Standardizing Excellent CAS Outcomes

Tools and strategies for improving procedural outcomes and generalizability.

BY WILLEM WILLAERT, MD, PhD, AND ISABELLE VAN HERZEELE, MD, PhD

After the introduction of carotid artery stenting (CAS) in the 1990s, the US Food and Drug Administration approved the first interventional CAS device system for use in high-risk patients in 2004.[1] Based predominately on data from CREST (Carotid Revascularization Endarterectomy Versus Stenting Trial),[2] this approval was extended in 2011 to standard operative–risk patients.[3] Although CREST showed that CAS was comparable to carotid endarterectomy (CEA) for the composite outcome of periprocedural death, stroke, or myocardial infarction, CAS was associated with a higher minor stroke rate than CEA (offset by a lower incidence of myocardial infarction).[2] These observations were largely in line with previous data from the large European trials such as SPACE and EVA-3S. Careful review of the CREST data, however, did reveal that a significant number of minor strokes after CAS resolved within 6 months but that the periprocedural individual endpoint of myocardial infarction (higher in the CEA group) resulted in increased early and late patient mortality.[4]

Nonetheless, a recent report reviewing national Medicare administrative data spanning more than 2 years (over 20,000 CAS procedures), shed light on real-world practice patterns and showed significantly higher mortality rates after CAS in comparison to the aforementioned trials, in part due to (lack of) operator experience and low caseloads.[5] Although CAS is an attractive option for patients with carotid disease due to its minimal invasiveness, it remains controversial due to the higher periprocedural minor stroke risk in a general and especially older patient population, as highlighted by a recent systematic review.[6]

Although the initial enthusiasm for CAS has been tempered, numerous trials have identified patient- and physician-related risk factors that have a profound influence on CAS outcomes. This article will concentrate on strategies (other than technical refinements) that may help improve CAS outcomes and its generalizability.

CAS LEARNING CURVE

CAS is a technically complex endovascular procedure that is associated with a distinct learning curve. Both individual operator experience and overall site volume are correlated with CAS results and outcomes. Lin et al clearly established an increase in the technical success rate after 50 CAS procedures, with the 30-day stroke and death rate falling to 8% after 50 interventions, 2% after 100 cases, and 0% after 150 procedures (0%; $P < .05$).[7] Similarly, this inverse relationship for individual physician volume was noted in the CAPTURE 2 study (Carotid Acculink/Accunet Postapproval Trial to Uncover Rare Events) ($r^2 = .81$).[8] The minimum number of CAS procedures (ie, the throughput) to achieve a major complication rate below the American Heart Association guidelines of 3% was 72.[8] Furthermore, the CAPTURE 2 data highlighted that site volume was a significant predictor of complications (death and stroke), irrespective of the specialty training of the operators.[8] Nevertheless, numerous consensus documents regarding CAS generally indicate lower volume requirements,[9] and randomized controlled trials like CREST have enrolled less-experienced physicians.[2] Naturally, the CREST trial revealed a clear relationship between the periprocedural complication rate and temporal patient inclusion, signifying obvious

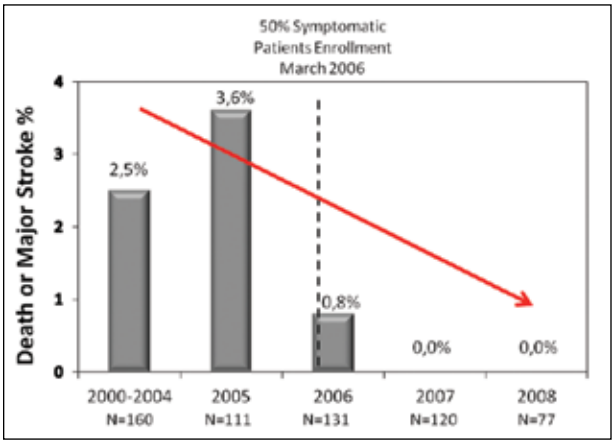

Figure 1. Evidence of in-trial learning during CREST: death or major stroke rates in CAS decrease for symptomatic patients with time. Modified with permission from Macdonald S. *Endovasc Today*. 2011;10:38-44.

within-trial learning (ie, increasing physician experience during the trial duration resulted in a risk reduction with time for patients undergoing CAS) (Figure 1).[2]

These data indicate that CAS should ideally be performed by experienced practitioners in hospitals that are accustomed to performing the procedure (with a higher caseload than initially considered). Unfortunately, analysis of "real-life" CAS practice patterns reveals that the median annual operator volume in Medicare beneficiaries was extremely low (three per year [interquartile range, 1.4–6.5]).[5] Low-volume operators (fewer than six CAS procedures per year) have increased mortality rates compared to high-volume operators (> 24 procedures per year). Inevitably, they also exhibited a clear learning curve—inexperienced practitioners (one to 11 cases) had mortality rates twice as high as more experienced interventionists (those with > 12 procedures). The overall 30-day mortality in this review reached 2%, which is significantly higher than mortality rates for elderly patients documented in the major trials and registries (0.7%–1%).[2] A probable explanation for these results is that 75% of the CAS operators in these Medicare beneficiaries performed fewer than six cases per year, and more than two-thirds of the CAS procedures were carried out by inexperienced interventionists who had only performed between one and 11 cases.

