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ORIGINAL ARTICLE

Benefits of First Pass Recanalization in Basilar Strokes Based on Initial Clinical Severity

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Abstract

Purpose Randomized trials demonstrating the benefits of thrombectomy for basilar artery occlusions have enrolled an insufficient number of patients with a National Institutes for Health Stroke Scale (NIHSS) score < 10 and shown discrepant results for patients with an NIHSS > 20. Achieving a first pass recanalization (FPR) improves clinical outcomes in stroke. We aimed to evaluate the effect of the FPR on outcomes among basilar artery occlusion patients, characterized by prethrombectomy initial NIHSS score.

Methods We retrospectively analyzed the Endovascular Treatment in Ischemic Stroke (ETIS) registry of 279 basilar artery occlusion patients treated with thrombectomy from 6 participating centers. We compared the 90-day clinical outcomes of achieving a FPR versus no FPR, categorized by initial clinical severity: mild (NIHSS < 10), moderate (NIHSS 10–20) and severe (NIHSS > 20). We used Poisson regression with robust error variance to determine the effect of the NIHSS score on the association between FPR and outcomes.

Results The FPR patients with NIHSS < 10 or NIHSS 10–20 were more likely to have a favorable clinical outcome (modified Rankin scale, mRS 0–3) than non-FPR patients (relative risk, RR = 1.32, 95% confidence interval, CI: 1.04, 1.66, *p*-value = 0.0213, and RR = 1.79, 95% CI: 1.26, 2.53, *p*-value = 0.0011, respectively). A similar benefit was not found in patients with severe symptoms. We found a significantly lower risk of poor clinical outcome (mRS 4–6) in FPR patients with NIHSS 10–20, but not among patients with an NIHSS > 20.

Conclusion Achieving a FPR in basilar artery occlusion patients with mild (NIHSS < 10) or moderate (NIHSS 10–20) symptoms is associated with better clinical outcomes, but not in patients with severe symptoms. These results support the importance of further clinical trials on the benefits of thrombectomy in severe strokes.

Keywords First pass recanalization · First pass effect · Thrombectomy · Basilar stroke · Mortality · Clinical outcome

Introduction

Strokes due to occlusion of the basilar artery have historically been associated with significant morbidity and mortality [1–3]. Endovascular thrombectomy (EVT) was recently found to be associated with better functional outcomes for patients with basilar artery occlusions than medical therapy alone based on two large randomized clinical trials conducted largely in China [4, 5]. These trials found that thrombectomy was superior to medical therapy alone for patients with basilar artery occlusion and an initial National Institutes of Health Stroke Scale (NIHSS) score of 10–20 but showed discrepant findings for patients with an NIHSS score > 20 and inconclusive results for patients with an NIHSS score < 10 [4, 5]. While patients with an initial NIHSS > 20 might have been too sick to benefit from

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endovascular therapy, it is unclear if patients with milder symptoms (i.e., NIHSS < 10) do well enough with medical management alone. Achieving a first pass effect (FPE) or first pass recanalization (FPR) in endovascular therapy (i.e., a complete recanalization after a single pass of endovascular device with no adjunctive therapy) has also shown to further improve outcomes of patients with basilar artery occlusions, and occlusions of the anterior circulation [6, 7].

Using a large multicenter registry of basilar artery occlusions treated with thrombectomy, we aimed to study the benefits of FPR across different groups of patients with basilar stroke based on the initial clinical severity NIHSS score. Our results will help physicians understand the understudied and controversial impact of EVT in mild and severe basilar artery occlusion stroke.

Material and Methods

We conducted our research and report our findings according to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines. According to the local authorities, institutional review board approval was not required for the secondary use of anonymized data.

Study Setting

Our retrospective observational study used the prospective multicenter Endovascular Treatment in Ischemic Stroke (ETIS) registry. The ETIS registry includes all patients with an acute ischemic stroke treated with thrombectomy. Our extraction period spanned from January 2012 to May 2019 and included all french patients treated with thrombectomy from the 6 participating centers in France that contributed to the registry. Patients included were treated with third-generation mechanical thrombectomy devices only, notably stent-retrievers and contact aspiration catheters.

