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Flow diverter devices in the treatment of posterior communicating artery aneurysms: mid-term clinical and radiological outcomes

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Abstract

Background: In the last decade, flow diverter (FD) devices are one of the widely used endovascular methods in the treatment of intracranial aneurysms. As the frequency of its use is increasing progressively, we thought that studies concerned with the use of FD at specific locations are helpful to clarify the efficacy and safety of FD as a treatment option in cerebral aneurysms. We represent our experiences in the treatment of posterior communicating artery (PCOM) aneurysms by FD devices aiming to assess its angiographic efficacy (complete aneurysm occlusion) and its related complications. This is a retrospective study of 47 patients harboring 47 PCOM aneurysms treated with Pipeline Embolization Device (PED). Acutely ruptured and non-saccular aneurysms were excluded from the study. Short- and mid-term radiological and clinical outcomes were analyzed.

Results: Procedure-related complications were observed in five patients (two ischemic events, two transient ischemic attacks (TIA), and one ipsilateral distal hemorrhage) with no procedure-related mortality. Complete aneurysm occlusion was encountered in 87.2%. In multivariable analysis, large-sized aneurysm and incorporated vessels were an independent predictor of non-occlusion ($P = 0.026$ and $P = 0.035$ respectively). A favorable clinical outcome (modified Rankin Scale, 0–2) was observed in 45/47 patients (95.7%); the incidence of postoperative complications was an independent predictor of unfavorable clinical outcomes ($P = 0.048$).

Conclusion: PED stent provides a high occlusion rate in the treatment of PCOM aneurysms with good post-treatment clinical outcomes.

Keywords: Cerebral Aneurysm, Complications, Endovascular, Flow diverter

Background

PCOM aneurysms is considered as the second common site of the brain aneurysms. It accounts for about 25% of overall brain aneurysms and about 50% of internal carotid artery aneurysms [1]. A wide range of anatomical variations exits with PCOM aneurysms, and it directly affects the treatment strategy and choices of appropriate line of treatment [2].

Treatment options of PCOM aneurysm include surgical clipping and endovascular techniques; surgical treatment is preferable in large aneurysm especially when it is causing mass effect on the oculomotor nerve, aneurysms with unfavorable fundus, and those associated with fetal PCOM artery origin [3, 4].

Endovascular treatment with detachable coils has been advocated as an alternative treatment of aneurysms with accepted efficacy and safety [5–7]. The proximal location

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of PCOM aneurysms, as well as a good visualization of aneurysmal neck and parent artery, makes coiling procedures of PCOM aneurysms more easily in comparison to other sites of the intracranial aneurysm, but a high rate of recanalization after endovascular coiling is still the most drawback of PCOM aneurysm coiling [2].

Flow diverter devices are promising new generation of brain stents with low porosity [8, 9] that have a different mode of actions, in contrast to endovascular coiling which depends on packing of the aneurysmal sac. Aneurysm occlusion via flow diversion (FD) explained by two mechanisms: (1) the effect of FD in inhibition of the blood in and outflow through the aneurysm and (2) reinforcement and repair of the parent artery wall using the stent mesh as the scaffold for an intimal generation (scaffolding effect) [10]. The interruption of the aneurysm inflow jet strikingly reduces shear stresses on the aneurysm fundus with progressive thrombosis of the aneurysm over time; shrinkage of the aneurysm occurred during healing after inflammatory response with reconstructing the parent artery lumen while preservingperforators and side branches [11].

Despite the large number of reports that evaluate FD in the treatment of intracranial aneurysms, the clinical and radiological outcomes of PCOM aneurysms treated by FD which consider as one of the frequent sites of brain aneurysms not evaluated in-depth in previous studies, we concern in this study the post-treatment complications and occlusion rate of PCOM aneurysms treated by Pipeline flow diverter stent on mid-term follow-up.

Methods

This is a retrospective analysis of 47 patients harboring 47 aneurysms arising from the PCOM artery and treated by Pipeline flow diverter stent between March 2014 and September 2016 in two tertiary institutes. Declaration of Good Clinical Practice was approved by the Ethics Review Board of the institutes, and signed informed consent was obtained from all patients before the procedure.

