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Original Article

Clinical Impact of Large Vessel Occlusion Achieved First Pass Effect with Stent Retriever Alone: A Single-Center Retrospective Analysis

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Objective: The first pass effect (FPE), which means the achievement of complete or near-complete reperfusion of large vessel occlusion (LVO) in the first pass, is one of the goals of mechanical thrombectomy (MT). However, the impact of FPE on the prognosis has not been assessed for Japanese patients with various degrees of independence before the onset of LVO. The purpose of this study was to investigate the prognostic effects of FPE in a comprehensive stroke center in Japan, which includes patients in a variety of self-independence states with different comorbidities before stroke onset.

Methods: Between April 2017 and March 2020, 151 patients who underwent MT with a stent retriever (SR) alone as initial strategy for anterior circulation (internal carotid artery terminal, M1, M2) LVO at our hospital and finally achieved modified treatment in cerebral infarction (mTICI) 2b–3 were analyzed. Forty-eight patients in whom first pass mTICI 2c–3 was achieved were classified into the FPE+ group, and the other 103 patients were classified into the FPE– group. We compared the characteristics and clinical outcomes between patients with and without FPE, and estimated the odds ratio for outcomes after adjusting for confounders.

Results: The puncture–reperfusion time was shorter (20 vs. 35 minutes; p <0.01), and cardiogenic embolism was more common (81.3 vs. 60.2%; p = 0.01) in the FPE+ group. The FPE was significantly associated with good neurological outcome after 3 months (p <0.01; adjusted odds ratio [aOR], 3.87; 95% confidence interval [CI], 1.69–9.38), reduction in all intracranial hemorrhage (p <0.01; aOR, 0.24; 95% CI, 0.10–0.54), and symptomatic intracranial hemorrhage (p = 0.04; aOR, 0.16; 95% CI, 0.01–0.98).

Conclusion: The FPE with an SR alone improved the neurological prognosis in a Japanese patient group.

Keywords ▶ acute ischemic stroke, large vessel occlusion, mechanical thrombectomy, first pass effect

Introduction

Regarding mechanical thrombectomy (MT) for acute large vessel occlusion (LVO), Zaidat et al. reported that complete recanalization on the first pass (first pass effect [FPE]) improved the neurological prognosis after 90 days and proposed that the FPE should be targeted when improving devices or establishing therapeutic strategies.[1)] Subsequently, Nikoubashman et al. pointed that the operative time in the FPE+ group was shorter than that in the FPE– group, but meanwhile, they also reported that the FPE is an independent predictive factor for an improvement in the neurological prognosis even after adjustment for the onset-to-reperfusion time as a confounding factor.[2)]

However, several previous studies did not note the details of the pre-onset modified Rankin Scale (pre mRS)[3)] score,[1,2)] and others excluded patients with a pre mRS score of ≥4[4,5)] or indicated that the pre mRS score was 0 to 1 in approximately 90% of the subjects.[6,7)] Therefore, no study has investigated the prognostic effect of FPE in Japanese patients with different daily life independence levels before

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the onset of LVO. Furthermore, strategies of MT vary among institutional conditions.

In this study, we used a stent retriever (SR) alone for initial treatment to examine whether the FPE is associated with an improvement in the neurological prognosis in a patient population with a pre mRS score of 2 to 5 accounting for approximately 30%.

Materials and Methods

Study design and subjects

Of 291 patients who underwent MT for acute LVO in our hospital between April 2017 and March 2020, the subjects of this study were 151 for whom treatment with an SR alone was selected as the first option for anterior circulation (internal carotid artery terminal [ICAt], M1, M2), and modified treatment in cerebral infarction (mTICI) 2b–3 recanalization was finally achieved. This was a single-center retrospective study. The protocol of this study was approved by the ethics review board of our institution (k200304), and the purpose of this study was to retrospectively investigate the content of medical care; therefore, it was considered unnecessary to receive informed consent from each patient.

