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Durability of Carotid Endarterectomy

Robert D. Ecker, MD; Mark A. Pichelmann, MD; Irene Meissner, MD; Fredric B. Meyer, MD

Background and Purpose—We sought to determine the incidence of recurrent stenosis after carotid endarterectomy.

Methods—One thousand consecutive carotid endarterectomy patients were followed prospectively. The surgery was performed in a standard fashion. Cerebral protection was provided with intraoperative electroencephalographic monitoring and selective shunting. All arteriotomies were repaired with a patch graft. Each patient was seen 3 months after surgery and then yearly, with a duplex ultrasound obtained at each visit. Evidence for new ischemic events or recurrent stenosis of ≥70% was recorded.

Results—The 30-day combined minor and major stroke and death rate was 1.9%. At 7.1-year follow-up, 0.1% of patients had recurrent stenosis ≥70%, the majority of which were asymptomatic.

Conclusions—Carotid endarterectomy is a low-risk procedure for the treatment of carotid occlusive disease, with excellent long-term durability. Although less invasive, carotid angioplasty must demonstrate equal robustness in long-term follow-up before it is considered a routine alternative to surgery. **(*Stroke*. 2003;34:2941-2944.)**

Key Words: carotid endarterectomy ■ stenosis ■ stroke

It is well established that carotid endarterectomy is a low-risk intervention that reduces the risk of stroke in patients who harbor both symptomatic and asymptomatic hemodynamically significant carotid stenoses.[1–3] It is now generally agreed on in the surgical community that an acceptable perioperative risk should be no greater than 3.0% in typical surgical patients who do not have significant medical comorbidities.[4] An ample number of independent surgical series support this contention.[5–12] In addition to a low perioperative complication rate, the risk of recurrent stenosis or late postoperative stroke is favorable.[13–16]

Recently, carotid angioplasty has emerged as a potential alternative treatment for extracranial carotid occlusive disease. Many small published series chronicle a wide range of risks.[17–26] Currently, there are no completed prospective randomized controlled studies with sufficient power to determine significant differences between carotid endarterectomy and carotid angioplasty/stenting in the typical patient evaluated for treatment.[27,28] Some data suggest that in high-risk surgical patients, angioplasty may be a good alternative.[22,29]

Most importantly, only a few outcome studies consider the long-term success regarding stroke reduction and patency after carotid angioplasty/stenting.[14–16] Although the literature suggests that angioplasty may have a higher risk of recurrent stenosis, there are no large, long-term surgical studies with sufficient patient numbers and years of follow-up to establish benchmarks for comparison. Accordingly, the purpose of this investigation is to determine the robustness of carotid endarterectomy by analyzing long-term follow-up data.

Subjects and Methods

One thousand consecutive carotid endarterectomies performed in 975 patients by a single surgeon (F.B.M.) during 1988–2000 were followed prospectively. Twenty-five patients underwent staged bilateral endarterectomies. All operations were performed on arteries with >70% stenosis. No operations for moderate stenosis were included in this study. When cerebral angiography was available, the degree of stenosis was determined with the use of North American Symptomatic Carotid Endarterectomy Trial (NASCET) methodology. However, carotid ultrasound and MR angiography (MRA) were the primary imaging modalities used in this study. MRA assessment of degree of stenosis has been shown to correlate well with traditional cerebral angiography in determining the presence of a hemodynamically significant lesion.[30,31] Baseline and follow-up demographic data were entered into a long-standing departmental database. A Sundt risk classification grade was determined preoperatively for each patient. The Sundt grade determines anatomic, medical, and neurological risk factors and has been documented to be of value in predicting perioperative surgical morbidity and mortality (Table 1).[4,32]

All patients were given 325 mg of aspirin perioperatively. Before carotid artery clamping, 5000 U of heparin was administered, and the patient's systolic blood pressure was elevated to approximately 150 to 170 mm Hg. The endarterectomy was performed in a standardized manner with the use of intraoperative electroencephalography.[4] In cases in which the intraoperative electroencephalograph demonstrated ischemic changes during clamping of the carotid arteries despite induced hypertension (attenuation of faster frequencies of >4 Hz by >50% along with an increase in the amplitude of delta activity by 50%), a shunt was placed. After removal of the carotid plaque, the arteriotomy was closed with a patch graft. Early in this series the saphenous vein was utilized. However, because of the small risk of vein graft rupture,[33] the vast majority of arteriotomies were repaired with a knitted, double-velour collagen impregnated graft (Hemashield; Meadox).[34]

