Carotid Artery Stenting and Patient Outcomes: The CABANA Surveillance Study

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Objectives: The purpose of the prospective, multicenter, nonrandomized CABANA study was to evaluate periprocedural clinical outcomes in high surgical risk patients with carotid artery stenosis treated with the Carotid WALLSTENT plus FilterWire EZ Embolic Protection System by a diverse group of clinicians.

Background: There is a need for additional evidence evaluating carotid artery stenting (CAS) performed by operators with various experience and training levels.

Methods: The study enrolled symptomatic (≥50% carotid artery stenosis) and asymptomatic (≥80% carotid stenosis) patients at high risk for carotid endarterectomy. Study centers were grouped into three tiers based on previous CAS experience while individual operators were grouped by their CAS training. The primary endpoint was the 30-day composite of major adverse events (MAEs; including stroke, death, and myocardial infarction (MI)). Individual event rates were evaluated across the overall study, and by center experience and physician training tier.

Results: Of 1,097 enrolled patients, 1,025 were evaluable for 30-day MAE rate. The stroke rate (3.3%) was a major contributing factor in the overall MAE rate (4.6%). Mortality was 1.3% and the MI rate was 0.5%. There was no statistically significant association between MAE rates among the

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Conflict of interest: L. Nelson Hopkins, MD, is on the Speaker’s Bureau or has received an honorarium from Abbott Scientific, Abbott Vascular, Bard, Cordis, Complete Conference Management, Cleveland Clinic, Memorial Healthcare System, and the Society of Cardiovascular Angiography and Interventions (SCAI). He has ownership/financial interest in Boston Scientific, Augmenix, AccessClosure, Claret Medical, Endomation, Micrus, and Valor Medical and has received research study grants from Toshiba. Dr Hopkins serves as a consultant or is on the advisory board at Abbott, AccessClosure, Boston Scientific, Cordis, Micrus, and Silk Road. Malcolm T. Foster, MD, is on the Boston Scientific Advisory Board and has received honoraria from Cordis Endovascular and Abbott Vascular. Christopher J. White, MD, Richard J. Powell, MD, and Gerald Zemel, MD, have no competing interests to declare. Juan Diaz-Cartelle, MD, is a Boston Scientific employee and shareholder.

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Evidence from recent randomized controlled trials [1,2], meta-analyses [3,4], and registries [5–14] indicates that treatment with carotid artery stenting (CAS) with embolic protection for carotid artery atherosclerosis yields periprocedural outcomes comparable to those achieved with carotid endarterectomy (CEA) in patients with suitable anatomy who are at high or average risk for surgical complications. Long-term results have established CAS treatment durability in these patient populations [2,15–17]. Moreover, broad-based, multisocietal clinical guidelines support CAS for treatment of carotid artery disease in symptomatic and asymptomatic patients with high or average surgical risk features [18,19].

Despite broad evidence supporting the noninferiority of CAS versus CEA, there have been reports from randomized controlled trials [2,20,21] and a registry [22] describing a higher stroke and death rate in the periprocedural period with CAS compared with CEA. Because much of the data on CAS are derived from trials with stringent inclusion/exclusion criteria for patient, institution, and operator selection, it is not clear how applicable the results of these trials will translate into community practices. As stenting becomes a more common alternative to CEA, more data on CAS safety and effectiveness in real-world patients treated by community physicians and surgeons of varied experience levels will better inform treatment decisions.

The primary aim of the CArotid Stenting Boston Scientific Surveillance ProgrAm (CABANA) trial was to evaluate periprocedural outcomes achieved with modern versions of the Carotid WALLSTENT and FilterWire EZ System (Boston Scientific, Natick, MA) by operators with a wide range of clinical specialties, CAS experience and training levels, and in patients with a broad range of high surgical risk conditions and lesion types.