Participants

Our inclusion criteria [6] for this study were all patients who underwent thrombectomy within 24 h from symptom onset for a basilar artery occlusion with at least one intracranial pass. Standardized definitions were used to collect patients' baseline radiological and clinical characteristics, procedure details, and outcomes.

In order to assess whether a FPR was achieved, original images were reviewed by three pairs of readers (always including one interventional neuroradiologist and one stroke neurologist). Discrepancies were resolved by consensus reading. Reviewers used original definitions to identify cases [7]:

1. FPR was defined by fulfilment of all three of the following criteria: (1) single pass/use of the device, (2) complete or near-complete revascularization of the large vessel occlusion and its downstream territory (modified thrombolysis in cerebral infarction, mTICI, score 2c or 3) [8], and (3) no use of rescue therapy. Specifically, we defined rescue therapy as adjunctive use of balloon angioplasty, stenting, or intra-arterial infusion of drugs in patients with an underlying intracranial atherosclerotic disease (i.e., a basilar artery stenosis in our cohort).
2. Patients for whom a FPR was not achieved (non-FPR) were patients who required > 1 pass/use of the device or adjunctive rescue therapy.

To determine the mTICI score, the anatomy of the posterior cerebral arteries (to look for the presence of a P1 segment or a posterior communicating artery) was studied on the initial angiogram (when runs from the carotid arteries were performed) or on the initial noninvasive vascular imaging using computed tomography angiography (CTA) or magnetic resonance angiography (MRA).

Outcome

Our primary outcome, favorable clinical outcome, was defined as a modified Rankin Scale (mRS) of 0–3 at 90 days postthrombectomy. The secondary outcomes were poor outcome and mortality, defined as an mRS score of 4–6 and an mRS score of 6, respectively, at 90 days postthrombectomy. The mRS scores were collected by the six trained physicians who evaluated each included case.

We categorized the NIHSS scores based on the ATTENTION [5] and BAOCHE [4] trials criteria/outcomes into three groups: NIHSS < 10, NIHSS 10–20, AND NIHSS > 20. We looked at the association between FPR and clinical outcome in basilar stroke for these NIHSS categories to help evaluate if FPR is a positive prognostic factor that varies with initial stroke severity. The NIHSS scores were collected by stroke neurologists involved in the initial management of included patients.

Statistical Analyses

Descriptive statistics were computed using counts with percentages for categorical variables and medians with ranges for skewed continuous and ordinal variables. To determine the association between the different predictors and primary outcome, the Wilcoxon rank sum, χ^2 and Fisher exact tests were performed. Particularly, the Wilcoxon rank sum test was used on ordinal and continuous variables with highly skewed observations whereas the χ^2 or Fisher exact tests were performed on categorical variables in accordance with expected cell count values.

To determine the effect of the NIHSS score on the association between FPR and outcomes, we used Poisson regression with robust error variance. This approach allows the conservative computation of relative risks (RR) and 95% confidence intervals (95% CI) for a binary outcome [9]. We computed crude and adjusted RRs controlling for age and IV thrombolysis for each stratum of FPR and NIHSS score categories. We used no FPR and high NIHSS as the reference category, and computed RRs for FPR within strata of NIHSS categories. Effect modification between the NIHSS score and FPR on the prevalence of favorable outcome was assessed on both the additive and multiplicative scales using independent and combined effect measures, an interaction term in the regression model and additive interaction measures, including relative excess risk due to interaction (RERI), the attributional proportion due to interaction (AP) and the Synergy index. The latter measures were calculated using the formulated Excel sheet created by Andersson et al. [10] from the adjusted independent and combined effect measures presented in Table 3. An RERI and AP significantly different than 0 and a Synergy index significantly different than 1 suggested a statistically significant additive interaction. The effect modification and interaction reporting recommendations by Knol and VanderWeele [11] were consulted during the development of this manuscript. A *p*-value below 0.05 suggested a statistically significant association. All statistical analyses were performed in SAS version 9.4 (SAS Institute, Inc., Cary, NC, USA).