Dual antiplatelet therapy is needed after PED placement which limited its use to highly selective cases of ruptured intracranial aneurysm. So, in our study, patients with recent ruptured aneurysms ≤ 30 days and non-saccular aneurysms were excluded from the study.

Pre and post-procedure medications

All patients were kept on dual antiplatelet therapy for 5 days before the procedure. All received 75 mg/day clopidogrel and 81 mg/day aspirin; the post-procedural antiplatelet regimen consisted of clopidogrel continued for 6 months following the treatment, and aspirin continued for 1 year.

Procedure

All procedures were done under general anesthesia via an 8F right femoral introducer. A long stiff introducer 6F was advanced to the level of the internal carotid artery (ICA); then, 3D rotational angiography obtained to select the work projection.

Pipeline-type flow diversion stent (ev3-Covidien, Irvine, CA, USA) deployed in co-axial navigation of a MARKSMAN microcatheter distal to the aneurysmal neck at least 10 mm and then pushing the stent to the tip of the delivery wire. The system is then aligned with the aneurysm under fluoroscopy, PED stent deployed, and the microcatheter is withdrawn. Closure of the femoral puncture point with a Femoseal system was done after checking the patency of the common femoral artery.

Follow-up

Angiographic follow-up by digital subtraction angiography (DSA) or magnetic resonance angiography (MRA) was scheduled at 180 days, 1 year, and 2 years after treatment. As DSA image is the golden standard to assess the aneurysm occlusion, we scheduled it two times during the first 24 months while MRI/MRA was done for patients with neurological symptoms during this period, then patients were followed annually by MRI/MRA. DSA and MRI/MRA were independently reviewed by two authors using O'Kelly-Marotta (OKM) [12] to evaluate the rate of aneurysm occlusion.

Clinical follow-up was done with modified Rankin Scale (mRS), and clinically significant procedure-related complications were reported.

Statistical analysis

Categorical variables were expressed as number (n) and percentage, and continuous variables were expressed as median ± quartiles and/or means ± standard deviation.The univariate conditional (matched) analysis was used to test covariates predictive of the following dependent variables: angiographic occlusion and clinical outcomes (modified Rankin Scale, 0–2 versus 3–6). Interaction and confounding were assessed through stratification and relevant expansion covariates. Factors predictive in univariate analysis ($P < 0.20$) were entered as multivariate conditional logistic regression analysis. P values of ≤ 0.05 were considered statistically significant. IBM SPSS Version 23.0 (IBM Corp., Armonk, New York, USA) was used for data administration and statistical calculations.

Results

Baseline characteristics

Patient's ages ranged from 32 to 73 years; the median was 51 years (IQR 44–64); 40 patients (85.1%) were

females; and seven patients (14.9%) were males. The mean size of the target aneurysms was 10.05 mm (SD ± 5.62); two aneurysms (4.3%) were giant ≥ 25 mm, 17 aneurysms (36.2%) were large-sized ≥ 10 mm, and 28 aneurysms (59.6%) were small-sized with 17 aneurysms (36.2%) that had unfavorable dome-to-neck ratio (≤ 1.5).

The presentation of the aneurysms was variable: ten (21.3%) manifested by third cranial nerve (CN III) compression symptoms, nine (19.1%) represented with headache, 12 (25.5%) aneurysms incidentally discovered, and 16 aneurysms (34%) were recurrent after previous treatment (Table 1).

Aneurysm treatment

Deployment of FD success in 46/47 (97.8%) patients, one PED failed to release during the procedure resulting in immediate ipsilateral ICA occlusion (Figs. 1 and 2). A single PED was inserted in the treatment of 37 (78.4%) aneurysms, two stents were used in the treatment of eight aneurysms (17%), and three stents were used in the treatment of two aneurysms (4.3%); the mean PED used per procedure was 1.25. Balloon angioplasty was acquired in three procedures (one FD with malposition required to use to post-deployment dilation and in two procedures to obtain optimal stent expansion after multiple PED stent deployed in a telescopic manner). Four (10.6%) aneurysms were treated with adjunctive coils in addition to PED stent(s) to completely secure the aneurysm neck and sac (one giant aneurysm treated with two PED and coiling, one large aneurysm with incorporated vessels treated with two PED and coiling, and two wide neck aneurysm treated with single PED and coiling).

