Carotid Stenting
Is There an Operator Effect? A Pooled Analysis From the Carotid Stenting Trialists’ Collaboration

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Background and Purpose—Randomized clinical trials show higher 30-day risk of stroke or death after carotid artery stenting compared with surgery. We examined whether operator experience is associated with 30-day risk of stroke or death in the Carotid Stenting Trialists’ Collaboration database.

Methods—The Carotid Stenting Trialists’ Collaboration is a pooled individual patient database including all patients recruited in 3 randomized trials of stenting versus endarterectomy for symptomatic carotid stenosis (Endarterectomy Versus Angioplasty in patients with Symptomatic Severe Carotid Stenosis trial, Stent-Protected Angioplasty versus Carotid Endarterectomy trial, and International Carotid Stenting Study). Lifetime carotid artery stenting experience, lifetime experience in stenting procedures excluding the carotid, and annual number of procedures performed within the trial (in-trial volume), divided into tertiles, were used to measure operator experience. The outcome event was the occurrence of any stroke or death within 30 days of the procedure. The analysis was done per protocol.

Results—Among 1546 patients who underwent carotid artery stenting, 120 (7.8%) had a stroke or death within 30 days of the procedure. The 30-day risk of stroke or death did not differ according to operator lifetime carotid artery stenting experience (P=0.8) or operator lifetime stenting experience excluding the carotid (P=0.7). In contrast, the 30-day risk of stroke or death was significantly higher in patients treated by operators with low (mean ≤3.2 procedures/y; risk 10.1%; adjusted risk ratio=2.30 [1.36–3.87]) and intermediate annual in-trial volumes (3.2–5.6 procedures/y; 8.4%; adjusted risk ratio=1.93 [1.14–3.27]) compared with patients treated by high annual in-trial volume operators (>5.6 procedures/y; 5.1%).

Conclusions—Carotid stenting should only be performed by operators with annual procedure volume ≥6 cases per year.

Key Words: carotid stenosis ■ carotid stenting ■ prevention

At present, randomized clinical trials in patients with symptomatic carotid disease show inferior results of stenting compared with surgery with regard to the risk of stroke or death within 30 days of treatment, which was mostly attributed to an excess of minor or nondisabling stroke.1 To improve the risk–benefit profile of stenting, it is crucial to establish which factors among patient characteristics and the procedure itself are associated with a high risk of stroke after carotid stenting. The Carotid Stenting Trialists’ Collaboration (CSTC) pooled individual patient data from the Endarterectomy Versus Angioplasty in patients with Symptomatic Severe Carotid Stenosis trial (EVA-3S), the Stent-Protected Angioplasty versus Carotid Endarterectomy trial (SPACE), and the International Carotid Stenting Study (ICSS). With this database, we recently showed that, compared with surgery, the risks of stenting were higher in patients aged ≥70 years.1 Carotid stenting is a technically demanding procedure. However, the minimum volume requirements and training criteria for potential operators remain largely unknown.2–4 In the present study, we assessed whether operator lifetime experience was associated with the 30-day risk of stroke or death after carotid stenting.
experience and annual in-trial operator volume were associated with 30-day risk of stroke or death.

Methods
EVA-3S (NCT 00190398), SPACE (ISRCTN 57874028), and ICSS (ISRCTN 25337470) were randomized clinical trials with blinded outcome adjudication. In all 3 trials, patients with recently symptomat ic moderate or severe carotid stenosis (≥70% reduction in the lumen diameter according to the method used in the North American Symptomatic Carotid Endarterectomy Trial [NASCET]),† who were considered equally suited for either procedure, were randomly allocated to undergo treatment by stenting or endarterectomy. The pooled analysis of individual patient data was prospectively agreed at the design stage of these trials. Details about experience required to join the trials and procedure supervision methods are shown in Table 1.

We assessed different variables of interest that are related to operator experience. The operator lifetime carotid artery stenting (CAS) experience was defined for each procedure as the total number of CAS procedures performed by each operator, including those performed before entering the trial and those performed within the trial at the time of the procedure. The in-trial operator volume was defined as the total number of CAS procedures performed in the trial by each operator. The annual in-trial operator volume was calculated by dividing the in-trial operator volume by the number of years between the first in-trial procedure and the end of the trial. In the SPACE trial, operator experience before joining the trial was not recorded in absolute numbers of procedures but was available in categories of 10 to 24 or ≥25 CAS procedures. We also assessed the operator lifetime experience in stenting procedures excluding the carotid before entering the trials. The outcome event for the present analysis was the combination of any stroke or death occurring within 30 days after treatment.

