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ORIGINAL RESEARCH

Radiation dose analysis of large and giant internal carotid artery aneurysm treatment with the pipeline embolization device versus traditional coiling techniques

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ABSTRACT

Background Flow diversion is an effective and increasingly accepted method for endovascular treatment of cerebral aneurysms. Additionally, the public has heightened concerns regarding radiation exposure from medical procedures. This study analyzes radiation dose and fluoroscopy time during treatment of large and giant proximal internal carotid artery (ICA) aneurysms with the pipeline embolization device (PED) versus traditional coiling techniques.

Methods Radiation dose, fluoroscopy time, and contrast dye administration were retrospectively analyzed in 55 patients undergoing endovascular treatment of aneurysms ≥10 mm from petrous to superior hypophyseal ICA segments. Patients were treated by either PED (37 patients) or traditional coiling techniques (18 patients). Aortic arch type and proximal ICA tortuosity were also assessed as markers of access difficulty.

Results Average radiation dose with PED treatment was 2840±213 mGy and 4010±708 mGy with traditional coiling techniques (p=0.048; 29% decrease with PED). Mean fluoroscopy time for PED was 56.1±5.0 min and 85.9±11.9 min for coiling cases (p=0.0087; 35% decrease with PED). These benefits existed despite more difficult arch anatomy and a trend towards greater proximal vessel tortuosity in PED cases. Contrast dye amounts were also reduced by 37.5% in PED cases (75±6 mL) versus coiling cases (120±13 mL, p=0.0008).

Conclusions Treatment of large and giant proximal ICA aneurysms using PED requires less radiation, less fluoroscopy time, and less contrast administration than standard coiling techniques. This further demonstrates the benefits of flow diversion for treatment of these aneurysms.

INTRODUCTION

Efforts to reduce ionizing radiation exposure from diagnostic medical imaging and interventional radiologic procedures have received increased attention in recent years. The effects of radiation on cellular DNA can lead to short term and long term adverse health issues, including skin injury, cataracts, and carcinogenesis.[1] These are of paramount concern to both patients and healthcare workers.

Endovascular treatment of cerebral aneurysms requires the use of fluoroscopy for real time intraprocedure monitoring of catheters, wires, and for device deployment. Additionally, digital subtraction angiography (DSA), a form of fluoroscopy, is utilized for assessing the aneurysm and parent vessels before, during, and after treatment. The dose absorbed by the patient in these procedures is a product of numerous functions, including the intensity of the X-ray beam, the size of the field, the type of acquisition, and the length of the procedure.[2]

Flow diversion has rapidly become an accepted technique for intracranial aneurysm treatment, particularly for large and giant wide neck and fusiform proximal internal carotid artery (ICA) aneurysms. This technique, using devices such as the pipeline embolization device (PED), is an alternative to more traditional endovascular treatments for these aneurysms, including stent assisted coiling and parent vessel sacrifice. Many studies have demonstrated the efficacy, safety, and cost effectiveness of PED embolization for these complex aneurysms.[3–10] However, less is known about radiation exposure for various endovascular aneurysm treatments, particularly with respect to newer flow diverter techniques.

Chalouhi *et al*[10] demonstrated statistically significant longer fluoroscopy times for stent assisted coiling cases compared with PED cases. However, fluoroscopy time is only a surrogate for actual radiation exposure, which can be influenced by numerous variables, including fluoroscopy pulse rate and acquisition frame rate.

We present the first study, to our knowledge, that compares radiation doses from aneurysm treatment with the PED versus treatment with more traditional coiling procedures in ICA aneurysms ≥10 mm. Additionally, we analyzed contrast dye administration in these different treatment groups.

METHODS

Study design

The study was an institutional based, nonrandomized, retrospective cohort study from a prospectively collected aneurysm database.

Patient selection

All patients treated at the Johns Hopkins Hospital and Johns Hopkins Bayview Medical Center (Baltimore, Maryland, USA) by endovascular techniques with ICA aneurysms ≥10 mm from the petrous to superior hypophyseal segments from April 2011 to December 2013 were included in the study. Patients selected for the study were treated in series.

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All patients presented with unruptured aneurysms. Patients presenting with severe headache and clinical suspicion of subarachnoid hemorrhage were screened with a CT scan of the head and lumbar puncture, as indicated, to rule out hemorrhage.

