

First Pass Effect

A New Measure for Stroke Thrombectomy Devices

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Background and Purpose—In acute ischemic stroke, fast and complete recanalization of the occluded vessel is associated with improved outcomes. We describe a novel measure for newer generation devices: the first pass effect (FPE). FPE is defined as achieving a complete recanalization with a single thrombectomy device pass.

Methods—The North American Solitaire Acute Stroke Registry database was used to identify a FPE subgroup. Their baseline features and clinical outcomes were compared with non-FPE patients. Clinical outcome measures included 90-days modified Rankin Scale score, National Institutes of Health Stroke Scale score, mortality, and symptomatic intracranial hemorrhage. Multivariate analyses were performed to determine whether FPE independently resulted in improved outcomes and to identify predictors of FPE.

Results—A total of 354 acute ischemic stroke patients underwent thrombectomy in the North American Solitaire Acute Stroke registry. FPE was achieved in 89 out of 354 (25.1%). More middle cerebral artery occlusions (64% versus 52.5%) and fewer internal carotid artery occlusions (10.1% versus 27.7%) were present in the FPE group. Balloon guide catheters were used more frequently with FPE (64.0% versus 34.7%). Median time to revascularization was significantly faster in the FPE group (median 34 versus 60 minutes; $P=0.0003$). FPE was an independent predictor of good clinical outcome (modified Rankin Scale score ≤ 2 was seen in 61.3% in FPE versus 35.3% in non-FPE cohort; $P=0.013$; odds ratio, 1.7; 95% confidence interval, 1.1–2.7). The independent predictors of achieving FPE were use of balloon guide catheters and non-internal carotid artery terminus occlusion.

Conclusions—The achievement of complete revascularization from a single Solitaire thrombectomy device pass (FPE) is associated with significantly higher rates of good clinical outcome. The FPE is more frequently associated with the use of balloon guide catheters and less likely to be achieved with internal carotid artery terminus occlusion. (*Stroke*. 2018;49:660-666. DOI: 10.1161/STROKEAHA.117.020315.)

Key Words: first pass ■ recanalization ■ Solitaire ■ stent retriever ■ stroke ■ thrombectomy

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Major technical advances in mechanical thrombectomy have resulted in a significantly improved rates of revascularization and subsequent clinical outcome in acute ischemic stroke (AIS) patients.^{1–4} Several landmark randomized clinical trials established the clinical efficacy of mechanical revascularization compared with intravenous (IV) tPA (tissue-type plasminogen activator).^{5–9} As a result, the American Heart and American Stroke Association currently recommends mechanical thrombectomy as the standard of care for select groups of AIS patients with proximal artery occlusions.^{10,11}

Although morbidity and mortality in AIS patients treated with stent retrievers remain high, achieving complete or near-complete reperfusion has been associated with improved clinical outcomes and reduced adverse effects.^{12–19} However, complete reperfusion is achieved in <50% of cases, and often requires multiple thrombectomy attempts, use of rescue therapy, and is rarely obtained from the first device pass.^{1–9} In addition to prolonging procedure time, multiple device passes may promote arterial endothelial injury, potentially reducing clinical efficacy while reducing safety.^{20–22} Hence, achieving complete revascularization with a single pass should be the primary angiographic goal as thrombectomy devices design continues to improve.

In this article, we introduce and evaluate a new metric for thrombectomy devices, the first pass effect (FPE), within a large cohort of patients from the North American Solitaire Acute Stroke (NASA) Registry database.^{3,12–15} FPE is defined as (1) single pass/use of the device, (2) complete revascularization of the large vessel occlusion and its downstream territory (Modified Thrombolysis in Cerebral Infarction [mTICI] 3), and (3) no use of rescue therapy. Here, the frequency of FPE, its clinical significance, and factors that may predict FPE are evaluated.

Methods

The data that support the findings of this study are available from the corresponding author on reasonable request and with approval from the NASA investigators. The NASA registry is an investigator-initiated, retrospective, postmarketing study, which included demographic, clinical presentation, procedural details, and site-adjudicated angiographic and clinical outcome data on consecutive AIS patients treated with the Solitaire FR device from March 2012 to February 2013 at 24 North American medical centers.^{3,12–15} Local institutional review board approval was obtained from each study site. The stent retriever procedure was performed using local protocols and standard of care. Procedural details, clinical events, and outcomes were collected using standardized definitions for the study. Angiographic data were reviewed to identify a FPE subgroup within the NASA registry using the following 3 criteria: (1) single pass/use of the device, (2) complete revascularization of the large vessel occlusion and its downstream territory (mTICI 3), and (3) no use of rescue therapy. For the purpose of this analysis, any mTICI 2c cases within the NASA database were included in the mTICI 3 population. Modified FPE (mFPE) was defined as meeting all criteria for FPE but achieving mTICI 2b after the first pass. Clinical and angiographic outcomes were compared among FPE and non-FPE populations, mTICI 2b, and mFPE populations.

