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# First-Pass Recanalization with EmboTrap II in Acute Ischemic Stroke (FREE-AIS): A Multicenter Prospective Study

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**Objective:** We aimed to evaluate the efficacy of EmboTrap II in terms of first-pass recanalization and to determine whether it could yield favorable outcomes.

**Materials and Methods:** In this multicenter, prospective study, we consecutively enrolled patients who underwent mechanical thrombectomy using EmboTrap II as a front-line device. The primary outcome was the first pass effect (FPE) rate defined by modified Thrombolysis In Cerebral Infarction (mTICI) grade 2c or 3 by the first pass of EmboTrap II. In addition, modified FPE (mFPE; mTICI grade 2b–3 by the first pass of EmboTrap II), successful recanalization (final mTICI grade 2b–3), and clinical outcomes were assessed. We also analyzed the effect of FPE on a modified Rankin Scale (mRS) score of 0–2 at 3 months.

**Results:** Two hundred-ten patients (mean age ± standard deviation, 73.3 ± 11.4 years; male, 55.7%) were included. Ninety-nine patients (47.1%) had FPE, and mFPE was achieved in 150 (71.4%) patients. Successful recanalization was achieved in 191 (91.0%) patients. Among them, 164 (85.9%) patients underwent successful recanalization by exclusively using EmboTrap II. The time from groin puncture to FPE was 25.0 minutes (interquartile range, 17.0–35.0 minutes). Procedure-related complications were observed in seven (3.3%) patients. Symptomatic intracranial hemorrhage developed in 14 (6.7%) patients. One hundred twenty-three (58.9% of 209 completely followed) patients had an mRS score of 0–2. Sixteen (7.7% of 209) patients died during the follow-up period. Patients who had successful recanalization with FPE were four times more likely to have an mRS score of 0–2 than those who had successful recanalization without FPE (adjusted odds ratio, 4.13; 95% confidence interval, 1.59–10.8; $p = 0.004$).

**Conclusion:** Mechanical thrombectomy using the front-line EmboTrap II is effective and safe. In particular, FPE rates were high. Achieving FPE was important for an mRS score of 0–2, even in patients with successful recanalization.

**Keywords:** *First-pass recanalization; Thrombectomy; Stent; Stroke*

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## INTRODUCTION

Achieving reperfusion to modified Thrombolysis In Cerebral Infarction (mTICI) grade 2b or 3 should be a technical goal in the endovascular treatment of acute stroke [1]. Moreover, reperfusion to mTICI grade 2b or 3 should be achieved as early as possible to ensure a clinical benefit. In addition to the clinical guidelines, nearly all studies have considered mTICI grade 2b or 3 successful recanalization. However, as the degree of reperfusion varies from merely over 50% to near-complete, even in one category of mTICI grade 2b, it often does not correspond with the patient's clinical outcome [2,3]. However, further improved reperfusion status, such as mTICI grade 2c (near-complete revascularization), was consistently associated with a better functional outcome [2,4,5]. Thus, recent studies have frequently adopted more extreme mTICI grade 2c or 3 for better endovascular performance [6-8]. A continuous time frame was segmented and specified according to the number of device passes [9,10]. Single-pass or first-pass recanalization has been proposed as a strategy to reduce the time required to achieve successful recanalization [11]. Finally, beyond the classical endpoint of endovascular treatment (mTICI grade 2b or 3, as early as possible), a new concept (mTICI grade 2c or 3 by the first pass of the device) has recently been highlighted for the best endovascular performance [11-18]. The conceptual relevance of the first-pass achievement of mTICI grade 2c or 3 has been demonstrated in several clinical studies. Briefly, first-pass recanalization to mTICI grade 2c or 3 was significantly associated with superior clinical outcomes [6,11-19].

EmboTrap (Cerenovus) is a stent retriever designed to engage and retrieve the clot in the neurovasculature. EmboTrap is also delivered, unsheathed, and deployed across the clot in a fashion similar to other stent retrievers. However, EmboTrap has unique structural features that maximize its efficacy in clot retrieval by minimizing incomplete clot engagement or clot dislodgement [20,21]. A novel dual-layer structure of EmboTrap was devised to improve clot engagement, and a closed distal mesh was used to reduce distal embolism during retrieval. EmboTrap was modified into EmboTrap II in its structural design. In EmboTrap II, the number of outer cages was increased from three to five to improve clot engagement and clot-device interaction [22].

Accordingly, we designed a prospective study of patients who underwent endovascular treatment with a newer version of EmboTrap (EmboTrap II) as a front-line modality. We aimed to 1) evaluate the efficacy and safety of EmboTrap II, especially of first-pass recanalization and 2) verify whether first-pass recanalization by EmboTrap II could yield favorable outcomes.

