Outcome of Patients With ≥70% Symptomatic Intracranial Stenosis After Wingspan Stenting

Wei-Jian Jiang, MD; Wengui Yu, MD; Bin Du, MD; Feng Gao, MD; Li-Ying Cui, MD

Background and Purpose—There were limited data on the long-term outcome of patients with symptomatic intracranial atherosclerotic stenosis ≥70% after Wingspan stenting. Using our Wingspan cohort data and the data from the Warfarin and Aspirin for Symptomatic Intracranial Atherosclerotic Disease (WASID) as a historical control, we tested the hypothesis that stenting provided no benefit over antithrombotic therapy alone for these high-risk patients.

Methods—Between January 2007 and February 2009, 100 consecutive patients with intracranial atherosclerotic stenosis ≥70% and symptoms within 90 days were enrolled into this prospective single-center Wingspan cohort study and followed up until the end of February 2010. Stenosis was measured per the WASID criteria. One-year risk of primary end point (any stroke or death within 30 days and ipsilateral ischemic stroke afterward) was compared with that of ipsilateral ischemic stroke in the WASID patients with ≥70% stenosis.

Results—The stent placement success rate was 99%. All patients but 1 had clinical follow-up of ≥12 months. During a mean follow-up of 1.8 years, 9 patients developed primary end point events (5 within 30 days and 4 afterward). The 1-year risk of the outcome events was lower than that in similar WASID patients: 7.3% (95% CI, 2.0% to 12.5%) versus 18% (95% CI, 13% to 24%; P<0.05).

Conclusions—The clinical outcome of Wingspan stenting for high-risk intracranial atherosclerotic stenosis patients in this high-volume center study compares favorably with that of antithrombotic therapy alone. A randomized trial comparing medical therapy alone with medical therapy plus Wingspan stenting, conducted at high-volume centers, is needed to confirm the stenting benefit. (Stroke. 2011;42:00-00.)

Key Words: angioplasty and stenting ▪ atherosclerosis ▪ intracranial stenosis ▪ outcome

The Warfarin and Aspirin for Symptomatic Intracranial Atherosclerotic Disease (WASID) trial showed that patients with symptomatic intracranial arterial stenosis (ICAS) ≥70% are at particularly high risk of recurrent stroke at the time of being on medical therapy.1,2 There has been increased enthusiasm for the use of Wingspan stents (Boston Scientific) to treat these high-risk patients in recent years.3–5 However, there were limited data on long-term outcome after this aggressive therapy. In a multicenter registry, Wingspan stenting seemed to have no advantage compared with medical therapy.3 However, the study showed a significantly lower stroke rate in high-volume centers versus low-volume centers.

The Stenting and Aggressive Medical Management for the Prevention of Recurrent stroke in Intracranial Stenosis (SAMMPRIS) trial is currently in progress comparing aggressive medical management alone with medical management plus Wingspan stenting in patients who have a 70% to 99% ICAS and a qualifying event within 30 days.6 The trial is anticipated to be completed by 2013. Until then, physicians and patients are in a quandary when making a decision on Wingspan stenting.

Using our Wingspan cohort data and the WASID data as historical controls of medical therapy, we tested the hypothesis that Wingspan stenting provided no benefit over antithrombotic therapy alone for high-risk ICAS patients.

Materials and Methods

Subjects
The protocol for this prospective single-center Wingspan study was approved by our institutional ethics committee. Written informed consent was obtained from all patients. Patient demographics, atherosclerotic risk factors, clinical data, images, and follow-up information were prospectively collected.

Inclusion criteria included angiographically verified ≥70% stenosis of a major intracranial artery that caused transient ischemic attack (TIA) or minor ischemic stroke (National Institutes of Health Stroke Scale score <9) within 90 days; lesion length <15 mm and normal arterial diameter adjacent to the stenosis between 2.0 and 4.5 mm; 18 to 75 years of age; and at least 1 atherosclerotic risk factor (arterial

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hypertension, diabetes mellitus, hyperlipidemia, and cigarette smoking).

