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Surgical Neurology International

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SNI: Neurovascular

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Original Article

Silk + flow-diverter stent for the treatment of intracranial aneurysms associated with balloon angioplasty: A retrospective study

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Received : 31 January 2023
Accepted : 05 April 2023
Published : 05 May 2023

DOI
10.25259/SNI_97_2023

Quick Response Code:

ABSTRACT

Background: The silk + flow-diverter stent is increasingly used to treat complex intracranial aneurysms including wide-neck and fusiform aneurysms. Balloon angioplasty has been used to better appose the flow diverter (FD) to the vessel wall and, thus, improve aneurysm occlusion rates and decrease periprocedural complications. Sparse data are available concerning the results of this technique. We report our experience with silk + FD associated with balloon angioplasty for the treatment of intracranial aneurysms.

Methods: A retrospective study was conducted on all patients treated by the silk + FD. Clinical charts, procedural data, and angiographic results were reviewed and compared between those treated with balloon angioplasty. A multivariate analysis was conducted to identify predictors of complications, occlusion, and outcome.

Results: Between July 2014 and May 2016, we identified 209 patients with 223 intracranial aneurysms. There were 176 (84.2%) women and 33 (15.8%) men. The most common stent size used was 4.5 mm in 101 patients (46.1%), followed by 4 mm in 57 patients (26%). Univariate analysis observed that stent diameter was significantly related to aneurysm occlusion ($P < 0.05$). Patients with more than 1 aneurysm treated with silk + stent have a 9.07 times greater chance of having complications in the procedure than patients with only 01 aneurysm (OR = 9.07; $P = 0.0008$). Patients who had angioplasty without the use of a balloon have a 13.69-times-higher risk of complications (OR = 13.69; $P = 0.0003$). Older age, larger aneurysms, and the use of more than 1 FD device were predictors of recanalization.

Conclusion: Endovascular treatment of intracranial aneurysms with the silk + FD associated with balloon angioplasty is a safe and effective therapeutic option. Balloon angioplasty in combination with FD lowers the risk of complications. Higher complication rates and worse outcomes are associated with older age and large aneurysms.

Keywords: Aneurysm, Balloon angioplasty, Complications, Flow diverter, Occlusion

INTRODUCTION

Over the past decade, flow diverter (FD) technology has emerged as a new generation of endoluminal implants for reconstructing the parent artery and treating brain aneurysms.[1]

They aim to redirect blood flow away from the aneurysm, causing stagnation, parent artery remodeling, resulting in gradual thrombosis, and complete occlusion of the aneurysm sac.[19,39] With the development of material technology, clinical and basic experiments have proven their efficacy and safety.[22,52] Despite this increase in use, contradictory data from numerous research studies show great results,[1-3,26], while other studies show decreased rates of aneurysm occlusion and significant morbidity.[38,46,54]

Device malapposition, underexpansion, and proximal migration are technical difficulties associated with FDs that can lead to delayed ischemia episodes or potentially life-threatening aneurysm rupture.[9,10,12] Aneurysm occlusion following FDs treatment is most likely due to stent wall apposition and neo-endothelialization derived primarily from cells in the surrounding parent artery.[17,25] Malapposition of FDs at the level of the aneurysm's neck has been shown in clinical and basic research to play a significant role in delayed aneurysm occlusion and an increase in periprocedural complications,[8,37,49] promoting late thrombosis, and increasing the risks for stroke events.[28]

Several supplementary procedures, such as coiling or the implantation of additional intrasaccular or intraparental artery devices such as FDs or stents, have been described to improve the safety and efficacy of FDs.[4,29,31] Balloon angioplasty has been used to better appose the FD to the vessel wall and, thus, improve aneurysm occlusion rates and decrease periprocedural complications.[14,29] However, there is only sparse data about the clinical benefit and the safety of balloon angioplasty placement within FDs in the treatment of intracranial aneurysms.

Therefore, the aim of our study was to present the safety and efficacy of balloon angioplasty as an adjunctive management option within a single type of FD (Silk+) for the treatment of intracranial aneurysms and discuss the results of this technique.

