# Rescue stenting for recanalization of intracranial atherosclerotic disease: the preliminary experience with Enterprise stent

Woo Sang Jung

Department of Medicine

The Graduate School, Yonsei University

# Rescue stenting for recanalization of intracranial atherosclerotic disease: the preliminary experience with Enterprise stent

Directed by Professor Sang Hyun Suh

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Woo Sang Jung

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This certifies that the Master's Thesis of
Woo Sang Jung is approved.

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Thesis Supervisor : Sang Hyun Suh

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Thesis Committee Member#1 : Kyung-Yul Lee

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Thesis Committee Member#2 : Chang-Ki Hong

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Yonsei University

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ABSTRACT

# Rescue stenting for recanalization of intracranial atherosclerotic disease: the preliminary experience with Enterprise stent

Woo Sang Jung

*Department of Medicine*
*The Graduate School, Yonsei University*

(Directed by Professor Sang Hyun Suh)

**Objective:** The purpose of this preliminary study is to evaluate the efficacy and safety of the rescue Enterprise stenting 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.

**Material and Methods:** A retrospective data analysis was performed in 15 consecutive patients who were treated with Enterprise stent as rescue method 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 rescue method in 15

patients for recanalization of steno-occlusion. All patients achieved final TIMI score improvement (53.3% with a TIMI score from 0 to 2 or 3, 46.7% with a TIMI score from 1 to 3). Two postprocedural complications (one symptomatic intracranial hemorrhage and one severe brain edema, 13.3%) were occurred among 15 patients. Among 12 patients with AIS, six patients (50%) had improvement of their NIHSS more than four at discharge. Seven patients (58.3%) had a good functional outcome with 3-month mRS $\leq$ 2 and mortality occurred (mRS = 6) in two patients (16.7%). None of the 10 surviving AIS and 3 TIA 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).

**Conclusions:** In this retrospective study suggest that Enterprise stenting can effectively and safely achieve recanalization from symptomatic steno-occlusive lesion as rescue method.

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Key words : Enterprise stent, rescue method, intracranial atherosclerotic disease

# Rescue stenting for recanalization of intracranial atherosclerotic disease: the preliminary experience with Enterprise stent

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## I. INTRODUCTION

Intracranial atherosclerotic disease (ICAD) is the cause of up to 20% of acute ischemic strokes and transient ischemic attacks (TIA), resulting in significant morbidity and mortality with more frequent in Asian populations (30-50%) than in Western populations.[1-4] Even with best medical therapy, the risk of recurrent stroke remains high.[5] Among patients with symptomatic ICAD who failed medical therapy, the subsequent rates of stroke or vascular death were as high as 45% per year.[6]

The relative limitations of the standard medical therapy to treat symptomatic intracranial large artery steno-occlusive lesion 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 the acute ischemic setting.[7-14] However, the Wingspan system is criticized for being bulky and requiring a multi-step deployment.[15,16] On the other hand, the Enterprise stent

(Codman, Raynham, Massachusetts, USA) can be shown 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. [17,18] Therefore, we tried to evaluate the efficacy and safety of Enterprise stent as rescue method for recanalization of symptomatic intracranial large artery steno-occlusion with underlying ICAD.

## II. MATERIALS AND METHODS

### 1. Patients

This retrospective analysis was approved by the institutional review board and the informed consent was waived.

The patients who underwent Enterprise stent replacement 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 Thrombolysis in Myocardial Infarction (TIMI) score (0=complete occlusion, 1=penetration without perfusion, 2=partial perfusion, 3=complete perfusion) as follows: 1) severe fixed luminal narrowing with initial TIMI score 1 or, 2) initial TIMI score 0 with evident residual severe stenosis (TIMI score 1 or 2) after the intra-arterial endovascular treatment. Symptomatic patient was defined as who presented with acute ischemic stroke (AIS) within 6 hours of symptom onset or recurrent transient ischemic attack (TIA) refractory to antithrombotic therapy. The antiplatelet regimen for recurrent TIA patients was a combination treatment with 100-325mg per day of aspirin plus 75mg per day of clopidogrel. Total 15 patients underwent rescue Enterprise stenting due to underlying ICAD lesion. Twelve of the 15 patients were treated due to AIS and remaining 3 patients were treated due to recurrent TIA.