Our institution has a comprehensive stroke center responsible for a medical care zone involving approximately 1500000 persons. Intravenous thrombolysis with recombinant tissue plasminogen activator (rt-PA) and MT are available for 24 hours every day. In LVO-suspected patients, head CT is initially performed. Subsequently, we perform CTA for those admitted to our hospital within 4.5 hours from the final time of healthy-state confirmation, and MRI or MRA (combined with perfusion images depending on the situation) for those with an interval of ≥4.5 hours. The indication of treatment is evaluated considering the presence of a clinical-imaging mismatch or diffusion–perfusion mismatch regardless of the time window.

For the procedure of anterior circulation LVO, the femoral artery is punctured under local anesthesia and a sheath is inserted. Subsequently, 3000 units of heparin is administered to rt-PA-treated patients and 5000 units is administered to non-rt-PA-treated patients. In the latter, the activated clotting time (ACT) is regularly measured and an additional dose is administered if necessary such that the ACT is ≥250 seconds. A balloon guiding catheter (9 Fr Optimo; Asahi Intecc, Aichi, Japan) is guided into the cervical internal carotid artery and the initial treatment procedure is performed using an SR alone, as a rule. The subsequent strategy or the goal of procedure is determined based on operator's judgment. However, as a team-sharing strategy, when effective recanalization is not achieved through one pass, if there is no immediate flow restoration (IFR) on initial stenting or if there is no change in the thrombus position on angiography immediately after treatment, switching to a combined technique should be considered on the second pass. When IFR is observed, if thrombi are partially retrieved or partial recanalization is achieved, the second pass should be attempted using an SR alone. Basically, the procedure is completed when TICI 2b or higher recanalization of an occluded blood vessel is achieved. However, additional treatment is considered when residual occlusion involves an area distal to the M2, where recanalization may reduce symptoms. The timing of starting postoperative antithrombotic drug administration is evaluated by the attending physician based on the size of an infarcted lesion or etiology in accordance with individual patients.

Criteria for selecting the subjects of this study included 1) the presence of a large anterior circulation vessel (ICAt, middle cerebral artery [M1, M2]) occlusion, 2) treatment with an SR alone as a first-choice procedure, and 3) the final achievement of effective recanalization (mTICI: 2b–3). As SRs for the first choice, a Solitaire FR (Medtronic, Minneapolis, MN, USA) or Solitaire Platinum (Medtronic) was used in 95 patients, a Trevo XP (Stryker, Kalamazoo, MI, USA) in 36, a Tron FX (Terumo, Tokyo) in 7, a Revive (Johnson & Johnson, New Brunswick, NJ, USA) in 2, an Embotrap (Johnson & Johnson) in 1, and a test device in 10. A Solitaire FR was frequently selected as the first option until 2017, but a Solitaire Platinum was selected since 2018. In patients with M2 occlusion, a Tron FX tended to be the first option. In those with ICA occlusion, a Trevo XP was used; the SR type was selected based on the subject's vascular anatomy or operator's evaluation. Patients with reperfusion in ≥50% of an occluded blood vessel-dominated area were regarded as achieving mTICI 2b, those with delayed perfusion or residual microembolism in a small number of cortical branches as achieving mTICI 2c, and those with compete recanalization as achieving mTICI 3.[8)]

We excluded 30 patients with posterior circulation (vertebral artery or basilar artery) occlusion, 20 with a tandem lesion in the intra- or extracranial large vessels, 9 in whom carotid artery stenting was performed during the treatment course, 23 who required percutaneous transluminal