Distal embolization was defined as fragmentation of a primary clot downstream to the primary occlusion and embolization into new territory. Primary clinical outcome was the modified Rankin Scale (mRS) score at 90 days; mRS scores 0 to 2 were considered good clinical outcomes. Additional clinical and safety outcomes included follow-up National Institute of Health Stroke Scale (NIHSS) score, symptomatic intracranial hemorrhage, and mortality. Symptomatic ICH was defined based on ECASS criteria (Electronic Consolidated Automated Support

System), as any intracranial hemorrhage associated with neurological deterioration of ≥ 4 points on the NIHSS score at 24 hours.

Statistical Analysis

Baseline variables were compared between the FPE, mFPE, and the non-FPE cohorts using the *t* test or χ^2 /Fisher test for proportions. Multivariate analysis was performed using logistic regression analysis to (1) identify independent predictors of clinical outcome (FPE included in the model) and (2) assess the demographic, clinical, and angiographic predictors of FPE. All analyses were performed using JMP 13 (SAS, Cary, NC).

Results

Frequency and Characteristics of FPE

Three hundred fifty-four patients were included in the NASA registry. The breakdown of angiographic reperfusion results is shown in Figure 1. Overall, 25.1% achieved FPE from the full cohort. For those who achieved final mTICI 3, almost 2 out of 3 (63%) will achieve it from the first pass.

No difference was shown in the age, comorbidities, stroke severity, or use of intravenous thrombolysis between FPE and non-FPE groups (Table 1). A significantly higher proportion of females and octogenarians were present within the FPE group compared with the non-FPE group. Patients with FPE were less likely to have internal carotid artery (ICA) occlusions, with a trend toward more middle cerebral artery occlusions (Table 1).

From a procedural standpoint, median time of onset to groin puncture was not statistically different in the FPE group and non-FPE cohort (270 versus 298 minutes, respectively). Moreover, balloon guide catheters (BGC) were used more frequently in the FPE group (64.0% versus 34.7%; $P=0.01$).

Angiographic and Clinical Outcomes in FPE Versus Non-FPE Cohorts

Procedural angiographic outcomes demonstrated a significantly shorter median time to revascularization in the FPE group (34 versus 60 minutes; $P=0.0003$; Table 2). The rate of distal embolization was lower in the FPE group (5.7%) compared with the rest of the NASA cohort (19.3%; $P=0.002$), with a trend toward lower rates of embolization into new territory (2.3% versus 6.4%) in FPE patients (Table 2).

The FPE patients had significantly better 90-day clinical outcomes than those in the non-FPE population (mRS score ≤ 2 61.3% versus 35.3%; $P=0.01$; odds ratio, 1.7; 95% confidence interval, 1.1–2.7; Table 2). When compared with the

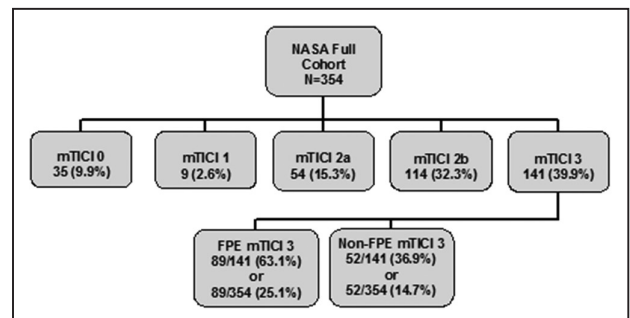


Figure 1. First pass effect (FPE) in the North American Solitaire Acute Stroke (NASA) cohort. mTICI indicates Modified Thrombolysis in Cerebral Infarction.