Table 1 Aneurysm characterization

Aneurysm characteristics	*n* (%)
Aneurysm presentation	
Incidental	12 (25.5)
Nerve palsy	10 (21.3)
Headache	9 (19.1)
Recurrent	16 (34)
Aneurysm size	
Small size < 10 mm	28 (59.6)
Large size 10–24 mm	17 (36.2)
Giant ≥ 25 mm	2 (4.3)
Dome-to-neck ratio	
> 1.5 (favorable dome-to-neck ratio)	30 (63.8)
≤ 1.5 (unfavorable dome-to-neck ratio)	17 (36.2)
Same segment another aneurysm	5 (10.6)
Thrombosed aneurysm	2 (4.3)
Fetal origin PCOM	1 (2.1)
Incorporated vessels	9 (19.1)

PCOM posterior communicating artery

Procedure-related complications

Procedure-related complications occurred in five (10.6%) patients (two ischemic events, two TIA, and one ipsilateral distal hemorrhage) and resulted in persistent neurological morbidity in two (4.2%) patients. No procedure-related mortality was encountered.

Hemorrhagic complications occurred in one patient who was an active smoker and hypertensive harboring a large sized 18.8-mm aneurysm treated by single PED stent and developed ipsilateral distal hemorrhage < 24 h after the procedure, and patient complained from decrease visual acuity in terms of homonymous superior quadrantanopia with last mRS 2.

Ischemic complications occurred in two patients. One patient with large sized aneurysm (19.5 mm) was treated with two PED stents which occluded 6 months after primary treatment with an ipsilateral infraction; the patient developed contralateral hemiplegia with last mRS 3. Another patient suffered from ischemic complications secondary to an intra-procedure event in terms of a failure of proper release of PED stent in the treatment of a small-sized (9 mm) aneurysm with ipsilateral ICA occlusion and immediate post-operative hemiplegia with last mRS 3.

Transient ischemic attacks occurred in two patients. One patient harboring giant aneurysm treated by two PED stents with adjuvant coiling developed transient contralateral hemiplegia 1 month after treatment which completely resolved with last mRS 0. Another patient with large sized aneurysm 13.8 mm treated by single PED stent patient developed transient receptive aphasia < 24 h after treatment which resolved spontaneously with last mRS 0.

Clinical outcome

All patients underwent clinical assessment during the follow-up period with the median follow-up time of 30 months (IQR 24–34). A favorable outcome (modified Rankin Scale ≤ 2) was observed in 45 patients (95.7%). The 2 patients who had a poor clinical outcome had experienced procedure-related complications, mRS was stationary in 36 (76.6%) patients, improvement in mRS observed in nine (19.1 %) patients, and deterioration in mRS occurred in two (4.2 %) patients; change in mRS overtime is listed in Table 2.

The following factors were tested for as predictors of outcome: age, sex, aneurysm size, wide neck, incorporated vessels, aneurysmal thrombosis, unfavorable dome-to-neck ratio, the fetal origin of PCOM, previous treatment, and postoperative complications. In univariable analysis, the only factor predicting the poor clinical

