Assessing the impact of distal protection filter design characteristics on 30-day outcomes of carotid artery stenting procedures

Natasha A. Loghmanpour, MS,[a] Gail M. Siewiorek, PhD,[b] Kelly M. Wanamaker, MD,[c] Satish C. Muluk, MD,[c] Rabih Chaer, MD,[d] Mark H. Wholey, MD,[e] and Ender A. Finol, PhD,[f]
Pittsburgh, Pa; and San Antonio, Tex

Objective: **This study aims to review retrospectively the records of patients treated with carotid artery stenting (CAS) to investigate the potential correlations between clinical variables, distal protection filter (DPF) type and characteristics, and 30-day peri-/postprocedural outcomes.**
Methods: **This is a multicenter, single-arm, nonrandomized retrospective study of patients who underwent filter-protected CAS in the Pittsburgh, Pennsylvania, region between July 2000 and May 2011. Analysis of peri-/postprocedural complications included myocardial infarction, transient ischemic attacks (TIA), stroke, death, and a composition of all adverse events (AEs). Filter characteristics for Accunet (Abbott Vascular, Santa Clara, Calif; n = 429 [58.8%]), Angioguard (Cordis Endovascular, Miami Lakes, Fla; n = 114 [15.6%]), FilterWire (Boston Scientific, Natick, Mass; n = 113 [15.5%]), Spider (ev3 Endovascular, Plymouth, Minn; n = 45 [6.2%]), and Emboshield (Abbott Vascular; n = 24 [3.3%]) were previously determined in vitro and were used to find correlations with CAS procedural outcomes. Both univariate and multivariate analyses were performed, as well as goodness-of-fit tests to find multivariate correlations with procedural outcomes.**
Results: **In total, 731 CAS procedures using six different DPFs were analyzed. Peri-/postprocedural AEs included 19 TIAs (2.6%), 38 strokes (5.2%), one myocardial infarction (0.1%), 19 deaths (3.6%), and a total of 61 patients with complications (8.3%). Univariate analysis for filter design characteristics showed that the composite of AE was negatively associated with both vascular resistance ($P = .01$) and eccentricity ($P = .02$) and was positively associated with porosity ($P = .0007$), number of pores ($P = .005$), and pore density ($P = .001$). Multivariate analysis and the goodness-of-fit test revealed that patients with a history of congestive heart failure, stroke, and TIA (each with odds ratio >1) led to a good-fit model *P* value of .72 for peri-/postprocedural AEs. Multivariate analysis was inconclusive for all filter design characteristics.**
Conclusions: **The following filter design characteristics are independently significant for minimizing peri-/postprocedural AEs: higher vascular resistance, concentric in shape, greater capture efficiency, lower porosity, lower number of pores, and lower pore density. Lower porosity and smaller wall apposition were also found to be independently significant for minimization of peri-/postprocedural TIAs. This information can be used when considering the desirable design characteristics of future DPFs.) (J Vasc Surg 2013;57:309-17.)**

Stroke is the third leading cause of death in the United States after heart disease and cancer,[1] and it is the leading cause of long-term disability, affecting more than 1.1 million Americans.[2] Approximately one million stroke-related events each year are composed of 600,000 new strokes, 180,000 recurrent strokes, and 240,000 transient ischemic attack (TIA).[1] Nearly one third of all strokes are due to atherosclerosis. Carotid endarterectomy (CEA) has been available since the 1950s and is the current gold standard treatment[3-6] for prevention of stroke, depending on the severity of the carotid stenosis.[7] For high surgical risk patients, CEA may not be the best treatment option. Carotid artery stenting (CAS) is a more recently implemented treatment that now serves as an alternative to CEA for asymptomatic high-risk patients[8] as well as other patient subsets as described by Ricotta et al.[9]

Although CAS has gained much attention, few studies have been conducted that incorporate filter use and type or consider design characteristics in the analysis of CAS patient outcome.[10-14] Previous studies conducted by our laboratory[15-19] tested these characteristics with an in vitro bench-top testing apparatus (Fig) and studied their effects on filter capture efficiency and flow resistance.[16] The characteristics included capture efficiency, vascular resistance, wall apposition, porosity, pore density, and eccentricity.

The purpose of this study was to conduct a retrospective review of CAS patients with the intent of finding

From the Biomedical Engineering Department[a] and Institute for Complex Engineered Systems,[b] Carnegie Mellon University, Pittsburgh; the Division of Vascular Surgery, Allegheny General Hospital, Pittsburgh[c]; the Division of Vascular Surgery[d] and Department of Radiology,[e] University of Pittsburgh Medical Center, Pittsburgh; and the Department of Biomedical Engineering, University of Texas at San Antonio.[f]

This work was funded in part by an American Heart Association postdoctoral fellowship and Carnegie Mellon University's Department of Biomedical Engineering.
Author conflict of interest: none.
Presented at the 2012 Vascular Annual Meeting of the Society for Vascular Surgery, National Harbor, Md, June 7-9, 2012.
Additional material for this article may be found online at www.jvascsurg.org.
Reprint requests: Ender A. Finol, PhD, Department of Biomedical Engineering, The University of Texas at San Antonio, AET 1.360, One UTSA Circle, San Antonio, TX 78249 (e-mail: ender.finol@utsa.edu).
The editors and reviewers of this article have no relevant financial relationships to disclose per the JVS policy that requires reviewers to decline review of any manuscript for which they may have a conflict of interest.
0741-5214/$36.00

http://dx.doi.org/10.1016/j.jvs.2012.08.113

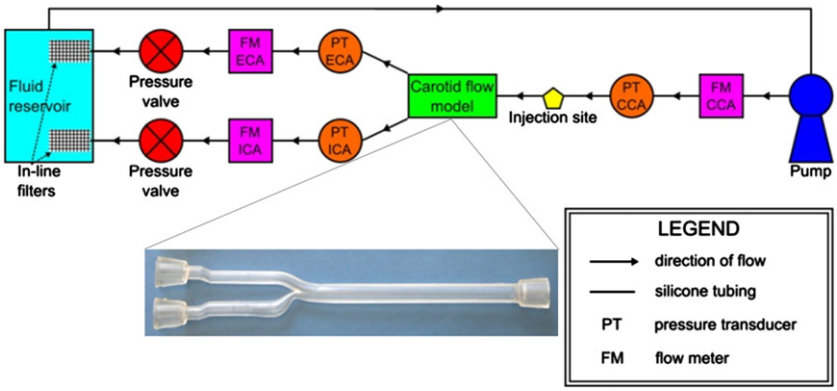

Fig. Schematic diagram of the experimental flow apparatus with a carotid flow model.[16] *CCA,* Common carotid artery; *ECA,* external carotid artery; *ICA,* internal carotid artery.

potential correlations between clinical variables, filter type and design characteristics, and peri-/postprocedural 30-day outcomes. This study provides a unique look at associating filter type as well as filter design characteristics with CAS procedural outcome.

METHODS

Subject population and data collection. In this multicenter, single-arm, nonrandomized study, the records of patients who underwent CAS at both the University of Pittsburgh Medical Center (UPMC) and West Penn Allegheny Health System (WPAHS) were retrospectively reviewed between July 2000 and May 2011. Data were collected from two UPMC sites: Shadyside Hospital and Presbyterian Hospital. At each of the two institutes, an Institutional Review Board protocol was approved under the Health Insurance Portability and Accountability Act authorization. The inclusion criteria were based on patients who underwent protected CAS with a distal protection filter (DPF) and had a complete registered medical history and documented 30-day follow-up. The primary exclusion criteria for this study were the unavailability of detailed documentation on 30-day outcome of the CAS procedures. Table I provides the complete list of baseline characteristics collected for each patient record.

