

EDITORIAL COMMENT

Credentialing Operators for Carotid Artery Stenting

Accepting the Occasional “Bad Apple” or Insisting on Airline Industry “Proficiency”*



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In the coming months, this nation will launch a landmark study to further investigate stroke prevention strategies for asymptomatic patients with high-grade carotid stenosis. The National Institute of Neurological Disorders and Stroke (NINDS) CREST-2 (Carotid Revascularization Endarterectomy Versus Stenting Trial-2) is a prospective multicenter randomized comparison of state-of-the-art contemporary medical therapy versus elective revascularization. Because the NINDS recognizes 2 complementary and equally safe and effective methods of revascularization—carotid stenting (CAS) and carotid endarterectomy—the trial will have parallel paths comparing each revascularization method to best medical therapy.

The investigators have set the bar high in defining best medical therapy. They have rightly designed a best medical therapy protocol to reflect an ideal approach to medical care that all expect to become a standard in future years. This “5 Starr” medical regimen requires rigorous pharmacological control and monitoring of hypertension, blood lipids, diabetes, and antiplatelet therapy. In addition, rigorous protocol-driven lifestyle modifications, including cessation of tobacco use, weight reduction, and exercise programs, will be instigated and monitored.

Needless to say, for this difficult scientific endeavor to produce meaningful results, the

revascularization arms will need to be conducted with equal rigor.

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Carotid endarterectomy, in standard practice for more than 50 years, enjoys the privilege of full reimbursement from the Centers for Medicare and Medicaid Services (CMS) and operator volumes remain adequate. Accordingly, the task of the CREST-2 surgical management committee to qualify experienced and creditable surgical operators should not be a challenge. The opposite exists for the stenting interventional management committee (IMC). Despite the excellent comparative outcomes for stenting in the CREST trial, CMS has determined not to cover this less invasive and less traumatic alternative to carotid endarterectomy. Accordingly, the number of stenting operators with a creditable current experience is “sparse.” As CREST-2 embarks on the important job of trial site initiation, the stenting IMC is tasked with the challenging mission of identifying operators that will do credit to the trial with “5 Starr” stenting outcomes.

The CREST IMC has requested prospective CREST-2 stenting operators to submit information on total volume experience and detailed records on their last 25 consecutive cases. The challenge in identifying the prospective “bad apple” from the safe and creditable operator (commercial airline pilot analogy) has proved enormously difficult. How many errors are pilots permitted before being grounded? From a statistical perspective, the number of cases submitted is too small to make “meaningful” evaluations on event rates in isolation.

The paper by Shishehbor et al. (1) in this issue of *JACC: Cardiovascular Interventions* is both timely and

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helpful in guiding the CREST-2 IMC in its mission of evaluating operator experience and outcomes. The investigators attempted to improve our understanding of operator-related factors on technical performance for CAS by undertaking a comprehensive analysis of previously reported and new metrics that might influence outcomes. This well-conducted analysis of a large cohort of operators and procedures (5,240 patients) in the U.S. Food and Drug Administration–sponsored, prospective CHOICE (Carotid Stenting for High Surgical-Risk Patients; Evaluating Outcomes Through the Collection of Clinical Evidence) registry focused on a specific combination of an embolic protection device (EPD) and stent. They excluded other known confounding effects using the comprehensive database of baseline factors and a multivariable logistic regression analysis. High-volume experienced operators have for many years taught that shortening EPD dwell times may be a way of avoiding adverse events during the carotid stent procedure. In this study, the investigators hypothesized that the EPD dwell time would be a measure of good technical performance and a predictor of good outcomes. Cardiologists ($p < 0.001$) along with operators with longer time interval from first CAS ($p < 0.001$) had reduced EPD dwell times (technical performance). Increased time interval between CAS was the only independent predictor of increased 30-day adverse events. Importantly, prolonged EPD dwell time was also associated with 30-day adverse events.

How might the CREST-2 IMC and others evaluating operator performance for CAS use this information? Total experience (likely reflected in this analysis by time from first CAS) has been previously demonstrated as a marker of low event rates, and now we can add 2 additional metrics—the average interval between submitted procedures and EPD dwell times. It should come as no surprise that operators performing a given procedure with frequency would be proficient at their work. But what of EPD dwell times? From the outset of the work with the development of EPD, it was known that the shear forces associated

with filtering blood through the micro pores of the devices was associated with the precipitation and adherence of fibrin deposits to the filters. This is likely a time-related (and device design-related) phenomenon. There are numerous reports of filters occluding during prolonged stenting procedures, with this “fibrin clogging” probably being the primary event.

There are numerous other potential factors that may make short EPD dwell times a measure of both proficiency and safe outcomes. The cognitive skill of the operator in understanding optimal patient selection immediately comes to mind. Even after “struggling” to deploy an EPD in the tortuous, calcified long complex lesion (which should not be treated with stenting), subsequent stent placement, dilation, and EPD retrieval are challenging and may prolong the EPD dwell time. In addition, the intervening increased manipulation may be associated with increased embolization. Then there is the facile, expeditious technique! Experienced assistants and the experienced team ready to assist with timely placement of the stent may also play a role. Limiting contrast runs (also a source of micro bubbles), minimizing post-dilation of the stent (the most potent source of embolic particles), and experience in knowing how to interpret the post-stent angiographic result are also reflected in shorter EPD dwell times.

The CREST-2 executive and IMC committees, in collaboration with the NINDS, have approached CMS to establish a CREST-2 registry that will facilitate the current stenting experience of potential operators. In addition to scrutinizing operator procedural technique and outcomes, we will now have 2 additional metrics (frequency of procedures and EPD dwell times) to aid us in selecting appropriate operators for the trial.

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REFERENCE

1. Shishebor MH, Venkatchalam S, Gray WA, et al. Experience and outcomes with carotid artery stenting: an analysis of the CHOICE (Carotid Stenting for High Surgical-Risk Patients; Evaluating Outcomes Through the Collection of Clinical Evidence) study. *J Am Coll Cardiol Intv* 2014;7:1307-17.

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