Results

From January 2012 to May 2019, 357 patients from 6 medical centers were treated with thrombectomy for basilar artery occlusion stroke. Of the patients 23 were excluded for access failure and 54 because recanalization had been achieved on the first angiographic run, 1 patient with missing outcome information was excluded resulting in a total study sample of 279 patients. Of these, 122 (43.7%) patients had a favorable outcome, 157 (56.3%) had a poor outcome and 115 (41.2%) died. The median age of our sample was 65 years (range: 8–96 years), and 60.9% of patients were male. More characteristics of our sample and their associations with outcomes are shown in Table 1.

While not statistically significant, the rate of FPR across NIHSS categories decreased with increasing stroke severity. The rate of successful FPR was 39.06% (25/64 patients) for patients with an NIHSS score <10, 37.00% (37/100 patients) for those with an NIHSS score 10–20 and 27.83% (32/115 patients) for those with an NIHSS score >20 (p-value $=0.1963$; Fig. 1).

Among patients with an initial NIHSS <10, those for whom a FPR had been achieved were more likely to have a favorable 90-day clinical outcome than those for whom no FPR had been achieved (RR = 1.32, 95% CI: 1.04, 1.66, p-value $=0.0213$; Fig. 2). Patients for whom a FPR had been achieved had a lower relative risk of a 90-day poor outcome, although this association was not significant (p-value $=0.0661$). None died (Table 2). Compared to patients with NIHSS >20 and for whom no FPR had been achieved, the adjusted RR of a favorable outcome was 4.35 (95% CI: 2.52, 7.51) for the independent effect of a low NIHSS

Table 1 Baseline characteristics by favorable outcome and non-favorable outcome

	Favorable outcome (*n* = 122)	Non-favorable outcome (*n* = 157)	*P*-value
Sex, male *n* (%)	73 (59.8)	97 (61.8)	0.7409
Age, years, median (range)	63 (8–96)	65 (25–96)	0.1300
Hypertension, *n* (%)	62 (50.8)	97 (63.0)	0.0422[a]
High cholesterol, *n* (%)	37 (30.3)	57(37.3)	0.2289
Diabetes, *n* (%)	19 (15.6)	39 (25.3)	0.0483[a]
Smoker, *n* (%)	31 (26.1)	37 (26.2)	0.9722
IV thrombolysis, *n* (%)	58 (47.5)	46 (29.3)	0.0018[a]
FPR, *n* (%)	56 (45.9)	38 (24.2)	0.0001[a]
No FPR, *n* (%)	66 (54.1)	119 (75.8)	
Modified FPR, *n* (%)	76 (62.3)	45 (28.7)	<0.0001[a]
No modified FPR, *n* (%)	46 (37.7)	112 (71.3)	
NIHSS 20+, *n* (%)	21 (17.2)	94 (59.9)	<0.0001
NIHSS 10–20, *n* (%)	51 (41.8)	49 (31.2)	
NIHSS 0–9, *n* (%)	50 (41.0)	14 (8.9)	
Pretreatment modified Rankin scale, median (range)	0 (0–3)	0 (0–4)	0.0071[a]

FPR first pass recanalization, *NIHSS* National Institutes of Health Stroke Scale
[a] Missing values for smoker = 19, hypertension = 3, diabetes = 3, cholesterol = 4, pretreatment modified Rankin scale = 3

