Impact of Endovascular Technique on Fluoroscopy Usage: Stent-Assisted Coiling versus Flow Diversion for Paraclinoid Internal Carotid Artery Aneurysms

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SUMMARY – *Flow diversion is increasingly being utilized for the treatment of internal carotid artery (ICA) aneurysms. The purpose of this study was to evaluate the impact of endovascular technique--flow diversion versus stent-assisted coiling (SAC) on fluoroscopy time in patients treated for wide-neck paraclinoid ICA aneurysms. A retrospective review identified the 20 most recent consecutive patients treated for wide-neck paraclinoid ICA aneurysms by flow diversion and SAC respectively. Fluoroscopy time, cumulative dose area-product (DAP), contrast usage, intra-procedural complications, and total procedure time were collected and compared between the two treatment techniques. Treatment groups were comparable in terms of demographics, contrast usage, and clinical and angiographic outcomes. Flow diversion was associated with a significant reduction in fluoroscopy time (52.0 minutes versus 77.4 minutes), and demonstrated a strong trend towards shorter total procedure time (172 minutes versus 202 minutes). Average patient radiation exposure as measured by DAP was lower in the flow diversion group, 13225 mGy*cm² versus 15124 mGy*cm², although this finding was not statistically significant. There was no significant difference in contrast usage between the two groups, 152 ml and 159 (flow diversion and SAC respectively). The rate of complete aneurysm occlusion was higher in the flow diversion group (80% versus 60%). Endovascular treatment of paraclinoid ICA aneurysms with flow diversion is associated with shorter fluoroscopy times compared to stent-assisted coiling. There is also a likely reduction in overall procedure time. These results should be considered when recommending a treatment course for patients with such lesions.*

Introduction

Flow diversion with the pipeline embolization device (PED) (ev3, Irvine, CA, USA) is becoming an increasingly utilized technique for the treatment of wide-neck internal carotid artery (ICA) aneurysms arising proximal to the posterior communicating artery origin. Previously published reports have established the efficacy of this approach, with high rates of complete aneurysm occlusion at six to 12 months following PED deployment, even for large or giant aneurysms¹⁻⁸. Furthermore, there appears to be greater durability of aneurysm closure following flow diversion than

after coiling or stent-assisted coiling (SAC), although more long-term follow up data are needed^{4,9-14}. Finally, despite concerns regarding potential complications of flow diversion, including delayed aneurysm rupture, stroke, and intraparenchymal hemorrhage remote from the treatment site, a recent meta-analysis of published series found overall procedure-related morbidity and mortality rates of 5% and 4% respectively². Even more favorable outcomes were noted with lesions either small in size or located in the anterior circulation². These results compare favorably to reported morbidity and mortality rates of coiling, with or without stent assistance^{12,13,15}.

Although various prior studies have evaluated the safety and efficacy of flow diverters for aneurysm embolization, the influence of this technique on patient radiation exposure has not been adequately examined. The purpose of our study was to compare the effect of endovascular technique - flow diversion or single stage SAC - on fluoroscopy time and radiation exposure in patients treated exclusively for paraclinoid ICA aneurysms. We defined paraclinoid as an ICA aneurysm arising anywhere from the ophthalmic artery origin to proximal to the posterior communicating artery. Our goal was to minimize potential confounding variables that may affect fluoroscopy usage, such as overall procedure complexity, by matching treatment groups by lesion location.

Methods

Patients and Study Methods

The protocol of this retrospective study was approved by our institutional review board. We identified the 20 most recent consecutive patients treated by flow diversion of an ICA paraclinoid aneurysm at our institution. Patients in the flow diversion group were treated over a 14-month period from September 2012 through October 2013. We then identified the 20 most recent consecutive patients treated by single stage SAC of a paraclinoid ICA aneurysm. Patients in the SAC group were treated over a 34-month period from July 2010 through May 2013. All lesions demonstrated either a wide neck (> 4 mm) or an unfavorable dome to neck ratio ($< 1.5:1$). In the time that both flow diversion and SAC were available as treatment options at our institution, the decision as to which method was utilized was based on the clinical judgment and preference of the operating physician.

