Original research

Predictors of futile recanalization in patients undergoing endovascular treatment in the DIRECT-MT trial

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ABSTRACT

Background Futile recanalization—when patients have a successful recanalization but fail to achieve a satisfactory functional outcome— is a common phenomenon of endovascular treatment of acute ischemic stroke (AIS). The present study aimed to identify the predictors of futile recanalization in AIS patients who received endovascular treatment.

Methods This is a post-hoc analysis of the DIRECT-MT trial. Demographics, clinical characteristics, acute stroke workflow interval times, biochemical parameters, and imaging characteristics were compared between futile and meaningful recanalization groups. Multivariate analysis was performed to identify the predictors of futile recanalization.

Results Futile recanalization was observed in 277 patients. In multivariable logistic regression analysis, older age ($p<0.001$), higher baseline systolic blood pressure (SBP) ($p=0.032$), incomplete reperfusion defined by extended Thrombolysis In Cerebral Infarction (eTICI) grades ($p=0.020$), and larger final infarct volume (FIV) ($p<0.001$) were independent predictors of futile recanalization.

Conclusions Old age, high baseline SBP, incomplete reperfusion defined by eTICI, and large FIV were independent predictors of futile recanalization after endovascular therapy for AIS.

INTRODUCTION

Endovascular thrombectomy (EVT), in addition to intravenous tissue-type plasminogen activator, is the standard of care for acute ischemic stroke (AIS) patients due to large-vessel occlusion (LVO) of the anterior circulation.[1] The results of the DIRECT-MT trial showed that EVT alone was non-inferior to thrombectomy preceded by alteplase administered with LVO in patients presenting directly at EVT-capable centers.[2] According to the results of DIRECT-MT, the proportion of patients with successful reperfusion (extended Thrombolysis In Cerebral Infarction (eTICI) ≥2b) was 82.0%. However, the rate of favorable outcome (defined as modified Rankin scale (mRS) score 0–2) was 36.7%, and >60% of patients failed to achieve a favorable outcome. Futile recanalization means patients who achieved successful recanalization but failed to improve the functional outcome. The risk factors of futile recanalization in patients with ischemic stroke undergoing EVT are yet to be identified. Thus, in this study, we analyzed data from the DIRECT-MT trial to identify the factors that predict futile recanalization.

METHODS

DIRECT-MT was an investigator-initiated, multicenter, prospective, randomized, open-label trial with blinded outcome assessment involving patients with AIS, eligible to receive intravenous alteplase and undergo EVT. The study methods and patient eligibility criteria have been reported previously.[3] In this subgroup analysis, additional exclusion criteria were the absence of follow-up, the presence of pre-stroke history, an admission mRS ≥1, patients who did not undergo catheter angiography, and patients who failed to achieve a successful recanalization (eTICI <2b).

The baseline information included: age, sex, baseline National Institutes of Health Stroke Scale (NIHSS) score, admission systolic blood pressure (SBP), diastolic blood pressure, and body mass index; history of hypertension, dyslipidemia, diabetes, smoking, atrial fibrillation, previous stroke/transient ischemic attack (TIA), or coronary artery disease; medication history of anticoagulation, antiplatelet, statin, or vitamin K antagonist therapy. Biochemical tests included serum creatinine level, serum glucose level, international normalized ratio, and activated partial thromboplastin time. The cause of stroke included cardioembolic, intracranial atherosclerosis, ipsilateral extracranial, or undetermined causes. The intervals from symptom onset to presentation in the emergency department, imaging, randomization, alteplase bolus, the start of the endovascular procedure, and recanalization were also recorded.

