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Original research article

Carotid artery stenting outcomes in high-risk patients receiving best medical therapy: Results from a single high-volume interventional cardiology practice

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ABSTRACT

Background: Carotid artery stenting (CAS) is now being widely used in the treatment of carotid artery stenosis. Recent clinical studies have demonstrated low adverse event rates after CAS. This study evaluates the 30-day and 1-year results in patients treated with CAS and receiving intensive medical therapy in a high-volume percutaneous coronary intervention center.

Methods: A total of 184 patients underwent CAS between January 2011 and December 2013. In addition to antiplatelet therapy, patients received intensive antihypertensive treatment, high intensity statin and heart rate normalization therapy. Patients were stratified according to age and symptomatic status.

Results: Most of the patients (86.4%) had at least one high surgical risk criteria. The procedural success rate was 98.4%. The 30-day and 1-year incidence of stroke were 4.1% and 4.5%, respectively. At 30 days the combined rate of stroke/cardiovascular (CV) death/myocardial infarction (MI) was 5.8% and 10.9% in 1 year. The 30-day incidence of stroke/CV death in asymptomatic and symptomatic patients was 5.4% and 4.2%, respectively. Age ≥80 years increased the risk of stroke/CV death/MI at 1 year (OR 4.41; 95% CI 1.06–18.36; $P = 0.04$).

Conclusions: The study demonstrated acceptable clinical outcome results in patients with high medical comorbidities treated with CAS and intensive medical therapy. Adverse event rate in symptomatic patients did not exceed the guideline recommended range while in asymptomatic patients it was increased.

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Introduction

Coronary artery disease is commonly associated with lesions in other vascular beds, including carotid arteries. More than half of patients with three vessel and/or left main coronary artery disease (CAD) have at least some degree of atherosclerotic carotid disease, while 7–11% of these patients have severe carotid artery stenosis (CAS) potentially mandating intervention [1]. Carotid artery stenosis frequently is newly diagnosed at the time of coronary angiography. Due to the high experience in the management of coronary atherosclerosis, a significant proportion of stenotic lesions in the carotids are now being treated by interventional cardiologists.

Low incidence of adverse events after stenting has been shown in several single and multicenter clinical practice studies [2–6]. One of the latest trials to date, Carotid Revascularization Endarterectomy vs. Stenting Trial (CREST) demonstrated comparable outcome rates after stenting and surgery. However, an interaction between age and treatment efficacy was detected with a crossover at an age of approximately 70 years [7]. Increasing risk for stroke after CAS was shown at older ages [8].

The objectives of this study were to evaluate the clinical outcomes and to analyze the impact of age in patients undergoing CAS in the background of intensive medical therapy.

Methods

A total of 184 patients underwent CAS from January 2011 to December 2013 and were enrolled in a prospective registry. The procedures were performed in a University Hospital Percutaneous Coronary Intervention (PCI) Centre with approximately 4000 PCI procedures per year. All CAS procedures were performed by high-volume interventional cardiologists with an experience level of more than 20 CAS procedures per year.

Patients were referred by their primary care physician or cardiologist after the diagnosis of carotid artery stenosis during a regular check-up, before coronary artery bypass grafting or valve surgery or after a stroke or transient ischemic attack (TIA). The stenosis was evaluated by duplex ultrasound, CT or invasive angiography. All patients underwent at least one CAS procedure. Patients with bilateral stenosis had revascularization at two stages.

The study was approved by an institutional review committee. All patients gave an informed consent. Patients were eligible for the study if the internal carotid artery diameter stenosis was ≥50% for symptomatic and ≥75% for asymptomatic patients confirmed by invasive angiography. The cut-off values were selected according to the inclusion criteria in randomized clinical trials and local revascularization practice. The exclusion criteria were allergy to antiplatelet therapy, recent gastric bleeding and/or hemorrhagic stroke.

All patients continued aspirin (75–100 mg/day) therapy and received clopidogrel loading dose 300 mg at least 24 h prior to CAS. During CAS, patients were anticoagulated with unfractionated heparin (100 U/kg). GPIIb/IIIa receptor antagonist administration was left to the discretion of the operator. Atropine was used before or during the procedure to prevent bradycardia. If severe hypotension developed during the procedure, dopamine or epinephrine infusion was initiated.

Unless otherwise indicated, dual antiplatelet therapy with aspirin (75–100 mg/day) and clopidogrel (75 mg/day) was prescribed for at least 6 months after CAS and aspirin continued lifelong. Patients with atrial fibrillation at least 6 months post-procedure received triple therapy with aspirin, clopidogrel and warfarin. Moderate intensity (20 mg atorvastatin or 10 mg rosuvastatin) or high intensity (40–80 mg atorvastatin or 20–40 mg rosuvastatin) statin therapy was prescribed lifelong for all patients. Antihypertensive therapy with the target blood pressure below 140/90 mmHg (or systolic blood pressure less than 130 mm/Hg in patients with diabetes) was prescribed for all hypertensive patients. Beta-blockers and/or ivabradine therapy was prescribed for heart rate normalization (60–70 beats per minute in patients with sinus rhythm).

Carotid arteries were accessed using a femoral approach with 6F introducer sheath or 8F, 9F or 10F guiding catheters. Embolic protection devices – distal embolic filters or MoMa (Invatech, Roncadelle, Italy) proximal cerebral protection device were used in all procedures. Predilatation was performed in patients with severe (≥90%) calcified stenosis if the stent could not be delivered through the stenotic lesion. Six types of stents were used, followed by a balloon catheter postdilatation.

Patients were defined symptomatic if they suffered a stroke or a TIA within the previous 180 days. Procedural success was defined as a successful stent placement with a residual stenosis of less than 30%. Patients were considered at high risk for CEA if they had at least one of the following criteria: age of ≥80 years; congestive heart failure NYHA III–IV; left main and/or ≥2 vessel coronary artery disease (CAD); urgent cardiac surgery in the preceding 30 days; MI within 30 days; contralateral carotid artery occlusion. Patients with any neurological symptoms after CAS were assessed by a neurologist. Any focal neurological deficit associated with stenosis lasting no longer than 24 h was defined as TIA. Any mild symptoms (minor stroke) or severe neurological symptoms (major stroke) persisting longer than 24 h were defined as stroke. Myocardial infarction was defined as elevation of cardiac biomarkers together with evidence of myocardial ischemia and with ECG changes indicative of new ischemia or development of pathological Q waves in the ECG. Vascular complications were defined as bleeding at the access site or any other bleeding that required a blood transfusion. Worsening renal function was defined as an elevation in the serum creatinine post-procedure.

Stroke, MI and cardiovascular (CV) death were analyzed 30 days and 1 year after stenting in the study population and in patients stratified by age <70 and ≥70 years. Stroke/CV death was analyzed in patients according to symptom status. Two patients were referred to CEA after the failure in gaining carotid access and were excluded from the clinical outcome analysis. The clinical follow-up included data about any cerebrovascular accidents, MI, death and other revascularization procedures (PCI, CEA, CABG) after the initial CAS. Follow-up information was not collected from 10 (5.5%) patients. In-hospital outcomes were analyzed in all study patients who

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