Original Paper

The Use of Aspiration Catheter Systems for Embolic Protection during Intracranial Vertebral Artery Angioplasty and Stenting

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New Orleans, New Orleans, La., USA**Key Words**

Atherosclerosis · Embolic protection device · Stroke · Vertebrobasilar insufficiency

Abstract

Background: Posterior circulation strokes comprise approximately 20–25% of all strokes of ischemic origin. Strokes affecting this area carry a significantly higher risk for subsequent stroke or death as compared to anterior circulation strokes. Embolic protection device (EPD) use for carotid artery stenosis has translated into percutaneous interventions of proximal vertebral artery (VA) stenosis. However, the use of EPDs when treating intracranial lesions has yet to be studied and may not be feasible as the vessel caliber is frequently smaller than in existing devices. **Objective:** The aim of this study is to describe a proximal aspiration technique used during the treatment of intracranial VA and basilar artery (BA) atherosclerotic disease. **Methods:** Proximal embolic protection was utilized during the treatment of intracranial VA/BA stenosis with angioplasty and stenting in patients with medically refractory disease. **Results:** Three patients with severe symptomatic posterior circulation stenosis refractory to medical management were treated with angioplasty and stenting utilizing proximal aspiration. Pre- and post-treatment angiograms and MRIs were compared. Treated vascular stenoses were significantly improved, without new neurological deficits or ischemic injury identified on imaging. **Conclusions:** The proposed technique of proximal embolic protection may help overcome the challenge of embolus propagation inherent to the treatment modality that was encountered during the treatment of intracranial VA/BA stenosis.

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Introduction

Atherosclerotic disease is a major cause of ischemic events worldwide [1–3]. Posterior circulation strokes comprise approximately 20–25% of all strokes of ischemic origin. Strokes affecting this area carry a significantly higher risk for subsequent stroke or death as compared to anterior circulation strokes in the acute phase [7 days following initial stroke or transient ischemic attack (TIA)] [4, 5].

Carotid artery stenosis has been treated with angioplasty and stenting for several decades [6–8]. One of the major concerns with these procedures is the risk of embolic sequelae following percutaneous angioplasty and stenting. The distal embolic protection device (EPD) and the proximal cerebral protection Mo.Ma Ultra device (Medtronic, Memphis, Tenn., USA) were both developed and utilized to mitigate this risk [7, 9, 10]. Additionally, the Centers for Medicaid & Medicare Services (CMS) require the use of EPDs for procedure reimbursement [11].

Due to the evidentiary support for protection devices in the treatment of carotid artery lesions, EPD use has translated into percutaneous interventions of proximal vertebral artery (VA) stenosis [9, 12]. Lesions of a VA origin and at the V1 segment lend themselves well for distal embolic protection as vessel size approximates the coronaries; there are several devices available for use. However, the use of EPDs when treating intracranial lesions has yet to be studied, and may not be feasible as the vessel caliber is frequently smaller than in existing devices.

The use of EPDs has been described in several studies involving angioplasty and stenting of lesions of a VA origin [1, 5, 7, 9, 10, 12–14]. To date, newer or alternative methods for cerebral protection for the treatment of vertebrobasilar (VB) stenosis have not yet been elucidated. Aspiration systems are currently in use for recanalization of large vessel occlusions in ischemic stroke and may represent an additional method for reducing posterior circulation emboli from stenting and angioplasty.

Methods

Three patients with medically refractory VB stenosis were treated preemptively with the Penumbra aspiration system during VB angioplasty and stenting. Pre- and post-treatment angiograms and MRIs were analyzed for vessel occlusion and new ischemic injury. Follow-up modified Rankin Scale (mRS) scores were also recorded at discharge and the 3- and 6-month clinic visits.

Procedure in Detail

All patients were placed on aspirin 325 mg and clopidogrel 75 mg daily prior to the procedure and were continued on this regimen postoperatively. Using the Seldinger technique, an 11-cm 6-Fr Cordis sheath was placed in the femoral artery. Using a 5-Fr DAV catheter (Cook Medical Inc., Bloomington, Ind., USA), a diagnostic angiogram was performed. Heparin boluses (70 U/kg) were given following the diagnostic portion of the angiogram. Activated clotting time was maintained between 250 and 300 s throughout the procedure.

