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Predictors of perioperative outcomes after carotid revascularization

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ABSTRACT

Background: The aim of our study was to compare and identify possible predictors of perioperative outcomes of carotid endarterectomy (CEA) with carotid artery stenting (CAS) using the procedure-targeted American College of Surgeons National Surgical Quality Improvement Program database.

Methods: Patients who underwent CEA or CAS were identified in American College of Surgeons National Surgical Quality Improvement Program (2011-2013). Univariate and multivariable logistic regression analyses were performed to evaluate the predictors of perioperative outcomes (any stroke or death, myocardial infarction [MI], 30-d readmission and reoperation). Final models were constructed based on the lowest Akaike Information Criterion.

Results: A total of 10,169 patients underwent carotid revascularization (CEA: 9817 [96.5%] *versus* CAS: 352 [3.5%]). Most patients were male (61%). Patients who had CAS were younger (mean age [±standard deviation]: 69.1 [±9.7] *versus* 71.3 [±9.4] y, $P < 0.001$); however, they showed a greater prevalence of diabetes (38.4% *versus* 29.2%), congestive heart failure (4.8% *versus* 1.4%), and chronic obstructive pulmonary disease (17.3% *versus* 10.2%) (all $P < 0.001$). The risk of postoperative stroke and/or death was nearly doubled with CAS (adjusted Odds Ratio = 1.84; 95% confidence interval: 1.07-3.18, $P = 0.028$). The odds of reoperation were higher in nonwhite patients compared with white patients (adjusted Odds Ratio: 1.34, 95% confidence interval: 0.97-1.84, $P = 0.078$). Perioperative MI and readmission were mostly related to patient's age and comorbidities.

Conclusions: In a national data set representing real-world outcome, CAS is associated with higher odds of postoperative mortality and stroke in comparison to CEA. Carotid revascularization procedure type is not a predictor of postoperative MI or readmission, suggesting that these outcomes are a function of other patient factors. Nonwhite race is a predictor of reoperation.

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Introduction

Current guidelines for stroke and transient ischemic attacks prevention recommend the use of carotid revascularization procedures in a select patient group in adjunct to optimal medical therapy.[1] Carotid endarterectomy (CEA) is recommended for symptomatic patients with >50% stenosis.[1] CEA is also recommended for appropriate risk asymptomatic patients with greater than 60% stenosis of the carotid artery. Carotid artery stenting (CAS) is recommended for patients with high medical or anatomic risk for CEA.[1] Historically, the use of CEA was not always encouraged. Early studies reported a high postoperative stroke rate and recommended restraining CEA use to only symptomatic patients with severe stenosis as the benefits did not outweigh the risks.[2] Refinement in the technique and perioperative management of CEA patients led to dramatic improvement in the outcome, and now, the benefit for CEA in symptomatic carotid artery stenosis and to lesser extent in more than 60% asymptomatic stenosis is well established. There was a parallel increase in the number of procedures performed in the western world.

Likewise, the initial postoperative outcomes of the minimally invasive CAS were prohibitive leading to premature termination of EVA -3s trial when the stroke rate was almost 3 times higher in the CAS compared with the CEA arms.[3] Ultimately, with advancing interventional expertise and the introduction of cerebral protective devices incorporated with better stents, the postoperative outcomes of CAS were improved.[4] The use of CAS has been expanding in the United States after publication of clinical trials that suggested noninferiority of CAS to CEA.[5] The utilization of CAS had increased from 3% in 1998 to 13% in 2008 of all carotid revascularization procedures, correlating well with clinical trials publication, such as SAPPHIRE that suggested favorable outcomes of CAS compared with CEA.[5] However, this had not been the case in the United Kingdom where the use of CAS remained cautiously low.[6] The difference between the rise of CAS in the United Kingdom and the United States can be attributed to the more conservative interpretation of the literature and trial results as well as the different payment and reimbursement systems that might not motivate the hospitals in the United Kingdom to endorse a new procedure when the cost of instruments and training is high to start with.

The SAPPHIRE trial as well the CREST trial later on, had shown that CAS is not inferior to CEA, and this conclusion had been determined based on the cumulative incidence of a composite end point of stroke, death, and myocardial infarction (MI).[7,8] The use of such an end point to compare the two procedures has been heavily criticized due to including minor MI with major stroke and death.[9] Furthermore, the main goal of carotid revascularization is to prevent stroke not MI. The risk of postoperative MI is mostly related to the invasiveness of the procedure and the patient's comorbidities. Nevertheless, the CREST trial had the lowest reported stroke outcome of both CEA and transfemoral CAS in symptomatic and asymptomatic patients to date. However, similar to any many other randomized clinical trials, CREST was also criticized for rigid inclusion criteria and inapplicability to real-world practice.

The American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP) database was developed as an initiative to improve the quality of surgical care.[10] The accuracy of administrative data had been constantly questioned, and its use to determine outcomes had been closely studied.[11,12] However, the recent procedure-targeted National Surgical Quality Improvement Program (NSQIP) provided detailed procedure-specific preoperative and postoperative variables that greatly improve the quality of evidence coming from this national data set.

The aims of this study were to use NSQIP data as a true representative of real-world outcomes and assess the effect of periprocedural parameters and patient characteristics on various outcomes after CEA and CAS.

Methods

Data source and study design

The ACS-NSQIP is a risk-adjusted, nationally validated data set examining post-surgical 30-d outcomes whether the postoperative outcomes occurred in inpatient or outpatient setting. Data entry is performed by certified Surgical Clinical Reviewers. Patients who underwent CEA surgery or CAS were identified in the corresponding procedure-targeted Participant Use Data File ACS-NSQIP for the years 2011, 2012, and 2013.[13-15]

Using procedure-targeted Participant Use Data File enabled us to control for the degree of internal carotid artery stenosis, patient's symptomatic status, and prior aspirin and beta blocker medications use. In addition, we controlled for the general risk factors that were obtained from the main NSQIP data set such as age, gender, race, smoking, history of diabetes and dialysis, preoperative laboratory values, and blood transfusion. Outcomes of interest were 30-d postoperative any death or stroke, MI, readmission, and unplanned reoperation. Postoperative MI was defined as a new transmural acute MI occurring during surgery or within 30 d as manifested by new Q-wave on electrocardiogram.

Statistical analysis

A new binary variable was generated to compare CAS with CEA. The type of carotid procedure is the primary predictor of interest. The Student's t test and Pearson chi-square test were used to estimate the mean and standard deviation of continuous and binary variables, respectively.

Univariate and multivariable regression models were developed to assess the predictors of each adverse outcome of interest. *P* value of significance was assigned at 0.05. For each outcome understudy, predictors were selected based on prior knowledge and the clinical relevance of the variables to fit a multivariable logistic regression model. Then, a T backward stepwise selection using the Akaike's Information Criterion[16] was performed. Final variables included in the model were patient's age, gender, race, smoking status, diabetes status, hypertension, symptomatic status, baseline internal carotid