



Emergent Intracranial Balloon Angioplasty and Bailout Self-Expandable Stent Placement in Acute Large Vessel Occlusion of the Anterior Circulation: Experience of a Single Institution

전방 순환계의 급성 대혈관 폐색에서 응급 두개내 풍선 혈관확장술과 구제적 자가 확장 스텐트삽입: 단일 기관의 경험

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Purpose: To evaluate the outcomes of angioplasty for recanalization after acute ischemic stroke (AIS).

Materials and Methods: The study population was selected from 134 patients who underwent endovascular revascularization therapy (ERT) for AIS between October 2011 and May 2014. Of those 134 patients, 39 who underwent balloon angioplasty with or without stent insertion were included in this study. Balloon angioplasty was the primary treatment for nine patients and a rescue method for 30 patients. The revascularization rate at 7 days, procedure-related complications, and clinical outcomes at 3 months were analyzed.

Results: The occlusion sites were the middle cerebral artery ($n = 26$), intracranial internal carotid artery ($n = 10$), and middle cerebral artery branch ($n = 3$). Angioplasty achieved successful revascularization (Thrombolysis in Cerebral Ischemia grade 2b-3) in 76.9% of patients. Computed tomography angiography performed 7 days post-procedure revealed a maintained reperfusion in 82.8% of successful cases. Only two patients had symptomatic intracerebral hemorrhage. At the 3-month follow-up, 18 (48.6%) and 10 (27.0%) patients showed good and poor functional outcomes, respectively (modified Rankin Scale scores, 0-2 and 5-6).

Conclusion: Emergent balloon angioplasty and bailout self-expandable stent placement may be safe and effective for achieving successful revascularization in acute large vessel occlusion of the anterior circulation. It could be a feasible rescue method as well as a primary method for ERT.

Index terms

Stroke
Reperfusion
Stents
Angioplasty

Received November 17, 2015

Revised December 30, 2015

Accepted October 18, 2016

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INTRODUCTION

Many revascularization techniques have improved clinical outcomes and reduced mortality in acute ischemic stroke (AIS) patients with large-vessel occlusion. Intravenous recombinant tissue plasminogen activator (IV-rtPA) is considered the first-line treatment for AIS within a 4.5 h time window (1, 2). However, endovascular revascularization therapy (ERT) is superior to IV-rtPA alone for achieving large-vessel revascularization (3-6). Although

there are many suitable devices for ERT, recanalization failure of ERT occurs in some cases, and balloon angioplasty has been performed as a rescue method (7). Balloon angioplasty can be useful in cases of *in-situ* stenosis or stenosis caused by atherosclerosis.

Previous studies have compared several methods for mechanical thrombolysis (8). To our knowledge, only a few studies focused on the use of balloon angioplasty, with or without stenting, to achieve recanalization in ERT for AIS (8). In this study, we retrospectively evaluate the outcomes of using balloon an-

angioplasty to achieve recanalization in ERT for AIS and report our single-center experience in the treatment of AIS.

MATERIALS AND METHODS

Study Population

This study was approved by the Institutional Review Board of our hospital, and informed consent was waived due to the retrospective design. There were 134 patients who underwent ERT for AIS between October 2011 and May 2014. We included 39 of these who were treated with balloon angioplasty, with or without stent insertion. Patients were retrospectively identified from our stroke databases. Nine patients were treated with balloon angioplasty as a primary method, and 30 patients were treated with balloon angioplasty as a rescue method.

Computed tomography (CT) and/or magnetic resonance imaging (MRI) was performed to evaluate the salvageable tissue and the presence of hemorrhage before beginning ERT. If no other contraindications were noted, bridging IV-rtPA treatment was initiated after radiologic evaluation. The indications for ERT were as follows: 1) clinical diagnosis of AIS; 2) National Institutes of Health Stroke Scale (NIHSS) score > 4 at symptom presentation; 3) steno-occlusive lesion of a major artery detected on MR angiography; 4) definite perfusion-diffusion or clinical-diffusion mismatch; 5) presentation within 24 h from first abnormal time or early neurologic deterioration after stroke; and 6) no intracranial hemorrhage present.