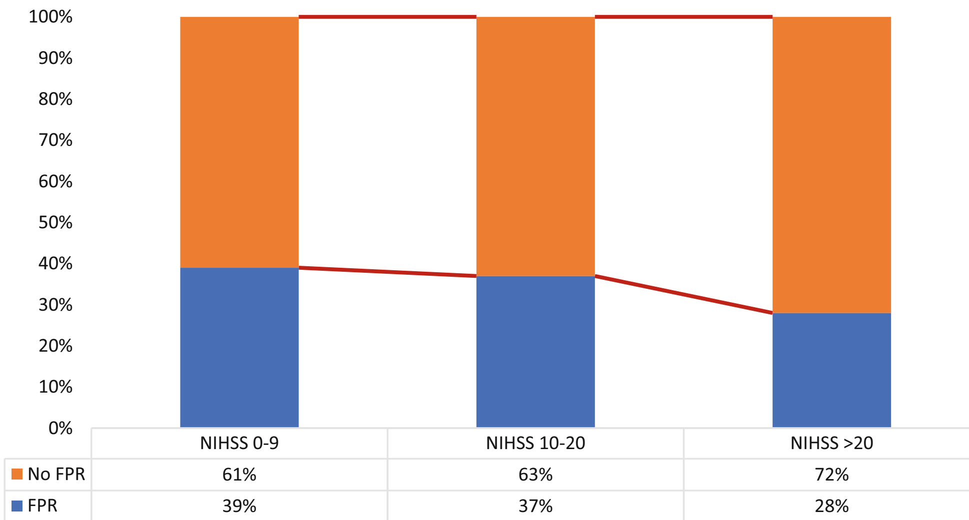

Fig. 1 Rate of FPR or no FPR across NIHSS categories

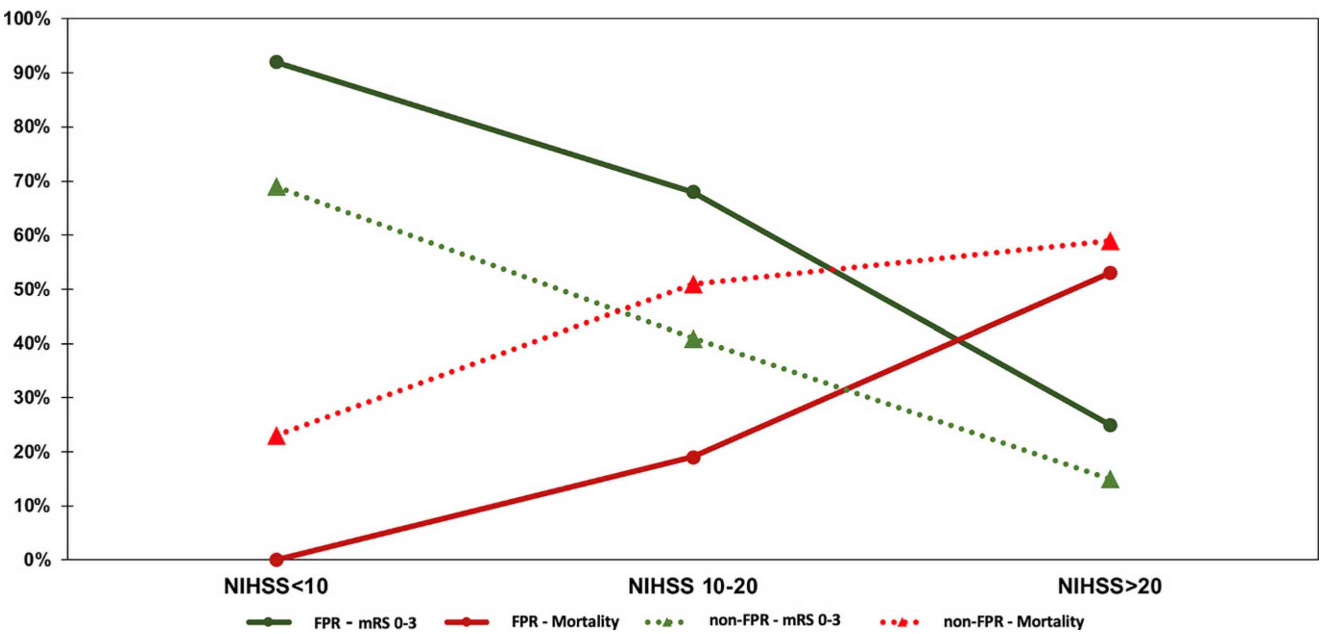

Fig. 2 Rates of good clinical outcome (mRS 0–3) and mortality for FPR and non-FPR patients treated with thrombectomy for basilar stroke amongst various ranges of clinical symptoms: mild (NIHSS < 10), moderate (NIHSS 10–20), and severe (NIHSS > 20)

and 1.64 (95% CI: 0.76, 3.55) for the independent effect of FPR. The chance of a favorable outcome was highest amongst patients with both a NIHSS score of 0–9 and for whom a FPR had been achieved compared to patients with an NIHSS score over 20 with no FPR (RR = 5.73, 95% CI: 3.42, 9.61; Table 3).