All patients except two in the SAC group were electively treated for unruptured aneurysms. Two patients treated by SAC had recently ruptured paraclinoid aneurysms that were not felt to be amenable to either microsurgical repair (secondary to location) or coil embolization without a stent (secondary to unfavorable neck to dome ratios). There was no instance of treatment failure by either technique of a paraclinoid ICA aneurysm in the time period included in the study. Recurrent or residual paraclinoid ICA aneurysms presenting after prior coiling or SAC were not included in the study.

Fluoroscopy Time and Radiation Exposure

Total fluoroscopy time was obtained from data generated from one of two Siemens (Munich, Germany) biplane fluoroscopy units. Total procedure time and volume of iodinated contrast administered were obtained from procedure reports available on operative records and our PACS. Aneurysm diameter, volume, and neck size were obtained from both procedure reports as well as from rotational 3D and 2D angiograms available on PACS. If more than one paraclinoid aneurysm was treated by flow diversion, the maximum diameter and volume of only the largest aneurysm was included in subsequent statistical analysis. Patient demographics, procedural details, and patient outcomes were obtained from the PACS and patients' electronic medical records.

Fluoroscopy time, total procedure time, and contrast volume were recorded for all patients in the flow diversion group. In the SAC group, fluoroscopy time data were available for all patients. Total procedure time was not documented in six patients following SAC, while three patients did not have contrast volume recorded.

Procedure Details

All patients were treated under general anesthesia. SAC was performed with a 6 French guide catheter placed in the cervical ICA. The stenting microcatheter was then advanced in the parent vessel across the aneurysm neck followed by placement of the coiling microcatheter into the lesion. Excelsior SL-10 (Boston Scientific, Fremont, CA, USA) and Prowler Select Plus (Cordis Neurovascular, Miami, FL, USA) microcatheters were most commonly utilized for coil embolization and stent deployment respectively. The stent was then deployed followed by coil embolization of the aneurysm through the jailed microcatheter. An Enterprise stent (Cordis Neurovascular) was most commonly used (18 of 20 patients, 90%) while in two cases SAC was performed with a Neuroform EZ stent (Stryker Neurovascular, Fremont, CA, USA).

Flow diversion was accomplished using a tri-axial system by placement of a 6 French shuttle sheath into the ipsilateral common carotid artery followed by advancement of an intermediate distal access catheter through the sheath with its tip positioned in the petrous or cavernous ICA. Next, a Marksman (ev3) microcatheter was navigated into either the supraclinoid ICA or the M1 arterial segment of the ipsilat-

eral middle cerebral artery. A PED was then deployed across the aneurysm neck through the microcatheter using a standard technique. The decision to deploy more than one PED in treatment of an aneurysm was determined by whether the first device provided adequate coverage of the aneurysm neck (approximately 5 mm of device both proximal and distal to the aneurysm neck) as well as lesion characteristics (large size, marked irregularity).

Patient Follow-up

Patients were evaluated in our neuro-interventional clinic generally two weeks following the procedure, as well as at three, six and 12 months. Although no standard imaging follow-up regimen was utilized for all patients, a post-procedure early follow-up gadolinium-enhanced MRA was typically performed within three months following treatment. Follow-up catheter angiography was usually performed six to 12 months following embolization.

Statistical Analysis

We used SYSTAT 12 (SPSS Science, Chicago, IL, USA) for analyses. We employed Lilliefors' test to determine distributions. To explore differences between the two groups we used the Mann-Whitney U test because of skewed distribution of data in one or two groups. We considered a probability level of <0.05 as significant.

Results

Eighteen patients in the flow diversion group and 17 in the SAC group were females. The average patient age in the flow diversion

and SAC groups was not statistically different, 53 ± 8 years and 56 ± 13 years, respectively, $p=0.374$. Aneurysm size, as determined by both lesion volume and maximal diameter, was larger in the flow diversion group (median 150 mm^3 , average 444 ± 1048 ; and median 7.0 mm, minimum 2.5, maximum 21.0, $N=20$) compared to the SAC group (versus median 54 mm^3 , average 135 ± 204 ; and 4 mm, minimum 3.0, maximum 11.0, $N=20$), and the resulted differences indicate trends toward significance, $p=0.07$, U statistic 133.0, and $p=0.103$, U statistic 140.0, for volume and diameter respectively (Table 1).

