Early Outcome of Carotid Angioplasty and Stenting With and Without Cerebral Protection Devices
A Systematic Review of the Literature

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Background—Carotid angioplasty and stenting (CAS) is increasingly being used for treatment of symptomatic and asymptomatic carotid artery disease (CAD). To evaluate the efficacy of cerebral protection devices in preventing thromboembolic complications during CAS, we conducted a systematic review of studies reporting on the incidence of minor stroke, major stroke, or death within 30 days after CAS.

Summary of Review—We searched for studies published between January 1990 and June 2002 by means of a PubMed search and a cumulative review of reference lists of all relevant publications. In 2357 patients a total of 2537 CAS procedures had been performed without protection devices, and in 839 patients 896 CAS procedures had been performed with protection devices. Both groups were similar with respect to age, sex distribution, cerebrovascular risk factors, and indications for CAS. In many studies the periprocedural complication rates had not been presented separately for patients with symptomatic and asymptomatic CAD. The combined stroke and death rate within 30 days in both symptomatic and asymptomatic patients was 1.8% in patients treated with cerebral protection devices compared with 5.5% in patients treated without cerebral protection devices (χ²=19.7, \( P<0.001 \)). This effect was mainly due to a decrease in the occurrence of minor strokes (3.7% without cerebral protection versus 0.5% with cerebral protection; \( χ²=22.4, P<0.001 \)) and major strokes (1.1% without cerebral protection versus 0.3% with cerebral protection; \( χ²=4.3, P<0.05 \)), whereas death rates were almost identical (≈0.8%; \( χ²=0.3, P=0.6 \)).

Conclusions—On the basis of this early analysis of single-center studies, the use of cerebral protection devices appears to reduce thromboembolic complications during CAS. These technical aspects should be taken into account before the initiation of further randomized trials comparing CAS with carotid endarterectomy. (Stroke. 2003;34:813-819.)

Key Words: angioplasty ■ carotid arteries ■ protective devices ■ stenosis ■ stents

Carotid endarterectomy (CEA) is one of the most commonly performed peripheral vascular procedures and is currently considered the most effective treatment for stroke prevention in patients with high-grade symptomatic or asymptomatic carotid artery disease (CAD).

However, in the past few years, evidence has accumulated that carotid angioplasty and stenting (CAS) might become an alternative to CEA for the treatment of these disorders. Despite an increasing enthusiasm for the application of CAS in CAD, only a single completed, prospective, multicenter trial comparing endovascular versus surgical treatment for CAD has been reported to date: the Carotid and Vertebral Transluminal Angioplasty Study (CAVATAS). This study reported a similar major risk and effectiveness for CAS compared with CEA. In contrast, a recent systematic comparison of the 30-day outcome of CAS and CEA for symptomatic CAD in single-center studies performed during 1990–1999 revealed a significantly higher risk of stroke or death for CAS than for CEA. Both this survey and CAVATAS elucidate the great challenges associated with the performance of trials comparing CEA with CAS. The field of endovascular therapy is subject to rapid technological advances. Therefore, the current state of the art may be outdated before completion of randomized trials. In CAVATAS, for instance, most of the CAS patients were treated with angioplasty alone, and only 55 of a total of 240 patients underwent carotid angioplasty in combination with stenting. No procedure was performed with cerebral protection devices. Similarly, the survey of Golledge et al included many case series in which angioplasty had been performed without stenting and only 2 case series, with a total of 82 patients, in which cerebral protection devices had been used.

Fear of distal embolization of plaque fragments to the brain has generated great concern regarding the safety of CAS.
Recent technical refinements therefore have led to the widespread use of CAS with cerebral protection devices. With accumulating experience and technical improvements aiming to reduce procedure-related embolic complications, it is likely that the results of the early CAS studies might not reflect current complication rates. Additionally, insurance companies and governments are increasingly demanding cost-effective healthcare. This raises the question of whether the widespread introduction of costly cerebral protection devices really improves the quality of care.

Therefore, the goal of this study was to search systematically for reports on CAS with and without cerebral protection devices to critically appraise the data and to determine the occurrence of minor and major strokes and death within 30 days according to the criteria set forth by the large CEA trials.1–3

Materials and Methods

Search Strategy

An extensive search of the literature from January 1990 to June 2002 was performed with PubMed with the advanced search option. We used the key words carotid artery, stenosis, angioplasty, stent, and protection in different permutations. We examined the reference lists of all included articles for other relevant references. Additionally, we performed a hand search of relevant general medical, neurological, radiological, surgical, and neurosurgical journals. Contact with other authors of the field was made to identify additional studies. The abstract of each article was carefully studied, and if there was any suggestion of relevant data, the full text was retrieved. All studies were independently assessed by 2 reviewers (A.K. and K.G.) and then cross-checked; disagreements were resolved by consensus.