## MATERIALS AND METHODS

### Study Design and Patient Enrollment

First-pass recanalization with EmboTrap II in acute ischemic stroke (FREE-AIS) was a prospective, open-label, registry-based study for all consecutive patients who underwent mechanical thrombectomy with EmboTrap II for acute intracranial large-vessel occlusion. This study enrolled patients from 18 stroke centers nationwide between February 2020 and June 2021. For enrollment, EmboTrap II should have been the first-line endovascular device, and patients had to meet the following inclusion criteria: 1) age ≥ 19 years, 2) baseline National Institutes of Health Stroke Scale (NIHSS) score ≥ 4, 3) premorbid modified Rankin Scale (mRS) score ≤ 2, 4) intracranial large vessel occlusion (internal carotid artery, M1 or proximal M2 segment of the middle cerebral artery, or basilar artery), 5) time from stroke onset to groin puncture < 24 hours, and 6) preprocedural CT-Alberta Stroke Program Early Computed Tomography Score (CT-ASPECTS) ≥ 6 or MR-ASPECTS ≥ 5, and 7) for patients with time from stroke onset > 6 hours, eligibility criteria of DWI or CTP Assessment with Clinical Mismatch in the Triage of Wake-Up and Late Presenting Strokes Undergoing Neurointervention with Trevo (DAWN) and Diffusion and Perfusion Imaging Evaluation for Understanding Stroke Evolution (DEFUSE 3) trials were also considered. Patients 1) with multiple simultaneous large vessel occlusions, 2) with a severe or fatal combined illness that would prevent follow-up or render the procedure unlikely to benefit the patient, or 3) whose anticipated life expectancy was < 12 months were excluded from enrollment. Eligible patients were treated with 0.9 mg/kg tissue-type plasminogen activator.

The Institutional Review Boards of all the participating centers approved this study (IRB No. 4-2019-1057). Written informed consent was obtained from patients or their next of kin for prospective enrollment.

### Endovascular Procedure

All endovascular procedures were performed under local


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anesthesia. Conscious sedation was administered when necessary. Using a balloon-guiding catheter or a distal access (or intermediate) catheter was not mandatory for enrollment. The device used exclusively for the first attempted treatment was EmboTrap II. Mechanical thrombectomy with EmboTrap II was performed according to the common recommendations and previous reports [9,23]. Concurrent contact aspiration with EmboTrap II thrombectomy (e.g., Solumbra, ARTS, and SAVE) was not performed in this study. The number of EmboTrap II attempts is not restricted. After sufficient thrombectomy attempts with EmboTrap II, the endovascular treatment technique can be switched to others for further recanalization. These include using retrievers other than EmboTrap II, contact aspiration thrombectomy, and non-thrombectomy rescue modalities (for example, percutaneous balloon angioplasty, intracranial stenting, and infusion of glycoprotein IIb/IIIa inhibitors). The choice of subsequent endovascular treatment technique and its timing of introduction were determined pragmatically according to the protocols of each participating center.

### Study Outcomes

The primary outcome was the rate of first pass effect (FPE) using EmboTrap II. FPE was defined as near-complete or complete revascularization (mTICI grade 2c or 3) after the first pass of EmboTrap II [14,24]. For FPE, first-pass mTICI grades 2c or 3 should be maintained without further treatment. The modified FPE (mFPE) rate was also assessed, which was defined in a less restrictive manner as mTICI grade 2b–3 after the first pass of EmboTrap II.

The secondary outcomes were as follows: 1) the ratio of patients with successful recanalization (mTICI grade 2b–3 at the end of the procedure, irrespective of endovascular modality), 2) the rate of symptomatic intracranial hemorrhage, 3) the ratio of patients with an mRS score of 0–2, and 4) mortality.

All mTICI grades were centrally assessed by two independent neurointerventionalists who were blinded to the clinical information and follow-up imaging. The κ-value for the inter-rater reliability was 0.88 FPE. The κ-value was approximately 0.82 for mFPE and successful recanalization. Discrepancies were resolved by consensus. Intracranial hemorrhage was evaluated using CT or MRI performed within 48 hours after endovascular treatment. Intracranial hemorrhage was defined as symptomatic if the patient's NIHSS score increased to ≥ 4 without any specific causes associated with neurological deterioration. Functional outcomes were assessed based on the mRS score 90 days after endovascular treatment. The mRS score was primarily evaluated during routine clinical follow-up 90 days after endovascular treatment by stroke neurologists. If a patient was not physically available for a follow-up appointment,

**Table 1. Baseline Characteristics of the Study Population**

| | n = 210 |
|---|---|
| Basic demographics | |
| Age, years | 73.3 ± 11.4 |
| Sex, male | 117 (55.7) |
| Risk factors for stroke | |
| Hypertension | 150 (71.4) |
| Diabetes | 40 (19.0) |
| Dyslipidemia | 38 (18.1) |
| Current smoking | 49 (23.3) |
| Coronary artery occlusive disease | 7 (3.3) |
| Atrial fibrillation | 95 (45.2) |
| History of previous stroke | 25 (11.9) |
| Clinical conditions | |
| Onset type, clear | 112 (53.3) |
| Premorbid modified Rankin Scale score | |
| 0 | 177 (84.3) |
| 1 | 23 (11.0) |
| 2 | 10 (4.8) |
| Initial NIHSS score | 15.0 [11.0, 19.0] |
| ASPECTS | 8.0 [7.0, 9.0] |
| Target of occlusion | |
| Side | |
| Right | 100 (47.6) |
| Left | 110 (52.4) |
| Location | |
| Internal carotid artery | 40 (19.0) |
| Middle cerebral artery, M1 segment | 147 (70.0) |
| Middle cerebral artery, M2 segment | 18 (8.6) |
| Basilar artery | 5 (2.4) |
| Intravenous tPA administration | 75 (35.7) |
| Associated image findings | |
| Hyperdense artery sign | 123 (58.6) |
| Good leptomeningeal collaterals | 184 (87.6) |
| Endovascular conditions | |
| Time from onset to groin puncture, minutes | 278.0 [155.0, 539.0] |
| Use of a balloon guiding catheter | 185 (88.1) |
| Use of a distal access catheter | 93 (44.3) |