The procedures were carried out by several physicians in the vascular surgery and cardiology departments at both UPMC and WPAHS. Patients were considered symptomatic if they had experienced amaurosis fugax, TIA, or stroke (includes both minor and major strokes) within 60 days before the CAS procedure. All documented complications that occurred periprocedurally and postprocedurally (within 30 days) were noted and recorded. The procedural and 30-day events are not differentiated in the statistical analysis due to the small sample size of each event category and will be referred to as combined peri-/postprocedural. Statistical analyses considered the following outcomes: myocardial infarction (MI), TIA, stroke, death, as well as combined adverse events (AEs), which included patients with any of the aforementioned complications.

Several stent systems and DPF types can be used, depending on physician preference, institutional availability, and trial protocol, because many of the procedures were part of a prospective clinical trial (Table II). The stent types included Acculink (Abbott Vascular, Santa Clara, Calif), Precise (Cordis Endovascular, Miami Lakes, Fla), Wallstent (Boston Scientific, Natick, Mass), Xact (Abbott Vascular), Protégé (ev3 Endovascular Inc, Plymouth, Minn), and Nexstent (EndoTex Interventional Systems, Cupertino, Calif). The filter types included Accunet (Abbott Vascular), Angioguard (Cordis Endovascular), FilterWire (Boston Scientific), Emboshield (Abbott Vascular), Spider (ev3 Endovascular Inc), and Fibernet (Lumen Biomedical Inc, Maple Grove, Minn). Patients who received proximal and distal occlusion devices, such as flow reversal devices, were excluded from the study.

Filter design characteristics. The DPF design characteristics were measured in previous studies conducted in our laboratory in an in vitro setting (Fig).[15-19] The characteristics are summarized in Table III and defined as follows.

Capture efficiency was measured using a flow apparatus with five milligrams of dyed 200-μm nominal diameter polymer microspheres (larger than the pore size of the devices, except Spider RX, which was tested with 300-μm-diameter particles) injected into the blood mimicking fluid, simulating potential plaque embolization. The ideal value is 100%.[17] Capture efficiency was calculated based on a particle suspension injected into a carotid artery bifurcation model and the number of particles missed by the DPF as seen in the following equation[16]:

$$\text{Capture efficiency} = 100 - ([\text{particles missed by DPF}] \div [\text{total particles} - \text{particles in external carotid artery} - \text{particles left in syringe}]) \times 100.$$

Vascular resistance is defined as the ratio of pressure gradient across the DPF to the flow rate in the bench-top apparatus.[17] The resistance to the flow was calculated as the ratio of the time-varying pressure gradient across the DPF to the time-varying flow rate in the internal carotid artery as seen in the following equation[16]: $R = (P_{CCA} - P_{ICA})/Q_{ICA}$.

Table I. Patient and procedural characteristics

Characteristic	*N (%), n = 729*	*TIA, n = 19 (2.6%)* P *value* *OR (95% CI)*	*CVA, n = 38 (5.2%)* P *value* *OR (95% CI)*	*Death, n = 19 (3.6%)* P *value* *OR (95% CI)*	*Adverse event, n = 61 (8.3%)* P *value* *OR (95% CI)*
Age ≥80 years	141 (19.3)	.15 .2 (.03-1.8)	.05 2.0 (1.0-4.1)	.04 2.7 (1.0-7.2)	.12 1.6 (.9-3.0)
Male	465 (63.8)	.05 .4 (.2-1.0)	.03 .5 (.2-.9)	.45 1.5 (.5-4.2)	.02 .5 (.3-.9)
Diabetes mellitus	246 (33.7)	.08 2.2 (.9-5.5)	.26 1.4 (.7-2.8)	.64 1.2 (.5-3.3)	.14 1.5 (.9-2.6)
History of hyperlipidemia	527 (72.3)	.51 1.4 (.5-4.4)	.20 .6 (.3-1.3)	.59 .8 (.3-2.0)	.42 .8 (.4-1.4)
History of hypertension	633 (86.8)	.32 2.8 (.4-21.1)	.62 .8 (.3-1.9)	.66 .7 (.2-2.6)	.76 1.1 (.5-2.6)
Current smoker	162 (22.2)	.90 .9 (.3-2.8)	.31 1.4 (.7-3.0)	.99 1.0 (.3-3.1)	.35 1.3 (.7-2.4)
Atrial fibrillation	117 (16.0)	.97 1.0 (.3-3.4)	.68 1.2 (.5-2.8)	.47 1.5 (.5-4.6)	.84 1.1 (.5-2.2)
Prior CEA	311 (42.7)	.20 1.4 (.8-2.5)	.59 .9 (.5-1.4)	.36 .7 (.3-1.5)	.82 .9 (.6-1.4)
Restenosis post CEA	179 (24.5)	.87 1.1 (.4-2.8)	.13 .5 (.2-1.2)	.23 .4 (.1-1.7)	.31 .7 (.4-1.4)
CHF	137 (18.8)	.40 1.5 (.5-4.4)	.10 1.8 (.9-3.8)	.12 2.2 (.8-6.0)	.04 1.8 (1.0-3.4)
Prior MI	182 (25.0)	.69 .8 (.2-2.4)	.56 .8 (.3-1.7)	.41 .6 (.2-2.1)	.39 .7 (.4-1.4)
Prior CABG	253 (34.7)	.21 .5 (.2-1.5)	.03 .4 (.2-0.9)	.26 .5 (.2-1.6)	.03 .5 (.3-.9)
Prior TIA	223 (30.6)	.04 2.6 (1.0-6.5)	.05 1.9 (1.0-3.7)	.44 1.5 (.6-3.8)	.02 1.9 (1.1-3.2)
Prior CVA	236 (32.4)	.13 .4 (.1-1.3)	<.0001 4.2 (2.1-8.1)	.04 2.6 (1.0-6.5)	.02 1.8 (1.1-3.1)
PVD	216 (29.6)	.41 .6 (.2-1.9)	.92 1.0 (.5-2.0)	.86 .9 (.3-2.6)	.46 .8 (.4-1.4)
CAD	479 (65.7)	.23 .6 (.2-1.4)	.73 .9 (.4-1.7)	.68 .8 (.3-2.1)	.61 .9 (.5-1.5)
ESRD	23 (3.2)	.60 1.7 (.2-13.6)	.45 1.8 (.4-7.8)	.07 4.1 (.9-19.0)	.12 2.5 (.8-7.6)
COPD	147 (20.2)	.92 1.1 (.3-3.2)	.78 .9 (.4-2.1)	.71 .8 (.2-2.7)	.76 .9 (.4-1.8)
Contralateral occlusion	129 (17.7)	.70 1.2 (.4-3.8)	.45 .7 (.3-1.8)	.61 1.3 (.4-4.1)	.87 .9 (.5-1.9)
Asymptomatic	430 (59.0)	.57 .8 (.3-1.9)	.0003 .3 (.1-.5)	.0038 .2 (.06-.6)	.0002 .3 (.2-.6)
Close cell stent	131 (18.0)	.28 1.8 (.6-5.1)	.07 1.9 (.9-4.1)	.88 .9 (.3-3.2)	.06 1.8 (1.0-3.3)

CABG, Coronary artery bypass graft; *CAD,* coronary artery disease; *CEA,* carotid endarterectomy; *CHF,* congestive heart failure; *CI,* confidence interval; *COPD,* chronic obstructive pulmonary disease; *CVA,* cerebrovascular accident (stroke); *ESRD,* end-stage renal disease; *MI,* myocardial infarction; *OR,* odds ratio; *PVD,* peripheral vascular disease; *TIA,* transient ischemic attack.

