Gender-specific 30-day outcomes after carotid endarterectomy and carotid artery stenting in the Society for Vascular Surgery Vascular Registry

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Objective: **Although the optimal treatment of carotid stenosis remains unclear, available data suggest that women have higher risk of adverse events after carotid revascularization. We used data from the Society for Vascular Surgery Vascular Registry to determine the effect of gender on outcomes after carotid endarterectomy (CEA) and carotid artery stenting (CAS).**
Methods: **There were 9865 patients (40.6% women) who underwent CEA (n = 6492) and CAS (n = 3373). The primary end point was a composite of death, stroke, and myocardial infarction at 30 days.**
Results: **There was no difference in age and ethnicity between genders, but men were more likely to be symptomatic (41.6% vs 38.6%; $P < .003$). There was a higher prevalence of hypertension and chronic obstructive pulmonary disease in women, whereas men had a higher prevalence of coronary artery disease, history of myocardial infarction, and smoking history. For disease etiology in CAS, restenosis was more common in women (28.7% vs 19.7%; $P < .0001$), and radiation was higher in men (6.2% vs 2.6%; $P < .0001$). Comparing by gender, there were no statistically significant differences in the primary end point for CEA (women, 4.07%; men, 4.06%) or CAS (women, 6.69%; men, 6.80%). There remains no difference after stratification by symptomatology and multivariate risk adjustment.**
Conclusions: **In this large, real-world analysis, women and men demonstrated similar results after CEA or CAS. These data suggest that, contrary to previous reports, women do not have a higher risk of adverse events after carotid revascularization. (J Vasc Surg 2014;59:742-8.)**

Cerebrovascular disease is a leading cause of death and the leading cause of serious long-term disability in the United States.[1,2] Carotid revascularization is an essential treatment option for select patients with significant internal carotid artery stenosis. Carotid endarterectomy (CEA) remains considered by many to be the gold standard procedure in carotid revascularization. The benefits of CEA over best medical therapy in subgroups of patients were demonstrated in several landmark randomized clinical trials during the past 2 decades.[3-6] Since its introduction, carotid angioplasty and stenting (CAS) has been touted as an alternative to CEA.[7,8] Although the clinical efficacy and effectiveness of CAS compared with CEA remain debated, there is clear utility in patients with select high-risk criteria.[9-11]

Gender plays an important role in cardiovascular disease. Epidemiologic studies have demonstrated that men have a higher incidence and prevalence rate of stroke than women.[12] The strokes that do occur in women tend to be more severe, however. In terms of revascularization, the available literature suggests that women have higher risk of perioperative adverse events.[5,6] This thus puts into question how much women actually benefit from carotid revascularization compared with men.

The Society for Vascular Surgery (SVS) Vascular Registry (VR) on carotid procedures was developed to collect long-term outcomes on patients treated with CEA and CAS.[13] As the first societal registry to enroll CEA and CAS patients, the VR is one of the largest published databases of carotid revascularization procedures in the United States. The purpose of this study was to use the SVS-VR to determine the effect of gender on outcomes after CEA and CAS.

METHODS

VR data are reported by providers through Web-based electronic data capture. The measurement schedule includes baseline (preoperative) information, such as patient demographics, medical history, carotid symptom

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The analysis of the SVS Vascular Registry carotid data set was supported exclusively by funds from the Society for Vascular Surgery (SVS).
Author conflict of interest: none.
Presented at the 2013 Vascular Annual Meeting of the Society for Vascular Surgery, San Francisco, Calif, May 30-June 1, 2013.
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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.2013.09.036

status, preprocedural diagnostic imaging, and laboratory values; procedural information, including procedural and predischarge complications; and follow-up information such as postprocedure mortality, stroke, myocardial infarction (MI), and other morbidity. All data entered into the VR are fully compliant with the Health Insurance Portability and Accountability Act regulations and are auditable. All data reports and analyses performed included only de-identified and aggregated data. Additional details regarding the SVS-VR have been previously discussed.[13] New England Research Institutes Inc (NERI, Watertown, Mass) maintains the online database. Funding for the administration and database management of the VR has been provided by the SVS (Chicago, Ill).

