Carotid endarterectomy in female patients: Are the concerns of the Asymptomatic Carotid Atherosclerosis Study valid?

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Objectives: **Although the results of the Asymptomatic Carotid Atherosclerosis Study clearly demonstrated the benefit of surgical over medical management of severe carotid artery stenosis, the results for women in particular were less certain. This was to some extent because of the higher perioperative complication rate observed in the 281 women (3.6% vs 1.7% in men). The objective of this study was to review a large experience with carotid endarterectomy in female patients and to determine whether the perioperative results differed from those of male patients.**

Methods: **A review was conducted of a prospectively compiled database on all carotid endarterectomies performed between 1982 and 1997. Operations performed in 991 female patients were compared with those performed in 1485 male patients.**

Results: **Female patients had a significantly lower incidence of diabetes, coronary artery disease, and contralateral carotid artery occlusion than did male patients. Female patients had a significantly higher incidence of hypertension. There were no significant differences in the age, smoking history, anesthetic route, shunt use, or clamp tolerance between the two groups. Of 991 female patients, 659 (66.5%) had preoperative symptoms, whereas 332 (33.5%) cases were performed for asymptomatic stenosis. Among 1485 male patients, 1041 (70.1%) had symptoms, and 444 (29.9%) were symptom free before surgery. There were no significant differences noted in the perioperative stroke rates between men and women overall (2.3% vs 2.4%, $P = .92$), or when divided into symptomatic (2.5% vs 3.0%, $P = .52$) and asymptomatic (2.0% vs 1.2%, $P = .55$) cases.**

Conclusions: **Carotid endarterectomy can be performed with equally low perioperative stroke rates in men and women in both symptomatic and asymptomatic cases. In this series, symptom-free female patients had the lowest overall stroke rate. The concerns of the Asymptomatic Carotid Atherosclerosis Study regarding the benefit of carotid endarterectomy in female patients should therefore not prevent clinicians from recommending and performing carotid endarterectomy in appropriately selected symptom-free female patients. (J Vasc Surg 2001;33:236-41.)**

Although the results of the Asymptomatic Carotid Atherosclerosis Study (ACAS)[1] clearly demonstrated the benefit of surgical over medical management of severe carotid artery stenosis, the results for women in particular were less certain. In men, carotid endarterectomy (CEA) reduced the 5-year event rate by 66%, compared with only a 17% reduction in women. It is suggested by the ACAS that this difference is caused by the higher perioperative complication rate in the 281 female patients who underwent CEA, although this disparity was not statistically significant. The perioperative complication rate for female patients (3.6%) was more than double that of male patients (1.7%), with a *P* value of .12. A review of the literature reveals a relative paucity of data with regard to surgical outcome of CEA analyzed by sex. However, there are certainly other investigators who have suggested that women in particular may have a higher complication rate after undergoing CEA.

Anecdotal experience in the Division of Vascular Surgery at the New York University Medical Center made us aware that some referring physicians were cognizant of these data and were therefore hesitant to refer symptom-free female patients for surgical evaluation. With these issues in mind, the objective of this study was to review a large experience with CEA in female patients and to determine whether perioperative results differed from those in male patients.

PATIENTS AND METHODS

A review of a prospectively compiled computerized database of all extracranial cerebrovascular surgery performed at the New York University Medical Center was conducted. All primary CEAs performed between 1982 and 1997 were included and analyzed (n = 2476). Carotid artery reoperations and combined CEA/coronary artery bypass grafts were excluded from this analysis. CEA was performed in female patients in 991 cases and in male patients in 1485 cases. Our standard technique includes a preference for regional anesthetic with selective shunting, routine shunting for those cases performed with patients

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Table I. Comparison of demographics between male and female patients

	Female patients (n = 991)	*Male patients (n = 1485)*	P *value*
Hypertension	62.0% (614)	53.6% (796)	< .001
Diabetes mellitus	19.5% (193)	23.0% (341)	.04
Coronary artery disease	37.5% (372)	49.9% (741)	< .001
Smoking history	36.3% (360)	38.0% (564)	NS
Age (mean)	68.6 years	69.1 years	NS
Contralateral occlusion	9.5% (94)	18.3% (272)	< .001

All *P* values (except age) are derived by the χ^2 test and corrected for continuity.
NS, Not significant.

