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Comparison of Pipeline Embolization and Coil Embolization for the Treatment of Large Unruptured Paraclinoid Aneurysms

Ryotaro SUZUKI,[1] Tomoji TAKIGAWA,[1] Yasuhiko NARIAI,[1] Akio HYODO,[1] and Kensuke SUZUKI[1]

[1]*Department of Neurosurgery, Dokkyo Medical University Saitama Medical Center, Koshigaya, Saitama, Japan*

Abstract

The efficacy of flow diversion (FD) in the treatment of paraclinoid aneurysms has been established. The pipeline embolization device (PED) is one of the most commonly used FD devices. Coil embolization is also useful for treating paraclinoid aneurysms. This study aimed to compare the efficacy and safety of PED treatment and coil embolization for large unruptured paraclinoid aneurysms. This was a single-center, retrospective study of large unruptured paraclinoid aneurysms treated endovascularly between 2009 and 2019 (coil embolization between 2009 and 2015, and PED between 2015 and 2019). Cases with a follow-up period of less than 1 year and recurrence after coil embolization were excluded. The treatment outcomes between coil embolization and PED were compared. We investigated 45 patients with 45 large unruptured paraclinoid aneurysms treated by endovascular surgery in our institution. Twenty-four patients were treated with coil embolization and 21 with PED. In the PED group, the device cost was significantly lower (2,770.4 ± 699.5 vs. 1941.2 ± 552.8 [1000 yen], $P = 0.03$), procedure duration was significantly shorter (155.4 ± 66.7 vs. 95.1 ± 35.4 min, $P < 0.01$), and the numbers of re-treatments were lower than those in the coil embolization group (41.7 vs. 14.3%, $P = 0.05$). Both PED and coil embolization were effective and safe for large unruptured paraclinoid aneurysms, and their treatment results were similar. The PED is more beneficial because of its lower cost, shorter procedure duration, and fewer retreatments, and is therefore more useful for the treatment of large unruptured paraclinoid aneurysms.

Keywords: coil embolization, flow diversion, pipeline embolization device, unruptured paraclinoid aneurysms

Introduction

Paraclinoid aneurysms are intracranial aneurysms arising from the segment of the internal carotid artery (ICA) between the roof of the cavernous sinus and the origin of the posterior communicating artery.[1)] According to the International Study of Unruptured Intracranial Aneurysms and the Unruptured Cerebral Aneurysms Study,[2,3)] the size and location of aneurysms are leading predictors of rupture. The annual rate of rupture of large unruptured paraclinoid aneurysms with diameters of >7 mm is 1%. Therefore, the presence of such large aneurysms may be a good indication for prophylactic treatment. The anatomic structures adjacent to the segments of the ICA, including the anterior clinoid process, cavernous sinus, and ophthalmic artery, make microsurgical treatment of a paraclinoid aneurysm challenging.[4)] Consequently, endovascular techniques have been widely applied for the treatment of these cases with better results than those with microsurgical treatment.[5,6)]

In April 2011, the pipeline embolization device (PED) (Covidien, Irvine, CA, USA), which is a flow diversion (FD) device, was approved by the Food and Drug Administration for the treatment of large

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or giant wide-necked intracranial aneurysms of the proximal intracranial ICA, but not for those of the posterior communicating artery; the Japanese government approved the use of PED for the same indications in March 2015 in limited facilities. The efficacy of FD in the treatment of cerebral aneurysms has been established. The PED is one of the most commonly used FD devices in Japan. It was found to be associated with good results,[7–10] and its use in the treatment of aneurysms with diameters of <10 mm was reported recently.[11] In Japan, the application of the PED was expanded to small aneurysms in September 2020.

In facilities where FD is not available, coil embolization remains an important treatment approach for paraclinoid aneurysms. Moreover, although the usefulness of FD has been shown, few reports have compared the outcomes of FD and coil embolization in the treatment of paraclinoid aneurysms. In this single-center study, the efficacy and safety of PED treatment and coil embolization for unruptured paraclinoid aneurysms with diameters of ≥10 mm were compared. To the best of our knowledge, this is the first study to evaluate and compare the efficacy and safety of coil embolization and PED for the treatment of large unruptured paraclinoid aneurysms.

Materials and Methods

Unruptured paraclinoid aneurysms with a diameter of ≥7 mm, particularly large aneurysms, are an indication for prophylactic treatment. However, we do not refuse treatment of small aneurysms (<7 mm) at our institution if patients express a strong desire to undergo.

