




Case series

Balloon guide catheter improvements in thrombectomy outcomes persist despite advances in intracranial aspiration technology

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ABSTRACT

Background First-pass effect (FPE) has been established as a key metric for technical success and strongly correlates with better clinical outcomes. Most data supporting improved outcomes with the use of a balloon guide catheter (BGC) predate the advent of last-generation large-bore intracranial aspiration catheters. We aim to evaluate the impact of BGC in FPE and clinical outcomes in a large cohort of patients treated with contemporary technology.

Methods Patients were recruited from the prospectively ongoing ROSSETTI registry. This registry includes all consecutive patients with anterior circulation large-vessel occlusion (LVO) from 10 comprehensive stroke centers in Spain. Demographic, clinical, angiographic, and clinical outcome data were compared between BGC and non-BGC groups. FPE was defined as the achievement of mTICI2c–3 after a single device pass.

Results 426 patients were included out of which 271 (63.62%) used BGC. BGC-treated patients had higher FPE rate (45.8% vs 27.7%; $P<0.001$), higher final mTICI ≥ 2 recanalization rate (76.8% vs 50.3%, respectively; $P<0.001$), shorter procedural time [median (IQR), 30 (19–58) vs 43 (33–71) min; $P<0.001$], higher NIHSS difference from admission to 24 hours [median (IQR), 8 (2–12) vs 3 (0–10); $P=0.001$], and lower mortality rate (17.6% vs 29.8%, $P=0.026$) compared with non-BGC patients. BGC use was an independent predictor of FPE (OR 2.197, 95% CI 1.436 to 3.361; $P<0.001$), and excellent clinical outcome at 3 months (OR 0.34, 95% CI 0.17 to 0.68; $P=0.002$).

Conclusions Our results support the benefit of BGC use on angiographic and clinical outcomes in anterior circulation LVO ischemic stroke remain significant even when considering recent improvements in intracranial aspiration technology.

INTRODUCTION

Several randomized clinical trials have demonstrated the clinical efficacy of mechanical thrombectomy (MT) for acute ischemic stroke secondary to large-vessel occlusion (LVO).^{1–8} The ultimate goal

of MT is to achieve a fast and complete recanalization, ideally after one single pass (referred to as first-pass effect, FPE).^{9–11} The FPE, an independent predictor of good clinical outcome, has become a new metric for technically successful MT. In this setting, previous studies have reported positive correlation between the use of a balloon guide catheter (BGC) and higher successful recanalization rates, shorter procedure times, better clinical outcomes, and lower risk of mortality.^{12–24}

As such, the use of BGCs is recommended in stent-retriever thrombectomy in current guidelines.¹ However, despite the preponderance of data in favor of BGC use, many neurointerventionists remain reluctant to use BGC due to different concerns including difficulty in navigating the device, the greater potential for groin complications due to the larger required femoral access, risk of carotid dissection, and compatibility of BGC with larger-bore distal aspiration catheters.²⁵ Indeed, the rate of BGC use has been only 45%–50% across large thrombectomy registries.^{12, 26} Furthermore, most of the existing data supporting the use of BGC predate the advent of last-generation large-bore intracranial aspiration catheters, which are known to be more effective than their smaller caliber predecessors.²⁷ Hence, the sustained benefit of BGC has been increasingly questioned in the face of current technology.

The aim of the current study was to investigate the impact of BGC use in the rates of FPE and good clinical outcomes in a large cohort of anterior circulation LVO patients treated with stent retrievers and last-generation large-bore intracranial intermediate aspiration catheters.