Table II. Comparison of preoperative symptoms and indications for surgery between male and female patients

	Female patients (n = 991)	*Male patients (n = 1485)*	P *value*
Asymptomatic	33.5% (332)	29.9% (444)	NS (.064)
Preoperative hemispheric symptoms (TIA or CVA)	66.5% (659)	70.1% (1041)	
Preoperative stroke (CVA)	21.8% (216)	25.9% (384)	.038
Preoperative TIA	44.7% (443)	44.1% (657)	

All *P* values are derived by the χ^2 test and corrected for continuity.
CVA, Cerebrovascular accident; *NS,* not significant.

under general anesthesia, and customary patch angioplasty for all cases. Information regarding preoperative patient characteristics, intraoperative courses, postoperative management, and perioperative complications was available for all cases. A perioperative neurologic deficit was defined as a new or worsening neurologic deficit, whether transient or permanent, manifesting during surgery or within 30 days after surgery.

Statistical analysis was performed with the statistical software package SPSS (SPSS, Inc, Chicago, Ill). A result was considered to be statistically significant with a *P* value less than .05. Comparisons were performed with the χ^2 test.

RESULTS

Comparison of patient demographics. Patient demographics were compared between male and female patients. The results are depicted in Table I. Female patients had a significantly lower incidence of diabetes mellitus (19.5% vs 23.0%), known coronary artery disease (37.5% vs 49.9%), and contralateral carotid artery occlusion (9.5% vs 18.3%) than male patients. Female patients had a significantly higher incidence of hypertension than male patients (62.0% vs 53.6%). There was no significant difference in the age or smoking history between the two patient populations. Hypertension, coronary artery disease, or contralateral occlusion were not significantly related to either perioperative stroke or death in the patient population as a whole or in female patients in particular.

Comparison of preoperative symptoms and indications for surgery. The indications for surgery and presence of preoperative hemispheric symptoms were compared between male and female patients. The results are depicted in Table II. There was no significant difference between the two patient populations with regard to the overall presence or absence of preoperative hemispheric symptoms. The proportion of female patients who underwent CEA for asymptomatic high-grade stenosis was not significantly different from male patients (33.5% vs 29.9%, *P* value .064 by χ^2 testing). Likewise, the proportion of female patients who underwent CEA for any hemispheric symptoms (either stroke or transient ischemic attack [TIA]) was not significantly different from male patients (66.5% vs 70.1%). However, when statistical analysis was performed comparing men and women with regard to all three preoperative symptom catergories (asymptomatic, TIA and stroke), there was a significant difference between the presentation of male and female patients (*P* value .038 by χ^2 test).

Comparison of intraoperative factors between female and male patients. Specific details regarding the conduct of surgery were compared between male and female patients. The results are depicted in Table III. No significant differences were found regarding the type of anesthetic used, regardless of whether clamping was tolerated under regional anesthesia, or the use of a shunt between the two patient populations.

Comparison of the perioperative neurologic deficits and complication rates between male and female patients. The incidence of perioperative neurologic deficit, myocardial infarction, and death was compared between male and female patients. The results are depicted in Table IV. There were no significant differences in the rates of perioperative neurologic deficit, myocardial infarction, or death between the two patient populations. In fact, the perioperative neurologic deficit rate was nearly

Table III. Comparison of intraoperative factors between male and female patients

	Female patients (n = 991)	*Male patients (n = 1485)*	P *value*
Regional anesthetic	80.5% (796)	82.2% (1221)	NS
Tolerated clamping	88.8% (707)	88.7% (1083)	NS
Shunt used	30.8% (305)	30.1% (447)	NS

All *P* values are derived by the χ^2 test and corrected for continuity.
NS, Not significant.

Table IV. Comparison of perioperative complications between male and female patients

	Female patients (n = 991)	*Male patients (n = 1485)*	P *value*
Perioperative myocardial infarction	1.1% (11)	0.8% (12)	NS (.58)
Perioperative mortality rate	0.5% (5)	1.1% (16)	NS (.19)
Perioperative neurologic event (overall)	2.4% (24)	2.3% (34)	NS (.92)
Perioperative neurologic event (symptom-free patients only)	1.2% (4)	2.0% (9)	NS (.55)
Perioperative neurologic event (patients with symptoms only)	3.0% (20)	2.5% (25)	NS (.52)
P value (comparisons within sex)	NS (0.12)	NS (0.81)	

All *P* values are derived by the χ^2 test and corrected for continuity.
NS, Not significant.

identical overall between male and female patients. Furthermore, when the two populations were subdivided into asymptomatic and symptomatic cases, there were again no significant differences in the perioperative stroke rates. Symptom-free female patients had the lowest perioperative stroke rate of all categories (1.2%). In both male and female patients there was a trend toward increased perioperative stroke in patients who had symptoms before surgery; however, this also did not reach statistical significance in either group. The causes of the perioperative neurologic events were similar in both male and female patients, with approximately 60% being caused by presumed postoperative thrombosis or embolization.

