Fast-track article

Comparing outcomes of carotid endarterectomy with international benchmarks: audit from an Italian vascular surgery department

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Key words:
Carotid endarterectomy; Morbidity; Mortality; Outcome.

Background. **The aim of this study was to compare the outcomes of carotid endarterectomy (CEA) in the current practice of our department of vascular surgery with international benchmarks.**

Methods. **In-patient data from 488 CEA performed in both symptomatic 145 (29.7%) and asymptomatic 343 (70.3%) patients with a ≥ 60% stenosis at the level of the internal carotid artery. Comprehensive retrospective review of the records for all the CEAs performed during a 2-year period. The main outcome measures were death rate, and fatal and non-fatal stroke rates perioperatively, and at 30 and 180 days.**

Results. **The fatal and non-fatal stroke rates of symptomatic patients were: 0.7% perioperatively, 0.7% at 30 days, and 0.7% at 180 days. The fatal and non-fatal stroke rates of asymptomatic patients were: 0.6% perioperatively, 0.6% at 30 days, and 0.3% at 180 days. The death rates of symptomatic patients were 0% for all time periods. The death rates of asymptomatic patients were: 0% perioperatively, 0% at 30 days, and 0.3% at 180 days.**

Conclusions. **The present comprehensive audit shows that our surgeons achieve CEA outcomes comparable with international benchmarks.**

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Introduction

Evidence exists on the effectiveness of carotid endarterectomy (CEA) in reduction of disabling stroke and death rates for patients who are symptomatic with ≥ 50% carotid artery stenosis ipsilateral to a recent carotid territory ischemic event[1]. Evidence also exists on the effectiveness of CEA in reducing the stroke rate in patients who are asymptomatic[2].

Hospitals, centers, surgeons, and patients who participated in trials that contributed to these were highly selected, however. Eligibility for participation in the North American Symptomatic Carotid Endarterectomy Trial (NASCET) required centers to have 30-day stroke and death rates of < 6%[3]. The surgeons participating in the Asymptomatic Carotid Atherosclerosis Study (ACAS) were required to have stroke and death rates of < 3% for patients who were asymptomatic and < 5% for patients who were symptomatic[4]. As a result, < 4% of all potential American institutions were selected for participation in either NASCET or ACAS[5].

Patients also were selected with strict eligibility criteria. A study that compared the mortality rates for patients from American hospitals in NASCET and ACAS ("trial" hospitals) with patients from other institutions that performed CEA ("non-trial" hospitals) found the mortality rate for patients who underwent the procedure at a trial hospital was higher (1.4%) than that reported in either NASCET (0.6%) or ACAS (0.4%)[5].

For symptomatic patients in NASCET with only 50-69% carotid artery stenosis (in whom stroke risk is less than in patients with greater stenosis) and with perioperative risk of 6% the number needed to treat to prevent stroke was 15. By comparison, in the European Carotid Surgery Trial (ECST), an 8% perioperative risk nullified the net benefit, which is a stark reminder that operative risk is critical in CEA where the complications are the same as what one is attempting to prevent[6].

For asymptomatic patients in ACAS the 30-day combined risk of stroke and death from angiography and surgery was 2.3%. The absolute risk-reduction projected to 5 years was 5.9%. The number needed to

treat to prevent one stroke in 2 years was at least 67. The benefit did not seem to depend on the severity of the stenosis, as measured by ultrasound alone.

The results of the latest and largest asymptomatic trial, the Asymptomatic Carotid Surgery Trial (ACST)[7] showed that surgical morbidity and mortality was 3.1%. The absolute risk reduction at 5 years was 5.4%. The number needed to treat to prevent one stroke in 5 years was at least 18.

Although randomized trials generate evidence for identification of best treatments, they are not designed to monitor routine practice[8].

Whether outcomes can be achieved in routine practice outside the strict conditions of surgical research is largely unknown. In Italy state-wide audit of CEA practices are still lacking. Yet demand is increasing for better information about the performance of the health system[9]. Therefore, the objective of this study was to compare the outcomes of CEA in the current practice of our department of vascular surgery with international benchmarks. Secondarily, we evaluated differences in surgical outcomes between symptomatic vs asymptomatic patients undergoing CEA.

Methods

We performed a comprehensive retrospective review of the records for all the CEAs performed during a 2-year period. Our department is one of the two vascular surgery units present in the province (about 630 000 inhabitants). In-patient data were from 488 CEA performed in both symptomatic and asymptomatic patients with a ≥ 60% stenosis at the level of the internal carotid artery.

