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Enterprise stent in recanalizing non-acute atherosclerotic intracranial internal carotid artery occlusion

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ABSTRACT

Objective: To investigate the safety and effectiveness of recanalization in non-acute occlusion of intracranial internal carotid arteries using the flexible Enterprise self-expanding stent.

Patients and methods: From June 2014 to June 2016, 12 consecutive patients with non-acute occlusion of intracranial internal carotid arteries received endovascular recanalization with Enterprise stenting. All patients received medication for anti-platelet aggregation therapy before and after the operation. The perioperative complications and recanalization efficacy were evaluated with the modified Rankin scoring system and digital subtraction angiography (DSA) follow-up, respectively.

Results: Endovascular recanalization was successfully performed in 10 out of 12 patients with Enterprise stenting. Stent implantation following balloon dilatation failed in one patient because the lumen diameter was too small. Another recanalization failed because the guide wire could not pass through the occlusion. No perioperative mortality was observed. One case of acute thrombosis and one case of intraoperative carotid spasm occurred, but these were resolved with thrombolytic therapy by microcatheter exposure treatment and antispasmodic medications, respectively. DSA follow-up in seven patients revealed no re-occlusion. One stroke event occurred in the 10 patients who completed the follow-up. A meaningful improvement in the modified Rankin score during follow-up was suggested by Wilcoxon signed-rank test results.

Conclusion: The Enterprise stent was shown to be safe and efficient in recanalizing non-acute atherosclerotic intracranial internal carotid artery occlusion. However, the long-term outcomes need to be further investigated.

1. Introduction

Non-acute atherosclerotic intracranial internal carotid artery occlusion (IICAO) forms on the basis of vascular stenosis and is associated with serious clinical symptoms and poor prognosis. Despite conservative therapies including antiplatelet aggregation, patients still suffer from repeated ischemic events due to the lack of compensatory collateral circulation. Safe and efficient therapeutic approaches have been developed, such as percutaneous vascular recanalization with a stent. This stent recanalization has been applied to intracranial occlusions of the basilar artery and vertebrobasilar arteries, but with a lower success rate and higher risk [1–4]. However, stent recanalization of non-acute atherosclerotic IICAOs has not be fully investigated nor has the selection of a suitable stent.

The self-expanding intracranial stents are commonly used in patients with intracranial arterial stenosis. The general idea of these self-expanding stents is that a Gateway balloon with a diameter slightly smaller than that of the target vessel is used to perform the subsatisfactory dilation followed by implantation of a relatively larger self-expanding stent. The Wingspan stent is one of the most commonly used and studied self-expanding intracranial stents in the clinical setting [5]. However, the Wingspan stent has been suggested to be difficult to accurately place and release due to its large radial support force and lower softness.

The Enterprise stent was designed as an adjuvant primarily for embolizing intracranial aneurysms and has been increasingly used [6,7]. It is a closed-loop (with the decreased radial support force) stent with better flexibility than the Wingspan stent, as shown in a previous in vitro study (Fig. 1) [8]. Studies from others [9,10] and our group [11] also have suggested the safety and efficacy of the Enterprise stent for atherosclerotic intracranial arterial stenosis (AIAS). However, it has not been investigated whether this stent can be used for recanalizing non-acute IICAO.

Thus, we designed the current study to assess the feasibility and safety of the Enterprise stent in the treatment of non-acute atherosclerotic IICAO.

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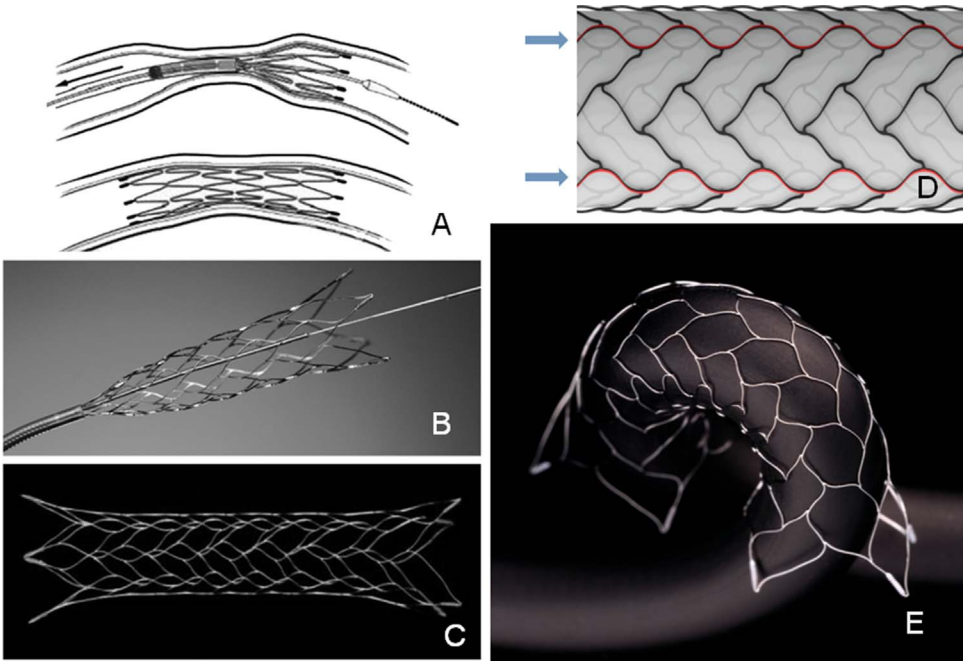

Fig. 1. Wingspan (A) and Enterprise (B–E) stents. A: Wingspan stent with open-loop design. B and C: Enterprise stent with close-loop design. D: Many longitudinal sine wave ridges (*arrow*) on the main body of Enterprise stents. E: Sinusoidal waveforms extend in outer radian and are self-compressed in the inner radian to better conform to the vessel curvature.