INTRODUCTION

The CABANA trial included patients with anatomic features and/or comorbid conditions that caused them to be poor candidates for CEA, as described in the Centers for Medicare and Medicaid Services (CMS) standards [23,24], and recently corroborated by an analysis of the Society for Vascular Surgery Vascular Registry [22]. Key CMS high-risk anatomical criteria included common carotid artery lesion(s) below the clavicle, previous neck radiation, high cervical internal carotid artery lesion(s), and restenosis of prior CEA; high-risk comorbidity criteria included age ≥80 years, recent myocardial infarction (MI), left ventricle ejection fraction <30%, contralateral carotid occlusion, and New York Heart Association Class III or IV congestive heart failure [24].

Symptomatic patients were required to have ≥50–99% stenosis, and asymptomatic patients, ≥80–99% stenosis of the common or internal carotid artery and/or the bifurcation by ultrasound or angiography. Bilateral carotid angiography and evaluation of the posterior circulation were performed on all patients before and after the procedure. The degree of stenosis was confirmed by angiography within 30 days of the index procedure, and it was recommended, but not mandated, that the angiogram be analyzed quantitatively utilizing the North American Symptomatic Carotid Endarterectomy Trial methodology [25–27].

Eligible patients with a reference vessel diameter ≥4.0 and ≤9.0 mm at the target lesion and a vessel diameter ≥3.5 and ≤5.5 mm distal to the target lesion were treated with a Carotid Wallstent Endoprosthesys and FilterWire EZ System (Boston Scientific) and enrolled upon attempted placement of the FilterWire EZ. Prior to the procedure, patients received medications consistent with current clinical practice. All patients were to undergo independent neurological and NIH Stroke Scale [28] assessments within 7 days prior to the procedure, before hospital discharge (within 24 hr of the procedure), and at 30 ± 7 days postprocedure. The NIH Stroke Scale was to be completed by a certified physician, nurse or other allied health professional, and the neurological assessment was to be completed by a similarly qualified health professional; both assessments were to be done independent of the treating investigator. All angiographic and ultrasound assessments done in conjunction with an adverse event were submitted to an independent Core Laboratory for review.

MATERIALS AND METHODS

Study Design

The CABANA trial was a prospective, multicenter, nonrandomized, open-label study. All investigational centers received study protocol approval from their respective Institutional Review Boards and all enrolled patients provided informed consent. Patient selection, device, procedure, and the follow-up methodology have been previously described [23].
All procedures were performed at investigational centers approved by CMS to provide CAS. Study centers were categorized into three experience tiers, based on the CAS experience level of the principal investigator (see Fig. 1A for definitions). Tier 3 represented the minimum required experience for a center/principal investigator to be eligible to participate in the study: the investigator must have performed more than 25 CAS procedures (at least 13 as primary operator) with any carotid stent and embolic protection system. All operators received device training, including live case proctoring and device module review where needed. Operators were grouped into three training categories (see Fig. 1B).

**Endpoint Definitions**

The primary endpoint was the composite rate of Clinical Events Committee (CEC)-adjudicated major adverse events (MAEs); namely: death, stroke, and MI through 30 days. The CEC classified strokes as major (i.e., a new focal ischemic neurological deficit of abrupt onset, lasting at least 24 hr, and does not meet the major stroke definition). The timing of MAE onset (i.e., ≤24 hr, between 24 hr and 30 days, and at ≥30 days) was also assessed.

Serious adverse events and technical success (the successful delivery, deployment, and retrieval of the devices) were also evaluated [23].

**Statistical Methods**

Sample size determination in the CABANA trial was based on the clinical results observed in the BEACH trial for evaluation of the Carotid Wallstent and FilterWire EZ [5]. A similar 30-day event rate in CABANA required a minimum of 1,000 patients to provide a two-sided 95% confidence interval ±1.5% of the estimated value.

