

Carotid Artery Stenting Operator and Institutional Learning Curves

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KEYWORDS

• Carotid artery stenting • Learning curve • Stroke

KEY POINTS

- Ideally, experience with carotid artery stenting (CAS) procedures should be sufficient to keep periprocedural death/stroke rates less than 3% for asymptomatic patients (<6% for symptomatic patients) in accordance with the American Heart Association's recommendations.
- Available data suggest that operators need to perform approximately 75 CAS cases before periprocedural complication rates decrease below this threshold, a level that would eliminate all but high-volume operators.
- Policies that would restrict the use of CAS to highly experienced operators might ensure the safety of CAS but would come at the expense of limited procedural access.
- Collaborative, cross-specialty dialogue around such policy decisions is urgently needed if CAS is to remain a viable treatment option for patients with carotid artery stenosis.
- Virtual reality simulated training initiatives might minimize the procedural volumes required to achieve proficiency, but that remains to be proven.

INTRODUCTION

Carotid artery stenting (CAS) is a unique interventional procedure. It requires an in-depth knowledge of vascular and intracranial anatomy, a robust experience with catheters and guidewires, and an understanding of disease pathology above and beyond that required for treating other vascular territories.^{1,2} When compared with other end organs, the brain is distinctly sensitive to small errors in endovascular procedural technique that may culminate in distal microembolization. Unique hemodynamic consequences also occur commonly during the periprocedural period.^{1,2} Standardizing CAS training has had its own inherent challenges in that the procedure is performed by operators

from multiple specialties, including interventional cardiovascular medicine, interventional radiology, vascular surgery, neurosurgery, and interventional neurology,^{1–3} specialists who possess varied clinical backgrounds and technical skill sets.

The utilization of CAS has increased significantly since the US Food and Drug Administration (FDA) approved the first carotid stent system in 2004.^{4,5} Reasons for the rapid uptake of CAS into clinical practice are multifactorial. They include a growing evidence base of randomized trials supporting its equivalence/noninferiority for stroke prevention when compared with carotid endarterectomy (CEA) among high- and standard-surgical risk patients, patient preference for less invasive treatment options, and the presence of a diverse and

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expanding group of physicians who are able to perform the procedure.^{5,6} Despite its promise, concerns have been raised around the increasing use of CAS.⁵ It is a technically demanding procedure for which there is a substantial learning curve, and this learning curve is an important determinant of both its technical success and periprocedural outcomes. In this article, the authors review existing data relating operator and institutional volumes to procedural outcomes and discuss the implications surrounding these relationships.

CAS LEARNING CURVE

Learning curves have been established for other catheter-based cardiovascular procedures, including atrial fibrillation ablation,⁷ balloon valvuloplasty,⁸ transcatheter aortic valve replacement,⁹ transradial percutaneous coronary intervention,¹⁰ complex endovascular interventions,¹¹ and intracranial angioplasty and stenting.¹² Accordingly, it should come as no surprise that a learning curve might exist for CAS.^{13,14} Very poor clinical outcomes were observed in early studies of CAS, which included physicians and institutions with little or no relevant procedural experience (Table 1)^{15,16}; and periprocedural complications were more common among inexperienced operators.¹⁷ Other studies^{18,19} have demonstrated a decrease in the incidence of periprocedural death and stroke over time (see Table 1). Both operator and institutional procedural experience likely influence this apparent learning curve.

OPERATOR LEARNING CURVE

Ahmadi and colleagues²⁰ found that greater experience seemed to overcome the initial learning curve associated with CAS. Among 4 groups of

80 consecutive symptomatic and asymptomatic patients undergoing CAS, they observed that the incidence of 30-day death and neurologic events for CAS procedures was 15% for the first 1 to 80 cases, 5% for cases 81 to 160, 6% for cases 161 to 240, and 5% for cases 241 to 320; the reduction in neurologic complications after the initial 80 interventions was statistically significant ($P = .03$). Similarly, Lin and colleagues¹⁷ analyzed 200 consecutive CAS procedures in 182 patients followed over a 40-month period and observed increased technical success, reduced fluoroscopic time, less total procedure time, reduced contrast volume, and fewer procedure-related complications with the increasing number of CAS procedures performed by an operator (Figs. 1 and 2). The 30-day stroke and death rates after 0 to 50 cases and 51 to 100 CAS procedures were 8% and 2% ($P<.05$), respectively; after 101 to 150 and 151 to 200 CAS cases, the event rates were 0% ($P<.03$ compared with group 1) and 0% ($P<.01$ compared with group 1), respectively. Increasing procedural volume ($P = .03$) was identified as an independent predictor of reduced complication rates in Cox regression analysis.

In an observational study using administrative data from Medicare beneficiaries ($n = 24,701$) who underwent CAS between 2005 and 2007, Nallamothu and colleagues⁵ found that only 11.6% of operators performed 12 or more CAS procedures per year (Fig. 3). Furthermore, these investigators identified annual operator volume and lifetime operator experience as important factors associated with 30-day mortality and with use of an embolic protection device (Fig. 4, Table 2).

In the Carotid ACCULINK/ACCUNET Post Approval Trial to Uncover Rare Events (CAPTURE-2), operator ($n = 459$)-related variables impacting CAS outcomes were evaluated at 180

Table 1 Observational studies suggesting the existence of procedure-related learning curve with CAS					
Study Name	Study Period	Population	EPD	Sample Size	Event Rate
Naylor et al, ¹⁵	1996	Sx	No	23	Periprocedural D/S CAS 45.5% vs CEA 0.0%, $P<.05$ Study halted prematurely
Alberts, ^{16,17}	Pre-2001	Sx	No	219	30-d D/S CAS 12.1% vs CEA 4.5% $P<.05$ Study stopped prematurely
Roubin et al, ¹⁸	1994–1999	Asx + Sx	No	528	30-d D/S rates by year • 1994–1995, 9.3% • 1998–1999, 4.3%

Abbreviations: Asx, asymptomatic; D, death; EPD, embolic protection device; S, stroke; Sx, symptomatic. CAS-related complications clustered around physicians with little or no previous CAS experience.

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