Outcomes. The primary outcome measure is a composite of the incidence of death, stroke, or MI. Stroke is defined as any nonconvulsive, focal neurologic deficit of abrupt onset persisting >24 hours. The ischemic event must correspond to a vascular territory. An MI is classified as:

- A Q wave MI in which one of the following criteria is required: (1) chest pain or other acute symptoms consistent with myocardial ischemia and new pathologic Q waves in two or more contiguous electrocardiogram (ECG) leads; or (2) new pathologic Q waves in two or more contiguous ECG leads and elevation of cardiac enzymes; or
- A non-Q wave MI, which is defined as creatinine kinase ratio >2 and creatinine kinase-myocardial band >1 in the absence of new, pathologic Q waves.

Analysis of the 30-day outcomes was based on only those patients who had at least a 30-day follow-up visit (>16 days) or who experienced an end point (death, stroke, or MI) ≤30 days of treatment.

Statistical methods. Tests of statistical significance were conducted with χ^2 or Fisher exact tests for categoric variables and *t*-tests for continuous variables. Descriptive statistics are listed as mean ± standard deviation for continuous variables and percentage (frequency) for categoric variables. Subset analyses were performed using the two-tailed *t*-test for continuous variables and the Fisher exact test for discrete and categoric data. Unadjusted and adjusted odds ratios (ORs) found through multivariate logistic regression were used to compare the primary outcomes across subgroups and are presented with 95% confidence intervals (CIs). ORs were adjusted for significant baseline factors that were retained after applying the backward elimination method. Differences were considered significant if P was < .05. All statistical analyses were performed by NERI using SAS statistical software (SAS Institute, Cary, NC).

RESULTS

For the purpose of this study, the analysis was limited to patients treated for carotid disease caused by atherosclerosis, radiation, and restenosis. This led to an exclusion of 454 patients treated for alternative etiologies (eg, dissection, fibromuscular dysplasia, and trauma). There were 9865 patients who had 30-day follow-up data, with 40.6% women (n = 4008) and 59.4% men (n = 5857). For CEA (65.8%; n = 6492), there were 41.3% women (n = 2678) and 58.7% men (n = 3814). For CAS (34.2%; n = 3373), there were 39.4% women (n = 1330) and (60.6%) men (n = 2043). The characteristics of the two gender groups can be found in Table I. Men and women had a similar age and ethnicity profile. Women were more likely to be treated for restenosis (10.2% vs 7.8%) and less often for radiation-induced disease (0.9% vs 2.3%). Men were more likely to be treated for symptomatic disease (41.6% vs 38.6%). There was an equal prevalence (55%) of patients with at least one high-risk factor as defined by the Center for Medicare and Medicaid Services.

Table I. Baseline demographics, disease etiology, and medical history

Variable[a]	*Female (n = 4008)*	*Male (n = 5857)*	P[b]
Age, years	71.1 (18-95)	70.9 (35-98)	.2874
White—Caucasian	92.4 (3705)	92.8 (5434)	.5302
Hispanic	3.5 (139)	3.4 (200)	.9104
Etiology			
Atherosclerosis	88.9 (3563)	89.9 (5268)	<.0001
Radiation	0.9 (37)	2.3 (132)	
Restenosis	10.2 (408)	7.8 (457)	
Carotid symptomatology, % symptomatic	38.6 (1547)	41.6 (2439)	.0026
Stroke	21.6 (864)	23.2 (1358)	.0589
Transient ischemic attack	20.4 (817)	20.7 (1210)	.7608
Transient monocular blindness	5.5 (219)	6.5 (379)	.0434
Any high-risk factor[c]	54.7 (2192)	55.4 (3245)	.4843

[a]Continuous variables are presented as mean (range) and categoric variables as percentage (number).
[b]*P* value for age was found using the *t*-test. All others were found using the χ^2 test.
[c]High-risk factors, as defined by Center for Medicare and Medicaid Services, include age >80 years, New York Heart Association Congestive Heart Failure Class III/IV, ejection fraction <30%, unstable angina, myocardial infarction (MI) ≤30 days, restenosis, radical neck dissection, contralateral occlusion, prior radiation to neck, contralateral laryngeal nerve injury, and high anatomic lesion.

