



Usefulness of Self-Expandable Stent for Recanalization of Intracranial Atherosclerotic Disease: Preliminary Experience with Enterprise Stent

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Purpose: The purpose of this preliminary study is to evaluate the efficacy and safety of the Enterprise stent for intracranial atherosclerotic disease (ICAD) in patients who presented with acute stroke due to vessel steno-occlusion and in patients with symptomatic disease despite optimum medical management.

Materials and Methods: A retrospective data analysis was performed on 15 consecutive patients who were treated with Enterprise stenting for recanalization of symptomatic intracranial steno-occlusive arteries due to underlying ICAD. Their clinical and radiological data were reviewed to evaluate procedural results, periprocedural and postprocedural complications, and clinical outcome.

Results: Enterprise stents were deployed as a rescue method in 15 patients for recanalization of steno-occlusion. All patients achieved final modified thrombolysis in cerebral infarction (mTICI) score improvement (53.3% with a mTICI score from 0 to 2b or 3, 46.7% with a mTICI score from 1 to 3). Two postprocedural complications (1 symptomatic intracranial hemorrhage and 1 severe brain edema, 13.3%) occurred among 15 patients. Among 12 patients with acute ischemic stroke (AIS), 6 patients (50%) had improvement in their National Institute of Health Stroke Scale of more than 4 at discharge. Seven patients (58.3%) had a good functional outcome with 3-month modified Rankin Score (mRS) ≤ 2, and mortality occurred (mRS=6) in 2 patients (16.7%). None of the 10 AIS and 3 transient ischemic attack patients experienced further ischemic events attributable to the treated steno-occlusion during the follow-up period (ranged from 4 to 36 months, median 12 months).

Conclusion: This retrospective study suggests that Enterprise stenting can effectively and safely achieve recanalization in symptomatic steno-occlusive intracranial arteries.

Key Words: Intracranial atherosclerosis; Intracranial stenting; Ischemic stroke

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INTRODUCTION

Intracranial atherosclerotic disease (ICAD) is the cause of up to 20% of acute ischemic strokes (AIS) and transient ischemic attacks (TIA), resulting in significant morbidity and mortality, and is more frequent in Asian populations (30–50%) than in Western populations.^{1,2} Even with the best medical therapy, the risk of recurrent stroke remains high.³ Among patients with symptomatic ICAD who failed medical therapy, the subsequent rates of stroke or vascular death have been as high as 45% per year.⁴

The relative limitations of standard medical therapy to treat symptomatic intracranial large artery steno-occlusive lesions have encouraged the development of more aggressive strategies, such as intracranial percutaneous transluminal stenting, especially with Wingspan stent, which can be alternative approaches to medical therapy and even in an acute ischemic setting.^{5–12} However, the Wingspan system is criticized for being bulky and requiring a multi-step deployment.^{13,14} On the other hand, the Enterprise stent (Codman Neurovascular, Raynham, MA, USA) can show ease of deployment and improved navigability. Although intended solely for aneurysm-embolization assistance, there has been a developing interest in the possible utility of this device for salvage stroke intervention.^{15,16} Therefore, we tried to evaluate the efficacy and safety of the Enterprise stent for recanalization of symptomatic intracranial large artery steno-occlusion with underlying ICAD.

MATERIALS AND METHODS

Patients

This retrospective analysis was approved by the Institutional Review Board and the informed consent was waived. The patients who underwent Enterprise stenting for symptomatic intracranial large artery steno-occlusion at a Gangnam Severance hospital between January 2010 and April 2017 were screened. Diagnosis of large artery steno-occlusion with underlying ICAD was made based on typical angiographic findings with a modified thrombolysis in cerebral infarction (mTICI) score (0=no perfusion, 1=penetration with minimal perfusion, 2a=partial perfusion with only partial filling less than two-thirds of the entire vascular territory, 2b=complete filling of all of the expected vascular territory is visualized but the filling is slower than normal, 3=complete perfusion)¹⁷ as

follows: 1) severe fixed luminal narrowing with initial mTICI score 1 or 2) initial mTICI score 0 with evident residual severe stenosis (mTICI score 1) after the intra-arterial (IA) endovascular treatment. Symptomatic patients were defined as those who presented with AIS within 6 hours of symptom onset or recurrent TIA refractory to antithrombotic therapy. The antiplatelet regimen for recurrent TIA patients was a combination treatment with 100–325 mg per day of aspirin plus 75 mg per day of clopidogrel. A total of 15 patients underwent Enterprise stenting due to underlying ICAD lesion. Twelve of the 15 patients were treated due to AIS and the remaining 3 patients were treated due to recurrent TIA.