All patients underwent head CT scan, and head and neck CT angiography (CTA) on admission; the baseline infarct range was assessed by the Alberta Stroke Program Early CT Score (ASPECTS) with non-contrast CT; the extent of intracranial thrombus was assessed using the Clot Burden Score (CBS ranges from 0 to 10, where a score of 0 implies complete occlusion of the ipsilateral anterior circulation vessels, and a score of 10 implies no occlusion); the baseline collaterals were measured using baseline CTA and dichotomized into good (2–3) and poor (0–1) based on pial arterial filling score[4]; and the location of intracranial artery occlusion was identified on baseline CTA (internal carotid artery (ICA), proximal M1, distal M1 and M2). The eTICI score assessed on the final angiogram and successful reperfusion was graded as 2b, 2c, or 3.[5] Perioperative medication and complications, including symptomatic intracranial hemorrhage (sICH) and asymptomatic intracranial hemorrhage (aICH),[6] infarction in new territory at 5–7 days, embolization into a new territory,[7] any other procedural complications, and the final infarct volume (FIV), were assessed on follow-up CT at days 5–7 using an automated algorithm.

STATISTICAL ANALYSIS

Clinical and radiological outcomes were dichotomized into the meaningful recanalization group (defined as 90-day mRS ≤2, eTICI ≥2b) and the futile recanalization group (defined as 90-day mRS >2, eTICI ≥2b). The association between baseline clinical variables, biochemical parameters, imaging characteristics, and acute stroke workflow interval times was examined in univariate analysis. Means and medians were compared using t-test and Wilcoxon rank-sum test, respectively. Frequencies were compared using the χ^2 test. To maximize sensitivity, variables with $p<0.1$ were entered in the multivariate logistic regression with a backward likelihood ratio model. Data are presented as adjusted odds ratio (OR) and its 95% confidence interval (95% CI). The adjusted factors included patient age, the NIHSS score at baseline, the time from stroke onset to randomization, mRS score before stroke onset, and cerebral collateral blood-flow status, which were adapted from the original statistical analysis plan. All the analyses were performed using SAS software, version 9.2 (SAS Institute), with a significance level of $p<0.05$ (two-sided).

RESULTS

After excluding 17 patients who did not undergo catheter angiography, 112 patients who failed to achieve successful recanalization, and two patients who were lost to follow-up, 463 patients were enrolled in this study. The median age of the cohort was 69 (IQR 61–76) years; 260 patients were men, the median NIHSS score was 17 (IQR 13–21), and the median ASPECTS value was 9 (IQR 7–10). The median time from stroke onset to recanalization was 270 (IQR 222–320) min. A total of 225 patients underwent endovascular thrombectomy alone, and 238 received combination therapy with intravenous alteplase and endovascular thrombectomy.

Futile recanalization was observed in 277 (59.8%) patients, and 186 patients achieved a meaningful recanalization. The baseline characteristics of the patients are listed in table 1. Patients in the futile recanalization group were significantly older (median 72 vs 67 years, $p<0.0001$) and had significantly higher NIHSS scores (median 19 vs 15, $p<0.0001$) on admission, higher baseline SBP (median 147 vs 141 mm Hg, $p=0.0087$), higher level of serum glucose (median 7.20 vs 6.62 mmol/L, $p=0.0035$), lower rate of smoking (19.49% vs 29.03%, $p=0.0174$), higher rate of hypertension (64.98% vs 53.23%, $p=0.0113$), and a higher rate of atrial fibrillation (54.51% vs 34.41%, $p<0.0001$) than those in the meaningful recanalization group. Also, a higher rate of occlusion site of ICA (43.48% vs 26.49%, $p=0.0006$), lower ASPECT score (median 8 vs 9, $p<0.0001$), higher CBS clot burden score, and poorer collateral score ($p<0.0001$) were observed in the futile recanalization group, with respect to the etiology of stroke caused by a cardioembolic condition ($p<0.0001$), than in the meaningful recanalization group. In addition, patients in the futile recanalization group had a longer interval from stroke onset to randomization (median 177 vs 156 min, $p=0.0066$), from randomization to revascularization (median 100 vs 85 min, $p=0.0009$), from hospital admission to intravenous administration (median 190

Table 1 Baseline characteristics of patients with futile and meaningful recanalizations

