Internal carotid artery stent placement without emboli protection: Results and long-term outcome

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Abstract—Patients with symptomatic ≥60% (n = 134), asymptomatic ≥80% (n = 143), and asymptomatic progressive ≥60% (n = 25) internal carotid artery stenosis underwent stenting and were followed clinically and by Doppler-assisted duplex imaging for 27.1 ± 15.6 months. Stroke and death from stroke occurred within 30 days after stenting in 4.7% of the symptomatic and in 3.0% of the asymptomatic patients and in the follow-up period in 2.3% of the symptomatic and in 1.2% of the asymptomatic patients.

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Carotid endarterectomy (CEA) improves symptomatic and asymptomatic stenosis of the internal carotid artery (ICA).[1-5] Recently, carotid angioplasty and carotid artery stenting (CAS) have been used as alternatives.[6-9] Few randomized trials compare CEA with CAS.[8,9] Nonrandomized series of CAS with long-term follow-up may contribute to better knowledge of this method.

Methods. Inclusion criteria were transient cerebral or retinal symptoms (TIA) or minor stroke (symptoms related to cerebral ischemia lasting ≤7 days[3]) within 120 days before CAS attributable to stenosis of the ipsilateral ICA of ≥60% luminal narrowing determined by carotid Doppler-assisted duplex imaging (CDDI), asymptomatic stenosis of the ICA of ≥80%, and asymptomatic progressive ≥60% stenosis (table).

CAS was performed by cardiologists (K.K., F.L.; local inguinal anesthesia, vital functions monitored, oral aspirin 100 mg/day plus ticlopidine 500 mg/day or clopidogrel 75 mg/day starting 2 days before CAS). From December 1997 through August 1999, the following protocol was administered: An arterial introducer sheath was placed in the femoral artery, and, after a heparin bolus (100 IU/kg body weight), an 8- French caliber guiding catheter (Multipurpose, Modified Cerebral, Cordis) was placed in the common carotid artery (CCA). ICA stenosis was transversed using a 0.014-inch coronary guidewire (Stabilizer, Cordis), predilated for 10 to 15 seconds with a 4.0- or 5.0-mm compliant balloon catheter (Bypass Speedy Schneider; Tacker, Cordis). Finally, a self-mounted slotted-tube stent (Peripheral Palmaz-Schatz, Jo-stent) was implanted at high pressure inflations (14 to 16 atm) for 10 to 15 seconds. From September 1999 through July 2002, a 6-French caliber guiding catheter (Zuma, Medtronic) and premounted coronary monorail stents (ACS-Ultra stents, Guidant) were used for primary implantations without predilatation. Emboli protection devices were not yet available. Control angiograms were performed and evaluated by cardiologists (KK, FL). CAS was considered successful if the degree of remaining stenosis was ≤30%. After CAS, aspirin 100 mg/day plus ticlopidine 500 mg/day or clopidogrel 75 mg/day were prescribed for 1 month followed by chronic aspirin 100 mg/day.

Patients were examined by a neurologist 24 hours before and 24 hours after CAS. Follow-up comprising clinical examination and CDDI was scheduled for 30 days and 3, 6, 12, 18, 24, 36, 48, and 60 months after CAS. Patients missing prescheduled follow-up visits were contacted by mail or phone. Cerebral complications were documented and, if necessary, investigated including cranial CT. Cause of death was obtained from the death certificate or autopsy report. Primary end point was the composite of nonfatal minor stroke, major stroke (symptoms lasting >7 days),[3] and death.

Results. Of 302 consecutive patients, 168 (55.6%) were asymptomatic and 134 (44.4%) were symptomatic (104 [34.4%] TIA, 23 [7.6%] minor stroke, seven [2.3%] major stroke).[3] Angiographic degree of stenosis[1] before stent placement was 60 to 69% in 14, 70 to 79% in 44, 80 to 90% in 186, and >90% in 81 ICAs. It correlated with the CDDI degree of stenosis (intraclass correlation coefficient r = 0.63). CDDI overestimated the angiographic degree of stenosis in 27% and underestimated it in 36%.[1]

A total of 298 (98.7%) patients underwent CAS of 321 ICAs (in 13 patients both sides in one session and in 10 patients in two sessions). In two symptomatic and two asymptomatic (1.3%) patients, CAS was impossible for technical reasons.

Peri-interventional nonneurologic complications. Nonfatal asystole, bradycardia (<50 beats/minute), or hypotension (systolic blood pressure <90 mm Hg) were observed in 48 (15.9%) patients; inguinal hematoma or aneurysma spurium with transfusion in 16 (5.3%) patients; allergy in three (1%) patients; mild myocardial infarction (after concomitant cardiac intervention) and anemia in one (0.3%) patient each. In eight patients (2.6%), asymptomatic carotid dissection distal to the stent (narrowing of the lumen <50%) occurred. Additional overlapping CAS was successfully performed.