Values represent mean ± standard deviation, median [interquartile range], or number of patients with percentages in parentheses. ASPECTS = Alberta Stroke Program Early Computed Tomography Score, NIHSS = National Institutes of Health Stroke Scale, tPA = tissue-type plasminogen activator


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a stroke neurologist or a trained nurse interviewed the patient or their family via telephone to determine the mRS score using a standard questionnaire. An mRS score of 0–2 was considered favorable for a functional outcome.

### Statistical Analysis

First, to evaluate the primary and secondary outcomes, we descriptively summarized the patient demographics, risk factors for stroke, endovascular details and outcomes, clinical outcomes, and periprocedural adverse events.

Second, to examine the effect of FPE on functional outcomes, recanalization status was compared between the mRS scores 0–2 and 3–6 groups. Recanalization status was categorized into three types: 1) successful recanalization with FPE (for patients who had successful recanalization after FPE), 2) successful recanalization without FPE (for patients who had successful recanalization after first-pass mTICI grade ≤ 2b by EmboTrap II or after any multiple passes), and 3) failed recanalization (for patients who did not achieve successful recanalization irrespective of endovascular modalities).

The Student's *t* test, Mann–Whitney U test, chi-square test, and Fisher's exact test were used for group comparisons. Multivariate logistic regression analysis was performed to adjust for the effect of FPE on functional outcomes. Relevant variables with statistical significance in the univariate analyses were entered into the multivariable model. Statistical significance was set at $p < 0.05$, with 95% confidence intervals (CIs). All statistical analyses were performed using the R software (version 4.0.1; R Foundation, https://www.r-project.org).

**Table 2. Primary and Secondary Outcomes of the Study**

| | |
|---|---|
| Endovascular outcomes (n = 210) | |
| First pass effect* | 99 (47.1) |
| Modified first pass effect† | 150 (71.4) |
| Successful recanalization | 191 (91.0) |
| Clinical outcomes | |
| Symptomatic intracranial hemorrhage (n = 210) | 14 (6.7) |
| Modified Rankin Scale score 0–2‡ (n = 209) | 123 (58.9) |
| Mortality‡ (n = 209) | 16 (7.7) |

Values represent the number of patients with percentages in parentheses. *mTICI grade 2c or 3 by the first pass of EmboTrap II, †mTICI grades 2b, 2c, or 3 by the first pass of EmboTrap II, ‡Excluding one patient lost to follow-up. mTICI = modified Thrombolysis In Cerebral Infarction

## RESULTS

### Participants

A total of 210 patients (mean age, 73.3 ± 11.4 years; male, 55.7%) were included (Supplementary Fig. 1). The initial NIHSS score was 15.0 (interquartile range [IQR], 11.0–19.0) and ASPECTS was 8.0 (IQR, 7.0–9.0) (Table 1). One hundred forty-seven (70.0%) patients had occlusion of the M1 segment of the middle cerebral artery. Seventy-five (35.7%) patients were treated with intravenous tissue-type plasminogen activator before endovascular treatment. The time from onset to groin puncture was 278.0 minutes (IQR, 155.0–539.0). A balloon-guiding catheter was used in 185 (88.1%) patients. One patient was lost during follow-up after endovascular treatment; thus, functional outcome results were available for 209 patients (Supplementary Fig. 1).

### Endovascular Outcomes

Ninety-nine (47.1%) patients had FPE (Table 2). None of the patients whose first-pass mTICI grade was 2c or 3 required further treatment for successful recanalization (Table 3). The first-pass mTICI grade was maintained without any changes. In addition to 51 patients with first-pass mTICI grade 2b, mFPE was achieved in 150 (71.4%) patients (Tables 2, 3). Among the 51 patients with first-pass mTICI grade 2b, 49 (96.1%) achieved successful recanalization. Of these, 38 (77.6%; 38 of 49) underwent further recanalization attempts to improve their mTICI

**Table 3. Recanalization Process according to First-Pass mTICI Grades by EmboTrap II**

| | First-Pass mTICI Grade | | | Total (n = 210) |
|---|---|---|---|---|
| | 0, 1, or 2a (n = 60) | 2b (n = 51) | 2c or 3 (n = 99) | |
| Successful recanalization | 43 (71.7) | 49 (96.1) | 99 (100) | 191 (91.0) |
| Without further recanalization attempts | 0 (0) | 11 (22.4) | 99 (100) | 110 (57.6) |
| With further recanalization attempts | 43 (100) | 38 (77.6) | 0 (0) | 81 (42.4) |
| EmboTrap II | 20 (46.5) | 34 (89.5) | 0 (0) | 54 (66.7) |
| Devices other than EmboTrap II | 23 (53.5) | 4 (10.5) | 0 (0) | 27 (33.3) |
| Failed recanalization | 17 (28.3) | 2 (3.9) | 0 (0) | 19 (9.0) |

Values represent the number of patients with percentages in parentheses. mTICI = modified Thrombolysis In Cerebral Infarction


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grades. Endovascular devices other than EmboTrap II were introduced in four (10.5%; 4 of 38) patients.

