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Orginal Article

Functional Outcome And Reebleding Risk In Patients With Ruptured Aneurysm Treated With Flow Diverter.

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Summary

Background: Intracranial aneurysms are abnormal dilatations in cerebral arteries, most often located at arterial bifurcations. They are part of cerebrovascular diseases and have a worldwide prevalence estimated between 5% to 10% in the general population.
Methods: Observational, descriptive, analytical, retrospective cohort study, with the aim of determining the functional outcome according to the Rankin scale of patients with ruptured intracranial aneurysms treated with flow diverter at 6 and 12 months post treatment.
Results: The population was 37 patients treated with flow diverter of which 12 met the inclusion criteria. The mean age was 43.9 years. 50% of patients were female and 50% of patients were male, with a M:H ratio of 1:1. 66.7% were ruptured aneurysms of infratentorial location treated with flow diversion, of which the basilar artery and vertebral artery were the most prevalent arterial segments with 33.3% respectively.
Conclusion: The use of flow diversion in patients with ruptured intracranial aneurysms is associated with excellent functional results (Rankin<1) in the medium and long term. In addition, the use of flow diversion devices showed occlusion rates at 6 months and aneurysmal exclusion in 100% of patients at 12 months.

Keywords: Intracranial aneurysm, Subarachnoid hemorrhage, endovascular aneurysm repair, Rankin functional classification.

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INTRODUCTION

Intracranial aneurysms are abnormal dilatations of the cerebral arteries. They are typically located at arterial bifurcations and are part of cerebrovascular diseases. The worldwide prevalence of these aneurysms is estimated to be between 5% and 10% in the general population [9]. Subarachnoid hemorrhage (SAH) is the presenting form of rupture of intracranial aneurysms. In the United States, aneurysm rupture occurs in 10 cases per 100,000 population. Associated risk factors include: age 30 to 60 years, smoking, obesity and family history of aneurysmal rupture. Up to 10% of patients with SAH die before reaching the hospital, and first-month mortality can be up to 45% [8]. The study "The International Study of Unruptured Intracranial Aneurysms Investigators (ISUIA)" published in 1988, analyzed the risk of rupture in aneurysms smaller than 10mm, finding a risk of rupture of 0.05% in patients without subarachnoid hemorrhage and 0.5% with a history of subarachnoid hemorrhage one year after stroke, as well as analyzed the risk of rupture in aneurysms of 10-25 and greater than 25mm, finding a risk of 1-2% and 6% respectively [5]. Thunderclap headache is the most common form of presentation, it may be accompanied by transient paraparesis, hemiparesis, paresthesia, hemianopsia, dysphasia, aphasia or even seizures. In posterior communicating artery aneurysms, there may be third nerve palsy.

The management of cerebral aneurysms by endovascular therapy has evolved since the early twentieth century with the introduction of various devices. They are divided into Coils (Endovascular Coil), Conventional Stents and Flow Dividers (FD) [13]. With the experience gained in the use of coils, several studies have concluded that a high percentage of large and giant aneurysms, previously thrombosed, have recanalization, this is explained by a phenomenon known as the "water hammer", in which blood flow causes constant stress on the diseased wall causing increased pressure, which conditions recanalization. The mechanism of action of these devices is to promote endothelialization of the paternal vessel, causing intraaneurysmal thrombosis, which allows treating the diseased vessel decreasing the chances of recanalization, which seems to be the cure for a diseased vessel. In this research the objective was to determine the functional outcome according to the Rankin scale of patients with ruptured intracranial aneurysms treated with flow diverter at 6 and 12 months post treatment.

MATERIALS AND METHODS

We performed an observational, descriptive, retrospective cohort study in a single center of neurosurgery/neurological endovascular therapy. The population was all diagnoses of intracranial aneurysm associated with subarachnoid hemorrhage in which treatment with flow diverter has been performed since January 1, 2011 to December 31, 2023, where the following primary outcomes were observed and described: functional outcome according to the Rankin scale of patients with ruptured intracranial aneurysms treated with flow diverter at 6 and 12 months post treatment; and secondary outcomes: To establish the socio-demographic characteristics of patients with ruptured intracranial aneurysms, to assess the risk of rebleeding in ruptured intracranial aneurysms treated with flow diverter and to analyze the risk of in-stent thrombosis associated with flow diverter placement in acute stage. Statistical analysis was performed using measures of central tendency (Mean, Median and Mode), measures of frequency and association.