Endovascular Treatment

Endovascular treatment was attempted in all patients under local anesthesia *via* the right femoral artery. If indicated, an intravenous tissue-type plasminogen activator (IV-tPA) was administered before the endovascular procedure in AIS patients. For the recanalization procedure, a 6F Shuttle guiding sheath (Cook Medical Inc., Bloomington, IN, USA) or 6F guiding catheter (Envoy; Codman Neurovascular) was placed in the relevant internal carotid artery (ICA) or vertebral artery. Then, a microcatheter (Prowler select plus microcatheter; Codman Neurovascular) was navigated carefully into the steno-occlusive artery over a 0.010-inch microwire (Asahi MW; Asahi Intecc, Aichi, Japan) under fluoroscopic guidance. In all patients, a self-expandable, closed-cell intracranial stent (Enterprise stent; Codman Neurovascular) was deployed for underlying ICAD during fluoroscopic control. All 15 patients underwent Enterprise stenting for severe ICAD or fixed stenosis after IA treatment failure. The Enterprise stent was available in 4.5 mm diameter with multiple lengths (14, 23, 28, and 37 mm), chosen at the discretion of the operator. Delayed angiography was performed at the end of the procedure to confirm the stent patency. IA glycoprotein IIb/IIIa inhibitor (tirofiban, 0.5–1.5 mg) was bolus injected in case of instant in-stent thrombosis. A closure device (Perclose; Abbott Vascular Devices, Redwood City, CA, USA) was used to seal off the femoral artery puncture. After the stent insertion procedure, all patients maintained dual antiplatelets (aspirin 100 mg+plavix 75 mg) orally for at least 3 months.

Outcome Measures and Follow-Up Evaluation

We evaluated successful recanalization with pre-post procedure findings with mTICI scores. After the stenting procedure, all patients underwent routine brain imaging (computed

tomography [CT] or magnetic resonance imaging) 24 hours after the procedure. Periprocedural complications (e.g., vessel perforation or dissection), postprocedure complications (e.g., symptomatic intracerebral hemorrhage, progressive brain edema), and any other in-hospital neurologic complications were recorded. In patients who initially had AIS, clinical outcomes were measured by the improvement of National Institute of Health Stroke Scale (NIHSS) score during hospitalization and 3-month modified Rankin Score (mRS). A good functional outcome was defined as a mRS of ≤ 2 . Symptom recurrence was defined as cerebral ischemic events in the territory that Enterprise stenting was performed during the follow-up period.

RESULTS

The baseline characteristics and the clinical follow-up results are shown in Table 1. The mean age of the patients (9 males and 6 females) was 69.3 years (range, 53–84 years). The number of patients with known comorbidities was as follows: 2 with atrial fibrillation, 12 with hypertension, 2 with diabetes mellitus, 4 with hyperlipidemia, 4 with coronary artery occlu-

sive disease. Eight patients (53.3%) were taking antiplatelet medication before the Enterprise stenting due to their recurrent ischemic symptoms ($n=3$) and/or comorbidities ($n=5$). The locations of steno-occlusive lesions were as follows: distal ICA in 4, distal ICA-middle cerebral artery (MCA) in 1, MCA in 6, distal vertebral artery in 3, and basilar artery in 1.

All patients underwent Enterprise stent deployment for underlying ICAD lesions after other techniques had already been attempted and failed. Techniques used prior to Enterprise stent deployment included IA urokinase administration (2 patients), stent retriever (6 patients), balloon angioplasty (5 patients), and failed Wingspan stent deployment (2 patients). Additional interventions performed after Enterprise stent deployment included balloon angioplasty (2 patients) and glycoprotein (GP) IIb/IIIa inhibitor administration (9 patients, 0.5–1.5 mg). The use of GP IIb/IIIa inhibitor during the procedure was performed when restenosis was suspected after stenting, regardless of previous antiplatelet medication.