Successful recanalization was achieved in 191 (91.0%) patients (Table 2). In the study population, 164 patients (78.1% of all patients; 85.9% of patients with successful recanalization) had successful recanalization exclusively with EmboTrap II without the aid of other endovascular devices (Tables 3, 4). The time from groin puncture to FPE was 25.0 minutes (IQR, 17.0–35.0) (Table 4). Procedure-related complications were observed in seven (3.3%) patients. All complications involved embolization of the distal or new territory.

### Clinical Outcomes

Symptomatic intracranial hemorrhage developed in 14 (6.7% of 210) patients (Table 2). As mentioned earlier, other functional outcomes were analyzed in 209 patients excluding, one patient lost to follow-up (Supplementary Fig. 1). One hundred twenty-three (58.9%) patients had an mRS score of 0–2. Sixteen (7.7%) patients died during the follow-up period.

For sensitivity analysis, endovascular and clinical outcomes were also analyzed in the subgroup of 125 patients (59.5%) with an anterior circulation occlusion who underwent treatment within 6 hours after stroke onset (Supplementary Table 1). Endovascular and clinical outcomes were not significantly different from those of all study populations.

### Association between Recanalization Status and mRS Score 0–2

The recanalization status was significantly different between the mRS score 0–2 and the mRS score of 3–6 groups. Patients who had successful recanalization with FPE were significantly more frequent in the mRS 0–2 score group (58.5%) than in the mRS score 3–6 group (31.4%, $p < 0.001$; Supplementary Table 2). In the multivariable analysis, successful recanalization with FPE was independently associated with mRS score 0–2 (adjusted odds ratio [aOR], 36.5; 95% CI, 5.22–255.0; $p < 0.001$; Table 5, Supplementary Table 3). Accordingly, mRS scores 0–2 were significantly more frequent in patients with successful recanalization with FPE (72.8%) than in those with successful recanalization without FPE (53.2%) and failed recanalization (11.1%; $p < 0.001$; Fig. 1).

Furthermore, in the subgroup analysis of patients with successful recanalization, successful recanalization with FPE was also independently associated with mRS score 0–2 (aOR, 4.13; 95% CI 1.59–10.8; $p = 0.004$; Table 5, Supplementary Tables 4, 5). However, successful recanalization with mFPE was not significantly associated with mRS score 0–2 (aOR, 2.40; 95% CI 0.83–6.91; $p = 0.106$).

**Table 4. Detailed Endovascular and Clinical Outcomes**

| | n = 210 |
|---|---|
| Pass number of thrombectomy device | 1.87 ± 1.05 |
| 1 | 110 (52.4) |
| 2 | 34 (16.2) |
| 3 | 52 (24.8) |
| 4 | 11 (5.2) |
| 5 | 3 (1.4) |
| Recanalization results | |
| First-pass mTICI grade by EmboTrap II | |
| 0 | 31 (14.8) |
| 1 | 24 (11.4) |
| 2a | 5 (2.4) |
| 2b | 51 (24.3) |
| 2c | 4 (1.9) |
| 3 | 95 (45.2) |
| Final mTICI grade | |
| 0 | 2 (1.0) |
| 1 | 2 (1.0) |
| 2a | 15 (7.1) |
| 2b | 26 (12.4) |
| 2c | 15 (7.1) |
| 3 | 150 (71.4) |
| Successful recanalization exclusively by EmboTrap II | 164 (78.1) |
| Time to recanalization | |
| From onset to successful recanalization, minutes | 305.0 [181.0, 540.5] |
| From groin puncture to first pass effect, minutes | 25.0 [17.0, 35.0] |
| Procedure-related complications | |
| Arterial dissection | 0 (0.0) |
| Vessel perforation | 0 (0.0) |
| Embolization to distal or new territory | 7 (3.3) |
| Hemorrhagic transformation | 46 (21.9) |
| HI1 | 19 (9.0) |
| HI2 | 12 (5.7) |
| PH1 | 5 (2.4) |
| PH2 | 10 (4.8) |

Values represent mean ± standard deviation, median [interquartile range], or number of patients with percentages in parentheses.
HI1 = hemorrhagic infarction type 1, HI2 = hemorrhagic infarction type 2, mTICI = modified Thrombolysis In Cerebral Infarction, PH1 = parenchymal hemorrhagic type 1, PH2 = parenchymal hemorrhagic type 2


