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Factors affecting the obliteration rate of Intracranial Aneurysms treated with a single Pipeline Embolization Device

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Abstract

Objective—To evaluate the clinical and angiographic outcomes of intracranial aneurysm treatment using a single Pipeline Embolization Device (PED), and to evaluate the factors affecting aneurysm obliteration rate.

Methods—The demographic characteristics and anatomical features of 58 aneurysms in 47 patients treated with a single Pipeline embolization device were reviewed retrospectively. All aneurysms treated with one PED at a single center, and with follow-up angiograms of at least six months were included in this study.

Results—The overall rate of complete and near-complete occlusion was 84% (49/58) after a mean follow-up period of 18.3 months. The complete aneurysm obliteration rate was reduced when an arterial branch arose from the aneurysm neck; 13% (1/8) compared with 68% (34/50) for aneurysms without an arterial branch (P value: 0.0075). The overall complete and near-complete aneurysm occlusion rate was 90% (45/50) in aneurysms without an arterial branch arising from its neck. There was no statistically significant association between neck-width, aneurysm size, type, or history of prior coil embolization on obliteration rate.

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DISCLOSURE

Dr. Solander is a proctor in the use of the Pipeline Embolization Device for Medtronic. The other authors report no conflict of interest concerning the materials or methods used in this study or the findings specified in this paper.

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Conclusions—Our data suggests that a single PED is sufficient to induce complete or near-complete obliteration of most aneurysms. The presence of a branching artery arising from the aneurysm neck is highly predictive of incomplete occlusion after treatment with a single PED.

Keywords

Flow diversion; Intracranial aneurysm; Occlusion rate; Pipeline Embolization Device

INTRODUCTION

The Pipeline Embolization Device (PED) has recently been introduced as an alternative endovascular technique in the treatment of intracranial aneurysms. The PED diverts flow from an aneurysm, causing shrinkage and thrombosis of the aneurysm, and promotes reconstruction of the vessel's endoluminal layer.¹ The safety and efficacy of the PED in the management of large or giant wide-necked aneurysms have been shown in several studies.²⁻⁷ Small aneurysms (<10mm) are more prevalent than large and giant aneurysms. Implantation of the PED in small aneurysms have been reported to be safe, with angiographic success as early as two months post-treatment.⁸⁻¹¹ In addition, the use of the PED in treatment of recurrent previously-coiled aneurysms has been described to be safe and effective in achieving aneurysm occlusion.¹² In a recent review article, the occlusion rate of aneurysms treated with the PED was reported as 83% at six months¹³ with the overall morbidity and mortality rate of 1.23% and 1.18% respectively.¹⁴ There are few studies evaluating the factors influencing aneurysm obliteration rate, and most of the previous reports did not isolate aneurysms treated with a single device compared to multiple devices.^{13,15}

The goal of our study is to analyze the outcomes of intracranial aneurysm treatment using a single PED. Specifically, we wanted to evaluate the potential factors influencing aneurysm obliteration rates such as demographics, aneurysm characteristics and the presence of arterial branches arising from the neck of the aneurysm. We also wanted to determine whether a single PED is sufficient to obtain high rates of aneurysmal occlusion.

METHODS

Patients

The demographic characteristics of patients with aneurysms treated with a single PED (Covidien/Medtronic, Irvine CA) at the University of North Carolina Hospitals in Chapel Hill, NC between March 2012 and May 2016, were reviewed retrospectively. All aneurysms treated with a single PED with follow-up angiograms of at least six months were included in this study. The obliteration rate was evaluated on follow-up angiogram. Aneurysm obliteration rate was defined as: complete (100%), near-complete (>90%) and incomplete (<90%). Aneurysm size was defined as small (<10mm) or large (>10mm), and neck width was also classified as small (<4mm) and large (>4mm). One fusiform and four dissecting aneurysms were included in our analysis along with saccular aneurysms. Previously-coiled aneurysms with neck remnants were also included. These aneurysms were included in order to evaluate them as variables in terms of aneurysm obliteration rate. This study was

approved by the Institutional Review Board and Office of Human Research Ethics at the University of North Carolina, Chapel Hill.