In the current single-center study, a total of 45 large unruptured paraclinoid aneurysms in 45 patients, treated between April 2009 to March 2019, were included. Twenty-four of these aneurysms were treated by coil embolization and the other 21 were treated using PED. Cases with follow-up periods of <1 year and recurrence after coil embolization were excluded. PED has been available in our institute since March 2015. Endovascular surgery for unruptured large paraclinoid aneurysms was performed with coil embolization before March 2015 and using PED after March 2015. After March 2015, all the large paraclinoid aneurysms were suitable for PED and treatment was successful in all cases.

The medical records of patients, including details of the radiographic characteristics, and the endovascular procedure reports were retrieved from the database and retrospectively reviewed. Patient characteristics, including age, sex, medical history (hypertension and diabetes mellitus), and smoking habit, were evaluated. Furthermore, the radiographic characteristics, including aneurysm size, neck size, dome/neck ratio and aneurysm location, were also evaluated. Paraclinoid aneurysms were categorized based on their location as those associated with the superior hypophyseal artery, ventral paraclinoid, ophthalmic artery, and carotid cave in accordance with the classification by al-Rodhan et al.[12] The patient and radiographic characteristics were compared between the coil embolization and PED groups. Further, treatment-related characteristics and outcomes, including diffusion-weighted imaging (DWI) positive rate, procedure duration, device cost, perioperative neurologic complications, modified Rankin Scale (mRS) at 1 year, complete occlusion or O'Kelly–Marotta (OKM) grading scale D at 1 year follow-up, and retreatment, were compared between both groups. The distal access catheter and other associated accessories were included in the device cost.

All patients were treated with dual antiplatelet therapy (daily dose of 100 mg of aspirin and 75 mg of clopidogrel) starting at least 7 days before the procedure. All procedures were performed under general anesthesia. After placement of the femoral sheath, systemic heparinization was initiated with a loading dose of 4000–5000 IU, and the activated clotting time was maintained at >250 s. In coil embolization, aneurysms were packed as densely as possible with coils. The decision to perform stent-assisted coil embolization was based on the risk of coil protrusion into the parent arteries with wide-necked aneurysms. In PED treatment, intradural aneurysms with inflow jet or cases in which the dome of the extradural aneurysms projected intradurally with inflow jet were simultaneously treated with coil embolization. In case of poor attachment of the PED to the wall of the parent artery, percutaneous transluminal angioplasty (PTA) was performed.

After the procedure, heparin was ceased and the patients continued antiplatelet therapy alone. Patients who underwent stent-assisted coil embolization continued to receive dual antiplatelet therapy for at least 6 months after the procedure, followed by 100 mg of aspirin or 75 mg of clopidogrel per day indefinitely, while patients without stents were treated with 100 mg of aspirin or 75 mg of clopidogrel per day for 6 months after the procedure, followed by no antiplatelet therapy. Patients who underwent PED treatment continued to receive dual antiplatelet therapy for at least 1 year after the procedure. Cases with aneurysm occlusion were observed during follow-up examination and were treated with 100 mg of aspirin or 75 mg of clopidogrel per day for the following year.

Perioperative complications were assessed based on clinical neurological symptoms and radiological findings. Perioperative complications were defined as those that occurred during hospital stay. Hemorrhagic complications were assessed by computed tomography immediately after the procedures, and ischemic complications were diagnosed by magnetic resonance imaging (MRI) with DWI after the procedure in all cases.

The angiographic outcomes of coil embolization were categorized as complete occlusion, neck remnant, or body filling in accordance with Raymond et al.'s classification.[13] The immediate angiographic outcomes were assessed using digital subtraction angiography (DSA) at the end of the treatment. Follow-up angiographic outcomes at 6 months and 1 year after treatment were assessed using MRI and magnetic resonance angiography (MRA). If the examination results were stable, MRI and MRA were performed annually thereafter. Additional follow-up angiography was performed in patients with a potential risk of recanalization, as determined by MRA, and retreatment was conducted based on the angiographic findings. No progress of the thrombus or significant recanalization in aneurysms on angiography was considered an indication for retreatment.

The angiographic outcomes of the PED were categorized based on OKM grading scale as OKM D (no filling), OKM C (entry remnant), OKM B (subtotal filling), and OKM A (total filling).[14] Follow-up angiographic outcomes 6 months after PED treatment were assessed using MRI and MRA and by angiography 1 year posttreatment. If the examination results were stable, MRI and MRA were performed annually thereafter. Additional follow-up angiography was performed in patients with suspected lack of progress of the thrombus in the aneurysm, as determined by MRA. No progress of the thrombus in the aneurysm on angiography (OKM A or OKM B) was considered an indication for retreatment.