Endovascular procedure

Aneurysm treatments were performed on a biplanar flat panel angiographic system (Artis zee, Siemens, Erlangen, Germany) under general anesthesia. All patients were treated preoperatively with a dual antiplatelet regimen consisting of aspirin 325 mg daily and clopidogrel 75 mg daily for 7 days prior to treatment. All procedures were performed with systemic anticoagulation consisting of a bolus dose of 5000 units of heparin administered at the start of each case followed by an intraprocedure re-bolus of 1000 units every hour. Accurate vessel size measurements for the parent vessel were determined from calibrated standard DSA images, either at the time of the intervention or from the preceding diagnostic angiogram.

For PED deployment, a triaxial system was used through femoral access, as previously described.[5 11] This consisted of a Flexor Shuttle sheath (Cook Medical, Bloomington, Indiana, USA), a distal intracranial support catheter, and a Marksman microcatheter (Covidien Vascular Therapies). PEDs were deployed, under real time visualization, using a combination of native fluoroscopy (7.5 pulses/s), roadmap, and DSA (3 frames/s). The distal PED was opened in the ipsilateral supraclinoid ICA or, more commonly, in the ipsilateral M1 segment. Proper device expansion and deployment was assessed with native fluoroscopy and DynaCT. Balloon angioplasty was used to dilate a short segment of the PED if it did not fully expand. In two cases, coils were placed in the aneurysm in conjunction with the PED. Control DSA was performed immediately after deployment and at 5 and 10 min after deployment to confirm vessel wall apposition, patency of the parent vessels, and to rule out intraluminal thrombus. Intra-deployment DSA runs were not routinely performed. At the end of the procedure, a DynaCT scan without contrast was performed to assess PED morphology and to evaluate for intracranial hemorrhage.

Coiling procedures were performed on a similar biplane angiographic system under general anesthesia. Systemic anticoagulation with heparin was used for all procedures in a similar fashion to the PED procedures. Coiling cases were performed with either biaxial or triaxial systems. Stents were used for aneurysms with wide necks and for aneurysms that involved significant circumferential portions of the parent vessel. DSA was performed prior to the embolization to assess aneurysm size, post-stent deployment, during coiling, and at the end of the procedure.

After the procedure, patients were monitored overnight in a neurocritical care unit. Most patients were discharged home on the first postoperative day.

Data collection and statistical analysis

Data collected included patient demographics, aneurysm size (mm) and location, treatment modality, radiation dose (mGy), total fluoroscopy time (minutes), number of DSA acquisitions, aortic arch type, presence of cervical carotid tortuosity, and volume of contrast administered (mL), obtained from operative reports and review of the images, and compiled into the prospectively collected database.

Data are presented as counts, percentages, and means. When means are presented, the SEM is used to assess sample distribution. Two tailed unpaired t tests were used to compare means. A probability value of <0.05 was considered statistically significant.

RESULTS

Patient demographics and aneurysm characteristics

Following US Food and Drug Administration approval of the PED, 37 patients were treated with PED embolization that met on-label criteria (ICA aneurysms ≥10 mm from the petrous to superior hypophyseal segments) from April 2011 to December 2011. Two of these patients were treated with adjunctive use of coils at the time of PED embolization. Within a similar time period, 18 patients fulfilling the same on-label criteria were treated with traditional endovascular techniques: nine patients with single stage stent assisted coiling, five patients with multistage stent assisted coiling, three patients with coiling alone, and one patient with parent vessel sacrifice.

Patient demographics and aneurysm characteristics are presented in table 1. Ninety-one per cent of the PED treated patients were women compared with 83% of the stent coiling patients ($p=0.67$). The two groups were similarly matched in age (PED 60.0±2.1 years, coiling 62.3±1.9 years; $p=0.49$). The mean aneurysm size was also similarly matched in the two groups, with a size of 14.9±1.5 mm in the coiling group and 13.5±0.6 mm in the PED group ($p=0.35$). The coiling group had a greater percentage of clinoidal/paraophthalmic aneurysms (78%) than the PED group (54%), and a smaller percentage of cavernous aneurysms (22% vs 46%, respectively).