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**Table 5. Association between Recanalization Status and mRS Score 0–2**

| | Adjusted Odds Ratio for mRS Score 0–2 (95% Confidence Interval) | *P* |
|---|---|---|
| All patients (n = 209)* | | |
| Successful recanalization with first pass effect | 36.5 (5.22–255.0) | < 0.001 |
| Successful recanalization without first pass effect | 9.04 (1.41–58.1) | 0.020 |
| Failed recanalization | Reference | |
| Patients with successful recanalization (n = 191)† | | |
| Successful recanalization with first pass effect | 4.13 (1.59–10.8) | 0.004 |
| Successful recanalization without first pass effect | Reference | |

*Adjusted for age, history of previous stroke, onset type, initial NIHSS score, location of occlusion, intravenous tissue-type plasminogen activator administration, good leptomeningeal collaterals, use of a distal access catheter, and symptomatic intracranial hemorrhage, †Adjusted for age, onset type, initial NIHSS score, location of occlusion, intravenous tissue-type plasminogen activator administration, good leptomeningeal collaterals, use of a distal access catheter, time from onset to recanalization, and symptomatic intracranial hemorrhage. mRS = modified Rankin Scale, NIHSS = National Institutes of Health Stroke Scale

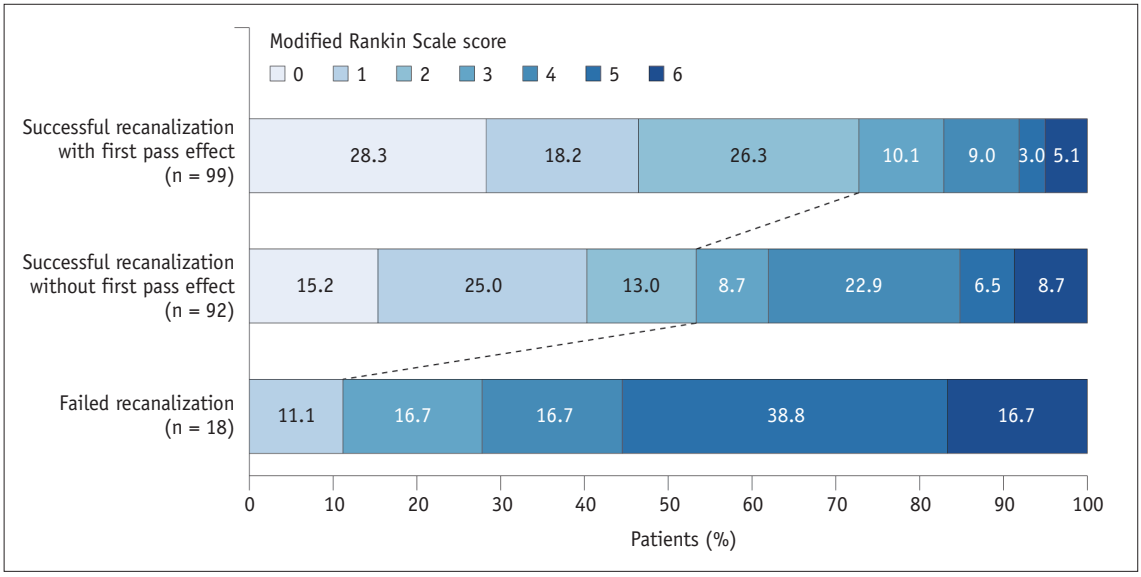


**Fig. 1. Distribution of modified Rankin Scale scores according to recanalization status.**

## DISCUSSION

To the best of our knowledge, this is the largest prospective study of EmboTrap II-based mechanical thrombectomy. More importantly, our study primarily focused on the endovascular results after the first pass of EmboTrap II. We found that front-line use of EmboTrap II was highly effective. Approximately half of the patients were able to have FPE by EmboTrap II, all of whom had successful recanalization without further attempts. In addition, mFPE was achieved in more than 70% of patients using EmboTrap II. Among patients with successful recanalization, more than 85% achieved so exclusively by EmboTrap II. We also found that the FPE was important for mRS scores of 0–2. Patients with successful recanalization with FPE were four times more likely to have an mRS score of 0–2 than those with successful recanalization without FPE.

First-pass recanalization has also been evaluated in mechanical thrombectomy using other stent retrievers (Supplementary Table 6) [14,25-27]. In contrast to EmboTrap, other stent retrievers mostly showed FPE in less than 30% of patients. The first-pass recanalization rates were much lower than those in the present study. One of the most convincing explanations for this difference may be the unique structure of EmboTrap. First, large openings in the outer cages might easily accept clots into the space between the inner and outer layers and minimize maceration of the clot [20,21]. Second, articulated outer cages might allow the outer layer to open consistently and


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appose the vessel wall when retracted [28]. Third, distal embolism during retraction may be limited by a distal closed structure at the tip of the stent [20-22]. Fourth, the inner closed-cell stent might stabilize the engaged clot during retrieval [28,29].

Factors affecting first-pass recanalization have been actively studied, with the evident effect of FPE on clinical outcomes. Thrombectomy techniques, such as a combination of stent retriever and contact aspiration, use of a balloon guiding catheter, thrombus characteristics (e.g., thrombus density, perviousness, length or its burden, and histology), and length or size of stent retrievers are common factors associated with first-pass recanalization. However, the structure or design of the stent retriever can also be an important factor. The structural design of EmboTrap was originally intended to maximize its efficacy in clot retrieval. Accordingly, EmboTrap concentrated on a higher endpoint in a few studies, where FPE or mFPE was set as the principal outcome.

