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Clinical Outcome of Carotid Artery Stenting According to Provider Specialty and Volume

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Abstract

Background—Several studies have demonstrated better outcomes for carotid endarterectomy with high-volume hospitals and providers. However, only a few studies have reported on the impact of operator specialty/volume on the perioperative outcome of carotid artery stenting (CAS). This study will analyze the correlation of CAS outcomes and provider specialty and volume.

Methods—Prospectively collected data of CAS procedures done at our institution during a 10-year period were analyzed. Major adverse events (MAEs; 30-day stroke, myocardial infarction, and death) were compared according to provider specialty (vascular surgeons [VSs], interventional cardiologists [ICs], interventional radiologists [IRs], interventional vascular medicine [IVM]), and volume (≥5 CAS/year vs. <5 CAS/year).

Results—Four hundred fourteen CAS procedures (44% for symptomatic indications) were analyzed. Demographics/clinical characteristics were somewhat similar between specialties. MAE rates were not significantly different between various specialties: 3.1% for IC, 6.3% for VS, 7.1% for IR, 6.7% for IVM ($P = 0.3121$; 6.3% for VS and 3.8% for others combined, $P = 0.2469$). When physicians with <5 CAS/year were excluded: the MAE rates were 3.1% for IC, 4.7% for VS, and 6.7% for IVM ($P = 0.5633$). When VS alone were compared with others, and physicians with <5 CAS/year were excluded, the MAE rates were 4.7% for VS vs. 3.6% for non-VS ($P = 0.5958$). The MAE rates for low-volume providers, regardless of their specialty, were 9.5% vs. 4% for high-volume providers ($P = 0.1002$). Logistic regression analysis showed that the odds ratio of MAE was 0.4 (0.15–1.1, $P = 0.0674$) for high-volume providers, while the odds ratio for VS was 1.3 (0.45–3.954, $P = 0.5969$).

Conclusions—Perioperative MAE rates for CAS were similar between various providers, regardless of specialties, particularly for vascular surgeons with similar volume to nonvascular surgeons. Low-volume providers had higher MAE rates.

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INTRODUCTION

It has been suggested that carotid artery stenting (CAS) is a reasonable alternative to carotid endarterectomy (CEA) in treating significant carotid artery stenosis in well-experienced high-volume centers.^{1,2} These data also suggest that future prospective trials comparing CEA and CAS outcomes should only include centers that are experienced in both treatment modalities.²

Multiple studies have documented that high-volume providers are a predictor of better outcomes with CEA.^{3–6} Therefore, it would be reasonable to expect that if the volume of cases performed by surgeons impacts the outcome of CEA, then the same should be expected with CAS.

There has also been an ongoing debate as to whether operator specialty impacts the outcome of CAS. This may directly affect credentialing decisions when discussed on a local or national level.

Only a few studies have reported on the impact of operator specialty/volume on the perioperative outcome of CAS.^{2,4,7–9} Our present study will analyze the correlation of CAS outcome and provider specialty and volume.