Access data (arches, tortuosity)

Aortic arch characteristics and cervical internal carotid tortuosity were assessed as surrogate markers of general access difficulty, and these data are presented in table 2. Aortograms were available for 8/18 (44.4%) of the coiling cases and for 26/37 (70.2%) of the PED cases. Of the patients with an aortogram, most had type 1 aortic arch (76.9% of the coiling patients vs 61.5% of the PED cases). Type 2 aortic arch was present in approximately 25% of cases in both groups. Type 3 arch was present in 15.4% of PED patients and in 0% of the stent coiled patients, and this was statistically significant ($p=0.043$).

Cervical ICA tortuosity (defined as a 90° turn, hairpin turn, or corkscrew loop) was defined as previously described.[12] Eight of the 18 (44.4%) coiling patients and 25/37 (67.6%) of the PED patients had tortuosity. This was not statistically significant

Table 1 Patient demographics and aneurysm characteristics

	Coiling	Pipeline	p Value
No of patients	18	37	
Patient distribution			
Single stage stent coil	9	0	
Multistage stent coil	5	0	
Coiling	3	0	
Parent vessel sacrifice	1	0	
Pipeline	0	35	
Pipeline+coils	0	2	
Sex (n (%))			0.67
Male	3 (17)	3 (9)	
Female	15 (83)	34 (91)	
Age (years)	62.2±1.9	60.0±2.1	0.49
Aneurysm size (mm)	14.9±1.5	13.5±0.6	0.35
Location (n (%))			
Cavernous	4 (22)	17 (46)	
Clinoid/paraophthalmic	14 (78)	20 (54)	

Values are mean±SEM.

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Table 2 Aortic arch type and cervical carotid tortuosity

	Coiling	Pipeline	p Value
Aortic arch classification (n (%))			
Type 1	6 (75.0)	16 (61.5)	0.492
Type 2	2 (25.0)	6 (23.1)	0.918
Type 3	0 (0)	4 (15.4)	0.043
No arch aortogram	10	11	
Cervical tortuosity (n (%))	8 (44.4)	25 (67.6)	0.117

(p=0.117), but the trend was for more tortuosity in the PED group.

Radiation and contrast dye analysis

Analysis of mean radiation dose, fluoroscopy time, contrast dye administration, and number of DSA runs is presented in table 3. Mean radiation dose for aneurysm treatments with PED was 2840±213 mGy and 4010±708 mGy for coiling procedures (p=0.048). This represented a 29% decrease in mean radiation dose for PED cases. Mean fluoroscopy times for PED were 56.1 ±5.0 min and 85.9±11.9 min for coiling cases (p=0.0087). This represented a 35% decrease in mean fluoroscopy time for PED cases. There was also a statistically significant difference in contrast used, with 75±6 mL and 120±13 mL of iohexol 300 during PED and traditional cases, respectively. This represented a 37.5% decrease for PED cases. The number of DSA runs was not statistically different between the two groups (PED 7.02 ±2.72, coiling 8.23±3.90; p=0.0924).

DISCUSSION

Advances in endovascular techniques and devices have led to an increasing proportion of cerebral aneurysms being treated by endovascular means.[13 14] Concomitantly, there has been a push to reduce radiation exposure to the patient and operator.[15 16] In this report, we demonstrate that endovascular treatments of anterior circulation aneurysms ≥10 mm from the petrous to superior hypophyseal segments of the ICA with the PED have statistically significant lower radiation dose, lower fluoroscopy time, and lower intraprocedure contrast administration than coiling treatments of similar aneurysms.

Radiation exposure can cause stochastic and non-stochastic effects. Stochastic, or delayed (years after exposure), effects include cancers in exposed individuals and mutations in the offspring of the exposed. Radiation dose is thought to correlate with the probability of the stochastic effect, but not its severity. Non-stochastic, or deterministic, effects (days–weeks after exposure) include tissue damage secondary to local cell damage or death. These include cataracts, skin damage, hair loss, and infertility. Radiation dose is thought to correlate directly with the severity of the deterministic effect.[16]