FPE by EmboTrap was first evaluated in the Analysis of Revascularization in Ischemic Stroke with EmboTrap (ARISE II) study, which primarily aimed to compare the efficacy and safety of EmboTrap with other stent retrievers [24]. In the ARISE II study, EmboTrap I and II were permitted, although their proportions were not specified. A few other studies have also focused on the endovascular results of the first pass of EmboTrap II [22,23,30]. In overall results, FPE could be achieved using EmboTrap in approximately 30%–40% of patients and mFPE in up to 50%. These first-pass recanalization rates were remarkable; however, they were somewhat lower than those in our use of a balloon-guiding catheter may be a possible factor for improvement [11,31,32]. In the ARISE II study, a balloon-guiding catheter was used for approximately 70% of patients, compared to 90% in our study. In another study in which a balloon-guiding catheter was not used, FPE was achieved in less than 35% of patients [30]. As expected, distal embolism by thrombectomy procedure was higher in previous studies (up to 7 %), which was approximately twice than that in our study [24,30]. In addition, the time from groin puncture to recanalization was longer than that in our study. In this study, using a balloon-guiding catheter was also a significant factor associated with an increased FPE ($p$ = 0.013).

In our study, we evaluated the association between FPE and mRS scores of 0–2 in a group of patients with successful recanalization defined by a final mTICI grade of 2b–3 and not by mTICI grade 2c or 3. Such an analysis has not been performed before, even though mTICI grades 2b–3 have been regarded as a common goal in most endovascular treatments. In our analysis, FPE was important, even if the patient achieved successful recanalization. Specifically, patients with successful recanalization through FPE were four times more likely to have an mRS score of 0–2. In addition, the recanalization or reperfusion degree appeared to be as important as the number of device passes in the functional outcome. In contrast to FPE, mFPE was not significantly associated with an mRS score of 0–2 in patients with successful recanalization. This might be due to the differences in the distribution of the final mTICI grades. Unlike FPE, mFPE does not guarantee a better final mTICI grade. Among patients with successful recanalization, the number of patients with final mTICI grade 2c or 3 was not significantly higher, even after achieving mFPE. In contrast, patients with final mTICI grade 2c or 3 were significantly more frequent after FPE, which might lead to a higher mRS score of 0–2. In this respect, the clinical utility of mFPE seems to be much lower than that of FPE. Thus, successful recanalization should be achieved from a strategic viewpoint. Next, FPE should be attempted as much as possible to achieve the best clinical outcomes.

This study has a few limitations. First, despite the prospective design, we could not conduct a direct comparison with other stent retrievers. We cannot conclude that EmboTrap II is superior to other stent retrievers in endovascular and clinical aspects, although the absolute values were generally better in our study. Therefore, the results of this study should be cautiously interpreted. As the endovascular results of mechanical thrombectomy can be influenced by various clinical, radiological, and endovascular factors that are not easily controlled, a randomized design might be the only way for comparison.

Second, as mentioned above, not all factors that might affect the endovascular results were controlled. For example, the occlusion pathomechanism or etiology could affect recanalization results, including first-pass recanalization. First-pass recanalization could be underestimated in patients with intracranial atherosclerosis-related occlusion because stent retriever thrombectomy is not as effective as embolic occlusion [33]. Also, there is a possibility that other unrevealed factors such as thrombus characteristics and arterial tortuosity can affect first-pass recanalization. However, we made every effort to incorporate various findings associated with recanalization results: occlusion

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location, intravenous tissue-type plasminogen activator administration, hyperdense artery sign, leptomeningeal collateral condition, time from onset to groin puncture, and use of a balloon guiding catheter or distal access catheter. Although endovascular procedures were not standardized under a specific protocol, operators performed stent retriever thrombectomy using the common procedure technique. More importantly, concurrent contact aspiration thrombectomy, which can potently influence first-pass recanalization, is prohibited in EmboTrap II thrombectomy.

Third, the study population might have been relatively heterogeneous. The broader inclusion criteria of this study (e.g., a wide range of time windows and inclusion of posterior circulation stroke) could have affected clinical outcomes. Due to heterogeneity, clinical outcomes can be worse, and it is cautious to compare clinical outcomes with those in other studies. To minimize this limitation, we additionally performed a subgroup analysis of patients with anterior circulation occlusion within 6 hours. We also evaluated the effect of FPE on mRS scores of 0–2 in patients with successful recanalization.

Despite these limitations, this study may have clinical value. This study aligns with previous reports that showed and supported the outstanding endovascular performance of EmboTrap. In addition, this study uniquely focused on FPE, a maximized form of endovascular performance, and reflected the real-world performance of EmboTrap II using practical inclusion criteria according to the most recent treatment guidelines. In addition, the present study showed the importance of FPE, especially in cases of successful recanalization.