### 2. Endovascular treatment

Endovascular treatment (EVT) was attempted in all patients under local anesthesia via the right femoral artery. If indicated, intravenous tissue-type plasminogen activator (IV-tPA) was administered before endovascular procedure in AIS patients. For recanalization procedure, a 6F Shuttle guiding sheath (Cook Medical Inc; Bloomington) or 6F guiding catheter (Envoy; Codman Neurovascular, Raynham, Massachusetts) was placed in the relevant internal carotid artery or vertebral artery. After 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) 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 as rescue method for severe ICAD or fixed stenosis after IA treatment failure. The Enterprise stent was available in 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. Glycoprotein IIb/IIIainhibitor (tirofiban, 0.5-1.5mg) was bolus injected intra-arterially in case of instant in-stent thrombosis. A closure device (Perclose; Abbott Vascular Devices, Redwood City, California)

was used to seal off the femoral artery puncture. After the stent insertion procedure, all patients maintained dual antiplatelet (aspirin 100mg+plavix 75mg) orally for at least 3 months.

### 3. Outcome measures and Follow-Up Evaluation

We evaluate the successful recanalization with pre-post procedure findings by a TIMI score. After the stenting procedure, all patients underwent routine brain imaging (CT or MRI) 24 hours after the procedure. Periprocedural complications (eg, vessel perforation or dissection), postprocedure complications (eg, 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 Institutes of Health Stroke Scale (NIHSS) score during hospitalization and 3-month modified Rankin Scale (mRS) score. A good functional outcome was defined as a mRS of $\leq$2. Symptom recurrence was defined as cerebral ischemic events in the territory that Enterprise stenting was performed during the follow-up period.

## III. RESULTS

The baseline characteristics and the clinical follow-up results are shown in Table 1. The mean age of the patients (9 men and 6 women) 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 occlusive 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 location of steno-occlusive lesion was as follows: the distal ICA in 4, distal ICA-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 lesion after more accepted techniques had already been attempted and failed. Techniques used prior to Enterprise stent deployment included intraarterial urokinase administration (2 patients), stent retriever (6 patients), balloon angioplasty (5 patients), failed Wingspan stent deployment (2 patients). Additional interventions performed after Enterprise stent deployment included balloon angioplasty (2 patients) and GP IIb-IIIa inhibitor administration (9 patients, 0.5-1.5mg).

All patients achieved final TIMI score improvement (53.3% with a TIMI score from 0 to 2 or 3, 46.7% with a TIMI score from 1 to 3). There were two (13.3%) postprocedural complications after stent deployment, one was

symptomatic parenchymal hemorrhage and the other was progressive brain edema, which led to mortality.

Among twelve AIS patients, three 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 of their NIHSS score more than four points at discharge. Seven patients (58.3%) had a good functional outcome with 3-month mRS $\leq$ 2 and mortality occurred (mRS = 6) in two 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 figures 1 and 2.

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

| No. | Sex/Age (yr) | Location | Initial IA treatment | Stent length (mm) | TIMI score | Initial NIHSS | NIHSS discharge | 3-month mRS | Postprocedural complication | Follow-up period (month) |
|---|---|---|---|---|---|---|---|---|---|---|
| 1 | M/71 | Right distal VA | Wingspan | 37 | 1→3 | 1 (TIA) | 0 | NA | no | 36 |
| 2 | F/75 | Right MCA, M1 | IA urokinase | 37 | 0→3 | 13 | 6 | 3 | no | 36 |
| 3 | F/59 | Right distal ICA | IA urokinase | 37 | 0→2 | 22 | NA | 6 | progressive edema | NA |
| 4 | F/79 | Left distal ICA | Stent retriever | 37 | 0→3 | 21 | 21 | 4 | symptomatic PH | 33 |
| 5 | M/77 | Left distal ICA-M1 | Stent retriever | 28 | 0→2 | 15 | 8 | 4 | no | 12 |
| 6 | M/53 | Left distal VA | Balloon angioplasty | 37 | 1→3 | 6 | 0 | 0 | no | 10 |
| 7 | M/84 | Right MCA, M1 | Wingspan | 14 | 1→3 | 6 (TIA) | 0 | NA | no | 8 |

