Neurointervention 2021;16:232-239
https://doi.org/10.5469/neuroint.2021.00227

# REtrospective Multicenter INdian Study of Derivo Embolization Device (REMIND): Periprocedural Safety

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**Purpose:** The treatment of aneurysms with characteristics such as complex morphology, fusiform, blister-like, wide neck, or large size has been revolutionized with the introduction of flow diverters. Though flow diverters have several advantages over coiling, they also have certain important disadvantages such as the lack of immediate protection against rupture, the risk of ischemic stroke, the need for antiplatelet therapy, and long latency for complete effect. The Derivo Embolization Device (DED) is a second-generation self-expanding device that is claimed to be less thrombogenic than conventional devices. We retrospectively evaluated the periprocedural safety and risks associated with the DED across 5 centers in India.

**Materials and Methods:** This is a multicentric, retrospective, observational study of DED, conducted at 5 high volume endovascular therapy centers in India from May 2018 to June 2020. Periprocedural demographic, clinical, and angiographic data were collected from a retrospective review of patient charts.

**Results:** A total of 96 patients, including 56 (58.3%) females, aged between 16–80 years (60±12.7 years) harboring 106 aneurysms were studied. Seven (7.3%) were noted to harbor multiple aneurysms: 6 had 3 aneurysms each, while 1 patient had 5 aneurysms. The following aneurysm characteristics were noted: average size, 9.8±8.2 mm; average neck size, 6.9±8.5 mm; wide-necked (>4 mm), 63 (59.4%); giant (>25 mm), 8 (7.5%); and anterior circulation location, 98 (92.5%). Eighteen (17%) of these were ruptured. Additional balloon angioplasty was performed in 5 (5.2%) patients. Intraprocedural problems were encountered in 3 (3.1%), of which only 1 had clinical implications, the device fish-mouthing with stent thrombosis resulting in a malignant middle cerebral artery territory infarction. The modified Rankin scale at 3 months was worse in 1 patient.

**Conclusion:** DED is a newer generation flow diverter stent with a low periprocedural complication rate.

**Key Words:** Aneurysm; Embolism; Hemorrhage; Stents; Thrombosis

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**Received:** May 11, 2021
**Revised:** August 2, 2021
**Accepted:** August 4, 2021



pISSN 2093-9043
eISSN 2233-6273

## INTRODUCTION

Endovascular therapy with coiling has been shown to be a feasible and safe procedure for ruptured intracranial aneurysms and superior to clipping in the International Subarachnoid Aneurysm Trial.[1] However, soon it was realized that the recurrence rates with this modality of treatment were quite high.[2] Further, this modality was not found suitable for all types of aneurysms, and some of the procedures required adjunctive use of balloons or stents. A new era, with a different concept of reconstructing the vessel lumen, emerged with the first generation of flow diverter devices. The Pipeline embolization device was the first in the series, and the Buenos Aires experience was the primal breakthrough.[3] The pipeline embolization device for the intracranial treatment of aneurysms trial and the pipeline for uncoilable or failed aneurysms: results from a multicenter clinical trials further strengthened the evidence for its use especially in unruptured aneurysms that are difficult to coil.[4,5] Flow diverter devices thus expanded the interventionists' armamentarium and were found to be a safe and effective treatment; unlike coiling, the occlusion rates were better the longer the follow-up.[6,7] Though they are especially useful for unruptured aneurysms, they may also be of use for some ruptured subtypes, like blister-like aneurysms, in which they may be the mainstay therapy.[8] The treatment of aneurysms with characteristics such as complex morphology, fusiform, blister-like, wide neck, or large size has been revolutionized with the introduction of flow diverter stents. The Pipeline Embolization Device was the first in the series.[9] Since then, newer devices with further refinements have emerged. Though these devices have several advantages over coiling, they have certain important disadvantages like the lack of immediate protection against rupture, the risk of ischemic stroke, the need for antiplatelet therapy, and long latency for complete effect.[10] As flow diverter devices gained popularity, studies brought out important risks associated with these devices. Thromboembolic events, intraparenchymal hemorrhage, and delayed aneurysm rupture are notable problems encountered in practice.[6] In-stent thrombosis has been noted in around 5% of individuals in different studies.[6,11-13] Intraparenchymal hemorrhage and delayed aneurysm rupture have been noted to occur in around 3% of individuals.[14]

