

Which is a better treatment for carotid artery stenosis: stenting or endarterectomy?

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Abstract. – Carotid stenosis amenable to surgical or interventional revascularization accounts for 5-12% of all new strokes. Several randomized trials have shown that carotid endarterectomy (CEA) for the treatment of symptomatic and asymptomatic carotid stenosis is superior to medical treatment. Application of a carotid artery stent (CAS) representing a good alternative for many patients. CAS application has become comparatively safe with the use of embolism-preventive systems developed in recent years. Complication rates reported in some randomized trials and case studies in the literature are similar with CEA. CAS may be recommended as the first choice or alternative treatment for patients with symptomatic stenosis carrying high risks for open surgery. However, more randomized studies are necessary to recommend CAS for patients carrying at low surgical risks or patients with asymptomatic stenosis. This is a systematic review of the literature investigating the effectiveness of the treatment methods for carotid artery stenosis.

Key Words:

Carotid stenosis, Carotid endarterectomy, Carotid artery stent application, Apoplexy.

Introduction

Carotid artery stenting (CAS) and carotid endarterectomy (CEA) are two common treatments for people at risk of the complications of carotid artery stenosis (e.g., stroke)¹. In the USA, 795,000 strokes of these, 610,000 were new were reported per year. According to the National Center for Health Statistics, stroke is the third leading cause of death, and is a leading cause of long-term disability². Carotid stenosis amenable to surgical or interventional revascularization accounts for 5-

12% of all new strokes. The annual incidence of stroke in 55-64 years is 300 per 100,000 population, whereas it is 800 per 100,000 for those aged 64-74 years³.

The degree of the stenosis, previous silent infarcts, contralateral obstruction, arterial collateralization in the area, and cardiovascular risk factors play important roles in the development of a stroke. The risk of stroke development at 1 year in patients with asymptomatic non-critical carotid stenosis has been shown to be 1-2%⁴. Stroke risk in patients with 50-80% stenosis having coronary bypass surgery is 10%, and increases up to 19% in patients with stenosis > 80%³.

Diagnosis

Auscultation should be a part of the clinical examination in patients with vascular risk factors. Carotid artery auscultation can be used as a screening test in asymptomatic patients with vascular risk factors. However, in patients in whom a carotid soufflé is heard, diagnostic imaging techniques must be used. The soufflé arises because of turbulence due to narrowing of the carotid artery and as the degree of narrowing increases; the soufflé can disappear in relation to the decrease in turbulent flow. This is why diagnostic imaging tests must be used in symptomatic patients even if a soufflé is not heard during the clinical examination.

Doppler ultrasonographic measurements are very important investigation tools providing an opportunity to collect morphological information with B-mode imaging in addition to hemodynamic findings (Figure 1A-B). Besides giving information about the degree of narrowing, they also give information about the morphology of the carotid plaque.

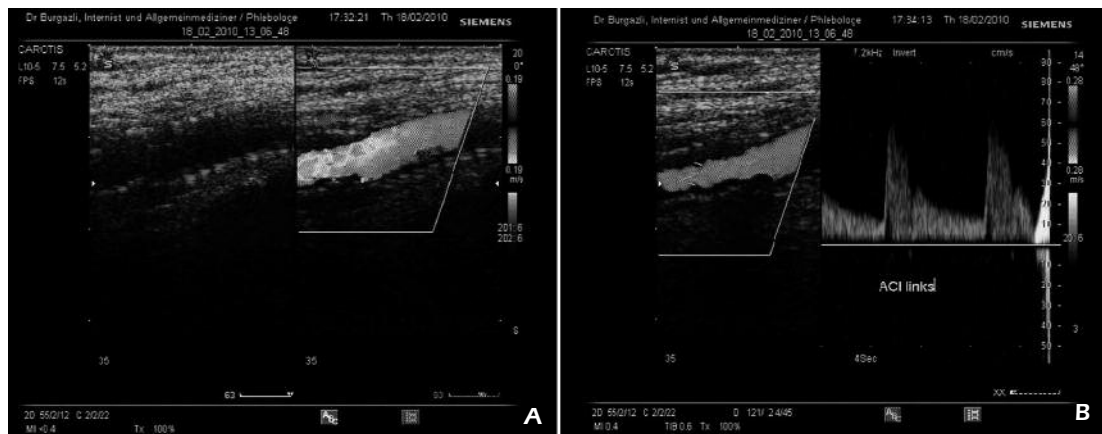


Figure 1. A-B, Doppler and duplex ultrasonographic images of the left ACI after stent implantation.