MATERIALS AND METHODS

The ROSSETTI registry is an ongoing investigator-initiated prospective study recruiting deidentified demographic, clinical presentation, site-adjudicated angiographic, procedural, and outcome data in consecutive patients with acute ischemic stroke treated with MT across 10 Comprehensive Stroke



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Ischemic stroke

Centers in Spain. The main objective of the ROSSETTI registry is to evaluate the efficacy and safety of the different techniques of MT used in anterior circulation LVO. The registry started in June 2019 and therefore incorporates the more recent device technology. The study inclusion criteria are the following: age ≥ 18 years; confirmed LVO in the anterior circulation (intracranial internal carotid artery, M1, proximal M2); time from last seen well to treatment up to 24 hours, baseline National Institutes of Health Stroke Scale (NIHSS) score ≥ 2 ; and pre-morbid modified Rankin Scale (mRS) score ≤ 2 . All participating centers received institutional review board approval from their respective institutions and patients or representatives signed informed consent. The study data were collected prospectively through an online questionnaire. The type of stent retriever, as long as it was EC approved, was at the discretion of the operator. At the time of the current analysis, 426 patients had completed the 3-month

follow-up period and were included in the study. Qualifying patients were categorized according to the use of BGC vs not.

The primary clinical outcome was the rate of excellent clinical outcome, defined as mRS score 0–1 at 90 days (no or minor symptoms but no functional limitations).²⁸ The primary technical outcome was the rate of FPE defined as achieving near-complete/complete revascularization [modified Thrombolysis in Cerebral Infarction (mTICI 2c–3)] after single-device and single-pass approach.

The mRS scores at 90 days, mTICI reperfusion scores, symptomatic intracranial hemorrhage (sICH) (ECCASS-II definition),²⁹ rates of modified-FPE defined as achieving mTICI 2b–3 after single-device and single-pass approach, final rates of successful (mTICI 2b–3) and complete (mTICI 2c–3) reperfusion, and 90-day mortality rate were assessed for the BGC and non-BGC subgroups. Groin puncture to revascularization

Table 1 Univariate comparison of the balloon guide catheter and non-balloon guide catheter groups of patients with anterior circulation stroke

	Overall (n=426)	Non-BGC (n=155, 36.38%)	BGC (n=271, 63.62%)	P-value
Age (years), median (IQR)	76 (65;84)	76 (65.5;83.5)	76 (65;84)	0.747
Female gender, n (%)	219 (51.4%)	78 (50.3%)	141 (52%)	0.735
NIHSS score at admission, median (IQR)	16 (10;20)	16 (12;20)	16 (10;20)	0.150
ASPECTS at admission, median (IQR)	9 (7;10)	8 (7;10)	9 (8;10)	0.001
Last time seen well (min), median (IQR)	248.5 (165;502)	287 (173;480)	235 (160;519)	0.362
IV tPA administered, n (%)				<0.001
None	313 (73.5)	101 (65.2)	212 (78.2)	
Partial dose	35 (8.2)	10 (6.5)	25 (12.5)	
Completed dose	78 (18.3)	44 (28.4)	34 (9.2)	
General anesthesia, n (%)	130 (30.5)	36 (23.2)	94 (34.7)	0.006
Local anesthesia, n (%)	94 (22.1)	30 (19.4)	64 (23.6)	
Conscious sedation, n (%)	202 (47.4)	89 (57.4)	113 (41.7)	
Left site occlusion, n (%)	225 (52.8)	79 (51)	146 (53.9)	0.563
Level of vessel occlusion, n (%)				0.009
ICA carotid terminus	73 (17.1)	37 (23.9)	36 (13.3)	
MCA–M1	232 (54.8)	83 (53.5)	149 (55)	
MCA–M2	121 (28.4)	35 (22.6)	86 (31.7)	
Groin puncture to first run (min), median (IQR)	6 (5;11)	8 (5;15)	6 (4;10)	0.016
Mechanical thrombectomy (min), median (IQR)	27 (14;51.2)	33 (23;53.8)	22.5 (12.5;75)	<0.001
Groin puncture to revascularization (min), median (IQR)	37(22;63)	43(33;71)	30(19;58)	<0.001
FPE, n (%)	167 (39.2)	43 (27.7)	124 (45.8)	<0.001
mFPE, n (%)	221 (51.9)	65 (29.4)	156 (70.6)	0.002
Final number of passes, n (%)	2 (1;3)	2 (1;3)	1 (1;3)	0.051
1	199 (46.7)	60 (38.7)	139 (51.3)	
2	107 (25.1)	48 (31.0)	59 (21.8)	
>2	120 (28.2)	47 (30.3)	73 (26.9)	
Final mTICI ≥ 2 b, n (%)	380 (89.2)	134 (86.4)	246 (90.8)	<0.001
Final mTICI ≥ 2 c, n (%)	286 (67.1)	78 (50.3)	208 (76.8)	<0.001
Symptomatic intracranial hemorrhage, n (%)	31 (10.4)	20 (14.2)	11 (7)	0.041
NIHSS score at 24 hours, median (IQR)	7 (2;14)	10 (4;17.5)	4.5 (1;12)	<0.001
Difference of NIHSS from admission to 24 hours, median (IQR)	6 (1;12)	3 (0;10)	8 (2–12)	0.010
mRS score 0–2 at 3 months, n (%)	135 (56.5)	62 (54.4)	73 (58.4)	0.532
Mortality, n (%)	56 (23.4)	34 (29.8)	22 (17.6)	0.026

