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Experience and Outcomes With Carotid Artery Stenting

An Analysis of the CHOICE Study (Carotid Stenting for High Surgical-Risk Patients; Evaluating Outcomes Through the Collection of Clinical Evidence)

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ABSTRACT

OBJECTIVES This study sought to examine operator experience measured by time-related variables on outcomes with protected carotid artery stenting (CAS).

BACKGROUND Studies on experience have focused on operator and institutional CAS volumes alone in the absence of a better metric.

METHODS Using the CHOICE (Carotid Stenting for High Surgical-Risk Patients; Evaluating Outcomes Through the Collection of Clinical Evidence) multicenter prospective data from October 1, 2006 to June 1, 2012, 5,841 evaluable subjects were identified. Operator experience within this study was assessed using 5 variables for each operator: 1) baseline CAS volume; 2) time from first CAS to each subsequent CAS; 3) time between each CAS; 4) CAS volume in the institution; and 5) medical specialty (cardiology, surgery, or radiology/neurology). Institutional experience was determined by CAS volume within the study. Embolic protection device dwell time was used to assess technical performance, and 30-day death, stroke, or myocardial infarction composed the clinical outcome. Hierarchical logistic regression and linear mixed models were used.

RESULTS Cardiologists ($p < 0.001$) along with operators with longer time interval from first CAS ($p < 0.001$) had reduced embolic protection device dwell times (technical performance). Increased time interval between CAS was the only independent predictor of 30-day death, stroke, or myocardial infarction (adjusted odds ratio: 1.05, 95% confidence interval: 1.02 to 1.09, $p = 0.005$). Prolonged embolic protection device dwell time was associated with 30-day death, stroke, or myocardial infarction (adjusted odds ratio: 1.08; 95% confidence interval: 1.01 to 1.17; $p = 0.03$).

CONCLUSIONS The time interval between CAS procedures, specialty assignment, and time from first CAS are important measures of operator experience that may significantly affect technical performance and clinical outcome. (J Am Coll Cardiol Intv 2014;7:1307–17) © 2014 by the American College of Cardiology Foundation.

Previous surveys have demonstrated a close association between carotid artery stenting (CAS) experience as represented by operator or institution volume and the occurrence of periprocedural adverse events (1–3). In fact, in the absence of a better measure, multispecialty consensus

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ABBREVIATIONS AND ACRONYMS

CAS = carotid artery stenting

DS = death and stroke

DSMI = death, stroke, or myocardial infarction

EPD = embolic protection device

MI = myocardial infarction

NIHSS = National Institutes of Health Stroke Scale

documents recommend a minimum number of CAS procedures to achieve competence, and this has also been a requirement for randomized trials (4–6). However, this simplistic and broad approach may be inadequate (7–9).

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In an attempt to improve our understanding of operator-related factors on technical performance for CAS, we hypothesized that the embolic protection device (EPD) dwell time previously shown to be predictive of periprocedural stroke risk (10,11) may potentially serve as an acceptable metric. We expanded on the previous measures of experience (operator and institutional volume) by including time-dependent variables such as time elapsed since first procedure (as a representation of duration of time the operator has been practicing CAS) and time interval between procedures within the study. Additionally, real-time CAS volume for each operator was considered. The aim of this analysis accordingly was to test the effect of several operator and institution experience characteristics on EPD dwell time (technical performance) and 30-day death, stroke, or myocardial infarction (DSMI; clinical outcome) using the large prospective Acculink/Accunet subgroup of the CHOICE (Carotid Stenting for High Surgical-Risk Patients; Evaluating Outcomes Through the Collection of Clinical Evidence) clinical study.

METHODS

STUDY DESIGN AND PATIENT SELECTION. CHOICE was a prospective, single-arm, adjudicated, multicenter, post-market study designed to examine outcomes of CAS using Abbott Vascular (Santa Clara, California) carotid stents (Acculink and Xact) and embolic protection systems (Accunet, Emboshield, Emboshield Nav6). The study was initiated in 2006 and completed in 2012 at 366 sites in the United States and included 17,925 evaluable patients (96% of the total enrolled population) treated by 913 operators. Evaluable subjects were defined as patients who completed their 30-day follow-up visit or experienced DSMI within 30 days following the procedure. The current analysis pertains to the subgroup of all evaluable patients (N = 5,841) from the CHOICE clinical data who were exclusively treated with the Acculink carotid stent in conjunction with the Accunet distal EPD and for whom the EPD dwell time was available. Because operator learning curve and post-procedural outcomes may vary across devices, this analysis focused on a single stent, Acculink, and a single EPD, Accunet, which have the longest history in the CAS practice in the United States.

To be enrolled, a patient had to be considered to benefit from carotid revascularization but be at high surgical risk for carotid endarterectomy and be able to provide an informed consent for CAS. Carotid disease requiring treatment was defined as an ultrasound or angiographic stenosis of the common or internal carotid artery of ≥50% for symptomatic or ≥80% for asymptomatic patients. Symptomatic status was determined based on ipsilateral transient ischemic attack (including amaurosis fugax) or stroke within 180 days before the study procedure. There were no exclusion criteria for this study. The operators represented a broad range of medical specialties grouped under 3 main categories: cardiology, surgery, and radiology/neurology. The CHOICE study mandated institutional review board approval and oversight, adjudication of neurological events, and annual reporting of study progress to the Food and Drug Administration.

PATIENT CHARACTERISTICS. Patient demographics, comorbidities, previous treatment for carotid stenosis, aortic arch type, presence of aortic arch disease, target lesion characteristics, and procedural data were obtained prospectively and recorded using electronic case report forms. The baseline characteristics are summarized in Tables 1 and 2. The patients (N = 5,841) were treated with Acculink/Accunet by 597 operators at 248 institutions. Overall, 14% of patients were symptomatic at the time of CAS, and 22% were octogenarians (Table 1). Patient characteristics differed across the 3 clinician medical specialties (Table 1). Cardiologists had a higher proportion of patients with concomitant coronary artery disease (71%) and congestive heart failure (26%). Alternatively, surgeons and radiologists/neurologists had more patients with previous interventions (42%) or carotid endarterectomy (40%) to the target lesion and symptomatic carotid disease (28%), respectively (Table 1). No clinically meaningful differences in vessel characteristics were noted among the 3 groups (Table 2).

OPERATOR AND INSTITUTION EXPERIENCE CHARACTERISTICS. Operator experience characteristics were assessed using 5 variables for each operator within this analysis: 1) baseline operator CAS volume (self-reported total number of CAS procedures performed as primary operator before the operator enrolled his or her first patient in CHOICE); 2) time from first CAS to each subsequent CAS procedure for each operator; 3) time between each CAS procedure for the same operator; 4) operator volume