Patient Population and Methods

This is a retrospective analysis of prospectively collected data of CAS procedures done at our institution during a 10-year period. Informed consent was not necessary as all data were anonymous and no personal patient information was identified. This study was approved by the Institutional Review Board of West Virginia University/Charleston Area Medical Center. It included all patients enrolled in several carotid clinical trials, including Carotid RX ACCULINK/RX ACCUNET Post-Approval Trial to Uncover Unanticipated or Rare Events (CAPTURE; Abbott Vascular, Santa Clara, CA), MAVeRIC (Medtronic AVE Self-Expanding CaRotid Stent System with distal protection In the treatment of Carotid stenosis, Medtronic, Minneapolis, MN) 1, 2, and 3, Parodi (Parodi Anti-Emboli System as an adjuvant cerebral protection device during Carotid Stent-supported angioplasty with the Boston Scientific Carotid Wallstent Monorail Endoprosthesis, Boston Scientific, Natick, MA), SHELTER (Stenting of High Risk Patients: Extracranial Lesion Trial with Emboli Removal, Boston Scientific, Natick, MA), EXACT (Emboshield and Xact Post Approval Carotid Stent Trial by Abbott, Abbott Park, IL), VIVA (ViVEXX Carotid Revascularization Trial), Carotid Stenting for High Surgical-Risk Patients (CHOICE; Abbott, Abbott Park, IL), CANOPY (Carotid Artery Stenting Outcomes in the Standard Risk Population for Carotid Endarterectomy by Abbott, Natick, MA), and Carotid Revascularization Endarterectomy versus Stenting Trial (CREST), by National Institute of Neurologic Disorders and Stroke. Indications for CAS were symptomatic patients (transient ischemic attacks [TIAs]/stroke) with 50% ipsilateral carotid stenosis by conventional angiography or 70% stenosis by duplex ultrasound, computed topography angiography, or magnetic resonance angiography and asymptomatic patients with 80% carotid stenosis based on duplex ultrasound and/or computed topography angiography/magnetic resonance angiography. All patients were treated with aspirin (325 mg) and clopidogrel (75 mg), 48–72 hr prior to the procedure,

which was continued for 30 days after the procedure for clopidogrel and indefinitely for aspirin. All CAS procedures were done according to their trial protocol and using cerebral protection devices.

Provider Specialty and Volume

All providers had full training in endovascular therapy and full privileges in carotid stenting at our institution, which included a minimum of 1 year of an interventional vascular fellowship for interventional cardiologists (ICs) and interventional radiologists (IRs), and 2 years of an interventional vascular fellowship for vascular medicine and completion of 25 carotid stentings (for all providers) during their training before being granted CAS privileges. All vascular surgeons (VSs) were board certified (Vascular Surgery Board/American Board of Surgery) and also completed 25 CAS procedures. Accordingly, providers were classified into: VSs, ICs, IRs, and interventional vascular medicine (IVM).

The annual provider volume for CAS was calculated using the number of CAS procedures done by each provider during the study period, divided by the number of years that the provider performed CAS procedures. Provider volume was classified as: low volume (<5 CAS procedures per year) versus median/high volume (≥ 5 CAS procedures per year).^{10,11}

Primary Outcome and End Points

The primary end point of the study was the composite outcome of major adverse events (MAEs), which included 30-day perioperative stroke, myocardial infarction (MI), and/or death. Periprocedural neurological evaluations were performed before and immediately after CAS and at 24–48 hr postprocedure. All patients, who were part of carotid clinical trials, had cardiac isoenzyme levels and electrocardiograms before the procedure and again at 24–48 hr postoperatively. These tests were also done on all patients who developed chest pain after the CAS procedure. MI was defined as electrocardiogram evidence of ischemia or biomarker elevation with chest pain.

STATISTICAL METHODS

A statistical analysis was performed using SAS 9.2 software (Cary, NC). A univariate analysis was performed on patient demographics and clinical characteristics. Continuous data were reported as means with a standard deviation. The 30-day MAE rates were compared between various providers, according to specialty and annual CAS volume. A logistic regression analysis was also used to examine the correlation between provider specialty and volume and the composite end point (MAE), adjusting for various patient demographics/clinical characteristics and indications for CAS. The threshold for significance was 0.05.

RESULTS

Four hundred fourteen CAS procedures were analyzed. Fifty-six percent were done for asymptomatic stenoses and 44% for TIA and/or stroke symptoms. Tables I and II summarize the demographics and clinical characteristics according to provider specialty (VS versus non-VS [other providers]) and volume. There were no statistically significant differences

among various clinical characteristics and provider specialties, except for CAS indications, where 49% of CAS performed by VS were for asymptomatic indications versus 61% for non-VSs ($P = 0.0146$). Similar observations were noted for low-volume providers versus high-volume providers (40% vs. 59%, $P = 0.0052$, for asymptomatic indications).

