Systematic Review of Early Recurrent Stenosis After Carotid Angioplasty and Stenting

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Background and Purpose—Carotid angioplasty and stenting (CAS) has emerged as a potential alternative to endarterectomy (CEA) for the treatment of carotid artery disease. Aside from the periprocedural complication rates, the benefits of CAS will be affected by the incidence of recurrent carotid stenosis.

Methods—We conducted a systematic analysis of all peer-reviewed studies reporting on the rate of restenosis (≥50%) after CAS based on duplex ultrasound or angiography that were published between January 1990 and July 2004. We identified 34 studies that reported on a total of 4185 patients with a follow-up of 3814 arteries over a median of 13 months (range, 6 to 31 months).

Results—The cumulative restenosis rates after 1 and 2 years were ≈6% and 7.5% in those studies, which used a lower restenosis threshold ≥50% to 70% and ≈4% in the first 2 years after CAS in those studies, which used a lower restenosis threshold >70% to 80%.

Conclusions—In reviewing the current literature, the early restenosis rates after CAS compare well with those reported for CEA. However, this analysis of the peer-reviewed literature also indicates that the early restenosis rates after CAS might be higher than previously suggested in observational surveys. Therefore, an active follow-up of all stented arteries seems to be warranted. Moreover, the bulk of endovascular data are derived from small studies with short follow-up periods so that the long-term durability of CAS still needs to be established in large trials. Ideally, these studies should use a clear and uniform definition of restenosis and identical follow-up schedules.

Key Words: angioplasty ■ carotid arteries ■ outcome ■ stenosis ■ stents

Since the conclusion of several large multicenter trials, carotid endarterectomy (CEA) has become the accepted standard treatment for revascularization of high-grade symptomatic and asymptomatic carotid artery disease (CAD). However, the benefit of CEA is highly dependent on a low perioperative risk and is eliminated when the combined 30-day stroke and death rates exceed ≈6% for symptomatic patients and 3% for asymptomatic patients, respectively. Especially for high-risk surgical patients, carotid angioplasty and stenting (CAS) has recently been introduced as a potential alternative to CEA for the treatment of high-grade CAD. Several case series and small trials have suggested that CAS can be performed with acceptable 30-day complication rates. Currently, several major trials directly comparing CAS with CEA are underway. Although these studies have focused primarily on the 30-day risks of stroke and death, the long-term durability of both CAS and CEA will also be affected by the incidence of recurrent carotid stenosis, as well as the need for a reintervention. The risk of recurrent carotid stenosis after CAS has been the focus of many single-center studies and was also analyzed in the Asymptomatic Carotid Atherosclerosis Study (ACAS). In contrast, the long-term patency rates of carotid stents have not yet been established in larger trials. Because CAS is performed with increasing frequency data on recurrent stenosis and its effect on long-term stroke-risk are increasingly important. Aside from the long-term durability of CAS, the question of how best to follow-up these patients for the short-term and medium-term must also be addressed. With limitations on medical costs, it has become necessary to optimize duplex scan surveillance while still maintaining good patient care and minimizing future stroke risk. Although the cost-effectiveness of a close routine ultrasound screening after CEA has been questioned, this may be warranted after CAS procedures because of potentially higher early restenosis rates.

In this study, we present a systematic review of restenosis rates after CAS published since the introduction of CAS.

Materials and Methods

Search Strategy

Two independent observers (K.G. and A.K) performed an electronic literature search with Entrez PubMed NIH. The key words carotid and stent were used to extract all relevant abstracts. Studies were
Eligibility Studies

Studies were included if the following criteria were fulfilled: (1) the study comprised at least 25 angioplasty and stent procedures with a minimum follow-up period of 6 months; (2) the follow-up was systematic and not just in case of complications; (3) patients were followed-up with either duplex/Doppler ultrasound (DU) or angiography; (4) a lower restenosis threshold ≥50% was used; and (5) they were written in English, German, Spanish, or French.

Articles were excluded if only angioplasty without stent placement had been performed. As mentioned, editorials, letters, and reviews were also excluded. In case of multiple publications from the same study population, we used the most recent publication.

Data Extraction

For all studies, the following data were extracted independently by 2 observers (K.G. and A.K.) by use of a predefined electronic data sheet: (1) year of publication, number of patients, or treated arteries; (2) patient characteristics (age, sex, medical and angiographical risk factors, symptomatic or asymptomatic carotid artery disease); (3) the lower threshold used to determine a restenosis; (4) the number of patients or arteries with restenosis; (5) the average follow-up time; (6) ipsilateral stroke events in patients with restenosis versus without restenosis beyond 30 days; (7) the time to occurrence of restenosis; and (8) the number of re-interventions performed.