Twenty-five paraclinoid aneurysms were treated in the flow diversion group, as well as two ipsilateral cavernous internal carotid artery aneurysms, which were not included in subsequent analysis of lesion size or success rate of aneurysm occlusion. One patient in the flow diversion group had four discrete ipsilateral paraclinoid aneurysms treated by one PED, while two other patients had two discrete ipsilateral paraclinoid aneurysms, which were also treated with one device. Only a single patient in the flow diversion group was treated with more than one flow diverter; this patient had two PEDs placed to achieve greater mesh coverage across a large dysplastic aneurysm neck. No patients undergoing flow diversion had additional coil embolization during the index procedure. Finally, in the SAC group, 21 aneurysms were treated; one patient had two discrete ipsilateral paraclinoid ICA aneurysms that were embolized following parent vessel stenting.

There was a trend towards shorter procedure times in the flow diversion group (median 165 minutes, average 172 ± 56 , minimum 77, maximum 322, $N=20$) compared to the SAC group (median 201 minutes, average 202 ± 66 , minimum 91, maximum 327, $N=14$), $p=0.066$, U

Table 1 Patient demographics and lesion characteristics.

	<i>Flow Diversion Group</i>	<i>SAC Group</i>	
<i>Patient Sex</i>	18 females 2 males	17 females 3 males	
<i>Patient Age</i>	53 ± 8 years	56 ± 13 years	$p=0.374$
<i>Aneurysm Volume</i>	Median 150 mm^3 Average 444 ± 1048	Median 54 mm^3 Average 135 ± 204	$p=0.07$ U statistic 133.0
<i>Aneurysm Maximal Diameter</i>	Median 7.0 mm Minimum 2.5 mm Maximum 21.0 mm	Median 4.0 mm Minimum 3.0 mm Maximum 20.0 mm	$p=0.103$ U statistic 140.0
<i>Number of Treated Aneurysms</i>	25 paraclinoid 2 cavernous	21 paraclinoid	

statistic 87.5. However, the average total fluoroscopy time was significantly shorter in the flow diversion group (median 48 minutes, average 53 ± 23 , minimum 30, maximum 124, $N=20$) compared to the SAC group (median 69 minutes, average 77 ± 29 , minimum 40, maximum 141, $N=20$), $p=0.003$, U statistic 88.5 (Table 2).

There was no statistically significant difference in the volume of the contrast used between the flow diversion group (median 160 mL, average 163 ± 37 , minimum 100, maximum 225, $N=20$) and the SAC group (median 160 minutes, average 158 ± 54 , minimum 47, maximum 260, $N=17$), $p=0.807$, U statistic 162.0.

Average and median values of patient radiation exposure as measured by dose-area product (DAP) were lower in the flow diversion group (median 11013 mGy*cm², average 13225 ± 5874 , minimum 6972, maximum 24851, $N=15$) than in the SAC group (median 14656 mGy*cm², 15124 ± 4334 , minimum 9879, maximum 25808, $N=14$). Although the difference was not statistically significant (two-tailed $p=0.190$, U statistic 75.0), lower minimum, maximum, average, and median values at this level of p value and small sample size indicate a trend toward significance.

In the flow diversion group, there were no intra-procedural complications. The rates of permanent neurologic deficit and mortality in the flow diversion group were 0%. In the SAC group, one patient had a second Enterprise stent placed for treatment of coil prolapse through the tines of the original stent. This event was without clinical consequence. Another patient treated with SAC of a ruptured

paraclinoid ICA aneurysm developed contralateral hemiplegia and aphasia secondary to thromboembolic infarcts in the right middle and anterior cerebral artery territories, which was subsequently complicated by hemorrhagic transformation. At the time of discharge, the patient's upper extremity weakness mildly improved, while lower extremity weakness and aphasia persisted. Overall, the rates of permanent neurologic deficit and mortality in the SAC group were 5% and 0% respectively.