Table 1. Baseline Characteristics of the NASA FPE vs Non-FPE NASA Cohort

	FPE (n=89), n (%)	Non-FPE (N=265), n (%)	P Value
Demographics			
Age, y, mean (SD)	68.8 (14.8)	66.79 (15.3)	0.28
Median (IQR)	71 (57–81)	70 (55–78)	...
Age >80 y	27 (30.3)	51 (19.2)	0.03
Sex (female)	54 (60.7)	125 (47.2)	0.03
Race (white)	73 (82.0)	185 (69.8)	0.07
Vascular risk factors			
Hypertension	71 (79.8)	200 (75.5)	0.34
Atrial fibrillation	40 (44.9)	108 (40.8)	0.44
Diabetes mellitus	24 (27.0)	63 (23.8)	0.51
Hyperlipidemia	50 (56.2)	132 (49.8)	0.26
Smoking history	25 (28.1)	83 (31.3)	0.57
Coronary artery disease	27 (30.3)	84 (31.7)	0.86
Clinical presentation			
TOG, min, mean (SD)	369.5 (239)	361.3 (239.5)	0.78
Median (IQR)	270 (210–468)	298 (210–430)	...
Initial NIHSS score, mean (SD)	17.3 (7.7)	18.4 (6.2)	0.18
Median (IQR)	16 (13–22)	19 (14–23)	...
Occlusion site			
M1	57 (64.0)	139 (52.5)	0.06
M2/M3	11 (12.4)	28 (10.6)	0.65
ICA terminus	9 (10.11)	73 (27.7)	<0.01
Vertebrobasilar	12 (13.5)	24 (9.1)	0.23
Initial systolic BP, mean (SD)	144.9 (29.4)	145.7 (27.6)	0.83
Median (IQR)	144 (129–161)	143 (125–165)	...
Initial diastolic BP, mean (SD)	77.7 (17.5)	78.9 (17.8)	0.61
Median (IQR)	78.5 (66–90)	78 (68–88)	...
IV tPA	39 (43.8)	115 (43.4)	0.97
Hospital transfer	35 (39.3)	124 (46.8)	0.61
Procedural factors			
DtG	140.6 (98.5)	140.6 (87.5)	0.99
Median (IQR)	113 (78–269)	126 (78–252)	...
General anesthesia	45 (50.6)	153 (57.7)	0.84
IA tPA	20 (22.5)	80 (30.2)	0.16
Balloon guide catheter	57 (64.0)	92 (34.7)	0.01

BP indicates blood pressure; DtG, door to groin puncture; FPE, first pass effect; ICA, internal carotid artery; IQR, interquartile range; NASA, North American Solitaire Acute Stroke; NIHSS, National Institutes of Health Stroke Scale; TOG, time of onset to groin puncture; and tPA, tissue-type plasminogen activator.

Table 2. Time, Technical, Angiographic, and Clinical Outcome Results in FPE vs Non-FPE NASA Cohorts

	FPE (n=89), n (%)	Non-FPE (n=265), n (%)	P Value
Procedural outcomes			
FT, min, mean (SD)	22.6 (18.9)	36.2 (26.8)	<0.0001
Median (IQR)	17 (12.3–24.8)	29 (18.4–47.3)	...
Time to revascularization, mean (SD)	52.5 (73.8)	85.6 (101.4)	0.0003
Median (IQR)	34 (20.5–47)	60 (36–89)	...
Angiographic outcome			
Distal embolization	5 (5.6)	51 (19.3)	0.002
Embolization into new territory	2 (2.3)	17 (6.4)	0.1
Clinical outcome			
mRS score ≤2 at 90 d	49/89 (55.1)	83/265 (31.3)	<0.0001
Available on 80 in FPE and 235 in non-FPE	49/80 (61.3)	83/235 (35.3)	0.01
NIHSS score at discharge, mean (SD)	9.1 (12.9)	17 (16.0)	0.0001
Median (IQR)	4 (1–11)	12 (4–35)	...
mRS score at discharge	38 (42.7)	41 (15.5)	<0.0001
mRS score ≤2 at 30 d	36 (40.4)	51 (19.2)	<0.0001
NIHSS at 90 d, mean (SD)	13.2 (17.4)	25.1 (18.3)	0.0003
Median (IQR)	3.5 (0–36.5)	42 (5–42)	...
Mortality at 90 d	13 (16.3)	85 (36.5)	0.001
slCH	5 (5.6)	30 (11.3)	0.11

FPE, first pass effect; FT, fluoroscopic time; IQR, interquartile range; mRS, modified Rankin Scale; NASA, North American Solitaire Acute Stroke; NIHSS, National Institutes of Health Stroke Scale; and slCH, symptomatic intracerebral hemorrhage.

overall NASA cohort, good clinical outcome was also higher in FPE patients (61.3% versus 42%, $P=0.002$; Table 3). NIHSS score (at both discharge and 90 days) and 90-day mortality rate were lower in the FPE group compared with the non-FPE cohort (Table 2).