All patients achieved final mTICI score improvement (53.3% with a mTICI score from 0 to 2b or 3, 46.7% with a mTICI score from 1 to 3). There were 2 (13.3%) postprocedural complications after stent deployment, 1 was symptomatic parenchymal hemorrhage and 1 was progressive brain edema, which

Table 1. Lesion locations and baseline characteristics and outcomes among 15 patients

No.	Location	Initial IA treatment	Stent length (mm)	mTICI score	Initial NIHSS	NIHSS discharge	3-month mRS	Postprocedural complication	Follow-up period (mo)
1	Right distal VA	Wingspan	37	1→3	1 (TIA)	0	NA	No	36
2	Right MCA, M1	IA urokinase	37	0→3	13	6	3	No	36
3	Right distal ICA	IA urokinase	37	0→2b	22	NA	6	Progressive edema	NA
4	Left distal ICA	Stent retriever	37	0→3	21	21	4	Symptomatic PH	33
5	Left distal ICA-M1	Stent retriever	28	0→2b	15	8	4	No	12
6	Left distal VA	Balloon angioplasty	37	1→3	6	0	0	No	10
7	Right MCA, M1	Wingspan	14	1→3	6 (TIA)	0	NA	No	8
8	Left MCA, M1	Stent retriever	28	0→3	4	0	0	No	12
9	Right distal ICA	Stent retriever	37	0→3	16	14	2	No	18
10	Basilar artery	Balloon angioplasty	28	1→3	6	5	2	No	36
11	Left distal VA	Stent retriever	37	0→2b	20	NA	6	No	NA
12	Left MCA, M1	Stent retriever	14	0→3	3	3	1	No	10
13	Left MCA, M1	Balloon angioplasty	23	1→3	0 (TIA)	0	NA	No	6
14	Right distal ICA	Balloon angioplasty	23	1→3	9	4	2	No	4
15	Left MCA, M1	Balloon angioplasty	23	1→3	16	8	2	No	4

IA, intra-arterial; mTICI, modified thrombolysis in cerebral infarction; NIHSS, National Institutes of Health Stroke Scale; mRS, modified Rankin Scale; VA, vertebral artery; TIA, transient ischemic attack; NA, not applicable; MCA, middle cerebral artery; ICA, internal carotid artery; PH, parenchymal hemorrhage.

led to mortality.

Among 12 AIS patients, 3 patients (25%) within the indication time were administered intravenous tPA. The median initial NIHSS score was 14 (range, 3–22). Six patients (50%) had improvement in their NIHSS score of more than 4 points at discharge. Seven patients (58.3%) had a good functional outcome with 3-month mRS \leq 2, and mortality occurred (mRS=6) in 2 patients (16.7%). None of the 10 surviving AIS patients and 3 TIA patients experienced further ischemic events attributable to the treated ICAD lesion during the follow-up period (ranged from 4 to 36 months, median 12 months). Two case examples are illustrated in Figs. 1 and 2.

DISCUSSION

The results of this preliminary study of 15 patients in whom other IA interventions had already failed show that Enterprise stenting can help achieve recanalization with a final mTICI score 2b or 3 in all patients with underlying ICAD and good functional outcomes with mRS \leq 2 (58.3%) in AIS patients.

ICAD is one of the major causes of acute/recurrent ischemic symptoms by hemodynamic insufficiency or occlusion by in-situ thrombosis in a stenotic lesion. Moreover, ICAD is reported more frequently in Asians, blacks, and Hispanics than in whites.¹⁸⁻²² Depending on the degree of vascular stenosis and other conditions, patients with ICAD have a cerebrovascular event rate of 10% to 50% per year.³ As previously