Porosity is defined as the ratio of porous surface area to total surface area.

Pore density is the ratio of total number of pores to total surface area. Porosity, pore density, and number of pores were calculated from confocal microscopic images of the filters removed from the guidewire and mounted flat on the microscope slide with deionized water.[19]

Eccentricity refers to whether or not the DPF design is concentric and can be categorized by viewing the symmetry of the DPF basket inlet.

Wall apposition refers to a gap between the DPF and the arterial wall and is expressed as a percentage of vessel cross-sectional area at the site of device deployment. This value was quantified using photographs of the DPF in the coronal plane. The ideal value is 0%, or no gap.[18] Wall apposition was measured by taking photographs of the DPF deployed in a 5.5-mm inner diameter silicone tube[18]; gaps between the DPF and the vessel wall were colored red and the ratio of the red area to the tube cross-sectional area was subsequently calculated.

The filter usage distribution is given in Table IV.

Statistical analysis. Peri-/postprocedural outcome complications, patient characteristics (Table I), filter type (Tables II and IV), and filter characteristics (Tables III and

Table II. Distal protection filter used in the carotid artery stenting procedures

Filter name	*N (%), n = 729*	*TIA* P *value* *OR (95% CI)*	*CVA* P *value* *OR (95% CI)*	*Death* P *value* *OR (95% CI)*	*Adverse event* P *value* *OR (95% CI)*
Accunet	429 (58.8)	.02 .3 (.1-.8)	.03 .5 (.2-.9)	.03 .3 (.1-.9)	.0007 .4 (.2-.6)
Angioguard	114 (15.6)	.06 2.6 (.9-6.9)	.98 1.0 (.4-2.5)	.44 1.5 (.5-4.8)	.30 1.4 (.7-2.7)
FilterWire	113 (15.5)	.19 2.0 (.7-5.6)	.16 1.7 (.8-3.8)	.60 .7 (.1-3.0)	.07 1.8 (.9-3.4)
Spider	45 (6.17)	.43 1.8 (.4-8.1)	.26 1.8 (.6-5.5)	<.0001 8.6 (3.1-24.2)	.02 2.7 (1.2-6.1)
Emboshield	24 (3.3)	n/a	.81 .8 (.1-5.9)	n/a	.48 .5 (.06-3.6)
Fibernet	4 (.5)	n/a	.003 19.1 (2.6-139.8)	n/a	.01 11.7 (1.6-84.7)
Accunet (baseline for below analysis)	429 (58.8)	n/a	n/a	n/a	n/a
Angioguard	114 (15.6)	n/a	.21 1.4 (.5-3.7)	.94 n/a	.59 2.2 (1.04-4.5)
FilterWire	113 (15.5)	n/a	.79 2.2 (1.0-5.2)	.96 n/a	.98 2.6 (1.3-5.3)
Spider	45 (6.17)	n/a	.97 2.5 (.8-7.9)	.92 n/a	.31 4 (1.7-9.6)
Emboshield	24 (3.3)	n/a	.36 1.1 (.1-8.8)	.95 n/a	.17 .8 (.1-6.2)
Fibernet	4 (.5)	n/a	n/a	n/a	n/a

CI, Confidence interval; *CVA,* cerebrovascular accident (stroke); *n/a,* not available; *OR,* odds ratio; *TIA,* transient ischemic attack.

Table III. DPF design characteristics

DPF	*Accunet, n = 429*	*Angioguard, n = 114*	*FilterWire, n = 113*	*Spider, n = 45*	*Emboshield, n = 24*
Capture efficiency	95.1	63.7	96.1	99.9	64.6
Vascular resistance	24.8	30.6	12.8	3.5	14.7
Porosity	4.5	11.3	12.9	50.4	2.2
No. of pores	912	1100	2576	1563	400
Pore density	4.4	14.4	13.6	10	1.4
Wall apposition	.075	4.2	.65	.49	0
Concentric	1	1	0	0	1

Capture efficiency, Percentage of emboli captured by DPF; *DPF,* distal protection filter; *Pore density,* ratio of total number of pores to total surface area DPF basket; *Porosity,* percentage of porous surface area to total surface area of DPF basket; *Vascular resistance,* expressed as a ratio of the vascular resistance in the internal carotid artery at full filter conditions normalized to the initial conditions; *Wall apposition,* represented by a gap between the device and the arterial wall and expressed as a percentage of the vessel cross-sectional area at the site of device deployment.

V) are described as event percentages. Logistic regression was performed using SAS version 9.2 (SAS Institute, Cary, NC) to determine correlations between patient characteristics, filter type, and procedure outcome. Univariate analysis with a significance level of $P \leq .05$ compared the binary recorded clinical variables to each potential outcome as well as to a composite AE outcome. The *P* value, odds ratio (OR), and 95% confidence interval (CI) were recorded for each variable and are given in Tables I and II. Note that OR >1 corresponds to an increased likelihood of AE occurrence, and, conversely, OR <1 corresponds to a decreased likelihood of AE occurrence. The significant variables identified in the univariate analysis were then used for multivariate analysis as well as those identified by the backward elimination method using SAS. A significance level of $P \leq .05$ was used, which correlated with a Wald $\chi^2 \geq 2$, determined if a variable was suitable for inclusion in the multivariate analysis. The Hosmer-Lemeshow goodness-of-fit test was used to identify good-fit models, where $P \leq .05$ represented an ill-fit model; all models with $P > .05$ were identified as good-fit models.[20] Because nearly 60% of the patient population used the Accunet filter, we performed two different statistical analyses to accommodate for the skewed nature of the filter distribution. The initial statistical analysis was conducted with all five filters being compared with the average. The second analysis used Accunet as the baseline performance with the remaining four filters compared against this new baseline.

RESULTS

A total of 1150 CAS records were reviewed, of which 713 patients and 731 procedures met the inclusion criteria,

Table IV. DPF distribution

DPF	*N (%), n = 729*	*TIA (%), n = 729*	*CVA (%), n = 729*	*Death (%), n = 729*	*Adverse event (%), n = 729*
Accunet	429 (58.8)	6 (.008)	16 (.02)	6 (.008)	23 (.03)
Angioguard	114 (15.6)	6 (.008)	6 (.008)	4 (.005)	12 (.02)
FilterWire	113 (15.5)	5 (.007)	9 (.01)	2 (.003)	14 (.02)
Spider	45 (6.2)	2 (.003)	4 (.005)	6 (.008)	8 (.01)
Emboshield	24 (3.3)	0	1 (.001)	1 (.001)	2 (.003)
Fibernet	4 (.6)	0	2 (.003)	0	2 (.003)

CVA, Cerebrovascular accident (stroke); *DPF*, distal protection filter; *TIA*, transient ischemic attack.

Table V. DPF design characteristics and statistical significance.

