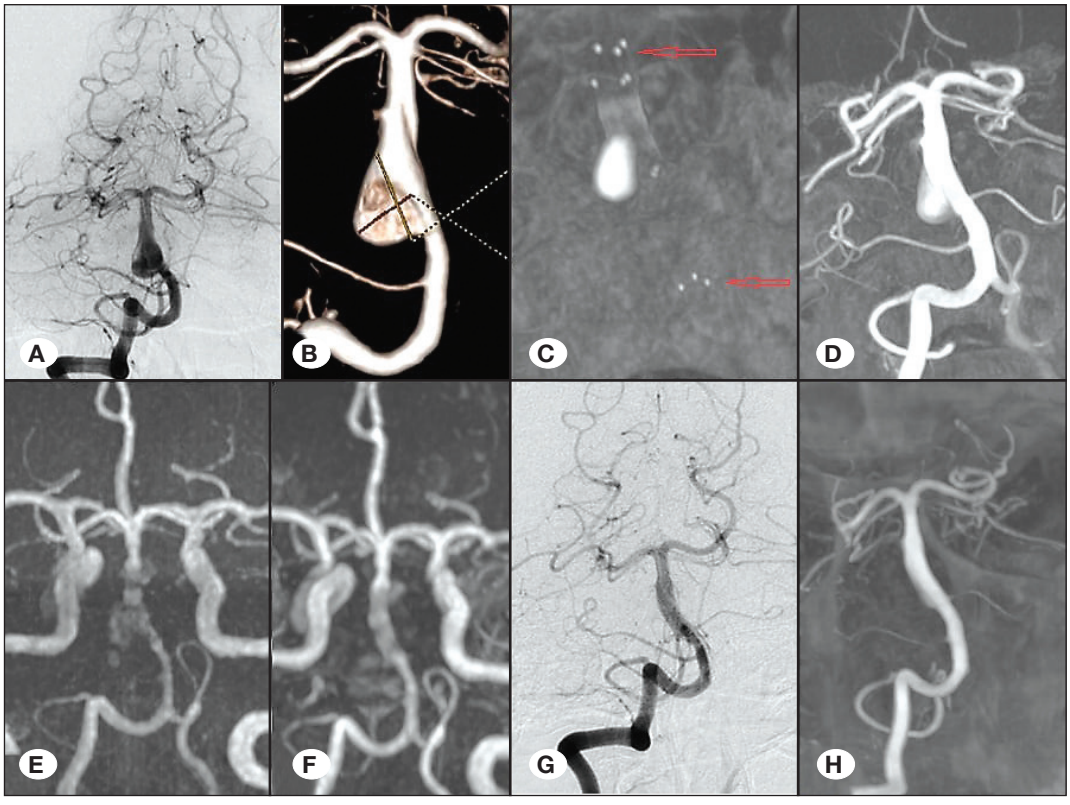

Figure 2: Preoperative digital subtraction angiography **(A)** and 3D reconstructed view **(B)** of the dissecting aneurysm of the basilar artery. Tridimensional pre- **(C)** and postcontrast **(D)** digital subtraction angiography reconstructed AP images after deployment of Derivo® embolisation device. Magnetic resonance imaging two **(E)** and six months **(F)** after treatment shows gradual closure of the aneurysm. Follow-up digital subtraction angiograhic AP image **(G)** and postcontrast 3D digital subtraction angiography reconstructed AP image **(H)** showed complete occlusion of the aneurysm (Red arrows shows the radiopaque markers of Derivo® embolization device).

Table I: Demographic Data of 146 Patients Treated with Derivo® Embolisation Device

Variable	n
Total number of patients	146
Sex	
Male	50
Female	96
Mean Age (min-max: 18-82) (years)	51.5
Presenting Symptoms	
Unbleed group (headache, diplopia, cranial nerve palsy etc)	100
SAH	46
Number of patients with multiple aneurysms	41
Aneurysm configuration	
Saccular	162
Other (dissecting, blister, fusiform etc)	20
Mean Aneurysm size (range 2-28) (mm)	8.3
<10 mm	124
10-25 mm	50
>25 mm	8
Mean Follow up Time (range 1-23) (months)	7.02
GCS on admission	
GCS 15	134
GCS 14	4
GCS 13	4
GCS 10	2
GCS 9	1
GCS 8	1

SAH: *Subarachnoid hemorrhage,* ***GCS:*** *Glasgow coma scale.*

DED-assisted coiling, and one patient had a severe condition, which occurred postoperatively owing to the occlusion of DED resulting in a massive cerebral infarction. In addition, there were five thromboembolic events (one middle cerebral artery aneursym, three ICA aneursym, one basillar artery aneurysm) including perforator infarctions, which were symptomatic during the perioperative period, resulting in a perioperative risk of procedure-related morbidity and mortality, and this phenomenonyielded a risk of 5.2% per patient and 4.8% per procedure. Thromboembolic events developed at the related segment of DED and two of these cases were related to perforating artery involvement. No statistical difference was