Endovascular Procedure

Prior to the procedure, all patients underwent a Clopidogrel Response Genotyping (CYP2C19) assay. Patients evaluated as normal metabolizers were started on Aspirin 325mg and Clopidogrel 75mg once daily, one week before the procedure. In other genotypes, the anti-platelet therapy was adjusted according to guidelines by the Clinical Pharmacogenetics Implementation Consortium¹⁶. All procedures were performed under general anesthesia. Intravenous heparin was administered after gaining arterial access. Angiograms were obtained after the PED was deployed to confirm the device position and the patency of the parent artery. All patients had postoperative neurological examinations and were admitted to the Neurosciences Intensive Care Unit for at least 24 hours post-procedure.

Follow-up

All patients underwent Magnetic Resonance Imaging (MRI) and Magnetic Resonance Angiography (MRA) three months post-procedure to assess the aneurysm and patency of the parent vessel. Follow-up angiogram was obtained six months post-procedure to evaluate aneurysm obliteration and in-stent stenosis. We report two follow-up times; an 'angiographic follow-up time', which is based on the most recently performed angiogram, as well as a 'total follow-up time', which is based on the patients' most recent clinic visit and non-invasive imaging. This is an important distinction since no additional angiograms were scheduled for completely obliterated aneurysms, although these aneurysms were followed with non-invasive imaging. If residual opacification of the aneurysm was noted at the six-month follow-up, patients were evaluated for repeat treatment or follow-up angiogram. Near-completely obliterated aneurysms were followed with repeat angiograms, and incompletely occluded aneurysms were more likely to undergo a second treatment. The total follow-up time ranged from 6 to 51 months and the angiographic follow-up time from 6 to 28 months.

Statistical Analysis

Statistical analysis was completed using SAS version 9.4 (SAS Institute, Cary, NC). The angiographic outcome of aneurysmal occlusion post-pipeline treatment was evaluated in the three categories of complete, near-complete and incomplete obliteration. These outcome categories were analyzed for each characteristic of gender, arterial circulation (anterior or posterior), aneurysm size, type, previous coil embolization, neck-width and arterial branching from the aneurysm neck.

For the categorical variables, preliminary bivariable analysis was carried out using the Mantel-Haenszel mean score tests with standardized mid-rank scores for the cross-tabulation of categorical variables with the primary outcome. Due to sparse sample size concerns, exact tests were used to test the null hypothesis of no association of such variables with the primary outcome. Analysis of Variance was conducted to assess variation in the mean of the continuous variables across the three categories of the outcome variable.

A multinomial logistic regression analysis using the proportional odds model for the cumulative logits of an ordinal response was used to assess multivariable relationships of patient factors with obliteration status of the aneurysm. The method of generalized estimating equations with working independence correlation matrices was used to estimate the model in order to account for clustering of multiple aneurysms within subjects; empirical sandwich standard errors for regression coefficients were computed.

RESULTS

This retrospective study includes 47 patients with a total of 58 aneurysms treated by single PED. The demographics and aneurysm characteristics are illustrated in Table 1. Seventeen patients had an initial presentation of subarachnoid hemorrhage. Fourteen of these patients underwent PED treatment of residual aneurysm when coil compaction was found on follow-up angiogram. Two patients underwent PED treatment of incidentally found aneurysm at a later stage. One patient underwent PED treatment of a previously wrapped dissecting aneurysm, also in delayed fashion. There were 8 aneurysms with a branching artery; 1 posterior inferior cerebellar artery (PICA), 2 PCOMs, and 5 ophthalmic arteries. The PICA aneurysm had a near-complete obliteration. The PCOM aneurysms included one near-complete and one incompletely obliterated aneurysm. Of the 5 ophthalmic aneurysms; 3 were incompletely occluded, 1 was near-complete with a patent ophthalmic artery, and 1 was completely obliterated with an occluded ophthalmic artery (Case 1).