ASPECTS, Alberta Stroke Program Early CT Score; BGC, balloon guide catheter; FPE, first-pass effect; ICA, Internal Carotid Artery; IQR, interquartile range; mRS, modified Rankin Scale; mTICI, modified Thrombolysis in Cerebral Infarction; NIHSS, National Institutes of Health Stroke Scale.

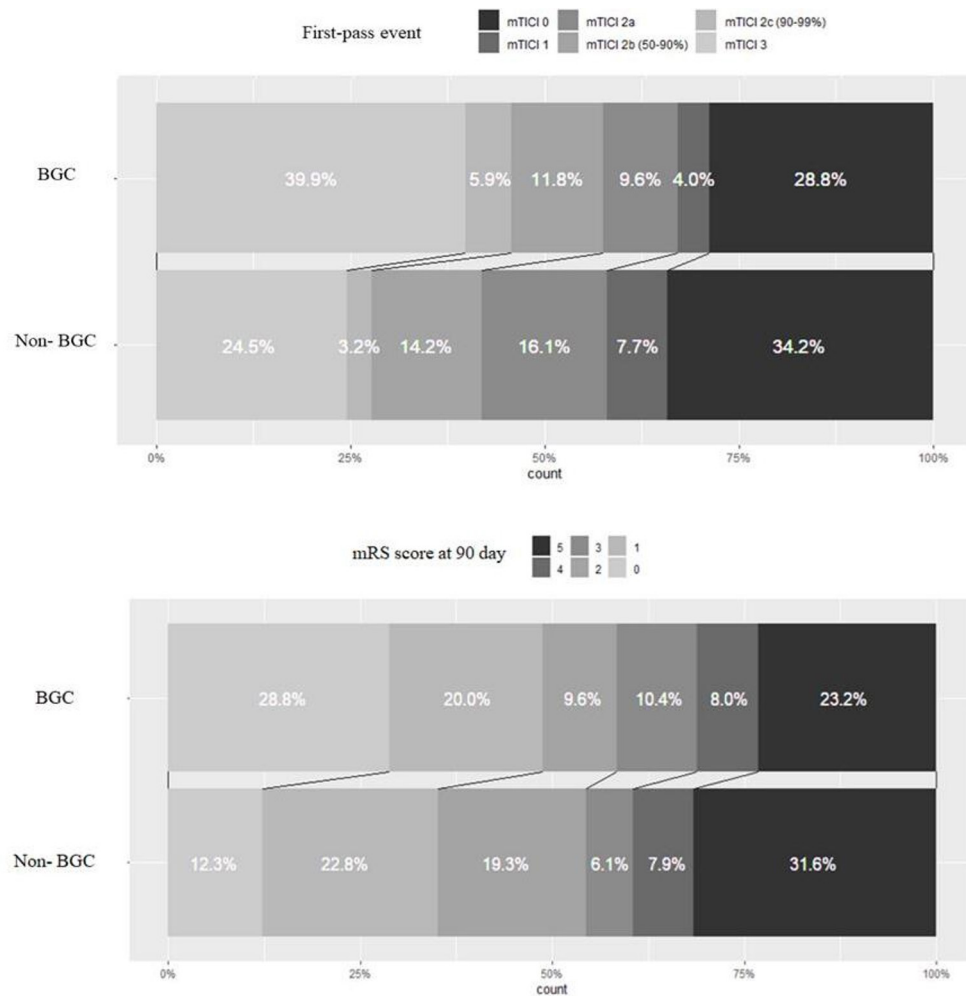


Figure 1 Distribution of recanalization results (above) and clinical outcome (below) comparing the balloon guide catheter and non-balloon guide catheter groups. The mTICI and mRSs distributions were not significantly different (Wilcoxon–Mann–Whitney *U* test, $P=0.394$ and $P=0.630$ respectively).

was subcategorized into groin puncture to first run and first run to final revascularization (MT time), and also compared between both groups. Reperfusion scores and sICH evaluation were center- adjudicated by experienced interventionists and functional outcome with the mRS score at 3 months by stroke neurologists blinded to the imaging data.

Statistical analysis

Demographic, clinical data, procedure details, and angiographic and clinical outcomes were compared according to: non-BGC-treated vs BGC-treated patients; FPE vs non-FPE events; and excellent ($mRS \leq 1$) vs non-excellent outcome ($mRS > 1$) at 3 months. Chi-square and Fisher's exact tests were used for categorical variables and the student's *t*-test/*F*-test for continuous variables. Variables with a P -value < 0.05 in the univariate analyses were entered into the multivariate models. Using binary logistic regression models in multivariate analysis, we evaluated the use of BGC as an independent factor contributing to FPE or/and functional clinical outcome at 3 months. The distribution of ordinal mRS and mTICI scores was analyzed by using