In a multivariate logistic regression model (adjusting for FPE, age, ICA occlusion, baseline NIHSS score, BGC use, symptomatic intracranial hemorrhage, and general anesthesia), FPE remained an independent predictor of favorable clinical outcome (odds ratio, 2.1; 95% confidence interval, 1.1–4.1; $P=0.03$).

Clinical Outcome of FPE Cohort Treated Within the Clinical Guidelines

To investigate whether the FPE clinical outcome is further improved within certain subsets of selected patients that met published American Heart Association and American Stroke Association clinical guidelines, or known predictors of clinical outcome, we restricted the FPE population to patients with time of onset to groin puncture ≤6 hours and IV tPA treatment before mechanical thrombectomy. The restricted FPE group demonstrated improved clinical outcome (mRS score ≤2) to 77.8%,

Table 3. Comparison of the Clinical and Angiographic Outcomes in FPE vs Overall NASA, Any Final mTICI2b, and mFPE Cohorts

	Full NASA (n=354)	FPE (n=89)	P Value; OR	Any mTICI 2b (n=114)	P Value (Any mTICI2b vs FPE)	mFPE (n=43)	P Value (FPE vs mFPE)
mRS score ≤ 2 (90 d)	132/315 (42%)	49/80 (61.3%)	0.002 (2.9; 1.7–4.9)	47/106 (44.3%)	0.02	22 (52.4%)	0.35
NIHSS score (90 d), mean (SD)	22.6 (18.8)	13.2 (17.4)	0.003	21 (20)	0.11	22.6 (19)	0.01
sICH	35/352 (9.9%)	5/89 (5.6%)	0.20	14/113 (12%)	0.10	5/43 (11.6%)	0.22
Mortality	95/315 (30%)	13/80 (16.3%)	0.01	32/106 (30.2%)	0.03	13/42 (31%)	0.06
DE	56/341 (16.4%)	5/88 (5.7%)	0.01	33/112 (29.5%)	<0.0001	13/43 (30.2%)	0.01
ENT	19/344 (5.5%)	2/89 (2.3%)	0.20	3/110 (3%)	0.8	0/43 (0%)	0.20

FPE, first pass effect; mFPE, modified FPE; mTICI, Modified Thrombolysis in Cerebral Infarction; mRS, modified Rankin Scale; NASA, North American Solitaire Acute Stroke; NIHSS, National Institutes of Health Stroke Scale; and OR, odds ratio.

with a further reduction in mortality and symptomatic intracranial hemorrhage rates to 11.1% and 3.2%, respectively (Figure 2B).

Predictors of FPE

The multivariate analysis included variables that were different between the FPE and non-FPE groups (middle cerebral artery occlusion, ICA occlusion, age >80 years, BGC use, female sex, race, IV tPA use, combined aspiration, and retriever approach) and showed only the use of BGC (odds ratio, 3.5; 95% confidence interval, 2.0–6.2; $P<0.001$) and absence of ICA terminus clots (odds ratio, 0.23; 95% confidence interval, 0.09–0.57; $P<0.0001$) as predictors of FPE.

FPE Versus Other Recanalization Outcome

To evaluate whether FPE is as safe and effective if defined as achieving mTICI2b from first pass (mFPE) and to explore whether mTICI3 without FPE or mTICI 2b without FPE are comparable to the FPE, we looked at outcomes with different recanalization results as outlined in Table 3 and in Figure 2C.

The results showed a higher rate of good clinical outcome with FPE when compared with final mTICI 3 with >1 pass, any mTICI 2b, or mTICI 2b from the first pass (61.3% versus 45% [$P=0.07$], 44.3% [$P=0.02$], and 52.4% [$P=0.35$], respectively; Table 3; Figure 2C). Similar findings were seen with a higher improvement in the NIHSS score at 90 days in the FPE group than the other recanalization groups (Table 3). Fewer adverse events were seen in the FPE group (Table 3; Figure 2C). In particular, mortality rate was significantly lower in the FPE group than in any other groups (16% in FPE versus 20.5% in TICI3 final with >1 pass, 29.5% in any mTICI2b, 30.2% in mFPE, and 30% in full NASA, respectively; Table 3; Figure 2C).