Following acquisition of imaging, the DAV catheter was then exchanged for a 0.070 6-Fr Neuron catheter (Penumbra Inc., Alameda, Calif., USA) using a Rosen Exchange 0.035 × 260 wire (Boston Scientific Corporation, Quincy, Mass., USA) in the subclavian artery. The Neuron catheter was then navigated as distally as possible in the target VA (V3 segment) proximal to the area of stenosis. Distal intracranial access was achieved with a Transcend Floppy 0.014 300-cm exchange-length wire (Boston Scientific Corporation). Proximal aspiration through the 6-Fr Neuron was achieved using the Penumbra aspiration pump. In one patient (case 1), aspiration was performed continuously during the entire procedure, resulting in a blood loss of 700 ml. Our technique was subsequently modified; in the rest of the cohort, Penumbra aspiration was only utilized while traversing the stenosis and during angioplasty and stenting, thus minimizing the blood loss to <150 ml. Following the intervention, pre- and post-treatment angiographic runs were compared. Post-treatment MRIs were acquired within 24 h.

Fig. 1. **a** Lateral pretreatment cerebral angiogram. **b** Lateral post-treatment cerebral angiogram. **c** Post-treatment diffusion-weighted MRI.

Results

Case 1

The patient was a 68-year-old female with a history of hypertension and a prior cerebrovascular accident with residual left-sided hemiparesis who presented with worsening dysarthria, dizziness and difficulty in balance refractory to medical management. Magnetic resonance angiography performed during evaluation confirmed severe stenosis of the right VB junction. On angiography, the left VA was hypoplastic with 80% stenosis of the V3 segment and termination in the left posterior inferior cerebellar artery. We were unsuccessful at accessing the right VA through a femoral approach; therefore, a 4-cm 6-Fr Cordis sheath was placed in the right brachial artery. The VA was selected with a 6-F Neuron catheter. Imaging revealed severe stenosis, >90%, of the V4 segment at the VB junction (fig. 1b). Our operative steps and supplies used were identical to the first patient's procedure; however, the Penumbra aspiration system was used continuously throughout the procedure, resulting in a 700-ml estimated blood loss. Post-treatment angiography demonstrated no residual stenosis (fig. 1c). Pre- and post-treatment MRI demonstrated stable areas of diffusion restriction in the anterior pons and bilateral cerebellar hemispheres (fig. 1a, c).

Case 2

The second patient was a 57-year-old male with a history of VB stenosis and posterior circulation stroke initially conservatively managed (aspirin/Plavix). He was readmitted after several recurrent episodes of dizziness and unsteady gait refractory to medical management. A cerebral angiogram demonstrated a dominant left VA with 60% stenosis of the V1 segment and 80–90% stenosis of the basilar artery (BA; fig. 2a). The 6-F Neuron catheter (Penumbra Inc.) was navigated to the distal V3 segment of the VA. Distal intracranial access was achieved with a Transcend Floppy 0.014 300-cm exchange-length wire (Boston Scientific), which was maintained in the distal posterior cerebellar artery. Pre-stent dilatation was performed with a 2.0 × 20-mm Gateway PTA balloon (Stryker Corporation, Kalamazoo, Mich., USA). Proximal aspiration utilizing the Penumbra aspiration system (Penumbra Inc.) attached to the base catheter was performed during manipulation of the stenosis (angioplasty and stenting). Following angioplasty, a Wingspan Stent 4.5 × 20 mm (Boston Scientific) was deployed across the area of stenosis under continuous proximal aspiration. Post-stent angioplasty was

Fig. 2. **a** Pretreatment diffusion-weighted MRI. **b** Post-treatment diffusion-weighted MRI. **c** Pretreatment anteroposterior (AP) cerebral angiogram. **d** Post-treatment AP cerebral angiogram.

performed with minimal residual stenosis (fig. 2b). Delayed imaging confirmed no platelet aggregation. Following the procedure, a MynxGrip closure device (Cardinal Health, Dublin, Ohio, USA) was placed. Post-treatment MRI demonstrated no new area of diffusion restriction (fig. 2c). At discharge and the 3- and 6-month follow-ups, the patient's mRS score was 0. Follow-up angiography was performed at 6 months, showing >70% in-stent stenosis; however, at the scheduled intervention date, repeat imaging showed improvement to <50% stenosis. This was attributed to the fact that the patient was an intermediate metabolizer of clopidogrel, which required raising the oral dose in order to increase the plasma levels of active metabolites [15].