the Wilcoxon–Mann–Whitney *U* test to the cumulative scores. Subjects with mRS or mTICI score missing were excluded from this analysis, and mRS scores 5 and 6 were combined into one category. A P -value < 0.05 was considered statistically significant. All statistical analyses were performed using R (version 3.6.1).

RESULTS

A total of 426 patients (median age, 76 [IQR, 65–84] years; female patients, 51.4%) were analyzed. Median values for the NIHSS score at admission and Alberta Stroke Program Early CT Score (ASPECTS) were 16 (IQR, 10–20) and 9 (IQR, 7–9), respectively. BGC was used in 271 patients (63.62%). The BGC and non-BGC groups were similar regarding the baseline characteristics except for a 1 point higher ASPECTS score in the BGC group (9 BGC vs 8 non-BGC), the use of general anesthesia which was higher in the BGC group and the use of rtPA, more frequently administered in the non-BGC patients. In all cases, stent retrievers were used. Adjunctive intracranial aspiration was employed in 37.9% and 95% of the BGC and non-BGC patients, respectively. Therefore, stent retriever alone was used in 62.1% and 5% of the BGC and non-BGC patients, respectively. Online supplemental table 1 summarizes the BGC and non-BGC approaches according to the recruiting centers. The inner diameter for the intracranial aspiration catheter was ≥ 0.068 in 43% of the cases with the Sofia Plus catheter (ID: 0.070") (Microvention, Tustin, California USA) being the most frequently used (23%). Table 1 summarizes the clinical characteristics of the whole sample. Online supplemental table 2 shows the type and size of the devices used.

The BGC group had shorter groin puncture to revascularization time [30 min (19–58) vs 43 min (33–71); $P < 0.001$] and