Table II: Distribution of the Aneurysms in Cerebrovascular System (ICA Aneurysms were Evaluated according to the Bouthillier Classification)

ICA ophthalmic	52
ICA Pcom	21
ICA choroidal	19
ICA sup hypophyseal	18
ICA supraclinoid	17
ICA cavernous	16
ICA wall	11
MCA	7
ICA bifurcation, petrous	5
ACA	3
ACom	1
Vertebrobasilar system	12
Total	182

ACA: *Anterior cerebral artery,* ***Acom:*** *Anterior comunican artery,* ***ICA:*** *Internal carotid artery,* ***PCom:*** *Posterior communicating artery,* ***Sup:*** *Superior.*

Table III: Variations of Treatment for Derivo® Embolisation Device and Additional Deployments

	Coil	Stent	Stent+coil	FD	FD+stent	Double stent	Other (Ballon, Squid)
SAH							
Other treatment just before Derivo® deployment	7	2	1	3	4	-	2
Treatments before Derivo® deployment at late period	18	-	2	-	-	-	-
Treatments before Derivo® deployment in unbleed group	2		-	2	2	-	-
Supportive treatments after Derivo® deployment							
Same session	12	38	1	16	4	3	4
Other session	-	1	-	3	-	-	-

FD: *Flow diverter,* ***SAH:*** *Subarachnoid haemorrhage.*

observed in terms of device-related morbidity and mortality rates between patients presenting with acute SAH and those presenting electively. One patient had a retroperitoneal hematoma that did not require surgical intervention. After the periprocedural period, one patient developed a small intracranial hematoma without residual morbidity in an unrelated vascular territory. This phenomenon was possibly related to antiplatelet therapy during follow-up, and this patient was treated for other aneurysms after endovascular intervention with DED. Thus, this adverse event was not associated with DED. During follow-up, no further neurologic events resulting in permanent morbidity or mortality were observed.

The GCS score at the time of discharge from the hospital was 15 in 134 of 146 patients. The GCS scores of the patients were as follows: 13 in 3, 12 in 1, 10 in 3 and 8 in 1 patient. Clinical improvement with regard to GCS score was observed in 8 patients, whereas clinical worsening was noted in 5 other patients. Four patients died owing to complications from SAH. During the last follow-up, with a mean follow-up duration of 7.02 months, mRS was 0 in 136 patients. Table V shows the summary of the clinical status during the last follow-up. With regard to the RR classification of aneurysm occlusion in patients with follow-up imaging, total aneurysm occlusion was noted in 115 patients (follow-up available in 130 patients). The aneurysm obliteration rate was 78.7%, and the mean follow-up duration was 7.02 months. Moreover, 4 patients had a slight opacification of the aneurysm in the neck (RR-2). In total, 7 patients had RR-3a and 4 had RR-3b aneurysm remnants (Table V).

DISCUSSION

The current flow diverters consist of cobalt and chromium alloys (e.g. pipeline device [Covidien, Mansfield, Massachusetts, the USA]) or are made from Nitinol (SILK [Balt Inc., France], FRED® [MicroVention, Tustin, California], p64 [Phenox, GmbH, Germany] and Derivo® [Acandis GmbH, Pforzheim, Germany]) (20). DED is a newer generation flow diverter, which was manufactured with enhanced visibility to ensure better surface properties (using a coating named as BlueXide), causing lower friction between the wires and potentially having a lower thrombogenicity than the other nitinol-based flow diverters (13).

The initial patient series on flow diverters were conducted in 2006, and the results of these series were published in the following year. This study showed no significant results in terms of morbidity or mortality and was associated with

Table IV: Technical and Unpredictable Complications During Peroperative and Postoperative Period of Treatment

		Treatment	Morbidity	Mortality
Peroperative				
Perop hemorrhage	2	Coiling	-	1
Perop thromboemboli	2	Catch mini thrombectomy	-	-
ICA dissection	1	Carotid stent deployment	-	-
Renal hematoma	1	-	-	-
Stent migration	2	Repeated deployment	-	-
Postoperative				
Stent occlusion	2	Antiaggregant treatment	1	-
Intimal hyperplasia	2	-	-	-

Table V: Postoperative GCS, Raymond and mRS Scores of 146 Patients Treated with Derivo® Embolisation Device

GCS at discharge			mRs score		Raymond classification	
GCS	15	134	0	136	Class 1	115
GCS	13	3	1	1	Class 2	4
GCS	8-12	5	2	2	Class 3a	7
			3	2	Class 3b	4
GCS improved	8		4	1		
GCS worsened	5		6 (Exitus)	4		

GCS: *Glasgow coma scale,* ***mRS:*** *Modified Rankin scale.*

strikingly high obliteration rates (3,16). A few other reports after this study have presented slightly higher yet still extremely low morbidity and mortality rates (23). After the enthusiasm in the initial series, the results of larger series were published (4,10,11,19), and in two recent studies by Zhou et al. and Rajah et al., flow diverters were found to be associated with a total aneurysm occlusion rate of 76% after 1 year, mortality rate of 2.8% and neurological morbidity rate of 4.5% (20,23). A further look into these latter meta-analyses showed that all except two studies have reported cumulative morbidity and mortality rates of 0%–1% in cohorts with approximately ≤50 aneurysms (23), indicates that a clearly higher rate of adverse events leading to permanent morbidity and mortality is noted in larger series, indicating that the complication rates of flow diverters may be better addressed in larger series than in smaller ones. Considering the morbidity and mortality rate of around 5%–7% in the current reviews, it is not surprising that the complications of flow diverters may not be encountered in smaller series of 20–30 patients. Small series that showed lower complication rates are more likely to be submitted for publication, leading to a bias.