Clinical Outcome and Provider Specialty and Volume

Table III summarizes the MAE rates (30-day stroke, MI, and death) according to provider. As noted, there were no significant differences in MAE rates between various specialties ($P = 0.3121$) and when all VSs were compared with all other providers (6.3% vs. 3.8%; $P = 0.2469$). The MAE rates were also similar between various specialties when only high-volume providers were analyzed (excluding providers with <5 CAS per year; $P = 0.5633$). High-volume VS also had similar MAE rates to other high-volume providers (4.7% vs. 3.6%, $P = 0.5958$). In addition, there were no significant differences in MAE rates between VSs and other providers, specifically when high-volume VSs were compared with high-volume other providers, regardless of the symptomatic status: for symptomatic patients (9.5% vs. 3.2%, $P = 0.1589$) and for asymptomatic patients (0% vs. 3.5%, $P = 0.1728$). Table IV summarizes the MAE rates according to provider volume only. As noted, there was a tendency toward higher MAE rates in patients with low-volume providers versus high-volume providers (9.5% vs. 4%, $P = 0.1002$). To be noted, this could have been statistically significant if the sample size was larger, that is, type 2 statistical error is likely to be the cause of the nonsignificant P value.

Logistic Regression Analysis

Table V summarizes the odds ratio of MAE rates according to provider volume/specialty and other comorbidities. As noted, high-volume providers had an odds ratio of 0.4, compared with low-volume providers ($P = 0.0674$). Meanwhile, VS (versus other providers) had an odds ratio of 1.3 ($P = 0.5969$).

DISCUSSION

It has been well documented in multiple studies that high-volume providers are a predictor of better outcomes with CEA.³⁻⁶ In a study by our group evaluating outcomes on 953 CEAs performed over a 2-year period at a single high-volume center; high-volume surgeons (<30 CEAs/year) had a significantly decreased perioperative stroke/death rate when compared with low/medium-volume surgeons (<30 CEAs/year; 1.3% vs. 4.15%).³ It would be reasonable to expect that if the volume of cases performed by surgeons impacts the outcome of CEA, then the same should be expected with CAS.

The preferred mode of treatment of carotid artery atherosclerotic stenosis has been a topic of debate. It is widely accepted that patients with carotid artery stenosis, who are at high risk for CEA, should be considered for CAS. However, in normal risk patients, the most appropriate choice of treatment is a controversial topic that is often discussed, with the results of the CREST dissected and debated by experts in all specialties that have a role in treatment.¹² Despite the controversy regarding the preferred mode of treatment, the number of CAS procedures performed in the United States has continued to increase with a

concurrent decrease in the annual number of CEA procedures that are performed.¹³ There has been an ongoing debate as to whether operator specialty and experience affect outcomes when CAS is performed. This is a very important topic since it directly affects credentialing decisions at both a national level and local level. Also, this raises the question as to whether low-volume operators should continue to perform CAS or should only a few selected high-volume operators perform CAS at institutions that can provide the necessary volume to maintain skilled and competent operators.

Our study was designed to add insight into this difficult dilemma and to address the effect of both operator experience and specialty on CAS outcomes. Our study was unique in that it was performed at a single high-volume center with multiple operator specialties and different operator experience levels. It demonstrated that operator specialty did not determine perioperative MAEs (death, stroke, and MI) but that low-volume providers did have higher MAE rates.

