

Key Questions

Carotid Artery Stenting: For treatment of atherosclerotic stenosis of the intracranial arteries or extracranial carotid arteries

Introduction

The HCA selected carotid artery stenting (CAS) for review. The topic was nominated based on high levels of concern around efficacy and cost, and on medium levels of concern around safety.

Cardiovascular disease (CVD) is the leading cause of mortality and morbidity in both men and women in the United States. One or more types of CVD affect more than 1 in 3 adults, mostly over 60 years of age or older. When considered separately from other CVDs, stroke is the fourth leading cause of death (behind heart disease, cancer, and chronic lower respiratory disease).

The carotid arteries provide the main blood supply to the brain and narrowing of these arteries (stenosis) due to atherosclerosis accounts for nearly 20% to 25% of these strokes. The most common site of plaque formation and stenosis in the carotid artery is near the bifurcation of the common carotid artery into the internal and external carotid arteries. The risk of stroke depends upon the severity of the carotid stenosis.

Persons with carotid artery atherosclerosis will generally have concomitant medical problems such as diabetes, high cholesterol or hypertension and various risk factors such as smoking and obesity. The standard of care is to address these problems and risk factors independent of the carotid artery disease.

Treatment options for extracranial carotid artery stenosis include medical therapy, surgery to remove the atherosclerotic plaques (carotid endarterectomy or CEA), and the percutaneous placement of stents (CAS) in the affected area. For atherosclerotic intracranial artery stenosis treatment options are fewer but may include medical therapy. In general, persons undergoing CEA or CAS will also be receiving medical therapy. During CAS, the clinician threads a catheter through an artery up from the groin and up to the carotid artery. The catheter has an attached balloon which expands the artery and inserts a stent to hold the artery open. Multiple stents may be placed depending on lesion length. Because there is a risk of disrupting the plaque along the artery walls during this type of procedure, CAS is usually performed along with a filter, or distal embolic protection device (EPD) which is used to capture any debris that becomes dislodged, reducing the risk of embolization.

Objectives

To systematically review, critically appraise, analyze and synthesize research evidence comparing the efficacy, effectiveness, and safety of carotid artery stenting procedures for subjects with symptomatic or asymptomatic atherosclerotic carotid stenosis or atherosclerotic stenosis of intracranial arteries. The differential effectiveness and safety as well as the cost-effectiveness of CAS will also be evaluated. Review will be limited to FDA-approved devices.

Scope of this HTA

Population(s):

- 1) Adults with extracranial carotid artery stenosis undergoing primary treatment for symptomatic or asymptomatic atherosclerotic carotid artery stenosis who have not had previous revascularization
- 2) Adults with atherosclerotic stenosis of intracranial arteries.

Intervention:

Stenting of carotid arteries (with or without use of embolic protection devices or strategies) or stenting of intracranial arteries, using FDA approved devices

Comparator(s):

Medical therapy or surgical alternatives including carotid endarterectomy (CEA).

Outcomes:

Outcomes include prevention of embolic events and stroke, death, myocardial infarction (fatal and nonfatal), neurological status, functional status (including cognitive function), health related quality of life (HRQOL) and patient reported outcomes. Additional outcomes may include composite outcomes measures and re-vascularization after index procedures. Additionally, safety and complications outcomes include device or procedure-related mortality, embolic complications, peri-procedural death/stroke rate, stent thrombosis, intracranial hemorrhage and others.

Key Questions

1. In symptomatic or asymptomatic persons with atherosclerotic carotid artery stenosis what is the evidence of short- and long-term comparative efficacy and effectiveness of:
 - a. Extra-cranial carotid artery stenting (CAS) and medical therapy compared with medical therapy alone?
 - b. Extra-cranial carotid artery stenting (CAS) and medical therapy compared with carotid endarterectomy (CEA) and medical therapy?
2. In symptomatic persons with atherosclerotic stenosis of the intracranial arteries, what is the evidence of short- and long-term comparative efficacy and effectiveness of Intracranial artery stenting and medical therapy compared with medical therapy alone?
3. What is the evidence regarding adverse events and complications, particularly during the periprocedural period and longer term, for stenting compared with alternative treatments? In persons with extracranial carotid artery stenosis, are rates of periprocedural death or stroke <3% for asymptomatic patients and <6% for symptomatic patients?
4. Is there evidence of differential efficacy or safety for special populations, (including consideration of age, gender, race, diabetes, atrial fibrillation or other comorbidities, ethnicity, or disability)?

5. What is the evidence of cost-effectiveness of CAS compared with other treatment options (medical therapy, CEA) in the short-term and the long term?

Public Comment & Response

See Key Question Public Comment and Response document published separately.

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