One-month neurologic outcome. In asymptomatic patients (n = 166), the rate of stroke and death was 3.0% (death from ipsilateral ischemic stroke in one [0.6%], nonfatal ischemic major stroke in three [1.8%; infarcts in the pons, posterior internal capsule, territory of the ipsilateral middle cerebral artery [MCA]; Scandinavian Stroke Scale [SSS] score[10] was not assessed in one patient, and it was 32 and 41 in the remaining two patients], ipsilateral ischemic minor stroke in one patient [0.6%; MCA]). TIA occurred in eight (4.8%) patients (all ipsilateral). In symptomatic patients (n = 132) the rate of stroke and death was 4.7% (death from ipsilateral ischemic stroke [MCA] and intracerebral hematoma, each in one [0.8%], ipsilateral ischemic major stroke in one (0.8%; SSS score 4;

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Table *Baseline demographic and clinical characteristics*

	Total, n	%	Symptomatic stenosis, n	%	Asymptomatic stenosis, n	%
Patients	302	100	134	100	168	100
Mean age, y	73.1 ± 9.0		73.6 ± 9.0		72.5 ± 9.1	
Male	206	68.2	90	67.2	116	69
Female	96	31.8	44	32.8	52	31
Comorbidities*						
Hypertension	220	72.8	95	70.1	125	74.4
Hyperlipidemia	187	61.9	68	50.7	119	70.8
Coronary artery disease	176	58.3	72	53.7	104	61.9
Diabetes	98	32.5	48	35.8	50	29.8
Atrial fibrillation	64	21.2	26	19.4	38	22.6
Current smoking	26	8.6	14	10.4	12	7.1
Congestive heart failure	16	5.3	5	3.7	11	6.5
Body mass index	28.2 ± 5.4		27.3 ± 3.9		28.5 ± 6.0	
No. of arteries	325		148		177	
Sonography grade of stenosis (%)						
60–69	10	3	7	4.7	3	1.7
70–79	46	14.2	22	14.9	24	13.6
80–90	194	59.7	88	59.5	106	59.9
>90	75	23.1	31	20.9	44	24.9

* Other comorbidities include malignancies (17 patients); peripheral arterial insufficiency (15 patients), compensated renal failure (10 patients), depression (10 patients), aortic valve insufficiency or stenosis (nine patients), chronic obstructive pulmonary disease (nine patients), dementia (eight patients), Parkinson disease (five patients), epilepsy (four patients), mitral valve insufficiency or stenosis (three patients).

MCA), ipsilateral minor stroke in three patients [2.3%; one thalamic lacune, two negative CTs]). Ipsilateral TIA occurred in eight (6.1%) patients. Patients stented for restenosis after CEA (n = 25) had no complications.

Primary end point rates were similar in symptomatic and asymptomatic (4.7% vs 3.0%), male and female patients (4.4% vs 2.2%), and patients 80 years and older compared with those younger than 80 years of age (4% vs 3.7%; $p > 0.05$; Fisher exact test).

Late results. Mean duration of follow-up was 27.1 ± 15.6 months (median 24). Of the 295 patients, 93 (31.5%) returned for each visit, 66 (22.4%) for 75 to 99% of visits, 102 (34.6%) for 50 to 74% of visits, and 27 (9.2%) for 25 to 49% of the prescheduled visits including CDDI. Twenty-one (7.1%) patients were finally lost to follow-up, 45 (15.2%) died (17 [5.8%] died of cardiovascular disease, seven (2.4%) of carcinoma, six (2.0%) of pulmonary disease, 15 (5.1%) of cause unknown). No fatal stroke was reported.

Asymptomatic patients (n = 165) had no major stroke. Two (1.2%) asymptomatic patients had ipsilateral ischemic minor stroke, six (3.6%) had ipsilateral TIA. Two (1.5%) of the 130 symptomatic patients had a major ischemic ipsilateral stroke, one (0.8%) an ipsilateral minor stroke (end point rate 2.3%), and five (3.8%) had an ipsilateral TIA. Patients stented for ICA stenosis after CEA remained complication free. One, 2, and 5 years after the first CAS, 94.2%, 93.1%, and 88.7% of the asymptomatic and 91.6%, 91.6%, and 87.9% of the symptomatic patients were stroke free (figure 1; Kaplan–Meier; SPSS for Windows 12.0, Chicago, IL).

The long-term primary end point rate was similar in symptomatic and asymptomatic (2.3% vs 1.2%), male and female patients (1% vs 3.3%), and patients 80 years of age and older compared with those younger than 80 years of age (1.3% vs 1.8%; $p > 0.05$, Fisher exact test).

Ultrasound follow-up and restenting. No restenosis (≥50%) occurred 30 days after CAS. Thirty patients (10.2%) including four with CAS after CEA had ≥50% late restenosis (18 stent crush, 12 intima proliferation, symptomatic in two, asymptomatic in 28 patients; 60 to 69% of restenosis in 19; 70 to 79% in seven, 80 to 90% in three, >90% in one patient; 17 (5.8%) within the first, eight (2.7%) within the second, three (1%) within the third, and two within (0.7%) the fourth year). The second CAS was successful in 12 of 12 patients, third in five of five (4 to 23 months after second CAS), fourth in two, and fifth in one. One, 2, and 5 years after the first CAS, 94.0%, 91.1%, and 80% of the asymptomatic and 91.4%, 88.8%, and 84.8% of the symptomatic patients were restenosis free (figure 2).