Endovascular Procedure

All procedures were performed under local anesthesia, with or without sedative agents, in an intervention room equipped for digital subtraction angiography. A bolus of heparin (2000–3000 units) was administered to patients who were not treated with IV-rtPA. In cases for which coaxial guiding catheters were used, a guiding catheter larger than 6 F was inserted into the distal cervical internal carotid artery. We used a 6 F guiding catheter (Envoy, Cordis Endovascular Corporation, USA), or a 6 F Envoy guiding catheter into a 6 F shuttle catheter (Cook Medical Inc., Bloomington, IN, USA), or a 9 F Optimo balloon tipped guiding catheter (Tokai Medical Products, Aichi, Japan) coaxially. A Gateway balloon catheter (Boston Scientific Corporation, Stryker Neurovascular, Freemont, CA, USA) and/or Wingspan stent

(Boston Scientific Corporation) was used for angioplasty.

We routinely used the Solitaire stent (Covidien/ev3, Dublin, Ireland) and Penumbra reperfusion catheter as the first-line method for mechanical thrombectomy. If the first-line method failed, balloon angioplasty was performed as a rescue technique. Balloon angioplasty was performed as the first-line method in patients who were certain to have severe in-situ stenosis or near occlusion caused by atherosclerosis. Control angiography was performed at the end of the procedure and graded for angiographic reperfusion. If reperfusion after ERT was not successful [Thrombolysis in Cerebral Ischemia (TICI) grade 0 or 1], angioplasty was repeated according to the operator's discretion.

All procedures were performed by two neurointerventionists. The occlusion sites were approached using a microcatheter (Echelon™ 14; eV3 Neurovascular, Irvine, CA, USA) and a microguide wire (Synchro™ 2 0.014"; Boston Scientific, Natick, MA, USA). Selective cerebral angiography was performed distal to the occluded site to confirm the length of the occluded segment, anatomical position, and absence of perforation or extravasation. The length from the proximal occlusion site to the beginning of the normal vessel was determined on the selective cerebral angiogram, and was considered the lesion length. The Synchro 14 microwire was then exchanged with the 0.014-inch microwire (Transcend; Boston Scientific, Natick, MA, USA) for the delivery of the angioplasty balloon and stent. The balloon size and length for pre-stent angioplasty were measured using cerebral angiography, and a balloon slightly smaller than the lesion was selected. In nine cases in which balloon angioplasty was used as the primary method, the intracranial stents were substituted for the balloon after balloon angioplasty in eight cases. The stent diameter was usually 0.5–1.0 mm larger than the vessel diameter. The mid segment of the stent was located at the point of occlusion. Balloon angioplasty after stent insertion was performed to treat residual stenosis. Delayed angiography was performed to evaluate complications such as thrombosis, spasm, and vessel perforation or dissection. If re-thrombosis after angioplasty persisted, intra-arterial tirofiban (Aggrastat; Merck, West Point, PA, USA; 1 mg) was administered for 10–15 minutes to restore blood flow (Fig. 1). The exchange wire and guiding catheter were removed after delayed angiography. After the procedure, dual antiplatelet agents were administered for at least one month.

Procedural Outcomes

The revascularization status was assessed by control cerebral angiography immediately and by follow-up CT angiography after 7 days. Angiographic reperfusion status was classified according to the TICI grade (9).

Clinical Outcomes

A complete neurologic examination was performed by a stroke neurologist after each procedure. Neurological improvement was assessed using the NIHSS score on day 7, and the functional outcome was assessed using the modified Rankin Scale (mRS) score at 3 months after the endovascular procedure (10). An mRS score ≤ 2 was considered a favorable clinical outcome (11), and neurological improvement was defined as an improvement of 4 points over the baseline NIHSS score.

All patients underwent non-enhanced CT immediately after

the procedure to exclude hemorrhagic complications. Symptomatic intracranial hemorrhage was identified by CT evidence of a new intracranial hemorrhage, with apparent neurological deterioration, manifesting as objective signs or an increased NIHSS score. Diffusion MRI and CT/MR angiography were also performed within 24 h and 7 days after the procedure to evaluate any ischemic events and the revascularization status of stenotic arteries.

