Proximal versus Distal Protection During Carotid Artery Stenting: Analysis of the Two Treatment Approaches and Associated Clinical Outcomes

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Key words
- Adverse events
- Carotid stenting
- Distal protection
- Embolic protection
- Proximal protection
- Treatment outcome

Abbreviations and Acronyms
CAS: Carotid artery stenting
DWI-MRI: Diffusion-weighted magnetic resonance imaging

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OBJECTIVE: **Cerebral protection device utilization during carotid artery stenting (CAS) has been shown to decrease risk of perioperative stroke. The two most commonly used devices are distal filters and proximal protection devices, which allow blood flow cessation or flow reversal. The goal of the present study was to examine anatomic and morphologic characteristics of the treated lesions using each type of cerebral protection device and compare clinical 30-day adverse event rates between the two cerebral protection groups.**

METHODS: **We conducted a single-center, retrospective review of consecutive CAS cases with proximal protection devices that were matched with CAS cases using distal filter protection devices based on indication (symptomatic vs. asymptomatic), age, and gender. We reviewed clinical, anatomic, and morphologic characteristics of the stented lesions in cases of proximal or distal protection and also studied the rate of major adverse events within the first 30 days after the procedure.**

RESULTS: **We identified a total of 70 patients treated with proximal protection devices who were matched in a blinded fashion to 70 cases with distal protection. There was a significantly higher number of high-risk lesions in patients who had CAS using proximal protection devices ($P = 0.009$). There was no significant difference in overall frequency of 30-day adverse outcomes (transient ischemic attack/stroke/reperfusion hemorrhage/death) between the two groups ($P = 1.0$).**

CONCLUSIONS: **Our study is the first attempt (to our knowledge) to review and compare anatomic and morphologic characteristics of the stented lesions in cases of proximal versus distal protection for CAS. Our data indicate that in properly selected patients both approaches could be equally safe and effective.**

INTRODUCTION

Carotid artery stenting (CAS) has become established as a less invasive alternative procedure to carotid endarterectomy for patients with carotid artery stenosis. Systematic reviews of previously published studies on protected and unprotected CAS indicate that the use of cerebral protection devices decrease the risk of perioperative stroke (4, 7). Distal filters (e.g., Filter Wire EZ; Boston Scientific, Natick, Masssachusetts, USA) and Emboshield NAV6 (Abbott Vascular, Abbott Park, Illinois, USA) are the most commonly used type of protection devices and have been incorporated into major recent trials. An alternative approach is to use proximal protection with the MO.MA device (Invatec, Roncadelle, Italy) or the GORE Flow Reversal System (WL Gore and Associates, Flagstaff, Arizona, USA) that create blood flow cessation or flow reversal during the stenting procedure by simultaneous balloon occlusion of the external and common carotid artery. Recent studies showed a reduction in the number of ischemic lesions documented by diffusion-weighted magnetic resonance imaging (DWI-MRI) with the proximal protection approach in comparison to the distal protection approach, although that did not translate into a reduction in adverse clinical outcomes (2, 8).

The choice of a particular protection approach depends on several factors, including anatomic features of the carotid vessel (e.g., tortuous or diseased internal carotid artery distal to the lesion), stenotic lesion characteristics (e.g., hemorrhagic plaque or intraluminal thrombus), and operator experience. The goal of this study was to examine anatomic and morphologic characteristics of the stenotic lesions and compare clinical 30-day adverse event rates between the two cerebral protection groups.

METHODS

Study Design, Setting, and Population

We conducted a single-center, retrospective review of consecutive cases of CAS in which proximal protection devices were used between January 2006 and March 2012. All procedures were done by

endovascular neurosurgeons proficient in performing the stenting procedure using both proximal and distal protection devices. Patients with symptomatic and asymptomatic carotid artery stenosis were included. Patients were considered symptomatic if they had an ischemic event corresponding to the affected carotid artery territory within 6 months of the intervention.

We matched these patients with CAS cases in which distal filter protection devices were used during the same time period, based on indication (symptomatic vs. asymptomatic), age, and gender. The matching procedure was performed by two of the investigators who were blinded to the clinical outcomes. Patients with CAS performed as a part of acute stroke intervention were excluded from the analysis.

The study was approved by the University at Buffalo Health Sciences Institutional Review Board.