Among patients with an initial NIHSS of 10–20, those for whom a FPR had been achieved were more likely to have a favorable clinical outcome than those for whom no FPR had been achieved (RR = 1.79, 95% CI: 1.26, 2.53, *p*-value = 0.0011; Fig. 2). Patients for whom a FPR had been achieved had a significantly lower relative risk of poor 90-day clinical outcome compared to patients in the non-FPR group (RR = 0.50, 95% CI: 0.30, 0.81), and they also had a significantly lower likelihood of mortality (RR = 0.33, 95% CI: 0.17, 0.652; Table 2).

Among patients with NIHSS > 20, there was no significant association between FPR and favorable outcome, poor outcome, or mortality (Table 2).

In both strata of FPR, there was an increasing risk of favorable outcome with each change in decreasing NIHSS score category (Table 3); however, the RERI was 0.74 (95% CI: –2.35, 3.82), the AP was 0.13 (95% CI: –0.38, 0.64) and the Synergy index was 1.18 (95% CI: 0.58, 2.44), suggesting no additive interaction between FPR and NIHSS. The measure of effect modification on a multiplicative

Table 2 RR for FPR vs. no FPR within strata of NIHSS

	RR (95% CI)	*P-value*	Adjusted RR (95% CI)[b]	*P-value*
NIHSS 20+				
Favorable outcome (mRS 0–3)	1.60 (0.73, 3.48)	0.2404	1.64 (0.75, 3.57)	0.2149
Very poor outcome (mRS 4–6)	0.89 (0.71, 1.11)	0.2969	0.88 (0.71, 1.10)	0.2730
Mortality (mRS 6)	0.88 (0.61, 1.28)	0.5048	0.88 (0.61, 1.27)	0.4863
NIHSS 10–20				
Favorable outcome (mRS 0–3)	1.64 (1.13, 2.37)	0.0089[a]	1.79 (1.26, 2.53)	0.0011[a]
Very poor outcome (mRS 4–6)	0.55 (0.33, 0.92)	0.0222[a]	0.50 (0.30, 0.81)	0.0053[a]
Mortality (mRS 6)	0.37 (0.18, 0.76)	0.0064[a]	0.33 (0.17, 0.65)	0.0014[a]
NIHSS 0–9				
Favorable outcome (mRS 0–3)	1.34 (1.05, 1.71)	0.0204[a]	1.32 (1.04, 1.66)	0.0213[a]
Very poor outcome (mRS 4–6)	0.26 (0.06, 1.07)	0.0612	0.27 (0.07, 1.09)	0.0661
Mortality (mRS 6)	N/A	N/A	N/A	N/A

CI confidence interval, *FPR* first pass recanalization, *N/A* not applicable, *RR* relative risk
[a] Significant association ($p < 0.05$)
[b]Adjusted for age over 80 years and IV thrombolysis

Table 3 Relative risks (RR) of a favourable outcome (mRS 0–3)—independent and joint effects of FPR and NIHSS

	Crude RR (95% CI)	*P-value*	Adjusted RR (95% CI)[b]	*P-value*
Favorable outcome (mRS 0–3)				
No FPR				
NIHSS 20+	Reference	–	Reference	–
NIHSS 10–20	2.64 (1.48, 4.70)	0.0011[a]	2.47 (1.37, 4.43)	0.0025[a]
NIHSS 0–9	4.42 (2.57, 7.60)	<0.0001[a]	4.35 (2.52, 7.51)	<0.0001[a]
FPR				
NIHSS 20+	1.60 (0.73, 3.48)	0.2404	1.64 (0.76, 3.55)	0.2094
NIHSS 10–20	4.31 (2.50, 7.45)	<0.0001[a]	4.23 (2.44, 7.35)	<0.0001[a]
NIHSS 0–9	5.87 (3.52, 9.81)	<0.0001[a]	5.73 (3.42, 9.61)	<0.0001[a]
Very poor outcome (mRS 4–6)				
No FPR				
NIHSS 20+	Reference	–	Reference	–
NIHSS 10–20	0.70 (0.56, 0.87)	0.0018[a]	0.74 (0.59, 0.93)	0.0094[a]
NIHSS 0–9	0.36 (0.23, 0.59)	<0.0001[a]	0.37 (0.23, 0.60)	<0.0001[a]
FPR				
NIHSS 20+	0.89 (0.71, 1.11)	0.2969	0.87 (0.69, 1.08)	0.1967
NIHSS 10–20	0.39 (0.24, 0.62)	<0.0001[a]	0.39 (0.24, 0.62)	<0.0001[a]
NIHSS 0–9	0.10 (0.03, 0.36)	0.0005[a]	0.10 (0.03, 0.36)	0.0005[a]
Mortality				
No FPR				
NIHSS 20+	Reference	–	Reference	–
NIHSS 10–20	0.84 (0.63, 1.14)	0.2641	0.90 (0.66, 1.21)	0.4794
NIHSS 0–9	0.38 (0.21, 0.70)	0.0017[a]	0.39 (0.21, 0.71)	0.0021[a]
FPR				
NIHSS 20+	0.88 (0.61, 1.28)	0.5048	0.86 (0.59, 1.24)	0.4150
NIHSS 10–20	0.31 (0.16, 0.63)	0.0010[a]	0.32 (0.16, 0.63)	0.0009[a]
NIHSS 0–9	N/A	N/A	N/A	N/A