A recent study by Peterson *et al*[15] quantified the rates of skin and hair complications from radiation exposure in 702 endovascular neurosurgical cases. They reported that 39.6% of patients receiving >2 Gy radiation developed subacute hair and skin changes, with permanent skin and hair changes reported in 30% of these cases. Radiation exposure exceeded 2 Gy in 72.1% of interventional treatment procedures, with median entrance skin dose for aneurysm embolization via coiling being 3.55 Gy (46 procedures). These results corroborate data from the Radiation Dose in Interventional Radiology multicenter study, demonstrating that over 75% of neurointerventions had radiation exposure over the 2 Gy threshold, and 25% of the procedures exceeded 5 Gy dose.[17–19]

The mean radiation dose for PED cases (2.8 Gy) reported in the current study is above the 2 Gy threshold, but it is also significantly less than the average dose of 3.55 Gy reported by Peterson *et al*[15] for aneurysm coilings. Our mean dose of 4.0 Gy for coiling cases is only mildly higher than the 3.55 Gy value reported by Peterson *et al*; however, aneurysm size was not specified for their 46 cases. Moreover, the current study includes only aneurysms ≥10 mm, and endovascular treatment of aneurysms >10 mm is associated with longer fluoroscopy time and total procedure time than for aneurysms <10 mm.[15] Two cases in the PED group also had adjunct coils placed during the embolization. Radiation doses for these cases was 2.5 Gy and 3.6 Gy, with one below and one above the mean of 2.8 Gy for the group. Adjunct use of coils is rare in PED cases and, when used, the aneurysm is typically lightly packed. Although the number of pipeline–coil cases in our study is small, they do not seem to significantly influence the results.

Chalouhi *et al*[10] analyzed fluoroscopy and procedure times in 127 patients treated with the PED, 86 patients treated with single stage stent assisted coiling, and 16 patients treated with Onyx HD 500. Fluoroscopy and procedure times were used as proxies for radiation exposure. The authors found that mean fluoroscopy time was significantly increased in the stent coiling group (55±31 min) and Onyx HD 500 group (91±36 min) compared with the PED group (34±23 min). Mean procedure time was also significantly longer for the coiling (155±50 min) and Onyx HD 500 (176±65 min) groups compared with the PED group (PED 131±36 min; p<0.001). Stent coiling and Onyx HD 500 were independent predictors of longer procedure and fluoroscopy times in multivariate analysis, despite a smaller mean aneurysm size in the stent assisted coiling group (7.5 mm vs 10 mm in the PED group). The aneurysm size difference in their study further accentuated the results that fluoroscopy and procedure times in PED cases were smaller. Our results mirrored these findings, with longer fluoroscopy time in the coiling group (85.9±11.9 min) compared with the PED group (56.1 ±5.0 min, p=0.0087), although our aneurysm sizes were better matched without statistically significant differences.

Difficult aortic arch anatomy and tortuosity can increase procedure time necessary to gain access and set up the device delivery systems. Longer procedure times would lead to longer fluoroscopy times and likely higher radiation doses. Chalouhi *et al*[10] postulated that PED cases would be particularly influenced by arch anatomy and carotid tortuosity because larger diameter access systems (0.027 inch inner diameter catheters) are used for PED deployment. We assessed aortic arch classification and cervical ICA tortuosity as a surrogate for access difficulty and therefore longer fluoroscopy time. We reported a statistically significantly larger number of PED cases with

Table 3 Radiation and contrast data

	Coiling	Pipeline	p Value
Total fluoroscopy time (min)	85.9±11.9	56.1±5.0	0.0087
Radiation dose (mGy)	4010±708	2840±213	0.0476
Contrast (mL)	120±13	75±6	0.0008
DSA acquisitions per case	8.2±3.9	7.0±2.7	0.0924

Values are mean±SEM.
DSA, digital subtraction angiography.

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difficult type III arches (15.4% vs 0% for coiling; p=0.043); however, this result is potentially biased by the lack of aortograms available for all cases. Additionally, there was a trend towards more cervical tortuosity in the PED cases versus the coiling group, but these were not statistically significant (arch p=0.1186, tortuosity p=0.6308). These trends further support our results that PED cases have lower radiation exposure despite more difficult anatomy and access.