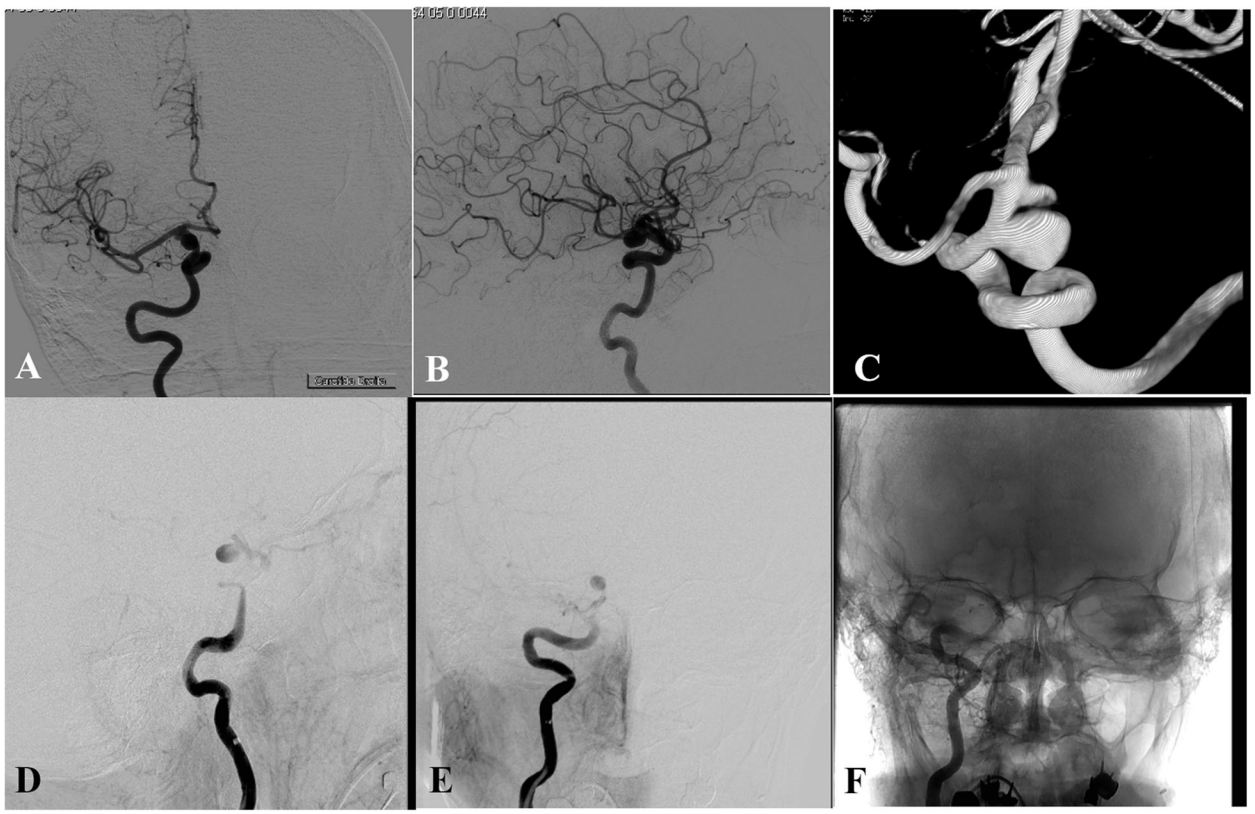

Fig. 1 **a**–**c** DSA of 54- years old patient with incidentally discovered small-sized right PCOM artery aneurysm, **d** failure of release PED stent 3.75 × 18 mm, with occlusion of ipsilateral ICA (**e**) and noted revascularization of the right ACOM artery and to a lesser extent of the right MCA (**f**)

outcome (modified Rankin Scale, > 2) was postoperative complications (odds ratio, 6.428; 95% confidence interval, 1.02–37.68; $P < 0.048$) (Table 3).

Angiographic outcome

All patients underwent angiographic DSA follow-up at least at one time according to our schedule at 180 days, 1 year, and 2 years (Table 4), excluding the patient with failed PED release. Thirty-eight patients (82.6%) underwent DSA twice, and 8 patients have DSA once during the first 2 years, while MRI/MRA was done for 11 patients during this period and then scheduled annually for all patients. We used the O'Kelly-Marotta scale to assess the occlusion of the treated aneurysm. At 24 months, all patients underwent DSA, with the exclusion of aneurysm with failed PED deployment; the overall complete occlusion rate was reported in 41 aneurysms (89.1%) (Fig. 3). Six aneurysms failed to achieve complete occlusion (one giant, one large-sized aneurysm with incorporated vessels, three aneurysms with incorporated vessels, and one aneurysm had incorporated vessels with fetal origin PCOM).

Retreatment was necessary for two un-occluded aneurysms; both were large-sized aneurysms (19 mm and 16 mm) that were retreated at 6th and 12th months after the primary treatment respectively.

The following factors were tested for as predictors of occlusion: age, sex, aneurysm size, wide neck, incorporated vessels, aneurysmal thrombosis, unfavorable dome-to-neck ratio, the fetal origin of PCOM, previous treatment, and post-operative complications. In univariable analysis, factors predicting non-occlusion were incorporated vessels ($P < 0.08$) and large size aneurysm ($P = 0.01$). In multivariable analysis, both large size aneurysm (odds ratio, 5.205; 95% confidence interval, 1.215–22.297; $P < 0.026$) and incorporated vessels (odds ratio, 3.205; 95% confidence interval, 3.215–28.297; $P < 0.035$) were statistically significantly independent predictor of non-occlusion (Table 5).