MATERIALS AND METHODS

Population

Our Institutional Ethics Committee authorized this retrospective study. Between July 2014 and May 2016, we identified all patients treated in our database with the Silk + stent, with and without balloon angioplasty (Copernic RC [BALT extrusion, Montmorency, France] compliant microcatheter) for 1 or multiple intracranial aneurysms. Individual treatment alternatives were assessed, and an agreement was reached among experienced endovascular neurosurgeons.

All patients underwent conventional angiography of both the internal carotid arteries (ICAs) and the vertebral arteries. Then, 3D-rotational angiography was performed to depict the aneurysm morphology. Adult patients (over the age of 18) who met the inclusion criteria were enrolled in the study. Any antiplatelet medication contraindications, pregnancy, breast-feeding, and aneurysms that could be treated with coils alone were all ruled out.

Variables evaluated

In the present study, the presence of balloon in angioplasty was considered, dichotomized, as the independent variable of interest, and the covariates selected as possible confounders were as follows: Gender, age (<60; ≥60), topography (in the ICA, in location other than the carotid artery), O'Kelly-Marotta (OKM) scale (A,B, C and D), silk + aneurysm (1; ≠ 1), circulation (Anterior; posterior), smoking, hypertension, rupture, associated coils (All with a yes or no response), aneurysm diameter (The maximal dimension of the aneurysm), stent diameter, and dome neck ratio (considered in the model as quantitative).

Endovascular procedure and follow-up

Antiplatelet therapy was administered to all patients 5–7 days before treatment. The antiplatelet reactivity test was not done, and the daily dose was set at 100 mg of aspirin plus 75 mg of clopidogrel. Following discharge, dual antiplatelet therapy was continued for at least 6 months after treatment. In the case of acute subarachnoid hemorrhage (SAH), the patients were perioperatively administered a dual antiplatelet combination of acetylsalicylic acid (300 mg) and clopidogrel (300 mg). After the procedure, the patient is maintained on aspirin (100 mg daily) for life and clopidogrel (75 mg daily) for approximately 6 months.

All of the patients with unruptured aneurysms were given local anesthetic and conscious sedation, unless the patient was previously under general anesthesia due to SAH. The femoral artery was the preferred artery for puncture. A 6F or 8F artery access was used for the procedures. Intravenous heparin was given once arterial access was achieved.

Clinical outcome evaluation

Clinical and neurological evaluations were done right after the procedure, at the hospital discharge, and 30 days, 180 days, and a year later. The modified Rankin scale (mRS)[5] was used to assess the clinical outcomes. The initial clinical status was matched to the mRS and neurological status.

Angiography outcome evaluation

Angiographical proof of full aneurysm closure was the study's endpoint. The OKM scale for flow diversion was used to do 6-month and 1-year angiographic follow-ups based on the

degree of filling (A: total filling, B: subtotal filling, C: entry remnant, and D: no filling).[43]

Statistical methods

Logistic regression models were developed considering as dependent variables: The occurrence of complications in the procedure or the occurrence of occlusions; and demographic and clinical variables as explanatory variables. Analyses were performed at the procedure level and in this case that we have the presence of data considered clustered data since each procedure can be performed more than once on the same patient. The main feature of pooled data is that results from the same pool are likely to be positively correlated. Statistical methods should take this into account; therefore, logistic regression models were then fitted using generalized estimating equations (GEE) with a symmetric correlation matrix.

The analysis took place in two stages: bivariate and multiple, in both odds ratios (ORs) and their respective 95% confidence intervals (CIs) were calculated. Initially, simple logistic regression models were fitted for each covariate. Those in which $P < 0.25$ were included in the multiple logistic regression analysis.[21] Subsequently, adjustments were made to these variables through a process of removal/inclusion of variables. Only those covariates with $P < 0.05$ remained in the final model. Subsequently, the independent variable of interest, angioplasty balloon, is included to verify the degree of association between it and the occurrence of complications or occlusions in the procedure after adjustment for possible confounders. At the end, the ORs and their respective 95% confidence intervals were calculated.

Multicollinearity between independent variables was assessed. It is considered as a limit for the presence of multicollinearity if the tolerance indicator assumes values >0.602.

The absence of symptoms assessed by the scale mRS and measured over a year of follow-up, among patients operated on with or without angiographic balloon, was tested using logistic regression models with GEE with covariance structure 1st-order autoregressive, adjusted for baseline measurements. Bonferroni correction was used to adjust for multiple comparisons.

