

Safety of Carotid Stenting (CAS) is Based on Institutional Training More than Individual Experience in Large-volume Centres

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WHAT THIS PAPER ADDS

There are conflicting data on the relevance of centre versus single-practitioner experience on the results with carotid stenting (CAS). This study would suggest that an effective team-working approach could significantly affect the performance of new trainees with CAS allowing improved outcomes and patients' safety.

Background: Operator training is a key factor for the safety of carotid stenting (CAS). Whether institutional practice is associated with improved individual operator outcomes is debated.

Objective: To evaluate the effect of the institutional experience on outcomes of new trainees with CAS, a retrospective analysis of a prospectively held database was performed.

Methods: The overall study period, 2004–2012, was divided into two sequential time frames: 2004–April 2006 (leaders-team phase) and May 2006–2012 (expanded team phase). In the first frame, a single leader-operators team that first approached CAS and passed the original institutional learning curve, performed all the procedures; in the following expanded-team phase, five new trainees joined. Institutional CAS training for new trainees was based on a team-working approach including selection of patients, devices and techniques and collegial meetings with critical review and discussion of all procedural steps and imaging.

Results: A total of 431 CAS procedures were performed in the leaders-team phase and 1026 in the sequential expanded-team phase. Periprocedural complication rates in the two time frames were similar: stroke/death (3.0% vs. 2.1%; $P = 0.35$), stroke (2.8% vs. 2.1%; $P = 0.45$) major stroke (0.9% vs. 0.6%, $P = 0.49$), death (0.2% vs. 0%; $P = 0.29$) during the leaders-team and expanded-team phase, respectively. However, rates of CAS failure requiring surgical conversions (3.7% vs. 0.8%; $P < 0.0001$) and mean contrast use (91.6 vs. 71.1 ml; $P = 0.0001$) decreased in the expanded phase. In the expanded-team frame (May 2006–2012), there was no mortality, and stroke rates were comparable between the leader and new operator teams: 2.6% vs. 1.2%; $P = 0.17$.

Conclusions: Institutional experience, including instruction on selection of patients and materials best suited for the procedure, is a primary factor driving outcomes of CAS. An effective team-working approach can reliably improve the training of new trainees preserving CAS safety and efficacy.

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Carotid stenting (CAS) is a technically demanding procedure and studies have demonstrated a substantial learning curve with it.^{1,2} The worse outcome from CAS when compared to carotid endarterectomy (CEA) recorded in multiple European randomised clinical trials (RCTs) has been in large part explained by the lack of adequate training with the endovascular procedure. International recommendations suggest minimum volume requirements and training criteria for potential CAS operators although with great variability among professional organisations.^{3–9} Some recent studies

indicate that individual physician volume has an impact on patient outcome from CAS.^{2,9–11} However, few studies have evaluated the effect of the institutional training on the single operator outcomes with CAS. The objective of this study was to analyse whether institutional experience and an effective institutional team working approach with CAS may provide appropriate technical training, proficiency and safe performance for new operators in a large-volume centre.

METHODS

Patients entered in a prospectively compiled computerised database of carotid procedures performed at a single vascular surgical centre were retrospectively analysed. Procedures were applied by multidisciplinary operative teams including vascular surgeons and interventional

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radiologists. The first 195 CAS procedures, reflecting the first approach to CAS at our centre performed from 2001 to 2003, represented the initial 'learning curve' phase of the institution. It was after this training that the rate of CAS-related major strokes (mainly occurring during the catheterisation and filter time frames of CAS) significantly decreased to <2% per year.¹ Thereby, this major stroke rate was assumed to define an 'experienced' operator. The operators who passed this learning curve frame were defined as the leader-operators team. From 2004 to April 2006, this team continued to perform all CAS. Subsequently, from May 2006 to 2012, the operative team expanded with five new trainees who joined and were denoted the 'new-operators' team. Results of the learning curve period have been previously published.¹ This study focussed on the following period 2004–2012 that was divided into two time frames: the leaders team frame (2004–April 2006) and the expanded team frame (May 2006–2012) when five new operators joined the leader-operators team (Fig. 1).