Table 2 Comparison between the groups for the first-pass effect

	NO FPE (mTICI 0–2b, n=259, 60.8%)	FPE (mTICI 2 c–3, n=167, 39.2%)	p-value	NO mFPE (mTICI 0–2a, n=205, 48.1%)	mFPE (mTICI 2b–3, n=221, 51.9%)	Pt-value
Age (years), median (IQR)	76 (65;83)	76 (63;85)	0.745	76 (66;84)	76 (63;84)	0.723
Female gender, n (%)	132 (51)	87 (52.1)	0.820	107 (52.2)	112 (50.7)	0.754
NIHSS score at admission, median (IQR)	16 (11;20)	16 (10;19.5)	0.204	16 (12;20)	15 (10;20)	0.092
ASPECTS at admission, median (IQR)	8 (7;9)	9 (8;10)	<0.001	8 (7;9)	9 (8;10)	<0.001
Last time seen well (min), median (IQR)	274 (165;541)	231 (160;448)	0.265	279 (171;530)	234 (155.5;472)	0.164
IV tPA administered, n (%)						
None	198 (76.4)	115 (68.9)	0.164	158 (77.1)	155 (70.1)	0.156
Partial dose	17 (6.6)	18 (10.8)		12 (5.9)	23 (10.4)	
Completed dose	44 (17.0)	34 (20.4)		35 (17.1)	43 (19.5)	
General anesthesia, n (%)	68 (26.3)	62 (37.1)	<0.001	55 (26.8)	75 (33.9)	0.008
Local anesthesia, n (%)	49 (18.9)	45 (26.9)		37 (18)	57 (25.8)	
Conscious sedation, n (%)	142 (54.8)	60 (35.9)		113 (55.1)	89 (40.3)	
Left site occlusion, n (%)	135 (52.1)	90 (53.9)	0.721	105 (51.2)	120 (54.3)	0.525
Level of vessel occlusion, n (%)			0.465			0.299
ICA carotid terminus	49 (18.9)	24 (14.4)		37 (18)	36 (16.3)	
MCA–M1	139 (53.7)	93 (55.7)		117 (57.1)	115 (52.0)	
MCA–M2	71 (27.4)	50 (29.9)		51 (24.9)	70 (31.7)	
BGC approach used, n (%)	147 (56.8)	124 (74.3)	<0.001	115 (56.1)	156 (70.6)	0.002
Symptomatic intracranial hemorrhage, n (%)	25 (12.3)	6 (6.3)	0.117	13 (6.3)	9 (4.1)	0.290
NIHSS score at 24 hours, median (IQR)	11(4;18)	3 (1;7.75)	<0.001	12(5;19)	3.5 (1;8)	<0.001
Difference of NIHSS from admission to 24 hours, median (IQR)	4 (0;10)	10(4;15)	<0.001	3 (-1;9)	9 (4;13.75)	<0.001
mRS score 0–2 at 3 months, n (%)	73 (47.1)	62 (70.5)	<0.001	54 (42.5)	81 (72.3)	<0.001
Mortality, n (%)	46 (29.7)	10 (11.9)	0.002	40 (31.5)	16 (14.3)	0.002

ASPECTS, Alberta Stroke Program Early CT Score; BGC, balloon guide catheter; FPE, first-pass effect; IQR, interquartile range; mRS, modified Rankin Scale; mTICI, modified Thrombolysis in Cerebral Infarction; NIHSS, National Institutes of Health Stroke Scale.

shorter MT procedural time [22.5 min (12.5–75) vs 33 min (23–53.8); $P<0.001$], with a higher rate of FPE (45.8% vs 27.7%; $P<0.001$) as well as modified-FPE (70.6% vs 29.4%; $P=0.002$) compared with the non-BGC group (figure 1). A fewer number of passes [1 (1–3) vs 2 (1–3)] and higher rate of final successful recanalization (mTICI $\geq 2c$) was more often achieved in the BGC group (76.8% vs 50.3%; $P<0.001$). There were no statistical significant differences between both groups in terms of good clinical outcome (table 1). The symptomatic hemorrhage rate was higher in the non-BGC group compared with the BGC group (7% vs 14.2%, $P=0.041$). All other clinical outcomes were more favorable in the BGC group (table 1 and figure 1).

The site of LVO was not associated with the achievement of FPE. On univariate analysis, patients who achieved FPE had higher ASPECTS at admission, lower 24h-NIHSS score, higher use of general anesthesia, higher use of BGC, higher difference between NIHSS score at baseline vs 24 hours, better functional outcome at 3 months, and lower mortality (tables 2 and 3).

