Angioplasty and stenting of the cervical carotid artery with distal embolic protection of the cerebral circulation

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Citation

Authors' objectives
The objective of this Assessment is to review and evaluate available evidence comparing outcomes of carotid angioplasty and stenting (CAS) with distal embolic protection (DEP) added to medical management (MM) versus outcomes of alternatives to reduce stroke risk in patients with carotid artery stenosis.

Authors' conclusions
The only trial reported thus far that directly compares outcomes of CEA plus MM versus outcomes of CAS with DEP plus MM included no patients with symptomatic (Indication 1) or asymptomatic (Indication 2) carotid stenosis at average risk for perisurgical complications from CEA. Because it included so few patients with symptomatic stenosis at high risk for perisurgical complications from CEA (Indication 3), reported differences in 30-day and 1-year outcomes between arms had wide confidence intervals and were not statistically significant. For those with asymptomatic stenosis at high risk for perisurgical complications from CEA (Indication 4), differences in 30-day outcomes also had wide confidence intervals and were not statistically significant. Although differences in 1-year outcomes for this last indication favored CAS with DEP and were statistically significant, the adequacy of follow-up duration is questionable since durability of benefits from CAS with DEP is unknown and since the time to benefit relative to medical management is long when surgical risks are high. The need for adequate follow-up is underscored by data in the FDA Reviewers Memo on a subset of SAPPHIRE patients followed for 2 years after treatment showing more frequent restenosis among those randomized to CAS + DEP (38.7%) than among those randomized to CEA (26.6%) (U.S. Food and Drug Administration 2004). Also, early study closure with insufficient patients compromised the statistical test for non-inferiority of treatments. Variance in differential complication rates for the two treatments across sites may have influenced results, since 5 of 34 sites contributed 64% of randomized patients and data were unavailable for comparison. Additionally, direct comparative evidence is lacking for optimal medical management alone as an alternative to adding CAS with DEP or CEA for high surgical risk patients. Thus, available evidence does not permit conclusions on outcomes of CAS with DEP for any indication considered in this Assessment.

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MeSH
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