Safety and Efficacy of Wingspan Stenting for Severe Symptomatic Atherosclerotic Stenosis of the Middle Cerebral Artery: Analysis of 278 Continuous Cases

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Objective: Our objective is to investigate the safety and long-term efficacy of the Wingspan stent (Boston Scientific, Natick, MA, USA) for treating severe atherosclerotic stenosis of the middle cerebral artery (MCA). *Methods:* A total of 278 consecutive patients from our stroke database with clinical symptoms within the prior 90 days and intracranial atherosclerotic stenosis of 70% or above of the MCA were enrolled in this study between September 2012 and November 2014, and these patients were followed until the end of June 2015. The endpoint events included any stroke or death within 30 days after stenting and any subsequent ipsilateral ischemic stroke. *Results:* Among the 278 enrolled patients, 277 patients (99.6%) successfully underwent stenting. The mean rate of stenosis decreased from 82.5 ± 7.9% to 9.0 ± 3.2% following treatment. Within 30 days after stenting, 12 patients (4.3%) experienced endpoint events, including 8 cases (2.9%) of hemorrhagic stroke and 4 cases (1.4%) of ischemic stroke; 2 perioperative deaths occurred. During 8-33 months of follow-up, 19 patients developed endpoint events. The 1- and 2-year endpoint event rates were 5.8% (95% confidence interval [CI], 5.0%-15.7%) and 7.2% (95% CI, 4.3%-10.1%), respectively. *Conclusions:* From this study, we can conclude that the treatment of severe symptomatic atherosclerotic stenosis of the MCA using the Wingspan stent was safe and effective and that the long-term stroke recurrence rate after stenting was low. **Key Words:** Middle cerebral artery stenosis—Wingspan stent—medical treatment—efficacy.

Introduction

Intracranial atherosclerosis is a major cause of stroke.[1,2] Currently, secondary prevention strategies for this disease include medication and stenting.[3] Studies have shown that medication alone cannot effectively reduce the development of stroke from severe intracranial atherosclerotic stenosis.[4] As a new treatment method, intracranial artery stent angioplasty has recently been implemented domestically and internationally.[5-8] However, different studies have obtained inconsistent results concerning the curative effects of stenting.[4,5] The middle cerebral artery (MCA) is the principal site of intracranial atherosclerotic stenosis and is the most common region of stroke in Asians.[9]

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Because the luminal diameter of this artery is small and its path is tortuous, endovascular stent angioplasty of the MCA is difficult, and the rates of recurrent stenosis and complications such as postoperative hemorrhage are higher in the MCA than in the posterior circulation.[10,11] Few domestic or international long-term follow-up studies with large sample sizes have focused on this issue.[12] Therefore, we evaluated the efficacy of Wingspan stent (Boston Scientific) implantation in 278 consecutive patients with severe atherosclerotic stenosis of the MCA to provide evidence to support future multicenter randomized controlled trials (RCTs) of Wingspan stent implantation in the MCA.

Materials and Methods

General Clinical Information

Two hundred seventy-eight consecutive patients with symptomatic stroke or transient ischemic attack (TIA) within 90 days were registered in the stroke database of the Department of Neurology at the Second Affiliated Hospital of the Third Military Medical University from September 2012 to October 2014. The inclusion criteria consisted of digital subtraction angiography verified stenosis of the MCA of 70% or higher that caused TIA or ischemic stroke within 90 days, with the degree of stenosis measured based on the Warfarin–Aspirin Symptomatic Intracranial Disease criteria[13]; over 24 hours from the final TIA event and over 7 days from the final stroke; lesion length of less than 15 mm and normal arterial diameter adjacent to the stenosis ≥2 mm; age between18 and 85 years old; at least 1 atherosclerotic risk factor (hypertension, diabetes mellitus, hyperlipidemia, and smoking); and a cerebral blood flow decrease of 30% or higher compared to perfusion on the contralateral MCA circulation territory on computed tomography perfusion (CTP) imaging. The exclusion criteria consisted of a nonatherosclerotic lesion confirmed by high-resolution magnetic resonance imaging (HR-MRI); concurrence with intracranial pathology including tumors, aneurysms, or arteriovenous malformation; contraindication to heparin, aspirin, clopidogrel, and anesthetic, metal, or contrast media; women during gestation period; and life expectancy of less than 1 year due to other medical conditions. All patients received evaluations by experienced experts in neurology and a series of corresponding evaluations were performed to confirm the feasibility of receiving stent implantation therapy.

The study was approved by the Medical Ethics Committee of Xinqiao Hospital, Third Military Medical University. Written informed consent was obtained from the participant or an authorized family member for all participants. The study protocol was performed in accordance with relevant ethical guidelines and regulations for human studies.

Preoperative Preparation

Examinations of coronary and cranial computed tomography angiography, whole-brain CTP imaging, and HR-MRI were performed before surgery. Routine oral aspirin (300 mg/day) and clopidogrel (75 mg/day) were administered 3-5 days before surgery. During the hospitalization and treatment periods, major risk factors (blood pressure was maintained at <140/90 mmHg) and minor risk factors (the glycated hemoglobin level of diabetic patients was maintained at <7.0%, or the fasting blood glucose level was maintained at <6.1 mmol/L) were controlled as appropriate. Hypercholesterolemia was treated to maintain low-density lipoprotein (LDL) levels at less than 2.5 mmol/L. Smoking and drinking were prohibited, and each patient's lifestyle was adjusted. Patients with indications of coronary artery involvement were evaluated by cardiologists, and if there were no contraindications, implantation of coronary artery and intracranial artery stents was performed simultaneously.

Stenting Procedure

Three surgeons with experience involving more than 100 cases of intracranial stent implantation performed the surgery. After general anesthesia, the patients received 3000 U of low–molecular-weight heparin sodium intravenously for systemic heparinization. Right femoral artery puncture was performed using the Seldinger technique to place a 6F/8F arterial sheath. A 6F guiding catheter (Cordis Corporation, Miami, FL) was delivered to the C2 segment of the internal carotid artery. Microcatheter insertion combined with guidewire exchange was performed to place the guidewire in the distal end of the stenotic vessel. A Gateway balloon was placed across the stenotic segment for balloon dilation. Then, the balloon was removed, and the Wingspan stent was placed in the lesioned vessel. After radiographic examination revealed that the degree of stenosis had significantly improved, the stent delivery system was removed. After observation for half an hour, intracranial angiography was repeated. If no abnormalities were observed, the surgery was completed.

Perioperative Management

CT scanning was performed immediately after surgery to exclude brain hemorrhage. Blood pressure was controlled at 110-130 mmHg/70-80 mmHg using antihypertensive drugs to prevent hyperperfusion syndrome. Patients who were free of hemorrhage were administered subcutaneous injections of low–molecular-weight heparin at 4000-6000 U/12 hours for 3-5 days. Oral treatment with aspirin (100 mg/day) and clopidogrel (75 mg/day) was continued for at least 1 month, followed by long-term oral administration of either aspirin (100 mg/day) or clopidogrel (75 mg/day). Oral atorvastatin