To address the distinct CAS learning curve, many medical societies have put forward consensus documents discussing competency requirements for CAS.[9] However, these consensus documents do not define uniform criteria for the credentialing process, nor do they provide specific benchmarks or endpoints to which CAS training programs must adhere.

PHYSICIAN TRAINING, PROCTORING, AND CREDENTIALING, AND THE ROLE OF VIRTUAL REALITY SIMULATION

At present, CAS training is still a process of mentored training on the patient, preceded by industry-sponsored training programs involving virtual reality (VR) simulation. Generally, these courses involve didactic and/or online training, case review sessions, and a technical hands-on VR simulation session. These training sessions are typically complemented by in-hospital proctoring and regional staff training. Although undoubtedly useful, this kind of mentored training has inherent drawbacks as it is potentially unstructured, relies on absolute caseload instead of proficiency benchmarks, and still exposes patients to the risk of the aforementioned learning curve.

Professional organizations representing the major endovascular specialties have tried to list certain criteria to guide credentialing/training processes for individual operators performing CAS.[9] These criteria include cognitive and technical aspects as well as volume requirements. There is, however, variation across the different subspecialties regarding threshold requirements, and caseload numbers seem low (often around 25 cases), especially in light of recent learning curve data.[3,8] Once again, one must keep in mind that absolute volume is only a surrogate measure of proficiency, as quantity does not necessarily guarantee clinical or qualitative competence.

The US Food and Drug Administration has encouraged educational initiatives with regard to CAS and stressed the use of simulation technology as an adjunct to CAS training programs.[1] This heightened interest in VR simulation has led to efforts to validate this technology for training and credentialing purposes. There is growing evidence that VR simulators can accelerate the learning process for the CAS procedure.[10] This kind of training can help physicians familiarize themselves with the endovascular material and techniques, automate procedure sequencing, and make interventionists accustomed to varying arch and carotid anatomies and different crisis scenarios. The EVEREST group has shown that a 2-day VR-based CAS course incorporating technical and cognitive elements leads to significantly improved performance with a reduction in procedural errors observed postcourse.[10] However, it is important to consider that this kind of simulator training is only useful if the training program is part of a structured, proficiency-based training curriculum including cognitive components, error identification, and technical skills acquisition to predefined expert benchmark levels.[11] Every effort should therefore be made to define

(Courtesy of Simbionix.)

Figure 2. Schematic overview of the steps in patient-specific rehearsal.

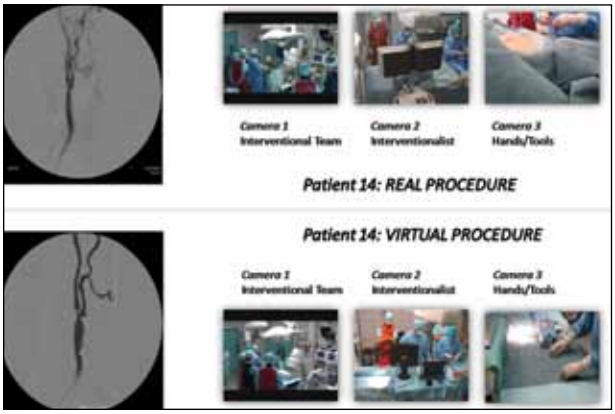

Figure 3. CAS team training with VR simulation. Reprinted with permission from Willaert et al. *Br J Surg*. 2012;99:1304–1313.[12]

these expert-derived benchmark levels of performance for CAS, as they are not available at present. Only then can one rely on simulation-based training programs to effectively prepare interventionists (and patients) for complex procedures such as CAS.