Eligibility Studies

Studies were included if the following criteria were fulfilled: (1) the study comprised a total of at least 10 stent procedures; (2) the number of peri-interventional complications rates (ie, minor stroke, major stroke, or death) within 30 days was reported for patients with high-grade symptomatic or asymptomatic CAD; and (3) the number of peri-interventional complications rates (ie, minor stroke, major stroke, or death) within 30 days was reported separately for stent procedures with and without cerebral protection devices. Articles were excluded if only angioplasty without stent placement had been performed. Further exclusion criteria were editorials, letters, and reviews. In case of multiple publications on the same study population, we used the most recent publication. All articles that did not clearly meet our inclusion criteria were excluded at this stage. Six articles1–12 were excluded because the case series included <10 patients.

Data Extraction and Analysis

For each study the following data were extracted: (1) general: year of publication, number of patients, institutions; (2) patient characteristics: sex, age, risk factors such as hypertension, hyperlipidemia, diabetes mellitus, smoking, hypertension, coronary artery disease; (3) initial diagnosis of high-grade CAD: carotid duplex ultrasound, cerebral invasive/noninvasive angiography; (4) indications for angioplasty and stent: asymptomatic, transient hemispheric ischemic attack, amaurosis fugax, minor stroke, and major stroke; (5) stent procedure: procedural technique, types of stents, types of cerebral protection devices; (6) number of patients and number of arteries treated; (7) periprocedural complications within 30 days: minor stroke, major stroke, and death.

In most studies peri-interventional complication rates within 30 days had been defined according to the criteria set forth by the large CEA trials.1–3 A minor stroke was defined as a persisting new neurological deficit that increased the National Institutes of Health

Stroke Scale score by <3 points and a major stroke as a persisting new neurological deficit that increased the National Institutes of Health Stroke Scale score by ≥3 points.

For statistical analysis, χ² tests were used, and a value of P<0.05 was considered statistically significant.

Results

Our literature search resulted in 40 studies of CAS without cerebral protection13–52 and 14 studies of CAS with cerebral protection17,31,53–64 that met the inclusion criteria. Of these, several articles were excluded because they reported on patients already used in other publications from the same institutions: Theron et al65 was excluded in favor of Guima-
raens et al66; several studies of the group of Roubin et al36–42 were excluded in favor of Roubin et al12; Jordan et al61 and Jordan et al64 were excluded in favor of Jordan et al22; Chakhtoura et al65 was excluded in favor of Hobson et al20; Henry et al66 was excluded in favor of Henry et al56; Jaeger et al60 was excluded in favor of Jaeger et al21; Macdonald et al61 was excluded in favor of Al-Mubarak et al55; and Angeli et al56 was excluded in favor of Reimers et al.62

One recent study49 evaluating the efficacy of abciximab in patients undergoing CAS was also excluded. Another small case series of 22 patients50 had included patients with carotid dissections after gunshot wounds and was therefore also excluded. One small case series with 33 patients published in the South African Medical Journal was not accessible in any library in Germany.51

The main characteristics of the remaining studies are summarized in Tables 1 and 2. The number of patients in the studies of stenting with cerebral protection devices totaled 839, and the number of patients in the studies without cerebral protection totaled 2357. Because most cerebral protection devices are currently being tested, 21 patients (ie, 0.8% of all patients without protection) had been stented with protection in 4 studies mainly reporting on the results of CAS without protection15,20,29,48(Table 1). Although the peri-interventional complications rates were not reported separately for stent procedures with and without cerebral protection devices in these studies, they were still considered for this analysis.

In both groups there was a similar age and sex distribution (69±3 years in the group without cerebral protection versus 68±2 years in the group with cerebral protection [P=NS]; 69% male, 31% female in the group without cerebral protection versus 73% male, 27% female in the group with cerebral protection [P=NS]). Additionally, the number of asymptomatic or symptomatic patients presenting with amaurosis fugax, hemispheric transient ischemic attacks, or minor stroke before stenting was comparable in the groups with and without cerebral protection (64% symptomatic patients and 36% asymptomatic patients in the group with protection versus 59% symptomatic patients and 41% asymptomatic patients in the group without protection [P=NS]).