In this series, we have shown that DED is associated with a mortality rate of 2.7%, permanent morbidity rate of 3.4% and total aneurysm occlusion rate of 78.7% at 7.02 months. These results are comparable with those of the contemporary series (published within the last 5 years) with large number of aneurysms (≥100 aneurysms, as shown in Table VI and relevant referans). Notably, the complication rates when newer generation devices are used are more likely to be lower (e.g. the device used in this series [Pipeline Flex, p64 and FRED®]). The most likely reason for this is the accumulation of experience by both interventionalists and the industry.

A learning curve is needed for flow diverters (8,14). It is not surprising that less complications have occurred because the current studies were performed by neurovascular team with cumulated experience at two institutions. The only exception for this is the Tubridge device, which was associated with a high complication rate in the largest series in the literature (14). However, the authors of this study acknowledged that this may be secondary to the insufficient overall experience of the operators.

The experience of the industry relates to the manufacturing of better devices based on the knowledge gained by the first-generation devices. This series reported a 3.4% permanent morbidity rate and 2.7% mortality rate, whereas that by Akgul et al. have reported rates of 8.4% and 4.3%, respectively. Moreover, most patients were treated with a prior generation DED (1). Improvements in the device are more likely in terms of safety compared with this series. Similar rates have also been recently reported in two small multi-centre series with 42 unruptured and 11 ruptured aneurysms treated with DED (7,12). Our results further confirmed the safety and efficacy of DED in a real-world setting and in a large series of patients. The results were similar to those obtained with contemporary versions of the widely used flow diverters (Table VI).

The striking result in our series is that DED was relatively safe to use in the setting of SAH. Our results were more favourable than those of previous studies about the treatment of acutely ruptured aneurysms (2). Almost half of the ruptured aneurysms in this series were treated after the hyperacute phase of SAH, which is several days after the incident, because our institution is a tertiary referral centre. This may account for more favourable results in this subgroup. An enhanced

Table VI: Case Series Using Flow Diverter with 100 or More Aneursyms

Author	Device	Number of patients/ aneursyms	Morbidity (%)	Mortality (%)	R/UR Aneursym	Total oclusion rate (%)	Mean follow up (month)
Fischer et al. (2015) (5)	p64	121/ 130	2.3	0.8	0/121	79.6	17
Wakhloo et al. (2014) (22)	Surpass	165/190	6	2.7	6/159	75	6
Killer-Oberpfalzer et al. (2018) (11)	FRED	531/579	0.8	1.5	65/466	69.2	6.6
Pierot et al. (2018) (18)	FRED	103/ 103	2	1	0/103	50	6
Foa Torres et al. (2018) (6)	SILK	246/ 293	4.2	2.1	20/226	93.9	12
Kaya et al. (2016) (10)	SILK	96/113	9.6	2.1	21/75	79.1	8
Shankar et al. (2016) (21)	SILK	92/103	5.4	2.2	19/73	83.1	6.6
Kallmes et al. (2017) (9)	PED	1092/1221	5.7	3.3	76/1145	85.5	10
Colby et al. (2018) (4)	PED	252 procedures	5.6	1.6	55/197	N/A	11.6
Colby et al. (2018) (4)	PED flex	316 procedures	1.9	0.6	22/294	N/A	11.6
***Liu et al. (2018) (14)	Tubridge	82 procedures	12	4.9	0/82	75.3	6
Daglioglu et al. (present study)	Derivo®	146/182	2.7	3.4	46/100	78.7	7

N/A: *Not avaliable,* ***R:*** *Rupture,* ***UR:*** *Unrupture,* ***PED:*** *Pipeline endovascular device.* ******:*** *Largest series for device.*

biocompatibility of DED may also be a potential contributor to safety particularly for SAH.

This study had limitations. It was conducted by a neurovascular team in two institutions and was retrospective in nature. In some patients, treatment with DED was supported with adjunctive methods based on the discretion of the primary operator, and a direct comparison with other series using only flow diverters must be made with caution. Finally, follow-up imaging was not conducted in approximately 10% of patients.

CONCLUSION

The new version of DED had a favourable safety profile and good aneurysm occlusion rates in patients with both ruptured and unruptured aneurysms in this series. This is the largest series in which DED was evaluated to date. The relationship of our results to the enhanced mechanics and biocompatibility of the latest version of DED is probable yet speculative. The added value of these improvements remains to be elucidated in future comparative studies.

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