Discussion

The article studies as regards PCOM treatment by flow diverter almost concern with patency of PCOM after PED deployment [13, 14] or discuss failure/low occlusion of PCOM aneurysms associated with a fetal origin posterior cerebral artery after flow diverter [15–18]; few articles discuss the clinical and radiological outcome of fetal and non-fatal PCOM artery aneurysms [6]. Our study describes the clinical and radiological outcomes of

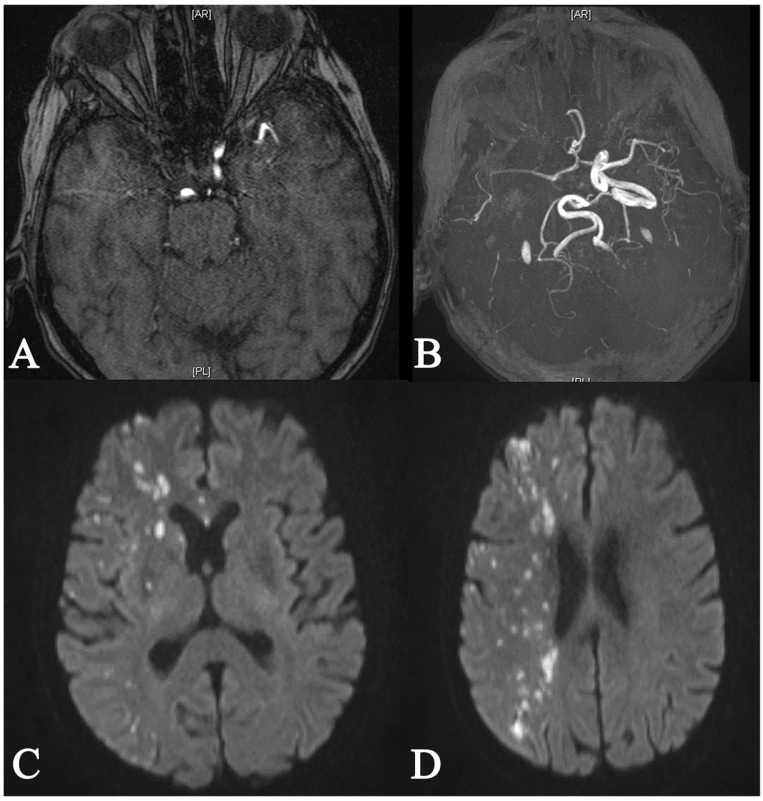

Fig. 2 a-d: MRI of the same patient demonstrates occlusion of right ICA with subsequent multiple ischemic infarcts along right MCA territory

PCOM aneurysms treated with flow diverter stent (PED type) in two tertiary institutes. This study has data regarding the anatomical variants and clinical presentation that give better ideas to assess the post-procedure complications and clinical and radiographic outcomes of PCOM aneurysms treated by PED stent.

Endovascular coiling remained the treatment of choice of most of the intracranial aneurysms, but it has low rates of occlusion in complex and large-sized aneurysms [19]. FD offered an alternate treatment option for those complex and large/giant aneurysms [20].

Table 2 modified Ranking Score (mRS) over time

mRS*	Admission	Discharge	1 year	2 years	Last mRS
0	32 (68.1%)	32 (68.1%)	36 (76.6%)	37 (78.7%)	38 (80.8%)
1	10 (21.3%)	9 (19.1%)	6 (12.7%)	5 (10.6%)	4 (8.5%)
2	3 (6.4%)	3 (6.4%)	1 (2.1%)	1 (2.1%)	1 (2.1%)
3	2 (4.3%)	2 (4.3%)	3 (6.4%)	3 (6.4%)	4 (8.5%)
4	0	1 (2.1%)	1 (2.1%)	1 (2.1%)	0
5	0	0	0	0	0
6	0	0	0	0	0

Data expressed in number(percentage)
**mRS* modified Ranking Score, *0* no symptoms, *1* no significant disability, *2* slight disability, *3* moderate disability, *4* moderately severe disability, *5* severe disability, and *6* dead

In our series, procedure-related complications occurred in five patients (two ischemic, two TIA, and one ipsilateral distal hemorrhage) with persisting major neurological deficits in two patients (4.2%) and no procedure-related mortality.