It was considered significant $P < 0.05$. Analyses were conducted using the SAS 9.4 application.

RESULTS

Patient characteristics

Demographic data, clinical presentation, aneurysm characteristics, location, size, and final outcome are summarized in Table 1.

Table 1: Baseline characteristics of the patients and aneurysms.

Baseline characteristic of the patients (*n*=209)	
Age median (range [years])	54 (27–80)
Female sex (*n* [%])	176 (84.2%)
Hypertension (*n* [%])	63 (43.8%)
Smoking (*n* [%])	25 (18.3%)
Ruptured (*n* [%])	7 (3.4%)
Balloon angioplasty	187 (89.5%)
Coil association	8 (3.9%)
Periprocedural complication	14 (6.7%)
Stent diameter ([mm], SD)	4.38±0.54
2.5 mm	3 (1.4%)
3 mm	2 (0.9%)
3.5 mm	16 (7.3%)
4 mm	57 (26%)
4.5 mm	101 (46.1%)
5 mm	24 (11%)
5.5 mm	16 (7.3%)
Aneurysm characteristic	
Anterior circulation (*n* ([%])	205 (96.8%)
Posterior circulation (*n* [%])	18 (3.2%)
Mean size of aneurysm ([mm], SD)	10.63±8.9
Giant aneurysms (>25 mm)	17 (7.6%)
Large aneurysms (10–25 mm)	140 (62.8%)
Small aneurysms (<10 mm)	66 (29.6%)
Wide-necked (>4 mm)	94 (42.3%)
Dome/Neck ratio ([mm], SD)	2.07±1.35
Saccular (*n* [%])	198 (88.8%)
Fusiform (*n* [%])	25 (11.2%)
Aneurysm location	
A1/A2	7 (3.2%)
MCA	14 (6.3%)
ICA - Cavernous/petrous	49 (22.2%)
ICA - PcomA	38 (17.2%)
ICA - Paraophtalmic	89 (40.3%)
Carotid bifurcation	6 (2.7%)
PCA	2 (0.9%)
Tip basilar artery	8 (3.6%)
Vertebro-basilar	8 (3.6%)
Clinical presentation	
Mass effect (*n* [%])	23 (11%)
Cranial nerve palsy (*n* [%])	10 (4.7%)
Headache (*n* [%])	146 (69.8%)
Aneurysm occlusion at 12 months	
Complete (OKM D)	179 (81%)
Near total	17 (7.7%)
Partial	25 (11.3%)
Outcome - mRS at 12 months	
Grade 0	187 (90.8%)
Grade 1	13 (6.3%)
Grade 2	5 (2.43%)
Grade 3	1 (0.5%)

OKM: O'Kelly-Marotta, mRS: Modified Rankin scale, ICA: Internal carotid artery, MCA: Middle cerebral artery, PCA: Posterior cerebral artery, SD: Standard deviation, OKM D:"D" is the OKM scale, A = Anterior cerebral artery; Pcoma = Posterior communicating artery, n = number of patients.

Two-hundred and nine patients with 223 intracranial aneurysms were identified. There were 176 (84.2%) women

and 33 (15.8%) men, with a median age of 54 years (range, 27–80 years). Two-hundred and two (96.6%) patients were diagnosed with unruptured aneurysms, and 7 (3.4%) presented with ruptured aneurysms. Among the 202 patients with no previous hemorrhage, 46 (22.7%) were asymptomatic, whereas 146 (69.8%) complained of headache, 10 (4.7%) had cranial nerve palsy, and 23 (11%) had a mass effect.

Aneurysm characteristics

Aneurysms were located in the anterior circulation in 205 cases (96.8%) and in the posterior circulation in 18 cases (3.2%). The most common localization was the paraophthalmic ICA (89 [40.3%]), followed by the cavernous/petrous ICA (49 [22.2%]). Among the posterior circulation aneurysms, 2 (0.9%) were located at the posterior cerebral artery, 8 (3.6%) were at the tip of the basilar artery, and 8 (3.6%) were at the vertebrobasilar segment. One-hundred ninety eight aneurysms were saccular (89%) and 25 were fusiform (11%). Aneurysm median size was 10.63 ± 8.9 mm. The aneurysm dome/neck ratio ranged from 0.6 to 15 mm (average 2.1 mm). Wide-neck aneurysms (≥4 mm) were present in 94 aneurysms (42.3%).