Discussion

In this substudy of the NASA Registry, FPE was seen in 25.1% of the full cohort. Patients with FPE had a better clinical outcome, lower mortality, and fewer procedural adverse events. Predictors of achieving FPE were the use of BGC, whereas the ICA terminus occlusion predicted failure to achieve FPE. Our findings support the importance of early and complete reperfusion in AIS and establish FPE as a potential benchmark to

measure the angiographic efficacy and a possible surrogate for clinical efficacy for emerging thrombectomy devices.

Stent-retrievers have redefined the standard of care for AIS in patients with large vessel occlusions; nonetheless, inability to achieve rapid and complete revascularization for some patients remains a frustrating reality faced by neurointerventionalists. The pathophysiologic causes of certain large vessel occlusions may preclude achieving rapid and complete revascularization using the current devices; these include proximal carotid or vertebral occlusions, either because of dissection or atherosclerosis, intracranial atherosclerosis with superimposed acute thrombus, and multiple vessel embolic events.^{23–26} Collectively, these lesions may be responsible for $\approx 15\%$ to 20% of stroke thrombectomy cases, which reduces the proportion of patients who present for mechanical thrombectomy with a straightforward clot potentially amenable to FPE $\approx 80\%$. In this study, FPE was achieved in 25% of the NASA registry patients, suggesting there is substantial room for improvement. Early in the history of interventional stroke therapy, achieving mTICI 2a was considered a success. However, this is no longer the case as mTICI 2b is now the new target (and perhaps mTICI3 FPE will be in the future). Prior literature has demonstrated a dose escalation effect for endovascular recanalization in AIS for clinical outcomes in terms of safety and efficacy.^{17–21,27,28} Using the newer generation devices, investigators have shown increased benefit in terms of both safety and clinical efficacy when achieving mTICI 3 versus mTICI 2b among anterior circulation cohorts and in the middle cerebral artery occlusion group.^{21–23,27,28}

The data from this study further demonstrate the importance of the number of passes required to achieve revascularization. Indeed, FPE seems to have the highest impact on outcomes when compared with final reperfusion of mTICI 3 after >1 pass, (Table 3; Figure 2C). For example, the 42% rate of mRS score ≤ 2 seen in the entire NASA cohort only improved to 45% with mTICI 3 reperfusion requiring >1 pass. In contrast, in FPE patients, the favorable clinical measure increased to 61.3%. These findings may be explained by the fact that FPE reduced the symptomatic intracranial hemorrhage rate to 5.6% and the mortality rate to 16%. Additionally, FPE patients had a faster procedure time, which may also have contributed to a better clinical outcome. Finally, less endothelial vascular trauma is more likely with a single device pass versus multiple passes.²³