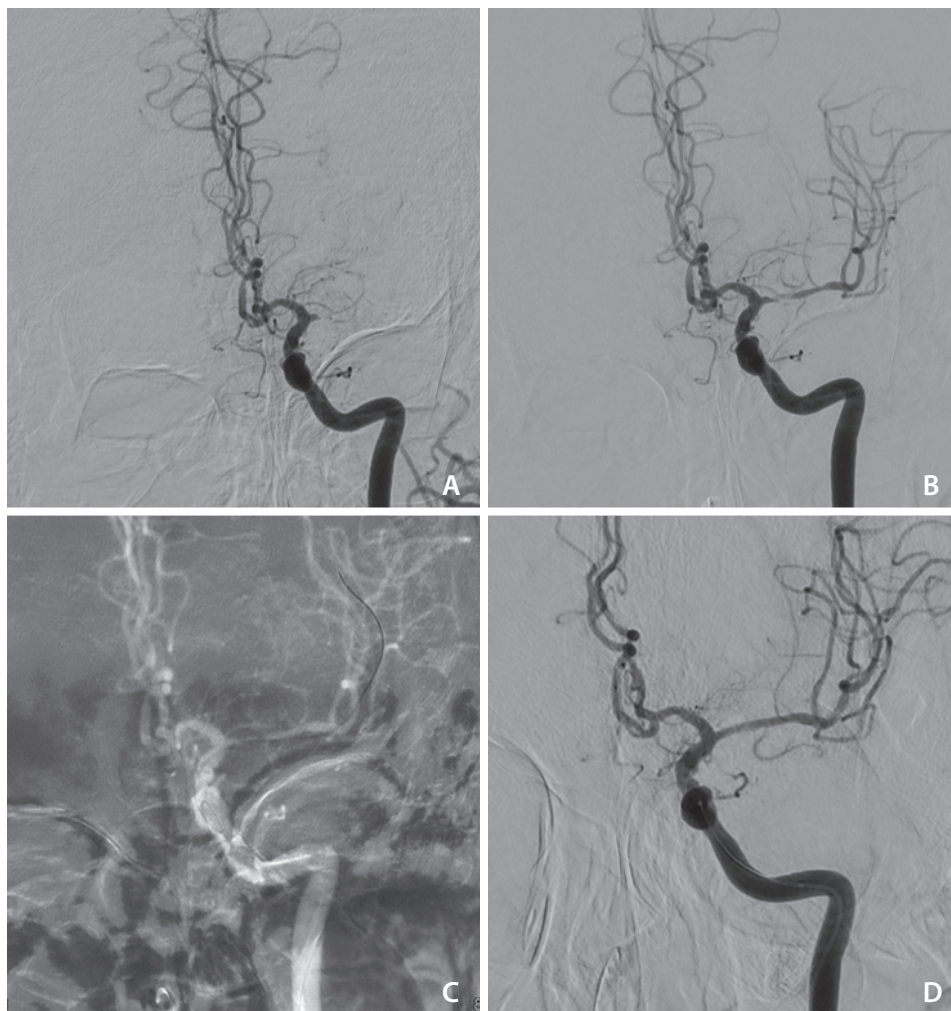


Fig. 1. An elderly patient who presented with acute left proximal MCA occlusion and NIHSS score 15. (A, B) The patient received mechanical thrombectomy initially with refractoriness due to underlying severe stenosis. (C) Enterprise stent (28 mm) was successfully deployed. (D) Fifteen minutes delayed angiography showed patent antegrade flow (mTICI score 3) in the stented segment without residual stenosis. MCA, middle cerebral artery; NIHSS, National Institutes of Health Stroke Scale; mTICI, modified thrombolysis in cerebral infarction.

reported in several studies, the Warfarin-Aspirin Symptomatic Intracranial Disease study and the Extracranial-Intracranial Bypass Study demonstrated that the results of medical or surgical management of ICAD remain far from ideal.^{23,24} Consequently, intracranial stenting has emerged and is increasingly being used in the USA and other countries.^{7-11,25} However, in 2011, the Stenting versus Aggressive Medical Therapy for Intracranial Arterial Stenosis study revealed that aggressive medical management was superior to intracranial stenting with the use of the Wingspan stent system for ICAD, because of high risk of early stroke after Wingspan stenting.²⁶ In addition, in cases with very difficult anatomy and complex lesion geometry, the Wingspan stent system failed stent de-

livery to the target lesion because of its cumbersome carrier system.¹⁴ Moreover, several studies reported sobering results with a high rate of recurrent stenosis, sometimes worse than the original lesion, and this observation raised the suspicion that the high radial force of the Wingspan stent might be a stimulus for intimal hyperplasia.²⁷⁻²⁹ However, the Enterprise stent has flexibility in delivery with a lesser radial force than the Wingspan stent, as the results with the Enterprise stent in previous studies have indicated that intracranial stenting may effective for ICAD and for primary revascularization in AIS patients. Vajda et al.³⁰ reported satisfactory results for the treatment of symptomatic intracranial atherosclerotic stenosis with the modified Bose method using the Enterprise



Fig. 2. An elderly patient presented with recurrent transient ischemic attack refractory to antithrombotic therapy. **(A)** Right vertebral angiogram showed long segment severe stenosis of the right distal vertebral artery. **(B)** Angiogram was performed again after 3 days due to recurrent ischemic symptoms during the hospitalization. Angiogram showed mTICI score of 1 with underlying stenosis. **(C)** Wingspan stent system failed to pass the lesion due to underlying severe stenosis. **(D)** Enterprise stent was successfully deployed as a rescue method with mTICI score of 3. mTICI, modified thrombolysis in cerebral infarction.

