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ORIGINAL ARTICLE

# Early stage occlusion of non-ruptured intracranial aneurysms using flow diverter devices in Mexico

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## Abstract

**Objective:** *The objective of the study was to describe the rate of embolization success, the risk of complications, and the functional outcomes in the first 6 months post-treatment in patients with non-ruptured intracranial aneurysms (IAs) using flow-diverter (FD) devices in Mexico.* **Methods:** *Longitudinal, retrospective study of patients with non-ruptured IAs who were treated at the National Institute of Neurology and Neurosurgery between November 2020 and April 2022. After treatment with FD, post-procedure control angiograms were performed 6 months later. The occlusion rate was evaluated using the O'Kelly-Marotta scale.* **Results:** *There were 23 patients – 2 of whom had two IAs – 20 women, with an average age of 51.4 years (± 13.3). A total of 19 saccular, 4 fusiform, and 2 dissecting IAs were treated. Measurements of the neck ranged from 1.9 to 19 mm. Angioplasties were performed as part of the procedure on four patients, and successful liberation was achieved after 23 procedures. Total occlusion was achieved in 14 IAs, and 3 had < 5% residual filling in the follow-up. Only three late procedural-related complications were found.* **Conclusions:** *The use of the FD devices in our population appears to be safe and to have a high level of effectiveness in early post-procedural months, supporting its use.*

***Keywords:*** *Intracranial aneurysms. Blood vessel prosthesis. Interventional radiology.*

## *Oclusión temprana de aneurismas intracraneales no rotos mediante dispositivos desviadores de flujo en México*

## Resumen

**Objetivo:** *El objetivo del estudio fue describir la tasa de éxito de la embolización, el riesgo de complicaciones y los resultados funcionales en los primeros 6 meses posteriores al tratamiento en pacientes con aneurismas intracraneales (AI) no rotos que utilizaron dispositivos desviadores de flujo (DF) en México.* **Métodos:** *Estudio longitudinal y retrospectivo de pacientes con AI no rotos tratados en el Instituto Nacional de Neurología y Neurocirugía entre noviembre de 2020 y abril de 2022. Tras el tratamiento con DF, se realizaron angiografías de control posprocedimiento a los 6 meses después. La tasa de oclusión se evaluó mediante la escala de O'Kelly-Marotta.* **Resultados:** *Se incluyeron 23 pacientes (2 de ellos con dos AI), 20 mujeres, con una edad promedio de 51.4 años (± 13.3). Se trataron 19 AI saculares, 4 fusiformes y 2 disecantes.*

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*Las medidas del cuello oscilaron entre 1.9 y 19 mm. Se realizaron angioplastias como parte del procedimiento en cuatro pacientes, lográndose una liberación exitosa después de 23 procedimientos. Se logró una oclusión total en 14 aneurismas intracraneales, y 3 presentaron un llenado residual < 5 % en el seguimiento. Solo se detectaron tres complicaciones tardías relacionadas con el procedimiento.* **Conclusiones:** *El uso de dispositivos DF en nuestra población parece ser seguro y presentar una alta efectividad en los primeros meses posteriores al procedimiento, lo que respalda su uso.*

**Palabras clave:** *Aneurismas intracraneales. Prótesis vasculares. Radiología intervencionista.*

## Introduction

Interventional neuroradiology has proven to be an effective technique for treating intracranial aneurysms (IAs) with a higher level of safety than periprocedural clipping[1-4]. However, the effectiveness of this method's occlusion threshold depends heavily on the aneurysm's morphology and location: large, giant, deep, "blister," and fusiform IAs, and those associated with segmental artery stenosis, only exhibit rates of complete obliteration in up to 33% of patients, and recanalization in up to 20% of cases with coils and stent technique[5]. Due to this, therapeutic alternatives that included the use of endoluminal implants were developed, leading to the creation of a low-porosity stent-type device known as a "Flow Diverter" (FD)[6].

