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Ischemia

Intracranial angioplasty with Gateway-Wingspan system for symptomatic atherosclerotic stenosis: preliminary results of 27 Chinese patients

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Abstract

Background: We investigated the safety of treatment of symptomatic intracranial atherosclerotic stenoses with the Gateway-Wingspan system and its initial effect on prevention of ischemic events.
Methods: Twenty-seven cases of symptomatic intracranial atherosclerotic stenoses were treated with angioplasty with a Wingspan stent. Location of stenoses, extent of stenoses before and after angioplasty, success rate of treatment, occurrence of procedural complications, and changes in recurrence of symptoms of ischemic events 30 days after treatment were recorded.
Results: Twenty-nine angioplasties with the Wingspan system were successfully carried out in 29 stenoses in 27 patients. Of 29 stenoses, 17 were in the posterior circulation, and 12, in the anterior circulation. The degree of stenoses was reduced from baseline 71.8% (56%-87.8%) to 24.9% (0%-45%) after stenting. Complications were seen in four patients (14.8%), 3 of which were lesion-related infarction of a perforated artery, and 1 was a non-lesion-related infarction. Two complications led to transient neurologic dysfunction, one led to defect of the visual field, and one led to hemiplegia. The prevalence of morbidity and serious morbidity were 7.4% and 3.7%, respectively, and no death occurred. No new ischemic events happened during 30 days after stenting.
Conclusion: Angioplasty with the Wingspan system to treat symptomatic intracranial atherosclerotic stenoses appears to be safe. Its initial effect on prevention of ischemic events is acceptable.

Keywords: Intracranial artery; Stenosis; Angioplasty; Stent

1. Introduction

Intracranial atherosclerotic stenosis is a main cause of acute stroke or TIA, and its prevalence differs between races [18]. A higher prevalence in Chinese subjects was reported [5,9,22]. The prognosis of patients with serious intracranial atherosclerotic stenosis was poor [4]. A high risk of ischemic events was noted even if patients were taking aspirin and warfarin, and the prevalence increased with stenosis severity [2,4,16,21]. Angioplasty with or without stents is recommended for serious intracranial atherosclerotic stenosis. Several studies have shown that recurrence rates for patients with intracranial atherosclerotic stenosis decreased after angioplasty with a balloon or balloon-mounted stent [10,11,15], but these procedures were associated with a high prevalence of complications (eg, vessel injury) [7,14].

The Gateway-Wingspan system uses a self-expandable stent to treat intracranial stenosis. Initial results indicated that it was safe and effective with an acceptable prevalence of complications and mortality [3,6,8]. The present study details the initial experiences and preliminary results after

Abbreviations: CT, computed tomography; DSA, digital substraction angiography; GESICA, Groupe d'Etude des Sténoses Intra-Crâniennes Athéromateuses; TIA, transient ischemic attack; WASID, warfarin and aspirin for symptomatic intracranial arterial stenosis.