Statistical Analysis
The analysis was done per protocol, including only those patients who received the randomly allocated CAS treatment as the first initiated revascularization procedure. Operator lifetime CAS experience, operator lifetime stenting experience excluding the carotid, and annual in-trial operator volume were divided into tertiles. Operator lifetime CAS experience was also categorized into 3 strata: <10, 10 to 24, and ≥25 to take SPACE data into account. The associations of lifetime operator experience and in-trial annual operator volume with occurrence of stroke or death within 30 days of treatment were assessed by crude risk ratios as calculated with Poisson regression using the highest tertile of in-trial annual operator volume and the highest tertile of operator lifetime experience as references.

To assess whether operators with 1 or 2 bad outcomes early in the trial withdrew (or put in fewer patients subsequently), we divided each operator period of participation (time between the first in-trial procedure and the end of the trial) into 3 equal periods and calculated for each operator the ratio of the number of patients treated during the first period of participation in the trial to the number of those treated during the second and third periods of participation. We compared operators who treated ≥21 patient who had a bad outcome (30-day stroke or death) during the first period of the study with those without any complication during the first period. We also compared operators who treated ≥2 patients who had a bad outcome during the first period of the study with operators who had ≤2 complications. The nonparametric Mann–Whitney U test was used to compare those ratios.

We performed a multivariate analysis adjusting the crude effect estimates for the following potential predictors of 30-day risk of stroke or death after stroke: age, sex, hypertension, history of coronary artery disease, contralateral severe carotid stenosis or carotid occlusion, use of cerebral protection devices, stent design (open- versus closed-cell stent), and source trial. These potential explanatory variables were selected on the basis of the results of the CSTC planned meta-analysis of individual patient data, a previous analysis of SPACE trial, a subgroup analysis of the Carotid Revascularization Endarterectomy versus Stenting Trial (CREST), and our previous review of literature.

To account for the inherent clustering within data (the same operator performs multiple procedures over time), we also constructed models using the framework of multilevel modeling with random intercepts included for individual operators. All 3 trials put into place schemes allowing operators who did not fulfill the required number of procedures to treat patients in the trial under the supervision of an experienced peer, as specified in Table 1. In the present analysis, these procedures were termed supervised. We compared outcomes between supervised procedures and procedures performed by operators meeting the full experience criteria. In addition, we compared outcomes across 3 successive periods of the trials (each including one third of patients) to assess a potential learning curve during the trials as a whole. In ICSS, monitoring of adverse events showed that 5 major strokes (disabling of fatal strokes) of a total of 26 (19%) came from 2 operators who treated only 11 patients. These operators were stopped from treating additional patients. We conducted a sensitivity analysis excluding the data from the 2 operators concerned. Statistical analysis was performed using SAS version 9.3 (SAS Institute, Inc, Cary, NC).

Table 1. CAS Operator Criteria Required to Join Trials

<table>
<thead>
<tr>
<th>Study</th>
<th>Operator Qualification Required to Join Study*</th>
<th>If Operator Criteria Nonfulfilled</th>
</tr>
</thead>
<tbody>
<tr>
<td>EVA-3S</td>
<td>≥12 CAS (or ≥30 stenting procedures in the supraaortic trunks including ≥2 CAS)†</td>
<td>Supervision by an experienced tutor (fulfilling criteria) until self-sufficient and required criteria to join study</td>
</tr>
<tr>
<td>SPACE</td>
<td>≥25 CAS (bifurcation or siphon)</td>
<td>Preliminary certificate if 10≤CAS&lt;25, but procedures performed under guidance of a local experience colleague‡</td>
</tr>
<tr>
<td>ICSS</td>
<td>≥50 stenting procedures including ≥10 CAS</td>
<td>Outside proctor until 20 cases within trial with acceptable results for proctor and credential committee</td>
</tr>
</tbody>
</table>

CAS indicates carotid artery stenting; EVA-3S, Endarterectomy Versus Angioplasty in patients with Symptomatic Severe Carotid Stenosis trial; ICSS, International Carotid Stenting Study; and SPACE, Stent-Protected Angioplasty versus Carotid Endarterectomy trial.

*Documented proof of procedures performed before beginning of the trials were used to assess previous experience. This had to be signed off by a credential committee.

