Stent-supported angioplasty versus endarterectomy for carotid artery stenosis

Evidence from current randomized trials

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Zusammenfassung Hintergrund
Die meist stentgestützte Ballondilatation (CAS) von Stenosen der Arteria carotis entwickelt sich zunehmend zu einer Alternative der Carotisendarterektomie (CEA). Der Stellenwert der CAS im Vergleich zur CEA ist jedoch noch umstritten. Deswegen führten wir eine Meta-Analyse der randomisierten Studien (RCT) zu diesem Thema durch. Methoden
Die RCTs wurden über eine MEDLINE Suche, Textbücher und durch persönliche Kontakte identifiziert. Ergebnisse
Es fanden sich 6 abgeschlossene RCTs zu diesem Thema mit insgesamt 1263 Patienten, 628 randomisiert zu CAS und 635 zu CEA. Die 30 Tage Tod- oder Apoplexrate betrug bei den CAS-Patienten 8,0% (50/628) und bei den CEA-Patienten 6,1% (39/635) (OR = 1,36, 95% CI: 0,88–2,11; p = 0,17; p für Heterogenität = 0,009). Die Hirnnervenläsionsrate betrug 7,1% in der CEA-Gruppe im Vergleich zu 0% in der CAS-Gruppe (p < 0,0001). Die Myokardinfarktrate wurde von 3,1% auf 1% (OR = 0,32, 95% CI: 0,12–0,81; p = 0,02; p für Heterogenität = 0,49) reduziert. Während der Nachbeobachtungszeit lag die Tod- oder Apoplexrate bei 12,1% bei den CAS-Patienten verglichen mit 12,2% bei den CEA-Patienten (OR = 0,99, 95% CI: 0,70–1,42; p = 0,98; p für Heterogenität = 0,02). Schlussfolgerung
Die verfügbaren Daten aus den RCT zum Vergleich des CAS versus der CEA zeigen eine gleich Effektivität bezüglich akuter und mittelfristiger Ergebnisse (Tod/Apoplex) beider Methoden. Das CAS ist jedoch mit weniger sonstigen Komplikationen behaftet. Da jedoch eine signifikante Heterogenität bei den Studienergebnissen vorlag, sollten die Ergebnisse der großen RCTs zum Vergleich beider Methoden abgewartet werden, bevor das CAS als Standartverfahren zur Behandlung von Carotisstenosen propagiert wird.

Schlüsselwörter
Carotisstenosen – Ballondilatation – Stents – Endarterektomie – randomisierte Studien

Summary Background
Carotid artery stenting (CAS) for carotid artery stenoses is evolving as an alternative to carotid endarterectomy (CEA). However, the value of CAS is still a matter of debate. Therefore, we performed a meta-analysis of the randomized controlled clinical trials (RCT) on this issue. Methods
RCTs were identified through searching MEDLINE, textbooks and by personal communication. Results
Six finished RCTs on this issue could be identified, including 1263 patients, 628 randomized to CAS and 635 to CEA. The 30-day death or stroke rate was 8.0% (50/628) in patients treated with CAS compared to 6.1% (39/635) in CEA patients (OR = 1.36, 95% CI: 0.88–2.11; p = 0.17; p for heterogeneity = 0.009). The rate of cranial nerve palsy was 7.1% in the CEA compared to 0% in the CAS group (p < 0.0001). The rate of myocar-
Carotid artery stenting versus carotid endarterectomy

Introduction

Carotid artery stenosis is one of the major reasons for cerebral ischemic events. Surgical desobliteration of high-grade carotid stenoses in patients with symptomatic as well as asymptomatic stenoses using carotid endarterectomy (CEA) has shown to reduce the rate of future ipsilateral ischemic events compared to medical treatment alone [11, 12, 14, 16, 27, 35].

Stent supported carotid angioplasty (CAS) may be a less invasive alternative to CEA. Carotid angioplasty was described in the late 1970s by highly specialized centers [3, 22, 24, 37, 39]. It took several years to disseminate this technique into broader clinical application. Registry data showed the feasibility and safety of CAS [23, 32, 36, 42]. After these „proof of the principle“ studies, CAS became an evolving technology, at first in special high-risk cases for CEA, such as restenotic lesions after CEA, radiogenic stenoses, very long lesions or difficult anatomic locations for CEA.

With growing experience of the interventionists and refinements of the technical equipment, such as a reduction in the size of the guiding catheters, the use of stents [1, 25, 31] and the introduction of cerebral embolic protection devices [17, 21, 28, 41], several randomized controlled clinical trials (RCT) comparing CEA with CAS were performed [2, 4, 5, 7, 26, 40].

However, due to the sample size sometimes being small, and to the rapid development in the interventional armentarium and conflicting results of the different trials, the results of these studies did not lead to unanimous recommendations on the use and indications of CAS compared to CEA. Therefore, larger RCTs again comparing CEA with CAS were initiated [13, 15, 19, 29]. However, it will take several years until the results of these RCTs are available.

Hence, the aim of our investigation was to systematically review the currently available data on RCTs on the acute and long-term effect of CAS compared to CEA in patients with high-grade carotid stenoses.

Methods

We reviewed RCTs that assessed the effect of CAS compared to CEA in patients with either symptomatic or asymptomatic carotid stenoses. Studies were identified through searching MEDLINE (1966 to December 2004), textbooks and by personal communication with established researchers in the field of CAS. The following key words were used in the database search: carotid stenosis and endarterectomy, carotid stenosis and stents, carotid stenosis and angioplasty or carotid arteries and randomized clinical trials. Relevant trials were selected independently by two authors (RZ, MH). They also extracted the data which were cross-checked by each of them.

Statistics

Analyses are based on published results of the clinical trials. Comparison of groups was made on an intention-to-treat basis, with the exception of the Naylor trial [26], which was interrupted prematurely. In this trial, 6 out of 23 randomized patients were not treated. For the events of interest, we established contingency tables by abstracting the cumulative incidences from the publications. The main endpoint chosen was the combined endpoint of death of any cause or stroke (ipsi – or contralateral) within 30 days after the intervention as well as during follow-up. To give an overview of the single study results and to check for outliers, we provided as graphical devices forest plots of the main effects as well as a plot of the 30-day risk in the CAS group vs. the risk in the CEA group as suggested by L’Abbé [10, 20]. As the complications were rare events and some zero cells occurred, we did not rely on the approximate normality of the estimators, but applied methods for the stratified analysis of binary data. Odds ratios were calculated using the Peto fixed-effect method which is especially suitable for randomized trials with equal group sizes [33]. Heterogeneity between the studies was assessed with the Breslow-Day test.