As the devices have evolved over the years and with the increasing experience with this technology, year after year, the complication rates have fallen. Improved radio-opacity, the ability to resheath partially deployed devices and reduced thrombogenicity are a few of the advanced features with the newer devices, aiding easier and more accurate device deployment with reduced periprocedural complication

**Table 1.** Characteristics of some of the commonly used flow diverter devices

| Variable | Derivo | Pipeline shield | FRED | Surpass | Silk |
|---|---|---|---|---|---|
| No. of wires | 48 wires | 48 wires | Overlap stent design | 64 Wires | 48 Wires |
| Wire construction | 48 Hybrid nitinol (DFT) wire | 12 Platinum, 36 cobalt chromium wires | 2 Platinum, 46 nitinol wires | 12 Platinum, 52 cobalt chromium wires | 2 Platinum, 46 nitinol wires |
| Surface finish | BlueXide | Phosphoryl-choline | NA | NA | NA |
| Distal/proximal marker | 3 Markers at both ends | NA | 4 Markers at both ends | NA | NA |
| Diameter | 2.5 mm to 6 mm | 2.5 mm to 5 mm | 2.5 mm to 5 mm | 2.5 mm to 5 mm | 2.25 mm to 5 mm |
| Length | 15 mm to 50 mm | 12 mm to 35 mm | 12 mm to 48 mm | 15 mm to 40 mm | 10 mm to 35 mm |
| Working length | End to end | End to end | Both ends 2/5 mm non-FD ends | End to end | End to end |
| Distal wire end | Closed | Open | Open | Open | Open |
| Catheter compatibility | 0.021 inch/ 0.027 inch | 0.027 inch | 0.021 inch/ 0.027 inch | 0.027 inch | 0.025 inch/ 0.029 inch |
| FDA approval | Not approved | Approved | Approved | Approved | Not approved |

Device specifications collected from the respective manufacturers.
FDA, US Food and Drug Administration; DFT, drawn filled tubes; FD, flow diverter; FRED, flow-redirection endoluminal device; NA, not applicable.

rates.[7,12,15] The Derivo Embolization Device (DED) (Acandis, Pforzheim, Germany) belongs to the newer generation of devices and is claimed to be superior to the older devices. The DED is a self-expanding device made up of Nitinol, and it is claimed to be less thrombogenic than other devices owing to its oxide and oxynitride coating. It has a porosity of 60–65% and surface coverage of 33–39%, and the cross-sectional diameter of the wires is 0.003 to 0.009 inches. Its platinum core makes the device radio-opaque with better fluoroscopic visualization, and additional radiopaque markers at each of the 3 flared ends enhance it. Also, the device can be recaptured and repositioned before full deployment.[6,8] Preliminary studies carried out in animal models show it to be less thrombogenic compared to the first-generation devices.[16] However, experience with the newer devices is still evolving.[17] Features and designs of some of the commonly used flow diverter stents are detailed in Table 1.

Experience with the use of this device, especially in the Indian context, is still in the preliminary stages. Nevertheless, it is becoming more and more popular across the country, as is seen with its use in the current study across 5 independent centers. We aimed to evaluate the periprocedural safety and risks for the DED in a retrospective manner.

## MATERIALS AND METHODS

This is a multicenter, retrospective, observational study conducted at 5 high-volume endovascular therapy centers in India. Patients undergoing treatment with DED over a period of around 2 years (from May 2018 to June 2020) were studied. Demographic and clinical data were collected from patient chart reviews. Data about aneurysms and the parent vessels were obtained from the pre-procedure 4-vessel digital subtraction angiograms. Neurologic complications during and after the procedure were noted until discharge. The modified Rankin Scale (mRS) at 3 months was noted as an outcome measure.

### Inclusion Criteria

Patients diagnosed with 1 or more aneurysms of the cerebral vessels who had undergone flow diverter stenting with the DED between 1st May 2018 to 30th June 2020 were included.

### Exclusion Criteria

1. Aneurysms treated with any other methods (such as flow diverters other than DED, coiling, or intrasaccular devices).
2. Patients with incomplete clinical and angiographic data.