In both groups arterial hypertension and hyperlipidemia were the most frequent vascular risk factors, followed by cigarette smoking and diabetes mellitus (Table 3).

In all studies the majority of patients had been treated for atherosclerotic CAD, and in some case series a few patients
had been treated for radiation-induced or inflammatory carotid artery stenoses.

In both groups the most commonly used stents were self-expandable Easy Wallstents (Boston Scientific–Schneider Corp), SMART stents (Cordis), and Palmaz biliary stents (Johnson and Johnson Interventional Systems Co). In most recent studies the periprocedural protocol was similar, and the patients had received either ticlopidine (250 mg twice daily) or clopidogrel (75 mg daily) as well as aspirin (100 mg daily) for at least 48 hours before the procedure and for at least 2

### TABLE 1. Carotid Angioplasty and Stent Without Cerebral Protection: Study Characteristics and 30-Day Outcomes

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Total: 2357

*10 patients stented with cerebral protection devices.

**2 patients treated with cerebral protection devices.

***3 patients treated with protection devices.

### TABLE 2. Carotid Angioplasty and Stent With Cerebral Protection: Study Characteristics and 30-Day Outcomes

<table>
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Total: 839

815
weeks after the procedure. Notably, in the early study of Diethrich et al., the patients had only received aspirin.

Although higher complication rates of CEA or CAS procedures in symptomatic patients have been reported in the past, the periprocedural and 30-day complication rates were not presented separately for patients with symptomatic or asymptomatic CAD in most studies.

Table 4 summarizes the overall complications within 30 days in patients treated with and without cerebral protection in patients with symptomatic and asymptomatic CAD. The combined stroke and death rate within 30 days was 1.8% in patients treated with cerebral protection devices compared with 5.2% in patients treated without cerebral protection devices ($\chi^2=19.7, P<0.001$). This effect was mainly due to a decrease in the occurrence of minor strokes (3.7% without cerebral protection versus 0.5% with cerebral protection; $\chi^2=22.4, P<0.001$) and major strokes (1.1% without cerebral protection versus 0.3% with cerebral protection; $\chi^2=4.3, P<0.05$), whereas the death rate was nearly identical ($\approx0.8%$; $\chi^2=0.3, P=0.6$).

When these numbers were used to calculate odds ratios, there was a 3-fold increased risk of any stroke or death and a >6-fold increase of minor stroke within 30 days of CAS without protection compared with protection.

When we analyzed those studies without protection that differentiated between symptomatic and asymptomatic CAD, the combined stroke and death rate within 30 days was significantly higher in symptomatic than in asymptomatic patients (6.4% versus 1%; $P<0.01$).

In both groups there was no clear relationship between the year of publication and the reported complications. However, the high combined stroke and death rate of 12% in the study of Diethrich et al. is likely due to the sole use of aspirin before and after stenting. Nonetheless, even after this study was excluded from the analysis, the combined stroke and death rate within 30 days was still significantly lower in those patients treated with cerebral protection devices than in those patients treated without protection (1.8% versus 5.2%; $P<0.01$).

**Discussion**

Since 1990 many single-center studies on CAS have been published, reflecting the increased enthusiasm for the application of CAS in the treatment of CAD. However, before widespread application of these new techniques, they must be evaluated critically by properly performed prospective, randomized trials. While only 1 prospective multicenter trial comparing endovascular versus surgical treatment for CAD has been reported to date, 3 state-of-the-art large-scale clinical trials have clearly established the value of CEA to reduce the risk of stroke in patients with symptomatic or asymptomatic high-grade CAD.

To validate CAS as an alternative treatment strategy, case series and uncontrolled trials are generally considered to be of low scientific value. Nevertheless, the collective information from these observational studies is useful for informing patients and as a source of decision making in everyday clinical practice until the results of further multicenter trials are available. Additionally, the collective information from observational studies is pivotal in planning further randomized trials.