Angiography can be used in cases in which a high degree of stenosis of the carotid artery cannot be shown with duplex ultrasonography. In these cases, arterial angiography is the “gold standard” method of diagnosis. Alternatively, non-invasive magnetic resonance (MR) angiography and multislice computed tomography angiography (MCTA) permit evaluation of intracranial and extracranial vessels. MCTA is a rapid and high-resolution imaging technique, but some adverse effects of X-rays and conventional roentgen contrast medium have been noted in the literature⁵. MR angiography is not dependent upon radiation or contrast material, and may be preferred for patients with renal insufficiency. MR and CT angiographic techniques are effective and reliable alternatives to the conventional digital subtraction angiography (DSA)⁵.

Treatment

Medical Treatment

Anti-aggregation treatment, aggressive hyperlipidemia treatment, and close control of hypertension are the basis of treatment for decreasing the risk of cerebral complications. In the literature, statin treatment has been shown to be effective for the stabilization of carotid plaques⁶.

However, it has been clearly shown that removal of extremely narrow areas of the arteria carotis constitutes the most effective form of treatment of carotid artery stenosis. Consequently, two treatments are available for the removal of narrowings: CEA and percutaneous transluminal angioplasty (PTA) namely dilatation of the vascular stenosis by stent implantation.

Surgical Revascularization

Surgical revascularization involves treating the narrowing with anucleation of the plaque causing the atherosclerotic stenosis and narrowing at the carotid bifurcation (Figure 2). The procedure (thromboendarterectomy) can be applied with/without patching or by creating transient shunts under local or general anesthesia (Figure 3A-B). However, with eversion thromboendarterectomy, seriously stenosed segments can be removed and the remaining parts of the arteria carotis interna can be anastomosed face-to-face.

Invasive Treatment

Endovascular therapy involves opening of the narrowings using stents or balloon dilatation through an access point such as the arteria

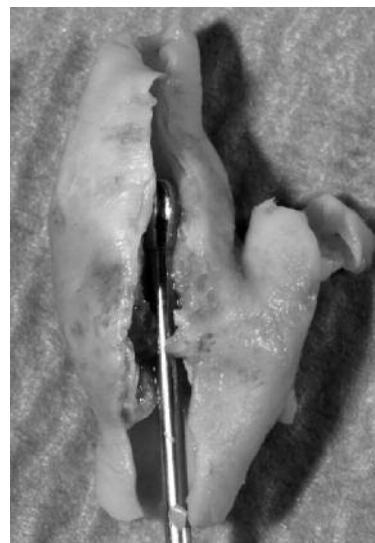


Figure 2. Carotid stenosis and endarterectomy.