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TABLE 1. Sundt Risk Classification (n=1000)

Grade 1—n=194: Neurologically stable patient with no major medical or anatomic risks with unilateral or bilateral ulcerative stenotic disease.
Grade 2—n=216: Neurologically stable patients with no major medical risks, but with significant anatomic risks including contralateral carotid occlusion, high bifurcation, or extended plaque.
Grade 3—n=496: Neurologically stable patients with major medical risks, with or without significant anatomic risks. Thus, this group is distinguished from the above 2 groups on the basis of the presence of medical risk factors, primarily documented coronary artery disease.
Grade 4—n= 89: Neurologically unstable patients with or without associated major medical or anatomic risks. The distinguishing characteristic of this group is the presence of active neurological symptomatology, ie, TIAs on heparin.
Grade 5—n=5: Acute internal carotid artery occlusion with progressive neurological deterioration consistent with evolving stroke.

Patients were seen in follow-up at 3 months postoperatively and then yearly thereafter. Duplex carotid ultrasound was performed at each visit, and if a ≥70% stenosis was identified, this was confirmed by either carotid MRA or transfemoral cerebral angiography. Patients with a stenosis of ≥70% or evidence of new ischemic symptoms were cataloged.

Results

The study included 680 men and 320 women aged 69±8 years. The cataloging of patients by Sundt risk grade is listed in Table 1. Of note, 194 patients had concerning anatomic risk factors, including contralateral carotid occlusion, and 496 patients had concurrent significant medical risk factors, primarily coronary artery disease. In 59% of patients, the carotid stenosis was symptomatic.

The combined 30-day death and stroke rate was 1.9%. There were 9 deaths (0.9%) (3 fatal myocardial infarctions, 4 intracerebral hemorrhages, 2 strokes). All deaths occurred in Sundt grade 3 and 4 patients. Any patient in whom there was concern for a possible perioperative ischemic event was examined by a stroke neurologist. There were 10 documented strokes (1.0%). Of these 10 strokes, 1 occurred in a Sundt grade 1 patient, 2 in Sundt grade 2 patients, 4 in Sundt grade 3 patients, and 3 in Sundt grade 4 patients. At 3-month follow-up by the neurologist, 7 of 10 patients were functionally independent as defined by Rankin 2 scores. Other surgical morbidity included 1 infection and 7 cranial nerve palsies, 6 cases of transient vocal cord paresis, 1 permanent spinal accessory nerve injury, and 3 cases of mandibular facial nerve paresis, of

TABLE 2. Studies With >500 Carotid Endarterectomies

Year	Author	Study Type	Mean Follow-Up, mo	No. of Operations	Symptomatic, %	Death/Major Stroke (% at 30 days)	% Restenosis Criteria	Method of Closure	Restenosis, %
1987	Hertzer et al[8]	PS	21	801	49	4	>30	Patch 49%	4.8
								Eversion 0%	—
								Primary 54%	14
1997	Lawhorne et al[9]	RS	24	500	71	1	>80	Patch 86%	0.7
								Eversion 0%	—
								Primary 14%	—
1998	Shah et al[11]	RS	18	2723	36	2.3	NR	Patch 3%	—
								Eversion 82%	0.3
								Primary 15%	1
2000	Cao et al[7]	PR	33	1353	59	2.6	>50	Patch 19%	1.5
								Eversion 50%	2.8
								Primary 31%	7.9
2000	Archie[5]	RS	55	1360	62	2.1	>50	Patch 99.6%	2.1
								Eversion 0%	—
								Primary 0.4%	—
2001	Scavee et al[10]	RS	49	600	46	0.9	>50	Patch 100%	5.8
								Eversion 0%	—
								Primary 0%	—
2002	Biasi et al[6]	RS	56	517	58	2.5	>60	Patch 62%	1.2
								Eversion 0%	—
								Primary 38%	5.1
2002	Trisal et al[12]	RS	NR	1648	NR	NR	>70	Patch 62%	3.8
								Eversion 0%	—
								Primary 38%	5.8
2003	Meyer	PS	82	1000	59	1.9	>70	Patch 100%	0.1
								Eversion 0%	—
								Primary 0%	—

PR indicates prospective randomized; PS, prospective series; RS, retrospective series; NR, not reported.