CI confidence interval, *FPR* first pass recanalization, *N/A* not applicable, *RR* relative risk
[a] Significant association ($p < 0.05$)
[b] Adjusted for age over 80 years and IV thrombolysis

scale was also insignificant (RR = 0.80, 95%: 0.36–1.80, *p*-value = 0.5939). As for our secondary outcomes, the relative risk of a very poor outcome was significantly reduced for the independent and joint effects of low NIHSS while the relative risk of mortality was significantly reduced for the independent effect of low NIHSS only (Table 3). Due to the lack of mortality incidence among those with FPR and NIHSS 0–9, the joint effect between low FPR and NIHSS could not be calculated.

Discussion

Interpretation of Findings

In this analysis of 279 consecutive patients with basilar artery occlusions undergoing endovascular thrombectomy, there was a positive association between achieving a FPR and functional outcome in patients with an initial NIHSS of less than 20. Our results suggest that the technical success of achieving a FPR in endovascular treatment of basilar stroke is a significant positive prognostic factor that is necessary but not sufficient to achieve good outcomes in severe stroke. To our knowledge, our study is the first to look at the association between FPR for posterior circulation stroke, functional outcome, and mortality by NIHSS strata in light of the two recently positive RCTs [4, 5], which supported thrombectomy over medical therapy in posterior circulation stroke patients.

Comparison to Previous Studies and Clinical Implications

These data contribute to our understanding of outcome in patients with basilar artery occlusion, as collected in two RCTs. Particularly, BAOCHE showed benefits for thrombectomy in patients with an NIHSS 6–20 but included only a small number of patients with an NIHSS 6–9 (6 patients in the thrombectomy group and 11 in the control group), and ATTENTION did not include patients with an NIHSS < 10 [4, 5]. As a consequence, some clinicians might argue that patients with basilar artery occlusion and NIHSS < 10 should not be treated with thrombectomy; however, not only does NIHSS underestimate clinical severity for patients with posterior circulation stroke [12] but data suggest that patients with basilar artery occlusion and low NIHSS do worse than patients with anterior circulation stroke and low NIHSS [2]. While multiple studies have shown an association between FPR and outcome in basilar artery occlusion [6, 13–15], none have evaluated the impact of this effect for patients with NIHSS < 10. Hence, our study is novel as it evaluates the association between FPR and outcome by NIHSS stratification.

While data on the safety of thrombectomy for patients with basilar artery occlusion with an NIHSS < 10 are scarce [16] but show safety and feasibility [17], our study supports improved outcomes in patients with FPR and the need for dedicated clinical trials to further evaluate the benefits of thrombectomy in mild stroke. Also, in this patient population most likely to benefit from efficient reperfusion therapy, predictors of FPR need to be clinically identified by physicians. Previous research has identified predictors of FPR (i.e., cardioembolic etiology, the use of contact aspiration rather than stent retriever, the mothership paradigm, and non-atherothrombotic etiologies) but, to our knowledge, predictors have not yet been studied by stroke severity [6, 15, 18].