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| 8 | F/72 | Left MCA, M1 | Stent retriever | 28 | 0→3 | 4 | 0 | 0 | no | 12 |
| 9 | M/77 | Right distal ICA | Stent retriever | 37 | 0→3 | 16 | 14 | 2 | no | 18 |
| 10 | F/72 | Basilar artery | Balloon angioplasty | 28 | 1→3 | 6 | 5 | 2 | no | 36 |
| 11 | M/57 | Left distal VA | Stent retriever | 37 | 0→2 | 20 | NA | 6 | no | NA |
| 12 | M/57 | Left MCA, M1 | Stent retriever | 14 | 0→3 | 3 | 3 | 1 | no | 10 |
| 13 | F/74 | Left MCA, M1 | Balloon angioplasty | 23 | 1→3 | 0 (TIA) | 0 | NA | no | 6 |
| 14 | M/60 | Right distal ICA | Balloon angioplasty | 23 | 1→3 | 9 | 4 | 2 | no | 4 |
| 15 | M/72 | Left MCA, M1 | Balloon angioplasty | 23 | 1→3 | 16 | 8 | 2 | no | 4 |

VA, vertebral artery; ICA, internal carotid artery; MCA, middle cerebral artery; IA, intra-arterial; PH, parenchymal hemorrhage; NA, not applicable; TIA, transient ischemic attack; mRS, modified Rankin Scale

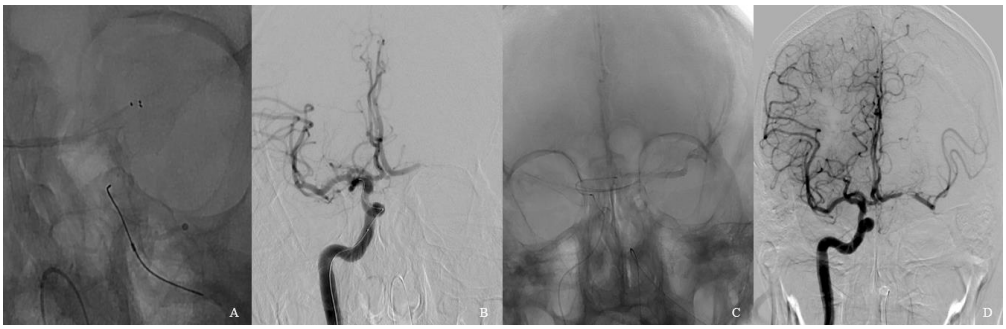


Figure 1. Seventy-seven year-old male patient who presented with acute left distal ICA and proximal MCA occlusion and National Institutes of Health Stroke Scale (NIHSS) score 15. A) The patient received mechanical thrombecotomy initially with refractoriness due to underlying severe stenosis via right internal carotid artery. B) Contralateral approach to the occlusion site was tried from the right ICA route and C) Enterprise stent (28 mm) was deployed successfully in the left MCA-ACA segment. D) 15 minutes delayed angiography showed patent antegrade flow (TIMI score 2) in the stented segment.