Exclusion criteria included nonatherosclerotic stenosis; intracranial hemorrhage in the territory of the stenotic artery within 6 weeks; potential source of cardiac embolism; concurrent intracranial tumor, aneurysm, or cerebral arteriovenous malformation; known contraindication to heparin, aspirin, clopidogrel, anesthesia, or contrast media; hemoglobin level <10 g/dL, platelet count <100 000 per microliter, international normalized ratio >1.5 (irreversible) and uncorrectable bleeding diathesis; and life expectancy <1 year because of other medical conditions. Patients with multiple intracranial stenoses or concomitant tandem stenosis ≥50% of the extracranial artery were not excluded from this study.

Between January 2007 and February 2009, 113 consecutive patients with symptomatic ICAS ≥70% underwent Wingspan stenting at our institute. One hundred patients with 105 lesions were treated within 90 days of the qualifying event. Thirteen patients with 13 lesions were excluded due to being stented >90 days after the qualifying event. Four of the 100 enrolled patients had multiple high-grade intracranial stenoses (3 with 2 lesions and 1 with 3 lesions), and 7 had concomitant tandem stenosis ≥50% in the extracranial carotid (n=3) or vertebral (n=4) artery. The multiple stenoses and the tandem extracranial lesion were also stented during the procedure.

End Point Assessment
National Institutes of Health Stroke Scale score and modified Rankin Scale score during hospitalization and end point events after enrollment were independently assessed by stroke neurologists. The primary end point was any stroke or death within 30 days and ipsilateral ischemic stroke afterward. The secondary end point included ischemic stroke outside of the territory of the stented artery, hemorrhagic stroke, and nonstroke death beyond 30 days; emergency cerebral artery revascularization without sequel; TIA in the territory of the stented artery; and other major hemorrhages at any time. Definitions of the events are shown in the Supplemental materials (http://stroke.ahajournals.org).

Periprocedural Management, Stenting Procedure, and Follow-Up
Brain MRI, CT perfusion imaging, and cerebral angiography were completed 1 to 7 days before stent placement. Stenosis was measured manually and blindly by a radiologist per the WASID criteria. The protocol of antiplatelet therapy was prespecified as follows: 300 mg aspirin plus 75 mg clopidogrel daily for 3 to 7 days before the procedure to prevent arterial spasm. Intravenous heparin was administered after placement of a 6-Fr sheath into the femoral artery as a bolus of 3000 U followed by 800 U/hr based on the protocol described in a previous study on intracranial stenting for a Chinese population. The study showed an activated clotting time of 245±65 seconds (range, 161 to 394 seconds), which was very close to the 250- to 300-second target used in the National Institutes of Health registry and US multicenter study. A 6-Fr guiding catheter was then advanced into the distal cervical vertebral or internal carotid artery. Using the guiding catheter as a reference, a quantitative angiogram for sizing a Gateway balloon (Boston Scientific) and Wingspan stent was performed as described previously (http://stroke.ahajournals.org). Under roadmap guidance, an assembly of a microcatheter and a 300-cm microwire was carefully steered through the target lesion to its distal segment. After the microcatheter was removed, the Gateway balloon was advanced over the microwire, centered across the lesion, and inflated slowly to 6 to 8 atmospheric pressure. Angiography was repeated before removal of the balloon. The Wingspan stent delivery system was advanced over the microwire across the target lesion followed by deployment of the stent and removal of the delivery catheter. Stent placement success was defined as complete coverage of the target lesion with the stent resulting in <50% residual stenosis and good anterograde blood flow.

The patient’s blood pressure was kept within 100 to 120/60 to 80 mm Hg with intravenous nimodipine or urapidil hydrochloride (ALTANA Pharma AG) to prevent hyperperfusion syndrome. Brain CT was performed postprocedurally to evaluate intracerebral hemorrhage.

After stenting, all patients were given a weight-based dose of 0.4 to 0.6 mL Fraxiparine (Sanofi Winthrop Industrie) every 12 hours subcutaneously for 3 days and monitored until discharge. After discharge, they had follow-up visits at 30 days. Subsequent follow-ups were completed by clinic visits or by telephone until the end of February 2010. Their modified Rankin Scale score at the last contact date was evaluated by stroke neurologists or a trained nurse. Brain MRI or CT was performed if patient had a new neurological event. Follow-up angiography was scheduled after 6 months on a voluntary basis or when restenosis was suspected clinically. In-stent restenosis was defined as an angiographically verified ≥50% stenosis within the stent or at the edge of the stent in the range of 3 mm.