DSA, including frontal and lateral views; three-dimensional rotational angiography; and working view were acquired on a biplane Axiom Artis QBA angiography system (Siemens, Erlangen, Germany). From the initial DSA, aneurysmal anatomic factors were measured on a dedicated workstation using syngo Workplace (Siemens).

The study was approved by the institutional ethics committee, and the requirement of informed consent was waived owing to the retrospective study design.

Statistical analysis

All statistical analyses were performed using SPSS for Mac (version 24.0 IBM Corp., Armonk, NY, USA). Continuous variables were presented as means with standard deviations. The χ^2-test and Fisher's exact test were used for categorical variables, and the Mann–Whitney U test was used for continuous variables in order to compare the two groups. A *P*-value of <0.05 was considered statistically significant.

Results

The mean age of the patients was 59.9 ± 10.6 years. The majority of the patients (24, 68.6%) were female. Twenty-seven patients (77.1%) had hypertension, 3 (6.7%) had diabetes, and 6 (13.3%) had a history of smoking. The mean aneurysm size, neck size, and dome/neck ratio were 12.6 ± 3.4 mm, 6.5 ± 2.2 mm, and 1.68 ± 0.57, respectively.

The direct comparison and examination of the 24 and 21 large aneurysms treated with coil embolization and PED, respectively, were performed. The characteristics of the patients and radiological characteristics of the aneurysms are summarized in Table 1. There was no significant difference in age

Table 1 The characteristics of the patients and radiological characteristics of the aneurysms

	Coil embolization	PED	*P* value
Cases	24	21	
Mean age (years)	60.6 ± 9.5	59 ± 11.6	0.85
Sex			
Male	7	4	
Female	17	17	0.5
Medical history			
Hypertension	15 (62.5%)	12 (57.1%)	0.77
Diabetes mellitus	1 (4.2%)	2 (9.5%)	0.59
Smoking habit	1 (4.2%)	5 (23.8%)	0.08
Aneurysm			
Size (mm)	12.9 ± 3.2	12.3 ± 3.6	0.53
Neck size (mm)	6.9 ± 2.5	6.1 ± 1.8	0.67
Dome/Neck ratio	1.6 ± 0.6	1.8 ± 0.6	0.45
Aneurysm location			
Superior hypophyseal	14	13	
Ventral paraclinoid	4	3	
Ophthalmic	4	2	
Carotid cave	2	3	0.89

PED: pipeline embolization device.

Table 2 The treatment details of coil embolization and pipeline embolization

Coil embolization (24 cases)	
Number of coils	15.3 ± 6.1
Adjunctive technique	24 (100%)
Balloon assisted	11 (45.8%)
Stent assisted	13 (54.2%)
Volume embolization ratio	37.0 ± 13.9%
Immediate angiographic outcome	
Complete occlusion	10 (41.7%)
Neck remnant	10 (41.7%)
Body filling	4 (16.6%)
Pipeline embolization (21 cases)	
Number of stents	
1	20 (95.2%)
2	1 (4.8%)
PTA	15 (71.4%)
With coils	4 (19%)

PED: pipeline embolization device, PTA: percutaneous transluminal angioplasty.

Table 3 The treatment outcomes of coil embolization and pipeline embolization

	Coil embolization	PED	*P* value
Cases	24	21	
DWI positive	16 (66.7%)	16 (76.2%)	0.53
Procedure duration (min)	155.4 ± 66.7	95.1 ± 35.4	<0.01
Device cost (1,000 yen)	2270.4 ± 699.5	1941.2 ± 552.8	0.03
Perioperative neurologic complications	4 (16.7%)	4 (19%)	0.93
Transient	4	3	
Permanent	0	1	
Ischemic	4	2	
Hemorrhagic	0	0	
Neuropathy	0	2	
Delayed complications	1	1	
mRS at 1 year			
0–2	23 (95.8%)	19 (90.5%)	
3-	1 (4.3%)	2 (9.5%)	0.59
Complete occlusion or OKM D at 1 year	15 (62.5%)	17 (81%)	0.2
Retreatment	10 (41.7%)	3 (14.3%)	0.05
Time to retreatment (month)	18.3 ± 13.0	8.5 ± 4.5	
Follow-up period (month)	55.0 ± 22.9	23.1 ± 9.5	<0.01

DWI: diffusion-weighted imaging, mRS: modified Rankin Scale, OKM: O'Kelly–Marotta grading scale, PED: pipeline embolization device.