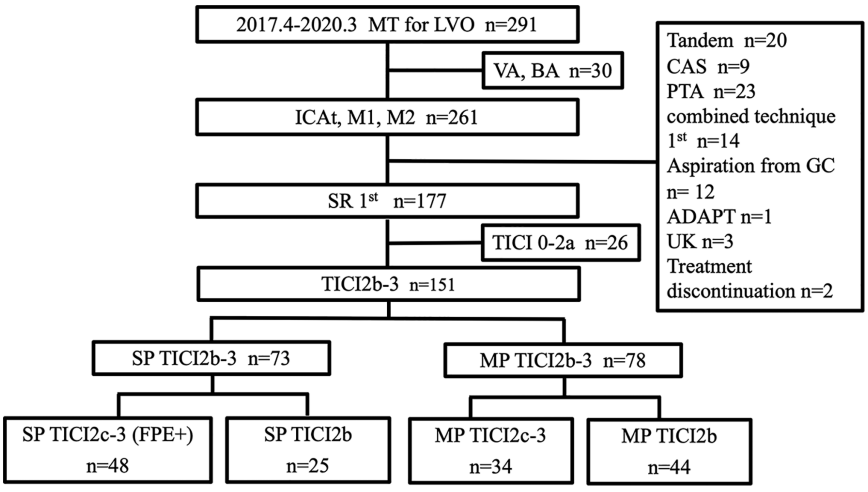

Fig. 1 Study flow chart. ADAPT: a direct aspiration first pass technique; BA: basilar artery; CAS: carotid artery stenting; FPE: first pass effect; GC: guiding catheter; ICAt: internal carotid artery terminal; LVO: large vessel occlusion; MP: multiple pass; MT: mechanical thrombectomy, PTA: percutaneous transluminal angioplasty; SP: single pass; SR: stent retriever; TICI: treatment in cerebral infarction; UK: urokinase; VA: vertebral artery

angioplasty, 14 in whom a combined technique with an aspiration catheter was conducted on initial intervention, 1 in whom a direct aspiration first pass technique (ADAPT) alone was performed, 3 in whom the arterial injection of urokinase was adopted, and 12 in whom wire passage or aspiration through a guiding catheter alone resulted in effective recanalization. Thus, 177 patients treated with an SR alone, selected as a first-choice procedure, were extracted, excluding 2 patients in whom the procedure was discontinued before stent deployment for some reason. Subsequently, 26 patients in whom effective recanalization was not achieved (mTICI: 0–2a) were excluded.

Patients in whom effective recanalization was achieved through a single session of stent passing were assigned to the single pass (SP) group and those in whom ≥2 sessions of approaching were required were assigned to the multiple pass group. In the SP group, patients achieving mTICI 2c–3 recanalization were assigned to the FPE+ group and the other patients were assigned to the FPE– group (**Fig. 1**).

Evaluation of the results and statistical analysis

The purpose of this study was to clarify the influence of FPE+ on the outcome in patients who underwent MT. Initially, we compared the patient background (age, sex, and medical history) findings on arrival (neurological findings, imaging findings, and hematological data), treatment procedure (presence of rt-PA use and time course), and the type of etiology between the FPE+ and FPE– groups.

Functional disorder before and after treatment was evaluated using the mRS.[3] The pre mRS score was evaluated by specialists in stroke based on the information obtained from the patient, family, or nursing person. In all patients, the Alberta stroke program early CT score (ASPECTS)[9] was assessed on plain CT images. The type of etiology was classified into cardiogenic, atherothrombotic, others, and unclear according to the Trial of Org 10172 in Acute Stroke Treatment (TOAST) classification.[10] Three neurologists without medical information on each patient were responsible for the assessment of cerebral angiography images and mTICI grading. When the assessments differed by the neurologists, they made a decision through a conference for each patient. Primary outcomes were a favorable neurological outcome (mRS score after 3 months: 0–2, and mRS score similar to that before onset in patients with a pre mRS score of >2), entire intracranial hemorrhage within 36 hours after onset, symptomatic intracranial hemorrhage within 36 hours after onset (deterioration of the clinical state with a ≥4-point increase from the pretreatment National Institutes of Health Stroke Scale [NIHSS] score or lowest NIHSS score within 24 hours after treatment, or fatal cerebral parenchymal hemorrhage involving ≥30% of an infarcted focus),[11,12] and mortality rate. To clarify the association between the FPE and primary outcomes, multivariate logistic analysis was arranged and performed using age (<75 years or ≥75 years), sex, site of occlusion (ICA and M1–2), and presence of intravenous thrombolysis with rt-PA as adjustment factors.