	Meaningful recanalization (n=186)	Futile recanalization (n=277)	P value
Male mean (SD)	112 (60.22)	148 (53.43)	0.1491
Age (years) median (IQR)	67 (56–72)	72 (64–78)	<0.0001
NIHSS score median (IQR)	15 (12–19)	19 (15–23)	<0.0001
Baseline SBP (mm Hg) median (IQR)	141.50 (124.00–159.00)	147.00 (134.00–166.00)	0.0087
Baseline DBP (mm Hg) median (IQR)	82.00 (74.00–94.00)	85.00 (78.00–93.00)	0.1644
BMI median (IQR)	23.69 (21.67–25.83)	22.86 (21.22–25.48)	0.0776
ASPECTS median (IQR)	9.00 (7.50–10.00)	8.00 (6.00–10.00)	<0.0001
Previous ischemic stroke	16 (8.60)	39 (14.08)	0.0741
Diabetes mellitus	28 (15.05)	56 (20.22)	0.1576
Hypertension	99 (53.23)	180 (64.98)	0.0113
Atrial fibrillation	64 (34.41)	151 (54.51)	<0.0001
Hypercholesterolemia	9 (4.84)	8 (2.89)	0.2739
Previous intracranial hemorrhage	0 (0.00)	2 (0.72)	0.5183
Smoking	54 (29.03)	54 (19.49)	0.0174
Serum glucose (mmol/L) median (IQR)	6.62 (5.81–8.09)	7.20 (6.10–9.10)	0.0035
Cause of stroke			
Cardioembolic	60 (32.26)	147 (53.07)	0.0001
Intracranial atherosclerosis	23 (12.37)	18 (6.50)	
Ipsilateral extracranial	22 (11.83)	20 (7.22)	
Undetermined	81 (43.55)	92 (33.21)	
Location of intracranial artery occlusion			
ICA	49 (26.49)	120 (43.48)	0.0006
M1	113 (61.08)	136 (49.28)	
M2	23 (12.43)	20 (7.25)	
Collateral score			
0–1	128 (68.82)	242 (87.36)	<0.0001
2–3	58 (31.18)	35 (12.64)	
CBS			
0–4	92 (49.73)	83 (30.07)	<0.0001
5–7	55 (29.73)	89 (32.25)	
8–10	38 (20.54)	104 (37.68)	
Intravenous thrombolysis treatment	93 (50.00)	145 (52.35)	0.6204
General anesthesia	61 (32.80)	98 (35.51)	0.5474
From stroke onset to randomization (min) median (IQR)	156.00 (120.00–199.00)	177.00 (127.00–218.00)	0.0066
From randomization to revascularization (min) median (IQR)	85.50 (65.00–117.00)	100.00 (77.00–136.00)	0.0009
From hospital admission to groin puncture (min) median (IQR)	82.00 (65.00–98.00)	84.00 (70.00–105.00)	0.0588

Continued

Table 1 Continued

	Meaningful recanalization (n=186)	Futile recanalization (n=277)	P value
From groin puncture to revascularization (min) median (IQR)	51.00 (37.00–78.00)	64.00 (43.00–92.00)	0.0021
From stroke onset to revascularization (min) median (IQR)	250.50 (201.00–299.00)	277.00 (230.00–328.00)	<0.0001
eTICI score assessed on final angiogram			
2b	48 (26.09)	110 (40.59)	0.005
2c	49 (26.63)	64 (23.62)	
3	87 (47.28)	97 (35.79)	
Tirofiban given during procedure	69 (37.10)	65 (23.55)	0.0017
Heparin given during procedure	93 (50.00)	125 (45.29)	0.3199
Asymptomatic intracranial hemorrhage	42 (22.58)	130 (46.93)	<0.0001
Symptomatic Intracranial hemorrhage	1 (0.54)	23 (8.30)	0.0002
Infarction in new territory	0 (0.00)	14 (5.05)	0.0018
Final infarct volume (mL) median (IQR)	15.54 (1.32–41.93)	63.54 (21.58–139.40)	<0.0001

*Data are n(%) unless stated otherwise
ASPECTS, Alberta Stroke Program Early CT Score; BMI, body mass index; CBS, Clot Burden Score; DBP, diastolic blood pressure; eTICI, extended Thrombolysis In Cerebral Infarction; ICA, internal carotid artery; NIHSS, National Institutes of Health Stroke Scale; SBP, systolic blood pressure.