Design characteristic, n = 725	*TIA* P *value* *Coefficient*	*CVA* P *value* *Coefficient*	*Death* P *value* *Coefficient*	*Adverse event* P *value* *Coefficient*
Capture efficiency	.20 −.0006	.92 .0001	.93 0	.65 −.0004
Vascular resistance	.56 −.0005	.08 −.002	.007 −.002	.01 −.003
Porosity	.11 .0009	.08 .001	<.0001 .002	.0007 .003
No. of pores	.07 .0005	.05 .0004	.35 .0003	.006 .0005
Pore density	.004 .004	.09 .003	.08 .002	.001 .007
Wall apposition	.03 .009	.63 .003	.29 .004	.10 .01
Concentric	.11 −.76	.04 −.75	.02 −1.09	.02 −.90
OR (95% CI)	.5 (.2-1.2)	.5 (.2-.9)	.3 (.1-.9)	.4 (.2-.7)

Capture efficiency, Percentage of emboli captured by DPF; *CI*, confidence interval; *CVA*, cerebrovascular accident (stroke); *DPF*, distal protection filter; *OR*, odds ratio; *Pore density*, ratio of total number of pores to total surface area DPF basket; *Porosity*, percentage of porous surface area to total surface area of DPF basket; *TIA*, transient ischemic attack; *Vascular resistance*, expressed as a ratio of the vascular resistance in the internal carotid artery at full filter conditions normalized to the initial conditions; *Wall apposition*, represented by a gap between the device and the arterial wall and expressed as a percentage of the vessel cross-sectional area at the site of device deployment.
A total of 725 patients were used in this analysis because Fibernet does not have quantified filter characteristics.

with 16 of the patients undergoing two CAS procedures that were both included in the study. The 30-day follow-up for 38% of the records reviewed was performed at regional hospitals and not at the center that performed the CAS intervention. Of the 731 records, there were 19 TIAs (2.6%), 38 strokes (5.2%), one MI (0.1%), 19 deaths (3.6%), and a total of 61 patients with AEs (8.3%). Due to the single MI complication, this record was excluded from the analysis. One death was due to non-neurologic complications and was also excluded from the analysis. The remaining 729 procedures had similar statistics, with 19 TIAs (2.6%), 38 strokes (5.2%), 18 deaths (2.5%), and 59 total complications (8.1%). The average age was 71 ± 9 years, with 141 octogenarians (19.3%). Nearly two thirds (n = 465 [63.8%]) were male, and a similar fraction were asymptomatic (n = 430 [59%]). The stroke and death rates for asymptomatic patients were 2.5% (n = 11 events per 430 patients) and 1% (n = 4 events per 430 patients), respectively. Conversely, the stroke and death rates for symptomatic patients were 9% (n = 27 events per 299 patients) and 4.7% (n = 14 events per 299 patients), respectively. Considering the composite of all AEs, these were 4.9% (n = 21 events per 430 patients) and 12.7% (n = 38 events per 299 patients) for asymptomatic and symptomatic patients, respectively.

Six different DPFs were used in the 729 procedures: Accunet (n = 429 [58.8%]), Angioguard (n = 114 [15.6%]), FilterWire (n = 113 [15.5%]), Spider (n = 45 [6.2%]), Emboshield (n = 24 [3.3%]), and Fibernet (n = 4 [0.5%]). Complete DPF distribution and associated procedural complications are given in Table IV. Due to the low number of patients treated with Fibernet, it was excluded from the filter analysis but was included in the clinical outcome analysis.

Univariate analysis. Several variables were found to be significant, as detailed in Tables I and II for the *P* value, OR, and CI of each variable and filter type, when compared with the response variables (peri/postprocedural complications). For the composite of AEs, gender (male; $P = .02$; OR, 0.5), congestive heart failure (CHF; $P = .04$; OR, 1.8), prior coronary artery bypass graft (CABG; $P = .03$; OR, 0.5), prior TIA ($P = .02$; OR, 1.9), prior CVA

(P = .02; OR, 1.8), and especially asymptomatic (P = .0002; OR, 0.3) were all found to be significant. Peri-/postprocedural death was associated with age (age ≥80 years; P = .04; OR, 2.7), prior CVA (P = .04; OR, 2.6), and asymptomatic (P = .0038; OR, 0.2). Peri-/postprocedural stroke was associated with age (age ≥80 years; P = .05; OR, 2.0), gender (male; P = .03; OR, 0.5), prior CABG (P = .03; OR, 0.4), prior TIA (P = .05; OR, 1.9), and especially prior stroke ($P \leq$ .0001; OR, 4.2) as well as asymptomatic (P = .0003; OR, 0.3). Peri-/postprocedural TIA was associated with gender (male; P = .05; OR, 0.4) and prior TIA (P = .04; OR, 2.6).

The univariate analysis for filter design type yielded significant variables when considering the average of the filter results to be the baseline, whereas no significance was established when the Accunet results were used as the baseline (being the majority of the filter demographics at nearly 60%). The DPF design characteristics revealed several significant results (Table V). The composite of AE was negatively associated with both vascular resistance (P = .01) and eccentricity (P = .02) and positively associated with porosity (P = .0007), number of pores (P = .005), and pore density (P = .001). Peri-/postprocedural death was negatively associated with both vascular resistance (P = .007) and eccentricity (P = .02) and positively with porosity (P < .0001). Peri-/postprocedural stroke was positively associated with number of pores (P = .05) and negatively associated with eccentricity (P = .04). Peri-/postprocedural TIA was positively associated with both pore density (P = .004) and wall apposition (P = .03).

Subgroup analysis. The outcome of the subgroup analysis is included in Tables VI and VII (online only) with several significant groups identified. Table VI (online only) shows the results for symptomatic vs asymptomatic patients with each patient characteristic. It also identifies correlations with each of the four response variables (TIA, stroke, death, and AE). Notable significance was seen for the following categories: (1) Symptomatic patients with a history of CHF have a higher risk of AE (P = .0015; OR, 3.3), peri-/postprocedural stroke (P = .008; OR, 3.1), and peri-/postprocedural TIA (P = .05; OR, 3.9). (2) Symptomatic patients who underwent CAS with a closed cell stent (Nexstent, Endotex, Wallstent, and Xact, but not Precise, Smart, Cordis, or Acculink) have a higher risk of AE (P = .02; OR, 2.5) and peri-/postprocedural stroke (P = .05; OR, 2.4). (3) Symptomatic patients with a history of stroke were at higher risk for peri-/postprocedural stroke (P = .002; OR, 4.4). (4) Asymptomatic octogenarian patients (P = .02; OR, 4.3) as well as those with a history of TIA (P = .05; OR, 3.5) both had higher risk of peri-/postprocedural stroke.

Similarly, Table VII (online only) shows the outcome of the subgroup analysis for octogenarians vs nonoctogenarians as compared with each patient characteristic and identifies correlations with each of the four response variables. Notable significance was seen for the following categories. (1) Nonoctogenarians with a history of stroke had a greater risk of peri-/postprocedural stroke (P = .0001; OR, 5.2), whereas those who were asymptomatic had significantly lower risk (P = .0003; OR, 0.2). (2) Male octogenarian patients had a lower risk (P = .02; OR, 0.2) of peri-/postprocedural stroke. (3) Nonoctogenarians with a history of CHF (P = .02; OR, 4.3) and stroke (P = .03; OR, 3.9) had greater risk of peri-/postprocedural death, whereas those who were asymptomatic had a lower risk of death (P = .01; OR, 0.1). (4) Octogenarians with a previous CABG procedure had lower risk of an AE (P = .05; OR, 0.2). (5) Nonoctogenarians with a history of CHF had a higher risk of a peri-/postprocedural complication (P = .02; OR, 2.3), and those who were asymptomatic had a lower risk (P = .0016; OR, 0.3).