The rate of complete aneurysm occlusion was higher in the flow diversion group. Sixteen patients (80%) had documented complete occlusion of their target lesion(s). One patient (5%) had incomplete occlusion at 12 months and will require re-treatment, while another patient (5%) has yet to undergo one-year follow up imaging. Finally, another two patients (10%) in the flow diversion group have been lost to follow-up. In the SAC group, 12 patients (60%) have documented complete occlusion of their target lesions, while four patients (20%) have mild, non-clinically significant residual filling at the aneurysm neck. An additional two patients (10%) have had recurrences of their lesions requiring additional coil embolization, while the remaining two patients have been lost to follow-up (10%) (Table 3).

Discussion

Our study demonstrates that the use of the flow diversion technique for treatment of wide-neck paraclinoid internal carotid artery (ICA)

Table 2 Comparisons of fluoroscopy time, procedure time, and contrast usage.

	<i>Flow Diversion Group</i>	<i>SAC Group</i>	
<i>Fluoroscopy Time</i>	Median 48 minutes Average 53 ± 23 Minimum 30 Maximum 124	Median 69 minutes Average 77 ± 29 Minimum 40 Maximum 141	$p=0.003$ U statistic 88.5
<i>Procedure Time</i>	Median 165 minutes Average 172 ± 56 Minimum 77 Maximum 322	Median 201 minutes Average 202 ± 66 Minimum 91 Maximum 327	$p=0.066$ U statistic 87.5
<i>Contrast Volume</i>	Median 160 ml Average 163 ± 37 Minimum 100 Maximum 225	Median 160 ml Average 158 ± 54 Minimum 47 Maximum 260	$p=0.807$ U statistic 162.0
<i>Radiation Exposure (DAP)</i>	Median 11013 mGy*cm ² Average 13225 ± 5874 Minimum 6972 Maximum 24851	Median 14656 mGy*cm ² Average 15124 ± 4334 Minimum 9879 Maximum 25808	$p=0.190$ U statistic 75.0

aneurysms is associated with shorter fluoroscopy times compared to the more traditional method of stent-assisted coiling (SAC). This finding is further supported by a strong trend towards a reduction in overall procedure time in the flow diversion group, corresponding to the reduction in total fluoroscopy time. Although we did not find a statistically significant reduction in patient radiation exposure as measured by dose-area-product, this is likely secondary to the relatively small sample sizes available for analysis.

Reducing fluoroscopy time and patient radiation exposure during interventional procedures is an important public health issue recently highlighted by the US Food and Drug Administration (FDA), which seeks to support the benefits of these medical imaging procedures while minimizing the health risks. In 2010, the FDA's Center for Devices and Radiological Health (CDRH) launched an Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging and held a public meeting on Device Improvements to Reduce Unnecessary Radiation Exposure from Medical Imaging (March 30-31, 2010). These efforts were in response to increasing exposure to ionizing radiation from medical imaging highlighted in the National Council on Radiation Protection and Measurements Report No. 160 and safety concerns highlighted in FDA's Safety Investigation of CT Brain Perfusion Scans. To reduce radiation doses medical imaging examinations should use techniques that are adjusted to administer the lowest radiation dose that yields an image quality adequate for diagnosis or intervention (i.e., radiation doses should be "As Low as Reasonably Achievable"). Reducing fluoroscopy time during interventional procedures is an important public health issue.

These issues were highlighted in a recent study by Peterson et al.¹⁶ that found 72.1% of neuro-interventional procedures resulted in a skin entrance dose greater than 2 grays, with nearly 40% of these patients subsequently de-

veloping subacute skin or hair changes, 30% of which were permanent. The potential long-term consequences of radiation exposure, including stochastic effects such as carcinogenesis, have not been well studied and remain uncertain. Given these concerns, the impact of a particular endovascular technique on fluoroscopy usage should be considered by the neuro-interventionalist when choosing a treatment method.