Several prospective multicenter studies have evaluated operator experience to determine if it predicts outcomes with CAS, with varying results.^{10–17} The Carotid ACCULINK/ACCUNET Post Approval Trial to Uncover Rare Events (CAPTURE 2) Study (5,297 patients) and CHOICE (Evaluating Outcomes Through the Collection of Clinical Evidence) Study (5,841 patients) both demonstrated that physician experience impacted CAS outcome.^{15,17}; conversely, the Carotid Stenting Boston Scientific Surveillance Program (CABANA) Study (1,025 patients) and CAPTURE Study (3,500 patients) did not find that operator experience impacted outcomes.^{14,16} It is important to note that in both the CAPTURE and CABANA studies, more emphasis was placed on operator experience with the investigational device, rather than carotid stenting volume in general, and this may have impacted the analysis.^{14,16} Also, the CAPTURE Study used the number of CAS procedures performed before the trial, instead of the annual volume or number of patients enrolled in the study by the operator, to define experience. The CABANA Study did use procedures/month as part of the metric for operator experience, but as stated previously, used operator experience with the investigational device.¹⁶ Interestingly, the CHOICE Study found that an increased time interval between the first CAS and subsequent CAS procedures was the only independent predictor of 30-day death, stroke, and MI after CAS.¹⁵ Meanwhile, the CAPTURE 2 study found that there was an inverse relationship between adverse events and operator volume.¹⁷ The results from these prospective multicenter studies are in general agreement with our findings. Our study demonstrated that low-volume providers had higher MAE rates than high-volume providers (9.5% vs. 4%, respectively). Although not statistically significant, there was a definite trend toward significance ($P = 0.0674$) with logistic regression analysis. We approached the experience of the operator by using annual volume as a measure of experience, rather than assessing the total volume of CAS procedures done by the operator in the past. Both CAPTURE 2 and CHOICE studies found that the operator's current CAS volume predicted outcome, which is in agreement with our findings.^{15–17}

Although our literature search did not identify a study similar to ours (where CAS outcomes were evaluated to address if operator experience impacted outcomes at a single center with multiple specialties); other studies have evaluated databases to address this issue. One such

study by Modrall et al.¹⁰ utilized the Nationwide Inpatient Sample(NIS) database to evaluate if CAS volume, endovascular aneurysm repair (EVAR) volume, thoracic endovascular aortic aneurysm repair (TEVAR) volume, and percutaneous coronary intervention (PCI) volume by the operator, affected CAS outcome defined by the in-hospital stroke/death rate. CAS volume, EVAR/TEVAR volume, and PCI volume were defined by the number of procedures per year. CAS volume was defined as low, medium, and high volume (<5, 5 to <15, and >15 procedures per year, respectively). The authors demonstrated that the risk of stroke/death with CAS decreased with increasing CAS volume, as well as with increasing EVAR/TEVAR volume by the operator.¹⁰ Conversely, increasing PCI volume was actually associated with an increasing likelihood of stroke/death after CAS. Other studies have also utilized regional and national databases to evaluate if annual CAS volume impacts outcome and, not surprisingly, have demonstrated decreased complications when CAS is performed by high-volume operators.^{18–20} However, a study of 4,001 CAS procedures by Steppacher et al.⁷ did not demonstrate a difference in the in-patient death/ stroke rate based on operator volume, but their categories for physician volume were different from ours, and this may have affected the results. Their categories were separated into low (<9 cases/year), medium (9–23 cases/year), and high (>23 cases/ year), while our study considered operators with < 5 cases/year as low volume.

One last important study that examined if operator volume impacted CAS outcomes was a study by “The Carotid Stenting Trialists” Collaboration, which pooled data from 3 randomized trials, including the Endarterectomy Versus Angioplasty in patients with Symptomatic Severe Carotid Stenosis trial, the Stent-Protected Angioplasty versus Carotid Endarterectomy trial, and the International Carotid Stenting Study.¹¹ In this study, 1,546 patients underwent CAS and both lifetime stenting experience excluding the carotid and lifetime CAS experience did not impact the 30-day risk of stroke or death. However, the annual in-trial CAS volume of the operator significantly impacted outcomes; low-volume providers (mean 3.2 procedures/year) had a 30-day death/ stroke risk of 10.1% and intermediate-volume providers (3.2–5.6 procedure/year) had a 30-day death/stroke risk of 8.4%, compared with high-volume providers (>5.6 procedures/year), who had a 30-day death/stroke risk of 5.1%.