The patient characteristics after separation by procedure and gender can be found in Table II. For both procedures, the age and ethnicity distribution were similar. There was a low prevalence (<2%) of CEA patients treated for radiation or restenosis. Men were more likely to be symptomatic (39.2% vs 35.8%; $P < .007$), driven by a higher (22.2% vs 19.2%; $P = .004$) previous history of stroke. For CAS patients, women had a higher prevalence of restenosis (28.7% vs 19.7%), and men were more likely to be treated for radiation-induced disease (6.2% vs 2.6%). The distribution by medical history within the two procedures was similar. Men tended to have a higher prevalence of coronary artery disease and history of MI and

Table II. Baseline demographics, disease etiology, medical history, and carotid evaluation—stratified by procedure

	CEA patients			*CAS patients*		
Variable[a]	*Female (n = 2678)*	*Male (n = 3814)*	P[b]	*Female (n = 1330)*	*Male (n = 2043)*	P[b]
Age, years	71.0 (37-95)	70.7 (35-98)	.2295	71.2 (18-94)	71.2 (35-96)	.8184
White—Caucasian	92.5 (2477)	93.0 (3546)	.4655	92.3 (1228)	92.4 (1888)	.9471
Hispanic	3.0 (81)	2.7 (102)	.4032	4.4 (58)	4.8 (98)	.6149
Etiology						
Atherosclerosis	99.0 (2650)	98.4 (3754)	.1787	68.6 (913)	74.1 (1514)	<.0001
Radiation	0.1 (2)	0.2 (6)		2.6 (35)	6.2 (126)	
Restenosis	1.0 (26)	1.4 (54)		28.7 (382)	19.7 (403)	
Carotid symptomatology, % symptomatic	35.8 (960)	39.2 (1494)	.0069	44.1 (587)	46.3 (945)	.2292
Stroke	19.2 (514)	22.2 (845)	.0040	26.3 (350)	25.1 (513)	.4431
Transient ischemic attack	19.1 (511)	19.1 (729)	>.9999	23.0 (306)	23.5 (481)	.7390
TMB	4.9 (131)	5.7 (217)	.1623	6.6 (88)	7.9 (162)	.1585
Medical history						
Coronary artery disease	40.4 (1082)	53.8 (2053)	<.0001	51.8 (689)	63.2 (1291)	<.0001
MI	12.8 (344)	18.9 (719)	<.0001	20.1 (267)	23.6 (482)	.0176
Valvular heart disease	8.8 (235)	7.2 (276)	.0246	6.3 (84)	6.0 (122)	.7131
Cardiac arrhythmia	11.2 (301)	14.2 (540)	.0006	14.4 (191)	15.0 (307)	.6196
Congestive heart failure	8.3 (221)	7.6 (288)	.3026	15.0 (199)	14.2 (290)	.5484
Hypertension	85.4 (2287)	83.4 (3182)	.0320	86.8 (1155)	81.1 (1657)	<.0001
Diabetes	31.1 (833)	31.8 (1212)	.5689	36.2 (481)	34.2 (699)	.2523
COPD	18.9 (505)	16.9 (645)	.0440	22.3 (296)	19.3 (394)	.0401
Chronic renal failure	2.9 (79)	3.7 (140)	.1244	3.4 (45)	4.1 (84)	.3126
Peripheral vascular disease	44.8 (1199)	42.2 (1611)	.0444	37.1 (494)	37.2 (760)	>.9999
GI ulcer/bleeding	3.6 (96)	2.7 (102)	.0399	5.4 (72)	4.4 (89)	.1610
Current or past smoker	56.8 (1521)	63.4 (2419)	<.0001	54.0 (718)	65.8 (1344)	<.0001
Cancer	12.3 (330)	13.5 (514)	.1774	14.2 (189)	23.0 (469)	<.0001
Coagulopathy	1.2 (32)	1.5 (58)	.2829	1.4 (19)	0.7 (14)	.0472
ASA grade <3	92.2 (2468)	90.2 (3440)	.0063	90.7 (1206)	92.8 (1896)	.0276
NYHA scale <2	95.2 (2550)	95.5 (3644)	.5474	88.9 (1182)	88.5 (1809)	.7814
Aspirin or clopidogrel	87.1 (2333)	88.1 (3359)	.2502	95.6 (1272)	96.3 (1968)	.3205
Any high-risk factor[c]	36.7 (984)	36.5 (1394)	.8729	90.8 (1208)	90.6 (1851)	.8260
Carotid evaluation						
Baseline ultrasound imaging >80%	68.8 (1717)	70.5 (2500)	.1548	77.6 (923)	77.5 (1362)	>.9999
Contralateral stenosis >70%	18.1 (482)	19.0 (722)	.3636	26.1 (342)	24.1 (489)	.2190
Stent information						
Use of embolic protection				96.7 (1286)	97.7 (1997)	.0797
No. of stents, >1				8.3 (110)	6.5 (133)	.0565

ASA, American Society of Anesthesiologists; *CAS,* carotid artery stenting; *CEA,* carotid endarterectomy; *COPD,* chronic obstructive pulmonary disease; *GI,* gastrointestinal; *MI,* myocardial infarction; *NYHA,* New York Heart Association; *TMB,* transient monocular blindness.