The 30-day event rates are presented as binomial proportions with exact binomial two-sided 95%
confident intervals. All enrolled patients who experienced MAE on or before 30 days postprocedure or were free of MAE and followed up through 23 days postprocedure (i.e., through the allowed 30±7 day window) were included in the analysis. The statistical rank correlation among Center Experience Tiers and Physician Training Categories was calculated using Kendall’s tau-b correlation coefficient.

All statistical analyses were performed with SAS software, version 9.1 or above (SAS Institute, Cary, NC).

RESULTS

Baseline and Procedural Characteristics

Between December 2008 and October 2010, a total of 1,097 patients were enrolled in the CABANA trial at 99 US centers (Supporting Information Table 1); 94.8% (1,040/1,097) underwent 30-day clinical follow-up. Of the 57 patients who did not complete the 30-day follow-up, 22 patients missed visits, 16 patients were lost to follow-up (three failed documented attempts to contact the patient), six patients withdrew from the study, and 13 patients died before completing the 30-day follow-up.

Baseline patient demographics and lesion characteristics are reported in Table I. The mean age of enrolled patients was 71.3±9.2 years, with 18.0% older than 80 years. Of the enrolled patients, 67.3% were asymptomatic; 34% met CMS anatomical high-risk criteria for CEA, 50% met CMS comorbidity high-risk criteria, 15% had both anatomical and comorbid risk factors, and 0.5% (6 patients) were not characterized.

Procedural characteristics are reported in Table II. Technical success was achieved in 97.1% of the 1,072 patients who had Carotid WALLSTENT deployment attempted.

30-Day Clinical Outcomes

A total of 1,025 patients were evaluable for 30-day MAE. Among the 72 patients not evaluable for 30-day MAE, 40 did not complete the expected follow-up and

| TABLE I. Baseline Demographics and Lesion Characteristics of the CABANA Study Population |
|-----------------------------------------|-------------------|----------------------|
| Characteristic                          | N = 1,097 Patients | 95% CI               |
| Age (years)                            | 71.3±9.2 (1,097)  | [70.7, 71.8]         |
| Male sex (%)                           | 62.3% (683/1,097) | [59.3%, 65.1%]       |
| Current or previous smoker             | 73.9% (811/1,097) | [71.2%, 76.5%]       |
| Diabetes mellitus (%)                  | 39.5% (433/1,097) | [36.6%, 42.4%]       |
| Medical history                        |                   |                      |
| Hypertension                           | 90.5% (993/1,097) | [88.6%, 92.2%]       |
| Hyperlipidemia                         | 86.0% (943/1,097) | [83.8%, 88.0%]       |
| Peripheral vascular disease            | 44.3% (486/1,097) | [41.3%, 47.3%]       |
| Stroke                                 | 21.1% (231/1,097) | [18.7%, 23.6%]       |
| Transient ischemic attack              | 25.1% (275/1,097) | [22.5%, 27.7%]       |
| Coronary artery disease                | 65.7% (721/1,097) | [62.8%, 68.5%]       |
| Congestive heart failure               | 21.0% (230/1,097) | [18.6%, 23.5%]       |
| MI                                     | 28.9% (317/1,097) | [26.2%, 31.7%]       |
| CABG surgery                           | 31.3% (343/1,097) | [28.5%, 34.1%]       |
| Lesion location                        |                   |                      |
| Internal carotid artery                | 85.4% (935/1,095) | [83.2%, 87.4%]       |
| Common carotid artery                  | 14.6% (160/1,095) | [12.6%, 16.8%]       |
| Lesion length (mm)                     | 16.9±8.8 (1,096)  | [16.4, 17.4]         |
| Preprocedure target lesion Diameter    | 85.0±8.6% (1,097) | [84.5%, 85.5%]       |
| stenosis (visual estimate)             |                   |                      |

Numbers are % (n/N) or mean±SD (n).