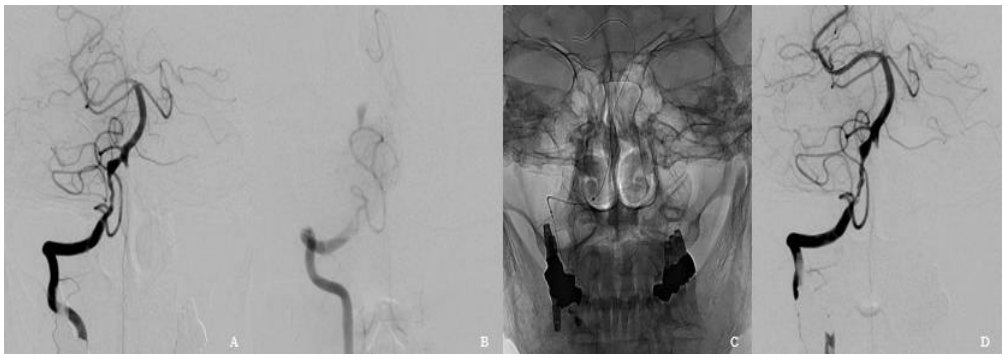


Figure 2. Seventy-one year-old male patient who presented with recurrent transient ischemic attack refractory to antithrombotic therapy. A) Right vertebral angiogram showed long segment severe stenosis of the right distal vertebral artery. B) Angiogram was performed again after 3 days due to recurred ischemic symptom during the hospitalization. Angiogram showed TIMI score 1 with underlying stenosis. C) Wingspan stent system was failed to pass the lesion due to underlying severe stenosis. D) Enterprise stent was successfully deployed as an rescue method with TIMI score 3.

## IV. DISCUSSION

In the results of this preliminary study of 15 patients in whom other intra-arterial interventions had already failed, we show that Enterprise stenting can help achieve recanalization with final TIMI score 2 or 3 in all patients (53.3% with a TIMI score from 0 to 2 or 3, 46.7% with a TIMI score from 1 to 3) with underlying ICAD and good functional outcome with mRS ≤ 2 (58.3%) in AIS patients.

ICAD is one of the major cause of acute/recurrent ischemic symptom 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.[4,19-22] Depending on the degree of vascular stenosis and other conditions, patients with ICAD have a cerebrovascular event rate of 10% to 50% per year.[5] As previously reported in several studies, the Warfarin-Aspirin Symptomatic Intracranial Disease (WASID) 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 United States and other countries.[7,10-13] However, in 2011, Stenting versus Aggressive Medical Therapy for Intracranial Arterial Stenosis (SAMMPRIS) study revealed that aggressive medical management was superior to intracranial stenting with the use of the Wingspan stent system for ICAD, because high risk of early stroke after Wingspan stenting.[25] In addition, cases with very difficult anatomy and complex lesion geometry, Wingspan stent system used to fail of stent delivery to the target lesion, because of their cumbersome carrier system.[16] 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.[26,27,28] However, Enterprise stent has a flexibility to delivery with a lesser radial force than Wingspan stent, the results with Enterprise stent of previous studies have indicated that intracranial stenting may effective for ICAD and for primary revascularization device in the AIS patients. Vajda *et al* reported satisfactory results for the treatment of symptomatic intracranial atherosclerotic stenosis with modified Bose method using the Enterprise stent with the median pre- and postprocedural stenosis rate was 65.4 ± 1% vs 25.1 ± 1% and 100% technical success rate.[29] In the setting of AIS, Travis et al reported that Enterprise stent was found to be a safe and effective revascularization tool with 90% recanalization rate and 15% major complication.[17] In addition, Mocco *et al* reported that three cases of failed Wingspan stenting that 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.[18] However, they did not consider the underlying cause of vessel occlusion. In this study, we focused the cause of vessel occlusion to the underlying ICAD. Although SAMPRIS with 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, our study suggests that high successful recanalization rate with Enterprise stent as rescue method 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 reported a major complication rate of 33% with intracranial stent placement.[30] However, in our series, we had two (12.5%) periprocedural complications (one symptomatic intracranial hemorrhage and one progressive brain edema) without stent malposition or inability to pass the ICAD lesion, and this can be considered an acceptable risk. Moreover, in two cases of this study, Enterprise stenting overcame the Wingspan stent's disadvantages – one inability to pass the stent due to severe stenosis and one inability to access lesion site due to vessel tortuosity.