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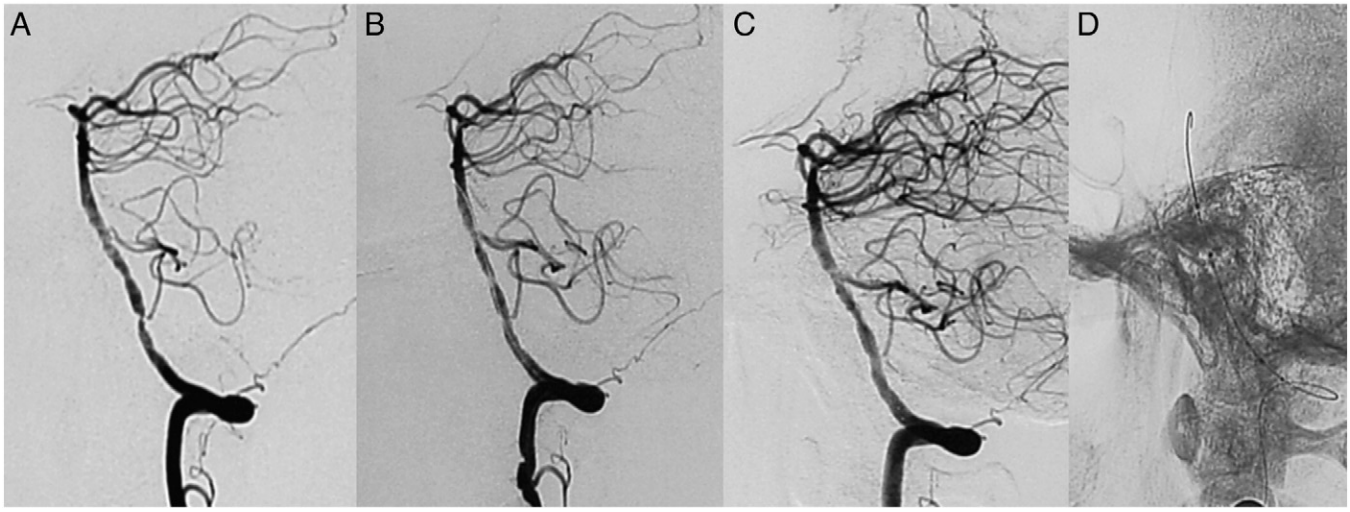

Fig. 1. Stenosis located at the vertebral artery; the degree of stenosis was 81%. A: Lateral projection before treatment showing obvious stenosis at the origin of the posterior inferior cerebellar artery. B: Reduced stenosis after angiography with the Gateway balloon. C: No serious residual stenosis after stenting; D: Lateral fluoroscopy showing the mark of the Wingspan stent during the procedure.

its use in Chinese patients with intracranial stenosis at our institution and after it was introduced in Chinese hospitals in April 2007.

2. Patients and methods

This was a retrospective review study. Twenty-seven patients (age, 36-71 years; mean, 60.1 years) with intracranial atherosclerotic stenoses received angioplasty with the Wingspan stent system in Tangdu Hospital (Xian, China) from May to October 2007. All subjects had a history of ischemic events before treatment. Fourteen patients presented with TIA including paroxysmal aphasia or hemiplegia, 9 patients presented with acute stroke but recovered well after taking medication, and 4 patients had transient or persistent dizziness. Before angioplasty, 17 patients were examined by digital subtraction angiography, 7 by CT angiography, and 4 by magnetic resonance angiography. Clinical risk factors included hypertension in 9 patients, diabetes mellitus in 8 patients, and both disorders in 4 patients (Fig. 1).

The method of stenosis measurement was in accordance with the WASID study [4]. Twenty-nine stenoses with a degree of more than 50% were found in 27 patients with a average length of 9.3 mm (3.9-15.9 mm), and 12 stenoses were longer than 10 mm. Stenoses were at the vertebra basilar artery in 15 patients, M1 of the middle cerebral artery in 10 patients, and the internal artery in two patients (Fig. 2).

2.1. Procedure

Interventions were via the common femoral artery. After conventional angiography, the targeted parent vessel was accessed through a 6F guiding catheter (Envoy, Johnson&-Johnson, Boston, MA, USA). A 300-cm exchange microwire (Transend Soft Tip or Tandsend Floppy, Boston Scientific, Boston, MA, USA) was manipulated across the