Our study found no difference in CAS outcomes between operators of different specialties. We have a very diverse group of specialties performing CAS procedures at our institution, including vascular surgery, interventional cardiology, IVM, and interventional radiology. Our results demonstrated that physician specialty does not predict adverse outcomes with CAS, which is in agreement with a majority of studies that have evaluated this intriguing topic, given the diversity of training paradigms adopted by each specialty. However, some studies have demonstrated differences. Probably the most well-known study that has demonstrated a difference in outcomes based on operator specialty was the lead-in phase of CREST, which found that vascular surgery had an increased death, stroke, and MI rate, relative to ICs.⁸ It was also surprising that the years of experience or number of CAS procedures submitted before the lead-in phase did not significantly affect outcomes.⁸ However, it is very important to realize that when the results of the randomized patients enrolled in CREST were published, there was no difference in outcomes for CAS, based on operator specialty.^{9,12}

Other prospective multicenter studies have likewise addressed this issue. The CAPTURE 2 study found that ICs tended to have a lower 30-day death/stroke rate than other specialties, but the difference was not statistically significant.¹⁷ The CHOICE study separated the specialties into surgery, radiology/neurology, and cardiology.¹⁵ This study demonstrated that cardiologists had reduced embolic protection device dwell times (the time during which the cerebral protection devices were deployed in place), compared with surgery and radiology/neurology, but the 30-day death/stroke/MI rates did not differ between the 3 specialties.¹⁵ The CAPTURE study also found no difference in the 30-day death/stroke/MI rate, based on specialty.¹⁴

A few other studies have used regional and national databases to evaluate if operator specialty affects CAS outcomes. Vogel et al.²¹ evaluated the State Inpatient Databases for New Jersey and found that in 625 CAS cases, the stroke rate was not significantly different between specialties (VSs, cardiologists, and radiologists). Interestingly, however, VSs did have a lower mean total hospital cost, compared with radiology and cardiology. Steppacher et al.⁷ used the State In-patient Databases from New York and Florida and evaluated 4,001 CAS procedures. They demonstrated no difference in the in-patient mortality or stroke rates between interventional cardiology, vascular surgery, and interventional radiology. Again, VSs did have significantly lower total hospital charges than the non-VS group. Finally, Sgroi et al.²² evaluated 20,663 CAS procedures from the NIS database. Operators were separated into surgeons and interventionalists, and the study demonstrated that the 30-day stroke/MI/death rates were not significantly different between the 2 groups.²² However, again it was demonstrated that the interventionalists did have increased hospital charges, compared with surgeons; and when interventionalists performed the procedure, the hospital stay was longer.²² Our study did not evaluate hospital charges or length of stay between specialties, but we may consider evaluating this in the future in our patient cohort.

Study Limitations

Our study does have some limitations. First, it was a single-center study and regional variations in patient population and providers may not apply to the entire United States population. Also, our provider volume results did not reach statistical significance, and this may be related to an inadequate sample size, given the strong trend that was seen in our results. We also used the composite end point of MAE (defined as the 30-day hospital stroke, death, and/or MI). We did not perform an analysis on the end points of death, stroke, and MI separately. An example of this is that the subgroup of IVM had 2 patients with a 30-day mortality and met the MAE end point, but no patients in that specialty's cohort had a stroke within the 30-day postoperative period. Finally, this was a retrospective analysis of prospectively collected data and reporting bias could lead to some error.

CONCLUSIONS

This study demonstrates that provider volume is an important predictor of outcome with CAS. Providers who have a low annual volume of CAS procedures have higher rates of MAEs. Conversely, provider specialty was not found to predict major adverse events. This

demonstrates the need for provider annual volume to be considered in maintaining CAS privileges in order to minimize the risk of adverse events.

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Table I

Demographic and clinical characteristics by provider specialty

Demographic/clinical characteristic	Vascular surgeons (total = 176); no. (%)	Other providers (total = 238); no. (%)	<i>P</i> value
Mean age	67.9 (range: 48–88)	69 (range: 40–88)	0.2709
Male gender	110 (63%)	143 (60%)	0.6181
Hypertension	155 (88%)	212 (89%)	0.7494
Diabetes	67 (38%)	113 (47%)	0.0562
Coronary artery disease	123 (70%)	182 (76%)	0.1326
Congestive heart failure	40 (23%)	60 (25%)	0.5596
Hypercholesterolemia	141 (80%)	169 (71%)	0.0347
Renal failure	31 (18%)	61 (26%)	0.0524
Smoking	105 (60%)	146 (61%)	0.7286
Indication—asymptomatic ^a	86 (49%)	145 (61%)	0.0146
Indication—TIA ^a	79 (45%)	74 (31%)	0.004
Indication—stroke ^a	14 (8%)	27 (11%)	0.2536

^a A few patients had multiple symptoms.