The main outcome measures were death rate, and fatal and non-fatal stroke rate collected perioperatively, and at 30 and 180 days. Eligible patients were those who underwent a left or right CEA for the first time. Patients were excluded from the audit if the operation was a "redo" on an internal carotid artery.

Descriptive statistics have been calculated. Logistic regression analysis was used to estimate odds ratios and associated confidence intervals for age and sex adjusted comparison between symptomatic and asymptomatic patients, the former serving as the reference group[10]. We tabulated the comparison with international benchmarks by 30-day morbidity and mortality rates (plus confidence intervals) as outcome measures stratified for symptom status. STATA® for Windows statistical package (release 7.0) was used. All the results are presented as means ± SD for continuous variables, and as count and/or percentage for categorical or dichotomous variables. Five percent was the level of significance accepted, and it has been expressed by means of 95% confidence interval and/or as $p < 0.05$.

Results

The characteristics of the 488 patients evaluated are described in table I. About one third of them (n = 145)

Table I. Characteristics of patients with a ≥ 60% stenosis at the level of the internal carotid artery (n=488).

	Symptomatic group (n=145)	Asymptomatic group (n=343)	Age- and sex-adjusted OR (95% CI)	p
Age (years)	72.04 ± 9.69	72.14 ± 7.48	0.99 (0.94-1.02)	0.91
Male sex	105 (72.6%)	252 (73.5%)	0.95 (0.72-1.26)	0.73
Right side	70 (48.3%)	159 (46.4%)	1.08 (0.73-1.59)	0.69
Left side	75 (51.7%)	184 (53.6%)	0.92 (0.63-1.36)	0.69
Soft plaque	72 (49.7%)	72 (21.0%)	4.20 (2.73-6.48)	0.001
Ulcerated plaque	14 (9.7%)	23 (6.7%)	2.56 (1.24-5.27)	0.011

CI = confidence interval; OR = odds ratio.

Table II. Surgical carotid enadrterectomy outcomes (n=488).

Outcome measure	Symptomatic group (n=145)	Asymptomatic group (n=343)	Age- and sex-adjusted OR (95% CI)	p
Fatal and non-fatal stroke rate				
Perioperatively	1 (0.7%)	2 (0.6%)	1.18 (0.11-13.16)	0.89
30 days	1 (0.7%)	2 (0.6%)	1.19 (0.11-13.34)	0.88
180 days	1 (0.7%)	1 (0.3%)	2.40 (0.15-38.91)	0.54
Death rate				
Perioperatively	0	0	–	–
30 days	0	0	–	–
180 days	0	1 (0.3%)	NA	NA

CI = confidence interval; NA = not available; OR = odds ratio.

Table III. Comparison of current audit mortality and morbidity rates at 30 days after carotid endarterectomy (CEA) by symptom status with prospective studies.

Study	Patient status before CEA	30-day death rate (%)	30-day fatal or non-fatal stroke rate (%)	Combined 30-day stroke and death rate (%)
Symptomatic				
Current audit (n=488)	≥ 60% internal carotid stenosis Undergoing CEA in 2-year period (n=45)	0 (97.5% CI one-sided 0.0-2.5%)	0.7 (95% CI 0.02-3.8%)	0.7 (95% CI 0.02-3.8%)
NASCET[3] (n=659)*	High-grade carotid stenosis (70-99%) Group allocated CEA (n=28)	0.6 (95% CI 0.1- 2.2%)	5.5 (95% CI 3.3- 8.5%)	5.8 (95% CI 3.5-8.9%)
ECST Collaborative Group[6] (n= 3018)*	All level of stenosis Group allocated CEA (n=1807)	1.2 (95% CI 0.8-1.8%)	6.4 (95% CI 5.3-7.6%)	6.8 (95% CI 5.6-8.0%)
Meta-analysis Cochrane Review[1] (n= 5841, 2 trials)	All level of stenosis Group allocated CEA (n=3181)	NA	NA	2.8 (95% CI 2.2-3.4%)
Asymptomatic				
Current audit (n=488)	≥ 60% internal carotid stenosis Undergoing CEA in 2-year period (n=343)	0 (97.5% CI one-sided 0-1.1%)	0.6 (95% CI 0.1-2.1%)	0.6 (95% CI 0.1-2.1%)
ACAS[4] (n=1662)*	≥ 60% carotid stenosis Group allocated CEA (n=825)	0.4 (95% CI 0.1-1.1%)	2.1 (95% CI 1.2-3.3%)	2.3 (95% CI 1.3-3.3%)
ACST Collaborative Group[7] (n=1560)*	≥ 60% carotid stenosis Group allocated immediate CEA (n=1560)	1.0 (95% CI 0.5-1.6%)	1.6 (95% CI 1.0-2.3%)	2.8 (95% CI 2.0-3.9%)
Meta-analysis Cochrane Review[2] (n=2203, 4 trials)*	Group allocated CEA (n=1087)	NA	NA	3.1 (95% CI 2.2-4.4%)