Statistical Analysis

Baseline characteristics of study patients were compared between patients where balloon angioplasty was the primary method and patients for whom it was a rescue method. Statistical analysis was performed with Student's *t*-test for continuous variables and the Fisher's exact test for categorical variables. *p*-values < 0.05 were considered to indicate statistically significant differ-

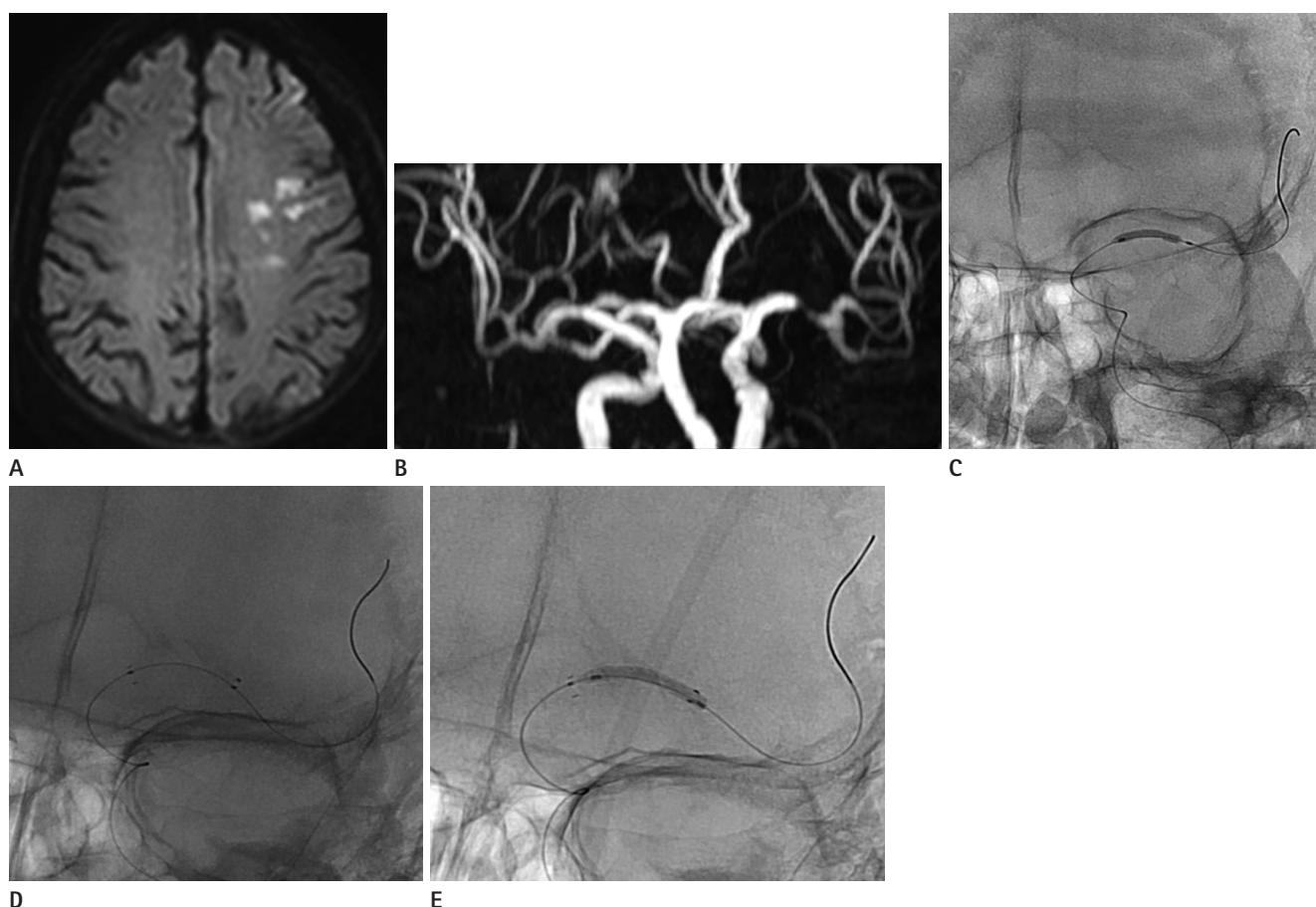


Fig. 1. Tirofiban was administered to restore blood flow for re-thrombolysis after angioplasty. An 81-year-old man who presented with multifocal middle cerebral artery territory infarction on diffusion weighted magnetic resonance imaging (A), shows left proximal M1 stenosis on MR angiography (B). Gateway balloon angioplasty (C) and Wingspan stent insertion (D) were performed, but in-stent thrombolysis persisted. Thus, tirofiban was administered to restore blood flow, and post-stent balloon angioplasty (E) was performed.

ences. All statistical analyses were performed with commercially available software (SPSS 19.0 for Windows; SPSS Inc., Chicago, IL, USA).