DISCUSSION

Many individuals in both the field of medicine and the lay public continue to perceive that the clinical manifestations of atherosclerosis are a considerably more significant problem among male patients. These generalizations may have a considerable impact on the way all patients are treated. A recent survey of medical students who watched a video of either a male or female patient reading from an identical script describing typical symptoms of angina, found that coronary artery disease was correctly diagnosed in the female patient by only 46% of students, compared with 74% for the male patient.[2] Subsequent differences in the treatment of coronary artery disease between male and female patients have received great attention in the literature.

Similarly, stroke is generally thought to be more common in men. However, population-based data reveal that more than one third of strokes in women occur after age 75, during which time there are three female for every two male patients with strokes.[3] Other data suggest that the incidence of ischemic stroke is greater in men than women only until age 65 years, when the incidence of stroke equalizes between the sexes.[4] Because of their overrepresentation in this older age cohort, women have an equal number of strokes as men on the whole; additionally, these cerebrovascular events are occurring at an age when the outlook for significant recovery may be less favorable.[3]

Indeed, it is not even firmly established that women have less carotid artery occlusive disease than men, and, notably, most of the information concerning the treatment and prevention of stroke is biased toward the male sex.[4] Of the three major symptomatic carotid artery stenosis trials, only two included women. Unfortunately, neither the original report of the North American Symptomatic Carotid Endarterectomy Trial[5] nor the European Carotid Stenosis Trial[6] specifically analyzed data by sex. Similarly, of the major asymptomatic carotid artery stenosis trials, only the ACAS[1] both included a significant number of female patients and reported the surgical results in both sexes individually.

Results such as those reported in the ACAS clearly influence medical practice. A recent survey of Connecticut hospitals over a recent 6-year period reviewed sex-related differences in the management of patients hospitalized with ischemic cerebrovascular disease.[7] Among 22,582 female and 19,729 male patients discharged, it was found that women hospitalized for ischemic cerebrovascular disease underwent angiography less and were less likely to undergo CEA than men.[7]

A number of previous studies have addressed or reported on the issue of sex-related differences in the outcome of CEA.[8-20] A representative sample of these reports is shown in Table V. Although this list is not meant to be comprehensive, the varied results are apparent. Of the

Table V. Recent series reporting outcome for CEA by sex

Study	*Female no.*	*Male no.*	*Stroke rate (female)*	*Stroke rate (male)*	*Comments*
Rockman, 2000	991	1485	2.4%	2.4%	No significant difference in perioperative stroke rate
Akbari[8]	520	778	1.6%	2.1%	No significant difference in perioperative stroke rate
Sternbach[9]	68	83	0%	1.3%	No significant difference in stroke rate
Ballotta[10]	168	371	1%	1.2%	No significant difference in stroke rate
Frawley[11]	312	688	1.9%	1.3%	No significant difference in overall stroke rate; significantly increased strokes caused by operative site thrombosis in women
Huber[12]	19,508	27,233	1.2%	0.9%	Significantly increased strokes in women; significantly decreased heart-related complications in women
Rigdon[13]	175	254	6.9%	3.5%	No significant difference in stroke rate, but mortality rate of 3.4% in women vs 0.8% in men
Schneider[14]	142	247	3.2%	1.5%	No significant difference in stroke rate
Golledge[15]	149	311	NR	NR	Women at significantly increased risk of perioperative stroke and death
McCroy[16]	406	754	NR	NR	Sex not predictive of outcome
Hertzer[17]	652	1272	1.3%	1.8%	Composite perioperative stroke and mortality rate significantly increased by female sex
Goldstein[18]	151	312	NR	NR	Perioperative stroke or death significantly higher in female patients (5.3% vs 1.6%)
Rothwell[19]	2520	4775	NR	NR	Meta-analysis; odds of perioperative stroke or death increased in women by 44%
Plecha[20]	3800	5995	NR	NR	Sex did not influence perioperative stroke or death rates

NR, Not separately reported.

recent studies specifically addressing this issue, most have found no significant difference in neurologic outcome after CEA between male and female patients.[8-11,13,14] A large review reported by Plecha et al[20] of 9795 CEAs performed by members of the Cleveland Vascular Society also found that sex did not contribute to either increased operative neurologic morbidity or mortality rates. However, a systematic meta-analysis by Rothwell et al[19] did find that the odds of perioperative stroke or death were increased in female patients by 44%. Additionally, a review of CEA in the state of Florida by Huber et al[12] encompassing more than 40,000 patients found that the central nervous system complication rate was significantly increased in women. However, the clinical significance of the small absolute difference found is questionable (1.2% vs 0.9%).