For statistical analysis, the chi-square test was used to compare categorical variables. The Student's t-test and Wilcoxon's log-rank test were used to compare quantitative variables. A p-value of 0.05 was regarded as significant. The results are expressed as the value (percentage) for categorical variables and mean (standard deviation) or median (interquartile range) for quantitative variables. For statistical analysis, we used JMP software (SAS Institute, Cary, NC, USA).

Results

The FPE+ group consisted of 48 patients. These accounted for 27.1% of 177 patients in whom the first pass with an SR alone for the anterior circulation system was achieved. In addition, they accounted for 31.8% of 151 patients in whom effective recanalization was achieved. The median age was 78 years and men accounted for 45.6%. The pre mRS score was 0 in 32 patients (66.7%), 1 in 2 (4.2%), 2 in 4 (8.3%), 3 in 2 (4.2%), and 4 in 8 (16.7%). The rates of patients with a pre mRS score of 0 to 1 were 70.8% in the FPE+ group and 65.1% in the FPE– group, with no significant difference. There were also no differences in the pretreatment NIHSS score, ASPECTS, blood pressure, or blood glucose level on arrival between the two groups.

In the FPE+ group, M1 occlusion was more frequent (45.8 vs. 39.8%; p = 0.48) and M2 occlusion was less frequent (31.3 vs. 37.9%; p = 0.43). The onset-to-reperfusion time was shorter (123.5 vs. 134.0 minutes; p = 0.66), but there were no significant differences. The puncture-to-reperfusion time was significantly shorter in the FPE+ group (20 vs. 35 minutes; p <0.01). Regarding etiological factors for cerebral infarction, the incidence of cardiogenic embolism was higher in the FPE+ group (81.3 vs. 60.2%; p = 0.01). In all 7 patients with other types, the final diagnosis was Trousseau's syndrome (**Table 1**).

Univariate analysis revealed that the rate of patients with a favorable neurological prognosis after 3 months was significantly higher in the FPE+ group (62.5 vs. 37.9%; p <0.01) and that the overall incidence of posttreatment intracranial hemorrhage was lower (20.1 vs. 47.6%; p <0.01). Multivariate logistic analysis was conducted using age, sex, occlusion site, presence of intravenous thrombolysis with rt-PA, and presence of a diagnosis of cardiogenic embolism as adjustment factors. FPE+ was an independent predictive factor for a favorable neurological prognosis after 3 months (p <0.01; odds ratio [OR], 3.87; 95% confidence interval [CI], 1.69–9.38), a decrease in the overall incidence of intracranial hemorrhage (p <0.01; OR, 0.24; 95% CI, 0.10–0.54), and a decrease in the incidence of symptomatic intracranial hemorrhage (p = 0.04; OR, 0.16; 95% CI, 0.01–0.98) (**Table 2**).

Discussion

In this study, the FPE was achieved in 27.1% of the subjects through MT with an SR alone for anterior circulation LVO. Regarding the type of etiology, the incidence of cardiogenic embolism was significantly higher in the FPE+ group. Furthermore, FPE was an independent predictive factor for an improvement in the neurological prognosis after 3 months, a decrease in the overall incidence of intracranial hemorrhage, and a decrease in the incidence of symptomatic intracranial hemorrhage.

Zaidat et al. reported that the FPE was achieved in 25.1%[1] of patients who received treatment by the first pass using a Solitaire FR alone for LVO including the posterior circulation. According to Jindal et al. and Di Maria et al., the FPE was achieved in approximately 22%[4,6] of patients who received different initial treatments, including treatment with an SR, aspiration, and a combined technique, for anterior circulation LVO. In this study, the FPE achievement rate was favorable in comparison with previous studies. This was possibly because the indication of treatment was evaluated using CTA before the procedure in the majority of patients in whom we may easily identify the distal end of a thrombus in the presence of favorable collateral pathways, facilitating determination of the site of initial SR deployment, in addition to advances in treatment devices.