Historical Control of Medical Therapy
The WASID data were used as a historical control of medical therapy. In the WASID subgroup of 206 patients with ≥70% intracranial stenosis, 40 (19%) developed ipsilateral ischemic stroke during follow-up of 1.8 years despite antithrombotic therapy. The cumulative probability of the stroke was 18% (95% CI, 13% to 24%) at 1 year.

Statistical Analysis
All data were analyzed according to the intention-to-treat principle. The patient characteristics, angiographic outcomes, and clinical outcomes were presented as mean±SD for continuous variables or median and interquartile range for continuous variables that had skewed distributions or as percentages for nominal variables. Using χ² or Fisher exact test (when the expected cell frequency was <5), we compared the percent of patients with good control of each risk factor at baseline versus last follow-up. Reported probability values were 2-sided, and probability values <0.05 were considered significant. Cumulative probability of primary end point events over time was estimated by the product-limit method with a 95% CI at 1 year and 2 years. The probability at 1 year was compared with that of the ipsilateral ischemic stroke in the WASID patients with ≥70% stenosis. Lack of overlap in the 95% CI was considered having statistical significance.

Results
Baseline Characteristics and Procedural Outcome
The 100 patients underwent elective stenting after clopidogrel and aspirin therapy for 11.1±2.5 days (median, 10 days; range, 3 to 40 days). The stenting was performed at 33.6±22.3 days (median, 29.5 days) from the qualifying event. Tables 1 and 2 summarize patient and lesion characteristics and angiographic outcomes after stenting. A representative case is shown in the Supplemental materials. The stent placement success rate was 99% (99 of 100 patients or 104 of 105 lesions). It failed in 1 patient because the Wingspan stent system could not be delivered to the site distal to the basilar artery stenosis after successful balloon predilatation. In this cohort, no patient underwent postdilatation with balloon after placement of the Wingspan stent, and the median time from stenting to discharge was 5 days (interquartile range, 4 to 7 days).
Prestenting stenosis, % 99.1 (104/105)
Basilar artery stenosis, % 18.1 (19/105)
Vertebral artery stenosis, % 24.8 (26/105)
Middle cerebral artery stenosis, % 41.9 (44/105)
Internal carotid artery stenosis, % 15.2 (16/105)
Severe tortuous access, % 11.4 (12/105)

Infarct in the territory of the stenotic artery, % 71.4 (75/105)
Stroke as a qualifying event, % 29.5 (31/105)

Table 1. Baseline Characteristics of 100 Patients

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y±SD</td>
<td>53.2±9.2</td>
</tr>
<tr>
<td>Male, %</td>
<td>87.0 (87/100)</td>
</tr>
<tr>
<td>Hyperlipidemia, %</td>
<td>63.0 (83/100)</td>
</tr>
<tr>
<td>Hypertension, %</td>
<td>72.0 (72/100)</td>
</tr>
<tr>
<td>Cigarette smoking, %</td>
<td>68.0 (68/100)</td>
</tr>
<tr>
<td>Diabetes mellitus, %</td>
<td>32.0 (32/100)</td>
</tr>
<tr>
<td>Stroke history, %</td>
<td>11.0 (11/100)</td>
</tr>
<tr>
<td>Antithrombotic therapy at the qualifying event time, %</td>
<td>37.0 (37/100)</td>
</tr>
</tbody>
</table>

SD indicates standard deviation.

Primary End Point
In this cohort, no one was lost to follow-up. One patient died of ipsilateral stroke 8 months after stenting. Other patients had clinical follow-up of ≥12 months. During a mean follow-up time of 21.4±8.2 months (median, 20.9 months), we observed 9 (9%) primary end point events (see Supplemental materials): 5 (5%) within 30 days (3 ischemic strokes and 2 intracerebral hemorrhages) without fatality and 4 (4%) after 30 days. Eight of the 9 events occurred in patients with single intracranial stenosis treated with a stent and 1 in a patient with concomitant tandem stenosis of an extracranial artery. The cumulative probability of primary end point (Figure) was 7.3% (95% CI, 2.0% to 12.5%) at 1 year, which was lower than the 18% (95% CI, 13% to 24%) risk of 1-year ipsilateral ischemic stroke in similar WASID patients (P<0.05).