Articles that met all inclusion criteria but in which special data extraction was not possible were marked as “NG” (not given). In contrast to some original publications, carotid occlusions were counted as restenosis in this review. Moreover, the restenosis rates were calculated in relation to the number of arteries followed up.

Data Analysis

Interoobserver agreement for the search results was assessed with kappa statistics and the $\chi^2$ method was used to calculate heterogeneity of the reported restenosis rates between the studies. The major goal of this systematic review was to determine the restenosis rates ≥50% after CAS. However, the duplex/DU criteria for determining a restenosis ≥50% were very heterogeneous. Moreover, several studies used a lower threshold higher than 50% to define a restenosis. To take the different lower thresholds and the heterogeneous DU criteria for defining and determining a restenosis into account, all studies were divided into the following 2 groups: those that used a lower threshold of ≥50% to 70% to define a restenosis and those that used a lower threshold >70% to 80% to define a restenosis. Because some studies presented data separately for both restenosis thresholds, they were included twice in the analysis.

Only a minority of studies presented life table data in tabular form so that it was not possible to determine Kaplan–Meier curves for each center or to construct a summary curve of cumulative restenosis rates after CAS based on such an analysis. To estimate the cumulative restenosis rates, we therefore plotted the proportion of patients/arteries in whom a restenosis developed against the average follow-up time. Because of the great heterogeneity of the data, statistically valid curve-fitting procedures could not be performed. However, using the sample sizes at risk as weights, both data sets were best fit by a straight line between 6 and 24 months. Therefore, this approach was used to estimate the restenosis rates after 1 and 2 years, although it does not reflect the inconstant incidence of restenosis over time.

Results

With the search terms carotid and stent, the electronic literature search with Entrez PubMed NIH yielded 1221 references. After excluding 160 animal studies, 315 case reports, 159 review articles that did not contain original data, and 86 letters/editorials, 500 potentially relevant abstracts were extracted ($k=0.91$ for interobserver agreement; 95% confidence interval, 0.89 to 0.94). Based on their abstracts, another 346 references ($k=0.89$ for interobserver agreement; 95% confidence interval, 0.84 to 0.93) could be excluded, so that a total of 154 articles were reviewed in full. No additional articles were found by the manual search.

Our literature search resulted in 34 studies that fulfilled all inclusion criteria. Two of these articles were published in German. Five articles published data on multicenter studies, whereas the remaining 29 articles were based on single-center studies.

The main patient characteristics of these studies are summarized in Table 1. A total of 4185 patients (66% male, 34% female, 4372 arteries) with a mean age of 70±2 years were analyzed. Most of the patients had multiple risk factors, 6% were treated for postradiation stenosis, 10% had an occlusion of the contralateral internal carotid artery, and 24% had a restenosis after CEA. The most common risk factors were arterial hypertension (75%), hyperlipidemia (59%), coronary artery disease (56%), tobacco use (53%), diabetes (28%), and congestive heart failure (17%). The proportion of patients with a symptomatic carotid stenosis varied from 22% to 100%. With respect to the entire study population, 49% of all patients were treated for symptomatic carotid artery disease and 51% were treated for asymptomatic CAD.

The follow-up data of all studies are summarized in Table 2. A total of 371 patients/arteries were lost to follow-up, leaving 3814 arteries at risk. The mean follow-up periods of the individual studies ranged from 6 months to 31 years (with a median of 13 months across all studies). The DU criteria for determining a restenosis ≥50% were very heterogeneous. In 3 studies, the primary diagnostic criterion was the degree of lumen reduction; in 2 studies, it was the peak systolic velocity; in 3 studies, it was the ratio of the peak internal carotid artery (ICA) to common carotid artery (CCA) velocity; and in 12 studies, several of these criteria were used.

In 14 studies, the exact definition of a DU restenosis ≥50% was not given. Twenty-five studies used a lower restenosis threshold ≥50% to 70%, whereas 16 studies used a lower threshold >70% to 80% to define a restenosis.