(*P* = 0.85), sex (*P* = 0.50), medical history, smoking habit (*P* = 0.08), aneurysm size (*P* = 0.53), neck size (*P* = 0.67), dome/neck ratio (*P* = 0.45), and aneurysm location (*P* = 0.89) between the two groups.

The treatment details are summarized in Table 2. In coil embolization, 15.3 ± 6.1 coils were used on average. Thirteen aneurysms (54.2%) were treated using stent-assisted coil embolization and 11 (45.8%) using balloon-assisted coil embolization. The mean volume embolization ratio was 37.0 ± 13.9%. Immediate angiographic outcomes of complete occlusion, neck remnant, and body filling were achieved in 10 (41.7%), 10 (41.7%), and 4 (16.6%) aneurysms, respectively. In PED treatment, almost all cases were treated using only one PED, and only one case was treated using two PEDs; PED was used in combination with coil embolization in 4 (19%) aneurysms and with PTA in 15 (71.4%) aneurysms.

The treatment outcomes of PED and coil embolization have been compared in Table 3. There were no significant intergroup differences in the DWI-positive rate (*P* = 0.53), aneurysmal complete occlusion (complete occlusion or OKM D) rate at 1 year (*P* = 0.2), and the mRS at 1 year (*P* = 0.59). Only 3 cases had an mRS ≥3 at 1 year. Of them, one and two cases were treated by coil embolization and PED, respectively. In one case of stent-assisted coil embolization, cerebral infarction developed 2 months after the procedure as a result of self-interruption of antiplatelet therapy, and hemiparesis occurred. One patient in the PED group developed intracerebral hemorrhage 1 month postoperatively, and hemiparesis occurred. Another patient in the PED group who was simultaneously treated with coil embolization had edema around the aneurysm before the procedure. The edema gradually worsened after PED placement, and disturbance of consciousness progressed. Aneurysm occlusion could not be obtained, and retreatment was performed 4 months postoperatively.

Eight (17.8%) perioperative neurologic complications occurred (1 permanent and 7 transient), including 4 (16.7%) after coil embolization and

4 (19%) after PED treatment. There were no significant differences in the perioperative neurologic complication rates between the two groups ($P = 0.93$). New visual symptoms were observed in 2 patients with PED treatment (1 patient had transient oculomotor nerve disorder and the other had permanent optic nerve disorder). In one case of optic nerve disorder, the patency of the ophthalmic artery was confirmed, which may have from a microembolism in the ophthalmic artery. In both cases of oculomotor nerve disorder, large, inward-looking aneurysms having a diameter of approximately 15 mm were presented near the cavernous sinus, and it is possible that the mass effect increased transiently after PED placement and led to the appearance of symptoms.

The device cost was significantly lower (2,270.4 ± 699.5 [1,000 yen] vs. 1941.2 ± 552.8 [1000 yen], $P = 0.03$) and the procedure duration was significantly shorter (155.4 ± 66.7 min vs. 95.1 ± 35.4 min, $P < 0.01$) in the PED group. The numbers of retreatment were lower in the PED group (41.7 vs. 14.3%, $P = 0.05$) compared to those in the coil embolization group. There were three cases of retreatments in the PED group. Two of them were retreated for incomplete occlusion. In the third case, the initial PED treatment had been performed in combination with coil embolization with exacerbation of edema around the aneurysm, and retreatment was performed because the aneurysm enlarged and recanalized.

The mean follow-up period was 55.0 ± 22.9 months in the coil embolization group and 23.1 ± 9.5 months in the PED group. None of the cases presented delayed rupture of the treated aneurysms during the follow-up period.

Discussion

In the Japanese cohort, the annual rupture rate of paraclinoid aneurysms was approximately 0.1%, 1%, and 10%, for aneurysms of sizes <7 mm, 7–24 mm, and >25 mm, respectively.[3] Therefore, the presence of aneurysms with diameters ≥7 mm, particularly large aneurysms, may be a good indication for prophylactic treatment.

Both PED and coil embolization were effective and safe for the treatment of large unruptured paraclinoid aneurysms. Previous studies have reported an incidence of 1–8.6% for neurologic complications and of 5–23% for the rate of retreatment with coil embolization for paraclinoid aneuryms.[15–20] In the present study, neurological complications developed in 4 of the 24 (16.7%) patients treated with coil embolization, and 10 (41.7%) of them required retreatment; these figures are higher than those reported in previous studies, which may be because, unlike the present study, those studies included small aneurysms as well. Neurologic complications and recurrence rates have been shown to be correlated with the aneurysmal size; large aneurysms have been described as significant predictors for neurologic complications and retreatment.[6,15,20–22]

Regarding the PED treatment, previous studies have reported an incidence of 3.4–31.7% for neurologic complications and of 0.9–15% for the rate of retreatment.[7,9,10,23–30] In the present study, neurologic complications developed in 4 of the 21 (19%) patients in the PED group and 3 (14.3%) of them required retreatment; these findings are similar to those observed in previous studies. In the present study, the rate of neurologic complications and retreatment was relatively frequent because only large aneurysms were included. Large aneurysms are reportedly significant predictors for neurologic complications following PED treatment.[9] Kallmes et al.[9] reported an 8.7% rate of neurologic complications in ICA aneurysms >10 mm, higher than the rate of 4.5% in ICA aneurysms <10 mm.