Table II

Demographic and clinical characteristics and provider volume

Demographic/clinical characteristic	Low volume (<5/year; total = 63); no. (%)	Medium/high volume (≥5/year; total = 351); no. (%)	<i>P</i> value
Mean age	66.9 (range: 43–83)	68.8 (range: 40–88)	0.153
Male gender	39 (62%)	214 (61%)	0.8884
Hypertension	57 (90%)	310 (88%)	0.6192
Diabetes	26 (41%)	154 (44%)	0.701
Coronary artery disease	44 (70%)	261 (74%)	0.4534
Congestive heart failure	14 (22%)	86 (25%)	0.6971
Hypercholesterolemia	49 (78%)	261 (74%)	0.5645
Renal failure	14 (22%)	78 (22%)	1
Smoking	38 (60%)	213 (61%)	0.9563
Indication—asymptomatic ^a	25 (40%)	206 (59%)	0.0052
Indication—TIA ^a	30 (48%)	123 (35%)	0.0569
Indication—stroke ^a	9 (14%)	32 (9%)	0.206

^a A few patients had multiple symptoms.

Table III

Perioperative major adverse events (stroke/MI/death): provider specialty and volume

Perioperative MAEs	Interventional cardiologists no. (%)	Vascular surgeons no. (%)	Interventional radiologists no. (%)	Interventional vascular medicine no. (%)	Total no. (%)	P value
All providers	6/194 (3.1%)	11/176 (6.3%)	1/14 (7.1%)	2/30 (6.7%) ^a	20/414 (4.8%)	0.3121
		Vascular surgeons no. (%)		Other providers no. (%)	Total no. (%)	P-value
All vascular surgeons versus all other providers		11/176 (6.3%)		9/238 (3.8%)	20/414 (4.8%)	0.2469
		Interventional cardiologists no. (%)	Vascular surgeons no. (%)	Interventional Vascular medicine no. (%)	Total no. (%)	P-value
High-volume providers only/specialty	6/194 (3.1%)		6/127 (4.7%)	2/30 (6.7%)	14/351 (4%)	0.5633
			Vascular surgeons no. (%)	Other providers no. (%)		P-value
High-volume vascular surgeons versus other high-volume providers			6/127 (4.7%)	8/224 (3.6%)		0.5958

^aNonstroke-related deaths.

Table IV

Perioperative major adverse events (stroke/myocardial infarction/death): volume only

	Low volume (<5/year);	High volume (≥5/year);	
Perioperative MAE	no. (%)	no. (%)	<i>P</i> value
MAE rate	6/63 (9.5%)	14/351 (4%)	0.1002

Table V

Logistic regression analysis: major adverse events

Demographic/clinical characteristic	MAE: odds ratio and 95% confidence interval	P value
Gender–male	1.2 (0.47–3.05)	0.7149
Hypertension	0.5 (0.16–1.53)	0.2202
Diabetes	1.6 (0.66–4.02)	0.2908
Coronary artery disease	1.1 (0.38–3.03)	0.89
Congestive heart failure	1.1 (0.37–2.96)	0.9279
Renal failure	1.2 (0.42–3.33)	0.7596
Indication–asymptomatic	0.4 (0.16–1.05)	0.0621
Volume(>5 per year) ^a	0.4 (0.15–1.07)	0.0674
Vascular surgeon ^b	1.3 (0.45–3.95)	0.5969
Age	1.0 (0.97–1.07)	0.4555

^aThis odds ratio and 95% confidence interval is for ≥ 5 CAS procedures per year versus <5 CAS per year.

^bThis odds ratio and 95% confidence interval is for vascular surgeons versus other providers.