FD diminishes hemodynamic circulation as well as the peak and average amount of kinetic energy that is transferred from the parental artery to the intrasaccular dilation (i.e., aneurysm) during each heartbeat. This is accomplished by creating obstruction to the flow by the low porosity stent. Reduced flow results in progressive intrasaccular thrombosis, the development of scar tissue, and ultimately endothelization both of the FD and of the neck of the aneurysm[7]. Later, over the course of days or weeks, a complicated platelet activation pathway gradually forms a stable thrombus. The reduction of the aneurysm's final mass effect is made possible by the thrombus's intrasaccular conversion to collagen[8].

Numerous publications from multiple institutions reported early positive results using FD[9,10]. In addition, although they are uncommon, complications such as infarctions, hemorrhages, and late aneurysm rupture may occur[11]. The publications that have been made, however, relate to social and health environments that are different from those in middle- and low-income countries, where different outcomes may be possible due to different confounding factors.

The cost of these devices is frequently a subject of debate in low- and middle-income countries, where limited resources impair treatments. Success and complication rates in the early months may support their treatment. Therefore, our goal was to determine the percentage of IAs that are completely occluded in the first 6$^{th}$ months post-treatment in patients using FD devices in a tertiary center in Mexico, as well as the functional outcomes and complications risk.

## Methods

Between November 2020 and April 2022, a descriptive, longitudinal, retrospective study that included all patients with non-ruptured IAs treated with FD devices at the National Institute of Neurology and Neurosurgery (INNN) was conducted.

The inclusion criteria were: Patients over the age of 18, who had the following aneurysm characteristics: Non-ruptured IAs of any type (saccular, fusiform, and dissecting aneurysm) in the anterior circulation from segment C4 to the union of the middle cerebral artery, as well as aneurysm(s) located in the posterior circulation from segment V4 of the vertebral artery to the posteroinferior cerebral artery. Bouthillier classification of the internal carotid artery was used[12]. Exclusion criteria were patients with contraindications for endovascular procedures due to non-suitable anatomy or contraindication to antiplatelet therapy, as well as patient with poor medication compliance.

Following the procedure, digital angiograms were performed on these patients at 6 months. Demographic factors studied included age, gender, hypertension, smoking, dyslipidemia, diabetes mellitus, obesity, and alcohol use.

The PREMIER study's recommendations were the main factor in the decision to place the FD[13], as determined by the interventional neuroradiologist. According to Zubillaga's proposed classification, it was determined to be a wide aneurysm[14] those IAs with necks larger than 4 mm, or by Debrun's proposed classification[15] if the dome/neck ratio is < 2.

All patients received dual antiplatelet therapy (DAPT) 7 days before the intervention. The procedures were carried out under general anesthesia. The location of arterial access (femoral or radial) and the catheters used were determined by the interventionist based on the patient's anatomical characteristics, degree of tortuosity, and location of the aneurysm. To evaluate the

aneurysm morphology, perform its measures, establish a working projection, and determine the dimensions of the devices to be used, orthogonal measurements and three-dimensional acquisition were attained. With direct fluoroscopy, the controlled release of the device was carried out while paying attention to the proper positioning of the device's entire body relative to the artery wall and the adequate coverage of the aneurysm neck. The FD effect and proper flow through the stent were demonstrated in all patients using angiographic controls in working positions and then orthogonal positions. Cone beam computed tomography (CT) was acquired as per protocol after the endovascular procedure to detect any lingering hemorrhagic complications. The DAPT was continued in all patients for 6 months, and thereafter single antiplatelet therapy was continued indefinitely.

Two researchers with expertise in interventional neuroradiology reviewed all of the studies of digital subtraction angiography in the Carestream Primary Agricultural Credit Society digital imaging system. Before the placement of the FD, the characteristics of the IAs were evaluated by identifying its type (saccular, fusiform, dissecting, or blister), its morphology (regular, complex), its location, its measures (neck length, dome-neck ratio), and the number of identified IAs. Successful liberation was assessed, as was the diverter's appropriate adhesion to the parental artery walls, full neck coverage, and documentation of any angioplasty using a balloon if needed.

