An update on the role of proximal occlusion devices in carotid artery stenting

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Carotid artery stenting performed with distal embolic protection devices continues to show elevated rates of periprocedural stroke, in particular with high-risk groups. This article discusses the factors associated with protection devices that may contribute to this complication, performs a literature review to assess outcomes of carotid stenting with proximal occlusion devices, and assesses the role of proximal occlusion devices in the management of patients with carotid artery stenosis. (J Vasc Surg 2016;■:1-5.)

The Society for Vascular Surgery guidelines for the management of carotid artery stenosis recommend that carotid artery stenting (CAS) be reserved for symptomatic patients with >50% stenosis who are at high risk for carotid artery endarterectomy (CEA).[1]

With half a decade having passed since the publication of the Carotid Revascularization Endarterectomy vs Stenting Trial (CREST), the incidence of periprocedural stroke in the course of CAS with embolic protection devices (EPDs) remains largely unchanged, in particular in high-risk groups including patients with symptomatic carotid stenosis and septuagenarians and older. A comparison of registries, randomized controlled trials, and cohort studies from the last few years graphically demonstrates this in Fig 1,[2-14] with the incidence being most striking in symptomatic patients. Similar findings were made by Paraskevas et al in a systematic review of 21 registries, in which the incidence of stroke/death was found to remain higher in CAS relative to CEA with an absence in the decline of procedural risk of CAS with time.[15]

Notable in Fig 1 are those groups represented by the prospective registries, cohort studies, and retrospective meta-analyses in which proximal occlusion devices (PODs; *blue markers within oval*), with and without flow reversal, are used in place of EPDs (*gray markers*). Although these are smaller or nonrandomized studies, they have repeatedly demonstrated benefit in decreasing the incidence of periprocedural stroke in performance of CAS, in particular in what have historically been high-risk groups, including patients who are symptomatic and older than 70 years.

In the meta-analysis of six prospective databases of CAS performed with two types of transfemoral PODs, incorporating either flow cessation or flow reversal and to be discussed further in this article, Bersin et al demonstrated a cumulative periprocedural rate of stroke of 1.71%. Outcomes were independent of symptomatic status, and although age continued to be an independent risk predictor of stroke, the incidence of stroke in octogenarians and older was only 2.38%. In patients 65 to 80 years, the incidence was 1.65%. The Safety and Efficacy Study for Reverse Flow Used During Carotid Artery Stenting Procedure (ROADSTER) prospectively evaluated the use of a transcervical POD with a flow reversal device (FRD) in 208 patients and found a cumulative periprocedural stroke rate of 1.41%, none of which occurred in symptomatic patients or those older than 75 years, those typically seen as highest risk.

Although the studies describing the outcomes of PODs do not have the level of evidence of a randomized controlled trial, there is further evidence from studies of EPDs that can help explain the difference in periprocedural stroke when the two are compared. Cerebral embolization during CAS performed with EPDs may occur during every portion of CAS, including during crossing of the internal carotid stenosis, while the filter is being deployed as a result of filter malapposition or embolization of particulate through the filter pores, during angioplasty and stenting, and while the filter is being retrieved. Pore sizes on filters range from 100 to 200 μm; smaller pore sizes on filters are not employed as this results in increased risk of filter thrombosis.

A meta-analysis by Stabile et al comparing EPDs with PODs demonstrated that in the POD group, there was a lower incidence of new ischemic lesions on diffusion-weighted magnetic resonance imaging and a lower incidence of contralateral lesions, likely because of the inclusion of CAS performed through a transcervical approach.[16] In a substudy of the International Carotid Stenting Study (ICSS), patients undergoing CAS with EPDs had a 73% incidence of new lesions on diffusion-weighted magnetic resonance imaging compared with