[a]Continuous variables are presented as mean (range) and categoric variables as percentage (number).

[b]*P* value for age was found using the *t*-test. *P* value for etiology was found using the χ^2 test. All others were found using the Fisher exact test.

[c]High-risk factors, as defined by Center for Medicare and Medicaid Services, include age >80 years, NYHA Congestive Heart Failure Class III/IV, ejection fraction <30%, unstable angina, MI ≤30 days, restenosis, radical neck dissection, contralateral occlusion, prior radiation to neck, contralateral laryngeal nerve injury, and high anatomic lesion.

tobacco use, whereas women had a higher prevalence of hypertension and chronic obstructive pulmonary disease. There was no difference in the use of antiplatelet therapy or the presence of Center for Medicare and Medicaid Services high-risk factors. The differences between the percentages of men and women with baseline ultrasound stenosis >80% or contralateral stenosis >70% were not statistically significant.

CEA patients. In patients undergoing CEA (Tables III and IV), there was no statistically significant difference in the 30-day outcomes. The primary end point was nearly identical (4.07% female and 4.06% male), as were the individual end points of mortality, stroke, or MI. Asymptomatic patients undergoing CEA had the lowest event rates, with the composite death/stroke/MI rate

Table III. Thirty-day outcomes for patients undergoing carotid endarterectomy (*CEA*)[a]

	CEA patients, % (No.)		
30-day events	*Female (n = 2678)*	*Male (n = 3814)*	P[b]
Mortality	0.86 (23)	0.87 (33)	>.9999
Stroke	2.58 (69)	2.49 (95)	.8724
MI	1.16 (31)	1.26 (48)	.7320
Death, stroke, or MI	4.07 (109)	4.06 (155)	>.9999

MI, Myocardial infarction.

[a]Events were defined as any event occurring intraoperatively, before discharge, or between discharge and 30 days. Rates are per-patient.

[b]*P* values were based on the Fisher exact test.

Table IV. Thirty-day outcomes for symptomatic and asymptomatic patients undergoing carotid endarterectomy (*CEA*)[a]

	Asymptomatic CEA, % (No.)			*Symptomatic CEA, % (No.)*		
30-day events	*Female (n = 1718)*	*Male (n = 2320)*	P[b]	*Female (n = 960)*	*Male (n = 1494)*	P[b]
Mortality	0.64 (11)	0.82 (19)	.5813	1.25 (12)	0.94 (14)	.5453
Stroke	1.51 (26)	1.68 (39)	.7062	4.48 (43)	3.75 (56)	.4007
MI	1.28 (22)	1.21 (28)	.8859	0.94 (9)	1.34 (20)	.4462
Death, stroke, or MI	3.03 (52)	3.19 (74)	.7845	5.94 (57)	5.42 (81)	.5912

MI, Myocardial infarction.
[a]Events were defined as any event occurring intraoperatively, before discharge, or between discharge and 30 days. Rates are per-patient.
[b]*P* values were based on the Fisher exact test.

Table V. Unadjusted and risk-adjusted odds ratios (*ORs*) for patients undergoing carotid endarterectomy (*CEA*)[a]

	Female vs male			
	Unadjusted		*Adjusted*	
30-day death, stroke, or MI	*OR (95% CI)*	P[b]	*OR (95% CI)*	P[b]
All CEA	1.00 (0.78-1.29)	.9900	1.15 (0.89-1.48)	.2958
Asymptomatic CEA	0.95 (0.66-1.36)	.7685	1.05 (0.73-1.52)	.7854
Symptomatic CEA	1.10 (0.78-1.56)	.5884	1.24 (0.87-1.78)	.2321

CI, Confidence interval; *MI,* myocardial infarction.
[a]Adjusted ORs were calculated after adjusting for American Society of Anesthesiologist grade <3 vs >3, presence of coronary artery disease, aspirin use, ejection fraction <30%, and unstable angina.
[b]*P* values were based on the Fisher exact test.