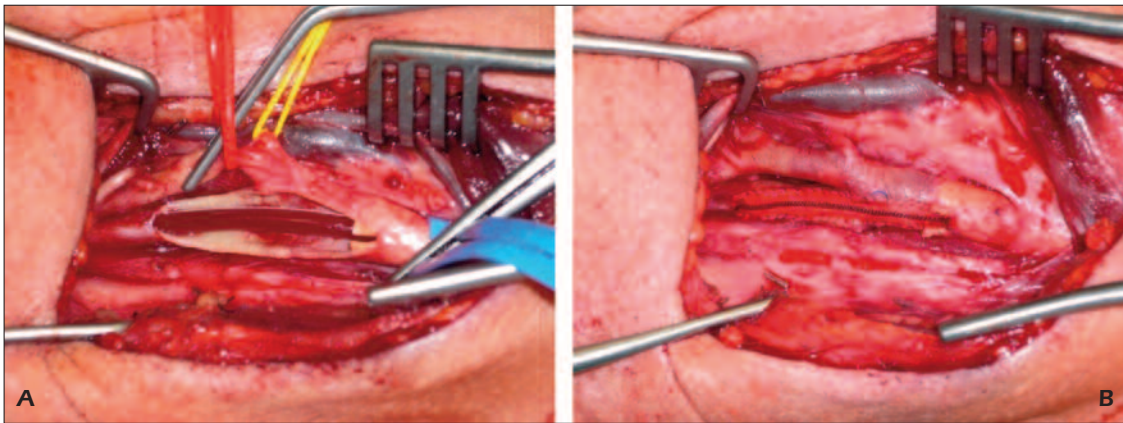


Figure 3. A-B, Endarterectomy for treatment of carotid-artery stenosis.

femoralis. The potential advantage of this method is not requiring an excessive surgical invasiveness or medication (Figure 4A-C).

Discussion

Stenting or Endarterectomy?

Both carotid stenting and CEA are continually improving stroke, myocardial infarction and death and have become “extraordinarily safe” for the treatment of carotid artery disease according

to investigators in the Carotid Revascularization Endarterectomy vs. Stenting Trial (CREST). The most important recent developments in percutaneous carotid intervention are embolism-prevention devices that prevent formation of cerebral emboli¹.

There are two concepts for the prevention of cerebral emboli namely proximal and distal prevention. There are no studies in the literature showing the advantage over other of these two concepts in preventing cerebral emboli. Hence, choosing one of these prevention methods is

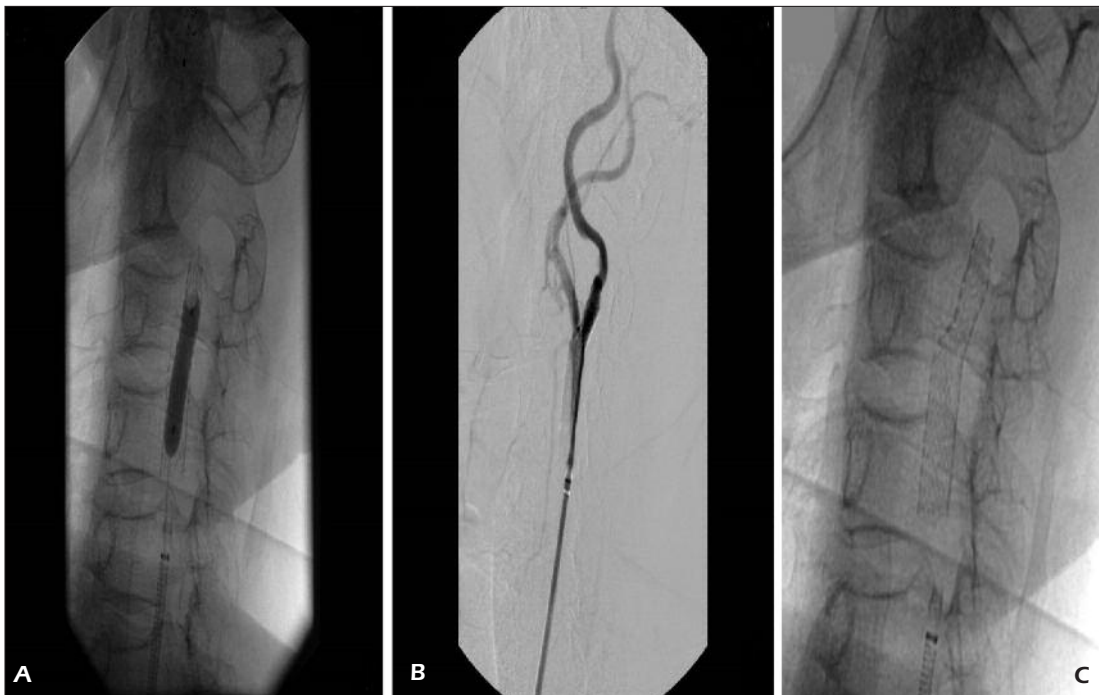


Figure 4. A-C, Stent implantations.

down to the physician according to the morphology encountered and personal experience⁷. At the moment, endarterectomy is regarded as standard treatment for symptomatic patients with $\geq 50\%$ stenosis and asymptomatic patients with $\geq 80\%$ stenosis⁸. Moreover, there is also an important prognostic advantage in asymptomatic patients with narrowing of the carotid artery of $> 60\%$. According to the recently published Asymptomatic Carotid Surgery Trial (ACST) in asymptomatic patients aged < 75 years with narrowing of $> 70\%$, stroke risk at 5 years decreased from 12% to 6% and, in patients in whom revascularization had been done, the prevalence of stroke/death fell to $< 3\%$ ⁹.