Multivariate analysis. The Hosmer-Lemeshow goodness-of-fit test revealed models for the response variables AE, death, and stroke to be good-fit models ($P \geq$ .05) in multivariate analysis.

Adverse events. Being male, asymptomatic, and use of a closed cell stent all had OR <1, significant univariate P values, and a combined model P value of .57. Having a history of CHF, stroke, and TIA (each with OR >1) led to a model P value of .72.

Peri-/postprocedural stroke. Asymptomatic male patients (both OR <1) had a model P value of .70. Octogenarian patients with a history of TIA and stroke (all OR >1) had a model P value of .97.

Peri-/postprocedural death. Octogenarians with a history of stroke (both OR >1) had a model P value of .62.

Multivariate analysis did not identify any significant DPF design characteristics but did reveal that the aforementioned clinical variables remained significant.

DISCUSSION

The purpose of this single-arm, multicenter study was to review retrospectively CAS procedures to find correlations between peri-/postprocedural complications, clinical variables, filter type, and filter characteristics determined by in vitro testing. The use of CAS for asymptomatic patients currently is not approved by Centers for Medicare & Medicaid Services. In our study, these patients were treated under the auspices of a trial or after they had received approval from non-Centers for Medicare & Medicaid Services payers. The outcome of this study can help provide additional information regarding filter choice to clinicians when evaluating patients potentially suitable for CAS. Of the seven DPF characteristics considered in this study, vascular resistance, eccentricity, and capture efficiency had a negative correlation with AE, whereas porosity, wall apposition, and pore density had positive correlations. Vascular resistance, porosity, pore density, and eccentricity were found to be significant with P < .05 (Table V). Similarly, vascular resistance and eccentricity had negative correlations with peri-/postprocedural death, whereas porosity had a positive correlation. The following filter design characteristics were independently significant for minimizing peri-/postprocedural AEs: higher vascular resistance, concentric in shape, greater capture efficiency, lower porosity, lower number of pores, and lower pore

density. Lower porosity and smaller wall apposition were also found to be independently significant for minimization of peri-/postprocedural TIAs. Because multivariate analysis was unable to identify any significant DPF design characteristics, we cannot definitively conclude that certain filters are safer to use than others. However, utilizing the univariate results, it appears that the Accunet, Angioguard, and Emboshield filters have a favorable design as it relates to the minimization of AEs (Table III).

As previously reported in the literature by Schlüter et al,[14] Voeks et al,[21] Roubin et al,[22] and Kastrup et al,[23] octogenarians had an increased risk of postprocedural stroke and death, which was consistent with our results (Table I). Interestingly, gender was seen to favor males as having lower risk of peri-/postprocedural TIA, stroke, and AE compared with females. This finding did not agree with the results of Schlüter et al,[14] who found males to be at higher risk than females. Their study also showed an increased risk for patients with diabetes mellitus, whereas no significance was found in our results. Consistent with our findings, Roubin et al[22] and Qureshi et al[24] did not find diabetes mellitus to have any significant impact on AEs. In our results, history of stroke, CHF, and TIA also showed significant increase in peri-/postprocedural complications.

To date, few studies have focused on correlating the type of DPF used and the 30-day outcome. According to Shah et al,[25] the ideal test would be a comprehensive comparative randomized trial using multiple types of filters. There is a need for both prospective and retrospective studies to determine if filter type, and thus filter design characteristics, correlates with CAS procedural complications. With the results of the present investigation, physicians will have more information regarding the filter of choice and clinical variables associated with procedural outcome.

Iyer et al[26] conducted a study correlating 30-day CAS outcomes to embolic protection devices (includes DPF and both proximal and distal balloon occlusion devices). The study concluded that there were no significant differences in risks of procedural AEs between different devices or types of devices. Their results showed an increased risk of 30-day AEs with the Accunet filter compared with FilterWire. As described in Table II, when the average filter result is the baseline, Accunet is significant for all three potential complications including TIA ($P = .02$; OR, 0.3), stroke ($P = .03$; OR, 0.5), and death ($P = .03$; OR, 0.3) as well as for any AE ($P = .0007$; OR, 0.4). These results would identify Accunet as the best filter choice because it has a small OR (<1), meaning that there is less chance of complication. The Spider filter is also seen as significant for both peri-/postprocedural death ($P \leq .0001$; OR, 8.6) and overall AEs ($P = .02$; OR, 2.7). One limitation of the study is that this outcome could be due to the fact that Accunet was the most frequently used device in the CAS procedures, whereas FilterWire was the most common in the study by Iyer et al.[26] Such comparison illustrates the importance of having an even distribution of filter types regarding correlation of DPF with CAS outcome.

An equally important study was conducted by Roffi et al,[27] who focused on the impact of filter design on blood flow impairment in the internal carotid artery among patients undergoing filter-protected CAS. They concluded that there was a positive correlation between the type of filter used and the occurrence of flow impairment.[27] Contrary to their findings, our results indicate that vascular resistance was significant for negative correlations with both peri-/postprocedural death and AEs (Table VII, online only). Among the DPF design characteristics listed in Table VII (online only) only capture efficiency was found not significantly correlated with any specific or comprehensive AE. These results strongly support the positive correlation between DPF design characteristics and CAS complications.

The CAS procedural stroke and death rates observed in our study are higher than the American Heart Association guidelines for carotid intervention, which are 3% for asymptomatic patients and 6% for symptomatic patients. A major contributing factor to this high neurologic AE rate is that a large fraction of the cohort (40%) was composed of symptomatic patients. Part of the cohort for this study were also participating in the SAPPHIRE (Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy), ARCHeR (ACCULINK for Revascularization of Carotids in High-Risk Patients), BEACH (Boston Scientific EPI: A Carotid Stenting Trial for High Risk Surgical Patients), or CABERNET (Carotid Artery Revascularization Using the Boston Scientific EPI Filterwire EX/EZ and the EndoTex NexStent) trials, all of which generally include high-risk patients considered unsuitable for CEA. Currently, both the American Heart Association 2011 and the UK National Institute for Clinical Excellence 2011 guidelines support the use of CAS for treatment of standard-surgical-risk patients, whereas the European Society for Vascular Surgery 2009 guidelines stress that CAS be restricted to high-surgical-risk patients. This discrepancy is due in part to the 2009 date for the European Society for Vascular Surgery decision, which predates the results of CREST (Carotid Revascularization Endarterectomy Versus Stenting Trial).[7] According to the most recent study conducted comparing CEA with CAS procedures, CREST released its final results at the end of 2010 and revealed that the primary outcome was similar between the two procedures, but that there was an age dependency. To date, CREST is the largest randomized trial of carotid revascularization,[7] and it reports an increase in procedural CAS complications for octogenarians.[21] In the present work, the subgroup of patients <80 years with a history of stroke had an increased risk of peri-/postprocedural stroke or death compared with octogenarians (Table VI, online only). Conversely, octogenarian males were at a much greater risk of peri-/postprocedural stroke (OR, 4.3) compared with younger male patients (OR, 1.2; Table VI, online only).

Study limitations. One limitation of our study is the apparently uneven distribution of filter type used. As seen from the high number of procedures using the Accunet

filter, statistical analysis for DPF design characteristics was conducted in the following two ways: first by comparing each DPF with the average of all DPFs used in the study, and second by comparing each DPF to Accunet, which was set at the baseline. For this reason, the study was not truly randomized because there are underlying reasons for choosing filter type, whether it is institution specific or physician specific. A future study should attempt a randomized, prospective study with an even distribution of filter type used for all CAS patients, albeit a challenging task to accomplish. Another limitation is that we did not take into account the experience of the physician or the frequency of CAS performed at the specific institutes, both of which can affect the outcome of the procedure. It must also be noted that the 30-day follow-up studies were documented by a combination of independent neurologists for those patients participating in sponsored trials and by neurologists at the UPMC and WPAHS hospital sites for those not participating in trial studies.