RESULTS

Patients

Thirty-nine patients with AIS were treated with intracranial balloon angioplasty. The baseline characteristics of the patients are described in Table 1. The patients included 18 men and 21 women with a mean age of 69.4 ± 12.6 years (range, 38–91 years). The mean baseline NIHSS score was 13.4 ± 4.07 (range, 5–23). The mean time interval from stroke symptoms to recanalization was 256.6 ± 124.1 min. Arrival time to recanalization time was 252.1 ± 127.1 min (primary method) and 258.2 ± 126.1 min (rescue method). The onset time of stroke was not clear in 16 patients. Stroke subtypes were significantly different between

patients with primary and rescue methods. Other baseline characteristics were not significantly different between the two groups.

Nine patients with severe stenosis or near occlusion were treated with balloon angioplasty as a primary method. Thirty patients underwent balloon angioplasty as a rescue method after thrombectomy using the penumbra reperfusion catheter, Solitaire device, or chemical thrombolysis as the primary method for ERT. In three cases, intra-arterial urokinase or tirofiban was used as the first-line method for ERT. Two patients were treated with only stenting; eight patients were treated with only balloon angioplasty; and 29 patients were treated with stent placement before or after balloon angioplasty.

Outcome Data

The results of angioplasty and stent insertion for AIS are summarized in Table 2. Overall successful revascularization (TICI

Table 1. Baseline Characteristics of the Study Patients

Characteristics	Overall (<i>n</i> = 39)	Primary Method (<i>n</i> = 9)	Rescue Method (<i>n</i> = 30)	<i>p</i> -Value
Age (years), mean \pm SD	69.4 \pm 12.6	68.9 \pm 14.1	69.2 \pm 12.8	0.288
Female, <i>n</i> (%)	21 (52.8)	5 (55.6)	16 (53.3)	1.000
LNT (min), median (IQR)	209 (60–852)	293 (76.5–1094.5)	204 (54–852)	0.881
FAT (min), median (IQR)	98 (40–210)	113 (47–213)	98 (34–207)	0.529
Baseline NIHSS score, mean \pm SD	13.4 \pm 4.1	13.7 \pm 3.7	13.2 \pm 4.3	0.092
Stroke subtype, <i>n</i> (%)				
Large artery atherosclerosis	27 (69.2)	9 (100)	18 (60.0)	0.036
Cardioembolic	12 (30.8)	0 (0)	12 (40.0)	0.036
IV-rtPA, <i>n</i> (%)	10 (25.6)	2 (22.2)	8 (26.7)	1.000
Occlusion sites, <i>n</i> (%)				
Distal ICA	10 (25.6)	3 (33.3)	7 (23.3)	0.669
MCA	26 (66.7)	5 (55.6)	21 (70.0)	0.447
MCA branch	3 (7.7)	1 (11.1)	2 (6.7)	0.223
Risk factors or underlying disease, <i>n</i> (%)				
Hypertension	26 (66.6)	8 (88.9)	18 (60.0)	0.225
Diabetes	16 (41.0)	4 (44.4)	15 (50.0)	1.000
Coronary disease	7 (17.9)	3 (33.3)	4 (13.3)	0.319
Atrial fibrillation	12 (30.8)	0 (0)	12 (40.0)	0.036
Current smoking	6 (20.5)	2 (22.2)	4 (13.3)	0.425
Old CVA	9 (23.1)	1 (11.1)	8 (26.7)	0.654
Cancer	7 (17.9)	2 (22.2)	5 (16.7)	0.653
Medication history				
Antiplatelet or anticoagulant	20 (51.3)	6 (66.7)	14 (46.7)	0.451
Statin	8 (20.5)	4 (44.4)	4 (13.3)	0.065

CVA = cerebral vascular accident, FAT = first abnormal time, ICA = internal carotid artery, IQR = interquartile range, IV-rtPA = intravenous recombinant tissue plasminogen activator, MCA = middle cerebral artery, NIHSS = National Institutes of Health Stroke Scale, LNT = last normal time, SD = standard deviation

grade 2b or 3) was achieved in 30 of 39 patients (76.9%). The follow-up CT angiography 7 days post-procedure showed that successful revascularization was maintained in 82.8% of patients. Re-occlusion after revascularization occurred in only two patients (6.8%). CT angiography was not performed for the other 10 patients due to patient refusal.