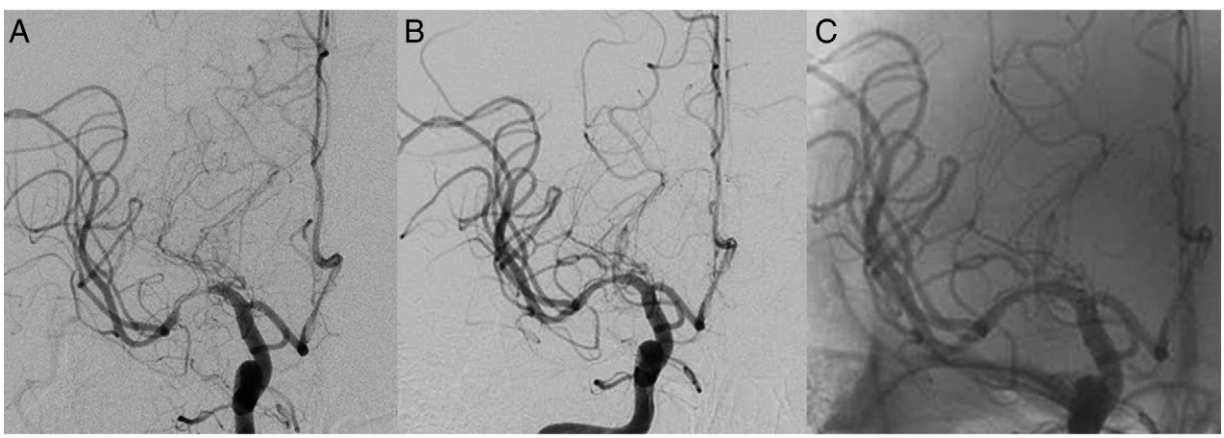

Fig. 2. Stenosis located at the M1 part of the right middle cerebral artery; the degree of stenosis was about 85%. A: Anteroposterior projection before treatment showing serious stenosis. B: A residual stenosis of about 34% after stenting. C: Fluoroscopy showing the marks of the Wingspan stent after treatment.

stenosis. A Gateway balloon was introduced via the microwire to the lesion. After ascertainment of optimal location by angiography, the balloon was slowly inflated at 6 atm for about 10 seconds. The balloon was removed and angiography done. A Wingspan stent was advanced through microwire to the stenosis and released at a suitable position. Stenosis measurement was carried out under calibration of a 1-cm metal ball. Balloon diameter was sized to 80% of the normal diameter of the parent vessel. Balloon length was selected to match lesion length. Stent diameter was sized to exceed the diameter of the normal parent vessel by 0.5 mm. Stent length was selected to completely cover the entire diseased segment and at least 3 mm of the normal vessel at the proximal and distal ends. Procedures were done under intubation and general anesthesia; monitoring was by digital subtraction angiography using an Innova 3100 machine.

2.2. Medication

Heparin was routinely infused at the beginning of the procedure. Heparin quantity was calculated according to the equation: 2/3 body weight (kg) × 125 (U). Every hour, half of the initial amount was infused to keep the activating time at about 300 s. Patients took aspirin (300 mg) and clopidogrel (75 mg) every day via the oral route at least three days before treatment. Typically, they were treated with the same dosage for a minimum of 3 months after stenting. Low-molecular-weight heparin was injected (SC) twice daily for 3 days after stenting. The blood pressure was not demanded to control to normal level before stenting, and it must be decreased to two thirds of the blood pressure preoperation after stenting.

2.3. Evaluation and follow-up

Success was defined as completion of Gateway balloon angioplasty and placement of the Wingspan stent across the target lesion despite the degree of residual stenosis or complications related to the procedure. All post-stenting angiograms were available and residual stenosis was measured. Cases with procedural-related complications were selected. Radiologic findings, clinical presentations, and clinical sequelae were recorded. Neurologic deficits were classified as transient deficits (resolved within seven days after stenting) or persistent deficits (persisted longer than 7 days). We defined procedure-related morbidity as persistent deficits. Patients were followed up by telephone, email, or outpatient visit 30 days after treatment. More attention was paid to recurrence of ischemic symptoms before stenting and occurrence of new stroke.

3. Results

Twenty-nine lesions in 27 patients were revascularized with 29 Gateway-Wingspan stent systems. Sixteen stenoses of the vertebra basilar artery in 15 patients were treated with 16 Wingspan stents; 9 stenoses of the middle cerebral artery in 9 patients were treated with nine Wingspan stents; and stenoses of the middle cerebral artery and basilar artery in 1 patient were treated with two Wingspan stents. The Gateway balloons crossed stenoses smoothly in all patients and there was no dissection after angioplasty. Stents were released at a suitable position with a procedural success value of 100%. The degree of stenoses was reduced from a baseline of 71.8% (56%-87.8%) to 24.9% (0%-45%) after stenting.