CABG, coronary artery bypass grafting; MI, myocardial infarction.

| TABLE II. Procedural Characteristics |
|---------------------------------------|-------------------|----------------------|
| Characteristic                        | N = 1,097 patients | 95% CI               |
| Lesion type                           |                   |                      |
| De novo                               | 78.5% (861/1,097) | [75.9%, 80.9%]       |
| Restenotic                            | 21.5% (236/1,097) | [19.1%, 24.1%]       |
| Lesion dilation                       |                   |                      |
| Present balloon angioplasty (%)       | 63.3% (694/1,096) | [60.4%, 66.2%]       |
| Poststenint balloon dilatation (%)    | 92.6% (1,015/1,096) | [90.9%, 94.1%]      |
| Stents per subject                    |                   |                      |
| 0                                     | 0.9% (10/1,074)   | N/A                  |
| 1                                     | 95.6% (1,027/1,074) | N/A               |
| >1                                    | 3.4% (37/1,074)   | N/A                  |
| Technical success                     | 97.1% (1,041/1,072) | [95.9%, 98.0%]     |

Numbers are % (n/N).
CI, confidence interval.

| TABLE III. 30-Day Clinical Outcomes |
|-------------------------------------|-------------------|----------------------|
| Clinical event                      | Event rate        | 95% CI               |
| Death, stroke, or MI               | 4.6% (47/1,025)  | [3.4%, 6.1%]         |
| Death and stroke                    | 4.1% (42/1,025)  | [3.0%, 5.5%]         |
| Stroke                              | 1.3% (13/1,025)  | [0.7%, 2.2%]         |
| Neurological                        | 0.5% (5/1,025)    | [0.2%, 1.1%]         |
| Cardiac                             | 0.5% (5/1,025)    | [0.2%, 1.1%]         |
| Non-neurologic and noncardiac       | 0.3% (3/1,025)    | [0.1%, 0.9%]         |
| Stroke b                            | 3.3% (34/1,025)  | [2.3%, 4.6%]         |
| Ipsilateral                         | 2.9% (30/1,025)  | [2.0%, 4.2%]         |
| Major ipsilateral                  | 1.8% (18/1,025)  | [1.0%, 2.8%]         |
| Minor ipsilateral                  | 1.2% (12/1,025)  | [0.6%, 2.0%]         |
| MI b                                | 0.5% (5/1,025)    | [0.2%, 1.1%]         |
| Q-wave MI                           | 0.0% (0/1,025)    | [0.0%, 0.4%]         |
| Non-Q-wave MI                       | 0.5% (5/1,025)    | [0.2%, 1.1%]         |
| Death, stroke, MI (≤24 hr)          | 2.8% (29/1,025)  | [1.9%, 4.0%]         |
| Death, stroke, MI (>24 hr and ≤30 days) | 2.1% (22/1,025)  | [1.3%, 3.2%]         |

*Patients could have more than one type of event.
*Death, stroke, and MI classifications were adjudicated by the Clinical Events Committee.
Numbers are % (n/N).
CI, confidence interval; MI, myocardial infarction.
were not reported to have had an MAE at the last contact. Thirty-two of the 72 nonevaluable patients had visits prior to the beginning of the follow-up window (i.e., at \(< 23\) days postprocedure) and were not reported to have had an MAE at the last contact.

At 30 days, the composite rate of CEC-adjudicated MAEs was 4.6\% (Table III). Over half [61.7\% (29/47)] of the reported 30-day MAE occurred within 24 hr of the procedure. Ten of the 13 deaths were classified as neurologic or cardiac; all MIs were non-Q-wave (Table III). No other serious, device-related adverse events were identified.

Stroke was the principal component of the 30-day MAE rate (34 of 47 patients with events) and the overall stroke rate was 3.3\% (Table III). Twenty (58.8\%) of these 34 patients had strokes that were conservatively adjudicated as “major” due to insufficient information to determine whether the event met the study definition.