Secondary End Point
We also observed 15 secondary end point events. Nine occurred within 30 days, including 7 TIAs (5 in the posterior circulation and 2 in the anterior circulation) and 2 emergency cerebral artery revascularizations. Six patients experienced TIA in the territory of the stented artery after 30 days; Five of them had catheter angiography, which revealed 4 (80%) in-stent restenoses. All of these events occurred in patients treated with a Wingspan stent, but 1 was a TIA and occurred intraoperatively in 1 patient with intracranial vertebral stenosis and concomitant tandem lesions of the intracranial and extracranial carotid artery.

In-Stent Restenosis
Forty-five stented vessels in 44 patients were evaluated by catheter angiography at a mean of 8.6 months (median, 7.2 months). The in-stent restenosis rate was 26.7% (12 of 45), and the symptomatic restenosis rate was 11.1% (5 of 45).

Pharmacological Therapy for Antiplatelet and Risk Factor Management
After stenting, all patients were treated with both aspirin and clopidogrel for 3 to 36 months, but 2 patients suspended clopidogrel therapy for 1 day or 30 days due to periprocedural intracerebral hemorrhage. During the hospitalization, 99% (99 of 100) patients took a statin, 97% (31 of 32) of patients with diabetes were prescribed insulin or an oral hypoglycemic agent, and 100% (72 of 72) of patients with hypertension were prescribed an antihypertensive agent (including an angiotensin-converting enzyme inhibitor used in 52 [72%] patients and an angiotensin II receptor blocker used in 20 [28%] patients). At the last follow-up, 97% (97 of 100) patients were on an antiplatelet agent, and 78% (78 of 100) took a statin; 81% (26 of 32) of patients with diabetes at baseline were prescribed insulin or an oral hypoglycemic agent; and 79% (57 of 72) of patients with a hypertension history at baseline were prescribed an antihypertensive agent (including an angiotensin-converting enzyme inhibitor used in 10 [14%] patients and an angiotensin II receptor blocker in 12 [17%] patients). Table 3 shows the percent of patients with good control of each risk factor at baseline versus last follow-up.

Outcome of Patients Who Were Excluded From This Study
We observed 1 secondary end point event (TIA) after 30 days and no primary end point event during a mean follow-up of 23.5±7.7 months (median, 25 months) in the 13 patients who were not included into this study. The catheter angiogram follow-up was performed in 6 of the 13 patients at a median of 9.5 months (11.3±5.5 months). It revealed 1 restenosis (16.7% [1 of 6]), which was symptomatic.

Discussion
The clinical outcome of Wingspan stenting for patients with ICAS ≥70% and symptoms within 90 days in this single high-volume center study compares favorably with that of antithrombotic therapy alone in similar patients of the WASID study.2,3 Of note, our cohort included 11 (11%) patients with multiple intracranial stenoses or tandem extracranial stenosis, representing a “real-world” setting in clinical practice. These patients may be at higher risk of recurrent stroke on medical therapy than those with single ICAS.11 However, 10 of the 11 patients had not experienced a primary end point event after stenting.
The favorable outcome in this cohort is probably due to the low 30-day rate of stroke or death (5%). So far, there have been 3 published multicenter Wingspan studies. Two of them showed a similarly low rate of 30-day stroke or death at 4.5% and 6.4%, respectively. However, the other study reported a 9.3% risk of periprocedural major complication in patients with ICAS ≥70%, mainly due to a much higher complication rate at the low-volume centers (17.2%) as compared with the high-volume center (6.8%). Similarly, results from INTRASTENT, the European multicentric registry for stent treatment of intracranial stenoses in 372 patients, showed a 7% risk of major periprocedural complications.