Complications occurred in 4 patients (14.8%). One patient with stenosis of the basilar artery presenting with hemiparesis experienced aggravated hemiparesis. CT did not reveal signs of hemorrhage, and 3 days later, the patient recovered to the condition before stenting. New hemiparesis was found in 1 patient with stenoses of the middle cerebral artery and CT did not show a new lesion after stenting. Angiography done 24 hours later revealed improved residual stenosis, and CT carried out 4 days later found new lacunar infarction at the basal ganglia. The hemiparesis resolved 4 days later. Focal defect of the visual field occurred in one patient with stenosis of the middle cerebral artery, and a small infarction at the occipital lobe was found at CT 2 days later. The most serious complication occurred in one patient with stenosis of the basilar artery presenting with paroxysmal hemiparesis. He suffered hemiplegia after stenting, and magnetic resonance angiography showed a new infarction in the brainstem. Overall, the morbidity and mortality of this case series were 7.4% and 0%, respectively.

Thirty days after treatment, patients were followed up by telephone, email, or outpatient visit. Of 23 patients without a complication, 11 patients with a history of TIA had no recurrent TIA, and 4 patients presenting with dizziness had greatly improved symptoms. Of 4 patients with complications, 2 patients experiencing transient neurologic deficit rehabilitated to the condition before treatment; the patient with defect of the visual field improved slightly; and the hemiplegic patient showed no improvement. No new ischemic events occurred to any patient during the 30-day follow-up.

4. Discussion

Cerebrovascular disease is one of the main causes of death worldwide. In the United States, about 700 000 patients are diagnosed with ischemic stroke every year [1], whereas up to 1.5 million are diagnosed with the same condition in China [19]. For whites, about 8% to 10% of cases of acute infarction are caused by intracranial atherosclerotic stenosis [18]. The prevalence is as high as 33% in Chinese subjects [22]. The cause was intracranial stenosis in nearly 50% of Chinese patients presenting with TIA [9]. Effectively treating intracranial atherosclerotic stenosis is clearly an important issue for Chinese patients. According to the WASID study, more than 10% of patients will experience acute stroke in one follow-up even if they are taking aspirin or warfarin [4]. As shown in the GESICA trial, the prevalence of ischemic events during 2-year

follow-up for patients with intracranial stenosis of the internal carotid artery was 38.2%, whereas it increased to 60.7% for patients with greater than 70% stenosis [16]. Even without the support of results from randomized controlled trials, angioplasty or stenting were recommended for patients with serious intracranial stenosis. Several reports involving small numbers of patients with intracranial stenosis who were treated with coronary angioplasty catheters or balloon-expandable stents have shown promising results [7,10,11,14,15].

The intracranial artery is more fragile then peripheral arteries due to lack of a muscle layer in the vessel wall and the support of peripheral tissues. The high inflation pressure of the balloon increases the risk of arterial rupture. Several methods have been adopted to avoiding disastrous bleeding during angioplasty with a balloon-mounted stent, including staged stenting [13], using undersized stents [17], and or expanding the stent very slowly [12]. To some degree, these methods reduced the rate of bleeding, but they increased the chance of ischemic complications [12,13]. Under the instructions of the Gateway-Wingspan stent system, the diameter of the Gateway balloon was 80%, and the diameter of the normal vessel and the Wingspan stent can be released without high inflation pressure and rapid expansion. Theoretically, the system could reduce hemorrhage risk. Analyzing reports of the Wingspan stent [3,6,8] of 4 patients who had bleeding complications, only 1 was directly related to the device. The characteristics of the stent produce a high degree of residual stenosis. This result could be seen in three related reports on the Wingspan stent, and the highest degree of residual stenosis was up to 38% [8]. Even the best result of our series produced a mean residual stenosis of 24.9%. According to Poiseuille's law, the increase in the amount of blood was 4 times the increase in the vessel diameter, so although the immediate angiographic result of angioplasty with the Wingspan stent was worse than with the balloon-mounted stent, the blood supply was sufficient. At the same time, the expanding strength of the Wingspan stent will persist, which may reduce the degree of residual stenosis. Bose et al [3] observed that the residual stenosis fell from a mean 31.9% immediately after stenting to a mean of 28% 6 months after stenting. Improved residual stenosis was also seen in our group only 24-h after treatment. If more cases with a longer time follow-up could produce an identical outcome, pursuing the immediate angiographic result would become less important, but these results needed more cases to test and the truth will be disclosed in the recent future. All patients in our group were advised to receive DSA follow-up at 6 months after operation.