The 30-day composite MAE rate was 4.2\% for asymptomatic patients and 5.5\% for symptomatic patients (Table IV). The overall stroke rate was similar among asymptomatic and symptomatic patients (3.2 \(\pm\) 3.7\%; \(P = 0.675\)). As shown in Fig. 2, strokes in eight of the 12 symptomatic patients with strokes (66.7\%) were adjudicated as major. Of the 22 asymptomatic patients who experienced strokes, 12 had major strokes (54.5\%). Neurologic death occurred at a statistically significant higher rate in the symptomatic cohort (1.2\%; 4/328) compared with the asymptomatic cohort (0.1\%; 1/697); \(P = 0.039\); Table IV.

No statistically significant or clinically meaningful differences were observed in 30-day clinical outcomes for subgroups based on sex, high-risk status, or age (Supporting Information Table 2).

### Table IV. 30-Day Clinical Outcomes by Symptomatic Status

|                  | Asymptomatic | Symptomatic | Difference | 95\% CI | \(P\) |
|------------------|--------------|-------------|------------|---------|-------|
| \(N\)            | 697          | 328         | NA         | NA      | NA    |
| 30-day MAE       | 4.2\%        | 5.5\%       | −1.3\%     | −4.2\%  | 1.5\% | 0.343 |
| Death            | 1.0\%        | 1.8\%       | −0.8\%     | NA      | NA    | 0.368 |
| Neurologic       | 0.1\%        | 1.2\%       | −1.1\%     | NA      | NA    | 0.039 |
| Cardiac          | 0.6\%        | 0.3\%       | 0.3\%      | NA      | NA    | 1.000 |
| Non-neurologic and non-cardiac | 0.3\% | 0.3\% | 0.0% | NA | NA | 1.000 |
| Stroke           | 3.2\%        | 3.7%        | −0.5\%     | −2.9\%  | 1.9%  | 0.675 |
| Stroke classification 1: major or minor | 1.7\% | 2.4% | −0.7\% | −2.6\% | 1.2% | 0.439 |
| Major            | 1.4\%        | 1.2\%       | 0.2\%      | NA      | 1.000 |
| Minor            | 1.4\%        | 1.2\%       | 0.2\%      | NA      | 1.000 |
| Stroke classification 2: ipsilateral or contralateral | 2.9\% | 3.0% | 0.1\% | −2.0\% | 2.3% | 0.910 |
| Ipsilateral      | 0.3\%        | 0.6\%       | −0.3\%     | NA      | 0.597 |
| Contralateral    | 0.3\%        | 0.6\%       | −0.3\%     | NA      | 0.597 |
| Stroke classification 3: ischemic or hemorrhagic | 2.9\% | 2.7% | 0.1% | −2.0\% | 2.3% | 0.910 |
| Ischemic         | 0.3\%        | 0.9\%       | −0.6\%     | NA      | 0.335 |
| Hemorrhagic      | 0.3\%        | 0.9\%       | −0.6\%     | NA      | 0.335 |

\(a\)Fisher’s exact test \(P\)-values; confidence interval for difference between groups is not provided in this case.

\(b\)All MI were non-Q-wave.

CI, confidence interval; MI, myocardial infarction; NA, not applicable.

![Fig. 2. Rate of stroke, 0–30 days postprocedure. Binary rates (% \(n/N\)) for all stroke, major stroke, minor stroke, ipsilateral stroke, contralateral stroke, ischemic stroke, and hemorrhagic stroke were calculated for all patients \((N=1,025)\) according to their baseline symptom status for the interval between 0 and 30 days postprocedure.](image-url)
Center Experience and Physician Training

No statistically significant differences in 30-day MAE rates were found among the center experience tiers \((P = 0.61)\) nor among the operator categories \((P = 0.26; \text{Fig. 1})\).