However, these studies were performed in clinics with high levels of experience and low complication rates after high-risk patients (Table I) had been excluded.

Choice of the method used for treating asymptomatic patients is controversial. The results of percutaneous intervention must be compared with the outcomes of CEA. The Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy (SAPPHIRE) study has published long-term data¹⁰. In the SAPPHIRE trial, 307 high-risk patients without symptoms and $> 80\%$ stenosis and symptomatic patients with $> 50\%$ stenosis were randomly placed in two treatment groups. Of these, 156 patients had a carotid stent implanted in addition to an intravascular, umbrella-shaped embolism-protection device. The other 151 patients had a CEA. Thirty days after the intervention, the prevalence of complication (death, apoplexy, cardiac infarction) was compared between the two groups. Only 9 out of 156 patients (5.8% cent) have had an incident, whereas 19 out of 151 (12.8%) patients were affected¹⁰. The Authors have concluded that stent-supported carotid angioplasty will have a promising future and will be the preferred option of the

two methods and stated: “The evidence of all trends will show the preference of the stent therapy”. However another group stated some of the serious limitations to this investigation.

According to an American report involving the screening of 11,243 patients, the prevalence of stroke and death was 4.7%. It was also shown that complication rates in procedures not using one of the prevention methods mentioned above were significantly higher compared with procedures undertaken using prevention (6.2% without prevention; 2.8% with prevention)¹². According to the study Prospective Registry of Carotid Angioplasty and Stenting (Pro-CAS) after 3853 invasive procedures, the prevalence of stroke and death risk was 2.4% in asymptomatic patients and 3.1% in symptomatic patients¹³. According to the European Long-Term Carotid Artery Stenting Registry (ELOCAS), the relapse risk of smaller narrowings in the 5 years after invasive treatment was 3.4%¹⁴.

Risk of Embolization

A survey about the opinions regarding the advantages of stent-supported carotid angioplasty as prophylaxis against cerebral infarction between cardiologists has shown that vascular surgery had been carried out with very low rates of complications for decades.

Goldstein et al⁴ supported stenting in their case load and argued that this minimally invasive intervention spares the patient general anesthesia and has the same effectiveness of surgical stripping of the carotid artery. Apparently, it also carries a lower risk of paralysis of the cranial nerves, which is a dreaded but rare (and usually reversible) postoperative complication.

However, carotid PTA is not completely riskless. It is often applied for plaque embolism, which can be relevant for $\approx 80\%$ of patients using protection filter systems⁷.

Table I. High-risk criteria for carotid surgeries.

Anatomic criteria	Comorbidity
High lesion ($> C2$)	> 80 years of age
Lesion location under the clavicle	Cardiac insufficiency NYHA scale III/IV
After radical neck surgery or radiation therapy	Angina pectoris CCS III/IV
Contralateral ACI: obstruction	Coronary artery disease with main artery lesion or two-artery disease
Restenosis after TEA	Emergency cardiac surgery (< 30 days)
Contralateral nervus laryngeus paralysis	Myocardial infarction < 30 days
Tracheostomy	Chronic obstructive pulmonary disease
	Advanced renal insufficiency

Earlier Surgery in the USA Than in Europe

In general, stenting is thought to be a less invasive method than surgical stripping of the carotid artery. However, this has raised concerns that PTA is becoming too widespread, even in asymptomatic patients without very high risks of stroke. The results of the ACST study which looked upon the PTA procedure were found to be a highly effective measure for the prevention of carotid-mediated apoplexy¹⁵.