2. Material and methods

2.1. Patients

Twelve consecutive patients with non-acute atherosclerotic IICAO treated with Enterprise stents (Codman, USA) were retrospectively enrolled in the Neurosurgery Department of the Second Hospital of Shandong University from June 2014 to June 2016. All patients had the history of hypertension. In addition, 5 patients had type 2 diabetes mellitus, and 8 patients had hyperlipidemia. All patients underwent routine electrocardiogram(ECG) examinations except for atrial fibrillation, and routine echocardiography except for atrial mural thrombus which could lead to cardioembolism.

In our hospital, patients found with symptomatic atherosclerotic intracranial arterial stenosis (AIAS) are routinely treated with antiplatelet drugs. And we had performed angioplasty with Enterprise stents in some cases [11]. All of the 12 patients were diagnosed with stenosis of intracranial internal carotid artery in our hospital earlier, and ischemic stroke recur during medication. IICAO was diagnosed with digital subtraction angiography (DSA) not less than 14 days from stroke onset, and the median time from onset of ischemic stroke to treatment was 18 days.

The inclusion criteria were: 1) non-acute atherosclerotic IICAO with consistent symptoms; 2) age less than 70 years; 3) requiring recanalization after insignificant improvement with aspirin and clopidogrel treatment; 4) no stenosis of the contralateral ICA or the degree of contralateral ICA stenosis was less than 50%, with an inadequate perfusion confirmed with computed tomography (CT) or magnetic resonance (MR) perfusion-weighted imaging by declined cerebral blood flow (CBF), cerebral blood volume (CBV), prolonged mean transit time (MTT), time to peak(TTP) in lesion side compared with normal side; and 5) collateral grading less than or equal to 3 according to the standard of the American Neuroradiology Association [12].

The exclusion criteria were: 1) non-atherosclerotic (arteritis, or induced by other factors such as the moyamoya disease) IICAO; 2) a modified Rankin score (mRS) ≥ 5 points, a serious neurological deficit, or inability to take care of themselves; and 3) acute cerebral infarction within 2 weeks. This study was approved by the Ethical Committee of the Second Hospital of Shandong University, and informed consent was obtained from all the patients.

2.2. Treatment

Patients were prescribed clopidogrel (75 mg/d) and aspirin (300 mg/d) at least 3 days before the stent operation, and systolic blood pressure was kept at < 160 mmHg before operation. Nimodipine was delivered to patients from 2 h before the operation to 24 h after the operation to avoid vasospasms (total dose of 0.6 mg/kg). For routine general anesthesia, heparinization was performed intraoperatively at a dose of 60–80 U/kg, and an additional 1000 U heparin per hour was given to maintain the activated coagulation time (ACT) of 250–300 s.

Using the Innova 3100 IQ digital flat-panel angiography instrument (GE Healthcare, Buckinghamshire, UK), cerebral angiography was performed prior to the treatments After whole body heparinization, the noninflated distal balloon of the Moma carotid protection device was placed in the external carotid artery, leaving the proximal balloon in the common carotid artery. An SL-10 microcatheter was guided with a Traxcess guide wire to pass over the block under the road map. After confirming the microcatheter location inside the lumen distal to the occlusion, a Monorail balloon was placed at the occlusion using the Transend 300 exchange guide wire. Then the distal and proximal balloons of the Moma were inflated, the Monorail balloon was pre-inflated at the occlusion site, and the fragments were extracted with a syringe via the Moma. This was followed by placement of the Plus micro-cather and Enterprise stent and the removal of fragments via the Moma again.

The Enterprise stent was at least 3 mm longer than the occlusion. Multi-stents were released one by one in a long segment lesion in two patients. The surgery was terminated after angiography confirmation that a stent fully covered lesions without thrombosis.

After operation, the heparin was naturally metabolized and the patient's systolic blood pressure was maintained at < 120 mmHg. Follow-up conventional CT examination was performed to exclude intracranial hemorrhage. For postoperative medications, low molecular weight heparin (IH q12 h 5000 U) was used for anticoagulant therapy for another 3 days after operation. Aspirin at a dose of 300 mg/d was prescribed for the first month, then titrated to 100 mg/d from the second month, and maintained thereafter. And platelet aggregation detection is routinely performed to guide medication. In two patients with bleeding tendency (gingival bleeding and epistaxis), aspirin 100 mg/d was prescribed for the first month. Clopidogrel 75 mg/d was prescribed for 3 months. Clopidogrel was given for another 6 months in