Technical outcome

Most patients were treated with a single silk + stent with only 9 (4%) cases using two devices and a single case using 3 (1.35%) devices, on the same occasion. Aneurysm neck coverage was complete in almost all cases except in 3, where the device migrated. Balloon angioplasty was performed in 187 patients (89.5%).

Ten aneurysms (4.5%) were adjunctively coiled at the time of silk + placement. Stent diameter median size was 4.38 ± 0.54 mm. The most common stent size used was 4.5 mm in 101 patients (46.1%), followed by 4 mm in 57 patients (26%). Univariate analysis observed that stent diameter was significantly related to aneurysm occlusion ($P < 0.05$).

Complications in the procedure

Overall periprocedural complication rate was observed in 14 patients (6.7%). Among the 209 patients with follow-up, four patients presented periprocedural complication in the immediate period after the procedure, (two patients with mRS 0–4; one mRS 1–3; and one patient mRS 1–2). These periprocedural complications were attributed to ICA occlusion, transient ischemic attack, small frontal bleeding due to microguide aneurysm rupture, and silk+ stent twist, which may not be related with balloon angioplasty. All these patients recovered to their basal mRS at the end of the 1-year period follow-up. One patient presented delayed stent occlusion, 4 days after treatment. Final clinical outcomes in 209 patients included 188 with mRS = 0; 14 with mRS = 1; six patients with mRS = 2, and one patient with mRS = 3.

The bivariate analysis identified that the variables age, smoking, aneurysm diameter, stent diameter, and silk + aneurysm were associated with complications in the procedure and because they had $P < 0.25$, they were included in the multivariate analysis [Table 2]. From the final adjustment of the multivariate model and with the inclusion of the independent variable of interest, it was found that patients aged 60 years or over have a 3.26 times greater chance of having complications in the procedure than patients younger than 60 years (OR = 3.26; $P = 0.0448$). For every 1 mm increase in aneurysm diameter, the chance of complications in the procedure increases by 13% (OR = 1.13; $P = 0.0020$). For every 1 mm increase in stent diameter, the chance of complications in the procedure decreases by 66% (OR = 0.34; $P = 0.0477$). Patients with silk aneurysms other than 1 have a 9.07 times greater chance of having complications in the procedure than patients with silk aneurysms equal to 1 (OR = 9.07; $P = 0.0008$). The absence of balloon in angioplasty after adjusting the confounders was significantly associated with the occurrence of complications in the procedure. Patients who did not use the angioplasty balloon have a 13.69 times greater chance of having complications in the procedure (OR = 13.69; $P = 0.0003$).

Occlusions in the procedure

Angiographic controls showed 179 complete occlusions (81%), 17 partial occlusion (7.7%), and 25 incomplete occlusions (11.3%) at 12 months. There were no procedural deaths reported in the acute and delayed period.

The bivariate analysis identified that the variables sex, age, aneurysm diameter, stent diameter, and silk + aneurysms were associated with occlusion in the procedure and because they had $P < 0.25$, they were included in the multivariate analysis [Table 3]. From the final adjustment of the multivariate model and with the inclusion of the independent variable of interest, it was found that female patients have a 2.56 greater chance of having occlusions during the procedure than male patients (OR = 2.56; $P = 0.0461$). For every 1 mm increase in aneurysm diameter, the chance of occlusions occurring in the procedure decreases by 8% (OR = 0.92; $P < 0.0001$). The use or not of balloon in angioplasty after adjustment of confounders was not significantly associated with occlusions in the procedure ($P = 0.5103$).

The tolerance indicator for multicollinearity ranged from 0.92 to 0.96, indicating that there is no multicollinearity between the independent variables in the adjusted models.

Clinical outcome after balloon angioplasty

Initially, a model was adjusted in which the interaction between follow-up time and the use or not of a balloon angioplasty was adjusted, to verify whether the behavior

Table 2: Logistic regression analysis with bivariate and multivariate generalized estimation equations for procedural complications.