Aneurysm Occlusion

Complete aneurysmal occlusion was achieved in 25 of 39 (64%) small-sized aneurysms, in comparison to 11 of 19 (57%) large aneurysms. Incomplete aneurysmal obliteration was observed in 9 of the total 58 (15%) aneurysms, small and large combined. The rate of complete aneurysmal obliteration in previously coiled aneurysms was 58% (10/17), while the rate of incomplete aneurysm obliteration was 6% (1/17). In 14% of the cases (8/58), a small artery originated from the neck of the aneurysm. On follow-up angiograms, 50% (4/8) of these aneurysms demonstrated incomplete aneurysmal obliteration and 37% (3/8) had near-complete obliteration. Only 13% (1/8) of aneurysms with branching vessels from its neck demonstrated complete occlusion, compared with 70% (35/50) of all other aneurysms (P-value: 0.0075). The only aneurysm with a neck branch that demonstrated complete aneurysmal occlusion was accompanied with the obliteration of the branch artery. In aneurysms without an arterial branch, the rate of complete aneurysm occlusion was 70% (35/50) compared with the rate of incomplete aneurysm occlusion, which was 10% (5/50). Overall, the rates of complete and near-complete occlusion were 62% (36/58) and 22% (13/58) respectively after a mean total follow-up period of 18.3 months. The obliteration rates and variable characteristics are described in Tables 2 and 3.

Statistical Analysis

Gender, aneurysm neck-width, size, type, history of prior coil embolization, and procedure fluoroscopy time did not statistically affect the obliteration rate. Adjusting for the aneurysm size and neck-width, patients with branching vessels from the aneurysm neck have a 21.0 (95% CI: 3.6-122) times higher odds of incomplete or near-complete obliteration, versus

complete obliteration in aneurysms without branching vessels. Conversely, 95% confidence intervals for the multivariable-adjusted odds ratios for aneurysm size and neck-width contained the null value of 1.0 (Table 4). Thus, as in the bivariable analysis, they were not statistically significant in relation to incomplete or near-complete obliteration. The model was supported in that its assumption of proportion odds was not rejected (GEE Score test = 0.471; 3 degrees of freedom, $p=0.925$).

Complications

Procedural related complications occurred in two patients. They both had small embolic strokes confirmed on MRI, combining for 4 % morbidity. One patient continued to have headaches and diplopia after the procedure but was otherwise neurologically intact. Her symptoms were likely unrelated to the MRI findings. The other patient developed left-sided weakness, facial droop and pronator drift after the procedure. MRI demonstrated a few tiny foci of restricted diffusion, but her symptoms resolved completely a few days later at discharge. Subsequent angiography in these patients failed to show any pipeline-related stenosis or thrombosis. There were no mortality or delayed complications. Asymptomatic mild in-stent stenosis was seen in three (6%) patients. In these patients, dual anti-platelet therapy was continued until angiographic improvement was noted.

Illustrative Cases

Right ophthalmic segment aneurysm (Case 1)—48-year old female who presented with an unruptured wide-necked right ophthalmic segment aneurysm that measured 13×15 mm (Fig 1A). A 4×16 mm PED was deployed across the aneurysm and some stagnation of blood was noted in the aneurysm after deployment (Fig 1B). There was no branching artery from the neck of the aneurysm. A 6-month follow-up cerebral angiogram demonstrated complete obliteration of the aneurysm (Fig 1C, D).

Left ophthalmic segment aneurysm (Case 2)—48-year old female who presented with an unruptured left ophthalmic segment aneurysm that measured 5×6 mm. The ophthalmic artery can be visualized arising from neck of the aneurysm (Fig 2A). The patient underwent treatment with a 4.25×18 mm PED. A 1-year follow-up angiogram showed little change in size of the aneurysm (Fig 2B). A 2.5-year follow-up angiogram continued to show contrast stagnation in the aneurysm remnant and patent left ophthalmic artery (Fig 2C, D).

DISCUSSION

PED has been demonstrated to be an effective tool for the treatment of large wide-necked aneurysms. It has also been shown to be a safe therapeutic alternative for aneurysms that are less favorable for surgical clipping or endovascular coiling.⁶

Comparative Studies

Predictive factors for achieving complete occlusion of aneurysms treated with the PED have been previously reported without complete statistical analysis. Jabbour et al assessed the age, sex, aneurysm location, size, morphology, adjunctive use of coils, procedural complications and the angiographic follow-up time as predictors of aneurysm obliteration.¹⁷

In their study, only fusiform aneurysms and a shorter follow-up duration negatively affected aneurysm occlusion rate. They also determined that the number of PEDs used was not a predictor of aneurysm obliteration, suggesting that the use of multiple PEDs provides no benefit in terms of angiographic obliteration, while unnecessarily increasing the procedural time, cost, and the risk of thromboembolic complications.¹⁷