CONCLUSIONS

Positive correlations between CAS procedural complications, clinical variables, and the type of DPF and its design characteristics can be derived by retrospectively reviewing procedural information and performing univariate and multivariate analyses. The analysis with Accunet used as the baseline in comparison with the other four filters did not show any statistically significant results when associating filter type to procedural outcome. The following filter design characteristics are independently significant for minimizing peri-/postprocedural adverse outcomes: higher vascular resistance, concentric in shape, greater capture efficiency, lower porosity, lower number of pores, and lower pore density. Lower porosity and smaller wall apposition were also found to be independently significant for minimization of peri-/postprocedural transient ischemic attacks. These appealing filter design characteristics should be taken into consideration for future generations of DPFs.

We thank Jennifer Spotti, MBA, David Lasorda, DO, and Dana Lowers, RN, BSN, for assisting with the data collection at Allegheny General Hospital. We also thank Professor Howard Seltman from the Department of Statistics at Carnegie Mellon University for his advice and recommendations on the statistical analysis of this work.

AUTHOR CONTRIBUTIONS

Conception and design: EF
Analysis and interpretation: NL, GS, SM, RC, EF
Data collection: NL, GS, KW
Writing the article: NL, GS, KW
Critical revision of the article: SM, RC, MW, EF
Final approval of the article: EF
Statistical analysis: NL, GS
Obtained funding: EF
Overall responsibility: EF

REFERENCES

1. Rosamond W, Flegal K, Furie K, Go A, Greenlund K, Haase N, et al. Heart disease and stroke statistics—2008 update: a report from the American Heart Association Statistics Committee and Stroke Statistics Subcommittee. Circulation 2008;117:e25-146.
2. Bates ER, Babb JD, Casey DE Jr, Cates CU, Duckwiler GR, Feldman TE, et al. ACCF/SCAI/SVMB/SIR/ASITN 2007 clinical expert consensus document on carotid stenting: a report of the American College of Cardiology Foundation Task Force on Clinical Expert Consensus Documents (ACCF/SCAI/SVMB/SIR/ASITN Clinical Expert Consensus Document Committee on Carotid Stenting). J Am Coll Cardiol 2007;49:126-70.
3. North American Symptomatic Carotid Endarterectomy Trial Collaborators. Beneficial effect of carotid endarterectomy in symptomatic patients with high-grade carotid stenosis. N Engl J Med 1991;325:445-53.
4. Randomised trial of endarterectomy for recently symptomatic carotid stenosis: final results of the MRC European Carotid Surgery Trial (ECST). Lancet 1998;351:1379-87.
5. Executive Committee for the Asymptomatic Carotid Atherosclerosis Study. Endarterectomy for asymptomatic carotid artery stenosis. JAMA 1995;273:1421-8.
6. Barnett HJ, Taylor DW, Eliasziw M, Fox AJ, Ferguson GG, Haynes RB, et al. Benefit of carotid endarterectomy in patients with symptomatic moderate or severe stenosis. North American Symptomatic Carotid Endarterectomy Trial Collaborators. N Engl J Med 1998;339:1415-25.
7. Cohen DJ, Stolker JM, Wang K, Magnuson EA, Clark WM, Demaerschalk BM, et al. Health-related quality of life after carotid stenting versus carotid endarterectomy: results From CREST (Carotid Revascularization Endarterectomy Versus Stenting Trial). J Am Coll Cardiol 2011;58:1557-65.
8. Sheffet AJ, Roubin G, Howard G, Howard V, Moore W, Meschia JF, et al. Design of the Carotid Revascularization Endarterectomy vs. Stenting Trial (CREST). Int J Stroke 2010;5:40-6.
9. Ricotta JJ, Aburahma A, Ascher E, Eskandari M, Faries P, Lal BK. Updated Society for Vascular Surgery guidelines for management of extracranial carotid disease. J Vasc Surg 2011;54:e1-31.
10. Henry M, Polydorou A, Henry I, Polydorou AD, Hugel M. Carotid angioplasty and stenting under protection: advantages and drawbacks. Exp Rev Med Devices 2008;5:591-603.
11. Barbato JE, Dillavou E, Horowitz MB, Jovin TG, Kanal E, David S, et al. A randomized trial of carotid artery stenting with and without cerebral protection. J Vasc Surg 2008;47:760-5.
12. Cloft HJ. Distal protection: maybe less than you think. Am J Neuroradiol 2008;29:407-8.
13. Atkins MD, Bush RL. Embolic protection devices for carotid artery stenting: have they made a significant difference in outcomes? Semin Vasc Surg 2007;20:244-51.
14. Schlüter M, Reimers B, Castriota F, Tubler T, Cernetti C, Cremonesi A, et al. Impact of diabetes, patient age, and gender on the 30-day incidence of stroke and death in patients undergoing carotid artery stenting with embolus protection: a post-hoc subanalysis of a prospective multicenter registry. J Endovasc Ther 2007;14:271-8.
15. Siewiorek GM, Finol EA, Wholey MH. Clinical significance and technical assessment of stent cell geometry in carotid artery stenting. J Endovasc Ther 2009;16:178-88.
16. Siewiorek GM, Wholey MH, Finol EA. In vitro performance assessment of distal protection filters: pulsatile flow conditions. J Endovasc Ther 2009;16:735-43.
17. Siewiorek GM, Wholey MH, Finol EA. In vitro performance assessment of distal protection devices for carotid artery stenting: effect of physiological anatomy on vascular resistance. J Endovasc Ther 2007;14:712-24.
18. Finol EA, Siewiorek GM, Scotti CM, Wholey MH. Wall apposition assessment and performance comparison of distal protection filters. J Endovasc Ther 2008;15:177-85.
19. Siewiorek GM, Eskandari MK, Finol EA. The Angioguard^{TM} embolic protection device. Exp Rev Med Devices 2008;5:287-96.
20. Hosmer DW, Lemeshow S. Applied logistic regression. New York: Wiley; 1989.
21. Voeks JH, Howard G, Roubin GS, Malas MB, Cohen DJ, Sternbergh WC 3rd, et al. Age and outcomes after carotid stenting and

endarterectomy: the Carotid Revascularization Endarterectomy Versus Stenting Trial. Stroke 2011;42:3484-90.
22. Roubin GS, New G, Iyer SS, Vitek JJ, Al-Mubarak N, Liu MW, et al. Immediate and late clinical outcomes of carotid artery stenting in patients with symptomatic and asymptomatic carotid artery stenosis: a 5-year prospective analysis. Circulation 2001;103:532-7.
23. Kastrup A, Groschel K, Schulz JB, Nagele T, Ernemann U. Clinical predictors of transient ischemic attack, stroke, or death within 30 days of carotid angioplasty and stenting. Stroke 2005;36:787-91.
24. Qureshi AI, Luft AR, Janardhan V, Suri MF, Sharma M, Lanzino G, et al. Identification of patients at risk for periprocedural neurological deficits associated with carotid angioplasty and stenting. Stroke 2000;31:376-82.
25. Shah SK, Balasundaram N, Clair DG. Advances in embolic protection devices. Endovasc Today 2011;10:9-12.
26. Iyer V, de Donato G, Deloose K, Peeters P, Castriota F, Cremonesi A, et al. The type of embolic protection does not influence the outcome in carotid artery stenting. J Vasc Surg 2007;46:251-6.
27. Roffi M, Greutmann M, Schwarz U, Luscher TF, Eberli FR, Amann-Vesti B. Flow impairment during protected carotid artery stenting: impact of filter device design. J Endovasc Ther 2008;15:103-9.