The aneurysm-related occlusion was evaluated with subsequent angiograms, and it was classified using the O'Kelly-Marotta (OKM) scale[16]. Its classifications are A: entire filling, B: partial filling (5-95%), C: entry remanent (< 5%), and D: no filling (0%), At the same time, this scale includes the degree of stasis found in the arterial (1), capillary (2), and venous phases (3). In addition, studies using cone beam CT (DYNA CT) were conducted to evaluate the presence of intimal hyperplasia.

The complications identified during clinical follow-up and imaging studies were classified as acute trans procedural or delayed complications (up to 6 months).

Outcomes were evaluated at 6 months. Efficacy outcomes were the degree of disability using the Modified Rankin Scale (considering a favorable outcome between 0 and 2); and the occlusion ratio assessed in angiograms using the OKM scale. Safety outcomes were mortality and complications related to the procedure (such as ischemic vascular events, bleeding from aneurysm rupture, and complications up to 1 month after the procedure).

The analysis included a description of the variables using frequencies and percentages (n, %) and medians with interquartile ranges (IQR). Using Fisher's exact test and the statistical analysis application STATA 16.1, the comparison of the outcome of interest (complete occlusion to the 180 days) was carried out. The study has received approval from the INNN's Ethics and Research Committees for its execution, CEI/101/2022.

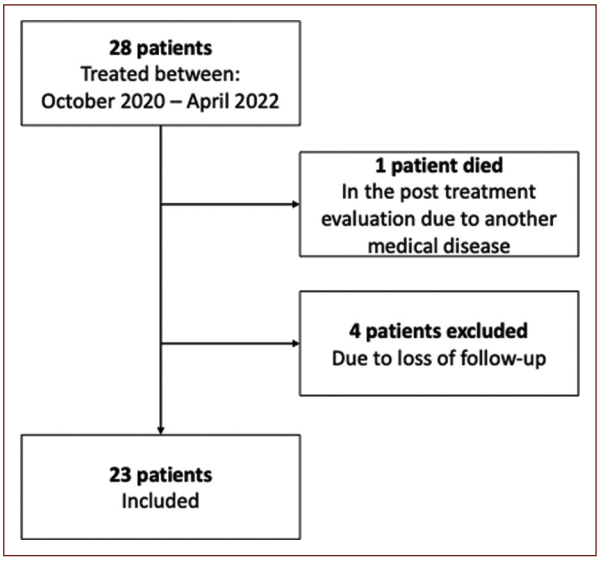


**Figure 1.** Study participant eligibility.

## Results

### *Population studied*

We identified 28 patients treated with FD, 26 of whom had unique IAs. One patient passed away from an undiagnosed metastatic prostate cancer, and four patients lacked follow-up angiograms for 6 months due to a variety of reasons (Fig. 1).

### *Risk factors studied*

We found a gender and age trend, since 20 (87%) of the 23 patients who were included in the analysis were female, and the average age was 51.4 (± 13.3 years). In this patient population, the most prevalent related disorders were obesity, dyslipidemia, and hypertension (Table 1).

### *Aneurysm characteristics*

Two of the patients had two IAs each, making the total number of IAs treated 25: 19 (76%) saccular, 4 (16%) fusiform, and 2 (8%) dissecting IAs. These

**Table 1.** Demographics of the study population

| | |
|---|---|
| Age (mean ± SD) | 51.4 ± 13.3 years (%) |
| Female sex, n (%) | 20 (87) |
| Clinical data, n (%) | |
| Hypertension | 12 (52.2) |
| Diabetes mellitus | 5 (21.7) |
| Dyslipidemia | 9 (39.1) |
| Obesity | 9 (39.1) |
| Smoking | 4 (17.4) |
| Alcohol consumption | 3 (13) |
| Modified Rankin scale, median (IQR) | 0 (0-3) |

SD: standard deviation; IQR: interquartile range.