Among the prospective, randomized studies, the most recent results from the North American Symptomatic Carotid Endarterectomy Trial analyzing patients with symptomatic moderate stenosis have in fact provided data with regard to sex.[21] CEA was performed on 321 women with symptomatic moderate stenosis. Male patients derived a greater long-term benefit from CEA than did female patients. However, sex did not influence the perioperative risk of stroke or death.

In this series female patients were found to differ from male patients in several respects. These included an increased prevalence of hypertension and decreased prevalence of diabetes, coronary artery disease, and total occlusion of the contralateral carotid artery. Female patients were somewhat more likely to undergo surgery for asymptomatic stenosis than male patients, although this finding was not statistically significant. Female patients were significantly less likely to have had a preoperative stroke. Although it is possible that these differences represent a selection bias in the referral or selection of surgical patients, the very small magnitude of differences suggests that male and female patients undergo the same selection criteria. Surgical management of female patients did not appear to differ from male patients. Finally, the perioperative stroke rates were nearly equivalent between male and female patients overall, and no significant differences were found in separate analyses of asymptomatic and symptomatic patients with respect to sex.

Limitations of this study include its retrospective nature, although our data were actually compiled prospectively. Furthermore, this study does not report the late results of CEA in female patients. Female sex is widely considered to be a significant risk factor for recurrent carotid artery disease.[22] Clearly, we do not have information on the medical treatment of carotid artery occlusive disease in women. Therefore, we cannot make a direct comparison between medical and surgical management, as did the ACAS. We are currently in the process of analyzing our long-term outcome.

However, this series does represent one of the largest cohorts of female patients undergoing CEA in the published literature. In contrast to the ACAS findings, these data add considerably to the literature that supports the hypothesis that CEA can be performed with equal safety in both male and female patients, regardless of whether they had symptoms. Symptom-free female patients in fact had the lowest perioperative stroke rate in this series. Several theories have been proposed to explain why outcome after CEA might be worse in female patients; most reports mention the comparatively smaller size of the average internal carotid artery in women, which might predis-

pose to technical errors or early postoperative thrombosis. It is possible that the use of routine patch angioplasty in conjunction with CEA at our institution has helped to overcome any negative effects of the smaller-sized carotid artery in women.

CONCLUSIONS

Carotid endarterectomy can be performed with equally low perioperative stroke rates in men and women, in both symptomatic and asymptomatic cases. In this series, symptom-free female patients had the lowest overall stroke rate. The ACAS concerns regarding the benefit of CEA in female patients should therefore not prevent clinicians from recommending and performing CEA in appropriately selected symptom-free female patients.

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DISCUSSION

Dr R. Eugene Zierler (Seattle, Wash). It appears that we have now arrived at a point where the major questions about indications for carotid endarterectomy have been answered by the randomized clinical trials, especially for symptomatic patients. However, uncertainties remain over some of the details, including various subgroup analyses. One such detail in the ACAS study is the difference in outcome between men and women who were randomized to surgical treatment. Although the difference in the 5-year event rates was not statistically significant, there was a clear trend toward less benefit among women. As you've heard, this result appears to have been driven largely by a higher perioperative complication rate for women as compared with men, that is, 3.6% versus 1.7%. So the key issue here in my view is not whether carotid endarterectomy is beneficial, but whether the operation can be performed as safely in women as in men.

This paper by Rockman and colleagues addresses this single question. The female cohort in their study included 991 patients, of which 332 were asymptomatic. The surgical arm of the ACAS included only 281 women. Thus, the results presented today are actually based on a total patient group that is larger than the corresponding group in the ACAS. In their study, the perioperative complication rate for asymptomatic women was only 1.2%, compared with 2.0% for asymptomatic men. So this review shows that carotid endarterectomy can be performed in both men and women with equally low perioperative complication rates.

One weakness of this study, which is pointed out in the manuscript, is that there are no data on long-term outcome, so we can't really compare the 5-year stroke and death rates in the ACAS with the corresponding event rates in the current study. I have just a few questions for the authors.