RESULTS

The study included 159 patients with intracranial aneurysms, of which 37 were treated by angioplasty with flow diverter, and of these only 12 patients met the inclusion criteria. It was observed that 6 patients were men with 50% and 6 patients were women with 50%, the female: male ratio was 1:1 (See **Table 1**).

Table 1. Gender distribution in patients with intracranial aneurysm treated with Flow Diverter.

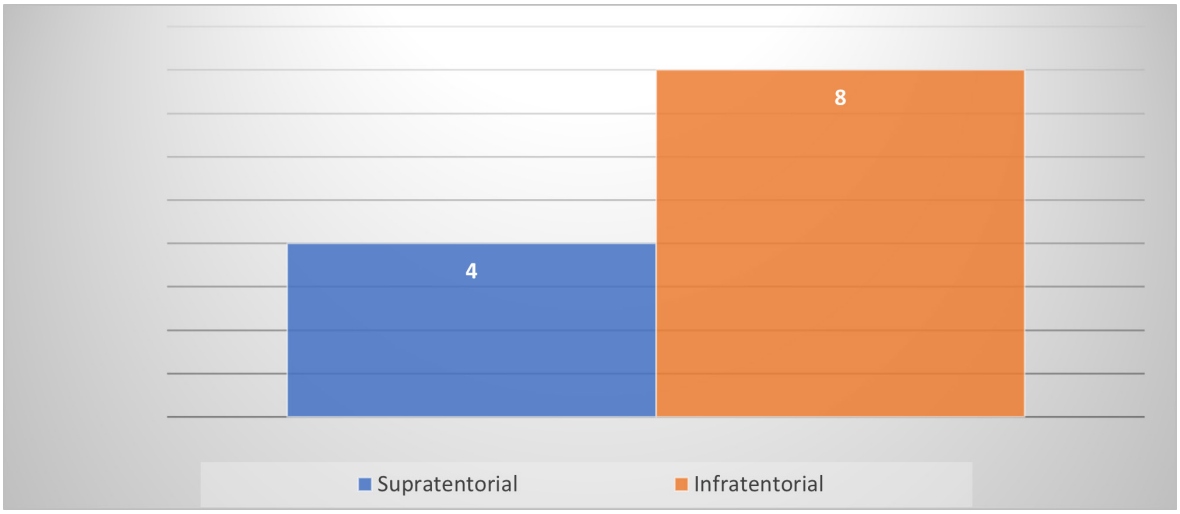
Gender	Number	Percent (%)
Feminine	6	50
Masculine	6	50
Total	12	100

The mean age was 43.9 years, with a minimum range of 16 years and a maximum range of 55 years. It was observed that the most frequent anatomical location of aneurysms treated by flow diverter were of the posterior circulation 66.6% (n=8) vs. 33. 3% of anterior circulation: it was studied by arterial segments or artery involved, where it was found that one third of treated aneurysms were both basilar artery and vertebral artery with 33.3% (n=4) respectively, followed by aneurysms of the ophthalmic artery with 25% (n=3) and middle cerebral artery with 8.33% (n=1) (see **Figure 1** and **Table 2**).

Table 2. Anatomical location of ruptured intracranial aneurysm treated with Flow Diverter, arterial segment.

Location	Number	Percent (%)
Basilar	4	33.3
Vertebral	4	33.3
Oftalmic	3	25.0
Middle Cerebral Artery	1	8.30
Total	12	100.0

Figure 1. Anatomical Location of ruptured intracranial aneurysm treated with flow diverter.