Good clinical outcome at 3 months was higher in younger patients and those with lower NIHSS score at baseline, higher ASPECTS at admission, lower procedure time, fewer number of passes, and higher FPE rate. Good clinical outcome at 3 months was also more common in patients with lower NIHSS score at 24 hours [4 (IQR1–8) vs 16 (9–22)] (table 3).

Multivariate analysis demonstrated that BGC use (OR 2.19; 95% CI, 1.43 to 3.36; $P<0.001$) was independently associated with FPE. The predictors of independent functional outcome

at 3 months were BGC use (OR 0.34; 95% CI, 0.17 to 0.68; $P=0.002$), NIHSS score at 24 hours (OR 1.52; 95% CI, 1.31 to 1.76; $P<0.001$), and number of passes (OR 1.58; 95% CI, 1.16 to 2.13; $P=0.003$).

DISCUSSION

In this interim analysis of the ongoing ROSSETTI registry involving a large sample cohort of acute stroke patients with LVO treated with different updated or state-of-the-art stent retriever endovascular approaches, we confirmed that BGC benefits with improved FPE and clinical outcome persist even with the use of the most modern aspiration catheters. Although state-of-the-art distal access catheters were used in 95% of the procedures performed in the non-BGC group, procedures performed with BGC achieved faster procedure times by increasing the rate of FPE and lowering the number of passes required.

Our results are in line with other previous BGC clinical studies. Recently, Baek et al found that the use of BGC was associated with successful recanalization and favorable outcome, independently of the type of first-line endovascular modality used, whether stent retriever or thromboaspiration.²¹ The North American Solitaire Stent Retriever Acute Stroke (NASA) registry also demonstrated improved clinical outcome and reperfusion scores with the BGC group compared with the non-BGC group.¹² In a subanalysis of 87 patients from the SWIFT PRIME randomized trial, the authors demonstrated smaller final infarct volumes and improved reperfusion scores in the BGC group.¹³ In

Table 3 Comparison of the groups according to the functional outcome at 3 months

	Good functional outcome (mRS ≤1, n=101)	Poor functional outcome (mRS >1, n=138)	P-value
Age (years), median (IQR)	72 (63;81)	76 (63.25;84)	0.114
Female gender, n (%)	54 (53.5)	70 (50.7)	0.675
NIHSS score at admission, median (IQR)	13(7;19)	17(12;21)	<0.001
ASPECTS at admission, median (IQR)	10 (8;10)	8 (7;9)	<0.001
Last time seen well (min), median (IQR)	252 (159.75;491.75)	289 (167.75;540.25)	0.578
IV tPA administered, n (%)			0.575
None	70 (69.3)	104 (75.4)	
Partial dose	5 (5.0)	5 (3.6)	
Completed dose	26 (25.7)	29 (21.0)	
General anesthesia, n (%)	51 (50.5)	50 (36.2)	0.062
Local anesthesia, n (%)	13 (12.9)	29 (21.0)	
Conscious sedation, n (%)	37 (36.6)	59 (42.8)	
Left site occlusion, n (%)	53 (52.5)	74 (53.6)	0.861
Level of vessel occlusion, n (%)			0.117
ICA carotid terminus	16 (15.8)	32 (23.2)	
MCA–M1	53 (52.5)	77 (55.8)	
MCA–M2	32 (31.7)	29 (21.0)	
BGC approach used, n (%)	61 (60.4)	64 (46.4)	0.032
Non-BGC approach used, n (%)	40 (39.6)	74 (53.6)	
Groin puncture to first run (min), median (IQR)	6 (4;10)	6 (5;11)	0.207
Mechanical thrombectomy (min), median (IQR)	22(10;35)	39 (23,63)	<0.001
Groin puncture to revascularization (min), median (IQR)	29.5 (17.75;45)	49.5 (32;80.75)	<0.001
FPE, n (%)	65 (64.4)	47 (34.1)	<0.001
Final number of passes, n (%)			0.002
1	59 (58.4)	46 (33.3)	
2	25 (24.8)	39 (28.3)	
>2	17 (16.8)	53 (38.3)	
Final mTICI score, n (%)			<0.001
Final mTICI ≥2 b, n (%)	100 (99)	108 (78.3)	
Final mTICI ≥2 c, n (%)	83 (82.2)	60 (43.5)	
Symptomatic intracranial hemorrhage, n (%)	2 (2.0)	11 (8.0)	0.044
NIHSS score at 24 hours, median (IQR)	2 (1;6)	12.5 (7;21)	<0.001
Difference of NIHSS from admission to 24 hours, median (IQR)	9 (4;14)	1.5 (-1;7)	<0.001
Mortality, n (%)	0 (0)	56 (46.4)	<0.001