The five-year risk for apoplexy in asymptomatic patients without risk constellation and with considerable stenosis is divided through CEA if the modifying risk factors are treated aggressively¹⁶. The risk of suffering from apoplexy in low-risk apoplexy patients without intervention has to be low (approximately 1.5% per year) and an invasive treatment shouldn't be used¹⁵. Owing to small absolute surgical benefits, the role of CEA in asymptomatic patients is still controversial. It is shown that symptomatic patients have a static risk of 5 to 10% per year to suffer from apoplexy; which will be highly reduced by surgery. There hasn't been a detailed study that shows reducing the rates of apoplexy by stenting on this lower standard¹⁵. In contrast to the USA, the tendency in Europe is to not to operate on such kind low-risk patients¹⁶.

A meta-analysis from the Cochrane Collaboration involving five studies concluded that there is insufficient evidence for changing the clinical practice of TEA (Thrombo-Endarterectomy) as a favored treatment for carotid stenosis. Therefore, 1269 patients (>75% of them symptomatic) were in equivalent comparison between stenting and open surgery. The report came to the conclusion that for patients with an indication for surgical treatment, stenting in line with randomized studies should be offered¹⁷.

Patient Selection Must be the Decisive Factor

The results of the SAPPHIRE trial indicate that the risk of death and perioperative apoplexy is 5.4% for patients getting a stent. Therefore, patient selection for stenting must be the decisive factor. In asymptomatic patients with carotid stenosis, TEA is justified only in correlation with a lower rate of complications from 2-3%, as reported in the ACAS (Asymptomatic Carotid Atherosclerosis Study)¹⁸. Inadequate selection of patients or poorly undertaken procedures can nullify all the advantages of the treatment. Some vascular surgeons support the necessity of trinomial

randomized prospective studies. These studies examine the comparison between surgery, stenting and drug-induced therapy⁶. In several studies, CEA was compared with medical treatment. It was found that it was more important to decrease stroke attacks in symptomatic patients, and that it was significantly more effective to decrease strokes in asymptomatic patients¹⁹.

Surgery has important advantages in symptomatic patients with > 50% stenosis in carotid arteries, and the importance of surgery increases with higher degrees of stenosis (>70%). According to the North American Symptomatic Carotid Endarterectomy Trial (NASCET) and ECST (European Carotid Surgery Trial), during the 5 years after surgery, the risk of ipsilateral stroke with surgical revascularization in comparison with conservative therapy is decreased by 48% at 70-99% narrowing and 28% at 50-69% narrowing²⁰.

According the studies of the difference between optimal drug therapy and the operative alternative therapy has to be probably very small because the non-surgical treatment has made good progress in the meantime. Instead of improving the technique of the two methods, to check which patients are in need of an operation or a stent has to be more important. Out of 100 symptomatic patients, only 30 are in need of treatment. However, all of them were treated with thrombocyte aggregation inhibition, statins and antihypertension drugs. Since this drug therapy exists, the risk of getting apoplexy has diminished by around 30%^{20,21}.

The necessity of comparing stenting/surgery with the drug therapy has been denied. Conservative therapy branch is not needed and SAPPHIRE offers objective data to justify the stenting as an alternative in the high risk patients²².

"Soft" Plaques are More Dangerous for the Patient

SAPPHIRE study was declared as "prehistoric" due to its selection criteria which doesn't include the plaque characteristics in the patients. Soft plaques, being available in 70% of all patients, are associated with a higher risk of embolisation and more frequently result in neurological deficits and cerebral infarction²³.

The Stent-protected Percutaneous Angioplasty of the Carotid versus Endarterectomy (SPACE) trial is a multicentered study involving 1.200 patients with symptomatic carotid stenosis. The goal of the SPACE study was to compare the carotid stent and CEA treatment methods in

asymptomatic patients with carotid narrowing > 50%. The primary endpoints were death, ipsilateral stroke lasting > 24 h, and intracerebral bleeding in 30 days. The primary intention of the study was to measure the frequency of apoplexy and death. In the interim analysis, 6.3% of operated patients and 6.8% of stent patients were affected. Even though the statistical evidence was insufficient complications were similar in the two groups. A major criticism was that cerebral protection systems were used in only one-third of stent angioplasty treatments²⁴.