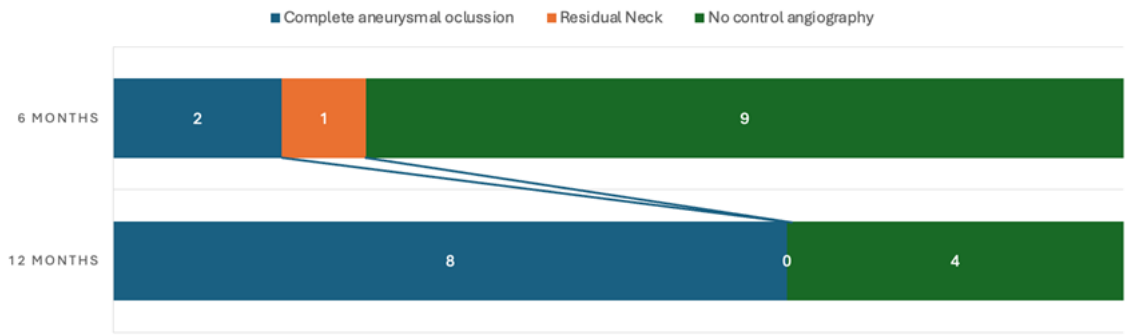


When analyzing the types of aneurysms according to their morphology we found that the most prevalent was the fusiform with 66.7% (n=8) of all patients, followed by saccular aneurysms and blister with 16.6% respectively (see **Table 3**). The average number of days that passed from the onset of bleeding to the day treatment was given was 10.8 days, with a minimum time of 2 days and a maximum time of 17 days; in turn, the endovascular treatment used in most patients was angioplasty with flow divider in 91.6% (n=11) and in 9.06% (n=1) angioplasty with flow divider plus protection of the dome with Coils was performed at the same time. At 6-month follow-up, control angiography was perform at 6 months in only 3 patients, of which residual aneurysm was detected in 1 patient, in the other 2 no residual aneurysm was detected. In the 12-month follow-up, the percentage of control studies improved, in this period a control study was performed to 66% (n=8) of patients, finding an occlusion rate of 100% (n=8) of the patients, which translates the great effectiveness of flow diversifiers in ruptured aneurysms (See **Figure 2**).

Table 3. Rupture intracranial aneurysm treated with flow diverter according to morphology.

Location	Number	Percent (%)
Blister	2	16.60
Fusiform	8	66.70
Sacular	2	16.60
Total	12	100

Figure 2. Follow up oclussion in patients treated with flow diverter.



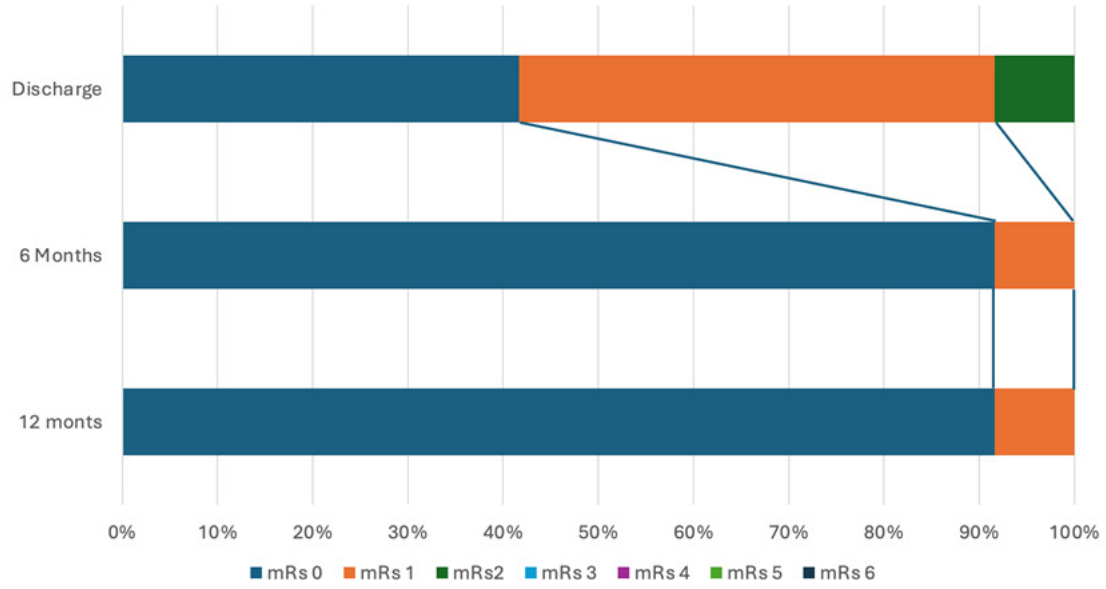
For functional capacity, the modified Rankin scale was used; these scales were applied at discharge and in the outpatient follow-up at 6 and 12 months after the endovascular procedure. It was observed that at discharge only one patient had mild disability (Rankin 2), while 50% (n=6) of the patients had very mild disability (Rankin 1) and 41.7% (n=5) were asymptomatic (Rankin 0). At 6 months follow-up, improvement was observed in many patients since we did not find any record of patients with Rankin 2; only one patient was recorded with mild disability, in the same follow-up period we found that 91.6% of the patients were asymptomatic. When analyzing the functional outcome at 12 months follow-up, we found that there was no