Discussion. In this study, the rates of death and stroke 30 days (3.0% in asymptomatic, 4.7% in symptomatic stenosis) and of stroke and death from stroke a median of 24 months after CAS (1.2% in asymptomatic, 2.3% in symptomatic stenosis; cause of

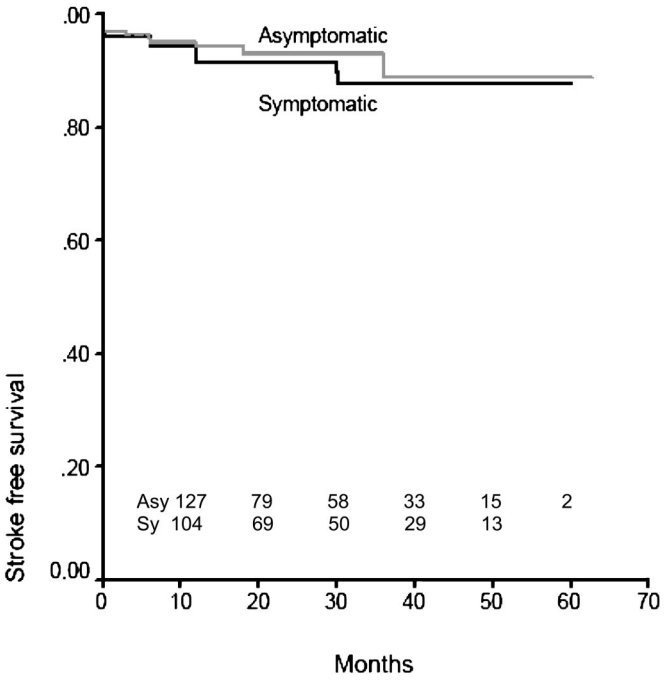

Figure 1. Stroke-free survival. These Kaplan–Meier curves show the probability of stroke-free survival after carotid artery stenting in asymptomatic (Asy) and symptomatic (Sy) patients. The numbers of patients who remained stroke free are shown in 10-month intervals along the abscissa of the graph; 166 asymptomatic and 132 symptomatic patients were stented at time zero.

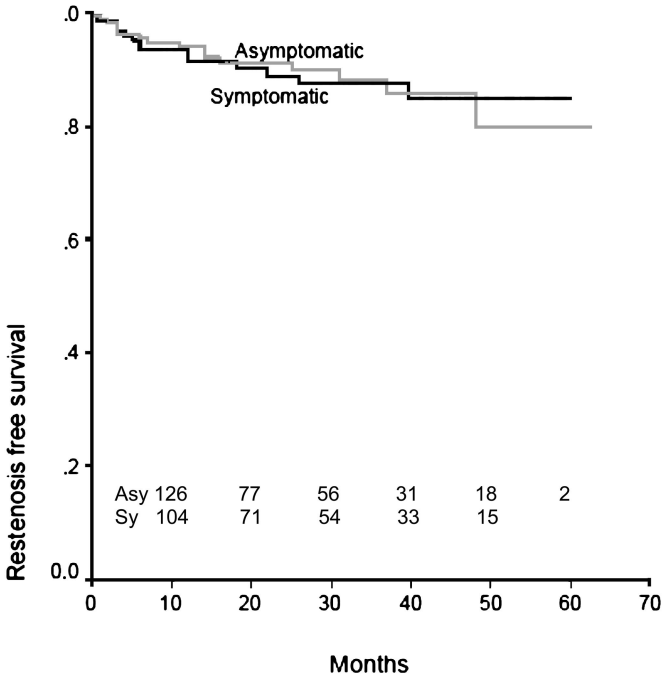

Figure 2. Restenosis-free survival. These Kaplan-Meier curves show the probability of restenosis-free survival after carotid artery stenting in asymptomatic (Asy) and symptomatic (Sy) patients. The numbers of patients who remained restenosis free are shown in 10-month intervals along the abscissa of the graph; 166 asymptomatic and 132 symptomatic patients were stented at time zero.

death unknown in 5.1%, loss to follow-up in 7.1%) were similar to CAS in patients with comparable stenosis rates and comorbidities (3% in asymptomatic and 4.7% in symptomatic stenosis).[6-8] In the literature, restenosis rates 6 to 26 months after stenting are 0.6 to 14%[6-9] and 10.2% in our study. In studies on CEA, the end point rates (30 days, 1.2 to 6.7%; long-term follow-up, 3.2 to 12.4%),[1-4,9] and the restenosis rates (1.1 to 14%)[5,8,9] are similar to our results. Fifty-eight of our patients (age >80) do not fulfill the inclusion criteria of CEA trials in which the mean age was lower (62 to 67 years),[1-4,9] and stenosis rates[2-4] and comorbidities[1-4,9] on average were similar or less severe than in our study. Emboli protection devices might contribute to improved neurologic outcome of CAS.[9]

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