The favorable outcome might also be related to more aggressive medical treatment or better control of blood pressure and cholesterol in this cohort patients than the WASID patients. Warfarin or a high dose of aspirin (1300 mg) was used in the WASID patients, whereas our patients were treated with dual antiplatelet agents for 3 months followed by an antiplatelet agent during follow-up. In the WASID patients, only 82% took a statin at any time during the trial (versus 99% in our patients). The proportion of patients with hypertension who were on an angiotensin-converting enzyme inhibitor at any time was similar (67% versus 72%), and the proportion of patients with diabetes who were treated with insulin or an oral hypoglycemic agent at any time was also similar (91% versus 97%). Among WASID patients who had 2-year follow-up, 53% had systolic blood pressure <140 mm Hg (versus 65% in our cohort), 56% had low-density lipoprotein <100 mg/dL (versus 81%), or 79% had cholesterol <200 mg/dL (versus 89%). However, in the WASID patients, there was better control of cigarette smoking: only 16% remained smoking (versus 41%); and control of blood sugar was also better for those with diabetes at baseline: 52% had hemoglobin A1C <7% or fasting blood glucose <6.1 mmol/L (versus 41%).

The 4% risk of ipsilateral ischemic stroke beyond 30 days of Wingspan stenting in this cohort was within the range of 3.1% to 4.4% reported in other Wingspan studies with a mean follow-up of 6 or 13 months. A previous study with balloon-expandable stents also showed a low (3.3%) rate of ipsilateral ischemic stroke beyond 30 days.

These findings indicate that the rate of ipsilateral ischemic stroke after 30 days of ICAS stenting is low and relatively constant, and the most important quality control in clinical practice or trials of ICAS stenting is to reduce periprocedural major complications. In addition to stenting skills and experience of the operators, preprocedural evaluation, management of comorbidities and risk factors, and periprocedural care should be optimized to warrant the benefit of intracranial stenting.

There are some limitations in this study. First, the WASID data were used as a historical control to estimate the stenting benefit. Despite the fact that the WASID was a well-done randomized trial, using the WASID data as a control may import additional variability. In addition, the medical treatment of ICAS patients in our days is not the same as it was in the WASID trial, especially regarding the use of antiplatelets, statins, and blood pressure control. Second, the restenosis rate may be overestimated, because catheter angiography follow-up was performed on a voluntary basis or when

<table>
<thead>
<tr>
<th>Risk Factors</th>
<th>Baseline, %</th>
<th>Last Follow-Up, %</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>SBP &lt;140 mm Hg</td>
<td>35</td>
<td>65</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>DBP &lt;90 mm Hg</td>
<td>50</td>
<td>64</td>
<td>0.05</td>
</tr>
<tr>
<td>Cholesterol &lt;200 mg/dL</td>
<td>85</td>
<td>89</td>
<td>0.4</td>
</tr>
<tr>
<td>LDL &lt;100 mg/dL</td>
<td>63</td>
<td>81</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Hemoglobin A1C &lt;7% or fasting blood glucose &lt;6.1 mmol/L</td>
<td>76</td>
<td>75</td>
<td>0.869</td>
</tr>
<tr>
<td>Hemoglobin A1C &lt;7% or fasting blood glucose &lt;6.1 mmol/L*</td>
<td>34</td>
<td>41</td>
<td>0.606</td>
</tr>
<tr>
<td>Ceasing cigarette smoking</td>
<td>36</td>
<td>59</td>
<td>&lt;0.01</td>
</tr>
</tbody>
</table>

SBP indicates systolic blood pressure; DBP, diastolic blood pressure; LDL, low-density lipoprotein.

*Patients with diabetes only at baseline (n=32).
restenosis was suspected clinically. Many patients would not like to undergo this invasive examination unless having recurrent symptoms. It is possible that a higher rate of angiographically verified restenosis was seen in patients with recurrent events.

In conclusion, our results suggest that Wingspan stenting at high-volume centers may provide a benefit over antithrombotic therapy alone for high-risk ICAS patients. A randomized trial comparing medical therapy alone with medical therapy plus Wingspan stenting, conducted at high-volume centers, is needed to confirm the additional benefit of stenting.

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Disclosures
None.