difference with respect to 6 months, finding Rankin 0 in 91.6% (n=11) of the patients, and Rankin 1 in 8.3% (n=1)(see **figure 3**). Due to the high morbi-mortality presented by complex ruptured intracranial aneurysms by various techniques and the promising results of treatment by flow diversifiers in these patients, a multivariate analysis was performed to assess the possible association between Fisher, Hunt and Hess variables, days of bleeding and aneurysmal morphology with the modified Rankin scale at discharge, at 6 months and 12 months, without finding an association between the Fisher scale, days of bleeding and aneurysmal morphology with functional outcome; However, when performing univariate analysis using Chi 2 test, a possible association was observed between Hunt and Hess and functional outcome at 6 and 12 months, finding a Chi 2 value of 11 and a p= 0. 004, which means that the higher the Hunt and Hess score, the less favorable the functional outcome (Rankin >2) (see **Table 4**).

Table 4. Multivariate Analysis in patients, Hunt & Hess, Fisher and time of rupture with functional outcome at discharge, 6 months and 12 months.

	Discharge Rankin		Rankin 6 months		Rankin 12 months	
	X2	**p**	**X2**	**p**	**X2**	**p**
Hunt y Hess	12.8333	0.012	11.0000	0.004	11.000	0.004
Fisher	7.6389	0.106	0.9167	0.632	0.9167	0.632
Post Rupture days	16.6528	0.163	11.0000	0.088	11.0000	0.088
Aneurysm Morphology	4.8667	0.561	2.1818	0.536	2.1818	0.536

Figure 3. Functional follow up according to MRs Score in patient treated with flow diverter.



DISCUSSION

The prevalence of intracranial aneurysm in the general population is low, in Latin America has been documented an incidence of 4.2 cases per 100,000 inhabitants, however many of these cases are not reported.

Most of the patients presented with hemorrhage[5], many of them are detected incidentally; on the other hand in the United States subarachnoid hemorrhage secondary to aneurysm rupture occurs in 10 cases per 100,000 inhabitants; in addition to this, a not insignificant proportion of these patients die before they can receive treatment, in the world literature preoperative mortality rates of up to 30% are reported[14]. Historically, management by means of neurological endovascular therapy has lower effectiveness or occlusion rates, however the reported morbidity and mortality is lower than microsurgical techniques [1,3]. Due to the possible complications related to the use of flow diverters, in our hospital few patients are treated with these

devices in ruptured aneurysms, this technique is restricted to complex aneurysms, where the technical complexity and securing the aneurysm associated with the risk of rupture justifies the risk of trans operative complications (rupture or in-stent thrombosis) [2,7,8]. In our research a total of 12 patients with ruptured cerebral aneurysms treated with flow diverter, the sex distribution varies from other series, because we found no difference in relation to sex, occurring in both genders equally, with a ratio of 1:1, this differs from what is reported in the literature because it is often mentioned a female: male ratio of 2:1 [5]. The age of presentation referred to in most of the literature ranges from 30-60 years [1,3,5], which is consistent with what was found in our study, where the mean age was 43.9 years. There are multiple morphological classifications to group cerebral aneurysms, however, many authors converge in the idea of classifying them into saccular, fusiform, blyster-like, dissecting aneurysms; by definition, due to their morphology and the fragility of its wall, complex aneurysms are considered to be those fusiform, dissecting and blyster-like aneurysms [13].