†No operator joined the trial based on this criterion.

‡Amendment of the study protocol in 2002.

Results
The pooled CSTC per-protocol analysis included 1679 patients who underwent CAS as their randomly allocated revascularization procedure. Baseline characteristics of patients are presented in Table 2. Absolute numbers of lifetime CAS procedures and lifetime stenting procedures excluding the carotid were available in 235 (90.4%) and 256 (98.5%) of 260 procedures, respectively, in EVA-3S and in 601 (72.6%) and 537 (64.9%), respectively, in ICSS. From the SPACE trial, it was known whether the operator had performed 10 to 24 or ≥24 CAS before the trial for 586 (99.2%) procedures. Details on annual in-trial operator volume were available in 1546 (92.1%) of 1679 procedures. The median (interquartile range) operator lifetime experience was 27 CAS procedures (13–46) and 100 (50–300) stenting procedures excluding the carotid. The median annual in-trial operator volume was 4.3 procedures (2.4–7.0) with tertiles of ≤3.2, 3.2 to 5.6, and >5.6 procedures. Stenting procedures were performed...
Table 2. Characteristics of Patients Treated With Carotid Artery Stenting

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age at randomization, mean (SD), y</td>
<td>69.4 (9.0)</td>
</tr>
<tr>
<td>Age ≥70 y</td>
<td>828/1679 (49.3%)</td>
</tr>
<tr>
<td>Men</td>
<td>1200/1679 (71.5%)</td>
</tr>
<tr>
<td>History of diabetes mellitus</td>
<td>391/1669 (23.4%)</td>
</tr>
<tr>
<td>History of hypertension</td>
<td>1204/1669 (72.1%)</td>
</tr>
<tr>
<td>Systolic blood pressure at randomization, mean (SD), mmHg*</td>
<td>144.8 (21.2)</td>
</tr>
<tr>
<td>History of hypercholesterolemia†</td>
<td>661/1078 (61.3%)</td>
</tr>
<tr>
<td>Any smoking history (current or past)</td>
<td>1072/1669 (64.2%)</td>
</tr>
<tr>
<td>History of coronary heart disease</td>
<td>401/1669 (24%)</td>
</tr>
<tr>
<td>History of peripheral artery disease†</td>
<td>173/1078 (16%)</td>
</tr>
<tr>
<td>Type of most recent ipsilateral ischemic event before randomization</td>
<td></td>
</tr>
<tr>
<td>Retinal ischemia</td>
<td>303/1667 (18.2%)</td>
</tr>
<tr>
<td>Transient ischemic attack</td>
<td>572/1667 (34.3%)</td>
</tr>
<tr>
<td>Hemispheric stroke</td>
<td>792/1667 (47.5%)</td>
</tr>
<tr>
<td>History of stroke before most recent event†</td>
<td>184/1088 (24%)</td>
</tr>
<tr>
<td>Treatment within 14 d of most recent event‡</td>
<td>372/1434 (25.9%)</td>
</tr>
<tr>
<td>Days elapsed between most recent event and treatment, median (IQR)‡</td>
<td>29 (14–65)</td>
</tr>
<tr>
<td>Score of the modified Rankin scale at baseline§</td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>805/1683 (48.4%)</td>
</tr>
<tr>
<td>1</td>
<td>449/1683 (27.0%)</td>
</tr>
<tr>
<td>2</td>
<td>286/1683 (17.2%)</td>
</tr>
<tr>
<td>3</td>
<td>105/1683 (6.3%)</td>
</tr>
<tr>
<td>4</td>
<td>17/1683 (1.0%)</td>
</tr>
<tr>
<td>5</td>
<td>1/1683 (0.1%)</td>
</tr>
<tr>
<td>Degree of ipsilateral carotid stenosis</td>
<td></td>
</tr>
<tr>
<td>Moderate (50%–69%)</td>
<td>323/1679 (19.2%)</td>
</tr>
<tr>
<td>Severe (70%–99%)</td>
<td>1356/1679 (80.8%)</td>
</tr>
<tr>
<td>Contralateral severe carotid stenosis (≥70%)</td>
<td>232/1534 (15.1%)</td>
</tr>
</tbody>
</table>

Data are n/N (%), unless otherwise indicated. Percentages exclude missing data (N=number of patients for whom data were available). IQR indicates interquartile range.