Case 3

The last patient in our case series was a 75-year-old, right-handed male with a history of stroke (right face, arm and leg weakness). Magnetic resonance angiography images revealed severe basilar stenosis. The patient was managed conservatively with aspirin, Plavix and a statin. He was readmitted 2 months later with recurrent symptoms. Pretreatment MRI demonstrated a new area of diffusion restriction in the pons (fig. 3d). A cerebral angiogram revealed an isolated posterior circulation and >90% stenosis of the distal basilar artery with minimal antegrade contrast penetration (fig. 3a–c). Following placement of the Neuron catheter in the V4 segment of the right VA, the procedure was performed under proximal aspiration. Pre-stent dilatation was performed with a 1.5 × 9-mm Gateway balloon (Stryker Corporation). This was followed by a 2.5 × 20-mm Wingspan stent (Stryker Corporation). Final angiographic imaging revealed a significant improvement in vessel filling (fig. 3c, d). This patient was followed as an outpatient at 3 and 6 months, with a mRS score of 0 at both

Fig. 3. **a, b** Lateral pretreatment cerebral angiograms. **c** Anteroposterior (AP) pretreatment cerebral angiogram. **d, e** AP and lateral post-treatment cerebral angiograms. **f** Post-treatment diffusion-weighted MRI.

visits and only complaining of residual hand paresthesia. No additional angiography has been performed to date.

All patients were transferred to the intensive care unit postoperatively for monitoring and received a brain MRI on post-procedural day 1 to detect the presence of new areas of diffusion restriction. Follow-up mRS scores in all patients were 0–1. Repeat angiography was performed at 6 months on all patients in the study to evaluate for restenosis or disease progression.

Discussion

Various studies have examined intracranial stenosis and the endovascular treatment of VB disease. They have demonstrated that in the acute phase, up to 7 days following a posterior circulation TIA or stroke, the risk of subsequent stroke or death is significantly increased as compared to anterior circulation strokes. Eberhardt et al. [16] reported that after VB TIA or stroke, the risk for subsequent stroke over the following 5 years is 22–35% [17]. The WASID trial demonstrated annual stroke rates for patients with symptomatic intracranial vertebral or BA stenosis at 7.8 and 10.7%, respectively [3].

Endovascular interventions are currently being undertaken in patients with symptomatic VB intracranial stenosis refractory to medical treatment. Proximal vertebral lesions lend themselves well to distal EPDs. Conversely, due to vessel size and lesional configuration, EPDs are not typically utilized in distal vertebral or BA disease, and endovascular inter-

vention may lead to subsequent cerebrovascular events. Canyigit et al. [6] reported that 29% of the study cases had diffusion-weighted imaging abnormalities after the procedure. Neurologic complication rates vary widely based on the current literature (from 0 to 23%), likely secondary to the limited number of studies that have been conducted on intracranial stenting of VB lesions.

The use of the Penumbra aspiration system during vertebral stenting has not been described to date. As a result of our series, we now use proximal aspiration only with manipulation of the stenotic lesion to reduce total blood loss, as encountered in our second patient. Finally, proximal aspiration can be applied to any base/therapeutic catheter [e.g., 90-cm 6-F Envoy (Codman Neuro, Raynham, Mass., USA)]. We have applied this technique during the treatment of proximal VA stenosis in an additional patient, who required catheter placement in the VA ostia.

Although our limited retrospective series requires further prospective validation, we claim that the risk profile for the utilization of this proximal aspiration technique is extremely low. As flexible catheters become more navigable, we are able to achieve distal intracranial access with larger-diameter catheters, which lend themselves to proximal aspiration. Future catheter generations may also include balloon options that could theoretically improve flow reversal and embolic protection.

Conclusions

Due to recent advancements in endovascular therapy, intracranial VB stenoses have become treatable with endovascular angioplasty and stenting. Current recommendations advise angioplasty and stenting in symptomatic high-grade stenosis of >70% in patients whose symptoms are refractory to medical management [18]. The use of an aspiration system selectively during angioplasty and stent deployment may reduce clinically relevant periprocedural emboli and stroke risk. We realize that proximal aspiration cannot eliminate the documented stroke risk of 8.2% that is associated with perforator occlusion [19]. However, a decrease in embolic phenomena could have profound effects on both patients' quality of life and health care utilization resulting from the morbidity and mortality associated with VB stenosis and its management.

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Disclosure Statement

The authors have no personal or institutional financial interest in the materials described in this paper.

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