Patient-specific or VR rehearsal, also referred to as "procedure" or "mission" rehearsal, is a new technology that may improve preoperative preparation (Figure 2).[12] It allows uploading of patient-specific computed tomographic data into the simulation software and use of the simulator as a device to practice an actual patient case instead of acting as a mere generic training tool. It allows patient-tailored preparation and precise evaluation of different approaches, identification of potential hazards, and optimization of endovascular tool selection. This is especially valuable for complex procedures such as CAS, as outcomes are dependent on operator experience, individual anatomic considerations, adequate patient selection, and a thorough knowledge of different endovascular devices and their indications.[8,13,14] Research has already shown that procedure rehearsal can positively influence both experienced and inexperienced interventionists in their operative endovascular tool choice, which may result in a more efficient intervention and increase patient safety, using fewer tools with a decrease in hazardous manipulations in dangerous anatomic regions.[15] Furthermore, procedure rehearsal has been shown to aid patient selection, providing information on procedure feasibility, specific hazards, and risk stratification.[16]

Successful training programs for CAS should not limit themselves to the interventionist audience alone. The endovascular suite is a complex, multidisciplinary environment in which communication errors and equipment-related malfunctions have been shown to account for nearly half of all operative failures.[17] Therefore, training the team members, including the assistant, scrub, and circulating nurse, in technical and nontechnical operative characteristics is imperative to ensuring a safe and streamlined intervention (Figure 3). There is evidence that these nontechnical and team interaction skills can be adequately taught in high-fidelity, full-team simulations, and that these crew resource management programs have a positive effect on procedural outcomes.[18] It seems reasonable to suggest that these training exercises should be repeated at regular intervals during the year to ensure that the staff remains adequately trained and protocols remain implemented. Training should focus on both standard and crisis scenarios, such as unexpected perioperative cardiac or cerebral events. Furthermore, it may act as a refresher course for team members after a period of inactivity.

To ensure that CAS is carried out by adequately trained interventionists, a certified credentialing process can complement proficiency-based training programs and serve as an important quality control for safe practice. The larger trials comparing CAS to CEA have instituted credentialing processes to ensure that the physician investigators overcome the initial CAS learning curve before trial commencement.[2] This credentialing process seems in part responsible for the superior results after CAS in the CREST trial as opposed to results observed in trials such as ICSS and EVA-3S. In these latter trials, inclusion criteria for enrolling physicians performing CAS were less controlled and stringent than the criteria set for physicians performing the CEA procedure.

VR simulators may also be used as part of the credentialing process, as observed in the European Board of Vascular Surgery exam. Here, board certification is granted only after performance in basic endovascular skill is deemed sufficient, as recorded by an endovascular simulator in conjunction with the use of dedicated generic