Variables	Total OR; CI 95%	*P*-value	Adjusted OR; CI 95%	*P*-value
Gender		0.9006		
Female	1	-	-	-
Male	1.11 (0.23–5.41)	0.9006	-	-
Age		0.0624		0.0448
<60	1	-	1	-
≥60	3.09 (0.94–10.10)	0.0624	3.26 (1.00–11.44)	**0.0448**
Smoking		0.0055		
No	1	-	-	-
Yes	5.53 (1.65–18.51)	0.0055	-	-
Hypertension		0.7659		
No	1	-	-	-
Yes	1.23 (0.31–4.82)	0.7659	-	-
Localization		0.9626		
Carotid artery	1	-	-	-
Other than carotid	1.04 (0.21–5.13)	0.9626	-	-
Rupture		0.5872		
Yes	1	-		
No	1.64 (0.27–9.83)	0.5872		
Aneurysm size	1.06 (1.01–1.11)	0.0210	1.13 (1.04–1.22)	**0.0020**
Dome/neck ratio	0.93 (0.75–1.15)	0.5190		
Coils association		0.5495		
No	1	-	-	-
Yes	2.00 (0.21–19.36)	0.5495	-	-
Stent diameter	0.48 (0.19–1.20)	0.1158	0.34 (0.10–0.99)	**0.0477**
OKM scale		0.7774		
A, B and C	1	-	-	-
D	1.22 (0.31–4.71)	0.7774	-	-
SILK aneurysm		0.0097		0.0008
1	1	-	1	-
≠1	5.34 (1.50–19.02)		9.07 (2.80–52.56)	**0.0008**
Balloon angioplasty		<0.0001		0.0003
Yes	1	-	1	-
No	15.22 (4.91–47.19)	<0.0001	13.69 (3.27–57.27)	**0.0003**

OR: Odds ratio, CI: Confidence interval, OKM: O'Kelly-Marotta, A: Total filling (>95%), B: Subtotal filling (5-95%), C: Entry remnant (<5%), D: No filling (0%), 1 = One Silk stent, ≠ 1 = More than one Silk stent, The bold values are the values where the *P*-value was < 0.05.

of patients, during the follow-up period, regarding non-disability or dependence in activities daily differs between those who were operated with or without angiographic balloon [Table 4]. From the adjustment of the logistic regression model with GEE, the interaction factor between time and use or not of the balloon angioplasty presented $P = 0.9268$, showing that the interaction is not significant and, therefore, the behavior, over a year, of patients operated with an angiographic balloon does not differ significantly from those operated without a balloon angioplasty. The graph [Figure 1] shows the evolution over a year of the absence of symptoms among those who were operated or not with a balloon angioplasty.

Subsequently, a model was adjusted without the presence of an interaction between follow-up time and the use or not of a balloon angioplasty, and it was observed that only the effect of time was significant ($P = 0.0057$). Patients after 30 days of follow-up showed no significant difference in terms of the absence of symptoms when compared to the moment immediately after surgery ($P = 1.0000$). Patients after 180 days and 365 days of follow-up had a 72% greater chance of not having symptoms when compared to the moment immediately after surgery ($P = 0.0033$ and 0.0030, respectively). The effect of using or not using balloon angioplasty was not significantly different regarding the absence of symptoms ($P = 0.5188$).

DISCUSSION

This study demonstrates that endovascular treatment of cerebral aneurysms with the silk + stent in combination with balloon angioplasty is a safe and effective treatment option with minimal periprocedural problems. Furthermore, using

Table 3: Logistic regression analysis with bivariate and multivariate generalized estimation equations for procedural occlusions.

Variables	Total OR; CI 95%	*P*-value	Adjusted OR; CI 95%	*P*-value
Gender		0.0958		0.0461
Female	1	-	1	-
Male	2.12 (0.87; 5.16)	0.0958	2.56 (1.00; 7.22)	0.0461
Age		0.1311		-
<60	1.71 (0.85; 3.41)	0.1311	-	-
≥60	1	-	-	-
Smoking		0.8360	-	-
No	1	-	-	-
Yes	1.12 (0.38; 3.25)	0.8360	-	-
Hypertension		0.2716	-	-
No	1	-	-	-
Yes	1.49 (0.73; 3.02)	0.2716	-	-
Localization		0.3551	-	-
Carotid artery	1	-	-	-
Other than carotid	1.57 (0.60; 4.07)	0.3551	-	-
Rupture		0.3139	-	-
Yes	1	-	-	-
No	1.78 (0.58; 5.44)	0.3139	-	-
Aneurysm size	0.92 (0.89; 0.96)	<0.0001	0.92 (0.88; 0.96)	<0.0001
Dome/neck ratio	0.93 (0.74; 1.17)	0.5215	-	-
Coils association		0.8852	-	-
No	1	-	-	-
Yes	1.17 (0.14; 10.04)	0.8852	-	-
Stent diameter	0.42 (0.20; 0.90)	0.0248	-	-
SILK Aneurysm		0.1787	-	-
1	1	-	-	-
≠1	2.31 (0.68; 7.86)	0.1787	-	-
Balloon angioplasty		0.7215		0.5103
Yes	1	-	1	-
No	1.23 (0.40; 3.76)	0.7215	0.67 (0.20; 2.20)	0.5103