Dossani et al, in their study of subarachnoid hemorrhage associated with complex aneurysms report a prevalence of fusiform aneurysms of 8.5%, dissecting 32.4%, and blister 41.5% [2]. In our research we found different data regarding the location and morphology referred to in the literature; most patients treated in our institution were infratentorial 66% (n=8) compared to supratentorial 33.3%; according to international literature the most frequent locations are mentioned as those of the anterior communicating artery and posterior communicating artery, followed by the middle cerebral and very infrequently those of posterior circulation (basilar, vertebral) [9], however, the most frequent locations are those of the anterior communicating artery and posterior communicating artery, followed by those of the middle cerebral and very infrequently those of posterior circulation (basilar, vertebral) [9], however, the most frequent locations found in our study were of posterior circulation, occupying the first place those of the basilar artery with 33.3% and the vertebral artery with 33.3%, followed by ophthalmic aneurysms with 25% and finally those of the middle cerebral artery with 8.3%, which contrasts with what is reported in the literature. We also found increased prevalence of fusiform aneurysms 66.6%, saccular 16.6% and blister; this difference in the prevalence found between saccular vs. fusiform and blister aneurysms in our series, is probably due to the type of patients who are treated in our institution, since treatment with flow diverter is reserved for patients with complex aneurysms associated with subarachnoid hemorrhage.

There is little information regarding the statistical significance of the use of flow diversion in ruptured cerebral aneurysms, however, despite its greater effectiveness compared to other endovascular techniques in terms of the degree of thrombosis, there are several points against the use of diversion; the main one is the risk of rebleeding, although the risk of thrombosis is also mentioned; however, every day the use of flow diverters is rising in the treatment of rupture intracranial aneurysms, especially in complex aneurysms (fusiform, blyster-like and large or giant saccular aneurysms). Dossani et al. described a series in patients with intracranial aneurysms associated with subarachnoid hemorrhage, only complex aneurysms were included, where the most common were blister (41.5%) followed by dissecting (32.4%) and third fusiform (8.5%); which differs from our series since most patients treated in our hospital were fusiform in 66.7% of cases [2]. Rimal eat col. report aneurysmal rupture associated with the use of flow diverter in 3.5% of patients with a mortality of 100%, among the factors found associated with rupture were aneurysms larger than 20 mm in which aneurysmal dome protection was not performed [2,7].

In our study there were no complications associated with treatment with flow diversion in ruptured aneurysms, specifically we looked for rebleeding and in-stent thrombosis, both trans operative and postoperative with a minimum follow-up of 1 year. Several series describe lower percentages of rebleeding in patients with fusiform aneurysms compared to saccular aneurysms [12], this coupled with the fact that in our series most of the aneurysms treated were fusiform, could explain the null presence of rebleeding in patients treated in our hospital. Within the group of saccular aneurysms, 3 patients were treated, and it was observed that all of them were larger than 15mm, because of this in 100% of patients dome protection with coils plus flow diverter angioplasty was performed; and no rebleeding was observed in any of the patients. Dome protection with coils associated with flow divider placement in large saccular aneurysms has been associated with lower rebleeding rates [11]. Rimal et al. reported aneurysmal rupture in 3.5%, in that study a cut-off point was performed in saccular aneurysms smaller and larger than 20 mm, finding that in the group of aneurysms smaller than 20 mm, the rupture was 1.9% while in the group of larger than 20 mm was 42.9%; in that study also analyzed the percentage of rupture in patients treated only with flow diverter and was 5.6%, while in those treated with diversor plus coils was 3.3%[2,9,11,12]. Madaelli et al. report a percentage of 6% of rebleeding in previously ruptured aneurysms, being more common in the first 24 hours, the percentage of re-ruptures in aneurysms smaller than 20mm was 2%, while in the group of more than 20mm was 57% [4,7]. These studies explain that in our series there was no rupture in aneurysms since rupture of saccular aneurysms is more common than fusiform aneurysms; it is also relevant to mention that in our research few patients with saccular aneurysms were treated and when it was relevant to treat these aneurysms, only one patient was treated with the presence of a saccular aneurysm greater than 15mm, in this case the dome was protected with coils plus flow diverter angioplasty. Intrastent occlusion