### Procedure

All interventionists carrying out the procedures had at least 10 years of experience in endovascular surgery. All the procedures were carried out under general anesthesia with an 8F and a 6F short arterial sheath for anterior and posterior circulation aneurysms, respectively. Heparin was administered as a bolus of 5,000 IU through a short arterial sheath at the beginning of each procedure and repeated in aliquots of 1,000 IU/hour IV until the end of the procedure. The embolization device was delivered through a 0.027 inch microcatheter, and the deployment was considered successful if the device covered the aneurysm neck completely and the post-procedure angiogram showed good apposition of the stent to the vessel wall. The use of adjunctive measures like balloon angioplasty and coiling was left to the discretion of the interventionist. All patients were treated with dual anti-platelets before the procedure and after the procedure (Aspirin and Ticagrelor/Clopidogrel) for at least 3–6 months and a single antiplatelet agent thereafter.

### Statistical Analysis

Frequencies and percentages are presented for categorical variables while means and standard deviations are stated for continuous variables. Statistical analysis was done using Microsoft Excel (version 2016; Microsoft, Redmond, WA, USA).

## RESULTS

A total of 96 patients aged between 16–80 years (60±12.7 years) were studied. Fifty-six (58.3%) of these were females. Seven individuals (7.3%) were diagnosed to harbor multiple aneurysms: 6 individuals had 2 aneurysms each, while 1 individual had 5 aneurysms. Thus, a total of 106 aneurysms were identified in the study cohort. Ninety-eight (92.5%) of the 106 aneurysms were located in the anterior circulation, whereas 8 (7.5%) were in the posterior circulation. Eighty-eight (83%) of the 106 were unruptured and 18 (17%) were ruptured. The average size of the aneurysms was 9.8±8.2 mm (range 1 to 35 mm) with an average neck size of 6.9±8.5 mm. Sixty-three (59.4%) of these had necks wider than 4 mm. Eight (7.5%) of the 106 were >25 mm in size. Saccular aneurysms constituted the most common sub-type (84, 79.2%), and the internal

carotid artery was the most common vessel involved (75, 70.7%) (Table 2).

Additional balloon-angioplasty was performed in 5 (5.2%) patients, and aneurysm coiling was performed in 12 (12.5%). Eighteen (17%) of these had ruptured aneurysms, including 6 (6.2%) that had been treated earlier with either clipping or coiling and were detected to have regrowth or a persistent residual neck, and hence received flow diverter stenting. The remaining 12 included 6 each of the dissecting type and the blister type. Fifteen of these had ruptured in less than 10 days of presentation (mean 3.9 days, range 2 to 9 days), while 3 had ruptured more than a month prior. Intraprocedural complications occurred in 3 individuals (3.1%), and 1 out of 3 (1%) was clinically significant. Device fish-mouthing occurred in a middle-aged patient who had a ruptured dissecting middle cerebral artery aneurysm with subarachnoid hemorrhage. Stent thrombosis followed by a malignant middle cerebral artery territory infarction occurred in him despite the use of Tirofiban infusion and a combination of Aspirin and Ticagrelor. Coiling also had been attempted with this patient. In another patient with an A1 segment of anterior cerebral artery dissecting aneurysm, the device landed at the terminal internal carotid artery (at the proximal M1 segment) resulting in flow-limitation in the middle cerebral artery; hence, a balloon was taken into the middle cerebral artery and angioplasty was done to push the device into the A1 segment of the anterior cerebral artery, which was successfully achieved. Finally, in the third patient who had undergone coiling for a ruptured anterior communicating artery aneurysm 1.5 years prior, aneurysmal regrowth was detected on follow-up angiogram; after deployment, the device migrated distally to the ipsilateral A2 segment of the anterior cerebral artery, leaving the aneurysm neck uncovered. Hence, a second device was deployed proximally to cover the aneurysm neck adequately (Fig. 1). The mRS at 3 months was noted to be worse in the patient who had suffered the malignant middle cerebral artery infarct (Table 2).

**Table 2. Aneurysm characteristics and outcome**

| Parameter | | Frequency (n=106) |
|---|---|---|
| Presenting pattern | Ruptured | 18 (18.7) |
| | Unruptured | 78 (81.3) |
| Location | Internal carotid artery | 75 (70.7) |
| | Middle cerebral artery | 9 (8.5) |
| | Anterior communicating artery | 6 (5.7) |
| | Anterior cerebral artery | 5 (4.7) |
| | Basilar artery | 4 (3.8) |
| | Vertebral artery | 3 (2.8) |
| | Posterior communicating artery | 2 (1.9) |
| | Anterior choroidal artery | 1 (0.9) |
| | Posterior cerebral artery | 1 (0.9) |
| Type | Saccular | 84 (79.2) |
| | Fusiform | 10 (9.4) |
| | Blister | 6 (5.7) |
| | Dissecting | 6 (5.7) |
| Size (mm) | | 9.8±8.2 (1–35) |
| mRS at presentation | 0 | 78 (81.3) |
| | 1 | 18 (18.7) |
| mRS at 3 months | 0 | 95 (99) |
| | 4 | 1 (1) |

Values are presented as number (%) or mean±standard deviation (range).
mRS, modified Rankin Scale.