Although one of the major concern of intracranial stenting in AIS patients is high rate of instant in-stent thrombosis right after the stent deployment (58.8% in this study) caused by insufficient antiplatelet premedication, low dose GP IIb-IIIa inhibitor administration solved these events effectively and safely in this study. Previous study about low dose IA tirofiban injection for instant re-occlusion by in situ thrombo-occlusion support this results.[31] However, although only one patient suffered from symptomatic intracranial hemorrhage in this study, care should be taken in patients who have received multiple coagulation-system-altering medications. Additionally, 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 result. So, the overall

clinical outcomes cannot be solely attributed to stent placement rather should be interpreted within the context of the full course of therapy.

Our study has several limitations. First, the study design with small case series was retrospective and treatment decisions were not based on a standardized treatment protocol. Second, the evaluation of underlying ICAD is only based on the angiographic finding. In fact, since there were two patients with arterial fibrillation, the possibility of embolic occlusion could not be totally ruled out. Third, there is lack of transfemoral catheter angiographic follow-up after Enterprise stenting. So, in-stent restenosis cannot be ruled out which is one of the major drawback after intracranial stenting, despite the absence of recurrent ischemic symptom during the follow-up periods. So, 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.

## V. CONCLUSION

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

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ABSTRACT(IN KOREAN)

# 두개내 동맥 경화증에 의한 병변의 재개통을 위한 대체 스텐트 삽입술: 엔터프라이즈 스텐트를 이용한 예비 결과

<지도교수 서 상 현>

연세대학교 대학원 의학과

정 우 상

**배경 및 목적:** 두개 내 동맥경화증에 의한 협착 또는 폐색은 동양인에서 급성 뇌졸중의 흔한 원인이다. 이 예비 연구의 목적은 급성 허혈성 뇌졸중 또는 내과적 치료에도 불구하고 재발하는 허혈 증상을 동반한 두개 내 협착 또는 폐색성 동맥의 치료에 대한 엔터프라이즈 스텐트 삽입술의 효능 및 안전성을 평가하는 것이다.

**대상 및 방법:** 2010년도부터 2017년도까지 후향적으로, 급성 허혈성 뇌졸중 또는 내과적 치료에도 불구하고 재발하는 허혈 증상을 동반한 두개 내 협착 또는 폐색성 동맥을 가진 환자들 중 다른 동맥 내 치료에 실패하고, 대체 방법으로 엔터프라이즈 스텐트를 삽입한 15명의 환자들을 대상으로 하였다. 대상 환자들의 시술 결과, 시술과 관련된 부작용,시술 후 부작용, 임상적 결과 등을 분석하였다.

**결과:** 15명의 환자 모두에서 TIMI점수의 향상을 얻을 수 있었다 (53.3%는 TIMI 0점에서 2점 혹은 3점으로, 46.7%는 TIMI 1점에서 3점으로 향상). 두명의 환자에서 시술 후 부작용 및 사망이 발생하였다. 12명의 급성 허혈성 뇌졸중 환자군 중, 여섯명에서 퇴원 시 4점 이상의

NIHSS 점수의 향상을 보였고, 7명의 환자에서 3개월 후 mRS 점수로 평가한 예후에서 좋은 결과를 보였다. 생존한 13명의 환자 중에서 각각의 추적 관찰 기간 동안, 스텐트 삽입된 동맥과 관련된 뇌허혈 증상의 재발을 보인 경우는 없었다.

**결론:** 엔터프라이즈 스텐트 삽입술은 유증상의 두개 내 협착 또는 폐색성 동맥을 가진 환자에서 동맥을 통한 일차적 치료에 실패했을 때 대체 방법으로 효과적이고 안전하게 시행될 수 있음을 확인하였다.

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핵심되는 말 : 엔터프라이즈 스텐트 삽입술, 대체 삽입, 두개 내 협착 또는 폐색성 동맥