The greater number and larger average size of aneurysms treated in the flow diversion group suggests that the current study may underestimate flow diversion's potential for reducing fluoroscopy time. Adjacent ipsilateral aneurysms are relatively easily amenable to treatment with a single flow diverter device, while the same lesions would need to be individually coiled using SAC. In addition, one would expect larger volume aneurysms to take longer to safely pack with coils under fluoroscopy, while flow diverter placement is generally unaffected by lesion size. Finally, flow diversion is a relatively new technique with only one flow diverter, the PED, currently approved for use in the US. If future advances in flow diverter design allow for greater ease of deployment, further decreases in the amount of fluoroscopy time required for device placement can be reasonably expected.

A few recently published reports have also shown reductions in fluoroscopy time with flow diversion compared to more traditional endovascular methods of aneurysm treatment. For example, Chalouhi et al.¹⁷ demonstrated shorter fluoroscopy and procedure times in patients treated by flow diversion compared to SAC or Onyx HD 500 embolization. However, aneurysm location varied considerably between treatment groups, with a significant number of lesions treated by SAC being in the posterior circulation, while flow diversion was generally reserved for ICA aneurysms. On the other hand, Colby et al.¹⁸ limited their analysis to only large or giant cavernous and clinoid/paraophthalmic ICA aneurysms. However, here flow diversion

Table 3 Rates of procedural complications and lesion occlusion on follow-up.

	<i>Flow Diversion Group</i>	<i>SAC Group</i>
<i>Permanent Neurologic Deficit</i>	0%	5%
<i>Mortality</i>	0%	0%
<i>Aneurysm Occlusion</i>	Complete 80% Incomplete 5% Lost to follow-up 10% < 1 year follow-up 5%	Complete 60% Incomplete 30% Lost to follow-up 10%

was compared to a variety of other endovascular treatment methods, including coil embolization alone, single and multistage SAC, and parent vessel sacrifice. As both lesion location and endovascular technique could have a profound effect on procedural complexity and resulting fluoroscopy usage, the validity of these prior results is called into question. We believe that the current study design has helped to overcome these shortcomings.

Limitations of the current study include its retrospective design, small sample size, lack of patient randomization between treatment methods, and missing data points for some measured variables. Despite these drawbacks, we believe our results show that flow diversion is a promising technique for the treatment of wide-neck ICA aneurysms, which reduces fluoroscopy time and likely overall procedure

length compared to the more traditional endovascular method of SAC. This reduction in fluoroscopy time likely results from fewer steps required during treatment, and is further enhanced by the ability of a single flow diverter device to treat multiple ipsilateral carotid artery aneurysms, regardless of size. Reductions in fluoroscopy time should be considered when recommending an endovascular treatment for paraclinoid ICA aneurysms.

Conclusion

The use of the PED is associated with shorter fluoroscopy time, and likely shorter procedure times, compared with SAC for the endovascular treatment of wide-neck paraclinoid ICA aneurysms.