Inadvertent occlusion of branch arteries covered by the PED has been raised as one of the potential draw-backs of this technology. Puffer et al assessed patency of the ophthalmic artery after treatment with the PED in 19 patients. They demonstrated occlusions of the ophthalmic artery without vision loss in 25% of their cases. They concluded that coverage of branch arteries that have adequate collateral circulation may lead to spontaneous occlusion of those branches without sequelae.¹⁸ Saatchi et al showed that by deploying the PED across the neck of aneurysms, branches arising from the aneurysms remained patent when there was flow demand through them.⁶ The same group evaluated the results of 46 aneurysms with branch arteries from the sac and found only 5 branch artery occlusions, all in posterior communicating artery (PCOM) aneurysms with sufficient supply to the posterior cerebral artery (PCA) from the posterior circulation. Obliteration rates of the aneurysms were not described, as the intention of the study was to maintain flow into the aneurysm to preserve the branch artery. Aneurysms arising from a fetal origin of the PCA have been described as less favorable for treatment with the PED in terms of obliteration.¹⁵ The objective of using Pipeline in these cases vary in the literature.

Zanaty et al evaluated the effect of fetal origin of PCA on occlusion rate of PCOM aneurysms. They described failed obliteration of these aneurysms due to the high flow and demand through the fetal PCA.¹⁵ In contrast to Saatchi et al, the goal of the treatment in their series was obliteration of the aneurysm, and these aneurysms subsequently underwent surgical clipping.²¹ Tsang et al reported similar obliteration rates for PCOM aneurysms with fetal PCA.¹³ They evaluated the effect of factors such as gender, aneurysm location, size, aspect ratio, neck-width and prior treatment on obliteration rate. They found that the female gender had a higher rate of aneurysm occlusion, but failed to show any statistically significant association between other factors and the result of the PED treatment.¹³ Aneurysms originating from the PCOM itself rather than the ICA at the origin of PCOM, may not have sufficient pipeline coverage of the aneurysm neck, which could explain the failed obliteration in these studies. Anatomical characteristics of aneurysms and branching artery are as important as flow or demand theory in terms of obliteration success rate with PED.

Aneurysm Obliteration

In our study, the goal of the PED treatment for all patients was to obliterate the aneurysm with or without occlusion of vessels arising from the aneurysm. Only 12.5% of aneurysms with an arterial branch from the aneurysm neck were completely obliterated on follow-up angiogram. In contrast, the complete obliteration rate was significantly higher (70%) in aneurysms without branching vessels. The mechanism for this is most likely due to the increased demand of blood supply by the branch artery, thereby preventing neointimal overgrowth on the PED. In the case of the one aneurysm with complete obliteration on

follow-up angiogram despite having an arterial branch from the aneurysm neck, the branching artery was an ophthalmic artery. The ophthalmic artery arising from the aneurysm neck was occluded on follow-up angiogram, thus allowing thrombosis of the aneurysm. However, occlusion of the ophthalmic artery did not result in any visual symptoms.¹⁹⁻²¹

Aneurysm neck-remnant or regrowth after coiling was successfully treated with a single PED in 94% of our cases, which is consistent with other published reports,^{12, 22, 23} though in contrast with some reports of reduced aneurysm obliteration rate.²² Sixty-seven percent of the aneurysms in this study were classified as small-sized (<10mm), and 64% of those aneurysms demonstrated complete obliteration without any complication. Our results are consistent with previous studies reporting a 70% to 80% occlusion rate and a 0% to 11% complication rate.^{24, 8, 25}