On the basis of a total of 2537 stented arteries, the overall stroke and death rate within 30 days of 5.5% in patients treated with CAS without cerebral protection is similar to the results of an unmonitored worldwide survey of 5210 CAS procedures (30-day procedure-related mortality rate of 0.86%, major stroke rate of 1.49%, and minor stroke rate of 2.7%). This figure is also comparable to the results of the large CEA trials, in which the overall stroke and death rates within 30 days were 5.8%, 1.7% for symptomatic patients, and 2.3% for asymptomatic patients. With the use of the data of those CAS studies that differentiated between symptomatic and asymptomatic CAD, the combined stroke and death rate within 30 days was 6.4% in symptomatic and 1% in asymptomatic patients. The combined stroke and death rate within 30 days of 6.4% in symptomatic patients is in the range of 7.8% found in a recent survey of the literature, in which most symptomatic patients had been treated with angioplasty alone. Although a comparison between these 2 reviews should be made with caution because of the wide heterogeneity in patients and study designs, the similar complication rates indicate that the additional stent deployment does not increase clinically relevant thromboembolic complications. While this might appear self-evident, the insertion of a stent is associated with an increased occurrence of microembolic signal as detected by transcranial Doppler, which could lead to more thromboembolic complications.

The increasing enthusiasm for nonsurgical endovascular procedures and the favorable comparison of the early outcome of CAS without protection with CEA in this analysis...
should not hide the fact that on average almost 6% of all patients had experienced a minor or major stroke or died within 30 days of the CAS procedure. In an attempt to reduce peri-procedural complication rates during CAS, cerebral protection devices were developed in the past few years. These are based either on a temporary distal balloon occlusion with subsequent aspiration of embolic particles, such as the PercuSurge system, or on intravascular filter devices such as the NeuroShield system (MedNova Ltd). From a theoretical point of view, the maintenance of antegrade blood flow might be an advantage of intravascular filter devices, whereas balloon protection systems have a favorable low-crossing profile.

The findings of our review suggest that the use of cerebral protection devices during CAS in general can significantly reduce thromboembolic complication rates, namely, the occurrence of minor and major strokes. Accordingly, a recent study has demonstrated a significant reduction of the frequency of microembolic signals during protected versus unprotected CAS. While the type of cerebral protection devices that offer the best results needs to be established in randomized trials, there was no significant difference in the overall stroke and death rate within 30 days in patients treated with balloon or intravascular filter protection devices. The missing difference in fatal outcomes within 30 days in comparison to CAS procedures without cerebral protection is likely attributable to the inclusion of all cardiac deaths in both groups.

Despite these encouraging preliminary results, there are several points of concern, some of which are also applicable to the CAS data without protection. In general, our systematic review of the literature is clearly limited by the retrospective analysis of the reported case series and small studies, some of which showed severe methodological weaknesses. There was a wide heterogeneity in the study designs, material, and patient populations. Furthermore, differential complication rates for CEA in symptomatic and asymptomatic patients are well known. However, only a minority of CAS studies presented the early complication rates separately for patients with symptomatic or asymptomatic CAD. As in any field of medical sciences, publication biases likely exist toward selective submission and acceptance of studies with good results over studies with poor results. Finally, this review concerned a newly developed treatment. Increasing expertise within single institutions might influence the complication rates. While the data were not sufficient to analyze the effect of learning on current complication rates, Roubin et al demonstrated a significant reduction of the overall 30-day minor stroke rate during CAS without protection with increasing experience in the largest single-center study reported to date. This possible effect on outcome must be taken into account when the favorable results of CAS procedures with cerebral protection are interpreted, particularly when one considers that these new therapeutic devices were tested primarily in very experienced centers.

To validate the effectiveness of CAS as an alternative to CEA, neither the results of CAS without protection nor the favorable results of CAS with protection of this systematic review can replace properly performed randomized trials. On the other hand, our results suggest that the use of cerebral protection devices can significantly reduce thromboembolic complications during CAS. Therefore, future randomized trials comparing CEA with CAS will have to take into account the rapid technological improvements in the field of endovascular therapy.

Irrespective of the results of large trials, it should be stressed that the usefulness of any revascularization procedure for stroke prevention is principally dependent on a low complication rate within each institution. To achieve a beneficial effect of CEA versus medical therapy alone, the combined mortality and morbidity rate should be <3% for asymptomatic patients and <6% to 7% for symptomatic patients. Although the heterogeneity of patient populations and different risk profiles might hamper the comparability of data across various institutions, the combined stroke and death rate was >8% in 3 CAS series without cerebral protection, indicating that CAS might not have been an efficient therapy in some institutions.

The large variability of the early complication rates, ranging from 0% to 17%, (or at least those that are reported and published) stresses the need for ongoing evaluations of all complication rates during CAS within single institutions. Since the low complication rates of large multicenter CEA trials cannot be generalized to everyday clinical practice without reservation, this call for continuing evaluations should also include all surgical procedures within single institutions.

References


Early Outcome of Carotid Angioplasty and Stenting With and Without Cerebral Protection Devices: A Systematic Review of the Literature
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