Direct comparisons between coil embolization and FD devices have been reported[23,24,26,31–35]; however, this is the only study to directly compare coil embolization and PED treatment in large unruptured paraclinoid aneurysms.

We observed that retreatment was required less frequently in the PED group, a result similar to that in previous studies.[24,25,36,37] However, all previous studies included small aneurysms or aneurysms in locations other than the ICA. Further, previous studies reported that the need for retreatment was equivalent in both groups.[23,26]

Although previous studies included small aneurysms, aneurysms in locations other than the ICA, or FD approaches other than the PED, the reported cost of FD treatment was lower than that for coil embolization,[25,34,35,37,38–41] especially when 9 or more coils were required during the coil embolization procedure.[34] However, almost all previous studies reported the costs for the entire hospital stay, including device costs. Coby et al.[40] reported a lower cost of implants and of the total procedure in the PED group. PED appears to be more useful than coil embolization from a medico-economic perspective.

There are few reports on procedure duration.[9,28–30] However, direct comparisons of the procedure duration between coil embolization and FD devices have not yet been reported. The procedure duration was reported in three large studies on PED (Pipeline for Uncoilable or Failed Aneurysms Study,[30] International Retrospective Study of the Pipeline Embolization Device,[9] and Aneurysm Study of Pipeline

in an Observational Registry[29]). Kallmes et al.[28] reported that the mean procedure duration of the three large studies conducted on PEDs was 105.7 ± 53.1 min. The mean procedure duration in the present study was 101.4 ± 41.2 min, which is similar to that in the previous studies. Based on our results, the procedure duration was significantly shorter in the PED group than in the coil embolization group, which has not been previously reported. Various factors influence procedural duration. Since in our institution, both treatment procedures were performed by the same team, differences between the operating teams can be effectively ruled out. The difference in the procedure duration could be attributed to the time-consuming nature of the placement of each coil in coil embolization and the use of 16.3 ± 5.99 coils on average per patient. It is therefore easy to justify how PED treatment requires a shorter duration than coil embolization. The benefits of a shorter procedure duration include a shorter anesthesia time and consequently, less invasive treatment.

Because the application of PED has been expanded to small aneurysms, FD may become the mainstream treatment for paraclinoid unruptured aneurysms in Japan. FD can theoretically be the treatment of choice in paraclinoid aneurysms as there are no important perforating arteries in this region and covering the ophthalmic artery with FD seems to be well tolerated.[25] Acceptable outcomes have been reported with FD for paraclinoid aneurysms.[7–11] A previous study found no significant differences in the complication rates of FD and coil embolization for small aneurysms in the ICA (<10 mm), though higher occlusion rates were noted with the FD.[40] Nonetheless, FD is associated with its unique complications, such as delayed migration of the device, distal parenchymal hemorrhage, aneurysmal rupture due to degradation of the aneurysmal wall, or endoleak.[25,36,42–44]

Limitations

There are several limitations to the present study. This was a retrospective single-center study with a small cohort. The follow-up was significantly shorter in the PED group than in the coil embolization group. The outcomes of PED and coil embolization in the treatment of small aneurysms were not assessed because the application of PED was only recently expanded to small aneurysms in Japan.

Conclusions

To our knowledge, this is the only study to directly compare coil embolization and PED in large unruptured paraclinoid aneurysms.

Both PED and coil embolization were effective and safe treatment procedures for large unruptured paraclinoid aneurysms. PED is more beneficial because of its lower cost, shorter procedure duration, and lower rate of retreatment, and is therefore a more useful treatment for unruptured paraclinoid aneurysms.

Conflicts of Interest Disclosure

There are no conflicts of interest to declare.

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Corresponding author: Ryotaro Suzuki, MD
Department of Neurosurgery, Dokkyo Medical University Saitama Medical Center, 2-1-50 Minamikoshigaya, Koshigaya, Saitama 343-8555, Japan.
e-mail: ryo096943@gmail.com