Over the study period, the Institutional CAS protocol was progressively refined including the lessons learnt with increasing experience. Accordingly, the case mix selection was based on physician-guided indications of best suitability for CAS accounting for overall periprocedural risk evaluation and presence of co-morbidities. Patients with >80 years, unfavourable aortic arch anatomy, unstable 'complex' carotid plaque especially if recently symptomatic, severe peripheral vascular disease precluding femoral access or extremely tortuous carotid anatomy were progressively excluded from CAS. Similarly, known allergies to aspirin, clopidogrel or contrast media and renal insufficiency were considered exclusion criteria for CAS.

With increasing experience and refined patient selection, the institutional CAS procedure expanded from the treatment of only patients at high risk for CEA to the treatment of common risk patients with carotid disease. Nevertheless, after publication of multiple European trials questioning the safety of CAS versus CEA,^{12–14} the institutional indications for CAS in symptomatic patients became more limited, as shown in Fig. 2.

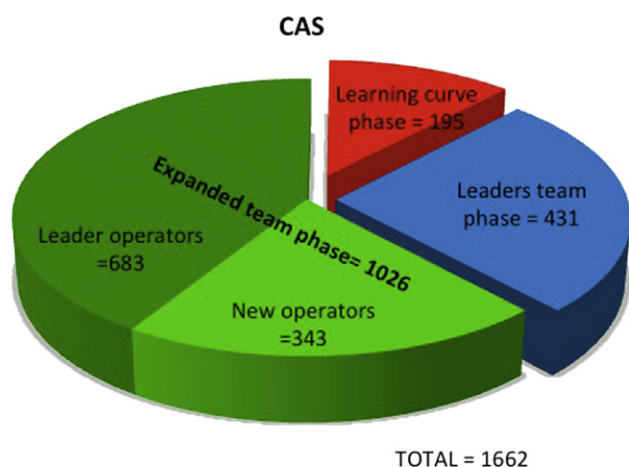


Figure 1. Study time frames and distribution of leader and new operators.

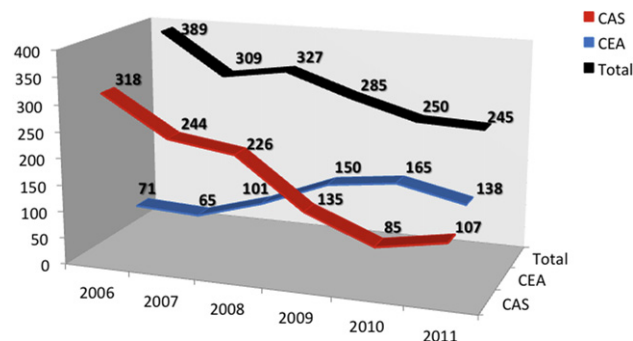


Figure 2. Institutional carotid volume by year.

To evaluate the overall effect of the institutional training on CAS results, patients' case mix, technical details and rates of complications between the leader team frame (2004 to April 2006) and the sequential expanded team frame (May 2006–2012) were compared. To assess the efficacy of the institutional team working on the new operators (who did not actively participate in the original institutional learning curve phase in 2001–2003), results between the leader-operators team and the new-operators team during the same expanded team phase (May 2006–2012) were compared.

Institutional training for new trainees

Before performing CAS independently, new operators had interacted with leader operators as observers and were occasionally proctored during the procedures. The team-working approach included routine institutional meetings that involved leader operators and new trainees with critical review and discussion of each CAS procedure regarding whole intraprocedural imaging and technical steps and selection of patients, materials, techniques and medications. No simulator technology was used for technical training.

Outcome measures

The primary 'end' point was the combined risk of any stroke or death within 30 days (perioperative). Secondary 'end' points were each component of the primary 'end' point (stroke and death), major stroke occurring within 30 days after the procedure, procedure time, technical failure (inability to complete the procedure without residual stenosis >50%), contrast use, radiation exposure and conversion to open procedure.

Patient evaluation

Features and time of preoperative symptoms were evaluated by external neurological audit. Patients were defined as symptomatic when ipsilateral hemispheric or retinal symptoms occurred within 6 months prior to the procedure. Stroke was defined as any new hemispheric or retinal neurological event persisting >24 h and classified as major (modified Rankin Score ≥ 3) or minor (modified Rankin Score <3).

The degree and characteristics of carotid stenosis were assessed with Duplex ultrasound.¹⁵

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