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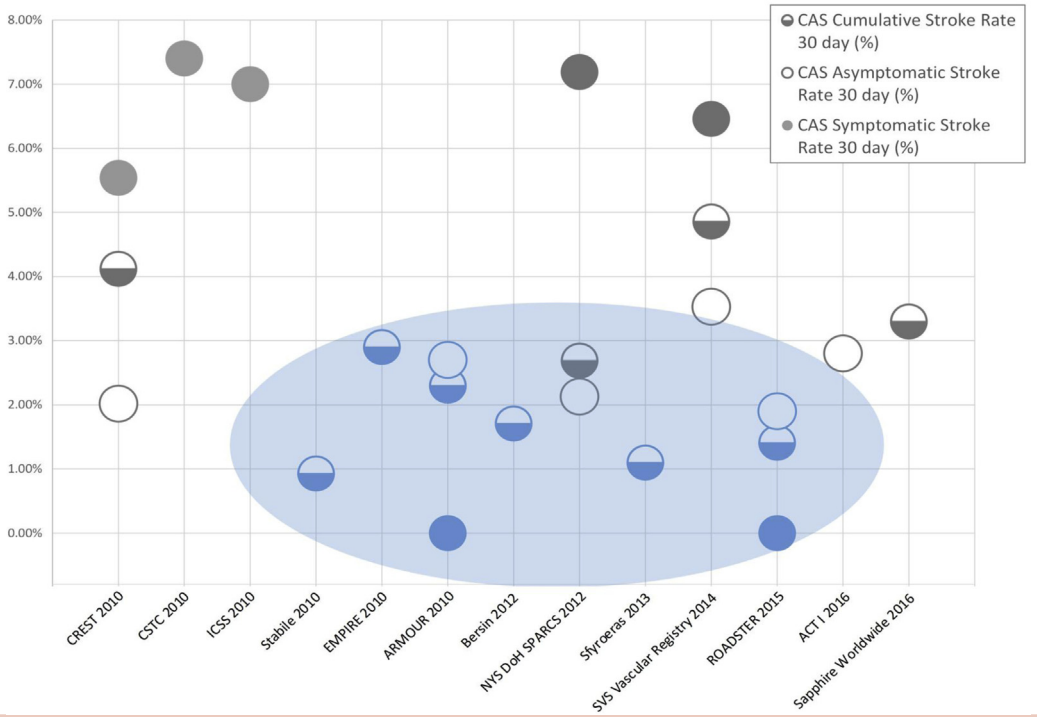

Fig 1. The 30-day stroke rate in a sample of carotid artery stenting (*CAS*) registries, cohort studies, and randomized controlled trials. The *gray markers* indicate studies performed predominantly with embolic protection devices (EPDs). The *blue markers* indicate studies performed with proximal occlusion devices (PODs), with and without flow reversal, through femoral or carotid access.

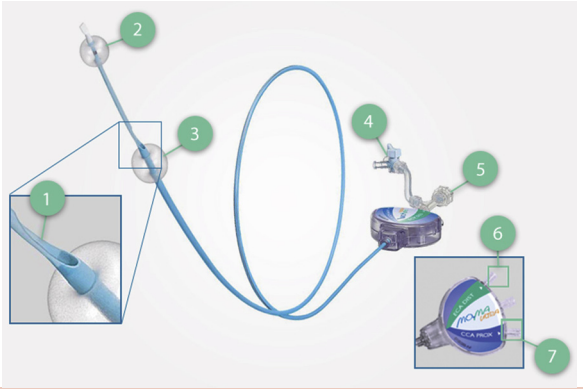

Fig 2. Medtronic Mo.Ma device: *1,* Exit port of working channel; *2,* distal, external carotid artery balloon; *3,* proximal, common carotid artery balloon; *4,* port for injection, pressure monitoring, and aspiration; *5,* entry port of the working channel; *6,* inflation port for distal balloon; *7,* inflation port for proximal balloon.

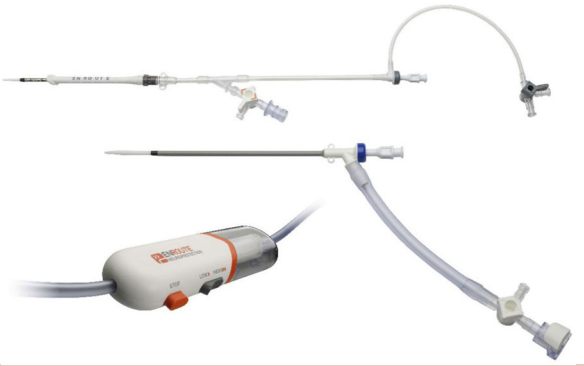

Fig 3. Silk Road Enroute Transcarotid Neuroprotection System. *Top,* Angled tip transcarotid arterial sheath and dilator. *Middle,* Venous return sheath and dilator. *Bottom,* Flow controller with integrated filter.

17% in the CEA group.[17] In a study validating the use of transcranial Doppler ultrasound for intraprocedural monitoring of embolic events during CAS, there was an increase in embolic signals during lesion crossing, before dilation, in stent placement, and after dilation in the CAS group using EPDs. Compared with the EPD group, the signal count was higher in the FRD group only during device removal.[18]

Transcervical access may reduce the incidence of cerebral embolization by avoiding a tortuous and atherosclerotic thoracic aortic arch. Up to 8% of strokes occur on the contralateral side of intervention,[3] suggesting that embolization occurs during manipulation of wires and catheters within this area. It is thought that the greater tortuosity and atherosclerotic burden in the aortic arch of elderly patients contribute to the higher incidence of stroke in this subgroup undergoing CAS with EPDs. The ROADSTER trial, which bypassed the thoracic aorta