Angioplasty as a primary method was successful (TICI grade 2b or 3) in seven patients (77.8%). The remaining two cases showed in-stent stenosis by delayed angiography. One of these showed asymptomatic improvement after tirofiban infusion, but the other patient showed residual stenosis despite tirofiban infusion, and underwent additional balloon angioplasty. Successful recanalization (TICI grade 2b or 3) was achieved in 23 patients (76.7%) who underwent angioplasty as a rescue method (Fig. 2). Two patients did not show successful revascularization after rescue angioplasty, despite the administration of adjuvant intra-arterial urokinase. In the other five patients, additional rescue methods were not performed.

Complications during the peri-procedural period occurred in 13 patients [9 asymptomatic intracerebral hemorrhage (ICH), 2 symptomatic ICH, and 2 in-stent thrombosis]. Two patients with in-stent thrombosis were treated with adjuvant intra-arterial tirofiban, and they did not show any residual symptoms. Vessel dissections or perforations did not develop during balloon angioplasty in any of the patients.

For 7 days after mechanical thrombectomy, 17 patients (43.5%) showed neurologic improvement, as assessed by a decrease in the NIHSS score by more than 4 points. Clinical outcome data at 3 months were available for 37 of 39 patients (94.8%). The functional outcome scores at the 3 month follow-up were: an mRS of 0–2 in 18 patients (48.6%); mRS of 3 or 4 in nine patients (24.3%);

and an mRS of 5 or 6 in 10 patients (27.0%). Mortality occurred in five patients (13.5%) with four of these patients exhibiting poor recanalization. Sudden cardiac death occurred at 7 days after ERT in one female patient 78 years of age. Two deaths were caused by malignant cerebral edema; the other deaths were not directly related to the thrombectomy procedure.

DISCUSSION

Successful recanalization improves the clinical outcome and mortality rate in AIS patients. Kulcsár et al. (12) reported that the Penumbra System produced successful recanalization in 93% of patients. Roth et al. (13) and Castaño et al. (14) also reported successful recanalization rates of 90% and 90.2%, respectively, using Solitaire stents in AIS patients. Despite the development of methods for intra-arterial thrombolysis for AIS, failure of arterial recanalization remains a problem (15, 16). Yoon et al. (17) found that 20% to 30% of AIS patients needed a second-line treatment for re-occlusion after mechanical thrombectomy. According to the previous Multi-MERCI trial, 57.3% of successful recanalizations were achieved with retrieval alone, and 69.5% were achieved in conjunction with another treatment method (18). In addition, an 81.6% recanalization rate was observed after revascularization using the Penumbra system with the adjunctive use of intra-arterial thrombolytic therapy (19).

Previous studies have reported that angioplasty is a safe and effective method. Siddiq et al. (20) reported similar rates of peri-procedural stroke and death with angioplasty compared to stent placement for AIS. In addition, angioplasty is proposed as a safe and effective method for patients who experience failed intra-arterial thrombolysis (7, 21). Yoon et al. (22) reported that revas-

Table 2. Results of Balloon Angioplasty and Stent Insertion for Acute Ischemic Stroke

Reperfusion Degree	Overall (<i>n</i> = 39)	Primary method (<i>n</i> = 9)	Rescue method (<i>n</i> = 30)	<i>p</i> -Value
TICI 2b–3, <i>n</i> (%)	30 (76.9)	7 (77.8)	23 (76.7)	1.000
TICI 3	8 (20.5)	2 (22.2)	6 (20.0)	
TICI 2b	22 (56.4)	5 (55.6)	17 (56.7)	
TICI 2a	2 (5.1)	0 (0)	2 (6.7)	
TICI 1	5 (12.8)	1 (11.1)	4 (13.3)	
TICI 0	2 (5.1)	1 (11.1)	1 (3.3)	
Re-occlusion of stent after 7 days (<i>n</i> = 29)*, <i>n</i> (%)	2 (6.8)	0 (0)	2 (6.7)	

*Follow-up CT angiography at 7 days post-procedure was available in 29 patients.