*Rounded to nearest 5 mmHg because of digit preference.
†Data were not gathered in the Stent-Protected Angioplasty versus Carotid Endarterectomy (SPACE) trial.
‡Date of the most recent ipsilateral ischemic event before randomization was not gathered in the SPACE trial initially, but for meta-analysis these dates (or if the exact date was not known, whether or not treatment and randomization took place within 24 d of the qualifying event) were gathered where available.
§Modified Rankin scores at baseline might indicate nonstroke impairments; protocols of contributing trials excluded patients with disabling strokes.

under supervision in 101 (38.8%) of 260 patients in EVA-3S, 51 (8.6%) of 591 in SPACE, and 99 (12.0%) of 828 in ICSS. CAS procedures were performed by a single operator in 60% of centers and by 2 operators in 26% of centers. The classification of patients into tertiles of (1) operator lifetime experience in CAS procedures, (2) operator lifetime experience in stenting procedures excluding the carotid, and (3) annual in-trial operator volume is shown in Table 3. There was no significant difference in baseline variables potentially influencing procedural risks between patients treated by operators of different

lifetime CAS experience or annual in-trial operator volumes: age, sex, hypertension, history of coronary artery disease, and contralateral carotid occlusion (Table 4).

Cerebral protection devices were used in 966 (57.9%) of 1662 procedures. Among 1679 patients who underwent CAS, 130 (7.7%) had a stroke or died within 30 days of the procedure. The risk of 30-day stroke or death was 7.8% in the 1546 patients who had available data on annual in-trial operator volume. The 30-day risk of stroke or death did not differ according to operator lifetime CAS experience (Table 5), classified into tertiles or into 3 arbitrary categories (<10, 10–24, and ≥25) to include SPACE data (Table 5). In contrast, the 30-day risk of stroke or death was significantly higher in patients treated by operators with low (10.1%; risk ratio [RR]=1.99 [1.27–3.10]) and intermediate annual in-trial volumes (8.4%; adjusted RR=1.66 [1.04–2.64]) compared with patients treated by high annual in-trial volume operators (5.1%; Table 5).

Annual in-trial operator volume was correlated neither with operator lifetime CAS experience before the beginning of the trials (P=0.29) nor with operator lifetime experience in stenting procedures excluding the carotid (P=0.32). As expected, annual in-trial operator volume was correlated with operator lifetime CAS experience, including procedures performed during trials (P=0.01). The ratio of the number of patients treated during the first period of operator participation in the trial to the number of those treated during the second and third periods of
operator participation did not differ in operators who had 1 or 2 bad outcomes early ($P=0.78$ and 0.94, respectively) compared with operators without any complication during the first period.

The 30-day risk of stroke or death did not differ according to whether procedures were supervised (RR=1.03 [0.65–1.63] versus nonsupervised). Compared with patients treated in the first period of the trial, the 30-day risk of stroke or death did not decrease in those treated in the second (RR=0.92 [0.61–1.40]) and third periods (RR=1.09 [0.73–1.62]) of the trials.

After adjustment for potential predictors of 30-day risk of stroke or death (see Methods section), the relative effects of CAS were even stronger in patients treated by operators with low (adjusted RR=2.30 [1.36–3.87]) and intermediate annual in-trial volumes (adjusted RR=(1.93 [1.14–3.27])) compared with patients treated by high annual in-trial volume operators.

Results of multivariate analyses were similar whether conventional models or multilevel models were used (data not shown). Results of univariate and multivariate analyses were not modified after exclusion of procedures performed under supervision or exclusion of procedures performed by the 2 ICSS operators who were stopped after monitoring of adverse events (data not shown).

### Discussion

In this pooled analysis of individual patient data from the European-based randomized clinical trials of stenting versus endarterectomy for symptomatic carotid stenosis, we showed that the 30-day risk of stroke or death was lower (5.1%) in patients treated by operators with the highest annual in-trial volume compared with patients treated by operators with the intermediate (8.4%) or lowest annual in-trial volume (10.1%). In contrast, the operator lifetime experience was not associated with the 30-day risk of stroke or death.