Zaidat et al. compared the FPE+ group with the FPE– group and reported that the rate of patients with a good outcome was significantly higher in the former.[1] In their study, patients with an mRS score of 0 to 2 after 90 days were regarded as achieving a good outcome. However, the patient's status before the onset of LVO was not described. In this study, we demonstrated that FPE led to a favorable functional prognosis even in subjects with a pre mRS score of ≥2, i.e., those with moderate or severe functional disorder before the onset of LVO, by defining a good outcome as an mRS score of 0–2 after 90 days or that as same as the pre mRS score.[13] As a mechanism that FPE contributes to an improvement in the clinical prognosis, several studies suggested that intracranial hemorrhage associated with vascular endothelial damage or microembolism to the peripheral arteries derived from dispersion of crushed thrombi, both induced by repeated SR deployment or

Table 1 Patient characteristics

Variable	FPE+ group (n = 48)	FPE– group (n = 103)	p-value
Patient characteristics			
Age, median (IQR), years	78 (70–86)	77 (67–83)	0.24
Age ≥75 years, n (%)	31 (64.6)	62 (60.2)	0.61
Men, n (%)	26 (45.6)	47 (54.2)	0.33
pre mRS 0, n (%)	32 (66.7)	63 (61.2)	0.59
pre mRS 1, n (%)	2 (4.2)	4 (3.9)	1.00
pre mRS 2, n (%)	4 (8.3)	8 (7.8)	1.00
pre mRS 3, n (%)	2 (4.2)	15 (14.6)	0.09
pre mRS 4, n (%)	8 (16.7)	11 (10.7)	0.30
pre mRS 5, n (%)	0 (0.0)	2 (1.9)	1.00
pre mRS ≤1, n (%)	34 (70.8)	67 (65.1)	0.48
History of hypertension, n (%)	26 (54.2)	52 (50.5)	0.67
History of diabetes mellitus, n (%)	10 (20.8)	18 (17.5)	0.62
History of dyslipidemia, n (%)	11 (22.9)	17 (16.5)	0.35
History of atrial fibrillation, n (%)	31 (64.6)	56 (54.4)	0.24
Findings on admission			
Systolic BP, median (IQR), mmHg	146 (129–159)	151 (136–170)	0.09
Diastolic BP, median (IQR), mmHg	81 (71–98)	88 (73–102)	0.13
NIHSS on admission, median (IQR)	17 (13–23)	19 (12–24)	0.68
ASPECTS on admission, median (IQR)	9 (7–10)	9 (6–10)	0.57
Glucose, median (IQR), mg/dL	126 (104–155)	125 (105–146)	0.74
Occlusion site			
ICA, n (%)	11 (22.9)	23 (22.3)	0.94
M1, n (%)	22 (45.8)	41 (39.8)	0.48
M2, n (%)	15 (31.3)	39 (37.9)	0.43
Procedure, time course			
rt-PA use, n (%)	24 (50.0)	52 (50.5)	0.96
Onset to door time, median (IQR), minutes	73.5 (47.5–239.8)	103.0 (50.0–251.0)	0.56
Onset to puncture time, median (IQR), minutes	91.0 (0.5–197.8)	86.0 (0.3–197.0)	0.67
Onset to recanalization time, median (IQR), minutes	123.5 (0.6–232.5)	134.0 (0.3–246.0)	0.66
Door to recanalization time, median (IQR), minutes	58 (0.6–95.0)	73 (0.4–94.4)	0.04
Puncture to recanalization time, median (IQR), minutes	20 (0.4–33.5)	35 (0.3–56.7)	<0.01
Stroke classification			
Cardioembolic, n (%)	39 (81.3)	62 (60.2)	0.01
Atherothrombotic, n (%)	0 (0.0)	5 (4.9)	0.12
*Others, n (%)	1 (2.1)	6 (5.8)	0.31
ESUS, n (%)	8 (16.7)	29 (28.2)	0.13

*7 patients with LVO due to other etiologies in our cohort were all finally diagnosed with Trousseau syndrome. ASPECTS: Alberta stroke program early CT score; BP: blood pressure; ESUS: embolic stroke with undetermined source; FPE: first pass effect; ICA: internal carotid artery; IQR: interquartile range; LVO: large vessel occlusion; mRS: modified Rankin Scale; NIHSS: National Institutes of Health Stroke Scale; rt-PA: recombinant tissue plasminogen activator