The definitions of "complication" are different in the literature: some authors defined it by clinical results, whereas others defined it by occurrence of adverse events. Henkes [8] observed one patient with transient neurologic deficit in his series of 15 patients (6.7%). A multicenter study by Fiorella et al [6] revealed the prevalence of major morbidity and complication with transient dysfunction to be 6.1% and 7.2% respectively, and mortality was 4.8%. Among 18 adverse events in a study by Bose et al [3], there was no serious clinical consequence. In the present study, the prevalence of complications was 14.8%, morbidity was 7.4%, and major morbidity was 3.7%. Compared with insertion of balloon-mounted stents in the literature, obvious superiority of the Wingspan stent was not shown in the present study. In a study by Jiang et al [10], 10% of patients treated with an Apollo stent had complications, and only 2.5% had clinical symptoms. In the Stenting of Symptomatic Atherosclerotic Lesions in the Vertebral or Intracranial Arteries study, procedure-related unexpected events occurred in 2 patients (3.3%) [20]. Besides differences in stents, complication are also associated with the technique as well as the experience and familiarity with the device of the surgeon. More cases are needed to judge if the learning curve could affect clinical results because the time for the Wingspan stent coming into clinical use was too short. Drawing conclusions as to which stent is safer by comparing complication prevalence in the literature is not persuasive. According to our experience, the Wingspan stent is safer than a balloon-expanded stent when it is used to treat stenosis in lesions (1) with an obvious difference in diameter between the proximal and distal normal vessels, (2) that were obviously angulated, (3) with a small parent artery (particularly with a diameter equal or close to 2 mm, (4) and with obviously tortuous proximal parent arteries. According to the instructions for selection of the size of the Wingspan stent, the diameter of the stent must be larger than that of the vessel. The stent therefore cannot expand sufficiently in undersized vessels, increasing the density of the metal and possibly increasing the risks that perforator arteries are covered. This could explain the 3 of 4 complications due to perforator infarction noted in the present study.

One of aims of stenting for intracranial stenosis is prevention of ischemic infarction. Among the 30 patients treated with angioplasty with a Wingspan stent in the study by Bose et al [3], one experienced acute ischemic stroke during 30 days, and another 2 patients experienced it between 30 days and 6 months, with a sum rate of 6.7%. Related information was not given in the other 2 reports using a Wingspan stent [6,8]. In the present study, a new ischemic event was not observed. Although treatment with a Wingspan stent can reduce the short-term risk of stroke in patients with intracranial atherosclerotic stenosis, long-term effects and the rate of restenosis need further investigation. A larger study group and long-term follow-up is also required to assess whether the Wingspan stent is superior to the balloon-mounted stent.

5. Conclusion

Angioplasty with a Wingspan system to treat symptomatic intracranial atherosclerotic stenoses appears to be safe, with acceptable morbidity and mortality. Its initial effect on

prevention of ischemic events is acceptable, and the long-term effect needs investigation. Preliminary results in a small patient population did not show obvious superiority of the Wingspan stent compared with a balloon-mounted stent.

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Commentary

This is an interesting series from a large Chinese center confirming the safety and short-term efficacy of intracranial stenting with the Wingspan system. This article does not report on long-term follow-up of stented patients, although this is a potential problem because of the high rate of restenosis observed with bare stents. The ongoing Sammpris trial—which is randomizing patients with severe symptomatic intracranial stenosis to stenting versus medical management—will answer many of the questions we have about the long-term benefit of intracranial stenting.

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