References

- 1 Becske T, Kallmes DF, Saatci I, et al. Pipeline for uncoilable or failed aneurysms: results from a multicenter clinical trial. *Radiology*. 2013; 267: 858-868. doi: 10.1148/radiol.13120099.
- 2 Brinjikji W, Murad MH, Lanzino G, et al. Endovascular treatment of intracranial aneurysms with flow diverters: a meta-analysis. *Stroke*. 2013; 44: 442-447. doi: 10.1161/STROKEAHA.112.678151.
- 3 Byrne JV, Beltechi R, Yarnold JA, et al. Early experience in the treatment of intra-cranial aneurysms by endovascular flow diversion: a multicentre prospective study. *PLoS One*. 2010; 5.
- 4 Chalouhi N, Tjoumakaris S, Starke RM, et al. Comparison of flow diversion and coiling in large unruptured intracranial saccular aneurysms. *Stroke*. 2013; 44: 2150-2154. doi: 10.1161/STROKEAHA.113.001785.
- 5 Lin LM, Colby GP, Kim JE, et al. Immediate and follow-up results for 44 consecutive cases of small (<10 mm) internal carotid artery aneurysms treated with the pipeline embolization device. *Surg Neurol Int*. 2013; 4: 114. doi: 10.4103/2152-7806.117711.
- 6 Lylyk P, Miranda C, Ceratto R, et al. Curative endovascular reconstruction of cerebral aneurysms with the pipeline embolization device: the Buenos Aires experience. *Neurosurgery*. 2009; 64: 632-642; discussion 642-633; quiz N636.
- 7 Nelson PK, Lylyk P, Szikora I, et al. The pipeline embolization device for the intracranial treatment of aneurysms trial. *Am J Neuroradiol*. 2011; 32: 34-40.
- 8 Saatci I, Yavuz K, Ozer C, et al. Treatment of intracranial aneurysms using the pipeline flow-diverter embolization device: a single-center experience with long-term follow-up results. *Am J Neuroradiol*. 2012; 33: 1436-1446. doi: 10.3174/ajnr.A3246.
- 9 Hwang G, Park H, Bang JS, et al. Comparison of 2-year angiographic outcomes of stent- and nonstent-assisted coil embolization in unruptured aneurysms with an unfavorable configuration for coiling. *Am J Neuroradiol*. 2011; 32: 1707-1710. doi: 10.3174/ajnr.A2592.
- 10 Molyneux AJ, Kerr RS, Yu LM, et al. International subarachnoid aneurysm trial (ISAT) of neurosurgical clipping versus endovascular coiling in 2143 patients with ruptured intracranial aneurysms: a randomised comparison of effects on survival, dependency, seizures, rebleeding, subgroups, and aneurysm occlusion. *Lancet*. 2005; 366: 809-817. doi: 10.1016/S0140-6736(05)67214-5.
- 11 Piano M, Valvassori L, Quilici L, et al. Midterm and long-term follow-up of cerebral aneurysms treated with flow diverter devices: a single-center experience. *J Neurosurg*. 2013; 118: 408-416. doi: 10.3171/2012.10.JNS112222.
- 12 Piotin M, Blanc R, Spelle L, et al. Stent-assisted coiling of intracranial aneurysms: clinical and angiographic results in 216 consecutive aneurysms. *Stroke*. 2010; 41: 110-115. doi: 10.1161/STROKEAHA.109.558114.
- 13 Shigematsu T, Fujinaka T, Yoshimine T, et al. Endovascular therapy for asymptomatic unruptured intracranial aneurysms: JR-NET and JR-NET2 findings. *Stroke*. 2013; 44: 2735-2742. doi: 10.1161/STROKEAHA.111.000609.
- 14 Yu SC, Kwok CK, Cheng PW, et al. Intracranial aneurysms: midterm outcome of pipeline embolization device--a prospective study in 143 patients with 178 aneurysms. *Radiology*. 2012; 265: 893-901. doi: 10.1148/radiol.12120422.
- 15 Wiebers DO, Whisnant JP, Huston J, 3rd, et al. Unruptured intracranial aneurysms: natural history, clinical outcome, and risks of surgical and endovascular treatment. *Lancet*. 2003; 362: 103-110. doi: 10.1016/S0140-6736(03)13860-3.
- 16 Peterson EC, Kanal KM, Dickinson RL, et al. Radiation-induced complications in endovascular neurosurgery: incidence of skin effects and the feasibility of estimating risk of future tumor formation. *Neurosurgery*. 2013; 72: 566-572. doi: 10.1227/NEU.0b013e318283c9a5.
- 17 Chalouhi N, McMahon JF, Moukartzel LA, et al. Flow diversion versus traditional aneurysm embolization strategies: analysis of fluoroscopy and procedure times. *J Neurointerv Surg*. 2014; 6: 291-295. doi: 10.1136/neurintsurg-2013-010777.
- 18 Colby GP, Lin LM, Nundkumar N, et al. Radiation dose analysis of large and giant internal carotid artery aneurysm treatment with the pipeline embolization device versus traditional coiling techniques. *J Neurointerv Surg*. 2014.

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