Table 2 Comparison of outcomes between FPE+ vs. FPE– groups

	FPE + (N = 48)	FPE– (N = 103)	Crude OR (95% CI)	p-value	Adjusted OR (95% CI)	p-value
Good outcome (mRS 0–2 after 3 months), n (%)	30 (62.5)	39 (37.9)	2.73 (1.36–5.63)	<0.01	3.87 (1.69–9.38)	<0.01
Any ICH, n (%)	10 (20.1)	49 (47.6)	0.29 (0.13–0.62)	<0.01	0.24 (0.10–0.54)	<0.01
Symptomatic ICH, n (%)	1 (2.1)	10 (9.7)	0.20 (0.01–1.08)	0.06	0.16 (0.01–0.98)	0.04
Mortality, n (%)	7 (14.6)	18 (17.5)	0.81 (0.29–2.01)	0.65	0.76 (0.26–1.99)	0.58

CI: confidence interval; FPE: first pass effect, ICH: intracranial hemorrhage; mRS: modified Rankin Scale; OR: odds ratio

retrieval, was minimized.[1,2] This study was consistent with previous studies in that the mechanisms that are not associated with the preoperative patient status bring the FPE-related improvement of the neurological prognosis.

In this study, the incidence of cardiogenic embolism was significantly higher in the FPE+ group. This result differed from the previous studies stating that the type of etiology is not a predictive factor for FPE.[2,6] The 29 patients with embolic stroke of undetermined source in the FPE- group may have included a large number of patients with cardiogenic cerebral embolism in whom paroxysmal atrial fibrillation was not detected. In Asians, the incidence of intracranial artery stenosis is high.[13,14] In our population, there was no patient with atherothrombotic brain infarction (ATBI) in the FPE+ group, whereas ATBI was observed in approximately 5% of the patients in the FPE– group. At our institution, which is a general hospital, there are many malignant tumor patients with LVO; therefore, all the patients classified with other etiology finally diagnosed with Trousseau's syndrome. A previous study found that the platelet fraction is larger in thrombi from patients with highly active malignant tumors.[15] Jeon et al. reported that such malignant-tumor-associated thrombi are not effectively contacted by an SR and that the FPE was not frequently achieved in comparison with using ADAPT or combined techniques.[16] In our study, it was also difficult to achieve TICI 2c–3 recanalization through the first pass using an SR alone in such patients; this may have resulted in a relatively higher incidence of cardiogenic embolism in the FPE+ group. In the future, switching a strategy other than an SR alone may improve the results of treatment for patients with strong suspicion of ATBI or malignant tumors' association with etiology before the procedure. However, in this study, the number of patients with ATBI or malignant tumors was small. Several factors, such as the thrombus length, stent size for an occluded blood vessel,[17] and vascular anatomy,[18] may also be associated with FPE achievement.

As a limitation of this study, the time course was not considered with respect to the association between FPE and an improvement in the neurological prognosis. However, there was no significant difference in the onset-to-reperfusion time between the FPE+ and FPE– groups, and the onset-to-reperfusion time at our institution was shorter than that in previous studies; therefore, there may have been no marked influence.

In addition, this was a retrospective study in which a therapeutic strategy on the first pass was standardized as balloon guiding catheter use + SR alone, and this strategy was not compared with other therapeutic strategies, including ADAPT or combined techniques. To assess devices or therapeutic strategies that facilitate FPE, a randomized controlled trial must be conducted in the future.

Conclusion

The FPE by an SR alone significantly improved the neurological prognosis in Japanese patients treated by MT, including those with a functional disorder before the onset of LVO.

Disclosure Statement

Nobuyuki Sakai received rewards, such as lecture fees, from Asahi Intecc Co., Ltd.; Daiichi Sankyo Co., Ltd.; Medtronic Japan Co., Ltd.; and Biomedical Solutions Inc. He received research funds from Terumo Corporation and Medtronic Japan Co., Ltd. Hirotoshi Imamura received rewards, such as lecture fees, from Medtronic Japan Co., Ltd. and Stryker Japan K.K. The other authors declare that they have no conflicts of interest.

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