In Figure 1, the proportion of patients/arteries in whom which restenosis developed is plotted against the average follow-up time. In both groups, the data were very heterogeneous (χ²=83, df=24 in the restenosis group ≥50% to 70%, P<0.01; and χ²=39, df=15 in the restenosis group >70% to 80%, P<0.01). The cumulative restenosis rates after 1 and 2 years were 6% and 7.5% in those studies that used a lower restenosis threshold ≥50% to 70% and ≥4% after 1 and 2 years in those studies that used a lower restenosis threshold >70% to 80%, respectively.
The time intervals to restenosis were available from 17 studies (1619 arteries at risk) that used a lower threshold of \(\leq 50\%\) to 70\%,\(^{10,11,13,15–17,19,21–24,26,28–30,33,34}\) and from 11 studies (1012 arteries at risk) that used a lower threshold of 70\% to 80\%,\(^{10,11,15–17,19,21,39,40,42,43}\) respectively. In both groups, 46\% of all restenoses occurred within the first 6 months, 25\% within 6 to 12 months, and 29\% beyond the first year. A further goal of this review was to estimate the relative risk of stroke in patients with recurrent stenosis compared with patients without recurrent stenosis. However, of the 34 studies, only 24 studies provided ipsilateral stroke rates for both patients with and without recurrent stenosis.\(^{10–13,15,20,22–24,26,29,31,33,34,37,39–41–43}\) Moreover, the number of ipsilateral strokes was zero in both the restenosis and no restenosis groups in 15 studies,\(^{10,13,15,20,22–24,26,29,31,33,34,37,39–41–43}\) zero in the restenosis group in 6 studies,\(^{12,19,22,23,28,32}\) and zero in the no restenosis group in 3 studies.\(^{11,25,38}\) Therefore, the data were insufficient to calculate a valid summary estimator of the relative risk of stroke in patients with recurrent stenosis compared with patients without recurrent stenosis.

Thirty-one studies provided data on how many patients/arteries with a recurrent stenosis \(\leq 50\%\) were retreated (Table 2). A second intervention (65 CAS or angioplasty procedures, 3 surgical procedures, 23 procedures not specified) was performed in 91 arteries (2.7\% of 3429 arteries followed-up). In these studies, about one-fourth (22\%) of the patients with a restenosis had experienced symptoms before the second intervention. The remaining patients underwent a second intervention for an asymptomatic recurrent carotid stenosis.

**Discussion**

In the past few years, CAS has been introduced as an alternative to CEA for the treatment of carotid artery stenosis. Evidence is accumulating that CAS can be performed with...
acceptable 30-day stroke and death rates (for review see Kastrup et al, 2003). However, the benefits of this procedure will also be related to the incidence of recurrent stenosis and whether symptoms develop in those patients. Because the results of currently performed randomized multicenter trials on short-term or long-term patency rates of carotid stents will not be available in the foreseeable future, we performed a systematic analysis of the current peer-reviewed literature on restenosis rates after CAS. For those studies that used a lower restenosis threshold (≥50% to 70%), the estimated restenosis rates of ≈6% to 8% within the first 2 years after CAS seem to be within the range of restenosis rates ≥50 that have been reported after CEA. In a recent systematic review of the literature, the cumulative incidence of recurrent stenosis (≥50%) after CEA was ≈10% in the first year. Similarly, an early restenosis rate of 7.6% to 11.4% (depending on the positive predictive value confidence level of the angiogram-validated Doppler data used) was found within 18 months of CEA in the ACAS. To date, the Carotid and Vertebral Artery Transluminal Angioplasty Study (CAVATAS) is the only published prospective multicenter trial that directly compared early carotid restenosis rates after endovascular versus surgical treatment. However, in CAVATAS most patients were treated with angioplasty alone, so that these results do not reflect the risk of recurrent stenosis after CAS. In contrast to the high restenosis rates of ≈20% after simple angioplasty within the first year in CAVATAS, the results of this review indicate that the additional stent deployment clearly improves the early durability of carotid angioplasty. Comparable with these results, coronary stenting has also been associated with significantly lower restenosis rates than angioplasty alone.

Contrary to our data, much lower restenosis rates ≥50% after CAS (2.70% after 12 months, 2.60% after 24 months, and 2.40% after 36 months) have been reported in the largest multicenter survey to date. However, this survey is limited

### TABLE 2. Follow-up Data of 34 Studies Reporting on Restenosis Rates (≥50%) After CAS

<table>
<thead>
<tr>
<th>First Author</th>
<th>Patients or Arteries at Risk, No.</th>
<th>Patients or Arteries Followed-up, No.</th>
<th>Lower Threshold, %</th>
<th>Follow-up Time, mo</th>
<th>Restenosis, No.</th>
<th>Restenosis, %</th>
<th>Repeat Procedures, No.</th>
<th>Ipsilateral Stroke* With Restenosis, No.</th>
<th>Ipsilateral Stroke Without Restenosis, No.</th>
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AG indicates angiography; ANG, angioplasty; CAS, carotid angioplasty and stenting; CEA, carotid endarterectomy; DU, duplex/Doppler ultrasound.