OR: Odds ratio, 1 = One Silk stent, ≠ 1 = More than one Silk stent

Table 4. Comparisson between time and balloon angioplasty

Variable	Odds Ratio (OR)	CI (95%)	p-value*
Times		0.0057	
Immediately	1	-	-
30 days	1.00	0.90; 1.10	1.0000
180 days	1.72	1.24; 2.38	**0.0033**
365 days	1.72	1.24; 2.39	**0.0030**
Angiography baloon		0.5188	
No	1	-	-
Yes	0.59	0.12; 2.95	0.5188
Interaction between time and Surgery	-	-	0.9268

*Values for comparing time versus baseline and the effect of using or not using an angiographic balloon were calculated using logistic regression models with generalized estimation equations (GEE) with a symmetric correlation matrix. Bonferroni correction was used to adjust the multiple comparisons in the time variable. The bold value indicate the *P* value < 0.05

balloon angioplasty throughout the procedure reduced the number of periprocedural complications. This work shows good technical success as well as immediate-term, short-term, and mid-term outcomes. These findings imply that placing a balloon angioplasty within FDs protects against periprocedural complications and is linked to a high rate of aneurysm occlusion.

The development of FDs for the thrombosis of wide-neck, fusiform, and giant aneurysms has elicited great enthusiasm in the neurointerventional community. Since the introduction in clinical practice, FDs devices have had excellent results.[1,3,7] Several early reports about the successful use of such devices, and the immediate technical and clinical outcomes, have been published, with impressive results.[34,42,57] Murthy *et al*.,[40] in his systematic review, patients with silk stent FD observed a periprocedural complication rate of 12.5%, with increased rates of thrombogenic events, device migration, vessel occlusion, and mortality. At short- and midterm follow-ups, our series revealed a very low rate of intrastent stenosis. The majority of the stenosis was asymptomatic, which is consistent with the earlier studies.[3,6,33]