## DISCUSSION

In this study, we noted that a wide variety of aneurysms could be treated with flow diverter stenting, notably unruptured ones, but also aneurysms that grew after coiling/clipping or recently ruptured ones that were deemed unsuitable for treatment options like coiling or clipping. The salient features and findings of the study are detailed below.

The study population showed a female predominance, as is noted in most previous DED studies. However, the mean age of the cohort was around 5–10 years older than that noted in most previous study populations.[6,8,12,17,18] In the current study, we noted that most patients harbored single aneurysms, while 7 were noted to have multiple ones. Multiple aneurysms have been noted in several earlier trials and are of clinical concern, as some of patients harbouring these would need treatment for more than 1 of them. In the study conducted by Trivelato et al.[6], 151 procedures were performed in over 146 patients harboring 183 intracranial aneurysms. Similarly, Daglioglu et al.[12] noted 182 aneurysms in 146 individuals. Kallmes et al.[19], Killer-Oberpfalzer et al.[20], and Foa Torres et al.[21] are other notable trials using other flow diverter devices where several patients harboring multiple aneurysms were identified. Other features pertaining to the

distribution, morphology, and clinical characteristics in the current study are that most of the aneurysms were located in the anterior circulation, most of them commonly involved the internal carotid artery, most were unruptured, and most were saccular. Most earlier studies are in line with these findings.[6,12] There was a large variation in aneurysm size noted in the current study, ranging from the very small (1 mm) to the very large (35 mm). Another notable feature was that a majority of the aneurysms were wide-necked. Small aneurysms and wide-necked ones, especially ruptured ones, are particularly difficult as they may not be amenable to coiling at all or may need adjunctive treatments. Flow diverter devices may be a feasible option in these cases.[7,8,12,17,18,22,23] In the current study, adjunctive balloon angioplasty was employed in 5 (5.2%) patients, while coiling of the aneurysmal sac was carried out in 12 (12.5%). Angioplasty was employed in 1 patient with an anterior cerebral artery dissecting aneurysm in whom the device had landed on the terminal internal carotid artery causing flow-limitation in the middle cerebral artery, which was described above. In the rest of the 4 patients, angioplasty was done to attain perfect apposition of the stent to the vessel wall when a focal area of suboptimal device expansion was noted by the operator after complete deployment. Taschner et al.[18] noted the use of adjunctive balloon angioplasty in 18 (19%) of the procedures, while additional coiling was done in 47 (49%). In their series, the mean aneurysm size was larger than in the current study. Trivelato et al.[6] had noted additional use of balloon angioplasty in 31 (20.5%) and coiling in 9 (6%). As far as periprocedural complications were concerned, despite the varied morphology