**Table 2.** Aneurysmal structural features and localization

| | |
|---|---|
| Aneurysm morphology (n = 25) | |
| Saccular, n (%) | 19 (76) |
| Fusiform, n (%) | 4 (16) |
| Dissecting, n (%) | 2 (8) |
| "Blister", n (%) | 0 |
| Complex morphology, n (%) | 15 (60) |
| Aneurysm measurements (n = 19) (mm) | |
| Neck width median (IQR) (min-max) | 3.3 (2.0) (1.9-19.0) |
| Dome median (IQR) (min-max) | 5.5 (5.3) (1.5-29.0) |
| Dome-neck ratio median (IQR) (min-max) | 1.4 (1.2) (0.6-4.6) |
| Wide neck aneurysm, n (%) | 16 (84.2) |
| Characteristics of fusiform and dissecting aneurysms (n = 6) (mm) | |
| Length median (IQR) | 15,5 (13.8) (7.6-27.8) |
| Maximum diameter median (IQR) (min-max) | 6.0 (5.8) (4.4-10.7) |
| Localization (n = 25) | n, (%) |
| Anterior circulation (n = 23) (%) | |
| ICA C4 | 1 (4) |
| ICA C5 | 2 (8) |
| ICA C6 | 10 (40) |
| ICA C7 | 5 (20) |
| MCA M1 | 4 (16) |
| MCA M2 | 1 (4) |
| MCA Bifurcation | 0 |
| ACoA | 0 |
| DACA | 0 |
| Posterior circulation (n = 2) | |
| Basilar | 0 |
| Vertebrobasilar union | 0 |
| Vertebral | 2 (8) |
| PICA-Vertebral artery union | 0 |

ACoA: anterior communicating artery; DACA: distal anterior cerebral artery; ICA: internal carotid artery; IQR: interquartile range; MCA: middle cerebral artery; PICA: posteroinferior cerebral artery.

latter two were located in the area of the vertebral artery. No "blister" type IAs were treated. In contrast to those typical aspect IAs without multiple lobes or "blebs," whose morphology tended to be simple, 15 of our series' IAs (or 60%) had complex morphology.

The measurements of the IAs' neck sizes ranged from 1.9 mm to 19 mm. We identified 14 (73.7%) IAs with wide neck, of which 5 (20%) met the Zubillaga and Debrun criteria and 7 (28%) the Zubillaga definition. The overall number of saccular wide neck IAs throughout the series was 16/19 (84.2%). According to width length, the smallest aneurysm measured 1.5 mm and the largest was 29 mm. The overall number of saccular wide neck IAs throughout the series was 16/19. (84.2%). In the width measurements, the smallest aneurysm measured 1.5 mm and the largest was 29 mm. (IQR 5.3 mm) (Table 2).

The PREMIER study classified the cerebral aneurysm as being in the anterior or posterior circulation. In our study, the section most frequently affected in the anterior circulation contained 12 IAs in the paraclinoid segment (48%) of which 10 (40%) occurred in the ophthalmic segment (C6) and 2 (8%) in the clinoid segment (C5); in second place were 5 (20 %) IAs located in the communicating segment (C7). There were only 2 (8%) posterior circulation IAs, both in the intradural segment of the vertebral artery (V4). Other locations of the IAs are shown in table 2.

## *Aneurysm's treatment*

Fourteen (60.9%) IAs were treated with cobalt-chrome FD, of which 12 (52.2%) were Pipeline Shield® (Medtronic), and two (8.7%) were Surpass Evolve® (Stryker). Ten (43.5%) of the patients were treated with nitinol FD: 8 (34.8%) with Silk+® (Balt Extrusion) and two (8.7%) with FRED® (Microvention). FD diameters ranged from 2.5 to 5 mm (IQR: 1.25), and between 15 and 30 mm for their length (IQR: 2.0).