*All minor, major, or fatal strokes beyond 30 days.
by the observational nature of the data and the fact that not all patients were followed-up systematically. Our analysis of the peer-reviewed literature clearly indicates that the problem of restenosis after CAS should not be underestimated and that an active follow-up of all stented arteries seems to be warranted. Although several studies mixed early with late restenosis rates, the risk of recurrent stenosis after CAS seems to be greatest in the first year after the procedure and then decreases over time. Likewise, the incidence of carotid restenosis after CEA also decreases with time,\(^{7,8}\) arguing for a similar mechanism of restenosis. In fact, it appears that neointimal hyperplasia is the major pathophysiologic process leading to early restenosis after carotid revascularization procedures.\(^{8,47-49}\) In support of this notion, neointimal proliferation prevailed up to 12 months after CAS in a recent prospective duplex ultrasound study, whereas no further relevant changes in the neointima were observed during the second year.\(^{47}\)

Aside from the patency rates of carotid stents, how many patients in whom symptoms develop because of restenosis and how many patients require a reintervention are questions that arise. Approximately 1% of all patients were retreated within the first 2 years after CAS because of a symptomatic restenosis. Comparable to this result, <1% (5/558) of the surgical patients had a second CEA because of symptomatic restenosis in the European Carotid Study Trial (ECST).\(^{50}\) However, the data were insufficient to calculate a valid summary estimator of the relative risk of stroke in patients with recurrent stenosis compared with patients without recurrent stenosis. In this context, it is noteworthy that patients with a recurrent stenosis after CEA seem to follow a benign course.\(^{50}\) In the ACAS study, for example, there was no association between late stroke and recurrent stenosis.\(^{8}\)

A review of the CAS literature with respect to restenosis rates after CAS is methodologically challenging and also clearly demonstrates the limitations of currently available data. Although the incidence of restenosis seems to be highest in the first 2 years after CAS, only a few small studies have been published to date that provide adequate information about long-term follow-up beyond 24 months. In this survey, the longest mean follow-up period was 31 months.\(^{15}\) In most studies, the mean surveillance was shorter, because the durability of CAS was not the specific outcome being investigated. Although the short-term restenosis rates after CAS found in this survey are promising, there is thus a need for further research on the long-term durability of CAS procedures. Because Doppler scanning is noninvasive and therefore offers significant advantages over angiography, it is considered the method of choice for determining restenosis rates after CAS. However, the currently applied criteria for determining a recurrent stenosis \(\geq 50\%\) with ultrasound are very heterogeneous. In this survey, the degree of lumen reduction was used as the primary diagnostic criterion in some studies, whereas in others it was the peak systolic velocity or the ratio of the peak ICA to CCA velocity (or a combination of these methods). In several studies, the exact technical definition of a restenosis \(\geq 50\%\) was not reported at all. Different lower thresholds were used to define a restenosis, thereby limiting the comparability of the results among the various studies, as well as with the surgical literature. Aside from this heterogeneity, it is worth mentioning that the blood flow velocity in the carotid artery may be principally altered by the placement of a stent\(^{51}\) so that uniform criteria for ultrasound evaluation of a stented carotid artery are required. Ideally, these uniform criteria should be used in all future studies. In this scenario, immediate poststenting ultrasound may provide a valuable baseline value for future follow-up comparisons.\(^{52}\)

Finally, there still is the need for identifying specific risk factors for the development of restenosis after CAS. Some studies have identified advanced age,\(^ {18}\) female gender,\(^ {18}\) hyperglycemia,\(^ {53}\) previous treatment with a CEA,\(^ {54}\) and increased serum levels of acute-phase reactants\(^ {21}\) as potential risk factors for the development of a restenosis after CAS; however, the definitive role of these factors remains to be elucidated in larger trials.

In conclusion, the early restenosis rates after CAS found in this review compare well with those reported for CEA. However, this analysis of the peer-reviewed literature also indicates that the early restenosis rates after CAS might be higher than previously reported in observational surveys. Therefore, the problem of restenosis after CAS should not be underestimated and an active follow-up of all stented arteries seems to be warranted. To date, only a few small studies have analyzed the restenosis rates after CAS beyond 2 years. Aside from the periprocedural complication rates, further trials will thus have to assess long-term patency rates of stented carotid arteries before the widespread introduction of endovascular techniques for the treatment of carotid stenosis.
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Systematic Review of Early Recurrent Stenosis After Carotid Angioplasty and Stenting
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