Long-Term Outcome of Balloon Angioplasty Without Stenting for Symptomatic Middle Cerebral Artery Stenosis

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Purpose: A recent randomized controlled trial demonstrated that aggressive medical management was superior to angioplasty with stenting for intracranial stenosis. The purpose of this study was to assess initial and long-term outcomes of balloon angioplasty without stenting for symptomatic middle cerebral artery (MCA) stenosis. *Methods:* We retrospectively analyzed the clinical data of 72 patients (mean age, 58.9 years old) with 84 balloon angioplasties without stenting for high-grade (>70%) atherosclerotic stenosis of the main trunk of the MCA. All patients had experienced recurrent transient ischemic attack or minor stroke resistant to medical treatment. We assessed perioperative and long-term outcomes such as restenosis and the recurrence of strokes. The follow-up period was a median of 63 months (range, 6-171 months). *Results:* Balloon angioplasty was successful in 97% of procedures. During the 30-day perioperative period, a total of 3 patients suffered from stroke (4.2%) without death. A total of 23 (31.9%) patients had restenosis at a time point that varied from 6 to 111 months. Diabetes mellitus (DM) was noted significantly more often in the restenosis group (39%) than in the nonrestenosis group (13%). Multivariate logistic regression analysis revealed DM (odds ratio, 4.84; 95% confidence interval, 1.196-19.62; $P = .027$) as an independent predictor of restenosis. Restenosis and DM were indicated as independent predictors of the recurrence of ischemic stroke and transient ischemic attack. *Conclusions:* Balloon angioplasty without stenting for symptomatic MCA stenosis can be performed with a high successful rate and a low risk of complications. Long-term outcome data suggest that this procedure reduces the risk of further strokes. **Key Words:** Intracranial artery stenosis—middle cerebral artery—angioplasty—long-term outcome.

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Introduction

Atherosclerotic intracranial artery stenosis is an important cause of ischemic stroke, particularly in the Asian population.[1,2] In a previous prospective Warfarin-Aspirin Symptomatic Intracranial Disease trial, ischemic stroke in the territory of the symptomatic artery or in any vascular territory occurred in 14% and 19% of the 569 patients within 2 years.[3] These reports showed that medical management alone is insufficient for the prevention of recurrent ischemic events in patients who had symptomatic intracranial stenosis.

Endovascular treatments, such as balloon angioplasty with or without stenting, have emerged as therapeutic options for symptomatic intracranial stenosis since the 1980s.[4] Although intracranial angioplasty had a high risk of complications initially, recent advances in neurointerventional devices has contributed to the improvement of the successful rate.[5] Intracranial stenting could have theoretical advantages over primary angioplasty by preventing early elastic recoil, negative remodeling, and acute dissection. However, the results of a randomized controlled trial of Stenting and Aggressive Medical Management for Preventing Recurrent Stroke in Intracranial Arterial Stenosis showed that aggressive medical management was superior to angioplasty and stenting with the use of the Wingspan stent system (Stryker Neurovascular, Maple Grove, MN, USA). Indeed, the 30-day rates of stroke and death were 14.7% (10.2% ischemic, 4.5% hemorrhagic) with stenting versus 5.8% with aggressive medical management.[6] However, this special medical treatment is not easy for many patients as a routine method.

Severe symptomatic stenosis of the main trunk of the middle cerebral artery (MCA) carries a high risk of recurrent stroke. Stenting for MCA stenosis has previously been suggested as a high-risk procedure because of perforator occlusion. Angioplasty without stenting for symptomatic MCA stenosis has been reported to be performed with a relative low complication rate. Recently, submaximal angioplasty for symptomatic intracranial atherosclerosis is noted as an alternative procedure; however, there are few reports on the long-term clinical outcome.[7] The purpose of this study was to investigate the immediate results and long-term clinical follow-up of using balloon angioplasty without stenting in the patients who had symptomatic MCA stenosis. We also estimated clinical parameters associated with restenosis, as well as the recurrence of ischemic stroke and transient ischemic attack (TIA) after the procedure.

Methods

Patient Selection

We retrospectively evaluated clinical and radiographic characteristics of 72 consecutive patients and 84 balloon angioplasties without stenting for symptomatic atherosclerotic MCA stenosis in our hospital between 2000 and 2014. During this study, neither coronary stents nor the self-expanding Wingspan stent was allowed to use for endovascular treatment of intracranial artery stenosis in Japan.

Inclusion criteria for this study were as follows: (1) angiographically significant stenosis (≥70%) of the main trunk of the MCA; (2) recurrent minor ischemic stroke or TIAs due to the MCA stenosis; (3) a lesion length of less than 10 mm; and (4) written informed consent obtained before treatment. In addition, the perfusion reserve was estimated in the majority of patients by single photon emission computed tomography or perfusion computed tomography. Exclusion criteria were (1) acute ischemic stroke treated at less than 24 hours from TIA and less than 30 days from a minor stroke; (2) a tandem extracranial lesion undergoing treatment; and (3) serious medical problems such as heart or renal failure. This study received our institutional review board approval. The approval number was 3177. Informed consent for the procedure was obtained from all patients.

The diagnostic criteria of atherosclerotic intracranial stenosis were as follows: (1) no angiographic finding of cerebral arterial dissection; (2) the patient had at least 2 of the following vascular risk factors: hypertension, dyslipidemia, diabetes, peripheral arterial disease, coronary artery disease, smoking, pre-existing atherosclerotic stenosis in other locations, or the presence of aortic plaques.

The degree of MCA stenosis was measured at the point of maximal narrowing and compared with a normal segment distal to the stenosis, or proximal to the stenosis if a bifurcation was identified downstream of the stenosis. All patients underwent preoperative magnetic resonance imaging.

Interventional Techniques

All procedures were performed with the patients under local anesthesia via a transfemoral approach. A 6-F guiding catheter was inserted into the distal cervical internal carotid artery. Heparin (5000 U) was given intravenously after placement of the guiding catheter. A Gateway balloon catheter (Stryker, Maple Grove, MN), an Unryu balloon catheter (Kaneka Medics, Tokyo, Japan), or coronary balloon catheters were used in procedures. A balloon catheter with a diameter (from 1.5 to 2.5 mm) smaller than that of the normal vessel just distal to the stenosis was chosen to reduce the risk of vessel rupture. Additionally, the balloon catheter was short in length (9 or 10 mm). A .014-inch micro-guidewire was navigated across the target site. The balloon catheter was gradually inflated over 60 seconds to a maximum atmospheric pressure of 6 and was kept inflated at this pressure for 15-30 seconds. In general, the balloon was inflated once and not upsized. After the rapid deflation of the balloon, the result was verified. Before the micro-guidewire was removed from the target lesion,