Only a few studies have addressed the relationship between operator experience and complications after CAS. In agreement with our results, none of them showed an association between lifetime operator experience and the 30-day risk of complications after CAS. In the lead-in phase of CREST, neither years of experience in performing carotid intervention nor the number of CAS procedures performed before the CREST lead-in phase was associated with 30-day risk of stroke, myocardial infarction, and death. In the Carotid Acculink/Accunet Post Approval Trial to Uncover Rare Events (CAPTURE), a multicenter, prospective postmarket registry, there was no difference in the 30-day risk of stroke or death according to operator lifetime experience as defined by combining stenting experience and the 30-day risk of complications after CAS. In agreement with our results, none of them showed an association between lifetime operator experience and the 30-day risk of complications after CAS. In the lead-in phase of CREST, neither years of experience in performing carotid intervention nor the number of CAS procedures performed before the CREST lead-in phase was associated with 30-day risk of stroke, myocardial infarction, and death. In the Carotid Acculink/Accunet Post Approval Trial to Uncover Rare Events (CAPTURE), a multicenter, prospective postmarket registry, there was no difference in the 30-day risk of stroke or death according to operator lifetime experience as defined by combining stenting experience and the 30-day risk of complications after CAS.

With regard to the relationship between in-study volume (which can be regarded as a measure of annualized rate of
CAS procedures during the study) and CAS complications, most previous studies support our findings. In the CAPTURE 2 study, a prospective, nonrandomized, multicenter clinical study that enrolled high–surgical-risk patients, an inverse relationship was found between the 30-day risk of stroke, myocardial infarction, and death and operator in-study volume.17 Among 24,701 patients identified in US Medicare data on patients who underwent carotid stenting by 2339 operators, patients treated by low-volume operators (<6 procedures per year) had a higher risk of 30-day mortality at 2.5% compared with those treated by high-volume operators (≥24 procedures per year) at 1.4%, independently of operator experience at the time of the procedure.18 In the SPACE study, a decrease in 30-day ipsilateral stroke or death rate was observed with increasing total numbers of patient enrollment per center.19 In contrast, the 30-day risk of stroke, death, or myocardial infarction did not differ according to the total number of procedures performed in the CREST lead-in phase.18 However, in the CREST study, operators with the highest experience before the lead-in phase performed less CAS procedures during the lead-in phase than those with the least experience.

Finally, our results on the effect of a learning curve on CAS outcomes differed from those of 2 previous studies.16,18 In a retrospective analysis of 182 consecutive patients who had 200 CAS during a 40-month period at Baylor College of Medicine–affiliated hospitals, the 30-day risk of stroke or death decreased in the 3 latter sequential groups of 50 consecutive procedures compared with the first group.18 In the study assessing the 30-day mortality after CAS in US Medicare data (see above), patients treated early (first to 11th procedure) during a new operator’s experience (operators who first performed CAS within the 3-year study period) had a higher 30-day mortality compared with those treated later (12th procedure or higher).16 In contrast to CREST,20 in our study, the 30-day risk of stroke or death did not decrease in 3 successive periods of the trials that each included one third of patients, suggesting the absence of learning curve. However, because carotid stenting was a relatively new procedure at the beginning of the trials, CSTC trials were designed to avoid or limit the effect of a learning curve. To join the trials, CSTC operators had to show proof of a previous experience in CAS or were supervised.

Our study has potential limitations. First, our results apply only to symptomatic carotid stenosis. Second, we did not take into account CAS procedures performed by study investigators outside trials during the study period. Focusing on in-trial volume could have provided potential underestimation of CAS volume during the study period. However, even if this would have led to misclassification of some operators in terms of experience, it is unlikely that misclassification would differ between operators with low or high complication rates, particularly in those with low in-trial volume.

Third, we cannot exclude that operators who had early bad outcomes on the trial withdrew or put in fewer patients subsequently. However, such a bias is unlikely because there was no difference in the evolution of the individual rate of CAS procedures during the trial between operators who had 1 or 2 bad outcomes early compared with those who did not.

Finally, a potential selection bias linked to unequal distribution of potential risk factors between tertiles of annual in-trial volume is possible in theory albeit unlikely because tertiles did not differ according to potential covariates of CAS outcomes.

Our study shows that contrary to lifetime experience at the time of procedure, interventionists who performed ≥6 CAS procedures every year had better outcomes than those performing fewer numbers. We, therefore, conclude that carotid stenting should only be performed at centers where interventionists can achieve this rate of CAS procedures. This adds to the conclusion of our previously published analysis that suggested that it would be reasonable to offer stenting as an alternative option to endarterectomy to patients aged <65 to 70 years with symptomatic carotid stenosis in centers in which acceptable periprocedural outcomes have been independently verified.1

Appendix

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Disclosures
None.

References
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