Submitted Jun 2, 2012; accepted Aug 22, 2012.

Additional material for this article may be found online at www.jvascsurg.org.

Table VI (online only). Symptomatic vs asymptomatic patient characteristics

Characteristic, n = 729	*TIA* P *value* *OR (95% CI)*		*CVA* P *value* *OR (95% CI)*		*Death* P *value* *OR (95% CI)*		*Adverse event* P *value* *OR (95% CI)*	
	Asym	*Sym*	*Asym*	*Sym*	*Asym*	*Sym*	*Asym*	*Sym*
Age ≥80 years	.95	.41	.02	.68	.11	.24	.40	.33
	n/a	.4 (.05-3.4)	4.3 (1.3-14.5)	1.2 (.5-3.0)	5 (.7-36.1)	1.9 (.6-6.0)	1.6 (.6-4.4)	1.4 (.7-3.1)
Male	.36	.07	.07	.19	.65	.53	.12	.07
	.6 (.2-1.9)	.3 (.07-1.1)	.3 (.1-1.1)	.6 (.3-1.3)	1.7 (.2-16.5)	1.5 (.4-4.8)	.5 (.2-1.2)	.5 (.3-1.0)
Diabetes mellitus	.11	.41	.58	.06	.67	.36	.45	.15
	2.8 (.8-1.2)	1.7 (.5-6.7)	.7 (.2-2.6)	2.1 (1.0-4.8)	.6 (.1-5.9)	1.6 (.6-4.9)	1.4 (.6-3.4)	1.7 (.8-3.4)
History of	.28	.88	.58	.12	.96	.33	.24	.12
hyperlipidemia	3.1 (.4-24.9)	.9 (.2-3.7)	1.5 (.3-7.2)	.5 (.2-1.2)	n/a	.6 (.2-1.7)	2.1 (.6-7.3)	.6 (.3-1.1)
History of	.70	.96	.22	.92	.54	.76	.51	.44
hypertension	1.5 (.2-12.1)	n/a	.4 (.1-1.7)	1.1 (.3-3.7)	.5 (.05-4.8)	.8 (.2-3.7)	.7 (.2-2.1)	1.6 (.5-5.6)
Current smoker	.96	.88	.20	.85	.97	.71	.36	.77
	1.0 (.2-4.6)	.9 (.2-4.3)	2.2 (.6-7.8)	1.1 (.4-2.7)	n/a	1.2 (.4-4.1)	1.6 (.6-4.2)	1.1 (.5-2.4)
Atrial fibrillation	.65	.70	.58	.49	.97	.27	.47	.5
	.6 (.1-5.0)	1.4 (.3-6.8)	.5 (.07-4.4)	1.4 (.5-3.7)	n/a	2.0 (.6-6.6)	.6 (.1-2.5)	1.3 (.6-3.1)
Prior CEA	.10	.93	.08	.13	.99	.50	.11	.23
	1.7 (.9-3.4)	1.0 (.3-3.2)	1.8 (.9-3.4)	.5 (.2-1.2)	1.0 (.3-3.7)	.7 (.2-2.1)	1.5 (.9-2.5)	.6 (.3-1.3)
Restenosis	.99	.70	.66	.11	.85	.37	.74	.30
post CEA	1.0 (.3-3.5)	1.3 (.3-5.5)	1.3 (.4-3.9)	.2 (.03-1.4)	.8 (.1-6.7)	.4 (.06-2.9)	1.1 (.5-2.7)	.6 (.2-1.6)
CHF	.45	.05	.39	.008	.15	.28	.54	.0015
	.4 (.06-3.6)	3.9 (1.0-15.2)	.4 (.05-3.2)	3.1 (1.3-7.3)	4.2 (.6-3.2)	1.9 (.6-6.4)	.7 (.2-2.3)	3.3 (1.6-7.0)
Prior MI	.51	.76	.62	.62	.38	.29	.92	.65
	.6 (.1-2.8)	1.3 (.3-6.3)	1.4 (.4-4.8)	.7 (.2-2.3)	2.4 (.3-17.3)	.3 (.04-2.6)	.9 (.4-2.5)	.8 (.3-2.0)
Prior CABG	.61	.23	.19	.16	.61	.19	.38	.09
	.7 (.2-2.8)	.28 (.03-2.2)	.4 (.08-1.7)	.5 (.2-1.3)	1.7 (.2-12.0)	.4 (.1-1.7)	.6 (.2-1.7)	.5 (.2-1.1)
Prior TIA	.63	.06	.05	.56	.97	.79	.23	.81
	1.5 (.3-7.1)	7.2 (.9-58.8)	3.5 (1.0-12.3)	.8 (.4-1.7)	n/a	.9 (.3-2.5)	1.9 (.7-5.4)	1.1 (.5-2.1)
Prior CVA	.37	.14	.26	.002	.89	.21	.73	.09
	.4 (.05-3.1)	.3 (.06-1.5)	2.0 (.6-6.7)	4.4 (1.7-11.2)	1.2 (.1-11.0)	2.1 (.7-6.3)	.8 (.3-2.5)	1.8 (.9-3.7)
PVD	.49	.64	.26	.41	.39	.52	.41	.13
	.6 (.1-2.7)	.69 (.1-3.4)	2.0 (.6-6.6)	.7 (.3-1.7)	2.3 (.3-16.9)	.6 (.2-2.4)	1.6 (.6-3.6)	.5 (.2-1.2)
CAD	.96	.13	.88	.93	.85	.91	.57	.66
	1.0 (.2-3.8)	.3 (.08-1.4)	1.1 (.3-4.2)	1.0 (.5-2.3)	1.2 (.1-12.1)	.9 (.3-2.8)	1.3 (.5-3.7)	.8 (.4-1.7)
ESRD	.25	.98	.98	.18	.05	.37	.12	.39
	3.5 (.4-29.5)	n/a	n/a	3.0 (.6-15.4)	1.6 (1-108.8)	2.7 (.3-22.9)	3.5 (.7-16.7)	2.0 (.4-1.1)
COPD	.43	.32	.37	.77	.97	.90	.22	.55
	.4 (.05-3.4)	2.0 (.5-8.4)	.4 (.05-3.1)	1.1 (.4-3.0)	n/a	1.1 (.3-4.0)	.4 (.1-1.7)	1.3 (.6-2.9)
Contralateral	.57	.28	.50	.56	.66	.82	.37	.74
occlusion	.5 (.1-4.4)	2.2 (.5-9.0)	.5 (.06-3.9)	.7 (.2-2.2)	1.7 (.2-16.2)	1.2 (.3-4.3)	.5 (.1-2.2)	1.1 (.5-2.7)
Closed cell stent	.39	.49	.50	.05	.97	.58	.59	.02
	1.8 (.5-7.2)	.18 (.3-9.0)	1.6 (.4-6.1)	2.4 (1.0-5.9)	n/a	1.4 (.4-5.4)	1.3 (.5-3.7)	2.5 (1.1-5.4)

Asym, Asymptomatic; *CABG*, coronary artery bypass graft; *CAD*, coronary artery disease; *CEA*, carotid endarterectomy; *CHF*, congestive heart failure; *CI*, confidence interval; *COPD*, chronic obstructive pulmonary disease; *CVA*, cerebrovascular accident (stroke); *ESRD*, end-stage renal disease; *MI*, myocardial infarction; *n/a*, not applicable (patient did not have characteristic and outcome in question); *OR*, odds ratio; *PVD*, peripheral vascular disease; *Sym*, symptomatic; *TIA*, transient ischemic attack.