rates reported by Madaelli et al. was 7%, in that series as in ours, treated patients had ruptured aneurysms; 65% of ruptures occurred between the 2nd and 7th day, 90% of them presented complete occlusion [9]. In the INTREPED study, 0.3% of in-stent thrombosis was reported [4]. Martin et al. in a series of 3 patients report 0% rupture and 0% in-stent occlusion[8,11]. Natarajan et al. reported a series of 14 patients with ruptured cerebral aneurysms treated with flow diverter, in which 5 saccular, 1 fusiform and 2 dissecting aneurysms were treated, in this series 0% rupture and 7.6% in-stent thrombosis were reported [10]. These statistics are consistent with the percentage of occlusion found in our research, because in these series as in ours, most of the treated aneurysms were fusiform. When analyzing the percentage of occlusion at 12 months, we found that only 25% (n=3) of patients had control study at 1 year, in them good results were achieved because in 66% (n=2) of patients no residual aneurysm was detected, the only patient in which residual neck was presented was a giant saccular aneurysm, reporting occlusion rate O'Kelly Marotta 1C, which was performed control angiography at 12 months post treatment finding complete occlusion. On the other hand, when analyzing the percentage of patients with ruptured intracranial aneurysms treated with flow diverter presenting complete aneurysmal occlusion at 12 months of follow-up, an occlusion rate of 100% was observed, in addition to this 0% presented rebleeding during follow-up. This percentage of aneurysmal occlusion corresponds to that reported in various studies, since at 12 months occlusion percentages ranging from 80 to 85% are reported, and at 2 years from 90 to 100%. Li et al. report complete occlusion in 78.3% of patients and 93% at 16 months [9]; Natarjan et al. report 100% of patients with complete occlusion at 24 months [6,10].

As previously stated, the results obtained in our study agree with the reported literature, where the percentage of occlusion in intracranial aneurysms at 12 months was greater than 90%, with a functional outcome of Rankin 0 to 1 in most treated patients. Martin et al. published the first series of ruptured intracranial aneurysms treated with flow diversion, obtaining 0% rebleeding and 100% with good neurological status (Rankin <2) [8]. Natarjan et al. report 0% re-rupture, 7.6% thrombosis and parenchymal hemorrhage, 30-day mortality was 18.2%, however at discharge, 81.8% of patients were in excellent condition and at 16-month follow-up 100% of patients had Rankin less than 2 [10]. Li et al. in 2014 described in their series, 7.6% rebleeding and 11.5% in-stent thrombosis; regarding functional outcome, 11.5% mortality and severe deficit and 77% good neurological status at 6 months are reported [6]. The immediate postoperative outcome in our investigation was favorable in most cases, which is very similar to that described in the literature; there were no trans or postoperative complications, and the high effectiveness rate of the flow divider allowed excellent functional outcomes at 6 months postoperatively. It is worth mentioning that most of the patients who were treated were in excellent pre-surgical condition. 91.6% (n=10) of the patients were in excellent pre-surgical condition. with a favorable Rankin (<2) at the time of treatment, only one patient (8.4%) entered the ward with a Rankin of 3 points; at the time of discharge 100% of the patients had a favorable Rankin (0-2).

When analyzing the 6-month follow-up, many patients presented a significant improvement, 83.3% (n=10) were asymptomatic while 16.6% (n=2) had Rankin 1. 6% (n=11) were asymptomatic, while only one patient (8.4%) had Rankin1. There were no trans-surgical or post-surgical complications at 18-month follow-up as a result of flow diverter placement in ruptured cerebral aneurysms.

CONCLUSION

The use of flow diverter in patients with ruptured intracranial aneurysms is associated with excellent functional results (Rankin < 1) in the medium and long term. In addition, the use of flow diverters showed occlusion rates at 6 months and aneurysmal oclussion in 100% of patients at 12 months; and it the use of this technique in ruptured intracranial aneurysms does not increase the likelihood of rebleeding mainly in those of fusiform and blister morphology; in the case of saccular aneurysms > 20mm, embolization with coils and the placement of flow diverters decreases the likelihood of rebleeding.

Statement of patient consent

Patient consent is not required, as patient identities were not disclosed or compromised.

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Conflicts of Interest

The authors declare that they have no conflicts of interest.

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