The post-procedure complications after PCOM treatment in Roy et al. [18] study occurred only in one patient who suffered from seizure with no major

Table 3 Univariate logistic regression of predictors of clinical outcomes

	P value	OR	CI 95%
Age	0.854	1.574	0.302–5.213
Sex	0.999	–	–
Large size	0.094	0.161	0.019–1.363
Wide neck	0.873	1.125	0.264–4.795
Incorporated vessels	0.481	1.846	0.335–10.165
Intraluminal thrombus	0.999	–	–
Unfavorable dome-to-neck ratio	0.844	0.857	0.185–3977
PCOM fetal origin	0.450	1.214	0.525–11.075
Previous treatment	0.485	0.464	0.054–4.003
Post-operative complications	**0.048***	6.428	1.02–37.68

CI confidence interval, *OR* odds ratio, *PCOM* posterior communicating artery
*Statistically significant difference (P ≤ 0.05)

Table 4 Angiographic (DSA) follow-up over time

OKM scale	180 days, *n* (%)	12 months, *n* (%)	24 months, *n* (%)
A	1 (5.5)	2 (5.5)	–
B	4 (22.2)	4 (11.1)	3 (8.8)
C	3 (16.6)	9 (25)	6 (17.6)
D	11 (61.1)	22 (61.1)	26 (74.5)
Missed	28	10	12

OKM O'Kelly-Marotta scale for the angiographic outcome, *A* total filling (> 95%), *B* subtotal filling (5–95%), *C* entry remnant (< 5%), *D* no filling (0%)

neurological complications. Daou et al.'s [14] study has no ischemic or hemorrhagic complications, and the same is reported by Kühn et al. [6].

As a meta-analysis including 3125 patients, the overall complications 17.0% with mortality rate 2.8%, and the neurological morbidity 4.5% [21], the authors concluded that the use of FD stents in aneurysms treatment yielded satisfactory results with regard to the complications and the mortality rate. In Trivelato et al.'s [22] study, the major strokes or mortality rate was 3.45%. Likewise, in Adeeb et al.'s [23] study, the symptomatic thromboembolic complications were 12% and symptomatic hemorrhagic complications 8% with no mortality; they concluded that the incidence of complications after PED is greater in giant and large aneurysms compared to smaller sized aneurysms.

Distal intraparenchymal hemorrhage is the most dreaded complication of flow diversion. In our study, only one active smoker, hypertensive patient with large PCOM aneurysm who suffered from ipsilateral parenchymal hemorrhage required surgical evacuation and complained from contralateral homonymous superior quadrantanopia, because of the effect of hemorrhage on Meyer's loop in the temporal lobe.

Distal parenchymal hemorrhage more in anterior circulation aneurysms was treated by FD [24]; the exact mechanism of bleeding is not clearly understood and may be explained by alteration of the parent artery morphology and decrease in the local compliance of the vascular segment affecting the aneurysm hemodynamics [25]; the presence of risk factors as smoking and hypertension with endovascular microvascular damage as well as the use of antiplatelet therapy increases the bleeding risks.

Delayed aneurysm rupture after FD is one of the serious complications with disastrous consequences and is more common in symptomatic and large/giant aneurysms [26]. In the current study, no delayed rupture occurred, it may be attributed to small sample size, and most of the treated aneurysms in our series were small-sized (59.6%).

In contrast to hemorrhage after FD, ischemic complications are more common in treated posterior circulation aneurysms [27] and also more common in large and