ASPECTS, Alberta Stroke Program Early CT Score; BGC, balloon guide catheter; FPE, first-pass effect; IQR, interquartile range; mRS, modified Rankin Scale; mTICI, modified Thrombolysis in Cerebral Infarction; NIHSS, National Institutes of Health Stroke Scale.

the ESCAPE trial, the use of a BGC was associated with shorter reperfusion time by 21% (8 minutes).³⁰ Likewise, Velasco et al¹⁴ demonstrated higher successful reperfusion with the BGC (89% vs 68%) and shorter procedure duration time in a sample of 183 patients. In another recent analysis, the use of the BGC in the Trevo Stent-Retriever Acute Stroke (TRACK) registry was also associated with lower mortality.³⁰ Against this background, the 2018 American Heart Association guidelines recommended that the use of a BGC rather than a cervical guide catheter alone in conjunction with stent retrievers may be beneficial (class IIa; level of evidence C).¹ Almallouhi et al have also reported the technical feasibility and safety of the transradial approach for neuroendovascular procedures.³¹

The FPE is now considered the benchmark of successful MT.¹⁰ We found that BGC was an independent predictor of FPE. In a

similar way, in the NASA study, FPE was more frequently associated with BGC use and was also an independent predictor of good clinical outcome.¹² Similar to our study, a meta-analysis of BGC studies including 2022 patients also demonstrated that the BGC group showed higher odds of FPE (OR 2.1, 95% CI 1.65 to 2.55).³⁰ However, in the TRACK BGC subanalysis, the FPE was not significantly different between the BGC and non-BGC groups.²⁴ In contrast to previous studies, we found that the FPE was not associated with either the site of LVO or the NIHSS at baseline. Demographic and clinical variables, including NIHSS score at admission and last time seen well, seemed relatively well balanced between the BGC and non-BGC groups, improving the performance comparison.

Several in-vitro and animal model BGC-related studies have shown why this device offers a multi-faceted approach

for clot retrieval for further understanding mechanisms of thrombectomy optimization. The pivotal point is that the antegrade flow arrest and concurrent aspiration at the balloon guide reduce migration of the entrapped thrombus or fragmented clots extracted by the stent retriever.³⁰ Recently, it has been also demonstrated that the use of a BGC provided reliable flow arrest and flow reversal with manual syringe aspiration, whereas aspiration with a conventional 8 F guide catheter resulted in either collapse of the vessel or oscillatory flow, which may permit antegrade flow.³⁰

This study has several limitations. There was no independent adjudication of the clinical outcome and angiographic results for each patient. The decision to use BGC as first option was determined by the internal protocols of each center. Experienced operators might be more likely to choose the use of BGC than less experienced ones.²¹ In fact, it has been suggested that operators' proficiency might be a confounder affecting the use of BGC and/or the treatment outcomes independently of the use of BGC. Although shorter times for MT and from groin puncture to revascularization were seen in the FPE cohort, the time from groin puncture to first run was similar between cohorts. This might indicate that the experience of the different neurointerventionists may be comparable. It has been shown previously that establishing a competitive environment and publicly presenting and discussing procedural times is also an effective and cost-efficient way of improving procedural times.³²

CONCLUSION

Our results demonstrated that the use of BGC in a real-life scenario resulted in a higher rate of FPE success as well as better clinical outcome in acute stroke patients with anterior circulation LVO. Randomized clinical trials to evaluate these findings may be important, along with the role of validating the BGC as a safe and effective option to minimize the number of passes during intervention.

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