Data Sources/Measurement

Clinical charts and imaging studies were reviewed for patient demographics, medical comorbidities, time of qualifying event, location and characteristics of stenotic lesions, and clinical outcomes. Plaque characteristics were classified based on the results of carotid Doppler imaging, computed tomographic angiography, magnetic resonance angiography, and digital subtraction angiography, according to previously published criteria (5, 12). Unstable/high-risk carotid plaque characteristics for increased risk of stroke were findings of irregular or ulcerated appearance of the plaque, heterogeneous plaque, intraplaque hemorrhage, and presence of intraluminal thrombus (3, 10, 13, 16, 18). Notes from cross-specialty preoperative planning conferences and operative records were reviewed to extract information explaining the rationale behind choosing a proximal or a distal protection device. Selection criteria included anatomic features (patency/presence of stenosis of the external and common carotid arteries influenced the choice of proximal protection balloon delivery and placement; tortuosity of the internal carotid artery beyond the lesion influenced the choice of distal filter deployment) and plaque characteristics (presence of intraluminal thrombus and unstable plaque features influenced the choice of a proximal protection balloon).

Procedure Description

All patients were placed on dual antiplatelet therapy with aspirin (325 mg daily) and clopidogrel (75 mg daily). In 2008, we started to routinely check for aspirin and clopidogrel resistance before the stenting procedure. Patients who were resistant to aspirin (defined as aspirin reaction unit value >550) were changed to a regimen of 325 mg of aspirin twice daily. Patients who were resistant to clopidogrel (defined as P2Y12 platelet inhibition percentage >237) were switched to prasugrel (10 mg daily). All procedures were performed under conscious sedation. Intravenous heparin was administered to achieve an activated coagulation time of 250–300 seconds.

For CAS cases with distal protection, a 6-F Cook Shuttle long sheath (Cook Medical, Bloomington, Indiana, USA) was used as the guide catheter and placed into the distal common carotid artery. A Filter Wire EZ or Emboshield NAV6 distal protection device was introduced over a 0.014-inch filter guide wire into the distal cervical internal carotid artery. Predilation of the stenotic lesion was typically not done, unless a critical degree of stenosis was encountered that precluded safe passage of the stent through the lesion. A self-expendable stent was then introduced over the filter guide wire and deployed. Angioplasty after stenting was performed with the balloon sized to the diameter of the nondiseased internal carotid artery, if indicated. At the end of the procedure, a retrieval sheath was advanced to capture and close the filter and remove it from the artery.

For CAS cases with proximal protection using the MO.MA device, a 9-F sheath was used to introduce the device. For CAS cases with proximal protection using the GORE device, a 9-F sheath for arterial access and a 6-F sheath for venous access were used. Occlusion of the external and common carotid artery after inflation of the balloons was demonstrated by contrast injection. Once flow cessation was confirmed, a 0.014-inch wire was advanced through the lesion and used to introduce the stent. Before or after dilation was performed, if necessary. Aspiration of 60–100 mL of blood was performed through the catheter before deflation of the external and common carotid artery balloons.

Variables

All patients treated with CAS were evaluated before the procedure to determine baseline neurological status. Patients admitted for a routine scheduled procedure were kept in the hospital for 24 hours after the procedure, and their neurological status, as well as laboratory data including electrocardiogram and troponin levels, was evaluated before discharge. Patients who were inpatients when they underwent CAS were similarly monitored for 24 hours after the procedure. All patients were seen in clinic for a 30-day follow-up examination.

The primary outcome measures were major adverse events occurring within the first 30 days after the procedure and were defined as follows. Stroke was defined as a new focal neurological deficit lasting at least 24 hours. If the symptoms lasted less than 24 hours and completely resolved, the event was defined as a transient ischemic attack. Myocardial infarction was defined as an increase in cardiac enzymes combined with electrocardiographic evidence of ischemia (17). Procedure-related mortality included deaths that were directly related to the procedure or occurred as a consequence of performing the procedure.

Statistical Methods

Statistical analysis for each outcome variable analyzed was performed with SPSS software (version19, IBM Software, Chicago, Illinois, USA). Univariate analysis comparing demographic factors and outcome was performed using Fisher's exact test for categorical data and a two-tailed t-test for continuous data. For all statistical analyses, a P value < 0.05 was considered statistically significant.

RESULTS

Descriptive Data

We identified a total of 70 patients treated with proximal protection devices during the CAS procedure. Of those, 49 patients were treated using the MO.MA proximal protection device (Invatec) and 21 patients were treated using the GORE Flow Reversal System (WL Gore and Associates). These patients were matched (based on stenosis symptomatology, age, and gender) with 70

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