DISCUSSION

Data from the CABANA Registry suggest that, while 30-day MAE rates were similar to those from other CAS registries [5–8,10–13,16; Supporting Information Figure], greater center, or operator experience with CAS or with the Carotid WALLSTENT and FilterWire EZ embolic protection system did not provide a significant safety advantage for treatment of symptomatic and asymptomatic high surgical risk patients in routine clinical practice. The observed 4.6% 30-day MAE rate is similar to the combined death, stroke, and MI rate of 4.8% in the randomized stent cohort of the SAPHIRE trial, and the 30-day MAE rates for asymptomatic (5.4% in SAPHIRE) and symptomatic (2.1%) patients are likewise similar between the studies [1]. Furthermore, the CABANA 30-day MAE rates among asymptomatic and symptomatic patients are comparable to the rates seen in recent CAS registries of high surgical risk patients, which range from 2.7 to 6.8% for asymptomatic patients and 0–12.0% for symptomatic patients [6–9,11–13,17]. Collectively, these results demonstrate favorable CAS outcomes in a high surgical risk population, and suggest that CAS may be considered as an alternative to CEA for these patients. In addition, the Carotid WALLSTENT and FilterWire EZ were successfully delivered, deployed and retrieved in 97.1% of cases.

The study centers selected for CABANA represent diverse treatment facilities, from large teaching hospitals to community medical centers, and the participating physicians constitute a broad range of CAS experience levels and medical specialties, including interventional cardiology, interventional radiology, neuroradiology, vascular surgery, and neurosurgery. However, when study centers were grouped based on their respective CAS experience levels, no statistical difference in the low and acceptable MAE rates was seen among the study center groups (Fig. 1); these results are similar to those of other CAS safety and efficacy assessments across experience levels [7,8,29]. These previous studies had approaches to ranking center/physician experience that were similar to those used in CABANA, but the specific thresholds differed. In the CABANA study, all centers had been approved by CMS to provide CAS, and each principal investigator met minimum tier 3 experience criteria. No significant differences were seen when operators with specific Carotid WALLSTENT and FilterWire EZ experience but no required device training or proctoring were compared to those with little or no device-specific or general CAS experience, but who underwent Carotid WALLSTENT and FilterWire EZ training and proctoring. It may be that operators with less experience treated the less complex patients at their study centers. Indeed, a previous report from the CAPTURE registry showed that an apparent relationship between 30-day death and less CAS experience disappeared after adjusting for symptomatic status and age, 2 factors that were predictive of patient outcomes in their study [7,29]. Overall, however, these data suggest that device-specific training and proctoring, especially under the supervision of a CAS-credentialed operator with some CAS experience (in this case, the center principal investigator), may compensate for a lack of CAS or device-specific experience on the part of the operator and lead to safe CAS outcomes.

Although three study center experience tiers were evaluated in the CABANA study, 90.3% of patients were enrolled at tier 1 (high experience) or tier 2 (moderate experience) centers. Since a substantially smaller proportion of patients were treated at low experience centers, the outcomes from this center triage should be interpreted with caution. The principal investigators supervising each study center were credentialed to perform CAS procedures and center experience in the CABANA trial was defined based on the experience of the center principal investigator. However, it may be difficult to draw conclusions about the relationship between the experience of the principal investigator at a given center and the center outcomes, because the carotid stenting experience of the center principal investigator may not accurately reflect the experience of the participating subinvestigators at the same center. Similarly, the individual operators in the CABANA trial were not evenly distributed across the three designated training categories. In addition, the high complexity and co-morbidities of the patients enrolled in the study make it difficult to predict treatment outcomes based solely on principal investigator experience or operator experience and training.

CONCLUSIONS

The CABANA study yielded a low composite rate of 30-day MAEs (4.6%) and low individual rates of periprocedural stroke, death, and MI. These rates were consistent across study centers and operators with varying levels of CAS experience and training. Thus, the results from the CABANA study support the notion that physicians with various medical specialties and CAS experience
levels can safely and effectively use the new generation of the Carotid WALLSTENT and FilterWireEZ embolic protection device to treat patients with carotid artery disease who are at high risk for CEA.

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