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TABLE 3. Carotid Angioplasty Studies >100 Patients

Year	Author	Study Type	Follow-Up, mo	No. of Patients	% Symptomatic	% Stenosis	% Death/Stroke	% Restenosis
2002	Henry et al[40]	PST of protected carotid stenting	11.2	167	56	81.5	2.7	0.5
2001	Brooks et al[37]	PSRT comparing CEA and CAS	?	104	100	82–88	0.9 in CEA	?
							0 in CAS	
2001	Vitek et al[41]	PST of CA restenosis	20	99	60	79	4	Unknown
2001	CAVATAS[36]	PSRT comparing CEA with CA ± stenting	12	251 CA (26% were stented)	97	85–86	10 CEA	14 in CA
				253 CEA			10 CA	4 in CEA
2001	Roubin et al[23]	PST of CAS	17	528	52	74	6.3–8.2	3.2
2000	Henry et al[39]	PST of CAS	17.1	290	42	82.3	3.2	4.7
2000	Gupta et al[38]	RS of patients >65 deemed inoperable	12.1	100	85	85	1	1

PST indicates prospective trial; PSRT, prospective randomized trial; RS, retrospective series.

which 2 resolved. There were no permanent significant twelfth nerve palsies.

Ten patients (0.1%) experienced a recurrent stenosis as defined by ≥70% stenosis on ultrasound, confirmed by either MRA or cerebral angiography. Of these, 2 were symptomatic. Five of the recurrences went on to reoperation, 3 were treated with carotid angioplasty/stenting, and 2 were left untreated. The time to recurrence was 4±2 years. The follow-up for this study was 7.1 (range, 2.0 to 11) years.

Discussion

This series of 1000 consecutive endarterectomies describes a combined 30-day minor and major stroke and death rate of 1.9% at a 7-year follow-up. These data are consistent with recent studies of >500 carotid endarterectomies that demonstrate 30-day major stroke and death rates ranging from 0.9% to 4% and a restenosis rate of 0.7% to 7.9% over an average of 3.5 years (Table 2).[5–12] The present study demonstrating a 0.1% critical restenosis rate provides the longest follow-up data available to date and confirms that carotid endarterectomy is an extremely durable operation.

A meta-analysis of 714 patients in which 44% had both angioplasty and stenting revealed a stroke and death risk of 8%.[35] Since the year 2000, 7 studies have been published with larger sample sizes (mean, 222 patients; range, 99 to 528) and 14.9-month follow-up (range, 11.2 to 20 months).[36–41] The reported 30-day stroke and death rates range from 1% to 4%, with early restenosis rates of 0.5% to 14% (Table 3).[36–41] Therefore, in experienced hands, the 30-day death and stroke rate for carotid angioplasty may be low. However, the available short-term follow-up data suggest that the durability of carotid angioplasty/stenting may be poor.

A review of the carotid endarterectomy literature with respect to restenosis is methodologically challenging because of variations in definitions of restenosis, methods of measuring restenosis, length of follow-up, method of closure at the initial operation, initial lesion pathology, and study design. However, some general considerations regarding method of arteriotomy closure can be drawn from the literature, including those studies listed in Table 2. The preponderance of data indicates that restenosis rates are generally lower with patch closure of the arteriotomy than with primary closure, ranging from 0.1% to 5.8% and 1% to 14%, respectively.[5–12]

Conclusions

These data demonstrate that the risk of perioperative complications is low and that the durability of carotid endarterectomy is excellent. Although less invasive, carotid angioplasty/stenting must demonstrate equivalent robustness for this procedure to be considered a viable alternative to surgery. Clinical trials comparing these 2 treatments must incorporate sufficient years of follow-up after treatment to assess restenosis rates and long-term functional outcome.

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