Predictive Factors

In our study, we evaluated the effects of gender, prior coil embolization, aneurysm size, type, neck-width and the presence of an artery arising from the aneurysm neck as potential predictive factors of the success rate of a single PED treatment. The only predictive factor for aneurysm obliteration after treatment was the presence of an artery arising from neck of the aneurysm, which dramatically reduces the rate of complete aneurysmal obliteration. This is in contrast with previous studies^{13,15} which showed a fetal PCA as the only predictor of failed aneurysm occlusion. Our study demonstrates that one PED is sufficient to induce occlusion or near-occlusion of most aneurysms, especially those without a branching artery from the aneurysm neck. We continue to follow nearly occluded aneurysms with repeat angiograms since the long-term outcome of near-occlusion is not currently known. If the 1-year post-procedure angiogram shows incomplete aneurysmal obliteration, we will consider treatment of the remnant with an additional PED or surgery. In one of our cases with ophthalmic artery arising from the aneurysm neck, we used a second PED after 2 years of incomplete aneurysm occlusion. Despite a second PED, the aneurysm remained patent on angiographic follow-up. This further emphasizes the mechanism of flow demand from branching artery as the single most important factor influencing aneurysm obliteration. We have not experienced any ruptures from incompletely obliterated aneurysms during the 1-year post-pipeline placement observation period. We favor using a single PED in all aneurysms when anatomically possible, since the use of multiple PEDs have been shown to increase procedural time, cost, and the risk of thromboembolic complications when compared with a single PED.¹⁷

Limitations

The retrospective nature, single-center series, relatively small sample size and short total follow-up time (mean time of 18.3 months) are weaknesses of this study. This emphasizes the need for further studies with larger sample sizes. The angiographic follow-up mean time of 8.1 months is shorter than the total follow-up mean time of 18.3 months since we do not obtain cerebral angiograms if a complete aneurysmal obliteration is noted on the 6-month angiogram. This study evaluated the results of treatment with a single PED, so our conclusions are not generalizable to cases where multiple PEDs are used. Further studies are

needed to assess the predictive factors and complications of aneurysms treated with multiple PEDs.

CONCLUSIONS

This study suggests that the management of small-sized and previously coiled aneurysms with the PED is safe and effective. The presence of a branch artery arising from the neck of an aneurysm is predictive of aneurysm obliteration failure after pipeline treatment, regardless of the aneurysm size or location. Our data also suggests that a single PED is sufficient to induce complete or near-complete obliteration of most aneurysms.

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Abbreviations

ANOVA	Analysis of Variance
CTA	Computed Tomography Angiography
MRA	Magnetic Resonance Angiography
MRI	Magnetic Resonance Imaging
NIH	National Institutes of Health
PED	Pipeline Embolization Device

PCA	Posterior cerebral artery
PCOM	Posterior communicating artery
PICA	Posterior Inferior Cerebellar Artery

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HIGHLIGHTS

- Factors affecting the obliteration rate of Intracranial Aneurysms were analyzed.
- 58 aneurysms treated with a single Pipeline Embolization Device were evaluated.
- Complete and near-complete occlusion rate was 90% in aneurysms without branching.
- Complete aneurysm obliteration rate was 13% in aneurysms with arterial neck-branch.
- Presence of arterial branch at aneurysm neck is predictive of incomplete occlusion.

FIG. 1.

A-D: Cerebral angiogram (lateral view of the right internal carotid artery injection). **A:** shows a right ophthalmic segment aneurysm. **B:** shows stagnation of blood in the aneurysm after deploying the PED. **C, D:** 6-month follow-up angiogram showing complete obliteration of the right ophthalmic segment aneurysm

FIG. 2.

A-D: Cerebral angiogram (lateral view of the left internal carotid artery injection). **A:** shows a left ophthalmic segment aneurysm with the ophthalmic artery arising from neck of the aneurysm. **B:** 1-year follow-up angiogram showing little change in size of the left ophthalmic segment aneurysm. **C, D:** 2.5-year follow-up angiogram showing contrast stagnation in the aneurysm remnant and patent left ophthalmic artery

Table 1**Patient and Aneurysm Characteristics**

Mean patient age (years)	52.8±11.9
Female	42 (89%)
Presenting with Subarachnoid Hemorrhage	17 (29%)
Multiple Aneurysms	11 (23%)
Mean time of Angiography follow-up (months)	8.1
Mean time of all imaging follow-up (months)	18.3
Decreased clopidogrel responders	2 (4%)
Anterior circulation aneurysms	44 (93%)
Cavernous segment aneurysms	9 (15%)
Ophthalmic segment aneurysms	25 (43%)
Supraclinoid segment aneurysms	14 (24%)
Basilar Apex aneurysms	2 (3%)
Vertebral segment aneurysm	2 (3%)
Dissecting aneurysms	4 (6%)
Mean aneurysm size (mm)	10.15±7.2
Large aneurysms (>10mm)	9 (15%)
Small aneurysms (<10mm)	39 (67%)
Previously coiled aneurysms	17 (29%)
Mean size of neck remnant in previously coiled aneurysms (mm)	9.0±6.4