CI = confidence interval; NA = not available. * intention-to-treat.

were symptomatic and 70.3% (n = 343) asymptomatic patients. Overall, they were aged and predominantly men (Table I).

Symptomatic patients had a higher prevalence of both "soft" (49.7 vs 21.0%, $p < 0.001$) and "ulcerated" plaques (9.7 vs 6.7%, $p < 0.02$) than asymptomatic ones (Table I).

Most patients were male (73%), consistent with international (NASCET: 69% male[3]; ECST: 72% male[6]). The median age of patients was 72.9 years, also consistent with present data (71.2 years).

The fatal and non-fatal stroke rates of symptomatic patients were: 0.7% perioperatively, 0.7% at 30 days, and 0.7% at 180 days. The fatal and non-fatal stroke rates of asymptomatic patients were: 0.6% perioperatively, 0.6% at 30 days, and 0.3% at 180 days. The death rates of symptomatic patients were: 0% perioperatively, 0% at 30 days, and 0% at 180 days. The death rates of asymptomatic patients were: 0% perioperative, 0% at 30 days, and 0.3% at 180 days. The overall perioperative local complication rate was 2.1% and 0.3%, respectively.

No significant differences in surgical outcomes were observed between the two groups (Table II).

Table III compares the present audit outcomes for symptomatic patients with international benchmarks from NASCET[3] and ECST[6] and for asymptomatic patients from ACAS[4] and ACST[7]. Results from meta-analyses for both symptomatic[1] and asymptomatic[2] patients also are shown.

Discussion

Stroke imposes a heavy burden of disease in western countries. Therefore, it is important to assure the public that surgical services achieve outcomes consistent with best evidence. We conclude that our mortality and morbidity rates for symptomatic patients are comparable with those from NASCET[3], ECST[6], and the combined meta-analysis[1]. Furthermore, results for asymptomatic patients in our audit also are comparable with data from the literature[2,4,7] (Table III).

Patients must recognize that with good medical care they face only a 2% annual stroke rate, which falls below 1% after successful CEA. But the benefits will exceed the risks only if the operative hazards remain low, otherwise they could be obliterated. Contemporary reports suggest that the rates of operative complications often exceed by 1 or 2% the low rates achieved by trial surgeons (3%)[11-13]. Thus, if such surgery is to be offered, audited results of surgeon's operative records should be readily available to referring physicians and patients. Institutions and departments should require totally independent audits of surgical morbidity rates and ensure their ready availability. Experts in examining the nervous system should be required to evaluate the postoperative conditions of all patients who have CEA.

Therefore, our findings might be of interest since data from Italian hospitals are still lacking. Nevertheless, few methodological aspects of our audit deserve comment. First, our findings might be affected by a selection bias since we did not use a random sample. In fact, we evaluated retrospectively all the patients who underwent CEA. Second, because of the low death rate (0.3%), examination of significant independent predictors of mortality was not possible.

Our audit confirms that outcomes comparable with those documented in randomized trials can be achieved in Italian vascular surgery departments even with less rigorous patient, hospital, and surgeon selection criteria, i.e. from practitioners "in the trenches". In particular, comparison of current audit with prospective studies by symptom status showed lower mortality and morbidity rates at 30 days after CEA (Table III). Moreover, we have also shown the statistical differences between symptomatic vs asymptomatic patients undergoing CEA in order to check that difference in outcomes due to surgery team did not exist. Otherwise, subsequent corrective actions to improve surgeons' skills should be undertaken for patients' safety.

In conclusion, the present comprehensive audit shows that our surgeons achieve CEA outcomes comparable with international benchmarks.

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