Scant data exist on the benefits of FPR compared to non-FPR for severe basilar artery stroke given that most data focus on the benefits of thrombectomy in general. While BAOCHE showed no benefits of thrombectomy for basilar artery occlusion in patients with an NIHSS > 20, ATTENTION showed benefits compared to medical therapy alone. The latter trial included only patients within 12 h of symptoms onset, while BAOCHE included patients within 6–24 h [4, 5]; we included all patients within 24 h. Faster recanalization leads to better outcomes [19], and the loss of benefits of FPR in patients with an NIHSS > 20 may be skewed by those treated later within 12–24 h [20]. The loss of an association between FPR and outcome may also be due to the already grim prognosis of patients with severe basilar artery stroke treated with medical treatment [16, 21–24]. In addition to confounders and crossovers, the two other existing negative RCTs showing non-superiority of thrombectomy over medical therapy (BEST and BASICS) were also dominated by patients in the intervention group with severe stroke (BEST median NIHSS = 32; BASICS median NIHSS = 21), likely skewing their results [25, 26]. More research is required to evaluate which prognostic factors could possibly benefit posterior circulation stroke patients with an NIHSS > 20 undergoing reperfusion therapy.

Our study suggests that achieving a FPR is associated with a lower mortality risk for mild and moderate stroke but that this association is lost in severe stroke; however, FPR is not associated with a worse mortality risk compared to non-FPR in severe stroke, and faster recanalization should always be within treatment goals to improve outcome [19]. Also, past studies showed mortality benefits of FPR compared to non-FPR for all combined stroke severities in both anterior and posterior circulation stroke [6, 27].

Strengths and Limitations

While our study was not randomized, we included a good number of patients within each NIHSS strata, an element that was not achieved in previous RCTs [4, 5, 25, 26]; however, our study did not collect information that is known to influence the outcome of FPR, such as the location of the occlusion or the etiology of the stroke [6, 15, 18]. While our analyses were adjusted for age and IV thrombolysis, one should be aware of potential unmeasured confounders and residual confounding present in studies with an observational design [28]. Given that the NIHSS underestimates clinical severity in posterior circulation stroke [12], there are limitations attached to using NIHSS stratifications to define posterior circulation stroke severity. Using more objective and reliable scoring methods such as CT perfusion imaging could be of value and of future research interest to evaluate prognosis and clinical severity in posterior circulation stroke [29] and refine clinical trials inclusion criteria. We also used the mTICI scale to define FPR in our posterior circulation stroke patients, but the mTICI scale has been developed as a reperfusion measure for anterior circulation stroke and its validation for posterior circulation stroke remains unclear [30]. There are limitations in using this scale for posterior circulation events due to different vascular territories and frequent collateral vessels, and interrater agreement between trained medical professionals is fair and suboptimal [31]. Providing information on recanalization in future research using a score such as the arterial occlusive lesion (AOL) could be appropriate for posterior circulation events [32]. More research should be placed on either validating reperfusion (such as the mTICI) and recanalization (such as the AOL) scoring systems for posterior circulation stroke, or on developing a score intrinsic to the complexity of posterior circulation occlusion. Finally, we evaluated associations between FPR and clinical outcome regardless of stroke etiology and the site of occlusion of the basilar artery, two predictors of outcome and recanalization [33, 34]. Future research stratified by etiology and site of occlusion could help researchers understand patients most likely to achieve complete recanalization/reperfusion and a better clinical outcome.

Conclusion

In conclusion, FPR is significantly associated with improved functional outcome and reduced mortality in basilar artery occlusion patients with mild (NIHSS < 10) and moderate symptoms (NIHSS 10–20); however, the association is lost in patients with more severe symptoms (NIHSS > 20). Our study is the first to evaluate the association between FPR and outcome by NIHSS stratification for posterior circulation stroke patients. Clinicians and researchers should identify positive predictors of FPR in basilar artery occlusion to improve endovascular techniques to achieve more FPR and optimize patient outcomes. Our study also supports the importance of conducting further research to understand why and where the benefits of FPR are lost in severe stroke.

Declarations

Conflict of interest V. Brissette, D.C. Roy, M. Jamal, M. Fahmy, A. Guenego, J. Fahed, M. Shamy, D. Dowlatshahi and R. Fahed declare that they have no competing interests.

Ethical standards For this article no studies with human participants or animals were performed by any of the authors. All studies mentioned were in accordance with the ethical standards indicated in each case.

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