Table 2

Aneurysm obliteration rates based on individual variables

Characteristic	Complete Obliteration (N = 30, 63.83%)	Near-complete Obliteration (N = 10, 21.28%)	Incomplete Obliteration (N = 7, 14.89%)	p value *
Gender				0.5306
Female	26 (61.90)	9 (21.43)	7 (16.67)	
Male	4 (80.00)	1 (20.00)	0 (0.00)	
Characteristic	Complete Obliteration (N = 36, 62.17%)	Near-complete Obliteration (N = 13, 22.41%)	Incomplete Obliteration (N = 9, 15.52%)	p value *
Circulation				0.7091
Anterior	33 (61.11)	12 (22.22)	9 (16.67)	
Posterior	3(75.00)	1 (25.00)	0 (0.00)	
Aneurysm Size				0.6180
Large (> 10mm)	11 (57.89)	5 (26.32)	3 (15.79)	
Small (≤ 10mm)	25 (64.10)	8 (20.51)	6 (15.38)	
Prior Coil Embolization				0.4704
Yes	10 (58.82)	6 (35.29)	1 (5.88)	
No	26 (63.41)	7 (17.07)	8 (19.51)	
Branching Vessels				0.0075 *
Yes	1 (12.50)	3 (37.50)	4 (50.00)	
No	35 (70.00)	10 (20.00)	5 (10.00)	
Neck Width				0.7261
Large (> 4mm)	23 (60.53)	9 (23.68)	6 (15.79)	
Small (≤ 4mm)	13 (65.00)	4 (20.00)	3 (15.00)	
Adjunctive Coiling				0.5705
Coil + Pipeline	1 (50.00)	1 (50.00)	0 (0.00)	
No	32 (62.50)	12 (21.43)	9 (16.07)	
Complications				0.4905
Yes	2 (100.00)	0 (0.00)	0 (0.00)	
No	32 (60.38)	16 (22.64)	9 (16.98)	
Type of Aneurysm				
Dissecting	4 (100.00)	0 (0.00)	0 (0.00)	0.2110
Fusiform	1 (100.00)	0 (0.00)	0 (0.00)	
Saccular	31 (59.52)	13 (40.48)	9(16.98)	

* Significant at 0.15 level.

Table 3

Continuous variable characteristics

Variable	Complete (n=36)		Near Complete (n=13)		Incomplete (n=9)		ANOVA *
	Mean $\pm$ s.d.	(Min, Max)	Mean $\pm$ s.d.	(Min, Max)	Mean $\pm$ s.d.	(Min, Max)	
Age (years)	44.89 $\pm$ 23.38	(35.0, 85.0)	42.77 $\pm$ 24.65	(50.0, 62.0)	43.22 $\pm$ 23.35	(48.0, 68.0)	0.9556
Fluoroscopy time (min)	21.91 $\pm$ 15.3	(0.0, 62.60)	44.72 $\pm$ 42.0	(15.30, 140.80)	22.28 $\pm$ 19.6	(14.80, 66.40)	0.2058
Aneurysm Size (mm)	10.44 $\pm$ 6.9	(3.0, 29.0)	12.62 $\pm$ 10.1	(3.0, 34.0)	10.00 $\pm$ 7.2	(5.0, 22.0)	0.6481
Neck Width (mm)	6.05 $\pm$ 3.4	(0.0, 16.0)	7.15 $\pm$ 3.9	(3.0-16.0)	6.00 $\pm$ 2.8	(4.0-10.0)	0.5943

* Analysis of Variance

Table 4

Odds ratios (95% confidence intervals) from the proportional odds model

Variables	Odds ratio (95% Confidence Interval)
Branching Vessel (Yes vs. No)	20.95 (3.58, 122.32)
Aneurysm size (Large vs Small)	1.57 (0.51, 4.87)
Neck width (Large vs Small)	2.52 (0.59, 10.81)