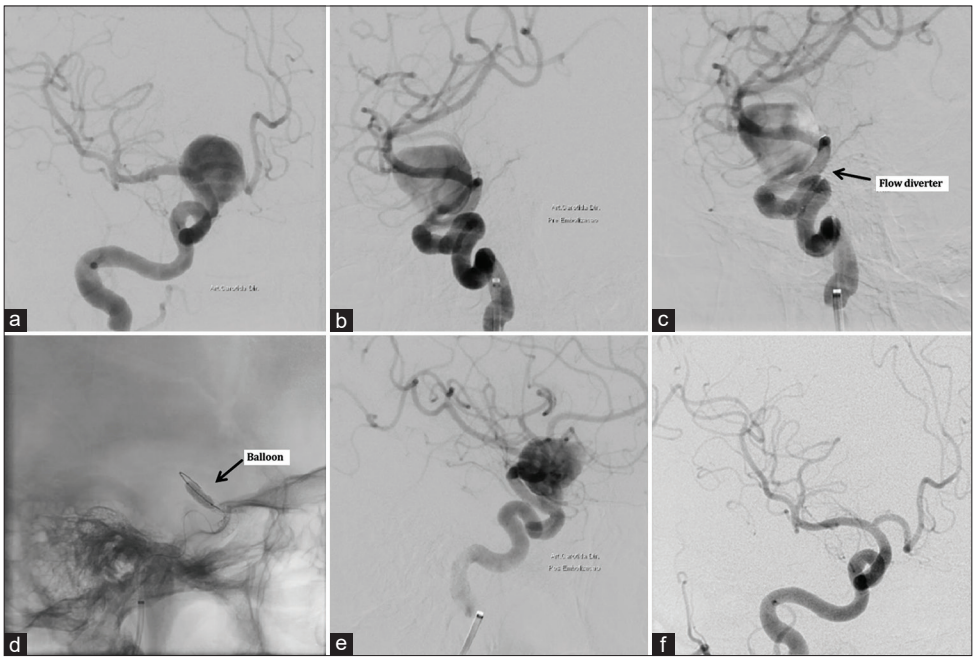

Figure 1: Examples of pretreatment and 1-year posttreatment angiographic images of giant carotid-ophthalmic aneurysm treated using silk + flow diverter, showing aneurysm occlusion. (a) Pre-procedural conventional angiography shows a complex wide-neck giant carotid-ophthalmic aneurysm. (b) Lateral view. (c) The intraoperative views show the delivery of the silk + flow diverter (arrow). (d) Angiography showing balloon dilatation placement (arrow). (e) Immediate post-procedure angiography. (f) Angiographic control at 1-year demonstrating the reconstruction of the parent artery and total occlusion of the aneurysm.

However, reports about the occurrence of procedure-related late thrombosis, fatal hemorrhage, and delayed complications have also been published.[16,58] FD silk stents have been linked to a greater risk of thromboembolic events in recent studies. During the follow-up of 12 patients with a basilar artery aneurysm treated with a silk stent, one occurrence of acute basilar artery blockage and three cases of symptomatic neurological episodes were documented.[57] Mortality and morbidity rates of 4% and 15%, respectively, were reported in another recent research of 29 patients with 34 aneurysms treated with the silk stent, with considerable parent artery stenosis in eight cases (33%) at 6 months.[2]

Incomplete vessel-wall apposition of FDs may also impede its ability to redirect blood flow away from the aneurysm sac, which then could interfere with stable intra-aneurysmal thrombus formation and flow stagnation, and may results in incomplete aneurysm occlusion, increase in periprocedural complications and delayed thromboembolic events.[20,28,45] In view of the risks associated with these complications of FDs placement, ensure proper device parent vessel deployment is critical.

The process of establishing an endothelium, which consists of an intact layer of vascular endothelial cells over the FD, is known as endothelialization. This layer helps the surrounding vascular tone by supplying nitric oxide and prostaglandins, as well as acting as a physical barrier, potentially minimizing the risk of thrombosis and delayed cerebral ischemia,[15,47] and increasing the higher rates of aneurysm occlusion.[23]

Several clinical researches, especially in coronary literature, highlight the potential for in-stent thrombosis and delayed ischemic events in incomplete stent apposition.[18,20,44,51] Furthermore, inadequate stent apposition of drug-eluting stents in coronary arteries has been shown to delay neointimal coverage of stent struts, slowing the endothelialization process and raising the risk of stent thrombosis.[44] Rouchaud *et al*.[49] create saccular aneurysms in 41 rabbits and by histopathological findings observed that good wall apposition is strongly associated with complete occlusion after FD therapy.

For the treatment of cerebral aneurysms and the prevention of delayed ischemic consequences, accurate measurement of FDs deployment and wall apposition is critical.[11,49] The present studies describe the potentially fatal consequences of stent malapposition and how to reliably detect partial vessel-wall apposition following stent insertion. Stent malapposition has previously been assessed using a variety of imaging modalities. Postoperative magnetic resonance imaging with gadolinium injection,[55] intraoperative optical computed tomography (CT), digital subtraction angiography (DSA),

dual cone beam CT,[59] C-arm CT acquisition with a low contrast medium,[30] and 3D C-arm acquisition,[27] has been used for intraprocedural FD deployment and postoperative evaluation of stent apposition. However, the precise structure of the stents and their three-dimensional spatial relation with the parent artery are still difficult to evaluate[13,27,30] and there is low interobserver agreement.[49,50]

Recently, novel self-expandable devices have been introduced to reduce thromboembolic complications, facilitate navigability, improve radial force, and increase aneurysm occlusion rate.[35,36,48,53] Although these new devices are often successful, there are several reports of FDs with proper coverage of the aneurysm neck and in a delayed fashion migration of the FD on follow-up angiograms. FDs may not completely open, or the proximal segment may not perfectly attach to the parent artery wall, or there is not enough radial force, and malapposition occurring at the end of the device, or in a curve, can be difficult to correct. Several techniques have been described to potentially archive a good wall apposition, such wires, microcatheters, balloon angioplasty, and additional, placement of FDs/stents.[29] However, no clear guidelines for the management of inadequate FDs wall apposition have been described.