TICI = Thrombolysis in Cerebral Ischemia

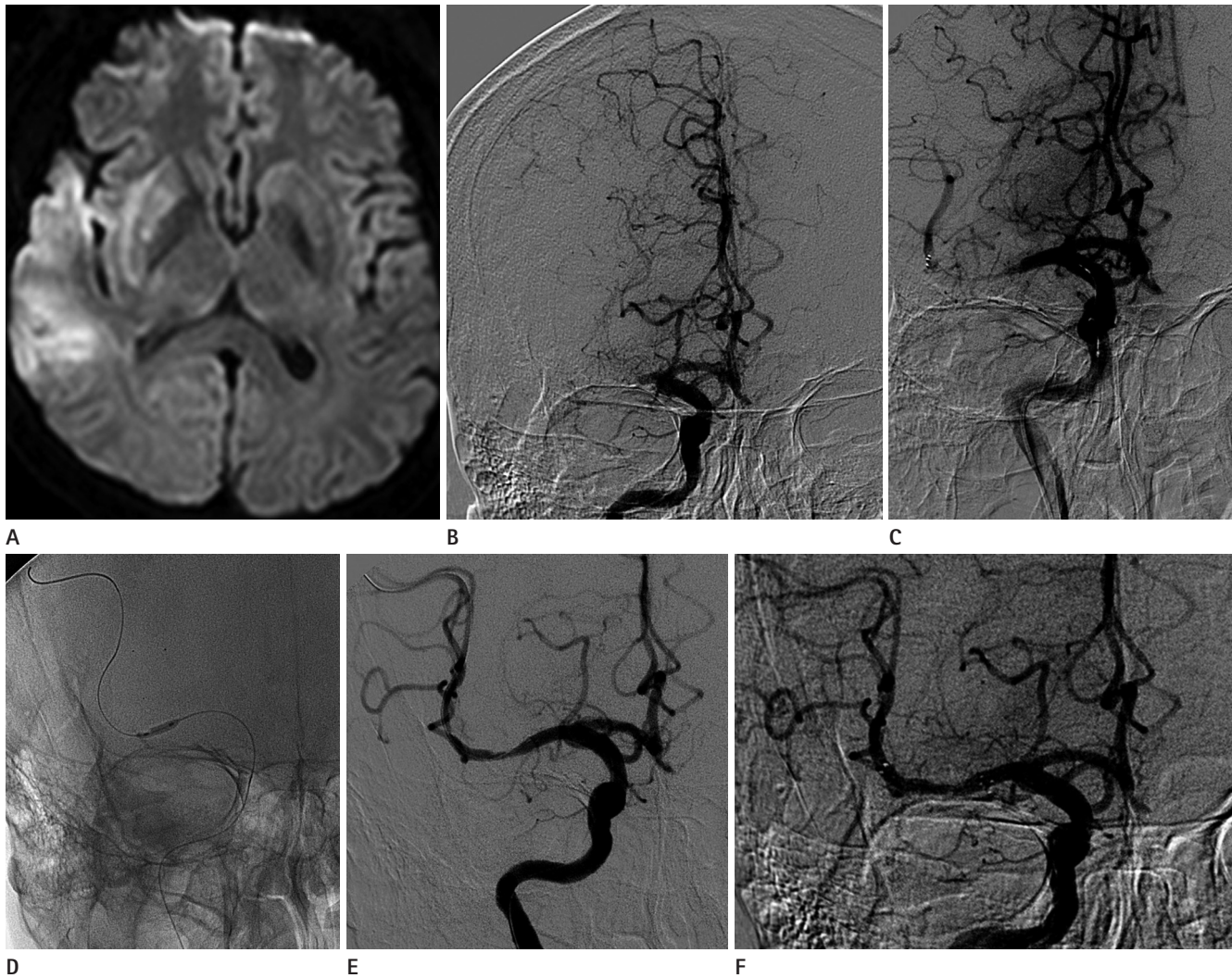


Fig. 2. Angioplasty was performed as a rescue method after failure of a Solitaire stent for mechanical thrombectomy. A 55-year-old man with left hemiparesis shows right middle cerebral artery (MCA) territory infarction on diffusion weighted imaging (DWI) (**A**), and a severe steno-occlusive lesion involving the right M1 segment (**B**) on angiography. After several trials of thrombus retrieval using Solitaire stents, only partial recanalization was achieved (**C**). A Gateway catheter and Wingspan stent were used for balloon angioplasty (**D**). However, progression of an in-stent thrombus is noted on delayed angiography (**E**). Thus, tirofiban was infused and the thrombus decreased (**F**).