In two IAs (8.7%) it was necessary to telescoping two FD, both cases were fusiform aneurysm of the middle cerebral artery, both treated with nitinol FD Silk+® (Balt Extrusion). In 1 (4.3%) there were three telescoped FD to treat a fusiform aneurysm of the middle cerebral artery, all of them made of nitinol: 2 Silk+® (Balt Extrusion) and 1 FRED® (Microvention).

## *Outcomes*

A successful liberation without stroke or hemorrhagic complications was achieved in 23 (100%) of the patients, with correct adhesion to the vessel wall in all of them. Incomplete neck occlusion, defined as the lack of the

attachment of the proximal third segment of the FD to the parental artery proximal to the aneurysm neck, was seen in 3 (13%) patients: One patient with a giant cavernous segment aneurysm which was also treated with coiling, another patient with a fusiform aneurysm of the middle cerebral artery, and one patient with a paraclinoid aneurysm in the C6 segment with a posterior circulation fetal pattern.

Four (17.4%) of the patients were treated with balloon angioplasty to assure adequate adhesion the arterial wall and to reduce the risk of stenosis: one patient with a fusiform aneurysm in the M1 segment of the middle cerebral artery treated with two telescoped FD, other patient with M1 segment aneurysm with a stenotic segment in the distal M1 segment, and in two patients with paraclinoid IAs (C6).

## *Follow-up*

According to the OKM grading scale, 14 (56%) of the patients achieved D grade; 3 (12%) C grade. Occlusion results are shown in table 3.

Thirteen (56%) patients were classified with a baseline mRs of 0, 5 (22%) with 1, and 5 (22%) with 2-3. At the 6 months follow-up, 16 (70%) were classified with 0, 4 (17%) with 1, and 3 (13%) with 3. In five cases (22%), the mRs at 3 months had improved by one point. There was no mortality associated with procedural complications.

There were not acute stroke or hemorrhagic complications during any of the procedures. Three (13%) patients developed late procedural complications: 2 (8.7%) with > 50% stenosis of the endoluminal area, both of which in the fusiform treated IAs of the middle cerebral artery; other patient with C7 segment of the left internal carotid artery with wide neck aneurysm presented FD migration toward the terminal portion of the internal carotid artery, who was scheduled for later retreating.

**Table 3.** Percentage of aneurysm-related occlusion according to the O'Kelly Marotta scale

| Classification | n (%) |
|---|---|
| A1 | 0 |
| A2 | 0 |
| A3 | 2 (8) |
| B1 | 0 |
| B2 | 1 (4) |
| B3 | 5 (20) |
| C1 | 1 (4) |
| C2 | 1 (4) |
| C3 | 1 (4) |
| D | 14 (56) |
| Total | 25 (100) |

## Discussion

This study comprises both anterior and posterior circulation IAs, with diverse morphology and defiant characteristics to the physician attempting coiling or clipping treatment, including dissecting, saccular, wide neck, and fusiform IAs. Our study is one of the earliest reports to come out of Mexico on the use of FD for treating intracranial non-ruptured aneurysm currently available.

The majority of IAs treated were saccular (76%) of which more than half (60%) had complex morphology by displaying multilobular structures or blebs appearance; of these, we found wide neck aneurysm in 82.4% of the cases. According to the definitions of the Unruptured Intracranial Aneurysms study[2], 16 (64%) of the total of the aneurysmatic lesions were small saccular with a width ≤ 10 mm, of which 10 (62.5%) achieved OKM D grade. This is inconsistent with what was reported in the metanalysis of Yao et al.[17], where the percentage of occlusion for cases of IAs with identical characteristics was 84.2%; although not far off from what was reported in 2020 by Fiorella et al. meta-analysis[18], whom reported 75% occlusion rate in the 1-year follow-up for the small and middle non-ruptured IAs, with an 8% complication rate. In our study, seven IAs in this group had control angiography after 3 months, demonstrating a complete exclusion in three of them (42.9%).

