Efficacy of Carotid Artery Stenting by the Universal Protection Method

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Purpose: To avoid distal plaques embolization during carotid artery stenting, we developed Universal Protection Method that combined the use of a proximal common carotid artery balloon, an external carotid artery balloon, and a distal internal carotid artery filter, with continuous flow reversal to the femoral vein. Herein, we assessed the efficacy of the Universal Protection Method by comparing stenting outcomes before and after its introduction. *Materials and Methods:* We assessed outcomes for 115 cases before and 41 cases after the Universal Protection Method was adopted (non-Universal Protection Method and Universal Protection Method groups, respectively). We then compared procedure details, magnetic resonance imaging (within 48 hours after the procedure), intraprocedural complications, and postoperative stroke rates. *Results:* Ischemic stroke was not observed in the Universal Protection Method group, but 1 major stroke and 2 minor strokes were observed in the non-Universal Protection Method group. High-intensity areas were seen in 6 (15.0%) and 49 (42.6%) cases in the Universal Protection Method and non-Universal Protection Method groups, respectively ($P = .001$). Contrastingly, intraprocedural complications were observed in 9 (22.5%) and 21 (18.3%) cases in the Universal Protection Method and non-Universal Protection Method groups, respectively. Among these intraprocedural complication cases, high-intensity areas were observed in 1 case (11.1%) in the Universal Protection Method group and in 15 cases (71.4%) in the non-Universal Protection Method group. *Conclusions:* Universal Protection Method is a safe technique that is applicable to all patients undergoing carotid artery stenting, irrespective of individual risk factors. Notably, the incidence rates of both distal embolization and unexpected intraprocedural complications are low. **Key Words:** Carotid artery stenting—embolization protection device—distal embolization—reversal flow.

Introduction

Carotid artery stenting (CAS) is used to treat carotid artery stenosis and prevent strokes, particularly when the risks associated with carotid endarterectomy (CEA) are high.[1] Several studies have also confirmed the noninferiority of CAS to CEA for patients at low risk of CEA-related complications or who had asymptomatic stenoses.[2,3] Intuitively, embolic protection devices (EPDs) are expected to provide advantages during CAS, yet no randomized clinical trial has shown a clear benefit.[4] Surgeons in most institutions therefore select protection systems based on patient risk factors, expected tolerance to flow cessation by clamping the common carotid artery (CCA), and plaque

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properties. To avoid distal embolization of the plaque during the procedures, we developed a Universal Protection Method (UPM) that combined a CCA balloon, an external carotid artery (ECA) balloon, and an internal carotid artery (ICA) filter, with continuous reversal flow to the femoral vein.[5] We standardized the UPM for all CAS procedures to avoid the need to consider the usual patient characteristics. Simply deflating the CCA balloon then allowed us to proceed safely if complications arose.

In this study, we aimed to assess the efficacy of UPM by comparing the outcomes of CAS following the introduction of UPM with the outcomes before its introduction.

Materials and Methods

Patients and Data Collection

We performed 154 CAS procedures between January 2012 and June 2017. Before December 2015, distal protection systems or proximal protection systems (PPS) were selected based on the patients' characteristics. Since January 2016, all CAS procedures were performed with the UPM. We divided patients into the UPM group and the non-UPM group based on these 2 periods. Data were obtained and assessed retrospectively, including the following: age, sex, stenosis laterality, symptoms before CAS, stenosis grade, and plaque properties; protection method used; procedure length; magnetic resonance imaging (MRI) results, including diffusion-weighted intensity (DWI) obtained within 48 hours after the procedure; intraprocedural complications or problems; procedure dilatation rate; and procedure-related postoperative stroke.

Definitions

Symptomatic cases were defined as those that suffered cerebral infarction or transient ischemic attacks due to ICA stenosis within 3 months before CAS. The grade of stenosis was calculated based on North American Symptomatic Carotid Endarterectomy Trial (NACET) measurements, using digital subtraction angiography.[6] Plaque properties were assessed by T1-weighted black-blood MRI, and the signal intensity of the plaques was compared with that of the adjacent sternocleidomastoid muscle. The plaque property was defined as vulnerable if its signal intensity exceeded 1.5 times that of the sternocleidomastoid muscle. The procedure time was defined as the time from the start of the local anesthesia to the removal of the sheath. DWI–MRI was performed within 48 hours after the procedure to check for high-intensity areas (HIAs), and the location and number of these areas were recorded. Procedure-related postoperative strokes were defined as minor strokes, if symptoms disappeared completely within a few days, and major strokes, if symptoms were permanent. The dilatation rate was defined as the preoperative NACET minus the postoperative NACET.

Indications for CAS

CAS was recommended for symptomatic patients with stenoses greater than 50% and asymptomatic patients with stenoses greater than 70% in the carotid artery. These recommendations held even if no high-risk factors were present for CEA based on the SAPPHIRE trial.[1] Informed consent was obtained from all patients.

The Universal Protection Method

All patients were prescribed 2 of the following antiplatelet drugs for at least 2 weeks before undergoing CAS: 75 mg/day of clopidogrel and 200 mg/day of cilostazol. CAS was performed under local anesthesia in all patients. A 4 French gauge (Fr) Sheath and a 9 Fr Sheath (Radifocus; Terumo, Tokyo, Japan) were inserted to the right femoral vein and right femoral artery, respectively. Heparin was given (5000-7000 units intravenously) to achieve an activated clotting time > 250 seconds during the procedure.

First, a stiff-type Radifocus Guidewire M (Terumo) was navigated to the ECA of the affected side within a 5 Fr JB2 catheter (Medikit, Tokyo, Japan), before the JB2 was exchanged for a Mo.Ma Ultra (Medtronic, Minneapolis, MN) proximal cerebral protection device. After inflating the ECA and CCA occlusion balloons, the Mo.Ma Ultra was connected to the femoral vein to establish a continuous reverse-flow circuit. Reverse flow or stagnation of the ICA was confirmed by slow injection before crossing the lesion.

A Spider FX (Medtronic) was introduced to the distal side of the stenotic lesion and preballoon dilation to 3.5-4.5 mm was performed. A Carotid Wallstent (Boston Scientific, Marlborough, MA) was used for stenting, unless the ICA was clearly nontortuous. Postballoon dilatation to 4.5-5.5 mm was added when residual stenosis exceeded 20% or when adaptation of the stent was unsatisfactory. After that, the ICA filter was removed and the balloons were deflated in a stepwise manner. When symptoms of interrupted blood flow were apparent, deflation and inflation of the CCA balloon were repeated. A 9 Fr Optimo guiding catheter (TOKAI Medical, Aichi, Japan) and a 200/cm PercuSurge Guardwire (Medtronic) were substituted for the Mo.Ma Ultra when the access route was too tortuous to navigate.

Procedure Used before Adopting the UPM

Distal filter protection was adopted for cases in which intolerance to flow cessation was predicted. For cases in which tolerance was predicted, we adopted PPS using a CCA balloon and an ICA balloon. Intolerance and vulnerability were predicted when the NACET exceeded .95, and the plaque surface was rough. In these cases, when it was considered especially difficult to cross the lesion smoothly, we adopted continuous reversal of flow to the femoral vein plus PPS with a CCA balloon and an ECA balloon.