vs 174 min, p=0.0328), from groin puncture to revascularization (median 64 vs 51 min, p=0.0021), and from stroke onset to revascularization (median 250.5 vs 277 min, p<0.0001) than those in the meaningful recanalization group. Fewer patients in the futile recanalization group received tirofiban during the procedure (23.55% vs 37.10%, p=0.0017) and achieved a complete recanalization of eTICI 3 (35.79% vs 47.28%, p=0.005) on the final angiogram than those in the meaningful group. In addition, patients with futile recanalization had more procedural complications such as aICH (46.93% vs 22.58%, p<0.0001), sICH (8.30% vs 0.54%, p=0.0002), infarction in new territory (5.05% vs 0%, p=0.0018), and embolization in a new territory (14.44% vs 5.38%, p=0.0021) than those with meaningful recanalization. Median FIV on follow-up CT was significantly larger in the futile recanalization group than in the meaningful recanalization group (63.54 vs 15.54 mL, p<0.0001), while the rate of intravenous thrombolysis before EVT did not differ between the two groups.

In multivariable logistic regression analysis (table 2), the following factors were associated with futile recanalization: older age (OR 1.120, 95% CI 1.055 to 1.189, p<0.001), higher baseline SBP (OR 1.026, 95% CI 1.002 to 1.051, p=0.032), incomplete reperfusion defined by eTICI grades assessed on final angiogram (OR 0.510, 95% CI 0.290 to 0.898, p=0.020), and larger FIV (OR 1.018, 95% CI 1.008 to 1.029, p<0.001).

Table 2 Logistic regression analysis identifying independent predictors of futile recanalization

Variable	P value	OR	95% CI
Age	<0.001	1.12	1.055 to 1.189
eTICI score assessed on final angiogram	0.02	0.51	0.290 to 0.898
Final infarct volume	<0.001	1.018	1.008 to 1.029
Baseline SBP	0.032	1.026	1.002 to 1.051

eTICI, extended Thrombolysis In Cerebral Infarction; SBP, systolic blood pressure.

DISCUSSION

With the development of new mechanical thrombectomy devices, the rate of successful recanalization has been greatly improved in patients receiving EVT. However, successful recanalization does not always predict a good outcome. In the current study, a subgroup analysis from DIRECT-MT research revealed that the rate of futile recanalization was 59.8%, which was higher than the 47% reported previously.[8] Earlier studies have shown that many risk factors, such as gender, age, baseline NIHSS, collaterals, time from symptoms onset to reperfusion, baseline ASPECTS, and anesthesia were associated with futile recanalization.[9 10] Our post-doc analysis demonstrated that old age, high baseline SBP, incomplete reperfusion, and large FIV contribute to the risk of futile recanalization. In theory, intravenous thrombolytic drugs may enter the distal branch vessels for patients with successful recanalization, improve macrovascular recanalization at the capillary level, and reduce distal embolism. On the other hand, intravenous thrombolytic therapy may also increase the risk of hemorrhage. However, in the current study, there was no significant difference in the rate of futile recanalization between the thrombectomy alone group and the combination therapy group.

Compared with the younger patients, those >80 years old who underwent endovascular treatment exhibited a lower rate of good clinical outcomes and increased mortality. The HERMES meta-analysis of several randomized controlled trials of EVT reported good functional outcomes in 46% of patients and a 15% mortality rate. However, among patients >80 years old who received endovascular treatment, the rates were 29.8% for 90-day functional outcomes and 28% for mortality.[11] Older patients had more underlying diseases than younger patients, and decreased neuronal plasticity may be difficult to achieve with age along with improved neurological functions post-reperfusion therapy. Leukoaraiosis and the vulnerable blood–brain barrier are more likely to make older patients suffer from intracranial hemorrhage (ICH); also, collateral blood supply may be worse in older patients than in younger individuals. Notably, compared with the best medical therapy, elderly patients may still benefit from EVT, especially those with a good pre-stroke functional status.[12]