cularization occurred in 95% of patients. Moreover, a favorable outcome was observed in 65% of patients with stroke caused by intracranial stenosis, who were treated with intracranial angioplasty with or without stenting. Our study also suggested that additional successful recanalization and favorable clinical outcomes were achieved with balloon angioplasty after failure of the first-line endovascular therapy. A previous study of acute basilar occlusion showed that intracranial balloon angioplasty in combination with stenting is helpful for recanalizing a large artery occlusion in the anterior circulation that is intractable to mechanical thrombectomy (23).

The overall recanalization rate in the current study was 79.5%,

and only two patients showed re-occlusion on the 7 day follow-up CT angiography. This result is similar to that of a previous study where 3 of 34 patients showed re-occlusion after endovascular treatment (22). A previous study using mechanical thrombectomy with angioplasty and stenting for acute basilar occlusions observed a favorable functional outcome (mRS at 3 months ≤ 2) in 46.2% of patients (23). Our study had clinical outcomes similar to a previous study that observed a good functional outcome (mRS at 3 months ≤ 2) in 18 of 39 patients (48.6%), and a poor functional outcome (mRS at 3 months = 5 or 6) in 10 patients (27.0%). However, the previous study examined a different occlusion site (23). The mortality rate was 13.5% in our study.

The results of our study suggest that balloon angioplasty is a useful method for intra-arterial therapy in AIS patients.

A limitation of the present study is that it was retrospective in nature, and therefore has the inherent limitation of selection bias. Thus, prospective, multicenter, randomized controlled trials with long-term clinical outcomes, and a larger study population, are needed to assess the efficacy and risk-benefit ratio of balloon angioplasty in AIS patients.

In conclusion, emergent balloon angioplasty and bailout self-expandable stent placement may be a safe and effective method to achieve successful recanalization in acute large vessel occlusion of the anterior circulation. It could be feasible as both a primary method and a rescue method for intra-arterial therapy.

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전방 순환계의 급성 대혈관 폐색에서 응급 두개내 풍선 혈관확장술과 구제적 자가 확장 스텐트삽입: 단일 기관의 경험

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목적: 급성뇌경색증의 혈관 내 재개통술에서 재관류를 위한 혈관확장술의 결과를 평가하고자 하였다.

대상과 방법: 저자들은 2011년 10월부터 2014년 5월까지 급성뇌경색에서 혈관 내 재개통술을 시행받았던 134명의 환자들 중 스텐트삽입술을 시행하거나 시행하지 않고 풍선혈관확장술을 시행받은 총 39명의 환자들을 포함하였다. 9명은 풍선 혈관확장술을 주된 치료로 시행하였고 30명은 풍선혈관확장술을 구출방법으로서 이용하였다. 시술 후 7일째 재관류율과 시술관련 합병증, 3개월째 임상적 결과를 분석하였다.

결과: 혈관 폐색 부위는 주중뇌동맥($n = 26$), 내경동맥($n = 10$)과 중뇌동맥 분지($n = 3$)였다. 혈관확장술로 잘된 재관류(Thrombolysis in Cerebral Ischemia grade, 2b-3)는 76.9%였다. 7일째 추적관찰한 컴퓨터단층혈관조영술에서 재관류는 82.8%에서 유지되었다. 2명의 환자에서만 유증상의 뇌내출혈이 발생하였다. 3개월째 시행한 추적관찰에서 18명(48.6%)은 좋은 기능적 결과(modified Rankin Scale (이하 mRS), 0-2), 10명(27.0%)은 나쁜 기능적 결과를 보였다(mRS 5-6).

결론: 응급풍선혈관확장술과 구제적 자가 확장 스텐트삽입은 앞순환계 급성뇌경색에서 성공적인 재관류를 획득하는 안전하고 효과적인 방법으로 여겨진다. 이는 혈관내 재개통술을 위한 일차적인 방법뿐 아니라 구출방법으로서도 실현가능해 보인다.

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