In conclusion, in this multicenter prospective study, mechanical thrombectomy using the front-line EmboTrap II was effective and safe. FPE using EmboTrap II was achieved in approximately half of the patients and mFPE in approximately 70% of the patients. Achieving FPE was an important factor for an mRS score of 0–2, even in patients with successful recanalization. Patients with successful recanalization with FPE were four times more likely to have an mRS score of 0–2 than those with successful recanalization without FPE.

## Supplement

The Supplement is available with this article at https://doi.org/10.3348/kjr.2022.0618.

### Availability of Data and Material

The datasets generated or analyzed during the study are available from the corresponding author on reasonable request.

### Conflicts of Interest

Sang Hyun Suh and Chi-Hoon Choi who is on the editorial board of the *Korean Journal of Radiology* was not involved in the editorial evaluation or decision to publish this article. All remaining authors have declared no conflicts of interest.

### Author Contributions

Conceptualization: Byung Moon Kim. Data curation: all authors. Formal analysis: Byung Moon Kim, Jang-Hyun Baek. Funding acquisition: Byung Moon Kim. Methodology: Byung Moon Kim. Supervision: Byung Moon Kim. Writing—original draft: Jang-Hyun Baek. Writing—review & editing: Byung Moon Kim, Jang-Hyun Baek.

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## REFERENCES

1. Powers WJ, Rabinstein AA, Ackerson T, Adeoye OM, Bambakidis NC, Becker K, et al. Guidelines for the early management of patients with acute ischemic stroke: 2019 update to the 2018 guidelines for the early management of acute ischemic stroke: a guideline for healthcare professionals from the American Heart Association/American Stroke Association. *Stroke* 2019;50:e344-e418
2. LeCouffe NE, Kappelhof M, Treurniet KM, Lingsma HF, Zhang G, van den Wijngaard IR, et al. 2B, 2C, or 3: what should be the angiographic target for endovascular treatment in ischemic stroke? *Stroke* 2020;51:1790-1796
3. Goyal M, Fargen KM, Turk AS, Mocco J, Liebeskind DS, Frei D, et al. 2C or not 2C: defining an improved revascularization grading scale and the need for standardization of angiography outcomes in stroke trials. *J Neurointerv Surg* 2014;6:83-86
4. Kaesmacher J, Dobrocky T, Heldner MR, Bellwald S, Mosimann PJ, Mordasini P, et al. Systematic review and meta-analysis on outcome differences among patients with TICI2b versus TICI3 reperfusions: success revisited. *J Neurol Neurosurg Psychiatry* 2018;89:910-917
5. Tung EL, McTaggart RA, Baird GL, Yaghi S, Hemendinger M, Dibiasio EL, et al. Rethinking thrombolysis in cerebral infarction 2b: which thrombolysis in cerebral infarction scales best define near complete recanalization in the modern thrombectomy era? *Stroke* 2017;48:2488-2493
6. Abbasi M, Liu Y, Fitzgerald S, Mereuta OM, Arturo Larco JL, Rizvi A, et al. Systematic review and meta-analysis of current rates of first pass effect by thrombectomy technique and associations with clinical outcomes. *J Neurointerv Surg* 2021;13:212-216
7. Jang KM, Choi HH, Nam TK, Byun JS. Clinical outcomes of first-pass effect after mechanical thrombectomy for acute ischemic stroke: a systematic review and meta-analysis. *Clin Neurol Neurosurg* 2021;211:107030
8. Bai X, Zhang X, Yang W, Zhang Y, Wang T, Xu R, et al. Influence of first-pass effect on recanalization outcomes in the era of mechanical thrombectomy: a systemic review and meta-analysis. *Neuroradiology* 2021;63:795-807
9. Baek JH, Kim BM, Heo JH, Nam HS, Kim YD, Park H, et al. Number of stent retriever passes associated with futile recanalization in acute stroke. *Stroke* 2018;49:2088-2095
10. Flottmann F, Brekenfeld C, Broocks G, Leischner H, McDonough R, Faizy TD, et al. Good clinical outcome decreases with number of retrieval attempts in stroke thrombectomy: beyond the first-pass effect. *Stroke* 2021;52:482-490
11. Zaidat OO, Castonguay AC, Linfante I, Gupta R, Martin CO, Holloway WE, et al. First pass effect: a new measure for stroke thrombectomy devices. *Stroke* 2018;49:660-666
12. Hassan AE, Dibas M, Sarraj A, Ghozy S, El-Qushayri AE, Dmytriw AA, et al. First pass effect vs multiple passes complete reperfusion: a retrospective study. *Neuroradiol J* 2022;35:306-312
13. Zaidat OO, Ribo M, Mattle HP, Saver JL, Bozorgchami H, Yoo AJ, et al. Health economic impact of first-pass success among patients with acute ischemic stroke treated with mechanical thrombectomy: a United States and European perspective. *J Neurointerv Surg* 2021;13:1117-1123
14. Jadhav AP, Desai SM, Zaidat OO, Nogueira RG, Jovin TG, Haussen DC, et al. First pass effect with neurothrombectomy for acute ischemic stroke: analysis of the systematic evaluation of patients treated with stroke devices for acute ischemic stroke registry. *Stroke* 2022;53:e30-e32
15. Yoo AJ, Soomro J, Andersson T, Saver JL, Ribo M, Bozorgchami H, et al. Benchmarking the extent and speed of reperfusion: first pass TICI 2c-3 is a preferred endovascular reperfusion endpoint. *Front Neurol* 2021;12:669934
16. Memon MZ, Daniel D, Chaudhry MRA, Grewal M, Saini V, Lukas J, et al. Clinical impact of the first pass effect on clinical outcomes in patients with near or complete recanalization during mechanical thrombectomy for large vessel ischemic stroke. *J Neuroimaging* 2021;31:743-750
17. den Hartog SJ, Zaidat O, Roozenbeek B, van Es ACGM, Bruggeman AAE, Emmer BJ, et al. Effect of first-pass reperfusion on outcome after endovascular treatment for ischemic stroke. *J Am Heart Assoc* 2021;10:e019988
18. Nikoubashman O, Dekeyzer S, Riabikin A, Keulers A, Reich A, Mpotsaris A, et al. True first-pass effect. *Stroke* 2019;50:2140-2146
19. Bruggeman AAE, Kappelhof M, den Hartog SJ, Burke JF, Berkhemer OA, van Es ACGM, et al. Successful reperfusion in relation to the number of passes: comparing outcomes of first pass expanded treatment in cerebral ischemia (eTICI) 2B with multiple-pass eTICI 3. *J Neurointerv Surg* 2023;15:120-126
20. Kabbasch C, Mpotsaris A, Liebig T, Söderman M,