Balloon angioplasty has been used to fully open the FD or to attach its proximal segment in the parent artery wall, with excellent results.[32,56,60] Although in some instances, oversizing has been shown to reduce the therapeutic benefit of FD in hemodynamic simulations,[41] few studies have examined its potential effect on the aneurysm occlusion rate.[24] We did not observe increased complications in patients treated with balloon angioplasty; moreover, we observed a decreased periprocedural complication rate. This might suggest that adjunctive measures such as balloon inflation should be considered in some clinical settings to improve wall apposition.

Although the silk + stent is self-expandable, the open cell design makes it exceedingly flexible, and it cannot ensure that all of the cells will line properly with the artery's axis. Due to misalignment, cells at the distal and proximal borders may not entirely attach to the arterial wall. Self-expandable stents combined with balloon angioplasty could help enhance wall apposition.

In such circumstances, a second FD or stent is certainly an option, but it is not always feasible, particularly in a perforator-rich zone where the increased metal-to-artery ratio may result in perforator occlusion. In addition, our research found an increase in the number of complications, which is consistent with the findings of other researchers. Lubicz *et al*.[32] reported after treatment with a second stent, there was an increased chance of delayed aneurysm rupture. Furthermore, adding another FD is a relatively expensive option.

With the expanding use of FDs to treat cerebral aneurysms, our standard recommendation of balloon angioplasty may be effective in enhancing wall apposition. Although we saw a decrease in the number of complications, this technique could lead to dissection or rupture of the parent artery due to balloon overinflation, as well as increased procedure duration and thromboembolic consequences.[60]

We believe that the association between silk+ and balloon angioplasty reduced periprocedural complications, as demonstrated in our cohort, which is best explained by the increased surface area of metal coverage provided by balloon angioplasty and increased wall apposition with the device. This increase in metal coverage is a consequence of best wall apposition due to the dilation of the balloon.

We also noted that intraprocedural age >60 years old, large aneurysm size, and use of more than 1 device are associated in the multivariate analysis with procedural complications, which are in accordance with the previous publications.[3,32,46] These findings suggest a possible role for the selection of the patients and stent sizes in long-term results.

Our research has some limitations. Because it was a retrospective study, it comes with its own set of limitations. We did not assess the antiplatelet response. Most likely, we have underestimated the percentage of subjects resistant to antiplatelet medication. Imaging follow-up was incompletely homogeneous and did not include postoperative imaging evaluation, other than DSA. Another limitation is that our study included small control groups (without balloon angioplasty). The majority of aneurysms were found in the ICA, which implies a lower risk of complications than those found elsewhere in the anterior circulation. Despite these limitations, this study answers various concerns that have previously gone unanswered, and it provides several independent predictors of problems, occlusion, and outcome.

CONCLUSION

Our research showed that balloon angioplasty inside an FD is both safe and effective. Our findings were based on a study of aneurysms treated with a silk + FD to promote wall apposition. Balloon angioplasty in combination with FD lowers the risk of complications. Complications are more likely in older patients, those with larger aneurysms, and those who utilize more than one FD device.

Our findings must be confirmed in larger cohorts, particularly from multicenter registries, and cannot be applied to all neurointerventional techniques. However, in certain instances, surgeons may consider placing a balloon angioplasty within a newly placed FD, which may help with occlusion rates and drastically reduce the procedure's risk.

Declaration of patient consent

Patients' consent not required as patients' identities were not disclosed or compromised.

Financial support and sponsorship

Publication of this article was made possible by the James I. and Carolyn R. Ausman Educational Foundation.

Conflicts of interest

There are no conflicts of interest.

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How to cite this article: Almeida Filho JA, Zimelewicz Oberman D, Freitas DG, Costa RA, Dantas S. Brandão T, Teixeira Maia Junior O. Silk + flow-diverter stent for the treatment of intracranial aneurysms associated with balloon angioplasty: A retrospective study. Surg Neurol Int 2023;14:160.