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1. Definitions of Endpoint Events
2. Choice of Balloon and Stent
3. Nine Primary Endpoint Events in This Cohort
4. Figure from A Representative Case and Figure Legend
1. **Definitions of Endpoint Events**
Ischemic stroke was defined as a new focal neurologic deficit of sudden onset that lasted \( \geq 24 \) hours and was not caused by hemorrhage. TIA was defined as an acute onset of a focal neurologic deficit lasting \(< 24 \) hours. Intracranial hemorrhage (ICH) was defined as evidence of blood in brain parenchyma or subarachnoid space on CT. Non-stroke death after 30 days was defined as any death other than from stroke. ECAR was defined as emergent endovascular intervention for acute artery occlusion that led to recanalization of the target vessel and complete resolution of neurologic deficits within 24 hours. Other major hemorrhage was defined as hemorrhage (other than ICH) requiring hospitalization, blood transfusion, or surgery.

2. **Choice of Balloon and Stent**
The Gateway balloon was chosen to approximate the length of the lesion, with its diameter at 80% of the adjacent non-diseased segment. The length of Wingspan stent was chosen to cover the stenosis plus up to 3 mm proximally and distally. The stent diameter was sized to exceed the diameter of the normal parent vessel by 0.5 to 1.0 mm.
3. Nine Primary Endpoint Events in This Cohort

<table>
<thead>
<tr>
<th>Event</th>
<th>Comment</th>
<th>NIHSS/mRS at prestenting</th>
<th>NIHSS/mRS at discharge</th>
<th>mRS at last follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Distal thromboembolic infarct</td>
<td>Acute BA occlusion due to severe dissection distal to the lesion after attempted Wingspan system delivery. It was treated successfully with 2 balloon-expandable stents following intra-arterial thrombolysis. Discharged 11 days after stenting</td>
<td>0/0</td>
<td>1/2</td>
<td>2</td>
</tr>
<tr>
<td>2. Pontine perforator infarct</td>
<td>Presumably due to perforator occlusion. Discharged 14 days after stenting</td>
<td>1/1</td>
<td>4/3</td>
<td>1</td>
</tr>
<tr>
<td>3. ICH</td>
<td>Perforation of distal posterior cerebral artery by tip of the microwire. Discharged 14 days after stenting</td>
<td>2/1</td>
<td>2/1</td>
<td>0</td>
</tr>
<tr>
<td>4. ICH</td>
<td>Hyperperfusion or vessel perforation or other cause. Discharged 15 days after stenting</td>
<td>2/1</td>
<td>1/1</td>
<td>0</td>
</tr>
<tr>
<td>5. Stroke at day 6 of VA stenting</td>
<td>Distal embolization. Discharged 4 days after stenting</td>
<td>0/0</td>
<td>0/0</td>
<td>0</td>
</tr>
<tr>
<td>6. Ipsilateral stroke 7 months after ICA stenting</td>
<td>Discharged 5 days after stenting. Worsening stenosis of ipsilateral cervical ICA, without in-stent restenosis on angiogram. Discharged 5 days after stenting. No available angiogram follow-up data. Fatal.</td>
<td>1/1</td>
<td>1/1</td>
<td>3</td>
</tr>
<tr>
<td>7. Ipsilateral stroke 8 months after MCA stenting</td>
<td>Discharged 3 days after stenting. No available angiogram follow-up data.</td>
<td>1/1</td>
<td>1/1</td>
<td>1</td>
</tr>
<tr>
<td>8. Ipsilateral stroke 13 months after MCA stenting</td>
<td>Discharged 4 days after stenting. Severe restenosis on catheter angiogram. It occurred 3 days after stopping aspirin and clopidogrel treatment due to ICH contralateral to the stented artery. Disabling</td>
<td>0/0</td>
<td>0/0</td>
<td>5</td>
</tr>
</tbody>
</table>
4. **Figure from A Representative Case and Figure Legend**

The patient presented with left-sided watershed infarction (A). Angiogram showed a severe stenosis in ipsilateral supraclinoid internal carotid artery (ICA) (B), with a mild tandem stenosis in cervical ICA (C). He underwent Wingspan stenting (D). However, he developed ipsilateral stroke 7 months later (E). Angiogram revealed no in-stent restenosis (F), but worsening stenosis in the cervical ICA (G), which was stented (H) without complication.