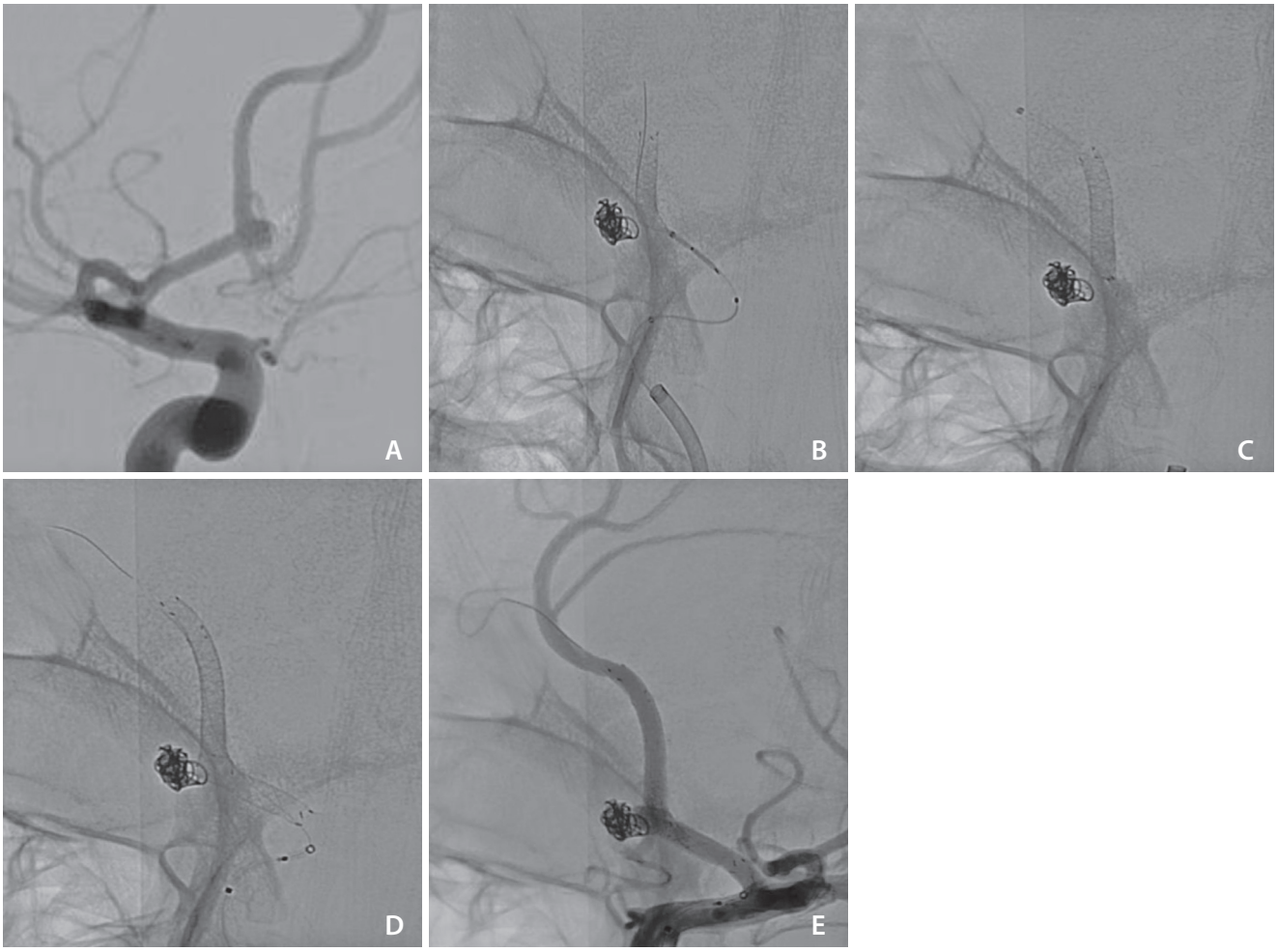


**Fig. 1.** A middle-aged individual who had undergone coiling of anterior communicating artery aneurysm (AComA) 6 months ago for subarachnoid haemorrhage, currently asymptomatic. (**A**) Regrowth of AComA aneurysm. (**B**) Derivo 2.5×20 device deployed through Neuroslider 21 microcatheter through 6F Benchmark guiding catheter. (**C**) Device migrated distally leaving the aneurysm neck unprotected. (**D**) Derivo 3.5×25 deployed in a telescopic fashion, covering the aneurysm neck. (**E**) Post-procedure angiogram showed normal distal vasculature and well covered aneurysm neck.

and size of the aneurysms, the safety profile with the DED was noted to be very favorable. This is underlined by the fact that clinically significant periprocedural complications were noted in only 1 individual out of the 96 studied. Other DED studies have noted periprocedural complications of clinical concern ranging from around 3% to just above 10% (Table 3).

Fish-mouthing was noted in one case in the current study. This is in contrast to the study conducted by Taschner et al.[18] who noted this problem to occur in 11.5% (11 of 96) of their cohort. However, Trivelato et al.[6] noted this particular problem in 1.8% (2 out of 151) procedures that they carried out, which, more or less, is similar to our findings. However, we note here that the study populations may not be comparable, as may be seen from the differences in the mean aneurysm sizes. In the current study, we noted thromboembolic complications in 1 individual. Periprocedural thromboembolism was noted in 5% in the series published by Taschner et al.[18], in 5.2% in the series by Daglioglu et al.[12], and in 8.5% in the series published by Goertz et al.[17] (Table 3). Pierot et al.[24] in their study with the flow-redirection endoluminal device (FRED) embolic device noted periprocedural thromboembolic events in 4.8% (5 out of 103) patients. In the study carried out by Berge et al.[25], a periprocedural complication rate of 7.7% (5 out of 65) with the use of the Silk flow diverter device was noted. We did not notice any periprocedural hemorrhages, which was an uncommon event in the other Derivo series as well.[6,8,12,17,18] A recent meta-analysis of 8 studies with the Pipeline Flex flow diverter device showed a periprocedural risk of major complications of 1.8% and periprocedural risk of death of 0.8%. However, here only unruptured aneurysms were studied.[26] Despite that, the low complication rates might suggest an overall trend towards better safety profiles of second-generation devices. So also, a recent prospective trial has shown the safety and efficacy of these devices in small- and medium-sized aneurysms; and, thus, they are a good alternative to coiling for this category of unruptured aneurysms.[27]