According to Mas et al study²⁵, which was conducted with symptomatic patients, lower rates of stroke or death at 30 days and 6 months were observed in endarterectomy group than the stenting group. But long term results were not yet clear.

In another work with 2502 patients and a follow-up period of 2.5 years²⁶, no significant differences were shown in the estimated 4 year rates of the primary end point between the stenting group and the endarterectomy group (7.2% and 6.8%), but rates of stroke or death were 6.4% and 4.7% respectively.

Stenting is associated with a 61% relative risk increase of periprocedural stroke or death compared to endarterectomy⁵. There are not enough evidence for any intervention in asymptomatic patients due to their low stroke risk. CREST and CAVATAS have indicated that mid-term stroke prevention after stenting is similar to endarterectomy. Although ESVS (European Society for Vascular Surgery) guidelines that refer to carotid stenting are enriched by the available clinical data, an objective update including the interpretation of the up-to-date evidence based data is needed⁵. The practice of CAS nearly doubled in 2005 after publication of the SAPHIRE in 2004 which was a CAS-favorable study, and decreased by 22% after publication of the CEA-favorable EVA-3S (Endarterectomy versus Angioplasty in Patients with Symptomatic Severe Carotid Stenosis) and SPACE in 2007. This correlation shows the influence and the importance of investigations on the treatment decisions²⁷.

The Carotid Revascularization Endarterectomy versus Stenting Trial (CREST) is one of the largest and most rigorous randomized stroke-prevention trials ever undertaken. Investigators of the CREST study¹ found that the overall safety and efficacy of the two procedures, based on the combined primary endpoint of stroke, heart attack and death, was largely identical

with equal benefits for men and women, and for patients who previously had a stroke and for those who had not. There were also some notable differences. Firstly, the age of the patient made a difference: younger patients did better with stents, older patients did better with surgery. For patients ≤ 69 years, stenting results were superior to surgical results; the younger the patient, the larger the stenting benefit. Conversely, for patients > 70 years, surgical results were slightly better than stenting; the older the patient, the larger the benefit of surgery. Secondly, there were twice as many heart attacks in the surgical group (2.3% compared with 1.1% in the stenting group). Thirdly, the overall prevalence of stroke was 4.1% in the stent group compared with 2.3% in the surgical group. Importantly, however, there was no difference for major disabling strokes between the two groups. There was a slight increase in the prevalence of minor, non-disabling strokes – the type of stroke in which symptoms largely resolve within several weeks¹.

Before the CREST study, CAS had only been considered as an alternative treatment method for carotid artery stenosis. However, the results of this study has enlightened the effectiveness and costs/benefits of CAS, especially in young and average risk patients with carotid artery stenosis. Although CREST study didn't show any significant difference for stroke, death, MI and other long term outcomes between CAE and CAS applications, the rates of strokes and deaths in CAS group was doubled²⁸. This is a result of the difference in the distribution of myocardial infarctions, many of which were minor, between the two groups. Additionally; the improvements in CAS treatment, such as techniques, better stents, better patients selections must be taken into consideration while comparing the treatment options.

In an editorial of the New England Journal of Medicine Davis and Donnan advised that more long-term data are needed before a full appreciation of the risks/benefits of CAS and CEA due to the lack of significant difference in the rate of long-term outcomes. According to them, CEA is the favored treatment for the patients with symptomatic carotid stenosis. However, the treatment for the asymptomatic patients is a still controversy point. They also mentioned the increased risk of stroke with CAS offset by an increased risk of MI with CEA and the risk/benefit relationship should be discussed with the patients²⁹.

Conclusions

CEA should be considered as the procedure of choice for stroke prevention in patients with severe, symptomatic carotid stenosis. CAS may be considered for patients with asymptomatic stenosis and those carrying a high risk for open surgery as a first choice or alternative treatment. Carotid percutaneous procedures seem to be most appropriate in the setting of recent trials, and they have been shown conclusively to be as safe and durable as CEA. Obviously there is a necessity for more studies about this subject because the benefit of revascularization by stenting versus endarterectomy has not been established for patients with CAS.

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