Lower radiation doses observed in the PED group are likely linked to reduced overall fluoroscopy times. The PED deployment time is longer than a self-expanding stent used to assist coiling procedures, so the reduction in fluoroscopy time for this group is from lack of coil placement. Vanzin *et al*[20] reported a mean of 16.1 and 28.7 coils necessary to occlude a large and giant aneurysm, respectively. In general, procedure time and fluoroscopy time are directly proportional to the number of coils deployed, which is directly proportional to aneurysm size. In PED cases, the use of multiple PEDs and use of post-processing (eg, balloon dilation) can negatively influence fluoroscopy time. However, the availability of longer devices and the improved technique secondary to operator experience can limit these influences.

Acquisition type can also influence the total radiation dose. We hypothesized that PED cases used fewer high dose DSA runs because the PED is deployed primarily with native fluoroscopy and single shot acquisitions. We further hypothesized that fewer DSA runs would result in lower total contrast dye administration during the case. The trend was for fewer DSA cases in PED cases (7.0±2.7 runs vs 8.2±3.9 runs for the coiling group); however, contrary to our hypothesis, the difference was not statistically significant. Despite similar use of DSA, less contrast dye was used during PED cases (75±6 mL) than during coiling cases (120±13 mL, p=0.0008). This difference is likely secondary to contrast used during access and for intraprocedure roadmaps. Reduced contrast dye administration is more favorable, particularly in patients with baseline impaired renal function. For this reason, aneurysm treatment with the PED can be considered as an alternative to coiling in patients with poor renal function secondary to lower contrast use.

This study demonstrated reduced radiation doses when the PED was used for the initial aneurysm treatment of ICA aneurysms ≥10 mm; however, there are likely extended radiation dose benefits after PED treatment. Six month angiographic occlusion rates following PED treatment range from 81.8% to 94.4%,[3–5 7–10] and there is initial evidence that similar rates can be achieved even sooner in smaller aneurysms.[11] Additionally, once an aneurysm is occluded after PED embolization, there has not been a single reported case of recurrence in the literature. Although long term follow-up for these devices is limited, the lack of aneurysm recurrence excludes future radiation exposure from re-treatment. In contrast, aneurysms treated by coiling and stent assisted coiling can have recurrence rates of 35.9% and 15.4%, respectively.[21] Re-treatment in these cases certainly increases radiation exposure to the patient.

The experience of the interventionalist is an important determinant of procedure length and therefore fluoroscopy time, radiation dose, and amount of contrast used. Of note, this study included cases from our initial experience with the PED, specifically the initial 10 on-label cases required for PED certification. These early cases presumably had longer procedure times than subsequent cases secondary to the steep learning curve of PED techniques. Including early PED cases actually strengthens our results and the conclusions of the study. We would expect that excluding these cases would lead to further reductions in the radiation dose, fluoroscopy time, and contrast administered in the PED group. Additionally, all of the PED cases included in this study were performed using the first generation PED. The second generation PED is expected to have improved deliverability, and we would expect that technological improvements in the second generation device would provide additional reductions in radiation and contrast doses.

Limitations of the present study include retrospective review, limited sample sizes, and single center study. ICA aneurysms ≥10 mm from the petrous to superior hypophyseal segments are relatively uncommon compared with smaller aneurysms, which limits aneurysms available for inclusion in the study. Procedure bias was reduced in this study by including cases performed within a similar timeframe. This insured that equipment used, fluoroscopy settings, and access techniques were similar between the two study groups.

CONCLUSION

This study demonstrates that treatment of large and giant proximal ICA aneurysms using the PED requires less radiation (29% decrease), less fluoroscopy time (35% decrease), and less contrast administration (37.5% decrease) than known coiling techniques. This enhances the growing body of literature demonstrating the efficacy and cost effectiveness of flow diversion for treatment of these difficult aneurysms. Although further studies are necessary, there is a potential health benefit to patients and operators secondary to these lower radiation doses. Reduction of radiation doses, as demonstrated, also helps to address the heightened public concern for radiation exposure from medical therapies.

Contributors All authors contributed to the design, implementation, and writing of this manuscript.

Competing interests ALC is a proctor for the pipeline embolization device (Covidien, Mansfield, Massachusetts, USA) and a consultant for Covidien. GPC is a consultant for Covidien.

Ethics approval The study was approved by the institutional review board.

Provenance and peer review Not commissioned; externally peer reviewed.

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