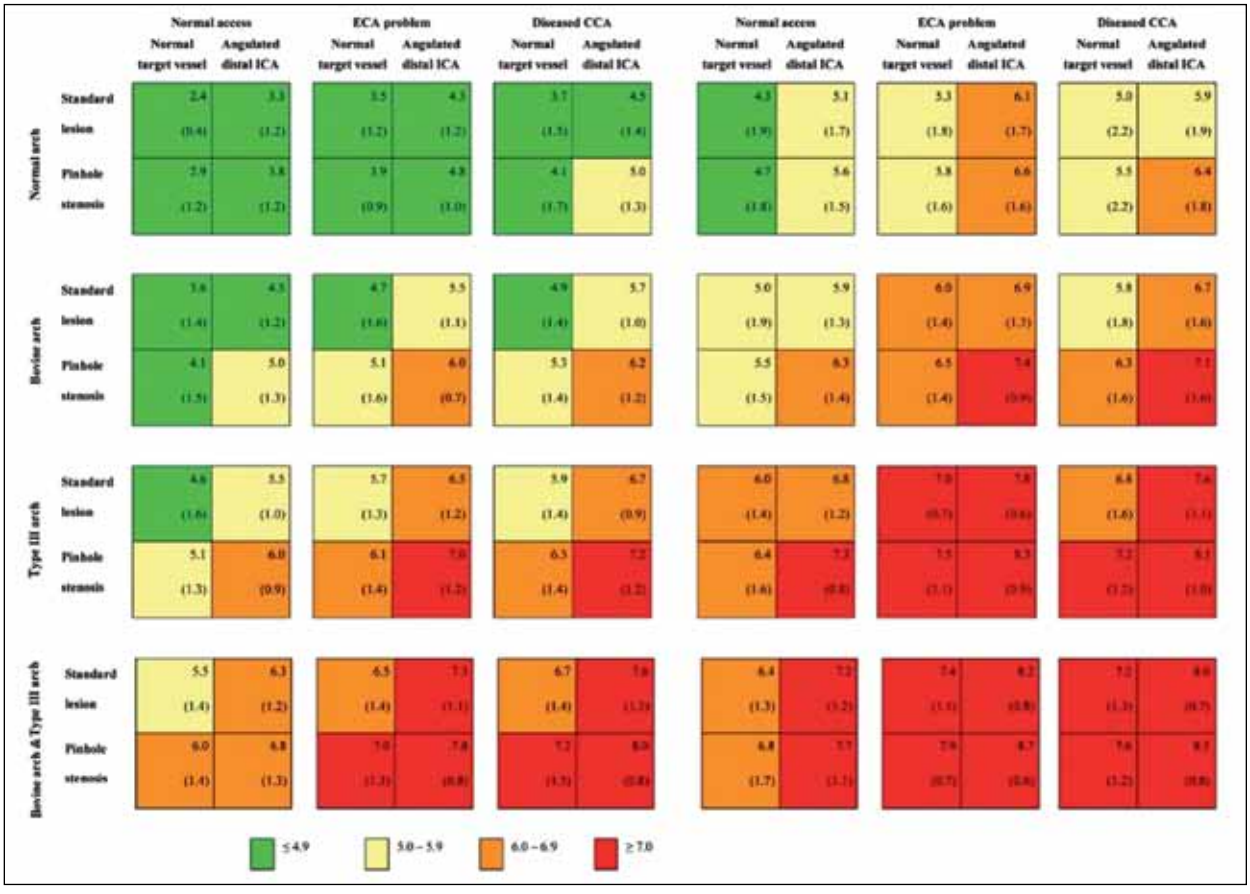

Figure 4. Anatomic scoring system for CAS. Predicted mean level of difficulty for CAS in each specified combination anatomy from the regression model (with interactions). Standard deviations are given in parentheses. The mean cutting score differentiating a "yes" response from a "no" response across the panelists was 5, with a mean score of 7 for a "no" response and a mean score of 4 for a "yes" response. The scores are therefore presented as traffic light colors; red for particularly difficult anatomy, a broad amber band (pale and dark allowing for the minor degree of uncertainty amongst panelists) representing moderate difficulty, and green representing lesser difficulty. Reprinted with permission from Macdonald S et al. *Stroke*. 2009;40:1698–1703.[23]

endovascular rating scales.[19] In an effort to enhance CAS results, an important next step would be to provide guidelines and a framework to which CAS training programs and objective credentialing processes must adhere. These programs should be based on proficiency criteria and benchmark levels of competency and not on crude caseload data. Once in place, individual physicians would be obligated to complete these standardized programs before independent CAS practice.

CAS PATIENT SELECTION

As is the case for every complex procedure associated with infrequent but severe complications, correct patient selection is paramount to achieving excellent outcomes. Patient-specific factors that may influence outcomes after CAS include patient comorbidities (age, sex, symptom status, cardiac comorbidities)[20] and anatomical patient characteristics. With regard to anatomical considerations, patients with an unfavorable aortic arch (type III, bovine, arch calcifications), specific carotid anatomy (vascular tortuosity), and those with certain lesion characteristics (free-floating thrombus, heavy circumferential calcification, long string-like lesions > 15 mm, ostial involvement) have been found to be at higher risk for periprocedural stroke.[20-23] In contrast, patients with distal carotid stenoses, post-CEA stenosis, and previous neck irradiation are probably better candidates for CAS than CEA.[24]

To address the issue of patient influence on outcome, scoring systems have been devised to improve patient selection by allowing more adequate identification of high-risk patients, especially for inexperienced practitioners.[21,25] A notable example is an anatomic scoring system devised by Macdonald and colleagues based on numerous

anatomic considerations and graded in individual and concomitant severity scales by expert consensus (Figure 4).[25] The use of this scoring system might reduce periprocedural stroke rates by selecting cases that are appropriate in terms of the operator's level of expertise. A patient-tailored approach toward CAS has been advocated and may be achieved by a more widespread implementation of these scoring systems in conjunction with patient-specific VR rehearsal, resulting in an enhanced procedural preparation, team performance, and patient safety.

SUMMARY

Due to its minimally invasive nature, CAS remains an attractive alternative to CEA for patients with (a)symptomatic atherosclerosis of the internal carotid artery. CAS has been scrutinized by a multitude of trials, and despite certain advantages, it is associated with a higher perioperative (minor) stroke risk in unselected patients compared to CEA. However, multiple strategies are available at present to achieve excellent CAS results, as witnessed in centers of excellence. Apart from ongoing technical advancements and optimal medical management, key components include increased physician training prior to performing CAS, an emphasis on accurate patient selection, and rigorous credentialing. Incorporation of VR simulation into proficiency-based curricula for CAS seems paramount to increase physician experience with this high-risk procedure, to ensure that CAS is only performed by competent interventionists, and to aid in accurate patient selection and team preparation.

National and international endovascular societies should focus on refined (and more stringent) guidelines for CAS training programs, competency statements, and credentialing criteria. If patients are treated by trained and experienced CAS interventionists in high-volume centers, CAS results will be optimized and comparable to CEA in specific patient subsets. CAS and CEA should not be considered mutually exclusive in a bid to treat all patients with a single-treatment strategy but should be utilized in a patient-tailored approach to stroke treatment in which some patients are more appropriate candidates for CAS and others for CEA. ■

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