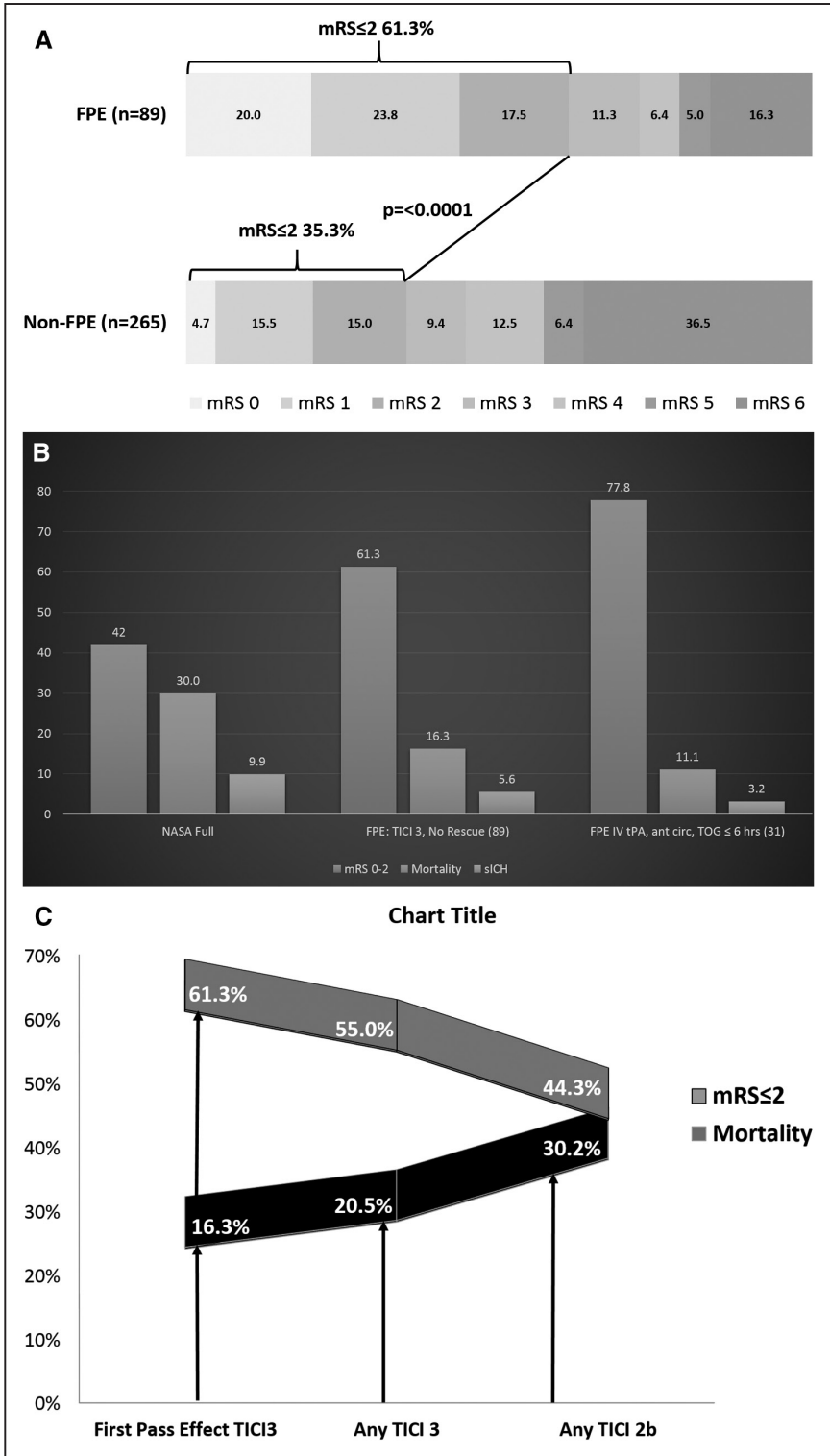


Figure 2. Effect of FPE on clinical outcomes. **A**, The primary outcome of modified Rankin Scale (mRS) score at 90 d of 0 to 2 in first pass effect (FPE) vs the rest of North American Solitaire Acute Stroke (NASA) cohort. **B**, Outcomes in NASA Full cohort, FPE, and FPE restricted to those who received IV tPA, anterior circulation, and Time of Onset to Groin Puncture (TOG) ≤6 hours. **C**, Comparison of FPE to any TICI 3 or any TICI2b showing better efficacy and safety profile with FPE. TOG indicates time of onset to groin puncture.

In our cohort, the 2 independent predictors of FPE were use of BGC (3–4 times more likely with BGC) and ICA terminus clot (negative predictor for FPE). These predictors are biologically plausible with recent data demonstrating consistently improved clot efficiency with BGC and a higher prevalence of longer clot in ICA terminus occlusion (making this occlusion resistant to current technology).^{12,29}

Limitations

Our research had limitations; the study had a small number of patients treated with the combined aspiration and stent retriever thrombectomy or aspiration-first approach, making it less feasible to find the effect of this approach on FPE. There is potential benefit of aspiration-first approach in achieving rapid and high rate of FPE from a single attempt; however, future aspiration-only approach studies may address this

outcome. We think that the FPE rate would improve over time with increased operator experience, increased use of BGCs, and newer devices designed to specifically improve efficiency of clot removal, or a combination of different strategies, such as aspiration and retrieval or chemolysis and mechanical clot removal.

Additional limitations of this registry include a heterogeneous stroke population and lack of independent angiographic and clinical outcome adjudication. However, the FPE concept was not established at the time the study started; therefore, sites would be less likely to be biased based on the operator reads. Furthermore, our rate of FPE (25.1%) seems to be underestimated based on other reported, prospectively collected core laboratory–adjudicated studies.^{1,2,5–8} Another limitation relates to the disproportionate number of white. Because pathophysiology and presentation may differ among races, this should be considered when interpreting the results. Finally, there was no clot histology data to further characterize the relationship of FPE with clot type.

Summary

NASA was an investigator-initiated, unfunded, retrospective multicenter registry of consecutive AIS patients treated with the Solitaire FR device at 24 North American centers with the stent-retriever procedure performed using local protocols.

The FPE in the current study was associated with improved angiographic, clinical, and safety outcomes. Use of BGC was associated with higher rate of FPE, whereas ICA terminus occlusion was associated with lower rates of FPE.

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Disclosures

None.

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