Table VII (online only). Octogenarian vs nonoctogenarian patient characteristics

	TIA P *value* *OR (95% CI)*		*CVA* P *value* *OR (95% CI)*		*Death* P *value* *OR (95% CI)*		*Adverse event* P *value* *OR (95% CI)*	
Characteristic, n = 729	*Age ≥80 years*	*Age <80 years*	*Age ≥80 years*	*Age <80 years*	*Age ≥80 years*	*Age <80 years*	*Age ≥80 years*	*Age <80 years*
Male	.95	.10	.02	.30	.73	.52	.06	.09
	n/a	.5 (.2-1.2)	.2 (.1-.8)	.7 (.3-1.4)	1.3 (.2-7.2)	1.5 (.4-5.9)	.4 (.1-1.0)	.6 (.3-1.1)
Diabetes mellitus	.96	.08	.21	.46	.88	.49	.63	.12
	n/a	2.3 (.9-6.0)	2.2 (.6-7.3)	1.3 (.6-3.0)	1.1 (.2-6.1)	1.5 (.4-5.0)	1.3 (.4-4.1)	1.6 (.9-3.1)
History of	.95	.65	.66	.08	.36	.18	.61	.23
hyperlipidemia	n/a	1.3 (.4-4.0)	1.3 (.3-5.2)	.5 (.2-1.1)	2.7 (.3-23.5)	.4 (.1-1.4)	1.4 (.4-4.5)	.7 (.3-1.3)
History of	.97	.36	.27	.83	.28	.70	.58	.46
hypertension	n/a	2.6 (.3-19.6)	.4 (.1-1.8)	1.1 (.3-3.9)	.4 (.07-2.1)	1.5 (.2-11.8)	.7 (.2-2.6)	1.5 (.5-4.3)
Current smoker	.98	.72	.86	.14	.97	.43	.90	.16
	n/a	.8 (.3-2.5)	1.2 (.1-1.5)	1.8 (.8-4.2)	n/a	1.6 (.5-5.7)	.9 (.1-7.3)	1.6 (.8-3.0)
Atrial fibrillation	.95	.64	.69	.95	.67	.26	.64	.85
	n/a	.7 (.2-3.1)	1.3 (.3-5.2)	1.0 (.3-3.1)	.6 (.1-5.4)	2.2 (.6-8.3)	1.3 (.4-4.5)	.9 (.4-2.2)
Prior CEA	.95	.18	.75	.48	.14	.94	.93	.82
	n/a	1.5 (.8-2.6)	1.1 (.5-2.8)	.8 (.4-1.5)	2.0 (.8-5.2)	n/a	1.0 (.5-2.4)	.95 (.6-1.5)
Restenosis	.96	.84	.74	.14	.61	.96	.85	.33
post CEA	n/a	1.1 (.4-2.8)	.8 (.2-3.5)	.4 (.1-1.3)	1.5 (.3-7.4)	n/a	.9 (.2-3.2)	.7 (.3-1.5)
CHF	.96	.21	.60	.17	.45	.02	.85	.02
	n/a	1.9 (.7-5.6)	1.4 (.4-4.9)	1.9 (.8-4.6)	.4 (.05-3.7)	4.3 (1.3-14.3)	.9 (.3-3.0)	2.3 (1.2-4.6)
Prior MI	.95	.97	.91	.37	.27	.72	.39	.51
	n/a	1.0 (.3-3.0)	.9 (.3-3.3)	.6 (.2-1.8)	.3 (.04-3.5)	.7 (.2-3.5)	.6 (.2-2.0)	.8 (.3-1.7)
Prior CABG	.95	.28	.15	.11	.23	.63	.05	.22
	n/a	.5 (.2-1.7)	.3 (.1-1.5)	.4 (.2-1.2)	.3 (.03-2.3)	.7 (.2-2.7)	.2 (.05-1.0)	.6 (.3-1.3)
Prior TIA	.95	.06	.64	.06	.70	.25	.46	.03
	n/a	2.5 (1.0-6.3)	1.3 (.4-4.4)	2.1 (1.0-4.7)	.7 (.1-3.8)	2.0 (.6-6.7)	1.4 (.5-4.3)	2.0 (1.1-3.8)
Prior CVA	.95	.17	.08	.0001	.64	.03	.18	.07
	n/a	.4 (.1-1.5)	2.9 (.9-9.7)	5.2 (2.2-12.3)	1.4 (.3-6.7)	3.9 (1.1-13.3)	2.0 (.7-5.8)	1.8 (1.0-3.3)
PVD	.95	.40	.60	.71	.59	.71	.31	.87
	n/a	.6 (.2-1.9)	.7 (.1-3.2)	1.2 (.5-2.7)	.5 (.06-4.8)	1.3 (.4-4.4)	.4 (.1-2.1)	1.0 (.5-1.9)
CAD	.95	.23	.50	.30	.06	.52	.99	.45
	n/a	.6 (.2-1.4)	1.7 (.4-8.2)	.7 (.3-1.4)	.2 (.04-1.1)	1.5 (.4-5.9)	1.0 (.3-3.3)	.8 (.4-1.5)
ESRD	.99	.58	.99	.20	.98	.01	.98	.03
	n/a	1.8 (.2-14.3)	n/a	2.7 (.6-12.2)	n/a	7.3 (1.5-36.5)	n/a	3.6 (1.1-11.4)
COPD	.96	.64	.44	.80	.96	.61	.66	.98
	n/a	.7 (.2-2.6)	.4 (.05-3.6)	1.1 (.4-2.8)	n/a	1.4 (.4-5.4)	.7 (.1-3.3)	1.0 (.5-2.1)
Contralateral	.96	.62	.97	.39	.41	.98	.84	.78
occlusion	n/a	1.3 (.4-4.1)	1.0 (.2-4.7)	.6 (.2-2.0)	2.0 (.4-11.1)	1.0 (.2-4.8)	1.1 (.3-4.4)	.9 (.4-2.1)
Asymptomatic	.95	.65	.47	.0003	.22	.01	.09	.0016
	n/a	.8 (.3-2.1)	.6 (.2-2.1)	.2 (.07-.5)	.3 (.07-1.9)	.1 (.03-.6)	.4 (.1-1.2)	.3 (.2-.7)
Closed cell stent	.96	.57	.13	.24	.96	.44	.12	.20
	n/a	1.4 (.4-4.3)	2.7 (.7-9.9)	1.7 (.7-4.2)	n/a	1.7 (.4-6.5)	2.6 (.8-8.1)	1.6 (.8-3.3)

CABG, Coronary artery bypass graft; *CAD,* coronary artery disease; *CEA,* carotid endarterectomy; *CHF,* congestive heart failure; *CI,* confidence interval; *COPD,* chronic obstructive pulmonary disease; *CVA,* cerebrovascular accident (stroke); *ESRD,* end-stage renal disease; *MI,* myocardial infarction; *n/a,* not applicable (patient did not have characteristic and outcome in question); *OR,* odds ratio; *PVD,* peripheral vascular disease; *TIA,* transient ischemic attack.