Higher baseline SBP levels have been reported with a lower likelihood of good functional outcomes in ischemic stroke patients receiving EVT.[13 14] Our findings indicate that higher admission SBP levels are independently associated with futile recanalization, which is consistent with the previous results.[13 14] Patients with AIS may have a reactive increase in blood pressure (BP), which may promote cerebral perfusion; however, higher BP may increase hyperperfusion and exacerbate cerebral edema after successful recanalization of a large artery occlusion, which in turn affects blood flow, especially in patients with a large ischemic core, eventually leading to infarct expansion and recurrent cerebral ischemia. Previous studies have shown a correlation between hypertension and ICH after recanalization.[15] In the current study, the BP variability is linearly associated with futile recanalization in the treatment of AIS, while in other studies, a J- or U-shaped correlation was established between BP and functional outcome—both low and high BP were associated with poor functional outcome.[16 17] Some studies also showed that

BP variability is a major predictor of outcome after ischemic and hemorrhagic strokes.[18 19]

In our model, the degree of reperfusion was associated with functional outcome, and incomplete revascularization on final angiography was a powerful predictor of futile recanalization. In accordance with our results, there was an unequivocal graded pattern of an increased proportion of subjects with no or minimal disability (mRS 0–1), which was found to be hierarchically linked with higher eTICI grades in the retrospective subgroup analysis of HERMES.[20] Similarly, a recent meta-analysis showed that compared with TICI 2b, TICI 3 revascularization was associated with a significantly higher rate of good functional outcomes and a lower rate of mortality and ICH.[21] Factors that cause incomplete recanalization include residual thrombus migration, stenosis of the target vessel, distal emboli, or increased downstream resistance, which might lead to hypoperfusion, infarction of new territory, and recurrent stroke. Together, these factors could increase the risk of futile recanalization.

Our analysis showed that large FIV at subacute points was an independent predictor of futile recanalization. In concordance with our results, several studies have included data from HERMES and reported the association of FIV and functional outcome after endovascular treatment of AIS with large vessel occlusion.[22 23] One reason for the discrepancy was the lower baseline non-contrast CT ASPECTS in the futile recanalization group, which was finally developed into real infarct volume. In addition, embolization into a new territory, ICH, and severe brain swelling may occur during endovascular treatment, and these factors may contribute to enlargement of the infarct. Another possible explanation is that, compared with patients in the meaningful recanalization group, patients in the futile recanalization group with less target mismatch have salvageable tissue and an increased likelihood of favorable clinical outcomes after reperfusion, but no-mismatch data were not available for all patients in our study.

The present study has some limitations. First, although patients were prospectively registered, all data of this subgroup analysis were assessed retrospectively. Second, the small sample size in our study limited the ability to comment on variables associated with futile recanalization, such as the history of diabetes, and time from onset to treatment. Third, many patients were excluded because of a history of pre-stroke with mRS ≥1, which might affect the true effect of the evaluation, although it reduces the influence of previous stroke history on the outcome. Fourth, in this study, BP was recorded on admission. However, BP was highly variable during the perioperative period, and BP control was not the same for each patient; a BP measurement protocol should therefore be established, and variability may be a better indicator of futile recanalization. Fifth, successful reperfusion was assessed on the final angiogram; however, recanalization assessed on CTA at 24–72 hours indicated that a small proportion of patients develop spontaneous recanalization or re-occlusion and cannot reflect the natural progression after reperfusion accurately.

CONCLUSIONS

In the pooled analysis, we observed that futile recanalization is common following endovascular treatment, especially among patients with older age, higher baseline SBP, and incomplete reperfusion defined by eTICI grades assessed on final angiogram and larger FIV.

Contributors TFZ, TXL, QL, ZSL, LFZ, YCL, YKH and MYW designed the study, PFY, YXZ, ZFL, JML, YWZ,TYY, WHC and SCW conducted the trial and collected information, TFZ drafted the manuscript, all authors critically reviewed the manuscript and approved the final version.

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Competing interests None declared.

Patient consent for publication Not required.

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