Table VI. Thirty-day outcomes for patients undergoing carotid angioplasty and stenting (*CAS*)[a]

	CAS patients, % (No.)		
30-day events	*Female (n = 1330)*	*Male (n = 2043)*	P[b]
Mortality	1.80 (24)	1.86 (38)	>.9999
Stroke	4.44 (59)	4.99 (102)	.5087
MI	1.65 (22)	1.08 (22)	.1634
Death, stroke, or MI	6.69 (89)	6.80 (139)	.9441

MI, Myocardial infarction.
[a]Events were defined as any event occurring intraoperatively, before discharge, or between discharge and 30 days. Rates are per-patient.
[b]*P* values were based on the Fisher exact test.

being 3.03% in women and 3.19% in men. The rate was higher in symptomatic patients, with the primary end point occurring in 5.94% women and 5.42% men. Even after risk adjustment (Table V), no difference remained (OR, 1.15; 95% CI, 0.89-1.48; $P = .2958$) between women and men undergoing CEA.

CAS patients. In patients undergoing CAS (Tables VI and VII), there again was no statistically significant difference in outcomes in the two gender groups. The composite death/stroke/MI rates were 6.69% in women and 6.80% in men, higher than the 4% rate in CEA patients. In asymptomatic patients, the event rate was higher for women (5.79% vs 4.55%; $P = .2353$). There was also a higher rate of primary end point in symptomatic men (9.42% vs 7.84%; $P = .3088$) than women. However, neither of these reached statistical significance. After risk adjustment (Table VIII), no difference remained between women and men (OR, 0.91; 95% CI, 0.68-1.21; $P = .5115$).

DISCUSSION

Revascularization has become an important treatment option for patients with carotid artery occlusive disease. In two landmark randomized control trials in the 1990s, the benefits of CEA over medical therapy were demonstrated for patients with moderate or severe internal carotid artery stenosis.[3,4] Additional studies since have demonstrated the safety and efficacy of CAS as an alternative treatment option.[9-11] Despite these findings, the benefit of carotid revascularization in women remains unclear.

The available literature suggests that women have a higher risk of perioperative adverse events during carotid revascularization. In the Asymptomatic Carotid Atherosclerosis Study (ACAS), women had a higher rate of perioperative events (3.6% vs 1.7% for men) during CEA.[4] Combining that with a lower rate of events for women (8.7% vs 12.1% for men) treated with best medical therapy, this led to a much lower 5-year risk reduction for women (17%) compared with men (66%). Among patients with moderate stenosis in the North American Symptomatic

Table VII. Thirty-day outcomes for symptomatic and asymptomatic patients undergoing carotid angioplasty and stenting (*CAS*)[a]

	Asymptomatic CAS, % (No.)			*Symptomatic CAS, % (No.)*		
30-day events	*Female (n = 743)*	*Male (n = 1098)*	P[b]	*Female (n = 587)*	*Male (n = 945)*	P[b]
Mortality	1.75 (13)	1.18 (13)	.3211	1.87 (11)	2.65 (25)	.3882
Stroke	3.90 (29)	2.82 (31)	.2287	5.11 (30)	7.51 (71)	.0719
MI	1.21 (9)	1.09 (12)	.8260	2.21 (13)	1.06 (10)	.0841
Death, stroke, or MI	5.79 (43)	4.55 (50)	.2353	7.84 (46)	9.42 (89)	.3088

MI, Myocardial infarction.
[a]Events were defined as any event occurring intraoperatively, before discharge, or between discharge and 30 days. Rates are per-patient.
[b]*P* values were based on the Fisher exact test.

Table VIII. Unadjusted and risk-adjusted odds ratios (*ORs*) for patients undergoing carotid angioplasty and stenting (*CAS*)[a]

	Female vs male			
	Unadjusted		*Adjusted*	
30-day death, stroke, or MI	*OR (95% CI)*	P[b]	*OR (95% CI)*	P[b]
All CAS	0.98 (0.75-1.29)	.8994	0.91 (0.68-1.21)	.5115
Asymptomatic CAS	1.29 (0.85-1.96)	.2367	1.23 (0.80-1.88)	.3538
Symptomatic CAS	0.82 (0.56-1.19)	.2891	0.72 (0.49-1.06)	.0964

CI, Confidence interval; *MI,* myocardial infarction.
[a]Adjusted ORs were calculated after adjusting for American Society of Anesthesiologist grade <3 vs >3, etiology of restenosis, history of prior neck radiation, age >80 years, and number of stents (>1).
[b]*P* values were based on the Fisher exact test.

