



## Experts Can't Pin Down Best Carotid Atherosclerosis Treatments

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There are still no clear answers about the best treatments to use to prevent stroke in patients with carotid artery stenosis, even with the input of a Medicare advisory panel of experts.

The Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) voted yesterday that they are only moderately confident that there is adequate evidence to determine which interventions – carotid artery endarterectomy (CEA), carotid artery stenting (CAS), or best medical treatment (BMT) – to use for different patient populations within the overall Medicare population. There's unlikely to be any consensus in the near future as patient populations, detection, and treatments evolve.

"If there was ever a moving target problem in assessing health care interventions, this was one. The epidemiology is changing, the patient population is changing accordingly, [and] all of the interventions continue to change. We've not been keeping up in our data collection for the safety and effectiveness of these interventions as they continue to evolve," commented committee chair, Clifford Goodman, Ph.D. "This means that to the extent that CMS is going to revisit its coverage decision making over time, this is an ongoing data collection issue. You're not done collecting these data; you may not ever be done collecting these data as long as the patient population continues to change and as long as we have very innovative people improving these interventions."

The panel was asked to vote on several questions regarding their confidence level that there is adequate evidence to identify specific patient populations and in some cases to select the best treatment option. Most scenarios garnered an "intermediate" confidence level. Confidence ran high only for the lowest-risk patients.

The panel voted that they had moderate confidence that the evidence is adequate to determine whether:

- Patients who are asymptomatic for carotid atherosclerosis can be identified as being at high risk for stroke in either cerebral hemisphere.
- Patients who are considering carotid revascularization can be identified as being at high risk for adverse events from CEA.
- Either CAS or CEA is the favored treatment strategy compared to BMT alone in patients with symptomatic carotid atherosclerosis and narrowing (at least 50% by angiography or at least 70% by ultrasound) who are not generally at high risk for adverse events from CEA.
- CAS, CEA, or BMT is the favored treatment strategy to decrease stroke or death for patients with asymptomatic carotid atherosclerosis.

In addition, for patients with symptomatic carotid atherosclerosis, who are not generally at high risk for adverse events

from CEA, the panel had intermediate confidence that CEA is the favored treatment strategy to decrease stroke and death. For patients with asymptomatic carotid atherosclerosis, the panel had intermediate to high confidence that BMT is the favored treatment strategy to decrease stroke and death.

However, the panel was less confident that for patients with asymptomatic carotid atherosclerosis but with carotid narrowing – who are not generally considered at high risk for adverse events from CEA – that there is adequate evidence to determine whether or not either CAS or CEA is the favored strategy compared to BMT alone to decrease stroke or death in the Medicare population. The panel had very low confidence that there is adequate evidence to determine whether carotid artery screening of asymptomatic people decreases stroke or death.

The panel primarily based its decisions on the results of a handful of randomized, controlled trials with different patient populations, at different time periods, using different criteria to assess efficacy and safety. The results of the most recent of these – the CREST trial (Carotid Revascularization Endarterectomy vs. Stenting Trial) – were announced in 2010. The overall safety and efficacy of the CAS and CEA at 4 years were considered equivocal in terms of benefits for both men and for women, for patients who had previously had a stroke, and for those who had not (N. Engl. J. Med. 2010;363:11-23).

However, differences were seen between the two procedures for heart attacks and strokes. More heart attacks occurred with CEA – 2.3% vs. 1.1% – than for CAS, while more strokes occurred in the stenting group – 4.1% vs. 2.3% – than for CEA in the weeks following the procedure. There was also a difference in outcomes based on patient age. At approximately age 69 and younger, stenting results were slightly better, with CAS benefits increasing for decreasing patient age. Conversely, for patients older than 70, CEA results were slightly superior to stenting, with larger benefits for surgery with older patient age.

Instead of answering the question of which technique has better outcomes and safety, the trial left proponents of each technique still arguing.

In addition, BMT has not been assessed in clinical trials for many years and has evolved substantially since that time with the development and growing use of statins, antiplatelet medications, beta-blockers, ACE inhibitors, calcium channel blockers, and others.

What is lacking is a randomized, controlled trial pitting all three treatments against one another in a head-to-head comparison of the most current techniques, the panel noted repeatedly.

"I think that drawing conclusions from indirect comparisons of things that were done in the past is incredibly hazardous and we need to have a contemporary direct comparison to know what the right thing to do is," argued panel member Dr. Larry B. Goldstein, who is a professor of neurology and director of the Duke Stroke Center in Chapel Hill, N.C.

Both surgery and CAS received a class I recommendation in guidelines published by the American Heart Association and other organizations in 2011 (J. Am. Coll. Cardiol. 2011;57:1002-44), but the level of evidence was stronger for CEA (level A) than for CAS (level B).

Planning is in the works for a possible CREST II trial in asymptomatic patients intended to compare intervention (with either CEA or CAS) vs. medical treatment alone. Many panel members expressed the need for this trial to proceed.

Twelve members of the panel reported that they did not have any relevant financial relationships. Dr. Spence reported receiving speaking fees from several pharmaceutical companies, Dr. Curtis reported that he owns stock in Medtronic and receives grant support from Boston Scientific, industry representative Dr. Peter Juhn works for Medco Health Solutions, and committee chair Dr. Clifford Goodman is the senior vice president at the Lewin Group, which has ties to both government and industry.

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