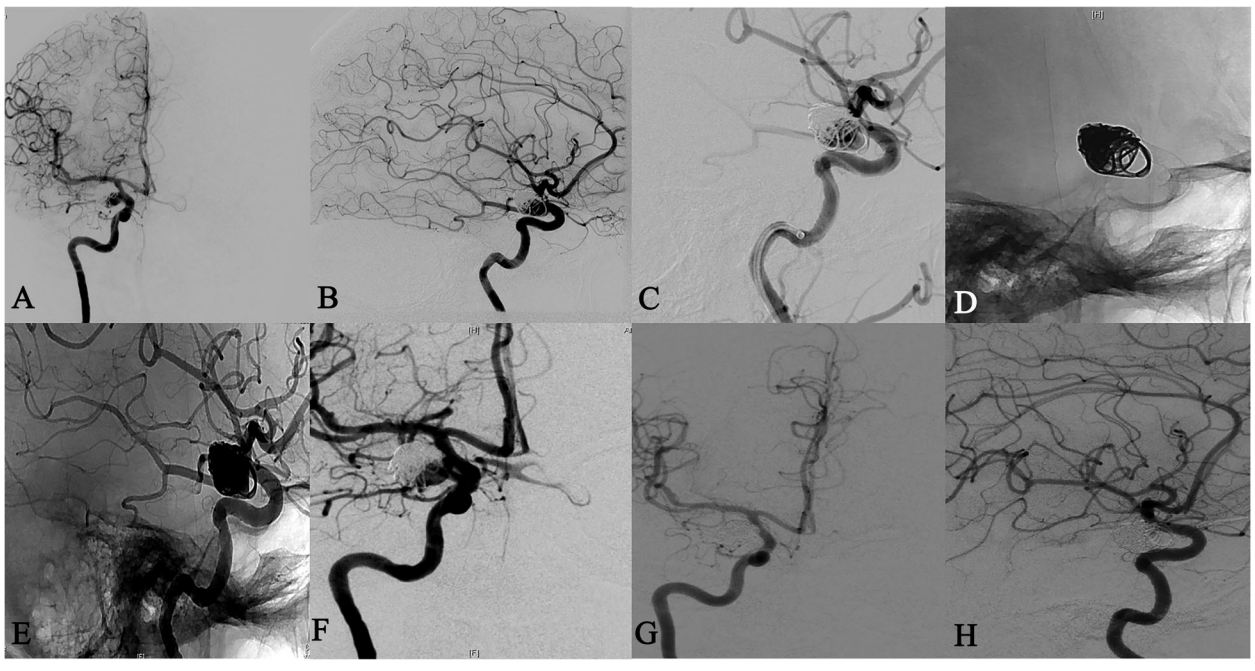

Fig. 3 **a**–**c** DSA of 43-years old patient, showing recanalized right PCOM aneurysm 1 year after coiling. **d** Insertion of single PED stent 4 × 16 mm. **e**, **f** Angiography immediately after PED deployment. **g**, **h** One-year follow-up revealed complete occlusion of the aneurysm

Table 5 Univariate and multivariate logistic regression of predictors of angiographic outcomes

	Univariate			Multivariate model		
	P value	OR	CI 95%	*P* value	OR	CI 95%
Age	0.763	0.776	0.148–4.060	–	–	–
Sex	0.858	0.869	0.135–4.012			
Large size	**0.007***	11.429	1.933–67.568	**0.026***	5.205	1.215–22.297
Wide neck	0.338	2.350	0.409–13.509	–	–	–
Incorporated vessels	**0.036***	6.250	1.128–34.639	**0.035***	3.205	3.215–28.297
Intraluminal thrombus	0.318	0.305	0.030–3.131	–	–	–
Unfavorable dome-to-neck ratio	0.118	0.267	0.051–1.401			
Fetal origin of PCOM	0.2580	0.2869	0.1035–1.012	–	–	–
Previous treatment	0.117	0.261	0.049–1.403	–	–	–
Postoperative complications	0.057	0.192	0.035–1.049	–	–	–

CI confidence interval, *OR* odds ratio, *PCOM* posterior communicating artery
*Statistically significant difference (P ≤ 0.05)

giant aneurysms [26, 28]. In our study, two patients suffered from thromboembolic events on the 1st day and the 6th month after FD procedures respectively. The first is due to improper deployment of PED and resulting in ipsilateral ICA occlusion. The second patient harboring large aneurysm was treated by two PED stents and developed intra-stent stenosis 6 months after treatment; it attributed to interruption of anti-platelet therapy, and also the use of multiple stents with intra-procedure microvascular injuries changes the hemodynamic and promotes the incidence of ischemic complications [29].

Complete aneurysm occlusion in the present study was achieved in 41/46 aneurysms 89.1% of treated aneurysms and re-treatment required in two aneurysms. The relatively high rate of complete aneurysm occlusion in our study is in line with the findings of previous series especially those concerned with PCOM aneurysm after PED stent: in Roy et al.'s [18] study, complete or near-complete occlusion was achieved in 85.4%, Daou et al. [14] reported 86.7% complete or near-complete obliteration at 6-month follow-up, Kühn et al. [6] observed complete or near-complete occlusion in 91.5% at 3 to 9 months, and Brinjikji et al. [13] realized 81.8% complete or near-complete occlusion at the last follow-up.

