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Subject: Washington State Health Care Authority's HTA of Carotid Artery Stenting – Draft Key Questions

Dear Mr. Morse,

On behalf of the American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS), we wish to thank you for the opportunity to comment on the Draft Key Questions for the Health Technology Assessment (HTA) of Carotid Artery Stenting (CAS) conducted by the Washington State Health Care Authority (HCA). As practitioners versed in both the surgical and endovascular management of carotid disease, we believe the Key Questions (KQs) must distinguish between primary and secondary stroke prevention. Moreover, the KQs must further separate consideration of extracranial and intracranial atherosclerotic disease. Blurring carotid disease, ICAD, and materially different catheter-based treatments will ultimately limit the HCA's ability to draw meaningful conclusions from this assessment.

Introduction

Based on the introductory language, the scope of the HTA appears designed to assess CAS for secondary prevention of ischemic stroke in patients with symptomatic and asymptomatic cervical internal carotid artery (ICA) stenosis. Cervical ICA stenosis is by definition extracranial and distinct from intracranial atherosclerotic disease (ICAD). ICAD carries very different treatment alternatives, natural history, and is not managed by CAS in the conventional sense. The following comments therefore reflect our reading of the stated HTA's objectives.

The nomination of CAS for this HTA review stemmed from "high levels of concern around cost and efficacy" and "medium levels of concern around safety." Our current understanding of stroke natural history in the setting of symptomatic and asymptomatic carotid disease stems from Class I evidence supporting carotid endarterectomy. NASCET and ECST for symptomatic disease and ACAS and ACST for asymptomatic disease established the benefits of carotid revascularization for secondary stroke prevention. The HTA may rely on these trials, including the Carotid Revascularization Endarterectomy versus Stenting Trial (CREST), to establish the natural history of carotid disease, and then examine primary data regarding CAS safety and direct CAS comparisons with Carotid Endarterectomy (CEA).

As surgeons versed in CEA and CAS, anatomical characteristics, prior surgery or neck radiation, tandem lesions, or medical comorbidities may render CEA and CAS complementary modalities in certain situations. The HTA should further explore these technical situations where CEA may be high risk and CAS favored. The draft KQ partially addresses these scenarios.

Population

- “External” should be substituted with “extracranial.”
- “Intracranial carotid distribution” should read “Internal carotid distribution.”

Intervention

Per above, “external” and “intracranial” should be changed. A sample intervention statement is below:

“Stenting of extracranial internal carotid artery with or without distal embolic protection, proximal protection or flow reversal adjuncts.”

Comparators

No edits to suggest.

Outcomes

These outcomes appear adequate. Carotid revascularization literature does tend to distinguish between minor (< 3 NIHSS point clinical change) and major (> 3 NIHSS point clinical change) strokes. Additionally, it is worthwhile to distinguish between ipsilateral stroke and strokes in other distributions. Finally, cranial neuropathies (i.e. facial or hypoglossal palsies) should be added as these are complications of CEA that do not occur with CAS.

Draft Key Questions

KQ 2: This question refers to the management of ICAD that carries a completely different natural history, medication alternative (Stenting and Aggressive Medical Management for Preventing Recurrent Stroke in Intracranial Stenosis [SAMMPRIS] protocol), and treatment options (intracranial angioplasty with or without intracranial stenting). These technologies are completely distinct from cervical CAS and should be treated in a separate assessment.

KA4: This question begins to address the potential for population subset advantages for CAS as detailed in the introduction. It further merits mention that certain primary stroke prevention efforts (i.e. the treatment of acute carotid dissection) rely on CAS technology.

Thank you for the opportunity to comment on the Key Questions. We look forward to commenting on the HTA draft report when it is published.

Sincerely,



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