stent with a median pre- and postprocedural stenosis rate of $65.4\pm 1\%$ vs. $25.1\pm 1\%$ and a 100% technical success rate. In the setting of AIS, Dumont et al.¹⁵ reported that the Enterprise stent was found to be a safe and effective revascularization tool with a 90% recanalization rate and 15% major complications. In addition, Mocco et al.¹⁶ reported that 3 cases of failed Wingspan stenting were subsequently treated with successful deployment of the more navigable Enterprise stent at the occlusion site, and they suggested a potential benefit to the use of the Enterprise stent when routine intervention methods failed. However, they did not consider the underlying cause of vessel occlusion. In this study, we focused on the cause of vessel occlusion to the underlying ICAD. Although SAMMPRIS with the Wingspan stent failed to show a benefit for intracranial stenting over intensive medical management in the secondary prevention of stroke recurrence in high-risk patients with symptomatic ICAD,²⁶ our study suggests that a high successful recanalization rate with the Enterprise stent in symptomatic patients due to underlying ICAD without stroke recurrence during the follow-up periods.

Intracranial stent placement has potential hazards, such as in-stent thrombosis, malposition of the stent, or the inability to pass the stent to the appropriate location. Kim et al.³¹ reported a major complication rate of 33% with intracranial stent placement. However, in our series, we had 2 (12.5%) periprocedural complications (1 symptomatic intracranial hemorrhage and 1 progressive brain edema) without stent malposition or inability to pass the ICAD lesion, and this can be considered an acceptable risk. Symptomatic intracranial hemorrhage was probably affected by low Alberta Stroke Program Early CT Score (ASPECTS) on the initial CT scan with a high NIHSS. Moreover, in 2 cases in this study, Enterprise stenting overcame the Wingspan stent's disadvantages—an inability to pass the stent due to severe stenosis and an inability to access the lesion site due to vessel tortuosity.

Although a major concern of intracranial stenting in AIS patients is the high rate of instant in-stent thrombosis right after stent deployment (58.8% in this study) caused by insufficient antiplatelet premedication, low dose GP IIb-IIIa inhibitor administration solved this effectively and safely in this study. A previous study about low-dose IA tirofiban injection for instant re-occlusion by in situ thrombo-occlusion supports these results.³² However, although only 1 patient suffered from symptomatic intracranial hemorrhage in this study, care should be taken in patients who have received multiple coagulation-system-altering medications. Addition-

ally, it should be noted that some patients in this series also received post-stenting adjunctive therapy like angioplasty and/or GP IIb-IIIa inhibitor administration to achieve maximal recanalization results. So, the overall clinical outcomes cannot be solely attributed to stent placement, and rather should be interpreted within the context of the full course of therapy.

Our study has several limitations. First, the study design was retrospective with a small case series, and treatment decisions were not based on a standardized treatment protocol. Second, the evaluation of underlying ICAD is only based on angiographic findings. In fact, since there were 2 patients with arterial fibrillation, the possibility of embolic occlusion could not be completely ruled out. Third, there were no findings of restenosis of the stented segment on follow-up CT angiography, but this could not be confirmed because there was a lack of transfemoral catheter angiographic follow-up imaging after Enterprise stenting. So, in-stent restenosis cannot be ruled out, which is a major drawback after intracranial stenting despite the absence of recurrent ischemic symptoms during the follow-up periods. So, a large prospective study is necessary in patients with ischemic symptoms with underlying ICAD, which may affect the decision to utilize endovascular revascularization procedures for that condition.

CONCLUSION

The preliminary study reported herein provides evidence demonstrating the safety and efficacy of the Enterprise stent system for recanalization of ICAD. Further follow-up and more experience are also necessary to determine long-term results of intracranial steno-occlusive lesions treated with the Enterprise stent system.

Fund

None.

Ethics Statement

The Institutional Review Board at the Gangnam Severance Hospital approved this study. Informed consent was waived due to retrospective study design.

Conflicts of Interest

SHS has been the Editor-in-chief of the *Neurointervention* since 2022. No potential conflict of interest relevant to this

article was reported.

Author Contributions

Concept and design: SK, KL, and SHS. Data collection: WSJ. Writing the article: WSJ. Final approval of the article: SHS. Overall responsibility: WSJ.

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