Progressive aneurysm occlusion over time was observed in many studies as in Dornbos et al. [30] and Saatci et al.'s [9] studies; in our series complete occlusion progress from 61.1% at 6–12 months to 74.5% at 24 months, the exact mechanism of progressive occlusion over time may be explained by progressive intra-saccular thrombus formation over time and shrinkage of the aneurysm with the inflammatory process reaction.

Failure of complete occlusion in our study was observed in six aneurysms; incorporated vessels and large size aneurysm were statistically significant factors associated with low occlusion rate, and among those with incorporated vessels, one aneurysm has a fetal origin of the PCOM artery which was identified as a predictor for low occlusion, but in our study, its non-statistical significant as a low number of cases with fetal origin was included in our series.

The presence of incorporated artery increases difficulties in endovascular treatment of the aneurysm; flow diverters provided a solution for those aneurysms [31]; we identified that incorporated vessels from the aneurysmal sac/neck is an independent predictor of incomplete aneurysm occlusion, the same announced in many studies [14, 22, 32–35]. It is explained by pressure gradient kept by incorporated branch toward the aneurysm that reduced the flow diversion effect of the stent and in PCOM aneurysm theoretical explanation by retrograde filling of the sac via the posterior circulation resulting in residual aneurysm filling after treatment [22].

A lager aneurysmal size is associated with low occlusion rate the same realized in many studies [9, 27, 32, 34, 36, 37]. Fetal origin PCOM artery almost always associated with failure of aneurysm occlusion [14–17]; it explains by high demand flow in large-caliber fetal PCOM artery keep the flow to it and disrupt the flow diversion effect.

Limitations

The limitations of our study are related to its retrospective design and absence of randomization and also the relatively small series of patients and shorter follow-up time. Despite these limitations, our study provides the first study concerned only with PCOM aneurysms treated by FD devices.

Conclusions

In this study, we assess the PED stent as a flow diverter device in terms of its efficacy and clinical outcomes in patients with unruptured saccular PCOM aneurysms. We found that the FD provides high aneurysm occlusion rates with lower retreatment rates. The morbidity and unfavorable mid-term clinical outcomes were not negligible when using FD devices. Caution and proper management of antiplatelet therapy are required when using FD devices to treat PCOM aneurysms.

Recommendations

Further studies on the underlying mechanism of the adverse events with a large number of patients are required.

Abbreviations

ACA: Anterior cerebral artery; ACOM: Anterior communicating artery; FD: Flow diverter; PCOM: Posterior communicating artery; PED: Pipeline Embolization Device; TIA: Transient ischemic attack; mRS: Modified Rankin Scale; ICA: Internal carotid artery; DSA: Digital subtraction angiography; MRI: Magnetic resonance imaging; MRA: Magnetic resonance angiography; OKM: O'Kelly-Marotta; CN: Cranial nerve

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Authors' contributions

A. A., M. O., and H.Y suggested and developed the research idea and reviewed the literature. M. M., P. P, H. Y., and M. A. were responsible for the data collection and analysis, perform statistical analysis, write and revise the manuscript, prepare cases and perform required measurements, and prepare figures and tables. M. M. and P.P. were responsible for reporting the clinical and angiographic outcomes of the cases during the follow-up period. All authors have a major contribution in preparing and editing the manuscript. All authors read and approved the final manuscript.

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Availability of data and materials

The data that support the findings of this study are available from Radiology department-Assiut University, but there are restrictions that apply to the availability of data, which used under license for this study and so were not publicly available. Data were available from authors upon request with permission of the head of the Radiology department- Assiut University.

Ethics approval and consent to participate

This study had approval from two tertiary institutes in Egypt (Assiut University, Faculty of Medicine Research Ethics Committee) and in France (Pierre Wertheimer Hospital, Lyon). All patients who participated in this study signed informed written consent for participation.

Consent for publication

A verbal consent to publish was obtained.

Competing interests

Authors declare that they had no competing interests.

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