As is depicted in Table 1, Pipeline Shield, FRED, and Surpass are US Food and Drug Administration approved while Derivo and Silk are not yet approved. Derivo and Pipeline Shield come with a surface coating and are claimed to be less thrombogenic compared to the other devices. FRED has an overlap stent design flow diverter and does not have a flow diversion effect at its ends. The newer generation of the Silk Vista Baby flow diverter is unique in the sense that it can be delivered in smaller vessels through a 0.17-inch microcatheter.[28] Thus the options for treatment of aneurysms have increased with the advent of new technology. However, without a head-to-head randomized controlled trial comparing different available devices, it is difficult to conclude the superiority of one device over the others. Newer generation devices seem preferable to the older generation ones given their ease of use, improved *in vivo* visibility, and lower profile. Nevertheless, it is important to note that, though there is an improvement in the safety profile of the newer devices, the risks with these devices are an important consideration and may lead to devastating consequences.

The most important limitation of this study is its lack of long-term follow-up data. The treatment of aneurysms with flow diverters cannot be deemed a success without demonstrating a complete and lasting cure, which mandates follow-up angiographic data over a period of several months if not years. Second, this was a retrospective single-arm study. A comparative study with prospective data collection and randomization to the use of other devices against the current device with appropriate blinding would have been an ideal scenario. Third, this was carried out at different centers by different interventionists who may show variations in skills

**Table 3. Periprocedural intracranial adverse events of clinical concern (thromboembolism/hemorrhage) with Derivo Embolization Device in various studies**

| Study | Number of patients | Aneurysm size (mm) | Adverse events | Ruptured |
|---|---|---|---|---|
| Current study | 96 | 9.8±8.2 | 1 (1) | 18 (18.7) |
| Taschner et al. (2020)[18] | 96 | 14.2±16.9 | 5 (5.2) | 15 (15.6) |
| Daglioglu et al. (2020)[12] | 146 | 8.3 | 8 (5.5) | 46 (31.5) |
| Trivelato et al. (2019)[6] | 146 | 6.7±5.1 | 5 (3.4) | 6 (4.1) |
| Goertz et al. (2019)[17] | 59 | 8.1±6.2 | 6 (10.2) | 8 (13.6) |
| Akgul et al. (2016)[8] | 24 | 9.5±8.2 | 3 (12.5) | 1 (4.2) |

Values are presented as number (%) or mean±standard deviation.

and techniques.

Nevertheless, to the best of our knowledge, this is the first Indian multicenter study pertaining to the DED. Even though the study design was not perfect, still, a low periprocedural complication rate gives confidence about its procedural ease and safety regarding the future use of this newer generation flow diverter device. We may look upon this study as a foundation for larger studies in the future to validate the current findings and observe the angiographic cure rates with this device over longer periods of time.

## CONCLUSION

The DED is a newer generation flow diverter stent with low peri-procedural complication rates. Though the construct of the device comes with a promise for better results, larger prospective studies with longer follow-ups, especially with a comparison with other available flow diverter devices may conclusively prove its efficacy and utility in the long run.

### Fund
None.

### Ethics Statement
This study was approved by the Institutional Review Board of Narayana Health City, Bangalore. The board waived the need for patient consent given the retrospective nature of the study. Since the consent for publication was not available for the patients mentioned in the figures, patient's information was anonymized by removing the sex and specific age.

### Conflicts of Interest
The authors have no conflicts to disclose.

### Author Contributions
Concept and design: VH and NPM. Analysis and interpretation: NPM, VH, and MM. Data collection: NPM, MM, AB, SP, ND, MC, VG, and VH. Writing the article: NPM, MM, and VH. Critical Revision: VH and NPM. Final approval of the article: NPM, MM, AB, SP, ND, MC, VG, and VH. Overall Responsibility: VH.

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