

Outlook for carotid stenting looks bright

“The new technology advances described herein give promise that carotid artery stenting will emerge as an effective and justifiable mainstream treatment, which has a bright future and will benefit many patients.”

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Carotid artery stenting or CAS has undergone its ups and downs since it was first introduced in the late 1980s. In its early years CAS was greeted with skepticism, particularly by vascular surgeons. Despite this, CAS was increasingly embraced by interventional cardiologists as an extension of their technical skills with coronary stenting procedures.

The demonstration that CAS usually produced showers of embolic particles lead to the introduction of a variety of cerebral protection devices to capture most of this debris [1]. These and other technical advances lead to improved results which in turn were followed by widespread usage of CAS to treat asymptomatic as well as symptomatic carotid stenosis. Again interventional cardiologists were foremost in this enhanced usage.

Nevertheless, because carotid endarterectomy (CEA), the alternative procedure for treating these lesions could be performed with good results and low morbidity and mortality, CAS remained highly controversial.

This led to several prospective randomized trials comparing the two procedures. The earlier of these trials, conducted in Europe, demonstrated lower periprocedural stroke rates for CEA in symptomatic patients, but were criticized for not employing state of the art CAS technology [2,3]. A major multicenter US trial, CREST, had its 4-year results published in 2010 [4]. Symptomatic and asymptomatic patients were included. With up to 4 years' follow-up, there was no difference in total adverse event rates between the two procedures. However, stroke rates were significantly higher in the CAS-treated patients,

while myocardial infarction rates were higher in the CEA-treated patients [4]. These data were interpreted in different ways by different specialists who were clearly influenced by their interventional or open surgical orientation and their bias. In addition, multiple society guidelines, all based on data from the same trials, also differed in their main conclusions, again based on specialty orientation and bias [5].

Nevertheless, at present, CAS usage is declining and CEA, because of its lower stroke rate, appears to be generally considered the procedure of choice for most patients around the world with symptomatic carotid stenosis. Exceptions in which CAS is chosen include some centers of excellence and some patients with unusual anatomy or surgical contraindications. This decline in CAS usage is furthered by the increasingly widespread opinion that most asymptomatic carotid stenosis patients are best treated by modern statin-based medical therapy and require neither CAS nor CEA. Increasing numbers of experts have even opined that with current medical therapy few if any patients with asymptomatic carotid stenosis should undergo invasive treatment because the annual stroke rate is so low (<1% per year) [6,7]. According to this opinion, most asymptomatic patients who have undergone CAS derive no benefit, and up to 90% of reported CAS patients have been asymptomatic.

Despite this dire status for CAS, I believe its future is bright for several reasons. All the level 1 evidence indicating that CAS carries a higher stroke rate than CEA were obtained from trials using CAS technology,



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which is now obsolete. Improvements in CAS technology now on the horizon will likely decrease its periprocedural stroke rates. These improvements include better embolic protection systems featuring cessation or reversal of flow during the stenting and ballooning phases of CAS, parts of the procedure that are most productive of embolic debris. There is already some evidence that such protection is more effective than the commonly used distal filters, particularly with high risk and symptomatic lesions [8,9].

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In addition, avoiding transit of CAS devices through the aortic arch by using cervical access to the common carotid arteries reduces embolization from manipulation in diseased or tortuous aortic arches or proximal great vessels. Such complex arches are particularly common in elderly symptomatic patients who make up the bulk of candidates likely to benefit most from CAS. The recent introduction of a proprietary system to facilitate both cervical access and reversal of flow protection seems to be a particularly attractive way to improve CAS results, although such improvement with this Michi System from Silk Road Medical remains to be conclusively demonstrated [10]. The current iteration of this system requires open exposure of the common carotid artery, but percutaneous modifications are on the drawing board.

It is well known that many strokes with CAS become apparent several hours or days after the procedure is completed and the embolic protection device has been removed. It is thought that these strokes are the result of debris trapped in stent interstices, and such debris has been observed in bench top models of stented carotid lesions [1]. When flow is restored, the trapped debris is freed as cerebral emboli, resulting in ‘delayed strokes’ after CAS. To obviate this

problem, three companies are evaluating membrane or mesh covered carotid stents with much smaller interstices to prevent delayed embolization (Roadsaver Micromesh Carotid Stent, MicroNet [C-Guard] Stent From InspireMD and Scaffold Stent From WL Gore & Associates).

Finally, evidence is accumulating that we are on the threshold of having methods available to select those few asymptomatic carotid stenosis patients that are at a high risk of having a stroke from their lesion [11]. These methods involve detection of cerebral microemboli by transcranial doppler, techniques to evaluate various characteristics of carotid plaque morphology with duplex, MRI or CT imaging and detection of silent cerebral infarcts by CT or MRI. Although none of these techniques is ready for widespread use, the likelihood is that one or more of them soon will be. If asymptomatic patients with such high risk lesions could be identified, it would become justified to treat them either by CEA or CAS, thereby adding to the patient group needing CAS treatment.

CAS has been slow to gain widespread approval as a method to treat carotid bifurcation stenosis. Controversy and bias have been connected to the procedure and the interpretation of its results. Registry and trial findings have generated more heat than light. The new technology advances described herein give promise that CAS will emerge as an effective and justifiable mainstream treatment, which has a bright future and will benefit many patients. Further studies to document that promise are in order.

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