First, how were the asymptomatic patients in your series selected for surgery? Did you actually use the 60% threshold as recommended in ACAS? If so, was arteriography performed in all patients, or were some procedures done on the basis of duplex scanning alone?

Second, a related question. The manuscript indicates that there was no difference in surgical technique between men and women in terms of shunting, patching, anesthesia, and so on. Could there have been any differences in patient selection with regard to severity of stenosis among men and women in your study? In other words, could the women have had more or less severe stenoses within the high-grade stenosis category?

I commend the authors on this paper that will help to clarify the indications for endarterectomy in women with asymptomatic

carotid stenoses, and I also thank Dr Rockman for sending me the manuscript well in advance of the meeting.

Dr Caron B. Rockman. With regard to how we select asymptomatic patients at our institution, it's true that these patients are not exactly an ACAS population. We initially select patients using the duplex criteria of the University of Washington. In asymptomatic patients our threshold for further evaluation is a reading giving us an 80% or greater stenosis. In the earlier years of this study, formal cerebral arteriography was used in all patients; but in the later years of this study we have turned to magnetic resonance angiography, often gadolinium enhanced, to confirm the duplex findings. So this is not exactly an ACAS population. If anything, probably these patients had a little bit higher degree of stenosis than an ACAS population. However, we feel that the important point is that our selection criteria for male and female patients have always been identical, and therefore, I don't think introduced any bias into these different patient groups. I do not have exact subset analysis of how many male or female patients had, for instance, 80% to 90% or 90% to 100% stenosis in this series.

Dr John J. Ricotta (Stony Brook, NY). One brief question, Caron, very nice. Can you speculate on the role of routine patching in your results and the fact that routine patching was not used in ACAS?

Dr Rockman. Certainly that's one thing that we brought up in our manuscript that's a possible reason for the difference in our findings. It's often mentioned that the worse outcome of carotid endarterectomy in female patients may be due to the smaller size of the artery, which might predispose toward technical errors or postoperative thrombosis. We heard some data yesterday here from large numbers of patients suggesting that patch angioplasty does in fact improve the perioperative results of carotid endarterectomy. So we clearly can speculate that our routine use of patch angioplasty played a role in these findings; however, we cannot prove that, of course.

Dhiraj M. Shah (Albany, NY). Again, nice presentation. My question is, following the similar trend that because of a smaller artery women are more prone to restenosis or occlusion, do you have data on that? What is the long-term patency or restenosis rate in female patients compared with male?

And the second is what type of intraoperative surveillance did you do: ultrasound, to see the competence of your surgery, or handheld Doppler or angiogram?

Dr Rockman. To answer your second question first, we do not use routine intraoperative surveillance after carotid endarterectomy, but instead rely on extensive exposure, long arteriotomies, and patch angioplasty.

With regard to the restenosis rates, at our institution we have found that restenosis requiring reoperation occurs with equal frequency in men and women. However, because we do not have perfect duplex follow-up in all of these cases, I cannot comment on what the exact amount of asymptomatic restenosis could be, but I can tell you that our reoperation rate for carotid restenosis is equivalent in men and women.

Dr Anthony J. Comerota (Philadelphia, Pa). Dr Rockman, could you tell us what your practice is for platelet inhibition, both in terms of short and long term, and are there any differences in women versus men?

Dr Rockman. The routine practice at our institution is to use preoperative platelet inhibition, which is usually by aspirin, and to continue it throughout the perioperative period and postoperatively. However, I have not been able to investigate any differences between men and women with this regard.

Dr John H. N. Wolfe (London, United Kingdom). I am afraid this is more of a comment. First of all, thank you very much for an excellent paper and for some very good results, and I am glad that women have just as much chance of doing well from the operation as men. But my comment relates to ACAS. I think there are some of us who still are very uncertain as to whether there is any role for surgery in asymptomatic disease. The current ACST has reached 2000 patients without the ethical committee stopping the trial. I do not think that all of us are yet convinced that there is a role for carotid endarterectomy in asymptomatic patients.

Dr Robert W. Hobson II (Newark, NJ). John, thank you for bringing that to our attention. We followed that trial with some interest, as a matter of fact. I'm surprised there are only 2000 patients recruited. It's been running for the last 5 or 6 years, but maybe it reflects the difficulty with recruitment or the surgeons' willingness to randomize. You'll comment on that later, I'm sure. Dr Rockman, would you like to comment on that?

Dr Rockman. No, thank you.