Regarding saccular IAs, 2 were large (10-25 mm) and 1 was giant (> 25 mm) achieving complete occlusion in one case. One patient in this group displayed a FD migration complication. The total percentage of saccular IAs that were completely excluded was 57.9%, which suggests that our results are still below the average percentage. According to Cagnazzo review of the use of FD in ruptured IAs, immediate occlusion is achieved in 32% of the cases, and long-term occlusion was 89%, with a complication rate of 18%[10], in contrast to Brinjikji[9], which included ruptured and non-ruptured IAs, and evaluated a total of 1654 treated with FD, where occlusion rate was 76% and complication rate was 5%. These

differences may be due to the length of the study period given that we report occlusions after 6 months, when studies typically value this information annually, in addition to the center's characteristics, such as the number of patients treated, as well as the unique characteristics of the IAs, since these expensive and infrequent procedures are reserved for patients with more complex IAs and, thus, lower chances of complete occlusion.

These occlusion rates were obtained at 6-month follow-up and in patients with successful FD placement, similarly to what was reported by Lylyk et al.[19], whom described 97% occlusion rate in the first series of IAs treated with the first-generation FD Pipeline®. Nevertheless, although high levels of occlusion were not achieved, our complications percentages were substantially lower, and our patient's late functional disability was low and dependent on their pre-existing conditions. These results are comparable to or less severe than those of larger retrospective studies[20].

In our geographical and socioeconomic environment, there are few studies that have assessed the outcomes of FD. A review from 2003 to 2023 found that in South America most of the reports of IA treatment that have been published correspond to the countries of Brazil, Argentina, Chile, and Colombia; however, not all of them used FD[21].

In Peru, a study was published in 2023 with results of the use of FD in IAs in four tertiary care centers. A complete occlusion rate of 76% at 12 months was found. This study only included one type of FD[22]. One of the studies with larger samples was reported by Lylyk et al. (2021) in Argentina, which reported a complete occlusion rate of 75.6% in a population of 1000 IAs[23]. In comparison to these reports, our study compared different types of flow diversifiers and their outcomes.

Studies have also been carried out in countries with limited resources but not geographically related populations, such as the African continent. Factors such as lack of access to specialized treatment clinics, post-operative mortality, and financial capabilities exert a burden on their patients[24].

A 2021 meta-analysis found an 85.6% occlusion rate in 1060 IAs treated using flow diversifiers with surface modifications[25]. A 2023 meta-analysis found that occlusion rates at 1 year were 77%[26]. Our study showed a lower percentage; however, it should also be considered that the response time evaluated was also earlier. This could guide subsequent reports with extended follow-ups.

Our study has some limitations, the first of which is that it only represents the local experience of one single national center of reference in Mexico and cannot be generalized to other Latin American settings; however, our center is reference for several hispanic-speaking countries and has the highest case study rate in our region. Second, the sample size is small compared to other reported studies. In addition, due to the complexity of the cases received and the limited resources available, we choose to be as selective as possible and only include the most complex cases, which may imply selection bias. As a result, our results may not be equivalent to other studies with larger populations.

## Conclusion

This study demonstrates that the embolization of intracranial non-ruptured IAs with FD stents is a safe and reproducible alternative with low associated morbidity rates and favorable success rates in the early post-treatment stage in a tertiary care center in Mexico, particularly in small-sized aneurysms with saccular morphology.

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The authors declare that this work was carried out with the authors' own resources.

## Conflicts of interest

The authors declare that they have no conflicts of interest.

## Ethical considerations

**Protection of humans and animals.** The authors declare that the procedures followed complied with the ethical standards of the responsible human experimentation committee and adhered to the World Medical Association and the Declaration of Helsinki. The procedures were approved by the institutional Ethics Committee.

**Confidentiality, informed consent, and ethical approval.** The authors have obtained approval from the Ethics Committee for the analysis of routinely obtained and anonymized clinical data, so informed consent was not necessary. Relevant guidelines were followed.

**Declaration on the use of artificial intelligence.** The authors declare that no generative artificial intelligence was used in the writing of this manuscript.

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