Carotid Endarterectomy Trial (NASCET), the number needed to treat with CEA to prevent one ipsilateral stroke was 12 and the number needed to treat to prevent one disabling stroke was 16 for men. The corresponding numbers for women were 67 and 125, respectively, potentially suggesting a lower long-term benefit of surgery for women.[3] The Asymptomatic Carotid Surgery Trial (ACST) produced similar findings, with men deriving a higher 5-year absolute risk reduction (8.21% vs 4.08%) than women.[6]

The data are somewhat unclear in the recent trials evaluating CAS and CEA. Women in the International Carotid Stenting Study (ICSS) had a higher 120-day event rate for CEA (7.6% vs 4.2%) but a lower rate for CAS (8.0% vs 8.7%).[10] The opposite was found in the Carotid Revascularization Endarterectomy vs Stenting Trial (CREST), with a lower periprocedural event rate for women undergoing CEA (3.8%) than men (4.9%) but higher in CAS (6.8% vs 4.3%).[14] With potentially higher perioperative event rates, these data raise the question of how much women actually benefit from intervention.

Gender clearly plays an important role in cardiovascular disease. A systematic review of epidemiologic studies found the stroke incidence rate was 33% higher and stroke prevalence was 41% higher in men than in women.[12] When strokes do occur, they tended to be more severe in women, with a 1-month case fatality of 24.7% compared with 19.7% for men. However, the specific factors that lead to differential gender-specific outcomes remain unclear. Several factors (including vessel diameter, plaque morphology, influence of sex hormones and thromboembolic potential) have been proposed to play an important role. However, the overall evidence for outcome differences by gender-specific characteristics in the published literature remains limited.[15]

This study identified 9865 patients who underwent carotid revascularization in the SVS-VR. The 30-day outcomes in women compared with men were essentially the same. Both gender groups had a similar 30-day composite rate of death/stroke/MI: ~4% for CEA and 7% for CAS. After stratifying by symptomatology, no differences remained in outcome. There are likely several reasons why the results from this study differ from the published clinical trial data. The SVS-VR was designed to capture real-world outcomes and is available to all clinical facilities and providers in the United States. As such, it represents more of the routine practice found in this country as opposed to the carefully defined patient selection criteria and practitioner credentialing that is seen in randomized clinical trials. This difference in outcomes for actual practice compared with clinical trials has been shown in the past for CEA and CAS.[16,17]

Another important distinguishing feature about this study is that data collection in the SVS-VR began in July 2005, almost 20 years after the first patient was enrolled in ACAS or NASCET. During the intervening two decades, best medical therapy improved significantly with the widespread availability of medications such as clopidogrel and statins. The use of these medications no doubt had an effect on patient outcomes.[18] Finally, we note that women were under-represented in carotid revascularization trials.[14] It thus merits emphasis that women represented >40% of this study cohort, more than any of the published randomized controlled trials.

Several limitations of this analysis need to be addressed. The inherent weaknesses in the use of a registry, such as the SVS-VR, have previously been addressed.[19] These include the potential for treatment bias, absence of certain anatomic information (such as plaque morphology), and reporting bias. Perhaps the most important limitation in this study is the lack of a comparison group for patients treated with best medical therapy.

The hesitation in recommending carotid revascularization to women is derived from two observations. This study addresses the first by focusing on the rates of perioperative complications with carotid revascularization. However, we were not able to determine if women had a lower event rate if treated solely with medical therapy. Further studies certainly are needed to determine the gender-based outcomes in medical management of carotid artery disease.

Finally, our analysis was limited to 30-day outcomes. As such, potential differences between genders in the development of recurrent disease were not investigated. Despite these limitations, data from this study still provide valuable information about the effectiveness of carotid revascularization in women.

CONCLUSIONS

In this large, real-world analysis, women and men demonstrated similar rates of perioperative events after carotid revascularization that were true for both CEA and CAS and were independent of symptomatic status. These data suggest that, contrary to previous reports, women do not have a higher risk of adverse events than men after carotid revascularization.