 https://doi.org/10.3348/kjr.2022.0618 

Holtmannspötter M, Cronqvist M, et al. First-in-man procedural experience with the novel EmboTrap® revascularization device for the treatment of ischemic stroke—A european multicenter series. *Clin Neuroradiol* 2016;26:221-228
21. Chueh JY, Marosfoi MG, Brooks OW, King RM, Puri AS, Gounis MJ. Novel distal emboli protection technology: the EmboTrap. *Interv Neurol* 2017;6:268-276
22. Valente I, Nappini S, Renieri L, Pedicelli A, Lozupone E, Colosimo C, et al. Initial experience with the novel EmboTrap II clot-retrieving device for the treatment of ischaemic stroke. *Interv Neuroradiol* 2019;25:271-276
23. Srivatsan A, Srinivasan VM, Starke RM, Peterson EC, Yavagal DR, Hassan AE, et al. Early postmarket results with EmboTrap II stent retriever for mechanical thrombectomy: a multicenter experience. *AJNR Am J Neuroradiol* 2021;42:904-909
24. Zaidat OO, Bozorgchami H, Ribó M, Saver JL, Mattle HP, Chapot R, et al. Primary results of the multicenter ARISE II study (analysis of revascularization in ischemic stroke with EmboTrap). *Stroke* 2018;49:1107-1115
25. Liang CW, Toor HJ, Duran Martinez E, Sheth SA, Chao K, Feng L, et al. First pass recanalization rates of Solitaire vs Trevo vs primary aspiration: the Kaiser Southern California experience. *Perm J* 2020;25:1-3
26. Mokin M, Primiani CT, Castonguay AC, Nogueira RG, Haussen DC, English JD, et al. First pass effect in patients treated with the Trevo stent-retriever: a TRACK registry study analysis. *Front Neurol* 2020;11:83
27. Jadhav AP, Desai SM, Budzik RF, Gupta R, Baxter B, English JD, et al. First pass effect in patients with large vessel occlusion strokes undergoing neurothrombectomy: insights from the Trevo Retriever Registry. *J Neurointerv Surg* 2021;13:619-622
28. Bourcier R, Abed D, Piotin M, Redjem H, Ferré JC, Eugène F, et al. Multicenter initial experience with the EmboTrap device in acute anterior ischemic stroke. *J Neuroradiol* 2018;45:230-235
29. Brinjikji W, Ikeme S, Kottenmeier E, Khaled A, M S, Khanna R. Real-world outcomes associated with the use of the EmboTrap revascularization device for ischemic stroke in the United States. *J Neurointerv Surg* 2022;14:1068-1072
30. Bala F, Ferrigno M, Personnic T, Estrade L, Karam A, Henon H, et al. Thrombectomy using the EmboTrap II device in late treatment patients in the real-world setting. *World Neurosurg* 2021;151:e387-e394
31. Tomasello A, Ribò M, Gramegna LL, Melendez F, Rosati S, Moreu M, et al. Procedural approaches and angiographic signs predicting first-pass recanalization in patients treated with mechanical thrombectomy for acute ischaemic stroke. *Interv Neuroradiol* 2019;25:491-496
32. Bai X, Zhang X, Wang J, Zhang Y, Dmytriw AA, Wang T, et al. Factors influencing recanalization after mechanical thrombectomy with first-pass effect for acute ischemic stroke: a systematic review and meta-analysis. *Front Neurol* 2021;12:628523
33. Lee JS, Hwang YH, Sohn SI. Factors contributing to an efficacious endovascular treatment for acute ischemic stroke in Asian population. *Neurointervention* 2021;16:91-110


https://doi.org/10.3348/kjr.2022.0618