AUTHOR CONTRIBUTIONS

Conception and design: JJ, FS, JR
Analysis and interpretation: CK, FS
Data collection: CK, FS
Writing the article: JJ, ED, GU, NO, CK, FS, RW, JR
Critical revision of the article: JJ, ED, GU, NO, CK, FS, RW, JR
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Statistical analysis: CK, FS
Obtained funding: RW
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APPENDIX

Society for Vascular Surgery Outcomes Committee. Rodney A. White, MD (Chair), Thomas E. Brothers, MD, Ellen D. Dillavou, MD, Patrick J. Geraghty, MD, David L. Gillespie, MD, Philip P. Goodney, MD, Jeffrey Jim, MD, Sarah Murphy, BS, Nicholas H. Osborne, MD, Joseph J. Ricotta, II, MD, Michael C. Stoner, MD, and Gilbert R. Upchurch, Jr, MD.

Submitted Jul 18, 2013; accepted Sep 14, 2013.

DISCUSSION

Dr Eva Rzucidlo (*Lebanon, NH*). You have presented so nicely the historical data showing that women have always been reported to have worse outcomes. So what is your hypothesis for this change to equal outcome with men: is it better risk factor medical management?

Dr Jeffrey Jim. I think within the past two decades there has certainly been a difference in terms of patient selection, which we cannot account for. I think everybody knows that medical management has gotten significantly better. When we compare the old studies from 20 years ago, the best medical therapy was essentially only aspirin and good blood pressure and glucose control. There was no consideration of statins and, obviously, the newer-generation antiplatelet agents. So I think that patient selection is a little bit different and medical management is very different as well.

Dr Richard Cambria (*Boston, Mass*). I wonder if your results were corrected for pathology. I think you showed us that fully 25% of the women in one of your subgroups were treated for recurrent stenosis. And at least in the paradigm of angioplasty and stenting, you would expect complications in that group to be significantly lower as a function of the fact that some of them, perhaps many, were treated for intimal hyperplasia as opposed to degenerative plaque. So I wonder if the results have been corrected by throwing out the restenosis patients?

Dr Jim. We did not throw them out per se but accounted for disease etiology in our analysis. We did not have additional data points, such as plaque characteristics, included in the data, but we certainly accounted for the etiology of the disease.

Dr Cambria. Is it true that 25% of the women were treated for recurrent stenosis, or was that only in the carotid angioplasty and stenting (CAS) group?

Dr Jim. That was only the stenting group. There was only 1% to 2% of the endarterectomy group that was treated for restenosis.

Dr Cambria. Well, I still think that with that percentage of patients in the CAS that has to be corrected for in terms of comparing complications, but appreciate your presentation of a lot of data.

Dr David Rigberg (*Los Angeles, Calif*). You did mention the selection bias. And I was wondering, from your data set, is there any way to know what the percentage of men vs women undergoing any intervention was, so what the number was, so that maybe what we are seeing is just fewer women undergoing a procedure based on the type and level of disease they have?

Dr Jim. The way the registry works is every patient in each individual center should be included. In our total study we had about 10,000 patients, with about 40% being women. And if you look at the different subgroups in terms of the stenting as well as the endarterectomy, they were about the same; it was about a 60/40 split.

Dr John Ricotta (*Washington, D.C.*). This is not the same as a comparison, like as in ACAS (Asymptomatic Carotid Atherosclerosis Study) or the ACST (Asymptomatic Carotid Surgery Trial) where you were looking at medical management vs surgical management. So it is conceivable that these results, while they don't show a difference in surgical outcome, still do not prove the hypothesis that for asymptomatic patients there is as much benefit for men as women. Can you comment on that?

Dr Jim. I think the hesitation to treating women comes from two factors. One is the fact that there was a higher rate of perioperative events, and the second one was that women tend to just have fewer events on medical therapy. Our study essentially is able to only address the first part. We were able to compare men and women essentially showing that they have equivalent surgical outcomes. But we did not have data on treatment with optimal medical therapy alone. And you are right, potentially, that is the group that has the best results and certainly do not need intervention.

Dr Ricotta. Did you have any data on the prevalence of the use of patching in these patients, or was that not available?

Dr Jim. That is not available because some centers were doing eversion endarterectomies so it is hard to separate those patients out.